UNIVERSITY OF WOLVERHAMPTON
DEPARTMENT OF LAW

# Patent Law and Non-Communicable Diseases (NCDs)

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of the Degree of Doctor of Philosophy -Ph.D. (Laws)

## Statement of Originality

I, Maria Vasiliou, confirm that the research presented in this thesis is my own work or that where it has been carried out in collaboration with, or supported by others, that this is duly acknowledged below, and my contribution indicated. Previously published material is also acknowledged below.

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## ABSTRACT

This thesis examines how patent law affects the right to health by influencing access to medicines for non-communicable diseases (NCDs). While acknowledging the critical role of patents in incentivizing pharmaceutical innovation, it underscores significant challenges posed by the current patent framework, which often prioritizes intellectual property rights over public health needs. The main research question is '*To what extent does patent law affect the right of health and access to medicines for non-communicable diseases?'*

The increasing global burden of NCDs, coupled with the lessons from the Covid-19 pandemic and previous health crises, highlights the urgent need to strike a balance between intellectual property protection and public health priorities. Patents have a special distinctive character highlighting the inherent conflict between the interests of inventors, who aim to protect their inventions and secure their exclusive rights, and the broader public which relies on access to these innovations for societal benefit. While patents incentivize creativity and technological progress, they can also restrict access to critical innovations, specifically in fields like healthcare, where public access to life-saving treatments may be limited. Therefore, this research highlights the need to strike a balance between patent protection and the right to health to prevent unnecessary barriers to essential medicines.

A key contribution of this thesis is its examination of patent legislation in the UK and Cyprus, analysing how patents are granted, protected, and enforced for each jurisdiction. Additionally, this work presents an original contribution by exploring the intersection of patent law, the right to health, and access to medicines for NCDs through the lens of Intellectual Property and Social Justice (IP-SJ). While much of the existing literature on patents and access to medicines focuses on infectious diseases, this thesis shifts the spotlight to NCDs, a growing yet often underexplored global health challenge. The application of IP-SJ is particularly prominent in Chapter Five, where the principles of access, inclusion, and empowerment are considered.

The main research finding highlights the critical role of international collaboration in improving access to medicines. To foster such collaborations, this study recommends promoting generic competition to enhance affordability and accessibility. Ensuring that medical innovations benefit society requires policymakers to adopt strategies that align intellectual property rights with public health objectives. By contributing to the ongoing discourse at the intersection of patent law, health rights, and global health equality, this thesis provides valuable insights into how legal frameworks can be reformed to facilitate broader access to life-saving treatments for NCDs.

## LIST OF ABBREVIATIONS

| | |
|---|---|
| ADHD | Attention deficit hyperactivity disorder |
| AMR | Antimicrobial Resistance |
| ARVs | Antiretrovirals |
| CDIP | Committee on Development and Intellectual Property |
| CDs | Communicable diseases |
| Chp | Chapter |
| CJEU | Court of Justice of the European Union |
| CML | Chronic myelogenous leukaemia |
| CPC | Community Patent Convention |
| CROs | Contract Research Organization |
| CY | Cyprus |
| DA | Development Agenda |
| EBA | Enlarged Board of Appeal |
| ECHR | European Convention on Human Rights |
| ECIS | European Cancer Information System |
| EEA | European Economic Area |
| EHN | European Heart Network |
| EPC | European Patent Convention |
| EPO | European Patent Office |
| EU | European Union |

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| FCTC | Framework Convention on Tobacco Control |
| FDA | Food and Drug Administration |
| GAP | Global NCD Action Plan |
| GATT | General Agreement on Tariffs and Trade |
| GHS | Globally Harmonized System |
| GIST | Gastrointestinal Stromal Tumour |
| HES | Hypereosinophilic Syndrome |
| HIV | Human Immunodeficiency Virus |
| HTA | Health Technology Assessment |
| ICESCR | International Covenant on Economic and Social Cultural Rights |
| IP | Intellectual Property |
| IP-SJ | Intellectual Property and Social Justice |
| IPO | Intellectual Property Office |
| IPRs | Intellectual Property Rights |
| LMICs | Low-and middle-income countries |
| MDGs | Millennium Development Goals |
| MPOX | Monkeypox virus |
| MPP | Medicine Patent Pool |
| MS | Multiple Sclerosis |
| MSF | Médecins sans Frontières |
| NCDs | Non-communicable diseases |
| NGOs | Non-governmental organization |
| NHS | National Health Service |
| NSAIDS | Non-steroidal anti- inflammatory drugs |

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|---|---|
| OECD | Organization for Economic Cooperation and Development |
| OHCHR | Office of the High Commissioner for Human Rights |
| OHID | Office for Health Improvement and Disparities |
| Paris Convention | Paris Convention for the Protection of Industrial Property |
| PCT | Patent Cooperation Treaty |
| Ph+ALL | Philadelphia-Positive Acute Lymphoblastic Leukaemia |
| PHE | Public Health England |
| R&D | Research and Development |
| SARA | Service Availability and Readiness Assessment |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| SDGs | Sustainable Development Goals |
| SPC | Supplementary Protection Certificate |
| TB | Tuberculosis |
| TBA | Technical Board of Appeal |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | Treaty on Trade-Related Aspects of Intellectual Property Rights |
| UDHR's | Universal Declaration of Human Rights |
| UHC | Universal Health Coverage |
| UK | United Kingdom |
| UKHSA | UK Health Security Agency |
| UN | United Nations |
| UNDP | United Nations Development Programme |
| UPC | Unified Patent Court |
| VCLT | Vienna Convention on the law of Treaties |

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|---|---|
| WHA | World Health Assembly |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

# INTRODUCTION

## 1. BACKGROUND TO THIS WORK

This research explores the relationship between patent law and the right to health, with a particular focus on the regulation of non-communicable diseases (NCDs). When the research began in 2019, global discussions on patents and access to medicines primarily focused on communicable diseases. At that time, the debates surrounding intellectual property law in relation to access to treatments for these diseases seemed largely settled. Attention was shifting towards chronic conditions and NCDs such as cancer, diabetes, and cardiovascular diseases, which require long-term treatment.[1]

The global response to communicable diseases like HIV/AIDS has led to notable changes in patent law aimed at enhancing access to medicines.[2] However, NCDs like cancer, diabetes and cardiovascular diseases post distinct challenges that current legal frameworks frequently overlook. Given the acute and epidemic nature of communicable diseases, international legal adaptations such as TRIPS flexibilities established by the World Trade Organization, allow countries to override patents in public health emergencies.[3] As Ellen ‘t Hoen, stated, many high-income countries cannot afford the medicines they need and are even limiting certain medicines on the World Health Organization’s Essential Medicines List. Therefore, it is essential to draw lessons from how these countries addressed HIV drug pricing challenges, particularly through the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to purchase lower-cost generics. However, the onset of the Covid-19 pandemic in 2020 significantly shifted global health priorities. Questions about

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[1] Aida Budreviciute *et al.,* ‘Management and Prevention Strategies for Non-communicable Diseases (NCDS) and Their Risk Factors (2020) 8(574111) 4, 1-11.

[2] Alexa B D’Angelo *et al*., ‘Breaking Bad *Patents*: Learning from HIV/AIDS to make COVID-19 treatments accessible’ (2021) 16(10) Glob Public Health 1523. It is state that the HIV/AIDS pandemic provides a useful lens through which we can analyse existing pathways for challenging pharmaceutical patents in the context of global pandemic.

[3] Ellen F M ‘t Hoen *et al*., ‘Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region’ (2018) 11 (31) Journal of Pharmaceutical Policy and Practice 3. It is stated that TRIPS flexibilities have been effectively used to procure and supply low-priced generic medicines for the treatment of HIV/AIDS, when voluntary licenses were not yet available.

the role of patent law in access to medicines became more pressing, as countries faced challenges with vaccine distribution, treatments, and the legal frameworks that could either facilitate or hinder access during a global emergency.[4]

This project draws on evidence provided by the World Health Organization (WHO), which has identified the area of NCDs as the new important policy priority for all Member States. While the WHO already recognises the risk factors contributing to NCDs, such as tobacco use, physical inactivity, the harmful use of alcohol, unhealthy diets, and air pollution, there are still insufficient regulations in intellectual property legislation to address the health risks comprehensively. Research on the health risks associated with unhealthy food is gaining more attention, with evidence suggesting that such risks contribute to serious illnesses. WHO, in collaboration with national regulators, is working to address these risks and raise awareness about the harmful effects of unhealthy diets, often referred to as 'junk food' to support stronger health policies worldwide.

Obesity is characterized by the excessive or abnormal accumulation of fat or adipose tissue in the body, which adversely impacts health due to its strong association with an increased risk of developing NCDs, such as diabetes, mellitus, cardiovascular diseases, hypertension, and hyperlipidemia.[5] Over the past five decades, obesity has emerged as a significant and escalating public health epidemic. Consequently, this condition markedly elevates the risk of various NCDs, including diabetes, coronary artery disease, and cancer.[6]

In both industrialized and developing countries, many people struggle with obesity and other NCDs resulting from the consumption of unhealthy products. This issue is particularly pressing in countries like the United Kingdom, where many people rely on fast food for its convenience

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[4] Jean-Louis Excler *et al*., 'Factors, enablers and challenges for COVID-19 vaccine development' (2023) 8 (6) BMJ Glob Health 1. See also D'Angelo *et al.,* (n 2). The authors address the urgent need to ensure access to Covid-19 treatments and examines strategies to challenge patents that restrict their access. The authors also compared the crisis for HIV/AIDS with the Covid-19, and they argue that barriers created by the patents on essential medications can be overcome using existing legal frameworks.

[5] Francisco Lopez-Jimenez *et al., '*Obesity and cardiovascular disease: mechanistic insights and management strategies. A joint position paper by the World Heart Federation and World Obesity Federation' (2022) 29 (17) European Journal of Preventive Cardiology 2218, 2218-2237.

[6] Tiffany M Powell-Wiley *et al*., 'Obesity and Cardiovascular disease' (2021) 143 (21) HHS Public Access 2.

and affordability.[7] In Cyprus, a high-income country and a member state of the European Union (EU), NCDs have posed an even greater burden on population health.[8] Some of the public health risks such as smoking, physical inactivity and childhood obesity are contributing to the growing NCD epidemic.[9] As a result, obesity and related conditions have become significant health and social challenges.[10] This issue also affects younger generations, who are adopting unhealthy habits that they perceive as 'normal' lifestyle choices. Addressing this problem is crucial, as an increasing number of people choose inexpensive fast-food options. Obesity is associated with various health issues, including type 2 diabetes, hypertension, gallstones, and gastro-oesophageal reflux disease, as well as psychological and psychiatric morbidities.[11] Chapter Five of this thesis provides a detailed case study on obesity.[12]

The Global Strategy on Diet, Physical Activity and Health,[13] along with the 2011 United Nations (UN) Political Declaration on NCDs 2013-20[14], stressed the need to give priority to increasing consumption of healthy food and beverages. In January 2023, the WHO published a report on the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs and mental health.[15] This report, provides an updated menu of policy options and cost-effective interventions for NCD prevention and control. It highlights that, despite two decades of global and national efforts, progress has been insufficient in reducing the burden of NCDs.[16] The WHO emphasizes the need for stronger health systems and policy measures to address this ongoing challenge. Additionally, the report underscores that NCDs affect people of all ages across all regions and countries, demonstrating the urgent

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[7] Sarah Shaw *et al*., 'The interplay between social and food environments on UK adolescents' food choices: implications for policy' (2023) 38 (4) Health Promotion International 1-13.
[8] Periklis Charalambous *et al*., 'Burden of non-communicable diseases in Cyprus, 1990-2017: findings from the Global Burden of Disease 2017 study' (2021) 79 (138) Archives of Public Health 2.
[9] Charalambous *et al.,* (n 8).
[10] Sharon B Whyatt *et al.,* 'Overweight and Obesity: Prevelance, Consequences, and Causes of a Growing Public Health Problem' (2006) 33(4) The American Journal of the Medical Sciences 166.
[11] Whyatt *et al.,* (n 10) 166.
[12] Using case studies are particularly useful at the investigating stage of research - Jennifer Rowley, 'Using Case Studies in Research' (2002) 25(1) Management Research News 16, 16-18.
[13] Amalia Waxman, 'WHO global strategy on diet, physical activity and health' (2004) 25(3) Food Nutr Bull 292, 292-302.
[14] Carl Lachat *et al.,* 'Diet and Physical Activity for the Prevention of Noncommunicable Diseases in Low- and Middle-Income Countries: A Systematic Policy Review' (2013) 10(6) PLOS Medicine 1. See also Harrieth P Ndumwa *et al.,* 'Mitigating the Rising Burden of Non-Communicable Diseases through Locally Generated Evidence-Lessons from Tanzania' (2023) 89(1) Ann Glob Health 77.
[15] Lachat *et al.,* (n 14) 1. See also Ndumwa *et al.,* (n 14) 77.
[16] Lachat *et al.,* (n 14) 2. See also Ndumwa *et al.,* (n 14) 77.

need for global action. Addressing NCDs requires a comprehensive, multi-sectoral approach involving collaboration across health, finance, transport, education, and agriculture to mitigate health risks and promote preventive interventions.[17]

The evolving landscape of global health has renewed attention to mechanisms such as the TRIPS Agreement, compulsory licensing, and the balance between patent protection and public health. This shift has occurred alongside continued concerns about NCDs, which have become a substantial global health issue. As a result, the field of patent law in relation to public health has developed rapidly during this research, particularly between 2019 and 2024. The literature on patents and medicines, as well as the right to health, is extensive and is addressed in Chapter One of this thesis. However, new studies in this area are continually emerging. This thesis applies a research cut-off date of December 2024, and any literature published after this point has not been included or considered.

Particularly during the Covid-19 pandemic, issues related to access to medicines and intellectual property rights drew urgent attention. While the global health crisis highlighted the tension between the need for widespread access to vaccines for Covid-19, treatments and diagnostics, the protection of intellectual property rights held by pharmaceutical companies was also crucial. Consequently, these issues led to discussions on the potential for waiving certain TRIPS obligations,[18] specifically for Covid-19 vaccines and treatments, to increase production, distribution, and access to medicines for the low- and middle-income countries who needed them.

The following sections build on this background by outlining the aims and relevance of the research, setting out the central questions and hypothesis, and situating the work within a theoretical and methodological framework.

[17] Abdesslam Boutayeb and Saber Boutayeb, 'The burden of non-communicable diseases in developing countries' (2005) 4(2) International Journal for Equity in Health 1.

[18] Jillian Kohler *et al*., 'Improving Access to Covid-19 Vaccines: An analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders' (2022) 24(2) Health and Human Rights Journal 159.

## 2. THE AIM AND RELEVANCE OF THIS WORK

This work examines the extent to which patent law affects the right to health and access to medicines for non-communicable diseases (NCDs).[19] By focusing on the intersection of patents and public health, it aims to provides a deeper understanding of the legal mechanisms and international agreements that shape access to medications, especially for diseases requiring long-term treatment. The relevance of this work lies in its exploration of the tension between incentivizing innovation through patent protections and ensuring affordable access to essential drugs. This issue has gained increased attention during global health crises since the HIV pandemic, with ongoing discussions about how intellectual property law can be regulated to address public health crises. The discussion surrounding NCDs is particularly relevant and vital due to their rising global prevalence, their significant economic, and social impacts, and the growing burden on the healthcare systems worldwide.[20] Furthermore, the Covid-19 pandemic has increased the need to reconsider the balance between intellectual property rights and public health policies.

The intellectual property protections in the UK, along with the valuable insights into how patent law affects the right to health on access to medicines for NCDs, contrast with Cyprus which has a smaller healthcare infrastructure but is established within the EU regulatory framework. These two countries provide perspectives on challenges and opportunities for balancing patent law and public health. By examining these two jurisdictions, this research explores the impacts of patent law on access to medicines, particularly for NCDs, and identifies legal reforms needed to improve access to those diseases.

## 3. QUESTIONS AND ISSUES RAISED BY THE TOPIC

There remains a research gap regarding the relationship between patent law and access to medicines for NCDs. This thesis is original because it addresses the following primary research question: '*To what extent does patent law affect the right of health and access to medicines*

[19] Brigitte Tenni *et al*., 'What is the impact of intellectual property rules on access to medicines? A systematic review' (2022) 18(40) Globalization Health 1.
[20] Boutayeb and Boutayeb (n 17) 1.

*for non-communicable diseases*?' The novelty of this work lies in its focus on the impact of patent law on diseases that are not transmitted from one person to another, an area that has received little or no attention in existing literature. While much has been written about the relationship between patent law and access to medicines for CDs, especially during the HIV/AIDS crisis, comparatively little scholarly work has examined the implications for NCDs.

This thesis synthesizes the existing literature on patents and public health, offering new insights into how patent law might influence access to treatments for NCDs. The primary question is further explored through subsidiary issues and related questions.

## 4. THE HYPOTHESIS

The central hypothesis of this work is that while patent law provides a framework for incentivizing innovation in the pharmaceutical industry, it also creates significant barriers to accessing affordable medicines for NCDs.[21] This thesis posits that the current international and national legal frameworks specifically those in the UK and Cyprus, are inadequate in addressing the unique challenges posed by NCDs, and that reforms or more flexible interpretations of patent provisions are necessary to better align patent law with the right to health. This happens because the high cost of patented medicines, resulting from patent monopolies, restricts access to essential treatments for NCDs, particularly in lower-income populations. Moreover, while patent law is intended to encourage pharmaceutical innovation, it often prioritizes the interests of patent holders over the public health needs of people suffering from NCDs. This imbalance between patent law and public health needs leads to limited access to cost-effective medications, highlighting the necessity for reforms that strike a better balance between intellectual property protection and the right to affordable treatment, particularly for the NCDs.

[21] Tenni *et al.,* (n 19) 1, 1-40. See also Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 International Review of Intellectual Property and Competition Law 1076.

Key aspects of this work include examining the impact of the TRIPS Agreement, which limits the availability of generic medicines by enforcing patent protection on essential drugs.[22] The Doha Declaration offers flexibilities such as compulsory licenses and parallel imports to which provide flexibility in responding to public health crises. However, these flexibilities have been largely overlooked in addressing the needs of people with NCDs. This thesis confirms this oversight, highlighting the need for reforms that better apply these mechanisms to the treatment of NCDs.

This hypothesis is grounded in the observation that existing patent systems often prioritize pharmaceutical profits over patient access, leading to significant disparities in the availability of essential medicines. Much of the existing scholarship[23] has focused on the impact of patent protections on access to medicines for CDs, such as HIV/AIDS, malaria, and tuberculosis.

By examining key developments in case law, particularly the Ozempic and Imatinib (Gleevec) cases, this research underscores a critical gap in the literature. These two cases highlight the complexities of patent law in regulating access to essential medicines but have predominantly been analysed in the context of CDs. Despite the alarming high number of deaths caused by NCDs worldwide[24], limited research has addressed whether similar legal and access treatments apply to treatments for NCDs. This thesis is original in its investigation of how patent law affects the right to health and access to medicines for NCDs, drawing on these case studies to explore whether systemic issues seen in CDs context extend to NCDs.

NCDs are often affected by high prices particularly in low-and middle-income countries.[25] However, NCDs pose unique challenges due to the chronic nature of their long-term treatment, often involving expensive therapies or medications such as treatments for cancer,

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[22] Marion Motari *et al*., 'The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement' (2021) 21(490) BMC Public Health 2.
[23] For detailed discussion on patent protection and access to medicines particularly on communicable diseases see Chapter One (Literature Review).
[24] Karl-Heinz Wagner and Helmut Brath, 'A global view on the development of non-communicable diseases' (2012) 54(1) Preventive Medicine 38.
[25] Tenni *et al.,* (n 19) 2, 1-40. In this article, it is stated that it is accepted that international legal requirements such as patents and data exclusivity can affect access to medicines, but to date, there has not been a comprehensive review of the empirical evidence on this topic.

cardiovascular diseases, and diabetes.[26] Moreover, there is less support from international organisations which often leads to financial burdens on individuals and domestic healthcare systems. Since NCDs impact both high- and low-income countries, pharmaceutical companies often prioritize profits in high-income markets, which can reduce the focus on affordability in low-and middle-income countries. Although this study does not specifically focus on low-income countries, the findings may still provide insights into the broader issue of affordability and access to essential medicines. If the findings confirm this hypothesis, it could highlight the need for policy reforms in patent law to better balance incentives for pharmaceutical innovation with the imperative to ensure affordable access to essential medicines. Such reforms might include stronger provisions for compulsory licensing or greater flexibility within the TRIPS Agreement, based on lessons from the global response to communicable diseases but adjusted to the distinctive context of NCDs.

## 5. THEORETICAL FRAMEWORK

Legal scholars and other academics propose and regularly debate a variety of theories and justifications for intellectual property protection.[27] Intellectual property law plays a crucial role in shaping which types of intellectual creations are developed and determining who can access the outcomes of these endeavours, including the knowledge and information contained in books and even the life-saving benefits of drugs and medicines.[28]

The theoretical justifications for intellectual property protection and its application cover a wide spectrum.[29] Leading rationales include natural rights[30] and positive social utility[31] and

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[26] Tingting Wu *et al*., 'Healthcare utilization and direct medical cost in the years during and after cancer diagnosis in patients with type 2 diabetes mellitus' (2020) 11(6) Journal of Diabetes Investigation 1661.

[27] Peter S Menell, 'Intellectual Property: General Theories' in Boudewijn Bouckaert (ed), *Encyclopedia of Law & Economics* (Edward Elgar, 2000) 129.

[28] Lateef Mtima 'Intellectual Property Social Justice: A Theoretical Rationale' in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024) 77. See also Lateef Mtima, 'Prolusion: What is Intellectual Property (And Why Should You care About it Anyway?)- A Lyperson's Guide to Intellectual Property Law in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024) xxvii.

[29] Mtima 2024 (n 28) 77

[30] Wendy J Gordon, 'A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property' (1993) 102 YALE LJ 1533. See also Mtima 2024 (n 28) 77.

[31] Adam Mossoff, 'Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause' (2007) 87(689) Boston University Law Review 689. (Explaining the economic social utility directive of the Constitutional IP Clause "[notwithstanding that the] nineteenth century conception of patents as serving to reward labour and remunerate the expense of inventive activities reflected a more substantive conception of property dominant at the time. It was a moral

employ both consequentialist[32] and non-consequentialist[33] implementation schemas.[34] Although these theoretical perspectives can sometimes conflict or contradict each other, they also often overlap and reinforce each other.[35]

Despite this, significant shortcoming persists. As intellectual property becomes increasingly central to everyday life, it has become clear that a more socially balanced and responsive theoretical underpinning to support the social function of IP protection in the political economy is needed throughout the global society.[36]

The two primary historical theories for IP protection, are the economic positive social utilitarianism and natural rights theory. Throughout much of the twentieth century, the economic positive social utility rationale of intellectual property dominated global IP law and policy discourse, particularly in the United States.[37] The fundamental premise of the economic utility rationale is that financial incentives are necessary to motivate individuals to create intellectual property. Without such incentives, it is argued, many potential innovators and creators would focus their efforts on other, more lucrative activities. To promote IP endeavour, IP law establishes private property rights over intellectual property outputs such as books or pharmaceutical drugs, which rights IP producers can exploit for their financial gain.[38]

While the economic utility rationale emphasizes the importance of economic incentives, it also highlights the need for these incentives to be cost effective. In other words, society should limit such incentives to those strictly necessary to include IP endeavour particularly where providing incentives will negatively affect the interests of society.[39] As a result, IP law should strike an optimal balance between granting private property rights as incentives and their

concept and legal right predicated on the labour-based theories of the natural rights philosophers”). See also Mtima 2024 (n 28) 77.

[32] Mark A Lemley, ‘Rational Ignorance at the Patent Office’ (2001) 95(4) Northwester University Law Review 1495.

[33] Mtima 2024 (n 28) 77.

[34] William Fisher, ‘Theories of Intellectual Property’, in Stephen R Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, 2001) 168. See also Mtima 2024 (n 28) 77.

[35] Mtima 2024 (n 28) 78. See also Matthews Fisher, *Fundamentals of Patent Law. Interpretation and Scope of Protection* (Hart Publishing 2007) 7. (analysing four leading theories of intellectual property and noting how jurists sometimes blend “discrete” theoretical perspectives).

[36] Mtima 2024 (n 28) 78.

[37] Mtima 2024 (n 28) 79.

[38] Mtima 2024 (n 28) 79.

[39] Mtima 2024 (n 28) 79.

social cost, the corollary restrictions upon the public's right to use IP works. "The goal is to set the incentives just right, ensuring society benefits from the greatest number of high-quality creations at the lowest overall social cost."[40]

In many European countries and other parts of the world, the predominant IP theoretical rationale is based on natural rights theory which incorporates both consequential and nonconsequential dimensions.[41] Natural rights theory asserts that all individuals are inherently entitled to fundamental human rights merely by virtue of being human. These rights have been applied to create and support both civil and political rights and liberties, and economic, social, and cultural rights.[42] While the economic utility rationale views IP protection as a tool to achieve broader societal goals, such as economic progress, natural rights theorists emphasize the inherent entitlement of creators to control their intellectual works.[43]

One of the most widely recognized applications of natural rights theory in intellectual property law is John Locke's labour theory of IP protection. Locke's labour theory is based upon his religious world view, which posits that, in a state of nature, resources are held in common by all through a grant from God.[44] According to Locke's reasoning, it is necessary that individuals apply their personal labour to natural resources, and by doing so they add value to these natural goods and are thus entitled to private property rights therein.[45]

IP scholars and policymakers rely upon economic social utilitarianism and natural rights theories to justify various IP regimes across the Western world and in many non-Western nations.[46] These theories are often used to justify the granting of IP rights in general, with a particular emphasis in supporting an expansive view of them in favour of commercial owners and transactors in particular.[47]

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[40] Mtima 2024 (n 28) 80.

[41] Lionel Bently *et al., Intellectual Property Law* (6th edn, Oxford, 2022). Locke's [natural rights] theory of property is itself subject to slightly different interpretations. One interpretation is that society reward labour with property purely on the instrumental grounds that we must provide rewards to get labour. In contrast, a normative interpretation of this labour theory says that labour should be rewarded. Locke's labour theory, under either interpretation, can be used to justify intellectual property"). See also Mtima 2024 (n 28) 80.

[42] Mtima 2024 (n 28) 80.

[43] Mtima 2024 (n 28) 80.

[44] Mtima 2024 (n 28) 81. See also Bently *et al.*, (n 41) 6.

[45] Mtima 2024 (n 28) 80. See also Bently *et al.,* (n 41) 6.

[46] Mtima 2024 (n 28) 82.

[47] Mtima 2024 (n 28) 82.

While the natural rights and economic incentives theories have historically dominated intellectual property law, their limitations have become increasingly evident.[48] While both natural rights theory and economic utilitarianism offer important foundations for understanding intellectual property law, they fall short in adequately addressing the socio-political dimensions of access and equity in public health. Natural right theory often grounded in Lockean principles of labour and ownership, tends to emphasize the creator's entitlement to exclusive control. However, this perspective does not fully consider the broader societal implications of withholding access to essential medicines, particularly in the context of NCDs. Similarly, economic utilitarianism focuses on incentivizing innovation through the promise of market rewards, but often neglects the distributive consequences, especially when patents lead to unaffordable treatment costs for vulnerable populations. These limitations highlight the need for a more socially responsive framework. It is for this reason that this thesis adopts the Intellectual Property and Social Justice (IP-SJ) theory, which better aligns intellectual property regimes with principles of equity, inclusion, and the right to health.

These limitations highlight the need for a more socially responsive framework. Before concluding, it is important to clarify why this thesis has adopted the IP-SJ framework in preference to other conceptual approached outlined earlier. The principal conceptual justifications for intellectual property protection, namely natural rights, utilitarian economic rationales, and innovation-based perspectives are examined. Although each contributed valuable insights the interrelationship between patent law, access to medicines for NCDs, and the right to health, further research is needed to explore their practical implications. Recognizing their limitation paves the way for considering IP-SJ as a more suitable analytical lens for the present study.

The natural rights tradition, based on Locke's labour theory, views patent protection as the inventor's rightful claim. While this perspective supports granting exclusive rights, it does not consider the wider social impact of such exclusivity. In cases where essential, life-saving treatments are unaffordable for many people, natural rights theory offers no guidance on

[48] Bently *et al.,* (n 41) 7.

balancing the inventor’s rights with the public’s health needs. Its focus on individual entitlements means it does not fully address the social responsibilities tied to the right to health.

Utilitarian theories of intellectual property, by contrast, stress patents as tools to stimulate innovation. This framework is influential in global IP policy, particularly through TRIPS, but it evaluates success primarily in terms of innovation output rather than equitable access. Although utilitarian reasoning recognises the need to balance incentives against social costs, in practice this often leads to privileging the commercial interests of patent holders over distributive equity. For chronic conditions such as NCDs, which demand long-term and affordable treatment, this model risks perpetuating exclusion and inequity.

A further possible lens is the human rights-based approach, which situates intellectual property in relation to the right to health recognised under international law. This perspective is valuable in affirming access to medicines as a matter of rights rather than charity. However, the human rights framework often operates at the level of formal legal entitlements, without interrogating the deeper structural dynamics of power, inequality, and market exclusion that characterise the patent system.

Against these limitations, the IP-SJ framework offers a more robust conceptual foundation for this thesis. By explicitly integrating principles of access, inclusion, and empowerment, IP-SJ reorients patent law analysis toward questions of equity and justice. It examines not only whether laws formally respect the right to health but also whether the operation of the patent system advances or obstructs substantive social justice outcomes. In this way, IP-SJ moves beyond the narrow inventor-public or innovation-access dichotomies of traditional theories, to capture how patent law shapes the distribution of health opportunities across society.

This approach is particularly well suited to the problem of NCD medicines. Unlike acute epidemics, NCDs require sustained access to affordable treatments for large populations over time. The distributive stakes are therefore especially pronounced. IP-SJ allows us to analyse whether patent regimes empower or marginalise affected groups, and to evaluate reforms not only for their economic efficiency but for their contribution to fairness in health access.

Moreover, IP-SJ connects the patent and access debate directly to broader commitments to social justice and human flourishing, aligning the legal analysis with the normative weight of the right to health.

For these reasons, this thesis adopts IP-SJ as its conceptual framework. While alternative theories highlight certain aspects of patent law, only IP-SJ provides the normative and analytical tools necessary to address the structural inequities in access to NCD medicines. Its emphasis on equity, inclusion, and empowerment makes it the most appropriate framework for examining how patent law can and should be reformed to serve the right to health.

This thesis finds the Intellectual Property and Social Justice (IP-SJ) theory a more suitable framework.[49] IP-SJ theory recognizes social justice as an inherent and essential obligation of the IP regime. This approach reframes intellectual property law as a tool for promoting equity and ensuring that the benefits of intellectual property systems are distributed more fairly across society. By adhering to the social justice principles of access, inclusion, and empowerment, the IP regime can foster diverse and socially beneficial participation in intellectual property systems and thereby fulfil its best and highest function in the total political economy.

Intellectual Property and Social Justice (IP-SJ) refers to the intersection of intellectual property law and the pursuit of fairness and equity across society. Intellectual property (IP) encompasses legal rights that protect creations of the mind, such as inventions (patents).[50] IP-SJ on the other hand addresses inequalities and ensures that resources, rights, and opportunities are distributed equitably, regardless of socioeconomic status, gender, or other identities.[51]

The IP-SJ approach examines how intellectual property laws and systems can be designed, interpreted, and implemented to address existing power imbalances.[52] Often, IP laws reflect and reinforce these dynamics, leading to disparities in who benefits from innovation and

[49] Lateef Mtima, 'IP Social Justice Theory: Access, Inclusion and Empowerment' (2019-2020) 55 Gonzaga Law Review 403.
[50] Mtima 2024 (n 28) 77.
[51] Mtima 2019-2020 (n 49) 420.
[52] Mtima 2024 (n 28) 78.

creativity. By applying an IP-SJ approach, the goal is to ensure that IP systems benefit all members of society, especially marginalized groups, while fostering a balance where innovation thrives without undermining basic human rights or social well-being. Economic incentives should be viewed as a means to achieve the broader goal of the IP system. If the potential for financial reward is allowed to outweigh the ongoing advancement of the arts and sciences, the IP ecosystem would become severely imbalanced.[53]

Intellectual property legal scholars have increasingly questioned the viability of the IP commodification paradigm and the prevailing law and economics perspective of intellectual property protection.[54] Traditional IP frameworks have largely prioritized economic interests, often at the expense of social justice concerns such as equitable access and inclusion. However, the evolving perspective on IP-SJ challenges this dichotomy, advocating for approaches that integrate both economic incentives and the broader public good.[55]

One of the most pressing areas of IP-SJ falls within the healthcare system. High prices for patented, life-saving medicines often make them inaccessible to people in low-income regions. Advocates for IP-SJ argue for reforms such as patent limitations or compulsory licensing to improve access.[56] This aligns with the belief that healthcare is a fundamental right, not a privilege for those with financial means. By prioritizing public health over strict economic incentives, IP-SJ provides a framework for challenging the exclusivity of pharmaceutical patents and addressing the global burden of non-communicable diseases.

In sum, IP-SJ requires a balanced assessment of the interests of IP creators, distributions, and users, considering not only economic concerns but also a broad range of cultural, technological, and social values all in the cause of human flourishing and self-actualization. This approach shares common ground with the intellectual property on human rights (HR)

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[53] Mtima 2019-2020 (n 49) 417.
[54] Mtima 2019-2020 (n 49) 407.
[55] Mtima 2019-2020 (n 49) 403. See also Peter S Menell, 'Mapping the Intellectual Property/Social Justice Frontier' in in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024) 21, 21-52. See also Mtima 2024 (n 28) 78.
[56] Lateef Mtima and Steven D. Jamar, 'Introduction: Intellectual Property Social Justice Theory: History, Development, and Description' in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024) 1-18. See also Mtima 2019-2020 (n 49) 407.

approach, which seeks to align intellectual property law with fundamental human rights[57], such as the right to access knowledge, health, and cultural participation. However, while IP-HR operates primarily within formal legal framework, IP-SJ offers a more expansive ethical perspective, emphasizing how IP systems function not only in principle but in actual practice. Central to this approach is the social utility the idea that the legitimacy of IP laws should be measured by their capacity to promote the common good, rather than merely incentivizing private economic gain. Social utility in this sense, requires that IP systems strike a fair balance between the protection of creators' interests and the broader public's access to knowledge and cultural goods. Therefore, IP-SJ insists that IP legal frameworks contribute to access, inclusion, and empowerment especially for marginalized communities aligning intellectual property not just as a tool for economic regulation, but as a mechanism for advancing social justice.[58]

## 6. METHODOLOGY

To answer the question, this thesis will employ three methodological approaches. The first approach is the doctrinal method, the second is the comparative method and the third method is case studies. To begin with, the main method of this original work is doctrinal analysis.[59] Doctrinal method in common law aims to systematise, rectify, and clarify the law on any topic by distinctive mode of analysis to authoritative texts that consist of primary and secondary sources.[60] The process typically starts with the collection and examination of case law and relevant legislation, which serve as primary sources. It then illustrates how the law has developed in terms of judicial reasoning and legislative enactment.[61]

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[57] For the intellectual property rights and human rights see Duncan Matthews, 'Intellectual Property, Human Rights and the Right to Health' in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar, 2010) 3.

[58] Lateef Mtima and Steven D Jamar, 'Researching Social Justice Aspects of Intellectual Property' in Irene Calboli and Maria Lillà Montagnani (eds), *Intellectual Property Research: Lenses, Methods*, and Perspectives (Oxford University Press, 2021) 1. See also Mtima 2019-2020 (n 49) 420.

[59] Mike McConville and Wing Hong Chui, 'Introduction and Overview' in Mike McConville and Wing Hong Chui, (eds), *Research Methods for Law* (Edinburgh University Press Ltd, 2007) 4. See also Ernst Hirsch Ballin, *Advanced Introduction to Legal Research Methods* (Edward Elgar, 2020) 7. See also Una Woods, 'The Case for a Qualified Veto System of Adverse Possession in Ireland: A Doctrinal Approach with Bells and Whistles' in Laura Cahillance and Jennifer Schweppe (eds), *Case Studies in Legal Research Methodologies* (Clarus Press, 2019) 11. Una Woods explains the doctrinal approach as a well-worn, traditional path popular with academic engaging with research questions involving a critique of the law and the need for reform.

[60] Ballin (n 59) 7.

[61] Ian Dobinson and Francis Johns, 'Qualitative Legal Research' in Mike McConville and Wing Hong Chui, (eds), *Research Methods for Law* (Edinburgh University Press Ltd, 2007) 19. See also Ballin (n 59) 7.

The doctrinal method here is a two-step process; firstly, the identification of relevant sources of law and secondly, the interpretation and analysis of the legal text.[62] In other words, doctrinal analysis explores how the law is interpreted and applied in practice. To do so, the first step is a critical analysis of primary sources, focusing specifically on patent law, with particular attention to the patent acts of the UK and Cyprus. Then, it will draw extensively on secondary sources including reports and, academic papers, and engages with the academic discourse on patent law and its impact on access to medicines for NCDs.

This study emphasizes the TRIPS Agreement[63] as a foundational instrument that sets minimum standards for patent protection across WTO member states while allowing certain exceptions to safeguard public health. The Doha Declaration[64] is also analysed for its clarification of the flexibility of TRIPS provisions during public health emergencies, alongside other human rights instruments like the International Covenant on Economic, Social, and Cultural Rights (ICESCR),[65] which enshrines the right to health. In addition, there is a discussion on the TRIPS-Plus which extends beyond the World Trade Organization' TRIPS Agreement.[66] Chapter One of the literature provides a detailed discussion on the TRIPS waiver, including insights from the scholars and experts who argue that TRIPS Waiver would help to increase access to essential medicines during public health crises such as Covid-19, and others who emphasize the importance of maintaining incentives for innovation. The research on Covid-19 was conducted in the English language, utilizing several databases, including HeinOnline, Google scholar, PubMed, online reports, and resources available through the university library. The ongoing discussions on TRIPS waiver highlights the complex relationship between intellectual property law and global health[67] and stress the importance of continued research

[62] Terry Hutchinson and Nigel James Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17(1) Deakin Law Rev, 112 (doctrinal analysis is more than scholarship or literature review alone), 113 ("Doctrinal research is centred on the reading and analysis of the primary sources of legal doctrine. It seeks to achieve more than simply a description of the law.")
[63] Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994) 1869 UNTS 299 (TRIPS).
[64] Ministerial Declaration of 14 November 2001, Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2(Nov.29,2001).
[65] International Covenant on Economic, Social, and Cultural Rights, Adopted by UN General Assembly on 16 December 1966 (ICESCR) (General Assembly Resolution 2200A (XXI), 16 December 1966).
[66] Mohammed El Said, 'The Impact of 'TRIPS-Plus' Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicine and Vaccine* (Springer, 2021) 297.
[67] Kohler *et al.,* (n 18) 159. See also Tenni *et al.,* (n 19) 11.

into mechanisms that can ensure equitable access to medicines while still fostering innovation.

Therefore, following the doctrinal analysis through the reading of legal sources, scholarly literature, and other legal documents, the dissertation explores how various aspects of the law are interpreted by scholars and explains the law as it currently exists.[68]

Following the second methodological approach, the comparative method, which is usually used to analyse and compare two or more legal systems of the world and analyse their performances and interactions[69] examines two distinct jurisdictions: the UK which was previously an EU member, and Cyprus, which remains an EU member. The analysis will focus on the similarities and differences between these jurisdictions. This comparative approach is demonstrated in Chapters Three and Four, where the patent law comparison is presented, and further explored in Chapter Five, which includes analysis and recommendations.

Finally, the third methodology is the case study approach[70] to demonstrate the practical implications of patent law on access to treatments for NCDs, highlighting how patent protection can both enable and restrict access to life-saving medicines, as illustrated by the cases of Ozempic and Imatinib (Gleevec).[71] These two case studies presented in Chapter Five, which explore the ongoing validity of patents for a drug in contrast to its generic version, providing a detailed analysis of the practical implications of patent law in this context. The analysis in based on the theoretical research, relying on the primary sources, augmented by a review of secondary sources, comparative and case law analysis, rather than fieldwork interviews. Therefore, the most reliable and solid sources of data for this thesis are the primary sources, which are central to the doctrinal method employed.

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[68] Hutchinson and Duncan (n 64) 112.
[69] Pier Giuseppe Monateri, *Advanced Introduction to Comparative Legal Methods* (Edward Elgar, 2021) vii.
[70] Rowley (n 12) 16-18.
[71] Case studies are particularly useful at the exploratory stage of research – here for patent law and access to medicines – Rowley (n 12) 16-18.

## 7. LIMITATIONS

This work concentrates on patents and the impact on access to medicines, with a particular focus on NCDs. The rationale for this focus lies in the pivotal role that patents play in the pharmaceutical sector, particularly in safeguarding innovative medicines. However, this emphasis on patents also introduces certain limitations to the scope of the analysis presented in this thesis.

While patents are central tools examined in this work, other aspects of intellectual property area such as trade secrets, design rights, or copyright are not explored. For instance, limitations in this work are the role of trade secrets, or the distinction between trade secrets and confidential information in the context of clinical trials could offer valuable insights. These issues are highly relevant to pharmaceuticals and NCDs, but fall outside the scope of this work, and could be investigated in future research.

As mentioned earlier, this thesis focuses on obesity as a significant risk factor for NCDs, particularly in relation to patent law, public health, and access to medicines. Another limitation of this study is the exclusion of other important risks factors for NCDs, such as tobacco and alcohol use, which also contribute significantly to the global burden of disease. Additionally, this study does not fully explore the socioeconomic and environmental determinants of obesity, which are essential for a comprehensive understanding of its role in NCDs. Future research could address these areas to provide a more holistic perspective on the intersection of intellectual property law and the broader public health challenges posed by NCDs.

## 8. THESIS STRUCTURE

Chapter One presents a comprehensive literature review, critically examining existing scholarship and expert perspectives within the field. To facilitate understanding and clarity, the critical evaluation of the literature in this area is arranged in chronological order. It begins with the historical development of the British patent system, followed by the implementation of the Paris Convention. The chapter then examines the impact of the TRIPS Agreement and the subsequent adjustments introduced by the Doha Declaration. Finally, it concludes with an analysis of the consequences brought about by the Covid-19 pandemic (Chapter One).

It then delves into the Chapter Two with a comprehensive review of the health framework, providing a foundational overview of essential concepts and institutions necessary for understanding the intersection of patent law, public health, and access to medicines particularly in relation to non-communicable diseases (NCDs). It also provides definitions and distinctions between communicable and non-communicable diseases to clarify the specific focus of NCDs and their unique challenges. It also examines the role of key Policy Makers (Organisations) in global health including the World Health Organization (WHO), the European Union (EU) and various UK institutions alongside an analysis of international legal frameworks that protect public health with particular attention paid to human rights treaties. The chapter concludes with a discussion of access to medicines highlighting the impact of patent law on drugs for both communicable and non-communicable diseases (Chapter Two).

Chapter Three discusses public interest in patent law, focusing on the limitations. It explores mechanisms such as compulsory licensing which address public health concern, particularly in the pharmaceutical sector. Furthermore, the chapter reviews key international frameworks, such as the TRIPS Agreement, and examines how their implementation impacts essential medicines. By addressing the balance between innovation incentives and social needs, this chapter provides a nuanced understanding of the public interest considerations inherent in patent law (Chapter Three).

Next, the Chapter Four, private interest in patent law, discussing private rights and drawing insights from significant legal cases that have shaped this discourse. It investigates the nature and scope of patent property rights in the pharmaceutical field, including the international and national legal frameworks within the UK and Cyprus contexts. Additionally, it provides an analysis of legal cases that have shaped private rights, particularly in the pharmaceutical sector (Chapter Four).

Finally, the thesis, synthesizes the key findings, reflects on their broader implications, and concludes the research with a discussion of the potential impact of these insights on further policy and practice (Chapter Five). The key findings highlight the unacceptable inequities in access, availability, and affordability of essential health technologies worldwide in addressing the NCDs burden. Additionally, Chapter Five provides recommendations to mitigate these disparities and improve equitable access to life-saving medicines through the promotion of generic competition and strengthening of public health protections. Collaborations with international organisations is essential. These organisations must prioritize the right to health over economic interests by promoting generic competition to ensure medical innovations remain accessible and affordable. Furthermore, mechanisms such as compulsory licensing should be applied more dynamically to improve affordability, particularly for treatments requiring prolonged use.

Chapter Five also evaluates how legal and regulatory frameworks impact the right to health and access to medicines for NCDs. A comparative analysis of Ozempic and Imatinib (Gleevec) illustrates the interplay between patent protections, market dynamics, and public health outcomes. Ozempic demonstrates the challenges posed by dual purpose medications. Originally developed for type 2 diabetes, its off-label use for weight loss has led to market shortages, limiting access for diabetes patients. Patent protections further restrict generic competition, exacerbating affordability concerns. On the other hand, Imatinib (Gleevec) highlights the conflict between patent exclusivity and public health needs. As a life-saving cancer treatment with a high market cost, many patients struggle to afford it, raising concerns about equitable access to essential medicines.

From an IP-SJ perspective, the two cases highlight the tension between protecting intellectual property rights and ensuring that patents do not hinder access to life-saving medications for those in need, especially in low-and middle-income countries. Therefore, Chapter Five emphasizes the necessity of a balanced approach that upholds pharmaceutical innovation while ensuring equitable access to medicines, in line with social justice principles. This balance is essential in safeguarding the fundamental right to health for all individuals, regardless of their economic status.

In conclusion, this work systematically explores the intersection of intellectual property and public health in the context of NCDs. Chapter One offers a comprehensive literature review, identifying gaps in current research and discourse. Chapter Two outlines the legal and regulatory framework governing NCDs, highlighting general rules and assessing the presence of specific provisions. Chapter Three focuses on the public interests of pharmaceutical companies, examining the balance between patent law and the broader goal of public health. The Fourth Chapter shifts to the private interest, detailing the process and rights granted under patent law. Finally, Chapter Five synthesizes the findings, presents recommendations, and uses case studies such as Gleevec and Ozempic, to demonstrate the practical implications of the proposed reforms. This structure paves the way for a deeper analysis of the health framework, ensuring that future discussions align with the principles of innovation and equitable access.

# CHAPTER ONE: LITERATURE REVIEW - RELATIONSHIP BETWEEN HEALTH REGULATION AND PATENT LAWS: SCOPING THE ISSUES IN NON-COMMUNICABLE DISEASES REGULATION

## 1. Introduction

The conflict between intellectual property, particularly patent law, and public health has long been a subject of intense debate. Historically, discussions have focused primarily on communicable diseases, especially in the context of the HIV/AIDS crisis, due to the urgent need for life-saving treatments in low-and middle-income countries. However, the rising global burden of NCDs has introduced new challenges, particularly concerning access to affordable medicines for chronic conditions. Unlike communicable diseases, NCDs often require long-term treatment, making the cost implications of patent protections even more significant. This tension remains one of the most contentious issues in global health. Scholars have extensively examined how patent laws influence drug pricing, availability and innovation, highlighting both the benefits and limitations of intellectual property frameworks in ensuring equitable access to essential medicines.

Accordingly, this chapter critically reviews existing literature on the interpretation of patent law and access to medicines with a particular focus on NCDs. Placing the literature review at the outset establishes the conceptual foundation for this interdisciplinary study. By surveying scholarship across both health regulation and patent law, the review identifies the key debates, gaps and tensions that frame the inquiry. This orientation provides the necessary context for the subsequent chapters: the health framework in Chapter Two, the public interest in patent law in Chapter Three, and the private interest in patent law in Chapter Four.

Addressing cardiovascular diseases, diabetes, cancer and respiratory conditions, which are major categories of NCDs presents significant global challenges. These diseases account for a substantial proportion of global mortality and morbidity, and access to their treatments is often hindered by stringent intellectual property protections such as those established under the TRIPS.

The research question for this original work is '*To what extent does patent law affect the right of health and access to medicines for non-communicable diseases?'* The research gap lies in the lack of a comprehensive analysis of how patent law impacts the right to health and access to medicines for NCDs. To bridge this gap, this chapter critically examines expert and scholarly literature to identify and address these issues. While extensive research has been conducted on the relationship between patent law and access to medicines, much of the focus has been on infectious diseases, particularly in the context of the HIV/AIDS crisis. However, there remains a lack of a comprehensive analysis of how patent law affects access to medicines for NCDs. This gap is particularly relevant given the increasing global burden of NCDs and the challenges posed by intellectual property frameworks in ensuring equitable access to treatments. By examining expert and scholarly discussions, this chapter highlights the ongoing tension between pharmaceutical innovation incentives and public health needs, with a specific focus on NCDs.

To facilitate clarity the literature in this chapter is organized chronologically. The discussion begins with an exploration of the British patent system, followed by the Paris Convention. It then transitions to the global stage, examining the pre-1994 patent rules under the Paris Convention, and the post-Paris Convention period, concluding with the adoption of the TRIPS Agreement.[72] Particular attention is given to key mechanisms such as compulsory licensing and parallel imports. The chapter further examines the adoption of the Doha Declaration in 2001[73] and concludes with an analysis of the Covid-19 pandemic's impact on vaccine distribution and access to medicines in 2020.

This chapter specifically focuses on scholarly reactions to the Waiver and related policy responses to the Covid-19. The purpose of this review is to position the current study within the broader academic discourse, demonstrating its significance within ongoing debates on intellectual property, public health and NCD treatment accessibility. Through a critical review of expert and scholarly research, this chapter emphasizes the persistent tension between incentivizing pharmaceutical innovation through patents and ensuring equitable access to healthcare. It also highlights how the neglect of NCDs within global health systems and

[72] TRIPS Agreement (n 63).
[73] Doha Declaration (n 64).

intellectual property frameworks has created complex challenges requiring urgent attention and solutions.

## 2. Literature Review on the relationship of patent law and its effect on the regulation of non-communicable diseases

The burden of NCDs is rising across all country income categories, in part because these diseases have been relatively overlooked on the global health agenda. The question of the extent to which patent law affects these diseases remains unanswered. In the past, when detailed data on NCDs were unavailable, experts often overlooked their significance.[74] However, with the emergence of solid numbers demonstrating the seriousness of these diseases and their global impact, it is has become crucial to address them.

Despite this growing recognition, challenges continue in funding new medicines, particularly as the global burden of both CDs and NCDs expands.[75] In particular, due to the Covid-19 pandemic, scholars[76] are again looking at the never-ending tension between patents and public health protection. The following sections will provide a detailed exploration of expert and scholarly perspectives on the topic.

### 2.1. History of the British Patent System prior to the Paris Convention

Scholars have examined the historical foundations of the British patent system, noting that its primary objective in the 16th and 17th centuries was economic rather than health related.[77] Initially, patents were granted as royal privileges without systematic regulation.[78] However, as the system evolved, particularly with the establishment of the Office for the Commissioners of Patents in 1852 which became the Patent Office in 1883[79], mechanisms were introduced to

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[74] Florencia Luna and Valerie A Luyckx, 'Why have non-communicable diseases been left behind?' (2020) 12(1) Asian Bioeth Rev 5 5-25.
[75] Brian Goodman *et al.,* 'Barriers for Access to New Medicines: Searching for the Balance Between Rising Costs and Limited Budgets' (2018) 6(328) Frontiers in Public Health 1-11.
[76] Enrico Bonadio and Andrea Baldini, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health' (2020) 11(2) European Journal of Risk Regulation, 390-395. See also Sarah B Mulkey *et al.,* 'Indirect effects of the Covid-19 pandemic on children related to the child's age and experience' (2023) 94 Pediatr Res 1586-1587.
[77] Birss *et al., Terrell on the Law of Patents* (18th edn, Sweet & Maxwell, 2016) 1-8. See also Bently *et al.,* (n 41) 411.
[78] Bently *et al.,* (n 41) 411.
[79] Bently *et al.,* (n 41) 412.

improve transparency in patent applications.[80] Despite these reforms early patent law did not explicitly consider public health concerns.[81] Patents on medical treatments primarily served inventors rather than ensuring equitable access to medicines. Therefore, patents were organized alphabetically and rules were introduced that helped to ensure that the titles of the patent corresponded to the patented invention. A statutory requirement was established to include a description of the invention, now referred to as a 'specification' in the patent application. Additionally, more attention was given to the form and nature of the information disclosed in the patent.[82]

Before the establishment of the Paris Convention of 1883, there was little to no legal discourse on the implications of patents for public health, particularly concerning NCDs.[83] Although medical inventions, including treatments for diseases, could be patented, there was no specific regulatory framework addressing the public health impact of patenting, especially in relation to access to medicines for NCDs.

NCDs were not recognized as a major global health priority and the impact of patents on public access to essential medicines was not an essential issue within the patent system. Early British patent laws were primarily designed to stimulate industrial growth and reward innovation rather than to serve public health objectives. The patent system provided inventors with exclusive rights to encourage advancements in various fields including medicine, but without explicit regulatory mechanisms to ensure that such innovations remained accessible to the public. As a result, medical patents functioned primarily as commercial assets, with limited consideration for broader societal needs.

The late recognition of public health considerations within patent law highlights a historical reluctance to prioritize access to medicines over commercial incentives. While the growing

[80] Bently *et al.,* (n 41) 412. In part, this was because in many cases, the information disclosed in the patent was of limited practical value. Given the lack of control exercised over the nature and content of the information disclosed in the patent, key aspects of inventions were often not disclosed. Consequently, third parties were often not able to work or practise the invention from the information disclosed in the patent. Even were the information disclosed in the patent was potentially valuable, it was often very difficult for third parties to locate the relevant information. See also Philip Johnson, *Privatised Law Reform: A History of Patent Law through Private Legislation* (Routledge, 2017) 113-18.

[81] Bently *et al.,* (n 41) 412

[82] Bently *et al.,* (n 41) 412

[83] Sam Ricketson, *The Paris Convention for the Protection of Industrial Property: a commentary* (Oxford University Press, 2015) 7 subsection 1.05.

burden of NCDs in the late 20th and early 21st centuries forced policymakers to recognize the implications of pharmaceutical patents, these reforms were largely reactive rather than proactive. The British patent system's historical emphasis on economic and industrial development over healthcare accessibility reflects a broader tension that remains at the heart of contemporary global IP debates.

The historical evolution of the British patent system reflects a broader trend in early patent law, where economic and industrial priorities took precedence over public health concerns. This national approach was mirrored in international legal frameworks, including the Paris Convention of 1883, which sought to harmonize patent rights globally. However, much like early British patent law, the Paris Convention primarily focused on protecting inventors' rights rather than addressing the accessibility of medicines. The following section examines how the Paris Convention shaped global patent policies and the extent to which it allowed states to regulate pharmaceutical patents in line with public health considerations.

### 2.2. Pre-1994: the Paris Convention

A review of legal and scholarly discussions from the period surrounding the development of the Paris Convention[84] reveals that while patents were firmly established as a component of intellectual property rights, the implications for access to medicines for NCDs received little direct engagement.[85] The literature from the late 19th century primarily focused on the harmonization of patent rights across jurisdictions, emphasizing their role in fostering economic and industrial development.[86] Discussions on the broader societal impacts of patents, particularly in the context of pharmaceuticals and public health, remained largely peripheral.[87] Although some legal analyses acknowledged the potential influence of patents on innovation in medicine, the issue of access to medicines especially for chronic conditions was not a prominent concern. Instead, prevailing legal and policy debates were largely shaped by the prioritization of acute public health challenges rather than the long-term treatment needs associated with NCDs.

[84] Sam Ricketson (n 83) 15-19 subsection 1.17.
[85] Sam Ricketson (n 83) 15 subsection 1.17.
[86] Sam Ricketson (n 83) 15 subsection 1.17.
[87] Sam Ricketson (n 83) 15 subsection 1.17.

The Paris Convention introduced certain flexibilities that allowed member states to tailor aspects of their national intellectual property laws, particularly in areas not explicitly harmonized by the treaty. One of its significant provisions, Article 5A(2)[88], recognized the principle of preventing patent abuse, which later influenced national policies on compulsory licensing. While the Convention itself did not mandate compulsory licenses, it provided countries with the discretion to implement measures including forfeiture or licensing to address patent misuse. The literature indicates that these flexibilities enabled states to shape their patent systems, according to national priorities, though the Convention did not prescribe rules regarding the exclusions of entire fields of technology or the duration of patent protection. Instead, such decisions were left to national discretion. Additionally, the Convention implicitly acknowledged that public interest considerations could justify deviations from strict patent exclusivity, demonstrating an early recognition of the tension between patent rights and broader societal needs.

In practice, these flexibilities allowed countries to designed national intellectual property regimes suited to their specific economic and public health contexts.[89] Many states particularly in the pre-TRIPS era leveraged this discretion to exclude certain technologies from patent protection, including pharmaceutical products.[90] The literature suggests that during this period both developed and developing countries opted to withhold patent protection for medicines to facilitate broader access to essential treatments without the constraints imposed by patent monopolies.[91] This approach aligns with the broader public health commitments of

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[88] Paris Convention 1883, Article 5(A)(2).

[89] For example, Switzerland and Italy did not provide patent protection for pharmaceutical products until 1977 and 1978, respectively. Fabio Pammolli *et al.,* 'The Intensity of Competition After Patent Expiry in Pharmaceuticals. A Cross-Country Analysis' (2002) 99 *Revue d'Economie Industrielle* 107-132. India did not provide pharmaceutical product patent protection until 2005. See also Frederick M Abbott and Ferome H Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amendment TRIPS Provisions" (2007) 10(4) Journal of International Economic Law 921-987. See also Duncan Matthews and Carlos Correa, 'The Doha Declaration Ten Years on and its Impact on Access to Medicines and the Right to Health' (United Nations Development Programme 2011) 5. Available: https://qmro.qmul.ac.uk/xmlui/bitstream/handle/123456789/3109/MATTHEWSTheDohaDeclaration2011FINAL.pdf?sequence=2

[90] Matthews and Correa (n 89) 5. An amendment in 1969 to the Brazilian legislation declared pharmaceutical products and processes non-patentable. In 1970s, developing countries attempted, in line with new perspectives on social and economic development, to move forward a revision of the Paris Convention that would have provided more flexibility in patent legislation, particularly in the area of compulsory licenses. This initiative, however, was defeated; a well-articulated counter-offensive by developed countries led to the negotiation of standards on IPRs as an item of the trade agenda. See also Paris Convention for the Protection of Industrial Property.

[91] Carlos M Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, (Reprinted edition, Zed Books Ltd, 2000) 167-196. See also Ellen F M 't Hoen, 'The Global Politics of Pharmaceutical Monopoly

the time, as states sought to balance incentives for innovation with the need for affordable medical treatments. Through the regulation of patent protection, national governments could influence the accessibility and affordability of essential medicines, directly impacting public health outcomes.

Intellectual property disputes within the context of patent law and access to medicines for NCDs remain an underexplored area in a legal scholarship from this period. While there is an extensive body of literature on the broader implications of patent law, in depth-analysis explicitly linking patent protection to access to medicines for NCDs remain limited. Legal discussions surrounding the Paris Convention's role in shaping national patent systems have primarily focused on its economic and industrial motivations with less emphasis on its potential impact on pharmaceutical accessibility.

A central question in this debate is whether the Paris Convention actively sanctioned the exclusion of pharmaceuticals from patent protection, or whether this was a policy choice exercised by individual states. If the Convention explicitly endorsed the exclusion of pharmaceuticals, this would suggest a stronger historical precedent for flexible patent policies, reinforcing arguments for expanding TRIPS flexibilities today. However, the absence of specific provisions regulating pharmaceuticals could also indicate that early international patent law was primarily concerned with harmonization and economic development, rather than public health.

While the Paris Convention undeniably allowed states exercised discretion over patentability, the extent to which it actively encouraged the exclusion of pharmaceuticals remains contested. Given the increasing global recognition of the need for equitable access to medicines, this debate remains particularly relevant today in discussions on TRIPS flexibilities, compulsory licensing and patent law reforms aimed at addressing the global burden of NCDs. To better understand how patent protection for medicines has evolved, the following sections

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Power: Drug Patents, Access, Innovation, and the Application of the WTO Doha Declaration on TRIPS and Public Health' (*AMB* 2009).Available:https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf will examine the pre-and post-TRIPS era, highlighting how shifts in international patent norms have influenced access to medicines.

### 2.3. Post 1994 -TRIPS Agreement to up to 2001

As discussed in the previous section, prior to the adoption of the TRIPS Agreement in 1995, national patent regimes were largely determined by domestic legal and policy considerations.[92] The absence of a unified international framework allowed countries to tailor their intellectual property laws to align with national economic and public health priorities. However, with the introduction of the TRIPS Agreement as a binding component of the WTO framework[93], member states became subject to standardized intellectual property rules[94], significantly reducing their discretion in patent policymaking. Given the profound implications of this shift, a body of literature emerged between 1994 and 2001 analysing the early impact of TRIPS on global patent governance, particularly in relation to access to medicines. The following section critically engages with these scholarly discussions, assessing the extent to which TRIPS redefined the balance between intellectual property rights and public health.

### 2.4. Review of the TRIPS Commentary and Related Scholarship

The TRIPS Agreement's provisions on patents and pharmaceutical products have been subject to discussions and debates, particularly concerning access to affordable medicines in developing countries.[95] These discussions have often focused on striking a balance between protecting intellectual property rights and ensuring access to essential medicines including those needed to treat non-communicable diseases.[96] Some developing countries delayed

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[92] Tenu Avafia and Savita Mullapudi Narasimhan, 'The TRIPS Agreement and Access to ARVs' (*United Nations Development Programme* 2006) 9-10. Available: https://www.undp.org/sites/g/files/zskgke326/files/publications/5.pdf India was one of the countries that as part of its obligations under TRIPS, was required to introduce product patent protection for pharmaceuticals by 1 January 2005.

[93] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (5th edn, Sweet & Maxwell, 2021) 40 subsection 1.34.

[94] Gervais (n 93) 56 subsection 2.02.

[95] Gervais (n 93) 72 subsection 2.23. See also Mary K Schug, 'Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa within the Framework of International Intellectual Property Law' (2001) 19(2) Minnesota Journal of Law & Inequality 229. Scholars have highlighted the insufficient access to essential medicines for HIV/AIDS treatment. One contributing factor to the limited availability of pharmaceuticals in the developing world is the WTO TRIPS Agreement, which keeps the prices of drugs high and mandates countries to respect intellectual property rights. This phenomenon persists today, particularly in the case of drugs for non-communicable diseases.

[96] World Trade Organization, 'Pharmaceutical Patents and the TRIPS Agreement' (*World Trade Organization* 2006) <https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm> accessed 25 March 2025. TRIPS set minimum standards to the Member States but also but also contains 'flexibilities' designed to address barriers to access to medicines.

patent protection for pharmaceutical products[97], until 1 January 2005.[98] This was allowed under Article 65.4, a provision that says a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (1 January 1995) has up to 10 years to introduce the protection.[99] This situation arises due to concerns raised about the availability and pricing of medicines under the TRIPS Agreement.

It is evident that experts[100] in this field have consistently directed their attention toward communicable diseases[101] rather than non-communicable diseases. Experts argue that the significance of communicable diseases[102] is highlighted, leading to their prioritization in many countries due to their perceived status as the primary disease burden, particularly among vulnerable and poor populations. Since the establishment of the TRIPS Agreement there have been several disputes dealing with intellectual property enforcement and TRIPS is one of the most active areas of the Dispute Settlement Body (DSB).[103]

As NCDs have become a major global health concern, there has been an increasing focus on research, prevention, and management of these diseases.[104] The expansion of literature on NCDs can be attributed to key declarations by WHO and the publication of related policy documents, particularly from the early 2000s onwards. The 2011 UN High Level Meeting on NCDs further solidified international recognition of these diseases as a pressing global issue. As a result, discussions on the prevalence and impact of NCDs have gained attention, and this

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97 United Nations Conference on Trade and Development, 'TRIPS Agreement and Developing Countries' (*United Nations* 1997) UNCTAD/ITE/1. 30. Available: https://unctad.org/system/files/official-document/ite1_en.pdf. See also Parliamentary Office of Science and Technology 'Access to medicines in the Developing World' (*Parliament Office of Science and Technology* 2001). Available: https://www.parliament.uk/globalassets/documents/post/pn160.pdf

98 World Trade Organization, 'Developing countries' transition periods' (*World Trade Organization* 2006) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm> accessed 25 March 2025.

99 TRIPS Agreement, Article 65.4. "An additional period of five years" Article 65 provides for transitional periods for developing countries: in general, five years from the entry into force of the WTO Agreement, 1 January 2000, and an additional five years to provide for product patents in areas of technology not so patentable as of 1 January 2000. Thus, in such areas of technology, developing countries are not required to provide product patent protection until 1 January 2005.

100 Gervais (n 93) 56 subsection 2.02.

101 Parliamentary Office of Science and Technology, 'Access to Medicines in the Developing World' (n 97) Discussions about HIV/AIDS persists to this day.

102 Avafia and Narasimhan (n 92) 7. The TRIPS Agreement allows several numbers of mechanisms that developing country governments can use to ensure more access to ARVs: these include compulsory licensing, parallel importation, and the importation of generics products under compulsory licenses. Compulsory licenses also been discussed in Chapter Three heading 3 ('Limitations on Patentability').

103 Gervais (n 93) 56 subsection 2.02.

104 Aida Budreviciute *et al*., 'Management and Prevention Strategies for Non-communicable Diseases (NCDs) and Their Risk Factors' (2020) 8 (574111) Front Public Health 2-11.

suggests a growing recognition of the significance and necessity for comprehensive policy responses to NCDs. Since then, there has been a notable growth in literature examining the intersection of patent law and NCDs, a discussion that will be explored in the following sections.

### 2.5. Examining the significance of Compulsory License

With the establishment of the TRIPS Agreement, scholarly attention began to focus on compulsory licensing.[105] The next section will therefore analyse the literature on compulsory licenses and how the Doha Declaration has influenced and encouraged the issuance of the compulsory license after 2001.

### 2.6. Literature on Compulsory licensing and its effects

Developing countries and human rights activists claim that high prices on drugs are the result of strong patent protection, which governments must provide under the TRIPS Agreement.[106] With the flexibilities provided by TRIPS such as compulsory licensing and parallel importing it provides some flexibilities for states to address their public health needs by allowing some exceptions to patent protection.[107]

South Africa, along with other developing nations, has attempted to take advantage of this flexibility by reducing prices for HIV/AIDS treatments.[108] However, the multinational drug companies with the US government, have aggressively opposed such legislation, categorising it as an infringement on their intellectual property rights.[109] With the academic perspective,

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[105] Behrang Kianzad and Jakob Wested, 'No-one is Safe until Everyone is Safe' – Patent Waiver, Compulsory Licensing and COVID-19' European Pharmaceutical Law Review (2021) 5(2) EPLR 71-91. It is states that the enactment of the TRIPS Agreement in 1994, and harmonization global protection of IPRs raised the debate on compulsory licensing, according with HIV/AIDS pandemic, and fears in developing world of increased pharmaceutical spending resulting from protection of patents. Compulsory licensing, it is when the generic copy is produced mainly for the domestic market, not for export. In response to a WIPO study on compulsory licensing, the most cited grounds for grant of compulsory licensing included non-working or insufficient working of the patented invention, refusal to grant licenses on reasonable terms and public.

[106] Lissett Ferreira, 'Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations' (2002) 71 (3) Fordham Law Review 1133.

[107] Ferreira (n 106) 1133.

[108] Debora Halbert, 'Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs (2002) 1(2) Seattle Journal for Social Justice 257.

[109] Daniel J Ncayiyana, 'Antiretroviral therapy cannot be South Africa's first priority' (2001) 164(13) CMAJ 1857-1858. See also Halbert (n 108) See also Erika George, 'The Human Rights to Health and HIV/AIDS: South Africa and South-South Cooperation for Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines' (2011) 18(1) Indiana Journal of Global Legal Studies 167.

scholars have differing perspectives on compulsory licensing.[110] From an academic perspective, scholars such as Lowri Davies *et al.*,[111] highlight compulsory licensing as a necessary tool to overcome access barriers, others[112] emphasize the need to balance public health concerns with intellectual property protection to maintain an environment of conducive to innovation.

In particular, Robert Bird acknowledges that compulsory licensing plays a crucial role in improving access to medicines for those who cannot afford them. However, he also raises concerns about the use of the compulsory license itself and how it can “negate the benefits from increases access” due to insufficient consideration by governments.[113] He argues that insufficient consideration in their application may ultimately negate the intended benefits of increased access. Critics of compulsory licensing further contend that such measures can reduce incentives for pharmaceutical innovation.[114] They believe that by undermining the financial returns companies rely on to fund research and development[115], compulsory licensing weakens the patent system and discourages investment in new drug discoveries.[116] As a result, fewer resources may be allocated to developing innovative treatments, potentially slowing medical advancements and limiting future breakthroughs in healthcare.

There are several reasons that compulsory mechanisms cannot be always a win for the innovators and pharmaceutical companies.  A compulsory license allows other companies to produce and sell a patented medicine without the patent owner’s consent. This reduces the exclusivity period during which the original innovator can recoup their investment. Also,

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[110] Ruth L Okediji and Margo A Bagley, *Patent Law in Global Perspective* (Oxford, 2014) 485. See also Cynthia M Ho, ‘A new approach to the compulsory license conundrum’ in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (Oxford, 2014) 485.
[111] Lowri Davies, ‘Compulsory Licensing: an effective tool for securing access to Covid-19 vaccines for developing states?’ in Lowri Davies (ed), *Legal Studies* (Cambridge University Press, 2022) 86-103. See also Okediji and Bagley (n 110) 485. See also Ho (n 110) 485.
[112] World Health Organization, ‘Intellectual Property rights, innovation and public health’ (*World Health Organization* 2003) Fifty-Sixth World Health Assembly A56/17. Available: https://apps.who.int/gb/ebwha/pdf_files/WHA56/ea5617.pdf. See also Okediji and Bagley (n 110) 485.
[113] Ferreira (n 106) 1133.
[114] Edwin Mansfield ‘Patents and Innovation: An Empirical Study’ (1986) 32(2) The Institute of Management Sciences 173. Mansfield’s research suggests that approximately 65% of medicines would not be launched by companies but “for the existence of legal patent protection” since companies invest significant amounts into the development of new medicines.
[115] World Trade Organization, ‘Compulsory licensing of pharmaceuticals and TRIPS’ (*World Health Organization* 2025) <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 25 March 2025.
[116] Jamie Feldman, ‘Compulsory Licenses: The Dangers Behind the Current Practice’ (2009) 8(1) Journal of International Business and Law page 137.

pharmaceutical companies often charge high prices for patented medicines to recover their R&D costs and funding. Generic versions of drugs often reduce the overall profits, leading inventors to be less willing to fund pharmaceutical companies.[117]

Nevertheless, a study by Chien *et al.,*[118] reaches the opposite conclusion about the effects of the compulsory license on innovation. Chien analysed a total of six cases of compulsory licenses between 1980 and 1990 (before the TRIPS Agreement), looking at the reason for issuing the license, the type of license and the impact on HIV medicines. Chien concluded that there was no notable decrease in innovation for HIV medicines by the companies during the years studied.[119] However, Chien argues that the licensing of orphan drugs-medicines that developed to treat rare diseases or conditions that affect a small populations was more likely to de-incentivize innovation in the pharmaceutical area.[120] In a similar vein Moser, in 2013, demonstrated that the loss of an intellectual property right actually promotes innovation, since companies want to remain competitive.[121] Moser also made a finding that compulsory licenses may even increase innovation in the licensing countries domestically, as opposed to the evidence that would discourage innovation.[122]

Compulsory licensing has long been a contested mechanism within intellectual property law, particularly regarding access to medicines.[123] While it has been instrumental in expanding treatment options for diseases such as HIV/AIDS, its broader implications for global health and pharmaceutical innovation remain debated. Compulsory licensing allows government to authorize the production of patented medicines without the patent holder's consent, typically in cases of public health emergencies or market failures.[124] Articles 30 and 31 of TRIPS[125]

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[117] Feldman (n 116) 137.
[118] Colleen V Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation' (2003) 18(853) Berkeley Technology Law Journal 855.
[119] Chien (n 118) 855.
[120] Beatrice Stirner and Harry Thangaraj, 'Leaning from practice: compulsory licensing cases and access to medicines' (2013) 2(2) Pharmaceutical Patent Analyst 195-213.
[121] Petra Moser, 'Patents and Innovation: Evidence from Economic History' (2013) 27 (1) Journal of Economic Perspectives 34.
[122] Moser (n 1098) 34. As evidenced by the literature review, it is possible to conclude that innovation has not been affected by the existence of the compulsory license.
[123] Samira Guennif, 'Evaluating the Usefulness of Compulsory Licensing in Developing Countries: A Comparative Study of Thai and Brazilian Experiences Regarding Access to Aids Treatments' (2017) 17(2) Dev World Bioeth 90-99. See also Eduardo Urias and Shyama V Ramani, 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3(4) National Library of Medicines 367-384.
[124] Guennif (n 123) 90-99. See also Stirner and Thangaraj (n 120) 195-213.
[125] Jennifer Sellin, 'Access to Medicine: The Problem' in Sellin J (ed), Access to Medicines: The Interface between Patents and Human Rights: Does One Size Fit All? (School of Human Rights Research Intersential, 2014) 445-473. See also Manisha A

provide a legal framework that enable member states to implement such measures, allowing flexibility in balancing patent protection with the right to access essential medicines.

Several scholars emphasize the public health benefits of compulsory licensing. Hilary Wong highlights its effectiveness as a policy tool during the HIV/AIDS crisis, where it significantly improved access to antiretroviral drugs in low-income countries.[126] Yousuf A Vawda frames compulsory licensing within the broader human rights discourse, arguing that it is a legitimate instrument for ensuring universal access to essential medicines.[127] Gorik Ooms and Johanna Hanefeld suggest that low-and middle-income countries can strategically leverage compulsory licensing to negotiate better access to medicines by counterbalancing pharmaceutical monopolies.[128] They contend that patent monopolies often enable pharmaceutical companies to impose excessive pricing, delay the entry of generic alternatives, and limit competition, all of which can hinder efforts to combat public health crises. By allowing governments to authorize the production of generic versions of patented medicines without the patent holder's consent, compulsory licensing serves a crucial mechanism to balance intellectual property protections with the right to health.[129]

In addition, other scholars argue that compulsory licenses are crucial for ensuring access to essential medicines in low-and middle-income countries, especially during public health emergencies. They have also discussed the balance between incentivizing pharmaceutical innovation and protecting public health, emphasizing continuing challenges and the need for

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Desai, 'Compulsory licensing: Procedural requirements under the TRIPS agreement' (2016) 18 Pharmaceuticals Policy and Law 31-44. Article 30 provides the exceptions to the rights of the patent holder which should meet the three criteria: the exception must be limited, the exception must not unreasonably conflict with normal exploitation of the patent and the exception must not unreasonably conflict prejudice the legitimate interests of the patent holder. Article 31 further clarifies that the 'other use' permitted under Article 31 refers specifically to exceptions other than those permitted under Article 30. Both Articles will be discussed in Chapter Three. Article 31 section 3 ('Limitations') and Article 30 section 4 ('Exceptions on patentability').

[126] Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1) J Glob Health 1-5. See also Yousuf A Vawda, 'Compulsory Licenses and Government Use: Challenges and Opportunities' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines* (Springer, 2021) 73-104.

[127] Vawda (n 126) 73-104.

[128] Gorik Ooms and Johanna Hanefeld, 'Threat of compulsory licences could increase access to essential medicines' (2019) 365(l2098) BMJ 1. See also Feldman (n 116) 137. See also Adi Gillat, 'Compulsory licensing to regulated licensing: effects on the conflict between innovation and access in the pharmaceutical industry' (2003) 58(4) Food Drug Law Journal 557-565. Advocates argue that it is necessary legal tool to address certain abuses of intellectual property rights, ensuring that life-saving medications remain accessible and affordable, especially in low- and middle-income countries where high drug prices can make essential treatments unattainable.

[129] Anselm Kamperman Sanders, 'Compulsory Licensing and Public Health' (2004) 11(4) Sage Journals 1. See also Divya Murthy, 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health' (2002) 17(6) The American University International Law Review 1307.

international cooperation.[130] Thomas J Bollyky writes that India's highest court unsettled the multinational pharmaceutical industry by refusing to grant a patent on a modified version of Gleevec[131], an anti-leukaemia drug. India also issued a compulsory license for a treatment for liver and kidney cancer and announced its intention to issue licenses on two breast cancer drugs, including a treatment for liver-cancer-causing hepatitis B. China and the Philippines amended their patent laws, making it easier to issue compulsory licenses for medicines. The author noted in his article that the emerging fight over patented NCD therapies in developing countries should not require the massive resources for HIV/AIDS. He suggested that frugal innovation, financial incentives, pooled procurement and intra-country differential pricing could provide a way forward in addressing the treatment.[132]

However, opposition[133] to compulsory licensing often revolves around concerns regarding its potential to discourage innovation and investment in pharmaceutical research. Behrang Kianzad argues that compulsory licensing represents an intrusive public intervention that undermines exclusive legal rights, often based on unclear justifications such as "public health" or "national emergency."[134] Critics maintain that allowing broad use of compulsory licensing could discourage pharmaceutical companies from investing in high-risk drug development, particularly for diseases requiring significant research funding. They emphasize the potential negative effects such intervention might have on investment and innovation incentives.[135] They argue that compulsory licenses undermine the exclusivity granted by patents, reducing the financial returns for pharmaceutical companies, and discouraging future investment in research and development. Without strong patent protections, companies may be less willing

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[130] Murthy (n 129) 1307. Thomas J Bollyky, 'Access to drugs for Treatment of Non-communicable diseases' (2013) 10(7) PLos Med 3.

[131] Bollyky (n 130) 3.

[132] Bollyky (n 130) 3,4.

[133] Samira Guennif, 'Is compulsory Licensing Bad for Public Health? Some Critical Comments on Drug Accessibility in Developing Countries' (2017) 15 (5) Applied Health Economics and Health Policy 557. See also Gillat (n 128) 557-565. See also Feldman (n 116) 137-167. See also Margo A Bagley, 'The Morality of Compulsory Licensing as an Access to Medicines Tool' (2018) 102(2463) Emory Law Scholarly Commons 2463. See also William W Fisher III and Talha Syed, *Infection: The Health Crisis in the Developing World and What We Should Do About It* (Stanford University Press, 2017). Chapter Five 1-55. (noting several reasons for the infrequent use of compulsory licenses despite the strong need for cheaper medicines, including that "the pharmaceutical firms disadvantaged by compulsory licenses and the governments of the countries in which those firms are based sometimes retaliate (or threaten to retaliate) against the countries that used them"). Against compulsory licenses see also Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) 3(3) International Journal of Social Science and Humanity 254.

[134] Behrang Kianzad and Jakob Wested, 'No-one is Safe Until Everyone is Safe' – Patent Waiver, Compulsory Licensing and COVID-19' (2021) 5(2) European Pharmaceutical Law Review 71-91.

[135] Guennif (n 133) 90-99. See also Adi Gillat (n 128) 711-740. See also Feldman (n 116) 137.See also Bagley (n 133) 2463. See also Fisher III and Syed (n 133) Chapter Five 1-55. Against compulsory licenses see also Abbas (n 133) 254.

to take the financial risks associated with developing new drugs, potentially slowing down innovation in critical medical advancements. Additionally, opponents claim that frequent or board use of compulsory licensing could lead to uncertainty in the pharmaceutical market, discouraging private-sector participation and international collaborations in drug development.

Recognizing these tensions, Olga Gurgula and John Hull acknowledges the practical challenges associated with compulsory licensing but suggest potential policy solutions to balance the interests of technology owners with public health needs.[136] They highlight the necessity for a complementary framework for compulsory licensing which could ensure that technology transfer mechanisms remain effective. This perspective raises important questions about whether existing TRIPS flexibilities are sufficient to address modern global health crises or if further reforms are required to make compulsory licensing a more predictable and transparent tool.[137]

Scholarly discussions of compulsory licensing and access to medicines suggest that while its use in addressing infectious diseases, such as HIV/AIDS has been widely analysed, its application to NCDs remains less explored. As discussed above, some researchers argue that compulsory licensing could be an essential tool in ensuring affordable access to life-saving treatments for conditions such as cancers, diabetes, and cardiovascular diseases. However, others highlight that its practical implementation in the context of NCDs presents unique challenges including regulatory obstacles, market incentives, and the chronic nature of these diseases.

The next section will examine scholarly discussions from 2001 to 2020, focusing on how the legal and policy debates surrounding the Doha Declaration evolved over time.

[136] Olga Gurgula and John Hull, ‘Compulsory licensing of trade secrets: ensuring access to Covid-19 vaccines via involuntary technology transfer’ (2021) 16(11) Journal of Intellectual Property Law & Practice 1242-1261.
[137] Gurgula and Hull (n 136) 1242.

### 2.7. Doha Declaration (2001-2020)

The most notable achievement in the post-TRIPS era has been the success of developing countries and LDCs in gaining recognition for intellectual property-related public health concerns and securing concessions through the Doha Declaration on TRIPS and Public Health in 2001.[138] While the Declaration primarily addressed access to medicines for infectious diseases, particularly in the context of HIV/AIDS[139], it also laid the groundwork for broader discussions on the role of intellectual property in global health. Despite the incorporation into TRIPS, research on intellectual property rules and public health continues, with a substantial body of literature exploring these issues.[140] This period witnessed a significant expansion of discourse on patent law and the emergence of critical debates on health-related intellectual property rights. Accordingly, this section will examine articles published between 2001 and 2020.

WTO Member States have not designated policies to adequately address NCD diseases. Instead, their policies and interventions prioritized communicable diseases[141], likely due to the risk of transmission, which serves as a primary rationale for this focus. As a result, NCDs

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[138] Doha Declaration (n 64). In 2001, the Doha Declaration underscored the necessity of incorporating the Agreement on TRIPS to be part of wider action to address public health problems afflicting developing economies and least-developed countries, confirming the right of WTO members to take measures to protect public health.

[139] Ellen 't Hoen and Carlos Andre Passarelli, 'The role of intellectual property rights in treatment access: challenges and solutions' 8 (1) 70.

[140] Ellen F M 't Hoen, 'TRIPS Pharmaceutical Patents and Access to Medicines: Seattle, Doha and Beyond' (2003) 11(8) MSF Access Campaign 39-68. In the time after the TRIPS Agreement was adopted, scholars have looked at a substantial progress been made in global access to costly medicines, such as antiretroviral drugs for HIV and also, they have looked and focused on the non-communicable diseases which this thesis focuses on. See also Philippe Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79(1) International Affairs 139-160. See also Ellen 't Hoen *et al.,* 'Driving a decade of change: HIV/AIDS, patents and access to medicines for all' (2011) 14(1) Journal of the International AIDS Society. 14. See also David Barnard, 'In the high court of South Africa, case no. 4138/98: the global politics of access to low-cost AIDS drugs in poor countries' (2002) 12(2) Kennedy Institute of Ethics Journal 159-74. See also Motari *et al*., (n 22) 1-19. There is still discussion about the intellectual property rights on access to medicines in the African region, particularly for the high prices of medicines. See also Murthy (n 129) 1326. Specifically, the author, states that pharmaceutical aim to make money and create new drugs that make people healthier and save lives. Some critics argue that making a profit can be risky when it comes to improving health, but the evidence strongly suggests that these companies have successful balanced both goals. See also Florencia and Luyckx (n 74) 5-25. See also Carlos Maria Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd edn, Oxford University Press, 2007) 573. See also Tim K Mackey and Bryan A. Liang, 'Patent and Exclusivity Status of Essential Medicines for Non-Communicable Disease' (2012) 7(11) PLos ONE 1-8. See also Goodman *et al.,* (n 75) 1-21. See also Olivia Heller *et al.,* 'The process of prioritization of non-communicable diseases in the global health policy arena' (2019) National Library of Medicines (2019) 34(5) Health Policy Plan 370-383. See also Steve Charnovitz, 'The Legal Status of the Doha Declarations' (2002) 5(1) Journal of International Economic Law 2007. See also Gervais (n 93)74 subsection 2.24.

[141] Luna and Luyckx (n 74) 5-25. See also Heller *et al.,* (n 140) 370-383.

remain neglected.[142] Studies have further highlighted that essential medicines used to treat chronic diseases in low- and middle-income counties often have limited availability and affordability, particularly in public sector settings.[143] The literature indicates a continued unmet medical need for new medicines across countries, especially for conditions such as cancer immunological diseases, and orphan diseases. Specifically, essential medicines for diabetes asthma cardiovascular diseases, and cancer have been identified as lacking in both availability and affordability.

Between 2001 to 2020, a significant body of literature has emerged regarding the Doha Declaration. This research included two hundred seventy-one articles in English and thirty-five books focusing on topics such as patents, access to medicines, TRIPS Agreement and the Doha Declaration. This research was conducted in English, using several databases, including HeinOnline, Google Scholar, WestLaw, LexisNexis, PubMed, and resources available through the library. Specifically, the articles including patents and access to medicines are all included in the literature review.[144]

The Doha Declaration on the TRIPS Agreement and Public Health acknowledges the impact of intellectual property rights on medicine prices and the development of new medicines.[145] To address these concerns, the declaration introduced TRIPS flexibilities which allow WTO Member States to implement measures ensuring equitable access to medicines for all.[146]

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[142] Sudip Bhattacharya *et al.,* 'Incorporating neglected non-communicable diseases into the national health program- A review' (2023) 10(1093170) Front Public Health 1-9. See also Joshua S Yang *et al.,* 'Incorporating a structural approach to reducing the burden of non-communicable diseases' (2018) 66 Globalization and Health 1-10. See also Alan D Lopez *et al.,* 'Remembering the forgotten non-communicable diseases' (2014) 12(200) BMC Medicine 1-19. See also Luna and Luyckx (n 74) 5-25.

[143] Shanti Mendis *et al.,* 'The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries' (2007) 85(4) Bull World Health Organ 279. See also Marie Stolbrink *et al.,* 'Availability, cost and affordability of essential medicines for chronic respiratory diseases in low-income and middle-income countries: a cross-sectional study' (2024) 79 Open Access 676-679. See also Luna and Luyckx (n 74) 5-25.

[144] Thomas John R, 'Pharmaceutical patents' in Toshiko Takenaka (ed), *Research Hnadbook on Patent Law and Theory* (2nd edn, Edward Elgar, 2019) 353.

[145] Doha Declaration (n 64).

[146] Ellen Fm 't Hoen *et al.*, 'Medicine procurement and the use of flexibilities in the Agreement on Trade- Related Aspects of Intellectual Property Rights, 2001-2016' (2018) 96(3) Bull World Health Organ 185. The authors highlight that the Doha Declaration recognized the implications of intellectual property rights for new medicines and for the price of medicines. Doha Declaration outlined measures, known as TRIPS flexibilities, that WTO Members can take to ensure access to medicines for all. The measures include compulsory licensing of medicines patents and the least-developed countries pharmaceutical transition measure.

These flexibilities include compulsory licensing, public non-commercial use (TRIPS article 31)[147], patent exceptions (TRIPS article 30), the Least-Developed Country (LDC) transition provisions (Paragraph 7) and parallel importation (Paragraph 5(d) Doha Declaration on TRIPS and Public Health.[148] Among these, Article 31 of TRIPS has been identified as an effective mechanism for reducing pharmaceutical costs.[149] Recent research led by Ellen t'Hoen and colleagues suggests that TRIPS flexibilities, particularly compulsory licenses "have been used more frequently than previously assumed"[150] in facilitating the procurement of generic essential medicines.[151]

Compulsory licensing, however, does not suspend patent rights or reduce their duration: rather it permits the government to authorize the production of a patented medicine without

[147] TRIPS Agreement Article 31 see Gervais (n 93) 479 subsection 3439. The article contains several provisions that restrict the use of compulsory licensing. The particular article allows the issuance of compulsory license under circumstances such as 'national emergencies', 'other circumstances of extreme urgency', 'public non-commercial use', or against 'anti-competitive' practices (WTO, 2006). This means that a member country can improve access to a particular patented medicine through making an exception to its existing patent without entering into price negotiation with the patent holder, this can be found in Urias and Ramani, (n 123) 367-384. See also Nicol D and Owoeye O, 'Using TRIPS flexibilities to facilitate access to medicines' (2013) 91(7) Bull World Health Organ 533-539. See also Jenny Wakely, 'Compulsory licensing under TRIPS: an effective tool to increase access to medicines in developing and least developed countries?' (2011) 33(5) European Intellectual Property Law 299-309. This article aims to explore whether, considering the extensive focus and developments that have occurred in the area of compulsory licensing, this flexibility represents an effective and practicable means by which developing countries can improve access to medicines under the TRIPS framework. It still appears to be significant barriers to the use of compulsory licensing, and this article examines the main such difficulties with a view to determining whether it is an effective and viable option for developing countries. Therefore, the conclusion is that little is known about the extent to which compulsory licensing has been effective in reducing prices of much needed patented drugs. Although compulsory licensing has promise, the current implementations that stated in the above articles, and the existing barriers need to be addressed to make it a more accessible and reliable option for developing and least developing countries.

[148] Doha Declaration (n 64) [7]. Doha Declaration reaffirmed the commitment of developed countries under Article 66.2 TRIPS to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs in order to enable them to create a sound and viable technological base.

[149] Bryan Mercurio *et al*., *Pharmaceutical patent law and policy in Africa: a survey of selected SAD member state* (Cambridge University Press, 2023) 345. Malaysia and Thailand are two examples of countries effectively making use of compulsory licenses, with the former reducing the prices of antiretroviral drugs by 83% in 2002 and Thailand reducing the prices of cancer, coronary diseases and HIV/AIDS drugs by 98% through compulsory licenses, issued between 2006 and 2008. See also M Khor, *Patents, compulsory licenses and access to medicines: some recent experience* (2nd edn, Third World Network, 2009) 6.

[150] Ellen Fm t'Hoen *et al.,* (n 146) 185.

[151] Ellen Fm t'Hoen *et al.,* (n 146) 185. It is observed that much of the public attention surrounding compulsory licensing and other TRIPS flexibilities concerning pharmaceuticals has concentrated to HIV/AIDS. Moreover, it is noted that scholars not only focused on compulsory licensing measure for increasing access to medicines but also to measures such as the least-developed countries pharmaceutical transition measure, parallel importation, and the research exception. However, it shows that TRIPS flexibilities have been successfully for procuring generic versions of essential medicines specifically for treating HIV/AIDS diseases. This indicates that many countries that facing problems in providing access to high-priced, patented medicines, their use should not view these flexibilities as a last resort. Instead, they should consider them for the routine procurement of generic versions of expensive, new, essential medicines, while ensuring adequate remuneration for the patent holder. Utilizing these flexibilities can foster and sustain the generic competition that has been effective in reducing medicine prices and could help achieve universal access to new, essential medicines for everyone.

the consent of the patent holder.[152] This practice reflects the broader tension between intellectual property protections and the right to health. While patent holders retain certain rights, they are constrained in their ability to set market-driven prices and instead limited to the discounted rates established by compulsory licensing frameworks.[153] This dynamic highlights the ongoing challenge of balancing IPR enforcement with the necessity of ensuring widespread and affordable access to essential medicines.

The Doha Declaration[154] established the right of WTO members to grant compulsory licenses and allowed them the freedom to define the criteria for granting such licences.[155] Since its adoption in 2001[156], it has significantly influenced decision-making regarding compulsory licensing. However, discussions among scholars and policy makers have persisted, particularly in relation to communicable diseases such as HIV, the TRIPS Agreement and the role of compulsory licenses.[157] Scholarly discourse continues to engage with the implications of compulsory licensing, emphasizing its relevance beyond the initial debates of 2001.[158] The Doha Declaration seeks to deliver context to the issue of intellectual property protection for medicines, acknowledging the necessity of balancing private rights with public health interests.[159] This balance remains particularly crucial for developing and least-developed

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[152] Samira Guennif (n 123) 99. See also Sanders (n 129) 1.
[153] Urias and Ramani (n 123) 367-384.
[154] Doha Declaration Ractital [5] (b).
[155] Correa and Duncan (n 89) 8. The Doha Declaration does not provide a closed list of diseases, on the contrary, it is intended to be used as guidance to address any public health need. In addition, the Declaration recognises the problems of the public health that afflicting many developing and least-developed countries, specifically those resulting from HIV, tuberculosis, malaria and other epidemics, hence, the Declaration is not limited as mentioned above, and it also applies to any disease, including NCDs.
[156] Doha Declaration (n 64). This change follows a decision at the 2001 Doha Ministerial Conference when Ministers recognized that countries unable to manufacture pharmaceuticals should be able to obtain cheaper copies produced under compulsory licences elsewhere if necessary.
[157] Correa and Duncan (n 89) 1-31. The Doha Declaration identifies public health crises related to HIV, tuberculosis, malaria, and other epidemics as situations of national emergency or other circumstances of extreme urgency. See also Duncan Matthews, 'Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation' (2004) 1 Law, Social Justice & Global Development Journal**.** During the HIV/AIDS epidemic in the late-1990s, the Declaration focuses on the potential adverse impact on IP on public health and acknowledges that compliance with TRIPS does not and should not prevent Members from adopting public health measures, for the comprehensive look at the AIDS epidemic and patented drug prices involving compulsory licensing – Doha Declaration Racital [4]. See also David Barnard (n 140) 159. For the 'TRIPS does not and should not prevent Members' see World Trade Organization (WTO) 'Ministerial Conference Fourth Session, Doha Declaration, 2001', WT/MIN(01)/DEC/2, 20 November 2001.
[158] This has been discussed in this Chapter (One) in section 2.6 ('Literature on Compulsory licensing and its effects').
[159] Divya Murthy (n 129) 1321.

countries, where severe public health crises requires mechanisms that ensure equitable access to essential medicines.[160]

The Doha Declaration on the TRIPS and public health seems to be necessary for several reasons. The research conducted reveals that the aim of the Doha Declaration was to balance the protection of intellectual property rights with the need to ensure access to essential medicines, especially in the context of public health crises such as HIV/AIDS, malaria and tuberculosis, while the TRIPS Agreement could possibly hinder access to affordable medicines particularly in developing countries.[161] The Declaration addresses the potential negative effects of IP on public health and explicitly states that compliance with TRIPS does not and should not prevent Members from adopting public health measures.[162]

While the Doha Declaration represents a critical step toward reconciling intellectual property rights with public health concerns, its practical effectiveness remains limited. The limited use of TRIPS flexibilities, due to legal and political barriers, has hindered their effectiveness, particularly in developing countries. Additionally, pharmaceutical industry pressures and trade-related constraints have discouraged the use of compulsory licensing. The complexity of implementation along with concerns about reduced incentives for pharmaceutical innovation, further complicates access to affordable medicines. Moreover, despite the Declaration's focus on infectious diseases, it has not adequately addressed the growing burden of NCDs, leaving gaps in access to essential treatments. Addressing these barriers is crucial to ensuring that its intended benefits are fully realized, particularly for populations in low- and middle-income countries.

The interpretation of Article XX of the General Agreement on Tariffs and Trade (GATT)[163] has been a subject of scholarly discussion, particularly regarding its application to public health

[160] Doha Declaration (n 64) [4]. Member States have the right to use TRIPS flexibilities in order to protect public health and promoting access to medicines.
[161] Doha Declaration Racital [5] (b).
[162] Doha Declaration Racital [4].
[163] General Agreement on Tariffs and Trade (GATT), Article XX. See also Matthew Kennedy, *WTO Dispute Settlement and the TRIPS Agreement. Applying Intellectual Property Standards in a Trade Law Framework* (Cambridge University, 2016) 231.

measures. Article XX outlines general exceptions that allow member countries to adopt measures that might otherwise conflict with their GATT obligations, as long as they meet certain conditions.[164] However, the provision does not explicitly reference patents for medicines related to NCDs, raising questions about its applicability in ensuring access to essential treatments for such conditions.[165]

Scholars examining the TRIPS Agreement, the Doha Declaration and Articles 7 and 8 of TRIPS[166] suggest that Article XX of GATT serves as a valuable legal basis for public health protections. In particularly, the exception clause referring to "public health in general" states that

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination […] nothing in this Treaty shall be construed to prevent the adoption or enforcement by a Party of measures: […] necessary to protect human, animal or plant life or health […].[167]

While Article XX of GATT provides a broader legal basis for public health, its lack of explicit reference to pharmaceutical patents and NCD treatments raises uncertainties about its practical application in ensuring access to essential medicines.

Despite the promises of the Doha Declaration, the challenges inherent in the TRIPS Agreement persist, resisting full resolution. Even with the recent agreements aimed at expanding access to generic medicines in low-income countries, serious differences in interpretation and implementation difficulties under the TRIPS Agreement are expected to continue. Scholars

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[164] Kennedy (n 163) 249. See also GATT, Article XX (n 163) 'Article XX General Exception' 526. Available: https://www.wto.org/english/res_e/booksp_e/gatt_ai_e/art20_e.pdf. This article outlines general exceptions. Specifically, under the GATT, Article XX(b) is provided an explicit exception for public health. WTO members have the right to determine the level of protection of health that they consider appropriate in each situation under this exception.

[165] GATT, Article XX (n 163) 562.

[166] Antony Taubman *et al., A handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2012) 13. For a detailed discussion of both articles, see Chapter One.

[167] GATT, Article XX (n 163) 562 'General Exception'.

such as Hoachen Sun advocate for a broader application of TRIPS flexibilities, urging WTO members to leverage these provisions to enhance access to essential medicines, particularly for NCDs.[168] The role of TRIPS flexibilities is thus paramount in addressing these enduring obstacles. However, overcoming these barriers necessitates a concerted effort from the WHO, international institutions, and civil society organizations, whose collective engagement is critical in navigating the complexities of global pharmaceutical governance. Hoachen Sun further contends that the Doha Declaration, while a significant milestone, still delays the implementation of policies that would ensure the availability of reasonably priced medicines.[169] Legal and economic constraints continue to hinder the swift implementation of policies that would ensure the availability of affordable medicines, leaving the promise of equitable healthcare access yet unfulfilled.

Other academics[170] suggest initiatives to improve access to treatment, such as expanding the National Health Insurance Fund Drug List and promoting healthy lifestyles. Scholars such as Luna and A Luyclx, strongly believe that to tackle NCDs effectively, robust health systems and a multi-sectoral, health-in-all-policies that address structural risk factors for NCDs and ensure equitable access to care through Universal Health Coverage and quality essential medicines and diagnostics are needed.[171] Ellen highlighted the importance of TRIPS flexibilities in improving access to treatments for NCDs and has worked on policies to support generic drug production.[172] Amy Kapczynski has investigated alternative models for pharmaceutical

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[168] Haochen Sun, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health' (2004) 15(1) European Journal of International Law, 123-150. Although this article mentioned the obstacles posed by TRIPS Agreement, it focused on HIV/AIDS rather than NCDs. Doha Declaration designed to address concerns about TRIPS Agreement on access to medicines, the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) adopted the Doha Ministerial Conference, explicitly clarified for the first-time what flexibilities within the TRIPS Agreement can be used by Members to combat a public health crisis. See also Enrico Bonadio, 'Patents as a tool to encourage the production of healthier food' in Alberto Alemanno and Enrico Bonadio (eds), *The New Intellectual Property of Health: Beyond Plain Packaging*, (Edward Elgar, 2016) 305-332. See also Toshiko Takenaka, *Research Handbook on Patent Law and Theory* (2nd edn, Edward Elgar, 2019) 376.

[169] After the adoption of the Doha Declaration, there were significant different viewpoints on the relationship between the TRIPS Agreement and Public Health, as if no compromise had ever been reached or promises made. One perspective is presented in Haochen Sun (n 168) 123-150. In particular, the pharmaceutical industry, which had traditionally lobbied for strong intellectual property protections in developing countries, argued that the main theme of the Declaration was to reaffirm the value of such protections and to recognize the TRIPS Agreement as part of the solution to better public health, rather than a barrier to access to medicines.

[170] Luna and Luyckx (n 74) 5-25.

[171] Luna and Luyckx (n 74) 5-25. Lessons from wealthier countries that have successfully managed non-communicable diseases indicate that effective strategies should cover various areas and involve different sectors. This includes promoting health, preventing disease, and providing treatment and involving the community as well as the health sector. See also Helen M Robinson and Krishna Hort, 'Non-communicable diseases and health systems reform in low- and-middle-income countries' (2012) National 18(1) Pac Health Dialog 179-190.

[172] See also Ellen 't Hoen, 'Private Patents and Public Health' (*Health Action International* 2016) Available: https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf

innovation including prize funds and patent pools, which aim to reduce drug costs and improve access to NCD treatment. Kapcyzynski emphasizes the need for policy reforms that strike a balance between innovation and addressing public health needs.[173]

Other scholars and the pharmaceutical industries[174] argue that intellectual property protection is essential for fostering pharmaceutical innovation and ensuring the development of new drugs, including those for treating NCDs. They argue that weakening intellectual property protections could undermine the incentives needed for the cost of the drugs. Hence, their viewpoint emphasizes the importance of maintaining strong IP frameworks to support the pharmaceutical industries to continue their research and development for new drugs for both communicable and non-communicable diseases.

The Doha Declaration emerges as a pivotal response to the challenges posed by the TRIPS Agreement, shedding light on its far-reaching consequences. Among these, restricted access to affordable medicines stands as a pressing concern, a barrier that the Declaration seeks to improve through TRIPS flexibilities, such as compulsory licensing. Beyond this, it confronts the stark inequities in global health, highlighting the necessity of ensuring that life-saving medicines reach the nations in greatest need. Furthermore, the Declaration serves as a call to action, urging countries to wield these flexibilities in the face of public health crises, ensuring swift and effective responses.[175] At its core, it strikes a delicate balance between protecting patent rights while fostering innovation, all in pursuit of a world where medical advancements are not confined by borders, but instead, reach those whose lives depend on them.[176]

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[173] Amy Kapczynski and Aaron S Kesselheim, 'Government Patent Use': A Legal Approach to Reducing Drug Spending' (2016) 35(5) Health Aff (Millwood) 791-7. See also Lawrence O Gostin, 'Global Health Law' (2015) 93(1) The Milbank Quarterly 211-2014. In his article he explores the use of the legal instruments to address the challenges of NCDs. See also Margaret K Kyle and Yi Qian, 'Intellectual Property Rights and Access to Innovation: Evidence from TRIPS' (2014) National Bureau of Economic Research 110. See also Margaret Kyle, 'Strategic Responses to Parallel Trade' (2011) 11(2) Industrial Organization and Healthcare 1-32. Margaret Kyle's article focus on drug prices and access, and she advocates for making NCD treatments more affordable and accessible through reforms in intellectual property law.

[174] Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (2nd edn, Taylor and Francis Group, 2006). See also Henry Grabowski, 'Patents, Innovation and Access to New Pharmaceuticals' (2002) 5(4) Journal of International Economic Law 849-860.

[175] Devi Sridhar, 'Improving Access to Essential Medicines: How Health Concerns can be Prioritised in the Global Governance System' (2008) 1(2) Public Health Ethics 83-88. See also JC Cohen *et al.,* 'TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana' (2005) 1(17) Globalization and Health 10.

[176] Cohen *et al.,* (n 175) 10.

Between 2001 and 2020, the world has come to recognize the rising burden of both communicable diseases and non-communicable disease, that weigh heavily on global health.[177] Among these, NCDs have risen to the forefront, demanding greater attention in research, prevention, and treatment.[178] In 2011, a high-level UN resolution on health raised the issue of NCDs, calling attention to the high numbers of global deaths.[179] There is increasing knowledge about the global burden of NCDs. Moreover, literature states that NCDs comprise the major global cause of death especially among more vulnerable populations. Experts have stated that factors which might contribute to the difference in the global response between communicable and NCDs are ethical, social, epidemiologic and economic.[180]

Yet in many low- and middle-income countries, access to life-saving therapies whether patented or not, remains elusive.[181] A central challenge lies in the absence of a sustainable pricing model for pharmaceuticals in these markets.[182] Drug companies argue that middle-income countries must bear their share of the cost of medical innovation, but this statement is fraught with controversy. Many of these countries simply cannot afford the high prices of essential medicines, leaving millions without the care they need. True equity in healthcare

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[177] Bollyky (n 130) 1. In 2012, a new controversy over patented medicines and their affordability in developing countries emerged, over NCDs. See also Nicol and Owoeye (n 147) 533-539. See also Mackey and Liang (n 140) 1-8. See also Saba Danawala and Zoe Zhang, 'Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower- and Middle-Income Countries' (2013) 1(1) GSTF International Journal of Nursing and Health Care (JNHC) 11. See also Hans V Hogerzeil *et al.,* 'Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration' (2013) 23(381) Lancet 680-689. See also Philip Baker *et. al.,* 'Trade and investment liberalization and Asia's noncommunicable disease epidemic: a synthesis of data and existing literature' (2014) 10(66) Globalization and Health 1-20. See also Roger S Magnusson and David Patterson, 'The role of law and governance reform in the global response to non-communicable diseases' (2014) 10(44) Globalization and Health 10. See also Sandeep P Kishore *et. al.,* 'Overcoming Obstacles to Enable Access to Medicines for Noncommunicable Diseases in Poor Countries' (2015) 34(9) Health Aff (Millwood) 1579-77. See also Aleksandra Kovacevic, *et al*., 'Pharmaceutical Expenditure and Burden of Non-communicable Diseases in Serbia' (2016) 7(373) Front Pharmacol 1-7. See also Hilde Stevens and Isabelle Huys, 'Innovative Approaches to Increase Access to Medicines in Developing Countries' (2017) 4(218) Frontiers in Medicines 1-6. See also Amir Sabet Sarvestani and Kathleen H Sienko, 'Medical device landscape for communicable and non-communicable diseases in low-income countries' (2018) 14(65) Globalization and Health 1-6. See also Luna and Luyckx (n 74) 5-25.

[178] Luna and Luyckx (n 74) 5-25.

[179] Luna and Luyckx (n 74) 5-25.

[180] David Reubi *et al.,* 'The politics of non-communicable diseases in the global South' (2016) 39 Health & Place 179-187. See also Luna and Luyckx (n 74) 5-25.

[181] Bonadio (n 168) 329. See also Takenaka (n 168) 376. It is widely known that by achieving the appropriate balance between pharmaceutical innovation and access to medicines is a pressing social issue.

[182] Santiago G Moreno and David Epstein, 'The price of innovation- the role of drug pricing in financing pharmaceutical innovation. A conceptual framework' (2019) 7(1) J Mar Access and Health Policy 1-9. In this article, critics claim that the prices of innovative drugs are excessive and argue that lowering prices will not harm innovation. Conversely, the pharmaceutical industry insists that restrictive pricing policies will negatively impact their ability to generate innovation.

demands a pricing system that does not merely reward innovation but ensures that is fruits reach those who need them most.[183]

Thomas J Bollyky[184] explores two key issues: the growing controversy surrounding patented medicine for NCDs and their affordability in developing countries, and the responses of these nations to this emerging health crisis.[185] As previously discussed in relation to compulsory licensing, Bollyky highlights how middle-income countries like India, China and Indonesia have taken measures to circumvent patents on medicines for diabetes, cancer, cardiovascular and chronic respiratory illnesses.[186] In the context of the Doha Declaration, these actions align with its emphasis on TRIPS flexibilities, supporting the argument that patent laws must accommodate public health needs.

Conflicts over patented NCD medicines are likely to increase, with potential adverse consequence for patients, drug firms and developed and developing country governments alike. Bollyky argues that global health investment has not kept pace with non-communicable diseases.[187] The intergovernmental institutions addressing trade and global health issues are unlikely to resolve these conflicts and alternatives to intellectual property have not attracted significant donor and multilateral support.[188] In the article, it is noted that addressing the NCD treatment-access crisis demands yet another transformation in global health, emphasizing affordable interventions and patient-centred approaches, as opposed to strategies centred solely on individual countries.[189]

While prevention is a predominant public health strategy, availability and affordability to life-saving medications is also critical. It is argued by Mackey and Liang that this includes assessment of the availability of essential generic medicines, which leads to a wider

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[183] National Academies of Sciences *et al.,* 'The Root causes of health inequity' in National Academies of Sciences *et al*., (eds) *Communities in Action: Pathways to Health Equity* (National Academies Press, 2017) 99.
[184] Bollyky (n 130) 2.
[185] Bollyky (n 130) 2.
[186] Bollyky (n 130) 2.
[187] A decade ago, a crisis over access to HIV/AIDS treatment transformed the global response to that disease and the other infectious neglected diseases disproportionately affecting the world's poor. Expanding access to treatment for those diseases saved the lives for millions and stabilized support for the international trade and IP systems that have since benefited developed and many emerging economies alike.
[188] Bollyky (n 130) 1.
[189] Bollyky (n 130) 2.

availability of more affordable medications compared to innovator products which are often protected by IPRs.[190] Comprehensive analysis of patents and exclusivity for essential medicines remains insufficiently explored.[191] Specifically, studies have identified essential medicines treating diabetes, asthma, cardiovascular disease, and cancer as lacking availability and affordability.[192]

There are a number of scholars who touch on the complexity of ensuring availability and affordability of generic formulations for NCDs.[193] Ensuring the availability and affordability of generic formulations for NCDs is challenged by regulatory barriers, market dynamics and healthcare system constraints. Patent protections and evergreening strategies delay generic entry, while weak competition and supply chain inefficiencies keep prices high. Additionally, global economic pressures impact production and distribution. Ellen 't Hoen, Frederick Abbott and Reinhard Busse have examined these complexities particularly in the context of global health equity and access to essential medicines.[194] Addressing these challenges requires strong regulatory frameworks, improved procurement strategies, and increased awareness to enhance the adoption of cost-effective generic medicines.[195]

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[190] Mackey and Liang (n 140) 1-8. See also Monirul Azam, 'The Experiences of TRIPS-compliant Patent Law Reform in Brazil, China, India and South Africa—Lessons for Bangladesh' in Monirul Azam (ed), *Intellectual Property and Public Health in the Developing World* (Cambridge, 2017) 89-148. See also Martin Khor, 'Rethinking Intellectual Property Rights and TRIPS', in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights—Knowledge, Access and Development* (Palgrave Macmillan, 2002) 201-213.Developing countries and the LDCs are apprehensive of strong patent protection as it may be harmful to their pharmaceutical industries and may have sever negative consequences for their citizens in terms of access to affordable medicines. In the case of HIV/AIDS, patent protection and related delayed market production of generic antiretroviral therapy (ARVs) led to pressure from civil society eventual generic production and price negotiation, and the subsequent dramatic lowering of the cost of ARVs for resource-poor settings. See also Gregory Shaffer and Susan K Shell, 'Transnational Legal Ordering and Access to Medicines' in Ruth L Okedji and Margo A Bagley (eds), *Patent Law in Global Perspective* (OUP, 2014) 100. The HIV pandemic highlights a significant tension between the protection of pharmaceutical patent rights and the benefits of liberalized trade by restricting consumer access through monopoly pricing power and delay the introduction of more affordable generic drugs. This restriction can lead to human rights issues, as limited access to medicines results in deaths.

[191] Mackey and Liang (n 140) 1-8.

[192] Mackey and Liang (n 140) 1-8.

[193] David Beran *et al.,* 'Noncommunicable diseases, access to essential medicines and universal health coverage' (2019) 12(1) Global Health Action 105.

[194] Reinhard Busse *et al., Tackling Chronic Disease in Europe* (European Observatory on Health Systems and Policy, 2010). See also Frederick M Abbott, 'Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access' (UNDP 2017) Available: https://frederickabbott.com/sites/default/files/2024-06/Abbott%20-%20Rio%202017%20-%20Session%201%20%28final%29_0.pdf. See also Frederick M Abbott, 'WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries' (2011) Available: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1924420 See also Ellen 't Hoen, 'Private Patents and Public Health' (*Health Action International* 2016) Available: https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf

[195] Ellen 't Hoen, 'Private Patents and Public Health' (*Health Action International* 2016) Available: https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf

Several scholars have written on broad issues such as the impact of patents on medicines[196], while others have examined their justifications within the pharmaceutical industry.[197] Experts also discuss the negative effects of global patent protection on access to essential medicines and the role of TRIPS flexibilities in addressing these challenges.[198] The key issue is how patent protections affect the availability and affordability of essential medicines, particularly generic formulations for NCDs. Some authors explore strategies to reduce barriers to NCD medicines, drawing lessons from the success of increased access to HIV/AIDS treatments.[199] Scholars like Vandana Shiva[200] have critically examined the justification of patents in the pharmaceutical industry, arguing that they often serve corporate interests over public health needs.[201]

A careful literature review shows that the discourse on the Doha Declaration and its impact on access to medicines for non-communicable diseases evolved significantly between 2001 and 2020. From 2001 to 2010, the primary focus remained on communicable diseases, particularly HIV/AIDS, tuberculosis, and malaria. Studies during this period emphasized the challenges associated with TRIPS implementation, the use of compulsory licensing and successes and failures in improving access to ARVs treatments for HIV/AIDS.

However, as the global burden of NCDs such as diabetes, cancer and cardiovascular diseases became more pronounced in global health discussions, scholarly and policy attention began to shift, particularly after 2010. Between 2010 and 2020, there was increasing recognition of the intersection between intellectual property rights, pharmaceutical innovation and access

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196 Levon M Khachigian, 'Pharmaceutical patents: reconciling the human right to health with the incentive to invent' (2020) 25(7) Drug Discov Today 1135-1141. See also Holger Hestermeyer, 'Conflict between Patents and Access to Medicine', in Hestermeyer Holger (ed) *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2008). See also Christophe Geiger, *Human Rights and Intellectual Property* (Edward Elgar, 2015) 496. See also Laurence R Helfer, 'Mapping the interface between human rights and intellectual property' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property*, (Edward Elgar,2015) 6-15. Academic commentators have paid considerable attention to both strength and weaknesses of developing a human rights framework for intellectual property law and policy. Therefore, Christophe Geiger edited important volumes in area, including Laurence Helfer and Graeme Austin. See also Peter K Yu, 'Intellectual property, human rights, and methodological reflections' in Irene Calboli and Maria Lilla Montagnani (eds), *Handbook of Intellectual Property Research* (Oxford, 2021) 1375.

197 Joan Busfield, 'Globalization and the pharmaceutical industry revisited' (2003) 33(3) International Journal of Health Services 581-605. See also House of Commons, 'The Influence of the Pharmaceutical Industry' (2005) 1 The Health Committee 1-124. See also Tom Latten *et al.,* 'Pharmaceutical companies and healthcare providers: Going beyond the gift- An explorative review' (2018) 13(2) PLos One 1-15. See also Gurgula (n 21) 1062-1085.

198 Sellin (n 125) 445-473. See also Haochen Sun (n 168) 123-150.

199 Tiny Masupe *et al.,* 'Integrated management of HIV/NCD knowledge, attitudes, and practices of health care workers in Gaborone, Botswana' (2019) 19(3) African Health Sciences 2312-2323.

200 Vandana Shiva, *Patents Myths & reality* (Penguin Books, 2001) 86. See also Beran *et al.,* (n 193) 561-562.

201 Shiva (n 200) 86. See also Beran *et al.,* (n 193) 561-562.

to medicines for both communicable and non-communicable diseases. This shift underscores the growing urgency of addressing barriers to treatment beyond infectious diseases, indicating a broader and more inclusive approach to global health policy.

Indeed, the Doha Declaration advanced the intersection between intellectual property rights particularly patents on medicines and public health, highlighting the role of TRIPS flexibilities in improving access to medicines. The Declaration not only strengthened the rights of WTO members by using mechanisms such as compulsory licensing, but also prioritized health equity. However despite these achievements, significant challenges remain in making these flexibilities into practical and sustainable solutions, particularly in addressing the growing burden of NCDs. Barriers such as regulatory complexities, political resistance, limited manufacturing capacity and economic constraints continue to hinder the full implementation of these provisions. To ensure broader access to medicines, the lessons from the Doha Declaration should be adapted and expanded to create more responsive and inclusive frameworks that better meet evolving public health needs.

### 2.8. Covid-19 (2020-2024): a Wealth of Literature

This section will explore scholarly reactions to the TRIPS Waiver and related policy responses to the Covid-19 pandemic from 2020 to 2024. Covid-19 left impacts on all sides of life including the availability, accessibility, and affordability of medicines and vaccines.[202] The pandemic not only affected people with communicable diseases,[203] but also had a considerable impact on people with long chronic illnesses (NCDs) who require consistent monitoring by health care providers.[204] The academic literature has identified several ways that Covid-19 pandemic

[202] The COVID-19 pandemic challenged the healthcare system and affected the low-income countries. Also, COVID-19 had impact on medicine supply. More information regarding the impact that COVID-19 had on access to medicines can be found in Manasvini Ramakrishnan *et al.,* 'Impact of COVID-19 pandemic on medicine supply chain for patients with chronic diseases: Experiences of the community pharmacists' (2023) 20(101243) Clinical Epidemiology and Global Health 2-8. See also Chunming Xu and Debao Zhu, 'On Conflicts between Pharmaceutical Patent Protection and the Right to Life and Health Based on a Stackelberg Game' (2021) 18(3) Int J Environ Res Public Health 1119. It confirms that pharmaceutical patent protection inevitably gives patent holders a certain monopoly power, and drug prices are often set by the patent holders; therefore, there is the possibility of abuse of the dominant position to manipulate the market. See also Robin C Feldman *et al.,* Negative innovation when patents are bad for patients' (2021) 39(8) Nature biotechnology 914-916.

[203] Jeremy I Schwartz *et al.,* 'Impact of a COVID-19 national lockdown on integrated care for Hypertension and HIV' (2021) 16(1) Global Heart 9. See also Henry Zakumumpa, *et al.,* 'Dispensing antiretrovirals during COVID-19 lockdown: re-discovering community-based ART delivery models in Uganda' (2021) 21(692) BMC Health Services Research 692. See also A O Salako, *et al.,* 'Challenges of Accessing Care in Art Clinic during COVID-19 Lockdown in Lagos' (2022) 25(1) Niger J Clin Pract 49-54.

[204] Lucia Yetunde Ojewale and Ferdinand C Mukumbang, 'Access to healthcare services for people with non-communicable diseases during the COVID-19 pandemic in Ibadan, Nigeria: a quantitive study' (2023) 23(1231) BMC Health Services Research

affected health care access for people with NCDs, including self-medication and disruptions in follow-up services, poor access to medications and emergency healthcare services, and postponement of NCD appointments were also reported.[205] In addition, Ojewale and Mukumbang, confirmed that during the Covid-19 pandemic, there was limited information about people with NCD accessing follow-up care.[206]

Since pharmaceutical companies own many innovations, it is important to recognize that access to medicines is closely linked to international trade and intellectual property rights.[207] Health scholar Gorik Ooms, along with Johanna Hanefeld, proposed a strategy for low-and middle-income countries to negotiate better access to medicines.[208] Other scholars such as Eduardo Urias and Shyama Ramani, argue that compulsory licensing through the facilitation of price reductions was considered an important countermeasure.[209] Scholars have noted that nonetheless, little is known about the extent to which compulsory licensing has been effective in reducing the price of much-needed patented drugs.

Professor Mercurio highlighted that during the Covid-19 pandemic, IPR systems demonstrated their importance as IPRs played a large role in the rapid development and availability of multiple vaccines.[210] Indeed, international access to Covid-19 vaccines and other health technologies has remained highly disproportionate.[211] This inequity had an impact in low-and middle-income countries, engaging concerns around human rights to health and to the equal

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2. It is confirmed that COVID-19 affected the healthcare access of people with NCDs in various ways and that the routine medical checks and medication adherence are essential requirements for NCD management. People with chronic diseases had to pay more out-of-pocket and had reduced access to specialist care. Also, those patients used their earlier prescriptions or empty drug containers to obtain medications.

[205] Ojewale and Mukumbang (n 204) 2. See also Huda Ismail *et al.,* 'The impact of the COVID-19 pandemic on medical conditions and medical adherence in people living with chronic Diseases' (2003) 62(3) J Am Pharmacists Association 834-839. Given the various ways identified in the literature, COVID-19 affected healthcare access of people with NCDs, it is also reported that those living with NCDs experienced a decline in their chronic health status.

[206] Ojewale and Mukumbang (n 204) 2.

[207] Gorik Ooms and Johanna Hanefeld, 'Threat of compulsory licenses could increase access to essential medicines' (2019) 365(1298) BMJ 1-4.

[208] Ooms and Hanefeld (n 207) 1-4. Compulsory licensing is often advocated as the main alternative to circumvent the potential negative impact of patents on access to medicines. Access to medicines can be improved under the current IPR system set by the TRIPS Agreement, shows that compulsory licensing is the most advised TRIPS safeguards to improve access to medicines.

[209] Urias and Ramani (n 123) 367-384.

[210] Bryan Mercurio, 'The IP waiver for COVID-19: bad policy, bad precedent' (2021) 52(8) International Review of Intellectual Property and Competition Law 983-988.

[211] Kohler *et al.,* (n 18) 159-175. See also Bawa Singh *et al.,* 'COVID-19 and Global Distributive Justice: 'Health Diplomacy' of India and South Africa for the TRIPS waiver' (2023) 58(5) Journal of Asian and African Studies 747-765.

enjoyment of the benefits of scientific progress enshrined under articles 12 and 15 of the International Covenant on Economic, Social and Cultural Rights.[212]

In 2020, an extensive waiver to the copyrights, patent, industrial design and undisclosed information rights of the TRIPS Agreement was proposed by India and South Africa, calling on WTO Members to waive IPRs relating to and having an impact on the "prevention, containment or treatment of Covid-19."[213] Reviewing articles, books and all the relevant peer-reviewed publications, reveals that while much of the literature focuses on the TRIPS waiver, scholars also examine broader issues concerning IP and global health. India and South Africa have demanded TRIPS waivers for access to vaccines for all developing countries.[214] This proposal raises numerous legal issues, with some scholars opposing the waiver, others supporting the waiver, and some attempting to compromise between the two extremes triggered by this proposal. More details of this distinction will be discussed in the following sections.

### 2.9. TRIPS Waiver – Opponents

Opponents of the TRIPS waiver argued that IP is not the real challenge hindering access to Covid-19 health technologies, and IP was not posing barriers.[215] John-Arne Rottingen[216], the chair of the World Health Organization (WHO) Solidarity of Covid-19 treatments, stated that the Waiver Proposal is the "wrong approach."[217] In his view, the main barriers for accessing Covid-19 related medicines are not intellectual property related but have to do with the complexity of biological medicines such as vaccines, healthcare infrastructures and production facilities.[218] It is highlighted that TRIPS Agreement already contains the necessary legal tools

[212] Kohler *et al.,* (n 18) 159-175.
[213] Singh *et al.,* (n 211) 747-765. This proposal was about to ensure equity, accessibility, and affordability of vaccines. See also Miquel Montana, 'COVID-19 and India's and South Africa's attempt to reopen the TRIPS Pandora's box: a proposal made in vain?' (2021) E.I.P.R 43(6) 349-351.
[214] Talat Chaudhary and Arshi Chaudhary, 'TRIPS waiver of COVID-19 vaccines: Impact on pharmaceutical industry and what it means to developing countries' (2021) 24 The Journal of World intellectual Property 447. See also Khorsed Zaman and M Rafiqul Islam, 'The proposal to the WTO for a new patent waiver on COVID-19 vaccines and pharmaceuticals: is it necessary under TRIPS?' (2021) 43(10) European Intellectual Property Review 645-652.
[215] Kohler *et al.,* (n 18).
[216] Miquel (n 213) 349-351. See also Ann Danaiya Usher, 'South Africa and India push for COVID-19 patents ban' (2020) 396(10265) The Lancet Summit 1790.
[217] Usher (n 216 1791.
[218] Miquel (n 213) 349-351. The TRIPS Agreement already contains the necessary legal armamentarium to address the concerns expressed by the Proposal Waiver, for example: art.31*bis*, which establishes waivers for exports to countries lacking production facilities, which is precisely one of the factors that, as mentioned, may limit access to COVID-19 treatments. The

to address the concerns expressed by the Proposed Waiver. For example article 31*bis* establishes waivers for exports to countries lacking production facilities. Following this article procedure would be cumbersome and time-consuming.[219] However no evidence is cited to support this proposition.

Less than two weeks after India and South Africa introduced the Waiver Proposal, the WTO Secretariat responded by publishing an information note on 15 October 2020 titled "The TRIPS Agreement and Covid-19".[220] This note illustrates that the TRIPS Agreement already provides sufficient legal mechanisms to address the challenges posed by the pandemic of Covid-19.[221] Jayashree Watal, India's negotiator to the TRIPS Agreement and a long-time WTO staff member, echoed this perspective. She characterized the waiver proposal as an "indirect attempt to put pressure on the original manufacturers to cooperate and license production to companies in their countries".[222] When asked whether a waiver would enhance vaccine availability and equity, Watal firmly responded "No, it won't". She opposed the TRIPS waiver for Intellectual Property Rights, including even a limited waiver for patents. Watal further argued that abandoning the existing system without concrete evidence that intellectual property rights were impeding pandemic response would be unjustified.[223]

Similarly, Bryan Mercurio supported efforts to facilitate the effective use of TRIPS flexibilities emphasizing the importance of ensuring the intellectual property rules do not become barriers to vaccine production. He advocated for coordinated action between governments and the private sector to ensure that all qualified generic manufacturers capable of producing vaccines do so. Additionally, he highlighted the importance of upgrading manufacturing facilities to meet necessary production standards, thereby increasing global supply. Mercurio's

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countries wanting the Proposed Waiver to be approved contend that following the art.31 bis procedure would be cumbersome and time-consuming. Moreover, no evidence is cited to support that proposition.

219 Miquel (n 213) 349-351. See also Zaman and Islam (n 214) 645-652.

220 Miquel (n 213) 349-351. See also Zaman and Islam (n 214) 645-652.

221 Miquel (n 213) 349-351.

222 Mercurio (n 210) 983-988. It is noted that when asked Watal if a waiver would improve vaccine availability and equity, the respond was "No, it won't". Her view was to not support the TRIPS waiver for IPRs or even a limited waiver for patents. Bryan Mercurio supports efforts to enable prompt and effective use of flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard.

223 Mercurio (n 210) 983-988. ("Little (if any) evidence has been presented that suggested IP protection is blocking COVID-19 vaccine manufacture. Rather, technical, and logistic issues are the biggest barriers currently standing in the way of increasing vaccine production and deployment. To boost vaccine availability right now, it would be better to address these").

perspective aligns with the broader legal framework of TRIPS Article 30[224], which allows for limited exceptions to patent rights, provided they do not unreasonably conflict with normal patent exploitation or unduly prejudice the legitimate interests of patent holders. His approach reflects a preference for leveraging existing TRIPS provisions rather than pursuing a broader waiver, arguing that effective implementation such as compulsory licensing would be a more immediate solution.[225]

In addition, Ajigboye and Olubiyi, believe that the role of intellectual property rights and access to medicines is very controversial, as IPRs encourage investment and innovation, although monopoly rights on drugs can result in very high prices and become barriers to medicines.[226] The experience of the HIV/AIDS pandemic in the nineties and the most recent the Covid-19, the search for an effective treatment and vaccine emphasizes the tension between intellectual property rights and public health interests.[227]

### 2.10. TRIPS Waiver - Proponents

Although Covid-19 vaccines were developed with unprecedented speed, their availability and accessibility remained deeply uneven, particularly for low-and middle-income countries.[228] The pandemic underscored global disparities in healthcare access, sparking debates among scholars about the necessity of intellectual property reform. Many argue that the TRIPS waiver should not be dismissed as it represents an urgent and moral response to the crisis.

Siva Thambisetty, a leading advocate for the waiver, asserts that the push for a TRIPS waiver is not merely about suspending intellectual property rights but about creating greater opportunities for low-and middle-income countries to take control of vital technologies.[229]

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[224] TRIPS Agreement, Article 30.
[225] Mercurio (n 210) 983-988.
[226] Mayowa O Ajigboye and Ifeoluwa Olubiyi, 'Impact of TRIPs Agreement on access to immunosuppressant drugs: another challenge in kidney transplantation and treatment in developing countries' (2021) 29(2) African Journal of International and Comparative Law 309-324. Authors discussed how TRIPS Agreement and legal framework affects the cost of immunosuppressant which is a life-long drug. There is insufficient access to immunosuppressant for kidney, unaffordability, and limited availability in developing countries. See also Tenni *et al.,* (n 19) 1-40.
[227] Motari *et al.,* (n 22) 1-19.
[228] Kunle Ola, 'COVID-19 strategic global north-south divide: access to knowledge quadrants, imperatives for granting the WTO waiver' (September 2021) European Intellectual Property Review doi.org/10.2139/ssrn.3927721 1-17.
[229] Siva Thambisetty, 'Termination of the TRIPS Agreement: Necessary and Impossible' (*OpinionJuris* 2023) <http://opiniojuris.org/2023/01/11/termination-of-the-trips-agreement-necessary-and-impossible/> accessed 25 March 2025.

Her argument critiques the TRIPS Agreement as an institutional barrier to equitable vaccine distribution, reinforcing structural inequalities in global health. Proponents of the TRIPS waiver believe that temporarily suspending intellectual property protections on Covid-19 vaccines and related technologies could significantly enhance global access, particularly for developing nations that lack the leverage to negotiate licensing arguments with major pharmaceutical companies.[230] Proponents of the TRIPS waiver expressed concerns that low- and middle-income countries might encounter institutional and legal difficulties when using existing TRIPS flexibilities, considering the process for importing and exporting of pharmaceutical products.[231]

Kunle Ola, another staunch supporter of the TRIPS waiver, maintained that such a measure could have fundamentally transformed vaccine production and distribution.[232] He argues that granting an intellectual property waiver would have allowed developing countries to produce vaccines more speedily, thereby improving accessibility and potentially saving countless lives.[233] A complementary perspective offered by Talat Chauhary and Arshi Chaudhari, emphasizes that waiving TRIPS restrictions is crucial for empowering member states to engage in the research, development, and distribution of vaccines.[234] The authors contend that the waiver would overcome the intellectual property barriers that obstruct the supply of Covid-19 vaccines and associated treatments, thus fostering a more equitable global health landscape.[235]

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[230] Zaman and Islam (n 214) 645-652. See also Mercurio *et al.,* (n 210) 43 332. This paper examines the intellectual property laws for better understanding of the nature, scope and depth of patent laws within particular emphasis on TRIPS flexibilities to facilitate of access to medicines. It is noted that countries lack explicit and workable provisions implementing key TRIPS flexibilities, hence these flexibilities have not been well utilized and it is often the complicated and unworkable domestic framework rather than the TRIPS.

[231] Zaman and Islam (n 214) 645-652. See also Fides A del Castillo, 'Temporary waiver of intellectual property on Covid-19 vaccines: toward the creation of a better, pot-pandemic society' (2021) 19(2) Journal of Public Health 1.

[232] Ola (n 228) 1-17.

[233] Ola (n 228) 1-17.

[234] Chaudhary and Chaudhary (n 214) 447. 'TRIPS waiver of COVID-19 vaccines: Impact on pharmaceutical industry and what it means to developing countries' (2021) 24 The Journal of World intellectual Property. It is also mentioned that the relationship between the TRIPS and public health is not a recent development as HIV/AIDS pandemic, and there has always been a conflict regarding access to public health and patent of the products. The referenced article highlights the HIV/AIDS pandemic but does not address NCDs.

[235] Chaudhary and Chaudhary (n 214) 447.

## 3. Conclusion

This chapter has critically examined the complex relationship between patent law and public health with a particular focus on NCDs. Historically, debates on intellectual property and public health have centred on communicable diseases, most notably during the HIV/AIDS crisis, where the urgent need for affordable, life-saving treatments spurred innovative regulatory responses. However, as the global burden of NCDs such as cardiovascular diseases, diabetes, cancer and respiratory conditions has grown, the challenges posed by stringent patent protections have become increasingly pronounced.

The literature reveals that while patents play a crucial role in stimulating pharmaceutical innovation, they also contribute to high medicine prices that can restrict access, especially in low- and middle-income countries. This chapter highlights the tension between incentivizing innovation and ensuring essential medicines remain both accessible and affordable. A significant research gap has emerged. Although extensive literature exists on patent law in the context of communicable diseases, there is a lack of comprehensive analysis addressing how these intellectual property frameworks impact access to medicines for chronic diseases. In particularly, limited empirical research has focused on the unique challenges that long-term treatments for NCDs face under the current patent regimes.

While compulsory licenses have proven to be effective tools in improving access to medicines for communicable diseases, particularly in low- and middle-income countries, their application to NCDs presents limitations. These limitations, which involve legal, political and logistical challenges, have been critically examined in scholarship. While compulsory licensing remains a useful strategy for some public health crises, it may not offer the same efficacy for NCDs. This issue, along with alternative strategies for improving access to medicines for NCDs, will be explored further in Chapter Five.

In addition to compulsory licensing, other instruments such as parallel imports have also been recognized for addressing access issues for communicable diseases. However, their efficacy in the context of NCDs treatments remain underexplored. To address this gap, further comparative studies on how different national regulatory systems reconcile patent protections with public health needs for NCDs are required. Moreover, as emerging biotechnologies and personalized medicine continue to evolve, it is essential to investigate how these innovations interact with existing patent frameworks and how trade agreements influence national policies governing access to NCD treatments.

In summary, while the literature on patent law and public health provides important insights, largely derived from the experience with communicable diseases, a significant gap persists in understanding its impact on NCDs. Addressing this gap is crucial given the rising global prevalence of chronic diseases and the unique challenges they pose for health systems worldwide. The lessons learned from communicable diseases, including the effective use of patent flexibilities and innovative pricing models, offer valuable guidance from future policy interventions.

This chapter has highlighted the key debates and gaps in the existing scholarship on patent law, access to medicines, and non-communicable diseases. While the literature provides valuable insights, it also reveals limitations in connecting legal analysis to the wider health policy and institutional context. The next chapter therefore sets out the health framework, outlining the systems and policies that shape responses to NCDs.

## CHAPTER TWO: THE HEALTH FRAMEWORK

### 1. Introduction

This research investigates the intersection of patent law and the right to health, with a particular focus on access to medicines and the regulation of non-communicable diseases (NCDs). NCDs, which account for a significant and growing proportion of global mortality, have become a pressing concern for societies, national governments, and international organizations.[236] The research will analyse evidence provided by the World Health Organization (WHO), which has prioritized NCDs as a crucial policy area for all Member States. Additionally, the research uses the regulation of communicable diseases (CDs) as a contextual background to provide comparative insights into regulatory strategies.

NCDs, the central focus of this thesis, are influenced by a range of factors, including self-management, genetic factors, environmental factors, factors of medical conditions, and socio-demographic factors.[237] Without urgent action, the chronic NCD burden will rise by the end of the decade. Lessons from successful strategies in HIV/AIDS treatment programs and other communicable disease regulations can provide valuable insights into managing NCDs effectively.

The Commonwealth System Framework for Health Policy[238] highlights the importance of systems thinking the formulating and implementing health policies. This framework is designed to help countries develop sustainable healthcare systems that effectively address complex challenges such as NCDs. It empowers member countries to tackle the NCD epidemic through integrated and sustainable solutions.[239] Complementing this, the WHO emphasizes the need for robust systems and services for NCD treatment, addressing sustainability issues, health protection, and public health priorities.[240]

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[236] Nweke Ebele Ndubuisi, 'Noncommunicable Diseases Prevention in Low- and Middle-Income Countries: An Overview of Health in All Policies (HiAP) (2021) 58 The Journal of Health Care Organization, and Financing 4.
[237] Aida Budreviciute *et al.,* (n 1) 2.
[238] The Commonwealth, 'Strengthening health policies and systems' (*The Commonwealth* 2025) <https://thecommonwealth.org/strengthening-health-policies-and-systems> accessed 25 March 2025.
[239] The Commonwealth, 'Strengthening health policies and systems' (n 76).
[240] Aakash Ganju *et al.,* 'Systemic Solutions for Addressing Non-Communicable Diseases in Low- and Middle-Income Countries' (2020) 13 Journal of Multidisciplinary Healthcare 695.

Regulatory context in public health plays a pivotal role in achieving health equity. The World Health Assembly, the decision-making body of WHO[241], has agreed to use the legal recognition of the right to health as an indicator of a government's commitment to improving access to essential medicines.[242] This recognition elevates access to medicine as both a human right and a governmental responsibility. Access to medicines should not be viewed as a privilege but as a priority and a fundamental reality for all.[243] Recognizing the right to health through the mechanisms is a transformative step toward achieving health equity and the broader goals of global health and human rights.

All the above aspects are explored in greater detail in the following sections of this chapter. This chapter begins by defining NCDs and CDs to clarify their distinct roles and impacts. It then explores the key contributions of the WHO and the EU in addressing NCDs. Additionally, it examines the roles of policy makers and organizations with direct roles in determining funding priorities which are essential for ensuring access to medicines, strengthening healthcare infrastructure for distribution and shortage, and investing in research and development (R&D) for relevant treatments. Policy makers and organizations discussed in this chapter include National Institutions, Legal Frameworks, Health Law and will conclude with Human Rights Law.

A significant focus of this research is the impact of unhealthy food consumption, which has been linked to serious illnesses. Foods high in sugar contribute to weight gain and insulin resistance, while excessive salt and processed ingredients strain vital organs such as the heart and kidneys.[244] Common illnesses associated with unhealthy diets include obesity, diabetes, cardiovascular diseases, and cancer. This research aims to address the overarching question: "T*o what extent does patent law affect the right of health and access to medicines for non-communicable diseases*?" Specifically, this chapter examines the related questions: '*What is the health legislation and what is the health framework?'*

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[241] Laura J Shallcross and Sally C Davies, 'The World Health Assembly resolution on antimicrobial resistance' (2014) 69 (11) Journal of Antimicrobial Chemotherapy 2883.
[242] Shallcross and Davies (n 241) 2885.
[243] Thomas J Papadimos, 'Healthcare access as a right, not as a privilege: a construct of Western thought' (2007) 2(2) Philosophy, Ethics, and Humanities in Medicine 1.
[244] Kacper Witek *et al.,* 'A High-Sugar Diet Consumption, Metabolism and Health Impacts with a Focus on the Development of Substance Use Disorder: A Narrative Review' (2022) 14(14) Nutrients 2940.

## 2. Definitions

In order to appreciate the rationale behind NCD regulation, this chapter first offers some working definitions of communicable and NCDs. The aim of this section is also to draw attention to the similarities and differences between the two categories, as they will lead to differences in regulation. These two types of diseases are different, and these differences might demand different responses from the government. The differences and their implications for regulation have already been examined in the literature review (Chapter One).

### 2.1. Communicable Diseases (CDs)

The World Health Organization (WHO)[245] a specialized agency of the United Nations responsible for global public health, plays a crucial role in the early diagnosis, prevention, and treatment of communicable diseases (CDs).[246] CDs, also known as infectious diseases, are caused by pathogenic microorganisms, and can be transmitted directly or indirectly between people. Notable examples include tuberculosis, malaria, HIV/AIDS, Covid-19 and Mpox.[247] CDs remain a significant global health challenge due to their ability to spread across populations, leading to widespread health, social, and economic impacts.

Human Immunodeficiency Virus (HIV) infection remains a major global health concern, with about 42.3 million[248] deaths worldwide attributed to HIV/AIDS since its discovery.[249] Specifically, statistics from the WHO shows that since the beginning of the HIV epidemic, 88.4 million people have been infected with the virus and about 42.3 million people have died of HIV. At the end of 2023, globally 39.9 million people were living with HIV. Approximately 0.6% of adults aged 15-49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. The WHO African Region remains most severely affected, with one in every 30 adults living with HIV and accounting for more than two-thirds of the people living with HIV worldwide.[250]

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[245] Jennifer Prah Ruger and Derek Yack, 'The Global Role of the World Health Organization' (2009) 2(2) Glob Health Gov 2.
[246] Ruger and Yack (n 245) 2.
[247] David Bell and Kristian Schultz Hansen, 'Relative Burdens of the Covid-19, Malaria, Tuberculosis, and HIV/AIDS Epidemics in Sub-Saharan Africa' (2021) 105(6) Am J Trop Hyg 1510.
[248] Guoping Ji *et al.,* 'The impact of HIV/AIDS on families and children – a study in China' (2007) 21(Suppl 8) AIDS 1, 1-10.
[249] Ji *et al.,* (n 248) 2. See also Bell and Hansen (n 247) 1511.
[250] Enos Moyo *et al.,* 'Key populations and Sub-Saharan Africa's HIV response' (2023) 10 (3389) Frontiers in Public Health 1.

The social and economic impacts of CDs are profound, with many individuals experiencing the loss of family members, friends, and colleagues, underscoring the extensive socio-economic effects.[251] WHO's work targets prevention treatment and control of HIV alongside efforts to reduce the overall public health burden of CDs.[252] The WHO also addresses socio-economic challenges posed by CDs, including high medical costs and loss of employment, through initiatives aimed at enhancing access to healthcare and reducing their overall impact.[253]

Tuberculosis, (TB) another major health threat, becomes particularly dangerous for individuals with compromised immune systems, like those living with HIV /AIDS. In regions with high HIV prevalence, particularly sub-Saharan Africa, the TB incidence tripled between 1990 and 2005, accounting for roughly 80% of global HIV-related TB cases by 2005.[254] In Eastern Europe, Russia alone saw 170,000 new HIV-related TB cases in 2005. In the UK, where TB remains a persistent issue, 10% of cases in London were co-infections with HIV. Similar trends are observed across Spain, Portugal, and Italy, highlighting the heightened risk of TB as a severe co-infection in HIV-positive populations.[255] The 1990s HIV/AIDS crisis revealed the crucial challenges posed by patents and access to essential medicines. In 2000, an estimated 40 million individuals in low-income regions were infected with HIV, 24.5 million in sub-Saharan African alone.[256] Despite the availability of life-saving antiretroviral (ARV) treatments in high-income countries since 1996, less than one in a thousand people in affected low-income areas could access these medicines due to driven by patents.[257]

This situation highlights how patent law can serve as a significant barrier to access to life-saving treatments, particularly in areas with limited resources.[258] While high-income countries could provide ARVs due to affordability and availability of generic alternatives, the

[251] Marc Suhrcke *et al.,* 'The Impact of Economic Crises on Communicable Disease Transmission and Control: A Systematic Review of the Evidence' (2011) 6 (6) Plos one 1.
[252] Suhrcke *et al.,* (n 251) 4.
[253] Suhrcke *et al.,* (n 251) 9. See also Matthew W Kreuter *et al.,* 'Addressing Social Needs in Health Care Settings: Evidence, Challenges, and Opportunities for Public Health' (2021) 42 Annu Rev Public Health 239, 329-344.
[254] World Health Organization, 'TB cases and deaths linked to HIV now at alarming levels in Africa' (*World Health Organization* 2025) <https://www.who.int/news/item/22-03-2005-tb-cases-and-deaths-linked-to-hiv-now-at-alarming-levels-in-africa> accessed 25 March 2025.
[255] World Health Organization, 'TB cases and deaths linked to HIV now at alarming levels in Africa' (n 92).
[256] 'T Hoen *et al*., (n 3) 2.
[257] 'T Hoen *et al.,* (n 3) 2.
[258] Tenni *et al.,* (n 19) 1.

strict enforcement of patent laws in low-income countries prohibited access to these same medicines, exacerbating the HIV/AIDS crisis.[259] The intersection of infectious diseases, patent law and access to medicines shows that these issues not only affect communicable diseases but also have broader implications for public health, especially in vulnerable populations.

Covid-19, a respiratory illness caused by the SARS-CoV-2 virus[260], first emerged in Wuhan, China, in late 2019 and rapidly became a global pandemic.[261] Covid-19, as a highly transmissible communicable disease, primarily affects the respiratory system, causing symptoms such as fever, cough, and difficulty breathing.[262] Covid-19's impact on public health has been extensively documented, with studies highlighting its mortality rate of 697.5 deaths per million at the pandemic's peak, making it the third leading cause of death globally, after heart disease and cancer.[263] The spread of Covid-19 through respiratory droplets spurred an unpresented demand for vaccines, promoting rapid innovation and collaboration within pharmaceutical industries.[264] These efforts highlight the necessity of equitable vaccine access to strengthen global health security.

The recent re-emergence of Mpox, (formerly known as monkeypox) highlights the ongoing threat of viral illnesses. Caused by the monkeypox virus, a member of the *Orthopoxvirus genus*[265], Mpox is characterized by symptoms such as skin rashes, fever, muscle, aches, and swollen lymph nodes. Transmission occurs through close contact with infected individuals, contaminated materials, or animals. There is also a vaccine for this particular disease.[266]

Therefore, the challenges faced in securing access to ARVs in the 1990s provide a foundation for continuing challenges related to the affordability, availability, and accessibility of medicines[267] which remains relevant in both the treatment of NCDs and CDs. Communicable

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[259] D'Angelo *et al.,* (n 2) 1523.
[260] Chih-Cheng Lai *et al., '*Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges' (2020) 55 (3) Int J Antimicrob Agents 1.
[261] Tanu Singhal, 'A review of Coronavirus Disease-2019 (COVID-19)' (2010) 87(4) The India Journal of Pediatrics 281.
[262] Lai *et al* (n 260) 7.
[263] Howard K Koh *et al.,* 'Deaths From COVID-19' (2021) 325(2) JAMA Network 133.
[264] Louis C Druedahl *et al.,* 'Collaborations in times of crisis: A study on Covid-19 vaccine R&D partnerships' (2021) 39 (42) Vaccine 6292.
[265] Mohammad Ali Zinnah *et al.,* 'The Re-Emergence of Mpox: Old Ilness, Modern Challenges' (2024) 12(7) Bomedicines 1457.
[266] Zinnah *et al.,* (n 265) 1457.
[267] Kingsley Oturu *et al.,* 'Barriers and enabling structural forces affecting access to antiretroviral therapy in Nigeria' (2024) 24(105) BMC Public Health 2, 2-13.

diseases continue to pose a serious threat to global health, disproportionately impacting low- and middle-income countries and creating extensive social and economic consequences. Efforts by the WHO and other international organisations have been instrumental in reducing the burden of HIV/AIDS, tuberculosis, malaria and other significant CDs while also addressing the socio-economic challenges associated with these diseases. However, as these organisations make strides in combatting CDs, the rise of NCDs represents an emerging public health challenge. In the next section, NCDs will be discussed, as addressing these diseases will also require similarly focused international efforts and innovative strategies to protect and improve global health.

### 2.2. Non-Communicable Diseases (NCDs)

NCDs, also known as chronic diseases, are long-lasting conditions that arise from a complex interaction of genetic, physiological, behavioural, and environmental factors.[268] With over 80% of NCD-related deaths occurring in low-and middle-income countries, addressing these risk factors has become a critical global priority.[269] Recent regulatory measures, such as those implemented in the UK, highlight the urgent need for global policymakers to act swiftly on this issue.

NCDs encompass a diverse range of diseases, including cardiovascular conditions like heart attacks and strokes, cancers such as oral cancer[270], diabetes, and chronic respiratory diseases like obstructive pulmonary disease (COPD) and asthma.[271] These illnesses can lead to long-term disability, chronic pain, reduced mobility, and psychosocial issues such as depression and anxiety. Beyond their impact on health, NCDs impose a significant economic burden due to rising healthcare costs and loss of productivity, which negatively affect individuals, families, and entire societies. While premature death is a critical outcome of NCDs, their impact on

[268] Valeria Calcaterra and Gianvincenzo Zuccotti, 'Non-Communicable Diseases and Rare Diseases: A Current and Future Public Health Challenge within Pediatrics' (2022) 9 (10) Children 1491.
[269] Calcaterra and Zuccotti (n 268) 1491. See also Ndubuisi (n 236) 1.
[270] Eric P Tranby *et al.,* 'Oral cancer Prevalence, Mortality, and Costs in Medicaid and Commercial Insurance Claims Data' (2022) 31(9) Cancer Epidemiol Biomarkers Prev 1849. Oral cancer is the sixth most common cancer worldwide, accounting globally for 377,713 new cases and 177,757 deaths in 2020, representing an increase in new cases from 2018 specifically, 354,864 new cases, 177,384 deaths in 2018.
[271] Ndubuisi (n 236) 1. See also Calcaterra and Zuccotti (n 268) 1491.

quality of life through physical, mental and economic challenges should not be underestimated.[272]

NCDs represent a significant global health challenge, accounting for 74% of all global deaths[273] and causing over 41 million deaths annually.[274] These diseases disproportionately affect low- and middle-income countries, where limited healthcare resources compound the problem. In addition to causing death, NCDs contribute to disability and place an immense strain on healthcare systems and economies through increased medical expenses and reduced workforce productivity.

Unlike CDs, NCDs are not transmissible from person to person[275] and are instead driven by a combination of modifiable and non-modifiable risk factors. Non-modifiable factors include age, gender and genetic predisposition, which cannot be altered.[276] However, modifiable factors such as tobacco use, excessive alcohol consumption, physical inactivity and unhealthy diets, play significant roles in the onset and progression of NCD.[277] Addressing these preventable risk factors is essential to mitigating the growing burden of NCDs globally.

Without urgent action, the global NCD burden is projected to increase by 40% by the end of this decade.[278] This section continues by examining the risk factors associated with NCDs, providing insights into strategies to address the critical public health challenge.

Tobacco use is one of the most significant risk factors for NCDs, contributing substantially to the global burden of disease. Both smoking and smokeless forms of tobacco are widely

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[272] Sehar-Un-Nisa Hassan *et al.,* 'Quality of Life and Adherence to Healthcare Services During the COVID-19 Pandemic: A Cross-Sectional Analysis' (2022) 16 Patient Prefer Adherence 2534.
[273] Daniele Piovani *et al.,* 'Non-Communicable Diseases: The Invisible Epidemic' (2022) 11 (19) J Clin Med 5939.
[274] Piovani *et al.,* (n 273) 5939.
[275] Piovani *et al.,* (n 273) 5939.
[276] Jahirul Hoque *et al.,* 'Modifiable and Non-Modifiable Risk Factors of Stroke: A Review Update' (2015) 1(1) Journal of National Institute of Neurosciences Bangladesh 22.
[277] Hidayat Arifin *et al.,* 'Analysis of Modifiable, Non-Modifiable and Physiological Risk Factors of Non-Communicable Diseases in Indonesia: Evidence from the 2018 Indonesian Basic Health Research' (2022) 15 Journal of Multidisciplinary Healthcare 2203-2221.
[278] Abdesslam Boutayeb and Saber Boutayeb, 'The burden of non communicable diseases in developing countries' (2005) 4 (2) Int J Equity Health 6.

prevalent[279], with tobacco responsible for approximately eight million deaths annually.[280] The impact of tobacco use on population health is profound. It is linked to at least sixteen types of cancer, including lung cancer, the world's leading cause of cancer deaths, accounting for nearly one in five cancer fatalities.[281] Additionally, tobacco use is associated with cancers of the throat and oral cavity, as well as cancer in diverse sites, such as the bladder, kidney, stomach, and uterine cervix.[282]

Beyond cancer, smoking is a major contributor to cardiovascular disease, the leading global cause of death.[283] Smoking increases the risk of heart disease and stroke by two to four times[284] and it is an independent risk factor for diabetes, with 12% of diabetes cases in the United States attributed to smoking.[285] Efforts to reduce tobacco use, such as smoking cessation programs, advertising bans and increased taxation on tobacco products, are among the most-effective strategies for preventing NCDs.[286]

In addition to tobacco use, heavy alcohol consumption and alcohol use disorders are significant global risk factors for NCDs, strongly linked to cancer, cardiovascular diseases, and liver disease.[287] Globally, alcohol has been identified as a leading risk factor for death and disability[288], accounting for 3.8% of deaths and 4.6% of disability-adjusted life years (DALYs) lost in 2004.[289] Its impact varies across income levels, ranking as the fifth highest risk factor for death in middle-income countries and ninth in high-income countries.

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[279] J S Thakur *et al.,* 'Tobacco Use: a major Risk Factor for noncommunicable Diseases in South-East Asia Region' (2011) 55 (3) Indian Journal of Public Health 155.
[280] Prabhat Jha *et al.,* 'Global Hazards of Tobacco and the Benefits of Smoking Cessation and Tobacco Taxes' (2015) in Hellen Gelband, Prabhat Jha, Rengaswamy Sankaranayanan and Susan Horton (eds) *Cancer* (3rd edn, World Bank Group, 2015) Chapter 10.
[281] Prabhat *et al* (n 279) 136.
[282] Thakur *et al.,* (n 279) 136.
[283] Thakur *et al.,* (n 279) 33.
[284] Thakur *et al.,* (n 279) 33.
[285] Thakur *et al.,* (n 279) 178.
[286] Stanton Glantz and Mariaelena Gonzalez, 'Effective tobacco control is key to rapid progress in reduction of non-communicable diseases' (2013) 379(9822) Lancet 1269-1271.
[287] Charles D Parry *et al.,* 'Alcohol consumption and non-communicable diseases: epidemiology and policy implications' (2012) 106(10) Addiction 1718.
[288] D Parry *et al.,* (n 287) 1719.
[289] D Parry *et al.,* (n 287) 1719.

To mitigate the harmful effects of alcohol, targeted interventions include enforcing advertising bans, limiting availability, increasing taxes, and implementing drink-driving laws.[290] These measures address the drivers of heavy alcohol use, which significantly contribute to the global burden of NCDs.

Beyond tobacco use and alcohol consumption, physical activity is another major contributor to the rise of NCDs. Physically inactive people are 20-30% times more likely at risk of early death compared to active individuals.[291] Global efforts are currently underway to reduce physical inactivity by 10% by 2025.[292] Research highlights the vital role of physical exercise in treating NCDs, as it enhances physiological functioning and improves cognitive, emotional, social, and psychosocial well-being. Exercise also helps shift health beliefs and increases acceptance of chronic disease.[293]

Despite its importance, physical inactivity has been described as the "Cinderella" of NCD risk factors, defined as *"poverty of policy attention and resourcing proportionate to its importance*."[294] It ranks as the fourth leading risk factor for NCD prevention, preceded only by tobacco use, hypertension, and high blood glucose levels, and was responsible for over 3 million preventable deaths globally in 2010.[295] While physical inactivity has been identified as a global public health priority, many countries have yet to implement the necessary policies and actions to address this issue effectively.[296] Promoting physical activity can be achieved through media campaigns, community-based education programs, and incorporating physical activity into routine primary healthcare services.

Furthermore, unhealthy diets, particularly those high in salt, sugar, and fat, significantly increase the risk of metabolic disorders, such as raised blood pressure, high blood glucose,

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[290] Long Khanh-Dao Le *et al.,* 'Interventions to prevent alcohol use: systematic review of economic evaluations' 2023 9(4) BJPsych Open 1-25. See also Kavita Singh *et al.,* 'What are the Evidence Based Public Health Interventions for Prevention and Control of NCDs in Relation to India?' (2011) 36 (S1) Indian J Community Med 23.
[291] Abraham Haileamlak, 'Physical Inactivity: The Major Risk Factor for Non-Communicable Diseases' (2019) 29(1) Ethiop J Health Sci 810.
[292] Amini H *et al.,* 'COVID-19 pandemic-induced physical inactivity: the necessity of updating the Global Action Plan on Physical Activity 2018-2030' (2021) 26 (32) Environmental Health and Preventive Medicine 1.
[293] Haileamlak (n 291) 810.
[294] Fiona C Bull and Adrian E Bauman, 'Physical Inactivity: The "Cinderella" Risk Factor for Noncommunicable Disease Prevention' (2011) 16(sup2) Journal of Health Communication 13, 13-26.
[295] Bull and Bauman (n 294) 13.
[296] Bull and Bauman (n 294) 13.

elevated blood lipids and obesity. These metabolic risk factors are strongly linked to cardiovascular disease, which are the leading cause of NCD in terms of premature deaths globally.[297]

Obesity, which is a growing global concern, especially among children, increases the risk of asthma, diabetes, osteoporosis, and heart disease.[298] The WHO reports that 2.8 million[299] deaths annually are linked to excessive weight. In response to the growing childhood obesity crisis, new regulatory measures are being implemented. Starting in October 2025, the UK will implement a ban on junk food advertisements before 9:00 pm on television and a complete ban on online paid advertisements for unhealthy foods.[300] The WHO advises that improving unhealthy diets involves reducing salt intake, which is one of the most cost-effective ways to improve health and reduce the burden of NCDs[301], eliminating trans-fats, and raising taxes on sugar-sweetened beverages.[302]

While both CDs and NCDs pose major global health challenges, they differ significantly in nature, causes, and approached to prevention and treatment. CDs such as HIV/AIDS, influenza, and tuberculosis are caused by infectious agents and are often acute conditions with effective prevention and treatment options like vaccines, and antibiotics. In contrast, NCDs are chronic, long-lasting conditions that arise from a combination of genetic, behavioural, and environmental factors. Responsible for substantial proportion of global deaths, NCDs also pose significant economic and social burden, particularly in low-and middle-income countries.

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297 Shuyi Wu et al., 'Global burden of cardiovascular disease attributable to metabolic risk factors, 1990-2019: an analysis of observational data from a 2019 Global Burden of Disease study' (2023) 13(5) BMJ Open 1-11.

298 BBC News, 'Childhood obesity' (*BBC* 2024) <https://www.bbc.co.uk/news/topics/cezzn69p46rt> accessed 25 March 2025. See also Annette Boles *et al*., 'Dynamics of diabetes and obesity: Epidemiological perspective' (2017) 1863 (5) Biochimica et Biophysica Acta 1026.

299 World Health Organization, 'Obesity' (*World Health Organization* 2025) <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3420#:~:text=Rationale%3A,caused%20by%20overweight%20or%20obesity> accessed 25 March 2025. See also BBC News, 'Obesity: Study of 2.8 million shows increased disease and death risks' (*BBC* 2019) <https://www.bbc.co.uk/news/health-48088391> accessed 25 March 2025.

300 Gov.uk, 'Junk food ad ban legislation progresses to curb childhood obesity' (*Gov.uk* 2024) <https://www.gov.uk/government/news/junk-food-ad-ban-legislation-progresses-to-curb-childhood-obesity#:~:text=Children%20will%20no%20longer%20be,plans%20to%20curb%20childhood%20obesity> accessed 25 March 2025. See also BBC News, 'Ban on junk food TV adverts before 9pm to come in next year' (*BBC* 2024) < https://www.bbc.co.uk/news/articles/cx2n2g5wze4o> accessed 25 March 2025.

301 Karolina Jachimowicz-Rogowska and Anna Winiarska-Mieczan, 'Initiatives to Reduce the Content of Sodium in Food Products and Meals and Impove the Population's Health' (2023) 15 (10) Nutrients 2393.

302 Anne Marie Thow *et al.,* 'Fiscal policy to improve diets and prevent noncommunicable diseases: from recommendations to action' (2018) 96(3) Bull World Health Organ. See also Rogowska and Mieczan (n 301) 2393.

Prevention and control are key in the fight with the risk factors causing NCDs. As mentioned above the risk factors associated with NCDs can begin before birth with maternal factors that affect the wellbeing of the foetus.[303] It is unacceptable that in the UK only 1.2% of food advertising focuses on fruits and vegetables.[304] Childhood obesity, exposure to tobacco, air pollution and inequalities in healthcare access contribute to the emergence of NCDs that will continue to have an impact into adulthood.[305] Reports show that in 2022, approximately 39 million children under the age of 5 were overweight or obese. Additionally, around 60% of children who are overweight before puberty are at risk of becoming overweight adults.[306]

Many NCDs are preventable through lifestyle changes, including healthy eating, regular physical activity and avoiding tobacco and excessive alcohol consumption. Early recognition and effective management are key to improving outcomes and enhancing the quality of life for those affected by NCDs.[307] While both CDs and NCDs demand global attention, their distinct characteristics require separate prevention and treatment strategies to mitigate their respective impacts. These proven, cost-effective strategies are particularly valuable in low and middle-income countries, where these measures and public health efforts can foster healthier societies and contribute to sustainable economic development, aligning with broader global health objectives.[308]

The growing threat of NCDs is one of the most pressing challenges to development in the 21st century, undermining social and economic progress worldwide. This issue is further compounded by the coexistence of CDs and the lasting effects of the Covid-19 pandemic. The pandemic highlighted the vulnerability of individuals with pre-existing NCDs such as obesity or smoking-related conditions, exacerbating their health risks and outcomes.[309] Addressing

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[303] Budreviciute *et al.,* (n 1) 4.
[304] Budreviciute *et al.,* (n 1) 5.
[305] Michael Marmot and Ruth Bell, 'Social determinants and non-communicable diseases: time for integrated action' (2019) 364 (Suppl 1) BMJ 1251. See also Budreviciute *et al* (n 1) 2.
[306] BBC News, 'Little change in child obesity, report finds' (*BB* 2024) <https://www.bbc.co.uk/news/articles/cy79x5p05rzo> accessed 25 March 2025.
[307] Budreviciute *et al.,* (n 1) 4.
[308] Budreviciute *et al.,* (n 1) 6.
[309] Gerard Thomas Flaherty *et al.,* 'COVID-19 in adult patients with pre-existing chronic cardiac, respiratory, and metabolic disease: a critical literature review with clinical recommendations' (2020) 6(16) Tropical Diseases Travel Medicine and Vaccines 3, 1-13.

NCDs and their risk factors is not only essential for individual well-being but also crucial for global development and resilience against future health crises.

### 3. International Policy Makers (Organizations and Rules)

It is important to emphasize the role of policy makers, especially the World Health Organization (WHO) in taking action to prevent deaths caused by NCDs. Highlighting the efforts of such organizations underscores the need for coordinated, large-scale efforts to tackle the NCD epidemic and reduce its global impact. This chapter continues by explaining the role of these organizations and how they manage to control this problem, especially in the European Union and the United Kingdom.

#### 3.1. World Health Organization (WHO)

The WHO is a specialized agency of the United Nations dedicated to promoting global public health, safeguarding the vulnerable and ensuring that everyone, everywhere, can achieve the highest attainable standard of health.[310] Established on 7 April 1948 and consisting of 194 Member States, it employs over 7,000 people from over 150 countries, working across 150 country offices,[311] six regional offices, and has its headquarters in Geneva, Switzerland.[312] Additionally, it runs the Global Service Centre in Malaysia, which supports its global activities. The WHO has been instrumental in setting global health policy goals, including addressing the growing burden of NCDs.

The WHO and the United Nations set a target to reduce premature mortality from NCDs by 25% among individuals aged 30-70 years by 2025,[313] known as the '25 by 25' goal. Building on this progress, new targets for 2030 have been established, aligned with the Sustainable Development Goals (SDGs) which will be discussed in the next sections. These include reducing premature mortality from NCDs by one-third, expanding health coverage with a

[310] Poul Erik Petersen, 'World Health Organization global policy for improvement of oral health – World Health Assembly 2007' (2008) 58 (3) International Dental Journal 115.
[311] World Health Organization, 'Who we are' <https://www.who.int/about/who-we-are> accessed 25 March 2025.
[312] World Health Organization, 'Who we are' (n 311).
[313] David J Hunter and K Srinath Reddy, 'Non communicable diseases' (2013) 369(64) N Engl J Med 1336. See also Ailiana Santosa *et al.,* 'Achieving a 25% reduction in premature non-communicable disease mortality: the Swedish population as a cohort study' (2015) 13(65) BMC Medicine 1.

particular focus on NCD prevention and care, and enhancing health systems and data surveillance. Central to these efforts is the integration of NCD services into primary healthcare and the promotion of healthier lifestyles to mitigate risk factors such as tobacco use, unhealthy diets and physical inactivity.[314]

However, the WHO also faces challenges, including resource constraints and the complexities of coordinating with diverse stakeholders.[315] These challenges can impact its ability to address emerging health threats, particularly in low-and middle-income countries. Despite these obstacles, WHO continues to lead initiatives such as the Framework Convention on Tobacco Control (FCTC) and the Global Action Plan for NCDs, which will be explored in the next sections.

### 3.1.1. The World Health Assembly

The World Health Assembly (WHA) serves as the decision-making body of the WHO. Comprising delegations from all 194 WHO Member States, the WHA meets annually in Geneva[316] to discuss and decide key global health priorities based on an agenda prepared by the WHO's Executive Board.

The main function of the WHA is to determine the organisation's policies, appointing the Director-General, supervising financial policies and approving the proposed programme budget. As the governing body of the WHO, the WHA plays a pivotal role in shaping the global health agenda by determining priorities, fostering international collaboration and guiding WHO's efforts to address urgent global health challenges.

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[314] Ashraful Kabir *et al.,* 'Health system challenges and opportunities in organizing non-communicable diseases services delivery at primary healthcare level in Bangladesh: A qualitative study' (2022) 10 (1015245) Front Public Health 2, 1-15.
[315] Sena Ozdemir *et al.,* 'Stakeholder diversity and collaborative innovation: Integrating the resource-based view with stakeholder theory' (2023) 164 (113955) Journal of Business Research 2 ,1-16.
[316] World Health Organization, 'World Health Assembly'(*World Health Organization* 2025) <https://www.who.int/about/governance/world-health-assembly#:~:text=The%20World%20Health%20Assembly%20is,prepared%20by%20the%20Executive%20Board> accessed 25 March 2025.

Notable achievements of the WHA include eradicating the global acute disease of smallpox[317], the endorsement of the International Health Regulations (IHR) for pandemic preparedness, and commitments to combat NCDs and promote the Universal Health Coverage (UHC). Decisions made at the WHA have fa-reaching impacts, serving as the foundation for coordinated global efforts to improve health equity and tackle emerging health threats.[318]

### 3.1.2. WHO's Role in Global Health

The WHO has played a critical role in managing several major pandemics and outbreaks throughout history. More broadly, it works to promote health, protect people from health risks and support vulnerable populations worldwide.[319] Its key responsibilities include providing technical guidance on prevention, diagnosis, and treatment, ensuring equitable access to resources particularly in low-income countries and fostering global collaboration among governments, researchers and organizations.

One of the WHO's primary goals is addressing the growing burden of NCDs. It has urged governments to take swift action to reduce the impact of NCDs in light of increasing challenges. Although the burden of NCDs is significant, an estimated 80% of cases are preventable, suggesting that most premature deaths could be avoided or delayed.[320] In addition, one WHO goal includes ensuring that an additional billion people gain access to UHC[321], protecting another billion from health emergencies such as pandemics and improving the health and well-being of a further billion people by addressing NCDs, mental health and other health challenges. These goals form the core of the WHO's mission to achieve health for all and are closely aligned with the United Nation's Sustainable Development Goals (SDGs).[322]

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[317] World Health Organization, 'Commemorating Smallpox Eradication- a legacy of hope for COVID-19 and other diseases' (*World Health Organization* 2025) <https://www.who.int/news/item/08-05-2020-commemorating-smallpox-eradication-a-legacy-of-hope-for-covid-19-and-other-diseases> accessed 25 March 2025. The WHA marked the end of a disease that had plagued humanity for at least 3000 years, killing 300 million people in the 20th century alone.

[318] World Health Organization, 'Working together for equity and healthier populations; Sustainable multisectoral collaboration based on Health in All Policies approaches' (*World Health Organization* 2023) <https://iris.who.int/bitstream/handle/10665/372714/9789240067530-eng.pdf> accessed 25 March 2025.

[319] World Health Organization, 'What we do' < https://www.who.int/about/what-we-do#:~:text=WHO%20works%20worldwide%20to%20promote,better%20health%20and%20well%2Dbeing> accessed 25 March 2025.

[320] Ndubuisi (n 236) 1.

[321] World Health Organization, 'Universal health coverage (UHC), (*World Health Organization* 2023) <https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)> accessed 25 March 2025.

[322] World Health Organization, Sustainable Development Goals' (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals> accessed 25 March 2025. See also World

To achieve these ambitious goals, the WHO leverages its global network, collaborates with governments and international organizations and engages a variety of stakeholders. It sets global health standards by developing evidence-based guidelines, monitoring health challenges and providing technical support to strengthen healthcare systems.[323] Additionally, the WHO plays a vital role in promoting health security by helping countries prepare for and respond to health emergencies such as outbreaks of infectious diseases.[324]

By integrating health initiatives into national health systems and advancing UHC, WHO aims to reduce health disparities, improve health outcomes and ensure that health services are accessible to everyone, everywhere. Through its leadership and collaborative efforts, WHO remains an indispensable force in addressing global health challenges and fostering a healthier, more equitable world.

### 3.1.3. WHO Global NCD Action Plan

The WHO Global NCD Action Plan (2013-2030) (NCD GAP)[325] refers to the prevention and control of NCDs, adopted by the World Health Assembly in 2013.[326] NCD GAP builds on previous WHO strategies to address non-communicable diseases (NCDs) like cardiovascular disease, cancer, respiratory diseases, and diabetes. Originally designed for 2013-2020, the plan was extended to 2030 to align with the Sustainable Development Agenda.[327] It identifies four main behavioural risk factors for NCDs including tobacco use, unhealthy diet, physical inactivity and harmful alcohol use, and emphasizes preventing NCDs by reducing these shared risk factors. In addition to these behavioural risks, other factors contribute to the burden of

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Health Organization, 'Promote Health Keep the World Save the Vulnerable' (*World Health Organization* 2019) WHO/PRP/18.1 7. Available: https://iris.who.int/bitstream/handle/10665/324775/WHO-PRP-18.1-eng.pdf

323 World Health Organization, 'Promote Health Keep the World Save the Vulnerable' (n 322).

324 World Health Organization, 'Promote Health Keep the World Save the Vulnerable' (n 322).

325 World Health Organization, 'Global action plan for the prevention and control of noncommunicable diseases 2013-2020' (*World Health Organization* 2013). Available: https://iris.who.int/bitstream/handle/10665/94384/9789241506236_eng.pdf?sequence=1

326 Sixty-Sixth World Health Assembly, 'Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases' (*World Health Organization* 2013) WHA66.10. Available: https://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf?ua=1

327 World Health Organization, 'Transforming our world: the 2030 Agenda for Sustainable Development' <https://sdgs.un.org/2030agenda> accessed 25 March 2025. See also World Health Organization, 'Updated Appendix 3 of the WHO Global NCD Action Plan 2013-2030' (*World Health Organization* 2022) <https://cdn.who.int/media/docs/default-source/ncds/mnd/2022-app3-technical-annex-v26jan2023.pdf> accessed 25 March 2025 1.

NCDs, including metabolic risks (such as raised blood pressure, obesity, high blood sugar and high cholesterol levels) and environmental risks, like pollution, which particularly impact cardiovascular and respiratory diseases.[328]

The NCD GAP outlines six key objectives: advocating for global attention, strengthening governance and partnerships, preventing NCDs at the population level, enhancing health system responses, advancing research, and improving monitoring and evaluation. It relies on principles like human rights, equity, multisectoral action and evidence-based strategies[329], with a specific emphasis on ensuring access to essential NCD medicines. The plan also recognizes the challenges to achieving these objectives, particularly in resource-constrained settings, and the critical need for international collaboration and sustainable funding.

The plan includes twenty-five indicators and nine global targets to track progress and features evidence-based interventions, categorized into best buys, effective interventions, and other recommendations.[330] It also proposes policy options and enabling actions to support these objectives[331], including ensuring equitable access to essential medicines. Recognizing the territorial nature of policies and actions, an implementation roadmap for 2023-2030[332] aims to accelerate progress by focusing on national responses, allowing individual countries to prioritize impactful interventions based on their specific contexts and ensuring reliable data. This roadmap reflects updates and new strategies to enhance the NCD GAP's effectiveness, further aligning with the SDGs to meet global health targets. An implementation roadmap for 2023-2030 aims to accelerate progress by focusing on national responses, prioritizing impactful interventions and ensuring reliable data. This roadmap reflects updates and new strategies to enhance the NCD GAP's effectiveness and meet global health targets.[333]

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[328] Budreviciute *et al.,* (n 1) 2.
[329] Nick Banatvala *et.al.,* '*The WHO Global Action Plan for the Prevention and Control of NCDs 2013-2030*' in Nick Banatvala and Pascall Bovet (eds), *Noncommunicable Diseases* (Routledge, 2023) 234.
[330] Banatvala *et al*., (n 329) 237.
[331] Banatvala *et al* (n 329) 237.
[332] World Health Organization, 'Implementation roadman 2023-2030 for the Global action plan for the prevention and control of NCDs 2013-2030' (*World Health Organization* 2025) <https://www.who.int/teams/noncommunicable-diseases/governance/roadmap> accessed 25 March 2025.
[333] Banatvala *et al.,* (n 329) 237.

### 3.2. European Union (EU)

The European Union (EU) occupies a unique role in the global health area.[334] As a regional authority with regulatory, legislative, and coordinating functions, it significantly influences health policy across its member states.[335] Although the primary responsibility for health policy lies with individual nations, the EU's unified regulatory systems and public health strategies play a critical part in addressing the prevention, management, and treatment of NCDs.[336] This section explores the legal institutional foundations of the EU's engagement in health, highlighting the impact of access to medicines for NCDs.

Under Article 168 of the Treaty on the Functioning of the European Union (TFEU)[337], public health is a competence shared between the EU and its member states[338] and it sets out the objectives[339] and legal basis for EU health policy. The EU engages in joint actions to tackle serious illnesses by promoting healthier lifestyles, facilitating access to better and safer healthcare, contributing to innovative, efficient and sustainable health systems, keeping people healthy throughout their lifetimes and harnessing new technologies and practices.[340] Prevention activities in the EU encompass a wide range of areas including initiatives against cancer, communicable and non-communicable diseases, vaccination and combatting antimicrobial resistance (AMR) that occurs when bacteria, viruses, fungi and parasites no longer respond to antimicrobial medicines.[341]

The relevant EU health strategies and frameworks are the EU Health Programme and the EU Pharmaceutical Strategy. The EU Health Programme was adopted as a response to the Covid-

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334 European Union, 'Global' <https://health.ec.europa.eu/internationalcooperation/global-health_en> accessed 25 March 2025.
335 European Council, 'EU health policy' <https://www.consilium.europa.eu/en/policies/eu-health-policy/> accessed 25 March 2025.
336 European Parliament, 'Report on non-communicable diseases (NCDs)' (*European Parliament* 2023) <https://www.europarl.europa.eu/doceo/document/A-9-2023-0366_EN.html> accessed 25 March 2025.
337 Article 168 TFEU 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities…'
338 Article 168 TFEU (n 337).
339 Article 168 TFEU (n 337).
340 European Parliament, 'Public Health' (*Fact Sheets on the European Union* 2024) <https://www.europarl.europa.eu/erpl-app-public/factsheets/pdf/en/FTU_2.2.4.pdf> accessed 25 March 2025.
341 European Commission, 'EU Action on Antimicrobial Resistance' <https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en> accessed 25 March 2025.

19 pandemic and to reinforce crisis preparedness in the EU.[342] This programme will also bring a contribution to the long-term health challenges by building stronger, more resilient and more accessible health systems.[343] The EU Health Programme outlines the strategy for ensuring good health and healthcare and is also a financial instrument to support cooperation between EU countries, and to support and develop EU health activities.[344]

The legal basis for the health programme has been agreed with the European Parliament and the Council for several years. The EU is called upon to ensure the protection of human health in all policy areas and to work with EU countries to improve public health, prevent human illness and avoid sources of danger to physical and mental health.[345] The EU Health Program aims to make the EU a smart, sustainable and inclusive economy promoting growth for all. The Programme focusses on important Commission priorities such as increasing employment and investment, internal markets in pharmaceuticals, drug inventions, cross-border healthcare directives and Health Technology Assessment.[346] In addition, the programme promotes a single digital market including eHealth like digital tools, for example through mobile health apps, justice and fundamental rights including reducing health inequalities, develops migration policies, security preparedness and management of serious cross-border health threats.[347]

Health regulation falls under the shared competence between the European Union and its member states. The Union has specific powers in this domain, particularly in Article 168 TFEU[348], which allows for action to support, coordinate or complement member states' health policies. However, it is crucial to recognize that health policy remains primarily the responsibility of member states, and the EU's role is to ensure a high level of human health protection through supporting and coordinating national efforts rather than imposing uniform

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342 European Commission, 'EU4Health programme 2021-2027- a vision for a healthier European Union' <https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en> accessed 25 March 2025.
343 European Commission, 'EU4Health programme 2021-2027- a vision for a healthier European Union' (n 342).
344 European Commission, 'EU4Health programme 2021-2027- a vision for a healthier European Union' (n 342).
345 European Commission, 'Health promotion' <https://health.ec.europa.eu/other-pages/basic-page/health-promotion_en#:~:text=The%20EU%20is%20required%20to,ensuring%20good%20health%20and%20healthcare> accessed 25 March 2025.
346 European Commission, 'Health monitoring programme' <https://health.ec.europa.eu/other-pages/basic-page/health-monitoring-programme_en> accessed 25 March 2025.
347 European Commission, 'Health monitoring programme' (n 346).
348 Article 168 of the TFEU (n 337).

regulations. This means that while the EU can set certain standards and provide guidance, the primary regulatory authority in health matters continues to reside with individual member states.

The EU plays a critical role in supporting initiatives that raise awareness about healthy lifestyles, promote mental health and well-being and aim to reduce the marketing of unhealthy diets.[349] The EU prioritizes the health of its citizens, working with various countries on health system-strengthening programs. For example, a fund of 30 million euros has been allocated to combat NCDs in collaboration with the WHO.[350] The EU's stance on NCDs is revealed in its public health decisions and priorities aimed at preventing deaths associated with these diseases.

In addition to the EU's efforts organizations like the European Heart Network (EHN) and European Cancer Information System (ECIS) are vital in the fight against NCDs. The EHN is an alliance of member organizations including heart foundations and other non-governmental organizations dedicated to the prevention of cardiovascular disease in Europe.[351] Additionally, the ECIS provides the latest information across Europe, exploring geographical patterns and temporal trends of incidence, mortality and survival data across Europe for the major cancer entities.[352]

While the scope of EU legislation in the field of health policy is very limited, it continues to encourage measures to promote and improve health. This approach laid the groundwork for the Health Programme 2014-2020[353] and has evolved into the current EU4Health Programme 2021-2027[354], which provides significant funding and support for the EU's health agenda. In

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349 Lindsey Smith Taillie *et al.,* 'Governmental policies to reduce unhealthy food marketing to children' (2019) 77 (11) Nutr Rev 786.

350 European Commission, 'Speech by Andriukaitis at the Plenary Session of the United Nations General Assembly High-Level Meeting on the Prevention & Control of Non-Communicable Diseases' (*European Commission* 2018) <https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_18_5929> accessed 25 March 2025.

351 ESC, 'A new European Heart Health Charter for a new Europe' (*European Society of Cardiology* 2023) <https://www.escardio.org/The-ESC/Press-Office/Press-releases/a-new-european-heart-health-charter-for-a-new-europe> accessed 25 March 2025.

352 European Commission, 'ECIS - European Cancer Information System' <https://ecis.jrc.ec.europa.eu> accessed 25 March 2025.

353 European Commission, 'Commission Implementing Decision -Annex 1' (*European Commission* 2022) 4. Available: https://ec.europa.eu/assets/sante/health/funding/wp2022_en.pdf

354 European Commission, 'EU4Health programme 2021-2027 - a vision for a healthier European Union' (n 342).

response to the Covid-19 pandemic, the EU4Health Programme aims to address ongoing health challenges, enhance health systems, and improve overall public health outcomes across member states[355] budgeted at an initial €5.3 billion, later revised to €4.4 billion following adjustments to the 2021-2027 Multiannual Financial Framework (MFF).[356] Despite this reduction, EU4Health remains the largest EU financial commitment to health to date. By emphasizing pandemic preparedness, disease prevention, digital health innovation and equitable healthcare access, the programme aims to address persistent health challenges, enhance healthcare resilience, and improve health outcomes. The EU4Health programme thus conveys a clear message that public health is a priority for the EU and serves as a primary instrument in paving the way toward a European Health Union.[357]

The EU is working with international organizations to develop, implement and promote its public health agenda. It is also strengthening the priority given to NCDs.[358] Specific cooperation arrangements exist with the WHO on an international level as well as with the Council of Europe and the Organization for Economic Cooperation and Development (OECD) within the EU context.[359] The Council of Europe and OECD contribute to health regulation from different angles[360], each bringing a distinct perspective to public health governance. The Council of Europe[361] was established in 1949 to promote democracy and protect human rights and the rule of law in Europe. The OECD takes an economic and policy driven approach, analysing healthcare systems, financing models and cost-effectiveness to guide evidence-based policymakers.[362] Through comparative health data and policy recommendations, the OECD helps shape strategies for sustainable healthcare investment, prevention of NCDs and

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[355] European Commission, 'EU4Health programme 2021-2027 - a vision for a healthier European Union' (n 342).
[356] European Commission, 'EU4Health programme 2021-2027 - a vision for a healthier European Union' (n 342).
[357] European Commission, 'EU4Health programme 2021-2027 - a vision for a healthier European Union' (n 342).
[358] European Commission, 'Healthier Together: EU Non-Communicable Diseases Initiative' (*European Commission* 2022) Available: https://health.ec.europa.eu/system/files/2022-06/eu-ncd-initiative_publication_en_0.pdf
[359] European Commission, 'International organizations' (*European Commission*) <https://health.ec.europa.eu/internationalcooperation/international-organisations_en> accessed 25 March 2025.
[360] European Commission, 'Health at a Glance: Europe 2022: State of Health in the EU cycle' (*European Union* 2022) Available: https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/12/health-at-a-glance-europe-2022_b73a1698/507433b0-en.pdf
[361] House of Commons Library, 'Work for the Council of Europe' (*Work for the Council of Europe* 2023) [2.1]. Available: https://researchbriefings.files.parliament.uk/documents/CDP-2023-0119/CDP-2023-0119.pdf
[362] Beata Gavurova *et al.,* 'Health system efficiency in OECD countries: dynamic network DEA approach' (2021) 11 (40) Health Econ Rev 1.

innovation in health systems.[363] Together, these organizations complement the EU's efforts in strengthening public health regulations and promoting effective healthcare policies.

The WHO, the WIPO and the WTO engage in trilateral cooperation to address global health challenges.[364] This collaboration focuses on the intersection of public health, intellectual property rights and trade policies. The aim is to harmonize efforts to improve access to essential medicines, promote innovation and ensure that intellectual property and trade regulations support public health objectives rather than hinder them.[365] While EU member states remain members of the WTO in their own right,[366] the allocation of internal regulatory powers between the EU and its member states determines who is responsible for breaches of WTO law.

NCDs undermine human health and well-being, the sustainability of healthcare systems and Europe's economic and social prospects.[367] Following the commitments made in Montevideo, Uruguay on 18-20 October 2017 to prevent and control NCDs, the WHO European Region has made progress toward achieving key global targets, including the Sustainable Development Goals (SDGs), the Global Monitoring Framework on NCDs and Health 2020. These efforts aim to reduce premature mortality and hypertension, as discussed further in the next section.[368]

The EU has implemented various health regulations targeting public health issues such as tobacco and obesity. For example, the EU is party to the WHO Framework Convention on Tobacco Control (FCTC)[369] which provides a global response to the tobacco epidemic. The

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[363] Gavurova *et al.,* (n 362) 1.
[364] WIPO, 'WHO, WIPO, WTO Trilateral Cooperation on Public Health, IP and Trade' <https://www.wipo.int/web/global-health/trilateral_cooperation#:~:text=The%20World%20Health%20Organization%20(WHO,property%20(IP)%20and%20trade> accessed 25 March 2025.
[365] World Health Organization, 'Trilateral cooperation on intellectual property and public health' (*World Heath Organization* 2025) <https://www.who.int/teams/health-product-policy-and-standards/medicines-selection-ip-and-affordability/cooperation> accessed 25 March 2025.
[366] Gracia Marin Duran, 'Untangling the International Responsibility of the European Union and Its Member States in the World Trade Organization Post-Lisbon: A Competence/ Remedy Model' (2017) 28(3) EJIL 697.
[367] European Chronic Disease Alliance *et al.,* 'Towards an EU Strategic Framework for the Prevention of Non-communicable Diseases (NCDs)' (*European Public Health Alliance* 2019) Available: https://easl.eu/wp-content/uploads/2019/05/Final-NCD-Paper-full-version.pdf
[368] European Chronic Disease Alliance *et al.,* 'Towards an EU Strategic Framework for the Prevention of Non-communicable Diseases (NCDs)' (n 367).
[369] Shannon Gravely *et al.,* 'Implementation of key demand- reduction measures of the WHO Framework Convention on Tobacco Control and change in smoking prevalence in 126 countries: an association study' (2017) 2 (4) The Lancet Public Heath 166.

FCTC emphasizes the right of all people to the highest standard of health and includes measures to minimize tobacco demand, proven to protect both adults and children from starting to smoke and from the harmful effects of tobacco use.[370]

Obesity has also been recognized by the EU as a critical public health concern.[371] The EU has launched initiatives to address obesity, including promoting healthier lifestyles, improving food labelling and reducing the marketing of unhealthy foods, particularly to children. These efforts reflect the EU's commitment to reducing obesity related to NCDs.[372] In the European Region, nearly 60% of adults and one in three children (29% of boys and 27% of girls) are affected by overweight and obesity, making it a top health priority for the EU.[373]

As an EU member state, Cyprus has actively participated in these initiatives.[374] The country has adopted policies to promote healthy diets and prevent obesity related NCDs. For instance, Cyprus was involved in the EU Action Plan on Childhood Obesity 2014-2020[375], aiming to curb the rise of overweight and obesity among children. However, despite these efforts, obesity remains a significant public health concern in Cyprus. A 2021 study highlighted that NCDs account for over 90% of all deaths in Cyprus, with neoplasms (cancers) being the leading cause.[376]

In conclusion, while the EU, including Cyprus, has implemented important health regulations to address obesity and related NCDs, challenges persist. The EU plays a vital role in shaping health regulations at both regional and international levels. By aligning with global health initiatives such as the WHO FCTC, and by promoting healthier lifestyles and regulatory frameworks, the EU continues to combat tobacco use, obesity and other NCDs. Ongoing collaborative efforts with international organizations such as the WHO are essential to improving public health outcomes and advancing the fight against NCDs. Through these

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[370] Gravely *et al.,* (n 369) 167.
[371] World Health Organization, 'WHO European Regional Obesity Report 2022' (*World Health Organization* 2022) Available: https://iris.who.int/bitstream/handle/10665/353747/9789289057738-eng.pdf?sequence=1
[372] World Health Organization, 'WHO European Regional Obesity Report 2022' (n 371).
[373] World Health Organization, 'WHO European Regional Obesity Report 2022' (n 371).
[374] Elena Pallari *et al.,* 'The contribution of Cyprus to non-communicable diseases and biomedical research from 2002 to 2013: implications for evidence-based health policy' (2018) 16(82) Health Research Policy and Systems 1.
[375] World Obesity, 'Cyprus: Policies, Interventions and Actions' (*World Obesity* 2025) Available: https://data.worldobesity.org/country/cyprus-53/actions.pdf?utm_source=chatgpt.com
[376] Charalambous *et al.,* (n 8) 2.

initiatives, the EU seeks to reduce the burden of NCDs both within its member states and globally, contributing to the achievement of global health targets.

## 4. National Health Law and Rules

Health law is a complex area that encompasses institutions and legal frameworks designed to regulate healthcare delivery, protects patient rights and promote public health.[377] This section examines the role of key national institutions and healthcare systems, such as the National Health Service (NHS) in the UK which serves a fundamental element of health law in providing universal access to healthcare. The NHS Long Term Plan will also be discussed to highlight ongoing reforms and the commitment to improving patient care and system efficiency. Additionally, the General Health System, known as 'Gesy' (GHS), which reflects a similar dedication to accessible healthcare in a different national context will be explained.

### 4.1. National Institutions

In 2021, Public Health England (PHE) replaced with two new bodies, the National Institute for Health Protection (subsequently renamed UK Health Security Agency [UKHSA]), and the office for Health Promotion (subsequently renamed the Office for Health Improvement and Disparities [OHID]).[378] The creation of the UKHSA was announced on March 24, 2021, marking a pivotal shift in the nation's approach to public health and security.[379] The UKHSA is tasked with protecting the population from infectious diseases, environmental hazards and biological threats.[380] It plays a leading role in managing health emergencies, providing public health surveillance and coordinating national responses to outbreaks.[381] This new agency works in conjunction with NHS England and other global health bodies such as the WHO to ensure a robust defence against health risks in England and the broader UK. [382]

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[377] Robyn Martin, 'Law and Public Health Policy' (2008) 26 International Encyclopedia of Public Health 33.
[378] Hunter and Reddy (n 313) 797.
[379] Hunter and Reddy (n 313) 797.
[380] Chartered Institute of Environmental Health, 'Call for Evidence: Roles and Responsibilities for Heath Protection in England' (*Chartered Institute of Environmental Health* 2024). Available: https://www.cieh.org/media/ohndni3n/cieh-submission-to-ukhsa-call-for-evidence-on-the-future-of-the-health-protection-system-fhps.pdf
[381] UK Health Security Agency, 'Research at UKHSA' (*UK Health Security Agency* 2025) <https://research.ukhsa.gov.uk> accessed 25 March 2025.
[382] Chartered Institute of Environmental Health (n 380).

During the Covid-19, the UKHSA, played a vital role in managing the public health response.[383] Building on the work of Public Health England, the agency was instrumental in monitoring Covid-19 cases, hospitalizations and emerging variants through enhanced surveillance and genomic sequencing. It oversaw the NHS Test and Trace system, expanded testing availability and supported the vaccine rollout by providing expert advice and tracking vaccine efficacy. Additionally, the UKHSA developed public health guidance and organizations played a key role in ensuring long-term preparedness for future health crises.[384] While its primary focus remains on infectious diseases, public health emergencies and health security, UKHSA also has responsibilities related to NCDs. However, given that both UKHSA and the OHID prioritize CDs, there is a risk that NCDs may receive less attention. Ensuring a balanced approach to managing both CDs and NCDs will require strong political commitment and sustained investment in public health strategies.[385]

Legislators have the responsibility to recognise that the right to health is a fundamental obligation of the government and the state.[386] They must take serious action to protect the right while strengthening social and economic well-being.[387] At the same time, industries such as alcohol, soda and food companies often seek to influence the policy environment, sometimes funding research to oppose progressive public health legislation, particularly related to non-communicable diseases (NCDs).[388] Public health legislation, however, has the power to address these determinants of health by shaping the legal and economic environment.[389]

Public health law provides governments with the authority and responsibility to create conditions conducive to the health and well-being of their populations.[390] It encompasses a

[383] Chartered Institute of Environmental Health (n 380).
[384] HM Government, 'National Risk Register' (*HM Government* 2023) 30. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1175834/2023_NATIONAL_RISK_REGISTER_NRR.pdf
[385] Hunter and Reddy (n 313) 798.
[386] World Health Organization and United Nations Development Programme, 'What Legislators Need to Know' (*World Health Organization* 2018) 5. Available: https://iris.who.int/bitstream/handle/10665/272640/WHO-NMH-NMA-18.96-eng.pdf?sequence=1
[387] World Health Organization and United Nations Development Programme 'What Legislators Need to Know' (n 386).
[388] World Health Organization and United Nations Development Programme 'What Legislators Need to Know' (n 386).
[389] Sarah Galbraith-Emami, 'Public Health Law and Non-communicable Diseases' (*UK Health Forum* 2013) 5. Available: https://www.rsph.org.uk/static/uploaded/18165127-73a3-4c7a-8eb01fd5b791e5b1.pdf
[390] Galbraith-Emami (n 389) 5.

broad range of legal frameworks, including legislation, regulations and policies aimed at identifying, preventing and mitigating risks to public health.[391] While public health measures often prioritize community health, they may also impose restrictions on individual autonomy, privacy or liberty, especially when necessary to protect the broader population.[392] Key interventions such as implementing smoke-free legislation, introducing taxes on sugary beverages, or mandating front-of-pack food labelling, have demonstrated significant success in addressing risk factors for NCDs, including tobacco use, unhealthy diets and physical inactivity.[393]

Public health laws also play vital roles in addressing health inequalities by ensuring equitable access to healthcare and prioritizing underserved populations.[394] In the UK, specific measures such as parliamentary codes of conduct aim to mitigate conflicts of interest between industry motives and public health goals, particularly in areas such as food marketing and alcohol regulation.[395] These efforts align with international frameworks such as the WHO FCTC, which provide guidance on the adverse effects of tobacco use. Furthermore, public health law in the UK integrates Health Impact Assessments to evaluate the implications of policies on health and promotes community engagement to ensure that legislative interventions resonate with public needs and values.[396]

Looking forward, emerging challenges such as the rise of digital marketing for unhealthy products and the growing prevalence of ultra-processed foods highlight the need for dynamic and adaptive public health laws.[397] By shaping environments, creating economic incentives and fostering public awareness, these laws remain a cornerstone of efforts to combat NCDs globally.[398] The UK's leadership in this area demonstrates how public health law can be a powerful tool in promoting healthier societies.

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391 Galbraith-Emami (n 389) 8.
392 Galbraith-Emami (n 389) 5.
393 Galbraith-Emami (n 389) 8.
394 Galbraith-Emami (n 389) 5.
395 Galbraith-Emami (n 389) 5.
396 Galbraith-Emami (n 389) 5.
397 Galbraith-Emami (n 389) 5.
398 Galbraith-Emami (n 389) 5.

While public health laws can influence infrastructure, shape information environments, create economic incentives and address health inequalities, the implementation of these laws is often challenged by conflicts of interest between public health priorities and industry motives. To manage these risks, countries such as the UK have adopted parliamentary codes of conduct and specific regulatory mechanisms to reduce undue influence from industries such as tobacco, alcohol, and ultra-processed foods, in areas that contribute to the burden of NCDs.[399]

### 4.2. National Health Service (NHS)

The public health authority plays a crucial role in improving public health and supporting healthier lifestyles. It provides guidance to the government and supports local authorities and the NHS in taking action. Established in 1948[400] the NHS is the national healthcare system in the UK, providing a comprehensive service that is available to all regardless of gender, race, disability, age, sexual orientation, religion or belief.[401] It prioritizes delivering healthcare based on medical need rather than financial status, collaborating with diverse organizations that bring unique roles, responsibilities and specialities.[402] People who live in the UK (citizens and residents) can visit their local doctor or a nurse at a general practice doctor's surgery, or if they have serious injuries or health problems they might need to access NHS hospital care.[403] Although the NHS is free for most people, medication needs prescription and most of the medication has to be paid for.[404] This will be discussed further in the next sections below.

### 4.3. NHS Long Term Plan

As the cornerstone of the UK's healthcare system, the NHS plays a crucial role in addressing the growing burden of NCDs through strategic and evidence-based approaches.[405] Central to these efforts is the comprehensive NHS Long Term Plan, which outlines targeted interventions designed to improve public health and healthcare outcomes over the next decade.[406] For the

[399] World Health Organization and United Nations Development Programme (n 386) 6.
[400] Konstantina Grosios *et al.,* 'Overview of healthcare in the UK' (2010) 1(4) EMPA J 530.
[401] Grosios *et al.,* (n 400) 530.
[402] Grosios *et al.,* (n 400) 531.
[403] Grosios *et al.,* (n 400) 529.
[404] Grosios *et al.,* (n 400) 529.
[405] Grosios *et al.,* (n 400) 530.
[406] Hugh Alderwick and Jennifer Dixon, 'The NHS long term plan' (2019) 346 (184) BMJ 1.

first time the plan aims to provide better services in the community for older people experiencing serious health problems who may not require hospitalization.

Additionally, the plan emphasizes improving services for children, young people, and their families, with specific attention to developing support systems for young adults up to the age of 25. By prioritizing care at home, increasing system flexibility expanding treatment options, and ensuring quicker access to diagnostics, the NHS Long Term Plan aims to transform healthcare delivery. Furthermore, significant investments in cancer care and faster, earlier diagnoses are expected to save thousands of lives. Finally, the plan includes robust measures to improve the prevention, treatment and management of diabetes, supporting individuals at every stage of the condition.[407]

### 4.4. General Healthcare System, 'GESY'

Given Cyprus's rising burden of NCDs and its commitment to improving health equity, GESY represents a pivotal response to the demand for accessible affordable, and high-quality healthcare for all citizens. This section examines the implementation of GESY, highlighting its role in addressing public health.

On 1 May 2004 Cyprus, an island in the Eastern Mediterranean, became a member of the European Union.[408] Since joining the EU, Cyprus has been committed to improving its healthcare system. A national institution established in 2019[409], 'GESY-GHS'[410] is the national health system in Cyprus, similar to the UK's NHS, providing comprehensive healthcare coverage for all citizens of Cyprus, ensuring universal access to healthcare services. The head of these services is the Health Insurance Agency.[411] Every resident of Cyprus has access to the healthcare system and they are free to choose their personal doctor or hospital, whether from the public or private sector.[412]

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[407] Alderwick and Dixon (n 406) 1.
[408] Elena Pallari *et al.,* (n 374) 1.
[409] Panagiotis Petrou, 'The 2019 introduction of the new National Healthcare System in Cyprus' (2021) 125(3) Health Policy, 284.
[410] Petrou (n 409) 285.
[411] Petrou (n 409) 285.
[412] Petrou (n 409) 285.

GESY-GHS was fully implemented from 1 June 2019[413] and provides a wide range of services, including personal doctors, outpatient specialists, laboratory services, pharmacies, medical devices, nurses, midwives and allied health services, accident and emergency departments, ambulance services home care, rehabilitation care, allied health professionals, inpatient healthcare services and palliative care.[414] The system operates similarly to the NHS, allowing individuals to book appointments with their personal doctors, with a particular focus on prioritizing care for the elderly. While appointments are free, patients are required to pay for prescriptions at pharmacies.

GESY was introduced to offer comprehensive outpatient and inpatient care, which is essential for managing chronic NCD conditions such as oncology, cardiovascular diseases, diabetes, mental health and respiratory conditions.[415] The system includes preventive measures, early diagnosis and ongoing management of these conditions, addressing one of the most significant health challenges in Cyprus. Additionally, the Ministry of Health provides a national breast cancer screening program for all women aged 45-74, free of charge.[416] Women residing permanently in Cyprus can participate, with screenings taking place every two years.[417]

### 5. Human Rights Treaties

The debate over the relationship between intellectual property rights and human rights has increasingly focused on the implications of patent-protected pharmaceutical products, particularly the negative effects they may have on access to medicines and the right to health. Human rights treaties, which are international agreements that protect fundamental rights and freedoms, play a crucial role in safeguarding health as a human right. Key treaties such as the International Covenant on Economic, Social and Cultural Rights (ICESCR) will be discussed in the following sections.

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[413] Petrou (n 409) 284.
[414] Petrou (n 409) 285.
[415] Sarah Cuschieri *et al.*, 'Re-engineering the Cypriot General Healthcare System for Syndemics' (2022) 10 (734796) Frontiers in Public Health 2. See also Pallari *et a.,l* (n 374) 21.
[416] Petrou (n 409) 285.
[417] Petrou (n 409) 285.

### 5.1. Human Rights Law

On 10 December 1948, the United Nations General Assembly announced the Universal Declaration of Human Right (UDHR),[418] a landmark in the history of human rights. Declared in Paris, the UDHR sets out fundamental human rights to be universally protected and has been translated into over 500 languages.[419] It has influenced many international treaties, regional human rights instruments, national laws, and constitutions.

Building on this interpretative framework, the UDHR included 30 articles that describe basic rights and freedoms for everyone, such as the right to life, liberty and security among others. The UDHR remains a fundamental text in international human rights law, representing a global agreement on the rights of all people and serving as a guide for promoting and protecting huma rights worldwide.[420] The right to health is a critical element in the legal framework for accessing essential medicines, as outlined in Article 25 of the UDHR.[421] However, repealing the Act could undermine the existing legal framework that protects these health rights.[422]

The general rule of treaty interpretation is outlined in Article 31 of the Vienna Convention on the Law of Treaties[423], which establishes a framework for interpreting international treaties, highlighting the principle of 'good faith'.[424] These principles are essential for ensuring that international agreements, including those related to patent law, are applied fairly and

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418 Universal Declaration of Human Rights Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810 (1948). Available: https://www.ohchr.org/en/resources/educators/human-rights-education-training/universal-declaration-human-rights-1948. See also Helfer (n 196) See also Duncan Matthews, 'Intellectual Property Rights, Human Rights and the Right to Health' in W Grosheide (ed) *Intellectual Property Rights and Human Rights: A Paradox* (Edward Elgar, 2009).

419 Universal Declaration of Human Rights (n 418).

420 Universal Declaration of Human Rights (n 418).

421 Jane McPherson, 'Article 25 Changed my life: How the Universal Declaration of Human Rights Reframed my Social Work Practice' (2016) 22 (2) Reflections: Narratives of Professional Helping 23. See also Health-related rights are also found in a number of international treaties particularly focusing on vulnerable groups, for example, Arts. 11.1(f), 12 and 14.2(b) of the 1979 Convention on the Elimination of All Forms of Discrimination Against Women and Art. 24 of the 1989 United Nations Convention on the Rights of the Child. In the regional context, one will also find human rights instruments which recognise health rights, such as Art. 11 of the revised 1961 European Social Charter, Art. 16 of the 1981 African Charter on Human and Peoples' Rights and Art. 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights. See also Sellin (n 125) 69. See also Office of the United Nations High Commissioner for Human Rights, 'The Right to Health' (*Office of the United Nations High Commissioner for Human Rights* 2008) Available: https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf See also United Nations, 'Universal Declaration of Human Rights' (*United Nations* 2023) <https://www.un.org/en/about-us/universal-declaration-of-human-rights> 25 March 2025.

422 Universal Declaration of Human Rights (n 418).

423 United Nations, 'Vienna Convention on the Law of Treaties 1969' (2005) 1155 United Nations, Treaty Series 331. Available: https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf

424 United Nations, 'Vienna Convention on the Law of Treaties 1969' (2005) (n 423) 12.

consistently. According to this article, a treaty should be interpreted in 'good faith,' which entails giving the terms of the treaty their ordinary meaning within their context and considering the treaty's object and purpose.[425] Treaty interpretation is an integrated process, where interpretative rules or principles must be understood and applied as linked and mutually supporting components of a holistic exercise.[426]

However, while the Vienna Convention provides rules for treaty interpretation, international patent law particularly concerning issues like access to medicines and public health requires additional legal analysis beyond what the VCLT alone can offer.[427] The requirement of good faith ensures that interpretative tools are not used to arrive at absurd or unreasonable results.

Similarly, the International Covenant on Economic, Social, and Cultural Rights (ICESCR), adopted by the United Nations in 1966[428] aims to ensure the protection and promotion of economic, social, and cultural rights. Article 12 of the ICESCR specifically recognizes the right of everyone to the highest attainable standard of physical and mental health.[429] This includes the obligation for states to take proactive measures to ensure access to healthcare services, including essential medicines and treatments.[430] The recognition of this right mandates that governments create health systems capable of providing necessary services to all individuals, without discrimination.

This commitment not only emphasizes the fundamental importance of health as a human right but also aligns with both national and international health policies aimed at improving healthcare access, reducing health inequalities, and addressing emerging public health challenges. By acknowledging health as a universal right, the ICESCR fosters international efforts to combat NCDs and improve overall health outcomes. Furthermore, it encourages countries to incorporate these principles into national policies, ensuring that vulnerable populations, including those suffering from NCDs, have access to timely and affordable care.

[425] Susy Frankel and Daniel Gervais, 'Plain packaging and the Interpretation of the Trips Agreement' (2013) 46(5) Vanderbilt Journal of Transnational Law 1167.
[426] Frankel and Gervais (n 425) 1170.
[427] United Nations, 'Vienna Convention on the Law of Treaties 1969' (2005) (n 423) 12.
[428] Yu (n 196) 186.
[429] Article 12 of the International Covenant on Economic, Social, and Cultural Rights (adopted16 December 1966, entered into force 20 May 1976). See also Sellin (n 125) 78.
[430] Sellin (n 125) 84. See also Yu (n 196) 184.

This international framework highlights the importance of health equity, urging governments to prioritize the health needs of all individuals and communities.[431]

The European Convention on Human Rights (ECHR), established in 1950, aims to protect human rights and fundamental freedoms across its 47 member states[432] including the United Kingdom and Cyprus. The Convention consists of numbered 'articles' protecting basic human rights.[433] The UK made these rights part of its domestic law through the Human Rights Act 1998.[434] While the ECHR does not explicitly mention the right to health[435], the European Court has addressed various health-related matters in its rulings, particularly the right to life (Article 2), and the right to respect for private and family life (Article 8).[436]

In some cases, the ECHR has found that the state's obligation to protect life under Article 2 extends to ensuring access to essential health care in certain situations. For example, when a person's life is at risk due to medical conditions, the state must take responsible steps to provide appropriate medical treatment.[437] Article 8 has been used to discuss the right to health services, specifically in cases involving healthcare access for people living with HIV/AIDS and individuals needing specialized care.

Article 8 involves the right to respect for private life, and is in a sense individualised, it will potentially affect patients and staff in the mental health services in a variety of ways.[438] This article not only has implications for patients but also for clinicians and healthcare organizations.[439] The following case illustrate the diverse use of Article 8 and demonstrate how it has been interpreted in various pertaining to clinical psychiatry. The case of

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431 Yu (n 196) 184. See also Sellin (n 265) 76.
432 Yu (n 196) 192.
433 Yu (n 196) 192.
434 Megan Richardson, 'Intellectual Property and Privacy Law' in in Irene Calboli and Maria Lilla Montagnani (eds), *Handbook of Intellectual Property Research* (Oxford, 2021) 146.
435 Paul Hunt, 'Interpretating the International Right to Health in a Human Rights-Based Approach to Health' (2016) 18(2) 109.
436 European Court of Human Rights, 'European Convention on Human Rights' (2022) Available: https://www.echr.coe.int/documents/d/echr/convention_ENG
437 European Court of Human Rights Court, 'Guide on Article 2 of the European Convention on Human Rights' (*European Court of Human Rights* 2024). Available: https://ks.echr.coe.int/documents/d/echr-ks/guide_art_2_eng
438 Martin Curtice, 'Article 8 of the Human Rights Act 1998: implications for clinical practice' (2009) 15 Advances in psychiatric treatment 23. See also Richardson (n 434) 140.
439 Curtice (n 438) 23.

*Passannante* v *Italy* (1998)[440] involves a 5-month wait for a neurological appointment within the public healthcare system, while a private appointment could be scheduled within 4 days.[441] The ECHR determined that Article 8 may impose positive obligations on the state to effectively ensure respect for private life, in addition to the negative obligation to avoid interference.[442] The court noted that delays in providing medical care could potentially violate Article 8 if the state has responsibility to provide such care and if excessive delays could significantly affect the patient's health. However, in this case the Court found that this duty did not arise, as no damage to health was alleged.[443]

Following its departure from the EU, the UK is no longer bound by the EU Charter of Fundamental Rights, although it remains subject to the ECHR. In contrast Cyprus, as an EU member state, continues to be bound by the EU Charter of Fundamental Rights. Article 35 of the Charter emphasizes the right to preventive healthcare and medical treatment, stating that '*everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*'[444]

A specific case from Article 35 of the Charter is *Aikaterini Stamatelaki* v *NPDD Organismos Asfaliseos Eleftheron Epangelmation (OAEE)*[445] which concerned the reimbursement of cross-border medical expenses and the extent to which national restrictions on such reimbursements comply with EU law. The applicant sought reimbursement for cancer treatment her late husband received in a private hospital in the UK, but the national authority denied the claim, arguing that reimbursement was only permitted for domestic private hospitals under certain conditions. The Advocate General (AG) found that this rule constituted an unjustified and disproportionate restriction on the freedom to provide services (Article 49 EC) and citizens' rights to healthcare under Article 35 of the EU Charter of Fundamental Rights.

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[440] *Passannante* v *Italy* (1998) ECHR (Admissibility Decision) Application no. 32647/96 1st July.
[441] Curtice (n 438) 23.
[442] Curtice (n 438) 23.
[443] Curtice (n 438) 23.
[444] Scott L Greer, *et al.,* 'Everything you always wanted to know about European Union heath policies but were afraid to ask' (*Health Policy Series* 2019). Available: https://www.ncbi.nlm.nih.gov/books/NBK551086/pdf/Bookshelf_NBK551086.pdf
[445] *Aikaterini Stamatelaki* v *NPDD Organismos Asfaliseos Eleftheron Epangelmation (OAEE)* (Case C-444/05) EU:C:2007:24.

The AG emphasized that healthcare is a fundamental right independent of social security systems and that absolute prohibitions on reimbursement are not appropriate to the objective of protecting public health. Instead, less restrictive measures could ensure a balance between financial sustainability and citizens' access to healthcare. This case highlights the importance of Article 35 in safeguarding access to medical treatment across EU Member States and limiting unjustified national restrictions on healthcare rights.

### 5.2. Millennium and Sustainable Development Goals (MDGs and SDGs)

The Millennium Development Goals (MDGs) and Sustainable Development Goals (SDGs) both represent two landmark frameworks in the global effort to address serious challenges like poverty, education, health and environmental sustainability.[446] The Millennium Development Goal adopted in 2000, committed to achieving a set of eight measurable targets for international development to be achieved by 2015.[447] Based on the lessons from the MDGs, the United Nations launched the 2030 Agenda for Sustainable Development in 2015, expanding the focus to 17 Goals which include 169 targets.[448] Both frameworks reflect a continued commitment to improving lives worldwide while adopting complex social, economic and environmental issues.

The MDGs and SDGs are relevant to patents and NCDs because they emphasize global health equity, access to medicines and the reduction of premature deaths from NCDs.[449] The MDGs laid the foundation for addressing health challenges[450], while the SDGs expanded this focus to include NCDs explicitly (Target 3.4).[451] Both frameworks highlight the tension between patents, which incentivize innovation, and the affordability of essential medicines, particularly

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[446] Local Governments for Sustainability, 'From MDGs to SDGs: What are the Sustainable Development Goals?' (*Local Governments for Sustainability* 2015) <https://www.local2030.org/library/251/From-MDGs-to-SDGs-What-are-the-Sustainable-Development-Goals.pdf> accessed 25 March 2025.

[447] Sustainable Development Goals Fund, 'Millennium Development Goals' (*Sustainable Development Goals Fund*) <https://www.sdgfund.org/mdgs-sdgs> accessed 25 March 2025.

[448] World Health Organization, 'Sustainable Development Goals' (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals> accessed 25 March 2025.

[449] Thakur (n 279) 155. See also Nivedita Sudheer and Gargi Bhadoria, 'The Intersection of Intellectual Property Rights (IPR) and Sustainable Development Goals (SDGs): Examining how the Former can either Hinder or Facilitate Progress towards achieving the Latter' (2024) 7(2) International Journal of Law Management & Humanities 3126.

[450] World Health Organization, 'Millennium Development Goals (MDGs)' (*World Health Organization* 2018) <https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs)> accessed 25 March 2025.

[451] NCD Countdown, 'NCD Countdown 2030: efficient pathways and strategic investments to accelerate progress towards the Sustainable Development Goal target 3.4 in low-income and middle-income countries' (2022) 399 (10331) Health Policy 1266.

in low-and middle-income countries.[452] This intersection is central to achieving universal health coverage (Target 3.8)[453] and ensuring access to affordable treatment for NCDs (Target 3.b).[454] More details will be given in the next sections.

### 5.2.1. Background: Millennium Development Goals (MDGs)

To understand the context of Sustainable Development Goals (SDGs) it is important to look at their predecessors, the Millennium Development Goals (MDGs) which were established as ambitious targets aimed at improving the lives of people, especially the poorest, all over the world.[455] Progress in meeting these goals is expected to have significant long-lasting impacts, especially for low-and middle-income countries (LMICs). Three MDGs specifically addressed health including MDG 4 (reducing child mortality), MDG 5 (improving maternal health) and MDG 6 (combating HIV/AIDS, malaria and other diseases).[456] However, none of the MDGs directly mention NCDs which cause the most death and disability. Significant progress has been made regarding the MDGs. The world has already realized the first MDG of halving the extreme poverty rate by 2015. However, the achievement has been uneven across different regions. As the MDGs concluded in 2015, a new agenda has been established.

### 5.2.2. Transition to Sustainable Development Goals (SDGs)

The Sustainable Development Goals (SDGs) established by the United Nations in 2015 outline an extensive plan for global development, with SDG Target 3 (Good Health and Well-being) focusing specifically on ensuring healthy lives and promoting well-being for everyone.[457] Within this framework, the SDG places significant emphasis on addressing NCDs with Target

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[452] Vijay Kumar Chattu *et al.,* 'Access to medicines through global health diplomacy' (2023) 13(1) Health Promotion Respect 40.
[453] Chattu *et al.,* (n 452) 40.
[454] Sustainable Development Goals, Target 3.b. Development assistance and vaccine coverage: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases <https://www.who.int/data/gho/data/themes/topics/indicator-groups/indicator-group-details/GHO/sdg-target-3.b-development-assistance-and-vaccine-coverage> accessed 25 March 2025.
[455] NCD Alliance, 'NCDs and the Millennium Development Goals' (*The NCD Alliance* 2017) <https://ncdalliance.org/ncds-and-the-millennium-development-goals#:~:text=Home%20%2F%20NCD%20Facts%20%2F%20NCDs%20and%20the%20Millennium%20Development%20Goals&text=As%20a%20result%2C%20three%20of,malaria%2C%20and%20other%20diseases> accessed 25 March 2025.
[456] NCD Alliance, 'NCDs and the Millennium Development Goals' (n 455).
[457] Sightsavers, 'What are the Sustainable Development Goals?' (*Sightsavers* 2025) <https://www.sightsavers.org/policy-and-advocacy/global-goals/?gclid=Cj0KCQjw6sHzBRCbARIsAF8FMpVevntGJnxGZSf2PvRC3aeolmuqHwLUrijeFE_xm9jEn6VcxksUAykaAvA-EALw_wcB> accessed 25 March 2025.

3.4[458] aiming to reduce premature mortality from NCDs by one-third by 2030. This target highlights the global importance of addressing NCDs through prevention, treatment and the promotion of mental health and well-being.

A robust monitoring framework for NCDs must integrate well-defined targets[459], but as past experiences with the Millennium Development Goals have demonstrated, isolated targets without contextual consideration are ineffective.

Ensuring equitable access to healthcare, essential medicines, and healthy food is central to achieving SDG Target 3.8[460] which emphasizes universal health coverage (UHC) including risk protection, access to quality essential healthcare services and access to safe, effective, quality, and affordable essential medicines and vaccines for all.[461] This target is particularly relevant to the global issue of providing equitable access to NCD treatments, especially in low-and middle-income countries. The SDGs also stress the need to reduce health disparities, ensuring that vulnerable groups can access necessary medications to effectively manage NCDs.

However, these efforts are deeply interconnected with broader social determinants of health. Addressing these determinants[462] requires a combination of regulatory mechanisms, corporate accountability and systematic public interventions to prevent exploitative marketing practices, particularly by "Big Food" and "Big Beverage."[463] Comprehensive process indicators must be established to evaluate the impact of crisis-response policies[464], measure corporate compliance, and ensure that regulations translate into tangible health outcomes.

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458 World Health Organization, 'Targets of Sustainable and Development Goal 3' (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals/targets-of-sustainable-development-goal-3> accessed 25 March 2025.
459 Pol De Vos *et al.,* 'A human right to health approach for non-communicable diseases' (2013) 381 (9866) The Lancet 533.
460 SDG 3: Ensure healthy lives and promote well-being for all at all ages. See World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (2023) CDIP/30/14.
461 World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (2023) CDIP/30/14. Available: https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_30/cdip_30_14.pdf
462 Vos *et al.,* (n 459) 533.
463 Gerard Hastings, 'Why corporate power is a public health priority' (2012) 345:e5124 BMJ 2.
464 Gonçalo Figueiredo Augusto, 'Cuts in Portugal's NHS could compromise care' (2012) 379 (9814) World Report 400.

The SDGs are closely interconnected with several other goals supporting the right to health. For instance, SDG Target 1 (No Poverty)[465], SDG Target 2 (Zero Hunger)[466] and SDG Target 10 (Reduced Inequalities)[467] play crucial roles in promoting health by addressing poverty, food security and inequality, factors that disproportionately affect those managing NCDs. Furthermore, SDG Target 17 (Partnership for the Goals)[468] emphasizes the need for strengthened global cooperation to overcome obstacles in healthcare access, including intellectual property rights and financial limitations.

While the SDGs provide a strong framework for addressing NCDs, their effective implementation faces several challenges. A key critique is that without robust enforcement mechanisms and political commitment, regulatory efforts may be undermined by industry politicisation or economic constraints. Additionally, while process indicators play a key role in promoting accountability, they do not automatically lead to effective action unless balancing with measurable health outcomes. Relying solely on corporate regulation to drive systematic change is insufficient, as it must be completed by well-executed policies, public awareness initiatives, and coordinated efforts across multiple sectors. Ensuring that process indicators are linked to tangible health outcomes is crucial for effective NCD prevention and control.

Significant challenges remain in achieving these targets due to financial constraints, unequal healthcare infrastructure and the complexities of intellectual property rights, which can limit access to essential medicines. To address these barriers, flexible IP policies and innovative financing mechanisms are essential. These challenges highlight the need for enhanced global collaboration to ensure that the right to health is upheld for all, especially regarding NCD prevention and treatment.[469] Progress towards these targets is monitored through UN and

[465] SDG 1: No Poverty. End Poverty in all its forms everywhere. Available: https://sdgs.un.org/goals/goal1

[466] SDG 2: End hunger, achieve food security and improved nutrition and promote sustainable agriculture. See World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (2023) CDIP/30/14. Available: Available: https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_30/cdip_30_14.pdf

[467] United Nations, 'SDG 10: Reduced Inequalities' (United Nations) <https://sdgs.un.org/goals/goal10> accessed 25 March 2025.

[468] SDG Goals, 'Goal 17: Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development' (*United Nations* 2025) < https://unstats.un.org/sdgs/report/2017/goal-17/> accessed 25 March 2025. See also World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (n 466).

[469] Margaret E Kruk *et al*., 'High-quality health systems in the Sustainable Development Goals era: time for a revolution' (2018) 6(11) The Lancet Global Health 1196.

WHO reporting frameworks, emphasizing the accountability and commitment of countries to work toward these critical health and equity goals.

In addition to international treaties and frameworks, organizations such as the WIPO[470] play a significant role in aligning intellectual property policies with global development goals. As a specialized agency of the United Nations, WIPO contributes directly to the achievement of the SDGs by providing concrete services to its member states, helping them leverage the IP system to drive innovation, competitiveness and creativity.[471] The WIPO Development Agenda, adopted in 2007, is central to WIPO's role in advancing the 2030 Agenda.[472] Since adoption, development considerations have become an integral part of WIPO's work, with an increased focus on ensuring equitable access to health innovations.

The successful implementation of the Development Agenda is a key priority and a major component of the assistance WIPO provides to its member states, within its mandate, to help achieve the SDGs.[473] The Agenda outlines initiatives that use IP to promote social and economic development, reinforcing efforts to meet SDGs Target 3 (Good Health and Well Being).[474] By fostering an inclusive and balanced IP system, WIPO supports SDG Target 3 by ensuring that innovations in healthcare contribute to equitable access to medicines and technologies. The connection between SDG Target 3 and WIPO's work on health-related IP issues highlights the importance of creating IP frameworks that foster both innovation and affordability, ensuring that life-saving treatments remain accessible for all.

These collaborations are crucial for bridging gaps in access to treatments for NCDs and ensuring that global health policies align with sustainable development goals. The WIPO Development Agenda and the SDGs share common goals, including innovation, equity and sustainability.[475] By promoting access to knowledge and healthcare technologies, WIPO plays

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[470] World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (n 466)
[471] WIPO, 'The Impact of Innovation, WIPO and the Sustainable Development Goals' <https://www.wipo.int/sdgs/en/story.html> accessed 25 March 2025.
[472] WIPO, 'The Impact of Innovation, WIPO and the Sustainable Development Goals' (n 471).
[473] WIPO, 'The Impact of Innovation, WIPO and the Sustainable Development Goals' (n 471).
[474] Sustainable Goals, 'Goal 3: Ensure healthy lives and promote well-being for all at all ages' (*United Nations*) < https://www.un.org/sustainabledevelopment/health/> accessed 25 March 2025. See World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (n 466).
[475] WIPO, 'The Impact of Innovation, WIPO and the Sustainable Development Goals' (n 471).

a pivotal role in reducing health inequalities and enhancing public health outcomes.[476] Strengthening these global partnerships and aligning IP frameworks with SDG principles will be essential in ensuring that advancements in healthcare remain both sustainable and widely accessible, particularly for NCD prevention and treatment.[477]

### 6. Essential Medicines

Essential medicines are those that effectively and safely treat the priority healthcare needs of the population.[478] They are selected based on public health importance, evidence of benefits and harms, affordability and other relevant factors.[479] These medicines should always be available within functional health systems in adequate quantities, suitable dosage forms, and at affordable prices for both individuals and healthcare systems.[480] While essential medicines address a broad range of global health needs, they constitute only a small fraction of the total medicines available worldwide. A carefully chosen list enhances supply, efficiency, promotes rational prescribing and reduces overall costs.[481]

More than 150 countries have adopted national lists of essential medicines based on the WHO Model List[482], guiding procurement, reimbursement policies and local pharmaceutical production.[483] The essential medicines concept introduced by the WHO in 1977[484] followed a 1975 resolution by the World Health Assembly (WHA) requesting WHO's assistance in

[476] SDG Knowledge Hub, 'WIPO illustrates How Innovation, Intellectual Property Can Support SDGs' (October, 2018) < https://sdg.iisd.org/news/wipo-illustrates-how-innovation-intellectual-property-can-support-sdgs/> accessed 25 March 2025.
[477] WIPO, 'Intellectual property offices and sustainable innovation, Implementing the SDGs in national intellectual property systems' (*WIPO* 2023) Available: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-10-en-intellectual-property-offices-and-sustainable-innovation.pdf
[478] Hans V Hogerzeil, 'The concept of essential medicines: lessons for rich countries' (2004) 329 BMJ 1169. See also Stephanie Kim *et al.,* 'Essential Medicines, Pharmaceutical Policy and Global Health' in Stella R. Quah (ed) *International Encyclopedia of Public Health* (3rd edn, Elsevier, 2024) 603. See also Sellin (n 125) 28.
[479] Sitanshu Sekhar Kar *et al.,* 'Concept of Essential Medicines and Rational Use in Public Health' (2010) 35 (1) Indian Journal of Community Medicine 10.
[480] Kar *et a.,l* (n 479) 10.
[481] Kar *et al.,* (n 479) 10.
[482] Thomas Piggott *et al.,* 'WHO Model list of essential medicines: visions for the future' (2024) 102 (10) Bull World Health Organ 722.
[483] Piggott *et al.,* (n 482) 722.
[484] Kim *et al.,* (n 478) 603. See also Hogerzeil (n 478) 1169. See also Richard Laing *et al.,* '25 years of the WHO essential medicines lists: progress and challenges' (2003) 361(9370) Lancet 1723.

developing national medicine policies.[485] The first WHO Model List[486] established that certain medicines were more useful than others yet often inaccessible to many populations.[487] When effectively applied, the essential medicines concept can contribute to improve health outcomes and progress toward UHC. The WHO defines essential medicines as those that should be available at all times in adequate quantities, appropriate dosage forms, and at affordable prices.[488] This model list is revised every two years[489] to reflect changing therapeutic needs, underscoring the importance of regular updates.[490]Studies have shown that essential medicines lists are linked to higher availability of essential medicines than non-essential ones, increased access, better prescribing and quality of care and cost savings.[491]

The WHO Model List[492] includes key treatments for managing NCDs such as hypertension, diabetes, asthma, cancer and chronic respiratory disease. These medicines are critical for reducing the global burden of NCDs and improving health outcomes. However, access remains a challenge, particularly in low-and middle-income countries, where unavailability is often due to high costs and weak healthcare infrastructure. WHO data from 2,779 health facilities across 40 developing countries show that the average availability of generic NCD medicines was only 36% in the public sector and 55% in the private sector.[493] Similar findings were reported in surveys conducted in Sierra Leone and Zambia.[494]

Without access to effective medicines and essential diagnostic and monitoring equipment in health facilities, patients with NCDs are at risk of both short- and long-term adverse effects from their disease. Recently, shortages of these resources have been reported even in many high-income countries, leading to the upgrading of reporting systems to enable rapid collection and dissemination of such data. To prevent and manage heart attacks, strokes and

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485 Sellin (n 125) 28.
486 World Health Organization, WHO Model List of Essential Medicines -23rd list, 2023-Web Annex A' (*World Health Organization* 2023) Available: https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1 See also Piggott *et al.,* (n 482) 722.
487 Laing *et al.,* (n 484) 1723. See also Hogerzeil (n 478) 1169.
488 Sellin (n 125) 25.
489 Sellin (n 125) 25.
490 Sellin (n 125) 26.
491 Laing *et al.,* (n 484) 1723.
492 World Health Organization, WHO Model List of Essential Medicines -23rd list, 2023-Web Annex A' (n 486).
493 World Health Organization, 'Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases' (*World Health Organization* 2025) <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3421> accessed 25 March 2025.
494 World Health Organization, 'Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases' (n 493).

diabetes complications, the WHO recommends drug treatments for high-risk individuals, including those with diabetes. This requires a set of essential technologies and medicines to implement cost-effective "best buy" interventions in primary care.[495] Basic technologies and generic essential medicines are required to treat major NCDs in public and private sector facilities, including converting enzyme inhibitor, thiazide diuretic, a long-acting calcium channel blocker, metformin, insulin, a bronchodilator and a steroid inhalant.[496] Basic technologies include blood pressure monitors, weighing scales, blood sugar and blood cholesterol measurement devices with strips and urine strips for albumin assay. [497]

These medicines should be available, affordable, and accessible to meet the population's health needs effectively.[498] Choosing essential medicines is a fundamental aspect of national drug policy, as it establishes priorities across all parts of the pharmaceutical system.[499] In the late 1990s two pivotal developments ignited international awareness around medicine accessibility: the establishment of the WTO and the TRIPS Agreement in 1995[500], and the introduction of life-saving antiretroviral medicines (ARVs) for HIV/AIDS.[501] The WHO recognised the serious nature of access to medicines, stating that improved access could save over 10 million lives annually.[502]

Despite these developments, significant barriers persist especially in low- and middle-income countries. High drug costs, often driven by patents and intellectual property laws under the TRIPS Agreement, limit access. Unlike typical commodities, medicines are a necessity, and patients often lack the ability to choose alternatives freely.[503] To address this, countries must prioritize medicine procurement and distribution under UHC policies, allocate adequate

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495 World Health Organization, 'Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases' (n 493).
496 World Health Organization, 'Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases' (n 493).
497 World Health Organization, 'Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases' (n 493).
498World Health Organization, 'Essential medicines' (*World Health Organization* 2024) <https://www.who.int/news-room/fact-sheets/detail/essential-medicines> accessed 25 March 2025. See also Sellin (n 125) 25.
499 Hogerzeil (n 478) 1169.
500 Amy Nunn *et al.,* Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil' (2009) 4 (2) Glob Public Health 131.
501 Bollyky (n 130) 1.
502 Sellin (n 125) 56.
503 Lee Joo- Young, 'A human rights framework for intellectual property, innovation and access to medicine' (2015) 11(2) Journal of Intellectual Property Law & Practice 149.

financial resources and implement price regulations. Strengthening healthcare systems and ensuring equitable access to NCD treatments are essential steps toward closing the health gap.

In many countries, medicines for NCDs are either not available when needed or unaffordable.[504] Rising prevalence due to increasing risk factors and ageing populations along with under-diagnosis and under-treatment[505] further complicate the challenge. Ensuring availability is only one aspect of providing care within the framework of UHC. This requires financial investment, priority setting, and robust monitoring and evaluation systems. Adequate resource allocation for medicines must emphasize equity, efficient procurement and price regulation. With the current UHC agenda, the WHO and countries must develop appropriate responses to guarantee equitable access.[506]

Medicines play a crucial role in treating NCDs such as cardiovascular disease, diabetes, chronic respiratory disease, cancer and mental health conditions.[507] The WHO Essential Medicines List highlights the critical need for accessible and affordable treatments.[508] However, patent laws often grant exclusive rights to pharmaceutical companies, leading to high prices and restricted access, particularly in low-and-middle-income countries. While patents incentivise innovation, they may also exacerbate health inequities by limiting the affordability of essential medicines.

In 2023 the WHO updated its EML to include new treatments for multiple sclerosis (MS), cancer, infectious diseases and cardiovascular diseases. The inclusion of treatments for MS, a chronic neurological disease affecting 2.8 million, marks a significant step.[509] For the first time the WHO Model List now includes cladribine, glatiramer acetate and rituximab, providing essential treatment options that address a long-standing gap in MS care. These medications,

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[504] Beran *et al.,* (n 193).
[505] Beran *et al.,* (n 193) 1.
[506] Beran *et al.,* (n 193) 2.
[507] Dele Abegunde, 'Essential Medicines for Non-Communicable Diseases (NCDs)' (*World Health Organization* 2006) Available: https://www.iccp-portal.org/system/files/resources/UNHLM-2011_WHO-EssentialMedicinesforNCDs.pdf
[508] Piggott *et al.,* (n 482) 723.
[509] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (*World Health Organization* 2023) <https://www.who.int/news/item/26-07-2023-who-endorses-landmark-public-health-decisions-on-essential-medicines-for-multiple-sclerosis> accessed 25 March 2025.

with varying administration methods and pricing structures, aim to enhance global access to MS treatments.[510] Notably, the off-label use of rituximab for MS, supported by strong evidence, has the potential to improve health outcomes on global scale. However, while these updates represent important progress, challenges remain in ensuring that these treatments are accessible in low-resource settings.[511]

Another important updated to the EML in 2023 is the inclusion of fixed-dose combinations of multiple medicine, commonly known as 'polypills', for the prevention of heart and blood vessels diseases.[512] These polypills typically combine cholesterol-lowering agents with one or more blood pressure-lowering drugs, with or without acetylsalicylic acid (aspirin). Following recommendations from previous EML Expert Committees, scientists from several countries conducted milestone trials confirming the benefit of these combinations for both primary and secondary prevention of heart disease.[513]

Further updates include new treatments for infectious diseases such as ceftalozane + tazobactam, an antibiotic effective against multi-drug resistant bacteria including tough infections caused by carbapenem-resistant Pseudomonas aeruginosa. Pretomanid has been added for treatment of multidrug-resistant or rifampicin-resistant tuberculosis. Ravidasvir, to be used in combination with sofosbuvir, is now listed for the treatment of chronic hepatitis C alongside monoclonal antibodies for Ebola virus.[514] These additions are crucial in addressing emerging infectious threats, but access to these medicines remains hampered by issues of cost and availability in many regions.

Lastly two new cancer treatments, pegylated liposomal doxorubicin for Kaposi sarcoma and pegfilgrastim which helps stimulate white blood cell production and reduces the toxic effects

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[510] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).
[511] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).
[512] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).
[513] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).
[514] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).

of certain cancer treatments on bone marrow have been included in the updated EML.[515] While these treatments are essential, the high costs of many cancer medicines continue to limit their accessibility. The rejection of certain expensive patented treatments such as PD-1/PD-L1 immune-checkpoint inhibitors and osimertinib for lung cancers, and CDK4/6 inhibitors for breast cancer further highlights the ongoing challenge of balancing innovation with equitable access.[516]

Essential medicines play a crucial role in addressing global health challenges, particularly in managing NCDs and infectious diseases. The WHO EML serves as a valuable tool in guiding global and national healthcare policies, promoting equitable access and improving health outcomes. The 2023 updates reflect WHO's commitment to evolving health needs, but significant barriers remain.

High costs driven by patent protection and intellectual property laws continue to restrict access, particularly in low-and middle-income countries. This issue is compounded by rising drug prices, supply chain disruptions and the increasing burden of NCDs. As the WHO and countries work toward achieving UHC, it is imperative to address these barriers to ensure that essential medicines are accessible, affordable, and available to patients, regardless of income or geographical indication. The WHO's ongoing efforts to revise the EML and promote equitable access to essential medicines are a step in the right direction, but greater global cooperation, policy changes and innovation solutions are needed to make healthcare truly accessible for all.

## 7. Conclusion

This chapter emphasizes the fundamental role of health organisations in ensuring that essential health services and medicines are accessible to all. It highlights how health frameworks, such as the WHO serve as the foundation for providing integrated, sustainable solutions to the complex challenges posed by CDs and NCDs. Governments must collaborate

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[515] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).

[516] World Health Organization, 'WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis' (n 509).

within these frameworks to design and implement effective policies that address the underlying social determinants of health and reduce health inequalities.

As this chapter shows, the WHO plays a central role not only in medical treatment but also in public health policy, regulation and international cooperation. By providing technical support and fostering collaboration between nations, the WHO ensures that countries can effectively address shared health threats. Beyond treatment, the WHO's role extends to prevention and addressing health disparities, which are critical in combatting the growing burden of NCDs worldwide.

Moreover, legal frameworks including human right treaties provide a foundation for achieving health equity, with the right to health being a fundamental principle. However, barriers such as lack of access to essential medicines, particularly in low- and middle-income countries, highlight the need for stronger commitments to equitable healthcare. To ensure the effectiveness of UHC it is crucial to focus on making essential medicines available, particularly to vulnerable populations. Governments must legally recognize the right to health, ensuring that essential medicines are accessible to all regardless of socioeconomic status. Therefore, health must remain a priority for governments, not only in terms of healthcare systems but also in ensuring that policies related to IP such as patent law do not hinder access to essential medicines for patients.

In addition, lifestyle choices, particularly unhealthy food habits, significantly contribute to health risk factors, leading to adverse health outcomes including NCDs. Preventative health measures are essential to reducing the burden of these diseases. Governments, in collaboration with WHO and other organizations, must not only focus on the treatment of diseases but also prioritize health promotion and disease prevention strategies. This includes addressing unhealthy lifestyle choices such as poor diet and lack of physical activity, which are significant risk factors for NCDs. Education campaigns and improved regulation of harmful products like unhealthy food can play a pivotal role in reducing the incidence of NCDs.

While international and national health frameworks aim to ensure equitable access to medicines, patent laws often create barriers to affordability. The intersection of health policies and intellectual property rights is a growing area of concern, as the exclusivity granted by patents can limit the availability of essential medicines. This raises critical questions about how intellectual property protections impact public health objectives and whether reforms are necessary to balance innovation incentives with the right to health.

Global cooperation remains critical in addressing these challenges, particularly as the burden of NCDs continues to rise and new health threats emerge. Strengthening partnerships between governments, international organisations, and policymakers will be key to creating a fairer and more sustainable healthcare system. Additionally, future policy innovations must integrate patent law reforms to ensure that essential medicines remain accessible while incentivizing pharmaceutical advancements. The next chapter will explore patent law and the extent to which it serves public interests, focusing on exclusions, limitations and exceptions on international, regional and national level.

## CHAPTER THREE: PUBLIC INTEREST IN PATENT LAW

### 1. Introduction

Patent rights confer significant benefits on inventors, but these rights are not absolute. Patent law is designed to balance the interests of inventors with broader societal needs, particularly in critical sectors such as healthcare.[517] This balance is achieved through exclusions, limitations and exceptions, ensuring that patent protection does not hinder public welfare. This chapter will analyse these mechanisms at the international, regional, and national levels, focusing on the UK and Cyprus.

Patents serve as commercial assets, enabling owners to trade, exploit and leverage them as business tools.[518] However, certain inventions are excluded from patentability to safeguard ethical, environmental and economic concerns.[519] Beyond these exclusions, legal frameworks impose limitations such as exhaustion of rights, parallel imports, compulsory licensing, the Bolar exemption and procedural mechanisms like pre-grant oppositions.[520] These limitations are crucial in preventing excessively high drug prices, particularly in low-and middle-income countries, where access to life-saving medicines is a pressing issue.

The TRIPS Agreement as will be discussed in more detail in the next chapter[521] sets minimum standards for intellectual property protection, significantly shaping national laws, particularly in developing countries.[522] While TRIPS introduced robust patent protections, concerns over access to medicines led to the recognition of TRIPS flexibilities, allowing governments to implement measures such as compulsory licensing and parallel imports. The role of such flexibilities will be discussed under the following subheadings of this chapter, as it is fundamental in ensuring that essential medicines, including those for NCDs, remain affordable and accessible. The Doha Declaration on TRIPS and Public Health adopted at the 4th WTO

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[517] Calixto Salomao Filho and Vitor Henrique Pinto Ido, 'Courts and Pharmaceutical Patents: From Formalist Positivism to Emergence of a Global Law' in Carlos M Correa and Reto M Hilty (eds), *Access to medicines and Vaccines* (Springer, 2022) 205.
[518] Bently *et al.,* (n 41) 687.
[519] Esra Demir and Evert Stamhuis, 'Patenting biological materials and data: balancing the reward of innovation with the *ordre* public and morality exception' (2023) 18 (7) Journal of Intellectual Property Law & Practice 548.
[520] Filho and Ido (n 517) 205.
[521] TRIPS Agreement - See Chapter Four - International section, subsection 2.1.2. ('World Trade Organization and TRIPS Agreement')
[522] Carlos M Correa, 'Interpreting the Flexibilities Under the TRIPS Agreement' in Carlos M Correa and Reto M Hilty (eds), (Springer, 2022) 1.

Ministerial Conference in November 2001[523] reaffirmed the right of nations to prioritize public health over patent rights, permitting necessary interventions consistent with TRIPS provisions.[524] Additionally, TRIPS-plus protections established through free trade agreements led by the US and the EU imposed stricter intellectual property rules on developing countries. Generic manufacturers argue that TRIPS-plus commitments undermine the rapid approval of generic medicines and therefore do not protect the public interest.[525] This chapter examines the implementations of such agreements and their impact on access to essential medicines, particularly for non-communicable diseases (NCDs).

At the national level, the UK and Cyprus offer contrasting approaches to patent limitations and flexibilities. The chapter will assess how these countries implement TRIPS provisions, including compulsory licensing, research exemptions and parallel imports to facilitate access to medicines while maintaining innovation incentives.

One of the most significant areas where patent law intersects with public interest is healthcare. Patent-related barriers have been particularly contentious in cases such as HIV/AIDS treatments, Covid-19 vaccines, and the rising burden of NCDs. This chapter will explore how compulsory licenses have enabled governments to respond to health crises by authorizing the production of generic medicines without patent holder consent under specific conditions. Compulsory licensing has played a critical role in expanding access to HIV/AIDS drugs, particularly in low-income countries. Governments such as Brazil, Thailand and South Africa successfully leveraged compulsory licensing to lower the costs of antiretroviral drugs, improving treatments' accessibility.[526] However, in the case of NCDs the use of compulsory licensing has been less frequent despite the growing burden of chronic diseases such as cancer and diabetes. The chapter will outline the legal framework for compulsory licensing and discuss its relevance in addressing public health challenges. Chapter Five then proposes, recommendations and policy considerations regarding the use of compulsory licensing for NCDs. Furthermore, research exemptions which allow generic manufacturers to prepare

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[523] Doha Declaration on the TRIPS Agreement and public health (n 64). See also Correa (n 522) 1.
[524] Correa (n 522) 1.
[525] Said (n 66) 297.
[526] Nathan Ford *et al.,* 'Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand' (2007) Suppl 4:S21-9 AIDS 21.

alternatives before patent expiration such as the 'Bolar' exemption' ensure the timely availability of affordable medicines. This section will analyse the effectiveness of these mechanisms in balancing public health needs with private patent rights.

The role of patent law extends beyond granting exclusive rights it directly impacts equity, access and fairness, particularly in critical areas such as healthcare, technology and innovation distribution. Debates surrounding how patents affect healthcare systems, especially in relation to access to medicines, align closely with the broader framework of Intellectual Property and Social Justice (IP-SJ). IP-SJ seeks to ensure that intellectual property law does not exacerbate inequalities or create barriers to essential medicines. It emphasizes equitable access to patented innovation, ethical limitations on patentability and the role of governments in preventing patents from disproportionately disadvantaging marginalized communities.[527] By examining exclusions, limitations and exceptions in patent law, this chapter highlights the legal mechanisms designed to balance private rights with public welfare, particularly in the healthcare sector. From an IP-SJ perspective these interventions are not just legal technicalities but moral imperatives, ensuring that patents serve the public good rather than solely corporate profits.

Ultimately, public interest is central to patent law, particularly in the context of access to medicines. This chapter will examine how legal mechanisms either restrict or facilitate access to essential medicines and, whether current patent frameworks strike the right balance between protecting private rights and promoting public health. By exploring international, national, and regional approaches, this chapter will evaluate the effectiveness of patent limitations and flexibilities in ensuring that innovation serves the public good rather than solely corporate profits.

[527] Mtima 2019-2020 (n 49) 55.

## 2. Exclusions on patentability

Most international and national laws including the TRIPS Agreement[528], the European Patent Convention[529] and various national laws[530], establish specific patentability criteria. This is typically means that the invention must be new, involve an inventive step and be industrially applicable. There are also exclusions that define what cannot be patented. The following sections will explore these exclusions, examining them at the international level (TRIPS Agreement), regional (European Patent Convention) and national levels particularly for the UK and CY, to provide a detailed understanding of what is excluded from patentability.

### 2.1. International rules on exclusions from patentability

Before the TRIPS Agreement, countries were free to develop their own policies to combat high prices and facilitate access to medicines.[531] In this pre-TRIPS era many countries either denied patent protection for medicines or provided only limited protection to the process of their manufacture.[532] However, with the implementation of the TRIPS Agreement in 1995[533] patent protection for medicines became mandatory.[534] The TRIPS Agreement allows its Member States to define the scope of the patent protection for drugs by setting patentability standards for these types of inventions in their national patent laws.[535] This flexibility allows countries to balance the interests of patent holders with public health objectives, especially regarding access to essential medicines.[536]

While Article 27 of the TRIPS Agreement[537] establishes the criteria for patentability, it also outlines significant exclusions to patentable subject matter, providing WTO members with flexibility to balance intellectual property rights with public interest considerations. Members

[528] Article 27 of the TRIPS Agreement.
[529] Article 52(1) of the European Patent Convention (2000) EPC.
[530] Patent Act 1977, Section 1(1) (as amended).
[531] Herbert Hovenkamp *et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (Wolters Kluwer Legal & Regulatory U.S., 2016). One traditional exclusion from patentable subject matter for many countries was an exclusion of drug and drug components because the higher cost of patented drugs would limit access to affordable medicine. See also Ricketson (n 83) 7 subsection 1.05.
[532] Sam Ricketson (n 83) 9, 10, 11 subsection 1.08 and 1.09.
[533] TRIPS Agreement (n 63).
[534] Gervais (n 93) 130 subsection 2.76.
[535] Sam Ricketson (n 83) 8 subsection 1.06.
[536] Cynthia M. Ho, 'Should All Drugs Be Patentable? A Comprehensive Perspective' (2015) 17 (2) Vanderbilt Journal of Entertainment & Technology Law 295.
[537] Article 27, TRIPS Agreement.

have the option to exclude inventions from patentability if preventing their commercial exploitation within their territory is essential to protect *ordre* public or morality. This exclusion may also serve to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[538]

In addition, Article 27(3) of TRIPS[539] provides further flexibility by permitting exclusions for diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, as well as certain biological processes and plant or animals varieties. This is particularly relevant to NCDs as many advanced treatments such as surgical interventions for cancer and diagnostic techniques for early disease detection may not be eligible for patent protection. By limiting patents on medical procedures, TRIPS allows healthcare providers to adopt innovative and cost-effective treatment methods without facing intellectual property restrictions. However, challenges remain in ensuring that related pharmaceutical products, biological, and medical technologies for NCDs are also accessible, as patents on these components often drive up costs and limit availability in low-and middle-income countries. Therefore, balancing IP rights with public health needs remains critical in addressing the growing burden of NCDs worldwide.

The flexibility provided by the TRIPS Agreement allows WTO members to adapt their patent systems to national priorities, such as restricting patents on essential medicines to promote public health, as seen in India's approach to pharmaceutical patents.[540] India has a pro-public health approach to pharmaceutical patents, balancing intellectual property rights with access to affordable medicines. This approach is shaped in Section 3(d) of the Indian Patents Act, 1970 as amended in 2005[541] to comply with TRIPS. Furthermore, TRIPS includes additional provisions which allow governments to authorize the use of a patented invention without the consent of the patent holder. This will be discussed in the next subsection.

[538] TRIPS Agreement, Article 27(2).
[539] TRIPS Agreement, Article 27(3).
[540] Section 3(d) of the Indian Patent Act 1970 (as amended in 2005).
[541] Section 3(d) of the Indian Patent Act 1970 (as amended in 2005).

## 2.2. Regional rules on exclusions from patentability

At the regional level, patent law is influenced by agreements that provide a harmonized framework for member states. The European Patent Office (EPO) operates under the European Patent Convention (EPC), which not only establishes general criteria for patentability but also sets out specific exclusions that determine which inventions cannot be patented. These exclusions are primarily based on ethical considerations, public policy concerns, and the need to prevent monopolies on fundamental scientific discoveries.[542]

Article 52 EPC[543] establishes the framework for what qualifies as a patentable invention. It explicitly excludes certain subject matter from patent protection such as discoveries, scientific theories and mathematical methods.[544] In the context of access to medicines, scientific discoveries such as naturally occurring compounds, are not patentable.[545] Therefore for medical methods there is no patent protection because of Article 53(c) EPC.[546]

Article 53(c) EPC explicitly excludes from patentability methods for treatment, including surgical, therapeutic and diagnostic methods practised on the human or animal body.[547] Such exclusion is permitted under Article 27(3)(a) of the TRIPS, and is based on public policy considerations primarily to ensure that doctors have the freedom to use any treatment method they consider appropriate. In *MEDI-PHYSICS/Treatment* by Surgery[548] the Enlarged Board of Appeal confirmed that the exclusion under Article 53(c) EPC protects doctors' ability to apply the best available treatments without the risk of infringing a patent.[549]

However, this exclusion of treatment methods does not prevent pharmaceutical companies from patenting substances used in medical treatments.  Article 53(c) EPC includes a key exception, stating that "this provision shall not apply to products, in particular substance or

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[542] Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How far has the European Patent Office Eroded Boundaries?* (Cambridge University, 2012) 135.
[543] Article 52 of the European Patent Convention (2000) EPC.
[544] Sterckx and Cockbain (n 542) 366.
[545] Varsha Venkatesh, 'Exclusions of Methods of Medical Treatment from Patentability: A Global Perspective' (2021) 14 Acclaims 1. Available: http://www.penacclaims.com/wp-content/uploads/2021/02/Varsha-Venkatesh.pdf See also Sterckx and Cockbain (n 542) 135.
[546] Article 53 (c) of the European Patent Convention.
[547] Article 53(c) of the European Patent Convention.
[548] G 1/07 [2010] E.P.O.R. 25; (2010) 116 B.M.L.R. 1.
[549] Article 53 (c) of the European Patent Convention.

compositions, for use in any of these methods [for treatment]".[550] This means that while methods for treatment themselves are excluded from patentability, the drugs used in these methods may still be patented. Under this exception if a compound is new, it can be protected by a product patent and used in a treatment method.[551] However, if the compound is already known but has not been previously used in treatment medicine, it cannot be protected by a product patent. Nevertheless, patent protection may still be granted for its new medical use. Even if a substance is already known for non-medical properties, it may still be patented for newly discovered therapeutic use.[552]

A major challenge in patenting medical inventions arises when the only novel aspect of an invention is a new use of a known substance. If a claim is drafted as "a method of treating diseases Y by administering compound X", it would be classified as a medical treatment method, which is explicitly excluded from patentability under the EPC.[553] To address this issue, Article 54(4) EPC 2000 and (formerly Article 54(5) EPC 1973) introduced an exception known as the first medical use.[554] This provision allows a previously known substance to be patented for medical purposes if it has not been used in surgery, therapy or diagnostic methods before.[555] This protection is purpose-limited, meaning it applies to the use of the substance rather than the substance itself.[556] Patents for "a use of known substance or composition in a medical method"[557] provide broad protection covering any use in a medical method, even if only one specific use is disclosed in the application.[558]

Further research on known pharmaceutical compounds may lead to the discovery of additional therapeutic applications. However, under the EPC 1973 patent protection was initially limited to new drugs or the first medical application of a known substance. No provisions existed for patenting new therapeutic uses of already known medicines.[559] To

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[550] Article 53 (c) of the European Patent Convention.
[551] European Patent Convention, Article 53(c).
[552] European Patent Convention, Article 53(c).
[553] Philip W Grubb *et al.,* Patents for Chemicals, Pharmaceuticals, and Biotechnology. Fundamentals of Global Law, Practice and Strategy (6th edn, OUP, 2016).
[554] Trevor Cook, *A User's Guide to Patents* (4th edn, Bloomsbury 2015) 384.
[555] European Patent Convention, Article 53(c).
[556] EPO Case Law of the Boards of Appeal (8th edn, 2016). See also *EISAI/Second medical indication* (G5/83) [1979-85] E.P. O. R. B241, para 15.
[557] EPO Case Law of the Boards of Appeal (n 556) Chapter IC, Section 7.1.1.
[558] *EISAI/Second medical indication* (n 556) para 15.
[559] Cook (n 554) 385.

encourage pharmaceutical companies to continue research into new uses of existing medicines it was considered necessary to provide protection for "second and subsequent uses."[560] The solution was found in a skilful drafting of patent claims, which used a legal fiction to overcome the issue. This was achieved through "Swiss-type claims", where patents were framed as:

> "Use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y"[561] (a purpose-limited *process* claim).

The EISAI/Second Medical Indication[562] case and rulings from UK courts[563] confirmed that "Swiss-type claims" were a valid way to secure patent protection for second medical uses under Article 54(5) EPC 1973 and Section 2(6) of the UK Patent Act.[564] However, these claims were process-based and provided narrower protection than product claims. To resolve this issue, EPC 2000 formally replaced "Swiss-type claims" by introducing Article 54(5) which now allows purpose-limited *product* claims.[565] Instead of relying on the older "use of substance X" claim format, patents can now be granted with the wording "product X for treating condition Y." This revision strengthened pharmaceutical patent rights by providing broader protection for second medical uses.

The Technical Board of Appeal (TBA) reinforced this interpretation in the case of University of Texas Board of Regents/Cancer Treatment, stating that product claims generally offer stronger legal protection than process claims.[566] Additionally, the Enlarged Board of Appeal (EBA) acknowledged that EPC 2000 broadened the scope of protection for second medical use patents, which could have implications for medical professionals. In Abbott Respiratory/dosage regime, the EBA noted that Article 54(5) EPC 2000 confers broader rights

560 Christopher M Holman *et al.,* 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131. See similarly in Christopher M Holman, 'In Defence of Secondary Pharmaceutical Patents: A response to the UN's Guidelines for Pharmaceutical Patent Examination' (2017) 50 (759) Ind. L. Rev 767.
561 Cook (n 554) 385.
562 *EISAI/Second medical indication* (n 556) [15].
563 *John Wyeth & Brother Ltd's Application* [1985] RPC 545.
564 Anatoli Tsakalidou, 'The Intricacies of Partly New Inventions: Should We Grant Patentability' (2015) 3 Legal Issues J 101.
565 Sterckx and Cockbain (n 542) 61.
566 Board of Regents, University of Texas /Cancer treatment [T1780/12) [2014] E.P.O.R. 28.

to patentees, which might lead to possible restrictions of the freedom of medical practitioners to prescribe or administer generics.[567]

The EPO Board of Appeal's decision in T1758/15 provides valuable clarification on the applicability of second medical use claims to medical devices under Article 54(5) of the EPC. The focus was the biocompatible filler material used in radiation therapy to separate tissues and reduce side effects. Although the method of use was innovative, the Board held that the therapeutic effect was achieved through the chemical composition. As a result the filler material did not meet the requirement under Article 54(5) EPC[568] as the provision applies exclusively to substances or compositions that exert their therapeutic effect through chemical properties. This decision highlights the challenges medical device inventions face in securing patent protection, as they often fall between the exclusions of Article 53 and 54(5) EPC. The decision also emphasizes that, for second medical use claims, there must be a direct and causal link between the therapeutic effect and the chemical properties of the claim substance. While bioactive materials or chemical dyes may meet this criterion, devices that rely on structural or mechanical effects typically do not qualify.

This ruling has significant implications, particularly for access to medicines for NCDs, many of which require medical devices as part of their treatment. By restricting second medical use patents to pharmaceutical compositions, the decision reduces market exclusivity for medical devices, potentially allowing generic or alternative products to enter the market more quickly, thereby improving accessibility. However, this could also raise concerns about incentives for innovation, as companies may prioritize pharmaceutical research over medical device development due to the strong patent protection available for drugs. The case highlights the need for policy considerations to strike a balance between encouraging innovation and ensuring affordable access to treatments for NCDs. These issues will be further explored in Chapter Five, which will represent recommendations.

567 *Abbott Respiratory/Dosage regime* (G 2/08) [2010] EPOR 26, [6.5].
568 European Patent Convention, Article 54(5).

### 2.2.1. The *OncoMouse* Case and Article 53(a) EPC

A key case that shaped the interpretation of Article 53(a) EPC is the *OncoMouse* decision. This case addressed the patentability of a genetically modified non-human mammal (specifically, a mouse) that had been altered to be highly susceptible to cancer, making it a valuable model for testing new cancer treatments.[569] Article 53(a) EPC stipulates that European patents shall not be granted for inventions whose commercial exploitation would be contrary to *ordre public* or morality. This provision serves as a safeguard to ensure that ethical concerns are integrated into the patent system, preventing the grant of patents that could be deemed inhumane, unethical or socially unacceptable.

The *OncoMouse* patent was initially granted by the EPO, but it faced significant opposition based on ethical concerns. The key legal and ethical question was whether it is morally acceptable to create genetically modified animals that suffer and eventually die from induced cancer. The commercial exploitation of such an invention was challenged on the grounds that it might violate principles of public morality. The EPO was required to balance scientific advancements with ethical considerations. While the *OncoMouse* provided valuable insights for cancer research, opponents argued that the suffering inflicted upon the animals outweighed the benefits. The case prompted a broader discussion on the extent to which biotechnology patents should be allowed, particularly when they involve animal suffering. The *OncoMouse* case set a precedent for future biotechnology patent applications. It influenced how the EPO interprets *ordre public* and morality exclusions, aligning with ethical principles later reinforced in the Biotechnology Directive (98/44/EC). The case underscores the need for ethical scrutiny in the patenting process, ensuring that advancements in biotechnology do not come at the expense of fundamental moral values.

The *OncoMouse* case remains a landmark decision defining the limits of patentability under Article 53(a) EPC. It illustrates how legal frameworks integrate ethical considerations into patent law, reinforcing the idea that not all scientific innovations should be commercially exploited if they conflict with public morality.

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[569] *Harvard/OncoMouse* [2003] OJ EPO 473 (Opp Div) 499.

### 2.2.2. Exclusions of Animal Varieties (Article 53(b) EPC and the *OncoMouse* Case

The *OncoMouse* case also played a crucial role in shaping the interpretation of Article 53(b) EPC, which excludes animal varieties from patentability.[570] The EPO's Opposition Division suggested that this exclusion might have been intended to leave open the possibility of creating such law for the protection of animal varieties in the future.[571] Another interpretation is that animal varieties were excluded simply because they were considered inappropriate subject matter for patents.[572]

When Article 53(b) EPC 1973 was originally drafted, the potential scope of the animal variety exclusion was straightforward and uncontroversial.[573] However advanced biotechnology patent law had to adapt to new developments in genetic modification. The legal interpretation of 'animal variety' became more complex, leading to significant cases such as the *OncoMouse* decision.[574] Initially, the Examining Division rejected the patent, arguing that the invention fell under Article 53(b) EPC exclusion for animal varieties.[575] However, on appeal, the Technical Board of Appeal (TBA) ruled that the exclusion should be interpreted narrowly.[576] It clarified that Article 53(b) does not exclude genetically modified animals in general, only specific animal varieties.[577] As a result, the case was sent back to the Examining Division for reconsideration, and the patent was ultimately granted.

The decision set an important precedent for biotechnology patents, demonstrating that genetically modified animals could be patented as long as they were not considered a single animal variety.

### 2.2.3. Ethical Considerations in the *OncoMouse* Case

In deciding whether the *OncoMouse* patent should be granted, the EPO had to consider whether its commercial exploitation would violate public morality. While the scientific

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[570] European Patent Convention, Article 53(b). See also Bently *et al.,* (n 41) 512.
[571] *Harvard/OncoMouse* [2003] OJ EPO 473.
[572] *Harvard/Oncomouse* [2003] OJ EPO 473 (Exam).
[573] Bently *et al.,* (n 41) 512.
[574] *Harvard/Oncomouse* [2003] OJ EPO 473.
[575] European Patent Convention, Article 53(b).
[576] *Harvard/Oncomouse* [1991] EPOR 525 (Exam).
[577] European Patent Convention, Article 53(b).

benefits of the *OncoMouse* were clear, the EPO had to assess if the commercial use of the invention could be seen as promoting unethical practices such as subjecting animals to unnecessary suffering. Under Article 53(a) EPC, if the exploitation of a patent is perceived to contradict moral values, in this case the deliberate suffering of animals, it could lead to rejection. Ultimately, the EPO determined that the societal benefits of cancer research outweighed the ethical concerns, but the possibility of rejections based on public morality was a key consideration.

The *OncoMouse* case raises a fundamental moral dilemma of whether the benefits of cancer research justify the genetic modification of animals that will inevitably suffer. The *OncoMouse* was designed to help researchers develop cancer treatments, potentially saving millions of human lives. The genetic modifications allowed for a better understanding of cancer mechanisms leading to more effective and targeted therapies. However, while the scientific benefits are significant, they come at a moral cost, the deliberate infliction of suffering in sentient beings. From an ethical standpoint, causing harm to animals solely for human benefit can be viewed as inherently wrong, especially when alternative research methods may exist.

In that case, the EPO decided to adopt a utilitarian approach when assessing morality of the invention.[578] This approach involves weighting the scientific and societal benefits against ethical costs, that is, the advances in cancer research and potential human health improvements against the disadvantages of animals suffering and death. The EPO concluded that the potential improvements in cancer research and human health outweighed the moral concerns and thus, the commercial exploitation of the invention was not deemed immoral. The patent was granted, based on the notion that the public good justified the suffering of the animals.[579]

The *OncoMouse* patent played a crucial role in advancing cancer research by providing a genetically modified model for studying the disease, leading to the development of new treatments for NCDs. However, the patent also raised concerns about access to research tools

[578] *Harvard/OncoMouse,* T 19/90 [1990] EPOR 501 (TBA). See also Bently *et al.,* (n 41) 512.
[579] Bently *et al.,* (n 41) 512, 513.

and medicines. Exclusive rights could increase costs and limiting smaller institutions' ability to conduct affordable drug development. This highlights the patent dilemma whereby while patents incentivize innovation they also can restrict access to life-saving treatments. Therefore the case highlights the need for balancing models for both scientific progress and public health.

Had the EPO applied an IP-SJ approach to the *OncoMouse* case, the outcome might have been different. Rather than focusing on the overall benefits to human health, the IP-SJ would prioritize fairness and the rights of non-human entities such as genetically modified animals. In this view, the commercial exploitation of the *OncoMouse* could be seen as unjust due to the deliberate infliction of suffering on sentient beings.

Under an IP-SJ framework, the ethical questions shift from utilitarian cost-benefit analysis to whether the patent system exploits vulnerable entities (animals) for human benefit. Instead of justifying suffering for scientific progress this approach would emphasize justice over societal benefit, potentially leading to the rejection of the patent. Applying IP-SJ could encourage a balance between scientific progress and ethical considerations, imposing stricter guidelines on patents involving animal suffering. This might result in a more restrictive patent regime, limiting or even preventing patents on inventions that cause harm, regardless of their potential benefits to humanity.

In addition, while *Plant Genetic Systems*[580] does not directly relate to medicines, it is still important to consider it because the courts took a different approach to morality and what would be deemed immoral in the European context. *Plant Genetic Systems* stated that "the concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC (and so the UK) the culture in question is the culture inherent in European society and civilisation. Accordingly, inventions that exploitation of which is not in conformity with the conventionally

[580] T 356/93 *Plant Genetic Systems/Plant cells* [21.02.1995] OJ EPO 1995, 545. Bently *et al.,* (n 41) 518.

accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[581]

*Plant Genetic Systems* is not about what the majority of people will think, is beneficial. It is generally accepted that the concept of *ordre public* covers the protection of public security and physical integrity of individuals as part of society. This concept also encompasses the protection of the environment. Accordingly, under Article 5(a) EPC, inventions the exploitation of which are likely to breach public peace or social order or to seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*.[582]

The court emphasized that the concept of morality involves societal norms about right and wrong which are deeply rooted in culture. For this case EPO examined whether the exploitation of the invention could potentially harm public security, physical integrity or the environment, and whether it was likely to disrupt public peace or social order. Therefore *Plant Genetic System* is less about what would be beneficial for the majority in a utilitarian sense and more about protecting societal norms, public order and moral values embedded within European culture, as well as safeguarding public safety and the environment. The focus on this case is culture morality and the public interest, rather than a purely utilitarian or the benefit to the majority.

From an IP-SJ perspective, *Plant Genetic System* aligns more closely with the idea that patents should not disproportionately harm vulnerable groups or undermine broader social justice principles. The case highlights that patenting decisions should consider public security, environmental impact and societal order, reinforcing an ethical duty to ensure that patents do not disrupt social cohesion to cultural values.

### 2.3. National rules on exclusions from patentability

The national laws of the UK and Cyprus outline specific exclusions from patent protection. A detailed explanation of these exclusions will be provided for each jurisdiction in the following

[581] European Patent Convention, Article 53(a). See also T 356/93 Plant Genetic Systems/*Plant cells* [21.02.1995] OJ EPO 1995 [6].
[582] T 356/93 Plant Genetic Systems/*Plant cells* [21.02.1995] OJ EPO 1995 [6].

sections, ensuring clarity on the legal framework governing patentability. The regulations for each jurisdiction will be examined individually to highlight any variations in their approach to patent exclusions.

### 2.3.1. United Kingdom

The exclusions for patentability in the UK can be found in Section 1(2)[583] and Section 1(3)[584] of the Patent Act 1977. Section 1(2) lists categories of subject matter that are not considered inventions, aligning with Article 52 EPC.[585] This includes abstract ideas, mathematical methods, and aesthetic creations which UK courts and the UK Intellectual Property Office (UKIPO) interpret in line with EPC principles. In contrast, Section 1(3) of the Patent Act 1977 does not exclude inventions outright but prohibits their patenting if their commercial exploitation is deemed immoral or against public policy.[586] This aligns with Article 53(a) EPC[587] which prevents patents on inventions that violate ethical principles or societal norms. As a result, even if an invention meets the requirements of novelty, inventive step and industrial applicability, it cannot be patented if its commercial exploitation would be considered morally unacceptable.[588]

The issue of morality in patents is particularly relevant in areas like cloning and human embryo research and biotechnology.[589] As scientific advancements raise ethical concerns, patent offices and courts have developed a balanced approach. Under Section 1(3), courts often face conflicting views on whether morality should limit patent rights, which has led to debates about the role of ethics in innovation. Specifically, exceptions related to *ordre public* and morality, especially in areas like human germline editing, should not be interpreted or applied in ways that undermine the goal of balancing technological innovation with the protection of

[583] Patent Act 1977, Section 1(2).
[584] Patent Act 1977, Section 1(3).
[585] European Patent Convention, Article 52. Specifically, Article 52(2) provides what shall not be regarded as inventions which are the same with Section 1(2) of the Patent Act 1977.
[586] Patent Act 1977, Section 1(3).
[587] European Patent Convention, Article 53(a)
[588] European Patent Convention, Article 53(a).
[589] David B Resnki, 'Embryonic Stem Cell Patents and Human Dignity' (2007) 15(3) Health Care Anal 211.See also Daniel J Gervais Fairness, *Morality and Ordre Public in Intellectual Property* (Edward Elgar, 2020) 243.

society's core ethical values.[590] A key case is *Oliver Brüstle* v *Greenpeace* [591] where the CJEU ruled that inventions involving human embryo destruction could not be patented, influencing UK and EU patent law. The *Brüstle* jurisprudence, later embraced by the EPO, differs from the more restrictive stance on patenting genetic innovations seen in earlier EPO Board of Appeal rulings such as the *OncoMouse* decision. Similarly, patents on genetic modification, such as in *OncoMouse*, illustrate how UK and European patent authorities assess ethical implications before granting protection. This approach ensures that patent law evolves alongside ethical and technological developments, maintaining a balance between encouraging innovation and protecting societal values.

In the UK the prevalence of NCDs underscores the need for affordable and accessible treatments. The provisions within UK patent law, specifically under the Patents Act 1977, regarding exceptions to patentability, such as those relating to inventions that are contrary to *public ordre* or morality can impact the access on NCDs in different ways. While it may facilitate generic production and lower costs, it could also discourage investment in innovative NCD treatment. Although aligning with the EPC and international TRIPS patent law, its practical effect depends on interpretation and enforcement, requiring a balance between ethical oversight and medical innovation.

### 2.3.2. Cyprus

The exclusions under Cyprus's Patent Law are outlined in Section 5(2)[592] and 5(3)[593] of the Patents Law of 1998.[594] Section 5(3) states that a patent shall not be granted for an invention whose exploitation would be contrary to *public ordre* or morality, provided that such exploitation shall not be deemed contrary merely because it is prohibited by law or regulations. This provision ensures that patent protection in Cyprus aligns with ethical standards, distinguishing between ethical concerns and legal prohibitions. It is in line with

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[590] Duncan Matthews *et al.,* 'Balancing innovation, 'ordre public' and morality in human germline editing: A call for more nuanced approaches in patent law' (2022) 29 European Journal of Health Law 562.
[591] *Oliver* Brüstle v *Greenpeace*, Case C-34/10 [2011] ECRI-9821.
[592] Patents Law 16(1)/1998, Section 5(2). Any discoveries, scientific theories and mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers and presentation of information shall not be regarded as inventions.
[593] Patents Law 16(1)/1998, Section 5(3).
[594] Patents Law 16(1)/1998, Section 5(3).

similar provisions in European and international patent law, such as Article 53 (a) EPC and Article 27 (2)[595] TRIPS Agreement, which also prohibit patents on inventions deemed immoral or disruptive to *public ordre.*[596]

As a member of the EPC, Cyprus is bound by the legal framework and decisions of the EPO, including rulings by the EPO's Enlarged Board of Appeal. However, the criteria for defining what constitutes an accepted norm deeply embedded in European society remain largely undefined. In the *Transgenic Animal* case, for instance, the EPO noted that no single definition of morality, whether based on economic or religious principles, represents the content of a widely accepted standard in European culture.[597] Similarly, in the WARF[598] case the EPO found that the legislature had incorporated morality into the EPC in the context of innovations related to embryos and declined to grant patents.

The exclusions in Section 5(3) of the Cyprus Patents Law 1998[599] which prevents patents on inventions deemed contrary to *public ordre* or morality, may also have implications for access to affordable and effective treatments. This exclusion could impact innovations related to medical treatments or biotechnologies, potentially limiting their availability in Cyprus despite their scientific or therapeutic value. As an EU member state Cyprus is further bound by Article 53(a) EPC[600] which prohibits patents on inventions whose commercial exploitation would violate *public ordre* or morality.[601] However, such exploitation is not automatically considered contrary to these principles merely because is it prohibited by law in some contracting states. This principle is reinforced by Article 5 and Article 6 of the Biotechnology Directive and Rule 28 of the Implementing Regulations to the EPC.[602]

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[595] TRIPS Agreement, Article 27.2. Members may exclude from patentability the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

[596] Article 53(a) EPC 2000 reads as follow: 'European patent shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to '*ordre public'* or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'

[597] T 315/03 *HARVARD/Trangenic Animal* [6 July 2004] OJ EPO 2005, 246.

[598] WARF/Embryonic Stem Cells [2009] EPOR 15, 143 [41].

[599] Patents Law 16(1)/1998, Section 5(3).

[600] European Patent Convention, Article 53.

[601] European Patent Convention, Article 53(a).

[602] Duncan Matthews, 'Access to CRISPR Genome Editing Technologies: Patents, Human Rights and the Public Interest' in Carlos M Correa and Reto M Hillty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Spring, 2022) 105. See also European Patent Convention, Article 53 establishes that methods for treatment of

By maintain these exclusions Cyprus upholds ethical and legal standards while its alignment with EPO decisions and international agreements ensures consistency in patentability assessments. However, as scientific advancements continue, ongoing legal interpretation will be necessary to balance ethical concerns with innovation and access to critical medical technologies.

## 3. Limitations on patentability

Although patents grant exclusive rights to the holder, meaning others are excluded from making, using or selling the invention, there are also limitations to this protection. These limitations are designed to balance the interest of the patent holder, other individuals or entities who are not the patent holder (referred to as 'third parties') and the public. The scope of enforcement of patent rights is therefore shaped by these limitations and exceptions under national patent law. This section focuses on these specific limitations. The decision to introduce or maintain such limitations is reserved for individual countries, in line with their international commitments under their international law.

### 3.1. International rules on limitations from patentability

One of the most significant aspects of the international framework is the TRIPS Agreement, which includes certain flexibilities[603] to balance intellectual property rights with public health needs. Compulsory licenses and parallel imports play a key role in maintaining access to essential medicines for NCDs. The following sections will provide separate explanations for each.

the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body ('methods for treatments') are specifically excluded from patentability.

[603] Gervais (n 93) 501 subsection 3.451. See also Srividhya Ragavan and Amaka Vanni, *Intellectual Property Law and Access to Medicine. TRIPS Agreement, Health, and Pharmaceuticals* (Routledge, 2012) 522. See also Nicol and Owoeye (n 147) 533.

### 3.1.1. Compulsory licenses

The TRIPS compulsory licensing framework was originally enshrined in entirety within Article 31. This provision was the object of lengthy and difficult negotiations.[604] It spawned the first internationally harmonized regime for compulsory licensing, breaking new ground in patent law that was previously left almost entirely to the discretion of each country.[605] From a socio-political perspective, this was a momentous development in the compulsory licensing dispute between developing and developed countries that started in the revision conferences of the Paris Convention and continued throughout the Uruguay Round.[606]

The key tenets of Article 31 can be summarized as follows: compulsory licensing can only be granted by governmental bodies, although no restrictions are imposed on their nature, composition or function.[607] Each application for compulsory licensing must be considered "on its individual merits."[608] This requirement does not preclude Members from enacting laws that establish presumptions in favour of issuing compulsory licensing in determinate circumstances[609], yet it does not exclude "blanket" compulsory licensing.[610]

The lawful grant of a compulsory licensing is conditional upon the perspective licensee having first undertaken "efforts" to obtain a consensual license from the patentee on "reasonable commercial terms and conditions" and that such efforts were not "successful within a reasonable period of time".[611] This negotiation requisite does not apply in "circumstances of extreme urgency" or for "public non-commercial use", though the issuing Member must notify the patent holder of issued compulsory licensing without delay.[612]

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[604] Gervais (n 93) 479 subsection 3.439. Article 31 TRIPS ('Other use without authorization of the right holder').
[605] Gervais (n 93) 479 subsection 3.439.
[606] Gervais (n 93) 12 subsection 1.12.
[607] Gervais (n 93) 479 subsection 3.439.
[608] Gervais (n 93) 479 subsection 3.439.
[609] For example, a Member might enact a law establishing that insufficient supply of a patented product at an affordable price is grounds for the granting of a compulsory licensing, placing the burden of patentees to prove otherwise.
[610] Ezinne Miriam Igbokwe and Andrea Tosato, 'Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31*bis*' (2022) 91 (5) Fordham Law Review 48.
[611] Gervais (n 93) 479 subsection 3.439. Article 31(b) TRIPS Agreement
[612] Igbokwe and Tosato (n 610) 49.

The government act awarding a compulsory licensing must specify its scope and duration and such limitations must legally binding on the licensee.[613] Members can only issue compulsory licenses that are non-exclusive and non-assignable.[614] Article 31 (f) specifies that compulsory licensing must be "authorized predominantly for the supply of the domestic market" of the issuing country. Notably, this provision does not impose a determinate methodology to qualify such predominance allowing Members to choose their own measuring parameters; nevertheless, the elasticity of the world "predominantly" is not boundless, making the substance of this restriction unequivocal.[615] Members must confer an "adequate remuneration" to patent holders subject to compulsory licensing based on the relevant circumstances and the economic value of the protected invention.[616] Consistently with the rule of law principle permeating the entirety of TRIPS[617], Members must ensure that patentees have a right to judicially challenge both the issuance of a compulsory licensing and the amount of compensation received.[618]

Despite its flexibilities, Article 31 TRIPS contained significant limitations. Issuing compulsory licenses, including scope, duration, distribution and compensation, does not limit the reasons for granting compulsory licensing or impose strict evidentiary requirements. Instead, it provides broad flexibilities, allowing countries to issue compulsory licenses at any time and for any type of patent, including pharmaceuticals.

The constraints imposed by Article 31(f) became particularly evident in the pharmaceutical sector, where developing countries without sufficient manufacturing capacity struggled to access essential medicines. The impact was most visible during the HIV/AIDS crisis when urgent demand for affordable patented drugs clashed with TRIPS-imposed restrictions. To address this issue WTO members introduced Article 31*bis,* an amendment aimed at enabling the export of medicines manufactured under compulsory licenses to countries facing public health emergencies but lacking domestic production capabilities. This reform marked a pivotal

613 Gervais (n 93) 479 subsection 3.439. Article 31(c) TRIPS Agreement.
614 Gervais (n 93) 479 -489. subsection 3.439. Article 31(d)-(e) TRIPS Agreement.
615 Andrew D Mitchell and Tania Voon, 'Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law' 43(3) Journal of World Trade 571.
616 Gervais (n 93) 480 subsection 3.439. Article 31 (h) TRIPS Agreement.
617 Igbokwe and Tosato (n 610) 49.
618 Gervais (n 93) 480 subsection 3.439. Article 31 (i)-(j) TRIPS Agreement

shift in the TRIPS compulsory licensing regime, allowing greater access to life-saving treatments.[619]

Under Article 31*bis*, a country with insufficient pharmaceutical manufacturing capacity can notify the WTO, allowing another WTO member to issue a compulsory license for the purpose of manufacturing and exporting medicines to that country. This system was intended to remove barriers that prevented developing countries from obtaining affordable medicines. However, while Article 31*bis* provided a legal pathway for addressing public health needs, many developing nations faced difficulties navigating the procedural requirements to benefit from this system.

Recognizing the ongoing challenges in accessing affordable medicines, WTO members adopted the Doha Declaration on TRIPS Agreement and Public Health in 2001.[620] This declaration reaffirmed that the TRIPS Agreement should not prevent governments from taking measures to protect public health. Specifically, it clarified that countries have the right to issue compulsory licenses and determine the grounds for doing so without undue restrictions.[621]

Compulsory licensing occurs when a government allows someone else to produce a patented product or process without the consent of the patent owner.[622] While this practice is often associated with pharmaceuticals it can apply to patents in any field. However, compulsory licensing can only occur under specific conditions aimed at protecting the legitimate interest of the patent holder.[623] Thus the flexibility of compulsory licensing under the TRIPS Agreement is invaluable for improving access to medicines and addressing public health needs. It strives to balance the need for access to existing drugs with the promotion of research into and development of new treatments.[624]

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[619] Gervais (n 93) 501 subsection 3.451. Article 31bis is the amendment of Article 31 TRIPS.
[620] Gervais (n 93) 74 subsection 2.24.
[621] The Doha Declaration recognized that member nations should not strive to uphold the TRIPS Agreement at the expense of the nation's public health. The clarification embodied in the Doha Declaration resulted from an increasing concern over public health problems affecting the developing and least-developed countries.
[622] Gervais (n 93) 501 subsection 3.451.
[623] Maura Nuno, 'A Fair Return Approach to Pharmaceutical Compulsory Licensing' (2016) 48(1) Case Western Reserve Journal of International Law, 396. See also Bollyky (n 130) 2.
[624] Gervais (n 93) 129 subsection 2.75 ('Access to medicines and public health').

The use of compulsory licenses has significant implications for ensuring affordable medicines, especially when addressing the matter of public health challenges with NCDs such as diabetes, cancer and cardiovascular diseases. These diseases often require long-term and costly treatments, making access to generic versions of patented medicines essential for countries with limited resources. While TRIPS flexibilities such as compulsory licensing were initially utilized to combat HIV/AIDS, their significance has expanded to include NCDs, given high prices and the need to ensure the availability of life-saving treatments to improve health equity.

Countries such as India and Brazil have utilized compulsory licensing in the pharmaceutical industry to address public health challenges, particularly during the HIV/AIDS and Covid-19 pandemics, where patents on life-saving medications can delay access to essential treatments.[625] Both countries invoked the flexibility of compulsory licensing to allow the production of generic versions of patented medicines without the consent of the patent holder. This approach is crucial in ensuring access to affordable medicines as many countries face significant challenges in affording essential drugs.

The ability of WTO member states to utilize TRIPS flexibilities, such as compulsory licenses is rooted in the fundamental objectives and principles of the TRIPS Agreement. Articles 7 and 8 of the TRIPS Agreement explicitly recognize that intellectual property protection should serve broader economic and societal needs by allowing governments to take necessary measures to protect public health and prevent the abuse of patent rights.[626] Both articles go beyond merely protecting intellectual property rights, as they also offer flexibility to ensure access to affordable medicines. These articles acknowledge the need to balance the promotion of technological innovation and the transfer and dissemination of such technology.[627] Particularly, Article 7 of the TRIPS[628] was one of the main proposals made by developing countries during the negotiations and states the following:

[625] Hilary Wong, 'The case for compulsory licensing during COVID-19' (2020) 10(1) J Glob Health 2. In the 2000s, Brazil and other countries such as Ecuador, Ghana, Indonesia, Malaysia, Mozambique, Thailand, Rwanda, Zambia, and Zimbabwe each issued compulsory licenses for antiretroviral drugs. See also Carlos M Correa, 'The use of compulsory licenses in Latin America' (2013) 71 South Bulletin. See also Bollyky (n 130) 2.
[626] Gervais (n 93) Article 7 237 subsection 3.110, Article 8 245 subsection 3.122.
[627] Sellin (n 125) 453.
[628] TRIPS Agreement, Article 7 and 8. Gervais (n 93) Article 7 237 subsection 3.110, Article 8 245 subsection 3.122.

> "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[629]

In essence, Article 7 TRIPS Agreement emphasizes that the protection of intellectual property rights should foster innovation, ensure technology transfer, and benefit both creators and users while promoting social and economic well-being and balancing rights and obligations.

Article 8 of the TRIPS Agreement[630] allows countries to adapt or change their laws to protect public health and nutrition, and support important interests related to their economic and technological development, as long as the measures follow the TRIPS Agreement rules. Moreover, this article enables countries to take necessary actions to prevent the abuse of intellectual property right holders, practices that unreasonably limit trade, or negatively affect the international transfer of technology.

As this thesis focuses on patents, it is important to recognise that patent protection can sometimes conflict with fundamental rights. In particular, the right to health especially in the areas of pharmaceuticals and drugs can be directly impacted by patent regulations.[631] The field of protection given over medication can restrict access to medicines due to extended periods of exclusivity or high prices, which can harmfully affect people. Alongside patent protection, the TRIPS Agreement also introduces data exclusivity, which further restricts the access to affordable medicines.[632]

The Doha Declaration reaffirmed that the TRIPS Agreement should not prevent members from taking measures to protect public health.[633] This included both promoting access to existing

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629 Gervais (n 93) 237 subsection 3.110. Article 7 TRIPS Agreement ('Objectives').
630 Gervais (n 93) 245 subsection 3.122. Article 8 TRIPS Agreement ('Principles').
631 World Health Organization, 'The Right to Health' (*Office of the United Nations High Commissioner for Human Rights* 2008). Available: https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf
632 Lisa Diependaele *et al.,* 'Raising the Barriers to Access to Medicines in the Developing World- The Relentless Push for Data Exclusivity' (2017) 17(1) Developing World Bioethics 1471.
633 Doha Declaration Recital [4].

medicines and fostering the development of new medicines.[634] The Doha Declaration responded to the challenges developing nations encountered in securing cost-effective treatments during the HIV/AIDS pandemic.[635] With the lessons from the HIV/AIDS crises, clarified the scope of the TRIPS Agreement and provided guidance for implementing flexibilities to improve access to affordable medicines, including generic antiretroviral drugs and other essential medicines for AIDS-related illnesses.[636]

The Declaration emphasized that TRIPS does not and should not prevent measures necessary to protect public health, including addressing public health crises through flexible use of patent laws.[637] It also demonstrated that while the TRIPS Agreement provides specific conditions for issuing compulsory licenses, it grants member states significant discretion in determining the grounds for granting such licenses and the criteria for establishing adequate remuneration.[638] The Doha Declaration aimed to improve access to essential medicines by allowing countries to issue compulsory licenses to support the production of generic drugs for export. While progress was made in the first decade following its adoption[639], the Doha Declaration has not fully addressed systematic barriers to accessing medicines.[640] The continued reliance on state-by state policymaking limits the effectiveness of compulsory licensing in addressing global public health challenges. Much more needs to be done, particularly for NCDs, as the attention given to communicable diseases remains disproportionately higher.

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[641] recognized that technology transfer and capacity building in the pharmaceutical sector are vitally important for overcoming the challenges faced by countries with insufficient or no

[634] Gervais (n 93) 56 subsection 2.02.
[635] Sun (n 168) 123.
[636] Correa (n 91) 3.
[637] Bently *et al.,* (n 41) 427. Gervais (n 93) 56 subsection 2.02. Correa (n 522) 4.
[638] Alan O Sykes, 'TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution' (2003) 3 Chicago Journal of International Law 47. See also Nuno (n 623) 396.
[639] Correa (n 522) 3.
[640] See Chapter One, specifically on Doha Declaration subsection 2.7.
[641] Gervais (93) 130 subsection 2.76. Doha Declaration on the TRIPS Agreement and Public Health, paragraph 6. See also Duncan Matthews, 'WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: a solution to the access to essential medicines problem?' (2004) 7(1) J Int Econ Law 73. The emergence of the "paragraph 6" system.

manufacturing capacity.[642] To address these challenges both importing and exporting members are encouraged to use compulsory licensing systems in a way that promotes the transfer of technology and capacity building in the pharmaceutical sector. This enhances the ability of importing countries to produce the medicines they need locally in the future. Moreover, developed country members are obliged to provide technical and financial cooperation in order to facilitate its implementation. Thus the overall goal of these rules is to strengthen pharmaceutical manufacturing capacities so they can finally produce medicines locally, reducing their dependency on imports in the long term. This aims to ensure that the system will not just provide a temporary solution to public health crises, but also contributes to a long-sustainable health solution by empowering countries to develop pharmaceutical production capacity.[643]

While TRIPS sets the minimum standards for intellectual property protection, many regional and bilateral trade agreements impose stricter patent rules, known as TRIPS-plus provisions.[644] These provisions requiring exclusive rights for originator products that go beyond what is mandated by the TRIPS Agreement are sometimes referred to as "TRIPS-plus" requirements.[645] One such provision is data exclusivity, which prevents generic drug manufacturers from using the clinical trial data of the original drug for a certain period, even after the patent has expired.[646] This delay in the entry of generic medicines extends the time during which only the patent holder can sell the drug, often at high prices. Consequently data exclusivity not only limits the availability of affordable generics but also exacerbates public health challenges in developing countries, particularly in the treatment of NCDs. The intersection of intellectual property law, human rights and the right to health is especially concerning when pharmaceutical products are protected by patents.[647] Developing countries often struggle to provide affordable medicines to their citizens due to the high costs of patented drugs, hindering access to essential treatments.[648]

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[642] Gervais (n 93) 130 subsection 2.76.
[643] Matthews (n 641) 73.
[644] Correa (n 91) 298.
[645] Correa (n 91) 297, 298.
[646] Diependaele *et al.,* (n 632) 1471.
[647] Geiger (n 196) 498.
[648] Correa (n 91) 297.

### 3.1.2. Parallel imports

Another important aspect that plays a crucial role in improving access to medicines especially in low and middle-income countries is parallel imports.[649] These relate to the principle of 'Exhaustion of rights' in Article 6 of the TRIPS Agreement.[650] Parallel imports are products marketed by the patent owner's permission in one country and imported into another country without the patent owner's approval.[651] In the case of pharmaceuticals this is crucial. Suppose company A has a drug patented in country X and Z which it sells at a lower price in Z. If a second company named B buys the drug in country Z and imports it into country X at a price that is lower than company A's price, that would be a parallel or grey import.

Based on the parallel imports, TRIPS Agreement, Article 6 states that 'none of its provisions, except those dealing with non-discrimination ("national treatment" and most-favoured-nation treatment") can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute.'[652] Therefore, even if another country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. This provision is particularly important for developing countries seeking to reduce medicine prices by importing cheaper versions from foreign markets.

While national exhaustion limits the circulation of patented products to within the domestic market, thereby potentially restricting access to affordable medicines, international exhaustion permits parallel imports once products have been legitimately placed on the market anywhere in the world. From an IP-SJ perspective, international exhaustion is generally preferable, as it promotes equitable access by allowing medicines to be sourced from markets where they are more affordable, reducing the exclusionary of patent rights.

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[649] Irene Calboli, 'Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines* (Springer, 2022) 31.
[650] TRIPS Agreement, Article 6.
[651] Calboli (n 649) 34.
[652] TRIPS Agreement, Article 6.

### 3.2. Regional rules on limitations from patentability

Within the European Union (EU) and European Economic Area (EEA)[653] the principle of regional exhaustion limits the rights of patent holders by preventing them from restricting the resale of patented goods once they have been legally placed on the market in any EU/EEA member state.[654] The rule of exhaustion has played a key role in safeguarding the EU internal market in the field of parallel imports among Member States. Directive 2001/83/EC[655] sets out the conditions under which medicinal products can be imported and sold across EU/EEA member states, ensuring compliance with safety and regulatory standards. The EEA aims to enhance trade and economic ties among the contracting parties, focusing primarily on the four key pillars of the internal market the free movement of goods, people, services, and capital.

The Court of Justice of the European Union (CJEU) has consistently upheld the exhaustion principle, reinforcing that once a product is first sold within the EU/EEA by or with the consent of the patent holder, they cannot invoke patent rights to prevent its further distribution. Notably in *Bristol-Mayers Squibb* v *Paranova*[656] confirming that once a product is first sold within the EU/EEA with the consent of the patent holder, they cannot invoke patent rights to prevent its further distribution. Similarly, in *Centrafarm BV and Adriaan de Peijper* v *Winthrop BV*[657]*,* the CJEU reinforced that restrictions on parallel imports must be objectively justified, ensuring that intellectual property rights are not used to create artificial market barriers.[658]

Although the EU provides Supplementary Protection Certificates (SPCs) which extend patent protection for pharmaceuticals beyond the term of 20 years under Regulation 469/2009[659], SPCs do not override the exhaustion principle, meaning that SPCs cannot be used to prevent

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[653] European Commission, 'European Economic Area (EEA) Agreement' <https://trade.ec.europa.eu/access-to-markets/en/content/european-economic-area-eea-agreement#:~:text=The%20European%20Economic%20Area%20(EEA,%2C%20economic%20and%20monetary%20cooperation)> accessed 25 March 2025.
[654] Calboli (n 649) 34.
[655] Directive 2004/27/EC of the European Parliament and the Council of 31 March 2994 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
[656] C427/93 *Bristol Myers Squibb* v *Paranova A/S* [1996] ECR 1-3457.
[657] C-16/74 *Centrafarm BV and Adriaan De Peijper* v *Winthrop BV* [1974].
[658] C-16/74 (n 657) [11].
[659] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products. For more detailed discussion see Chapter Four, in Regional section, subsection 2.2.3. ('Supplementary protection certificate (SPCs)').

parallel imports within the EU/EEA once the original product has been lawfully placed on the market. Overall, regional exhaustion acts as a limitation on patent rights, ensuring that parallel trade is permitted while balancing the interests of patent holders with the EU's commitment to market integration, fair competition and consumer access to affordable medicines.

### 3.3. National rules on limitations from patentability

National laws in both the UK and Cyprus, regulate compulsory licensing and parallel imports, though they approach these issues differently. Both countries allow compulsory licensing when a patented invention is not commercially exploited or available on reasonable terms. The UK has expanded its export control regime to cover emerging technologies, including semiconductors, although such technologies are explicitly excluded from certain licensing exceptions, subjecting them to stricter national export controls.[660] In contrast, Cyprus grants the Council of Ministers the authority to issue licenses for restricted technologies, including semiconductor technology, if deemed necessary for national security or public safety. The following sections will provide a detailed examination of compulsory licensing and parallel imports in both jurisdictions separately.

#### 3.3.1. United Kingdom

In the UK, Section 49 of the Patent Act 1977[661] allows government departments to apply for a compulsory license when it is in the public interest, while broader provisions for compulsory licensing are set out in Sections 48 to 54 of the Act.[662] Parallel importation of pharmaceuticals operates under the exhaustion of rights principle and is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). The Agency is responsible for ensuring that medicines and medical devices work and are acceptably safe.[663]

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[660] Morrison and Foerster, 'UK Expands Export Controls to Semiconductor and Other Emerging Technologies' (*Morrison and Foerster* 2024) <https://www.mofo.com/resources/insights/240314-uk-expands-export-controls-to-semiconductor> accessed 25 March 2025.
[661] Patents Act 1977, Sections 49.
[662] Patents Act 1977, Sections 48 to 54.
[663] Natalie Richards and Ian Hudson, 'UK medicines regulation: responding to current challenges' (2016) 82(6) BBr J Clin Pharmacol 1471.

### 3.3.1.1. Compulsory licensing

Compulsory licensing provisions were first introduced into British patent law in the late nineteenth century.[664] During the early twentieth century, these provisions expanded in response to concerns that large, often foreign entities with dominant market positions might buy up patents and decline to exploit them.[665] Additionally, there were fears that patent holders could hinder technological progress by refusing to grant licenses for improvements or restrict access to essential medicines.[666]

In recent years, compulsory licensing has remained a contentious issue, particularly in discussions at the WTO regarding access to medicines in developing countries.[667] The legal conditions for granting a compulsory license in the UK are outlined in Section 48 of the Patents Act 1977[668], which distinguishes between patents held by WTO members and non-WTO proprietors.[669] A compulsory license cannot be issued until three years after the patent is granted, allowing the patent holder sufficient time to exploit the invention or enter licensing agreements.[670]

For patents owned by WTO members, the criteria for granting a compulsory license are specified in Section 48A.[671] A license will only be issued if the applicant has made genuine efforts to obtain authorization from the patent holder on reasonable commercial terms but has been unable to reach an agreement within a reasonable period.[672] However, compulsory licenses are not available for patented inventions in the field of semiconductor technology[673] except in cases where the patent owner fails to meet demand in the UK on reasonable terms[674], or the exploitation in the UK of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered.[675] In such cases the

[664] Bently *et al.,* (n 41) 698.
[665] Bently *et al.,* (n 41) 698.
[666] Bently *et al.,* (n 41) 698.
[667] Bently *et al.,* (n 41) 698.
[668] Patents Act 1977, Section 48.
[669] Bently *et al.,* (n 41) 699.
[670] Bently *et al.,* (n 41) 699.
[671] Patents Act 1977, Section 48(A).
[672] Patents Act 1977, Section 48(A).
[673] Patents Act 1977, Section 48(A).
[674] Patents Act 1977, Section 48A(1)(a).
[675] Patents Act 1977, Section 48A(1)(b)(i).

Comptroller must be satisfied that the proprietor of the later invention is willing to grant a reciprocal license under fair terms.[676] In addition, the compulsory license may not be granted if the owner's failure to license unfairly prejudiced industrial[677] or commercial activities in the UK[678], including restrictions on the manufacture, use or disposal of materials not protected by the patent.

#### *3.3.1.2. Exhaustion of patent rights*

Before Brexit, the UK followed the regional exhaustion principle of the EU/EEA.[679] However, since Brexit the UK now applies a unilateral exhaustion regime, meaning it continues to allow parallel imports from the EEA, but UK products may not necessarily benefit from reciprocal treatment in the EU.[680] Pharmaceutical parallel imports into the UK require a parallel import license issued by the Medicines and Health Products Regulatory Agency (MHRA).[681] To obtain this license, the imported medicine must be essentially identical to the UK-licensed product, meet UK safety, efficacy and quality standards, and pose no overriding public health concerns.[682] Trade marks over medicines have caused many issues in UK courts, but this thesis will not address these disputes.

### 3.3.2. Cyprus

Similarly, in Cyprus Sections 49 to 56 of the Patents Law[683], Law 16(1) of 1998, set out the provisions for compulsory licensing. Parallel importation of pharmaceuticals fall under EU regulations based on the principle of regional exhaustion of rights[684] and is regulated by national pharmaceutical legislation and the Cyprus Ministry of Health.

[676] Patents Act 1977, Section 48A(4).
[677] Patents Act 1977, Section 48A(1)(c).
[678] Patents Act 1977, Section 48A(1)(b)(ii).
[679] Katharine Stephens, 'Brexit Exhaustion of Intellectual Property Law' (*Bird & Bird* 2021) Available: https://www.twobirds.com/en/insights/2019/uk/exhaustion-of-intellectual-property-rights-post-brexit
[680] Amendment Regulation 2023 (SI 2023/1287). Statutory Instruments, 'The Intellectual Property (Exhaustion of Rights) (Amendment) Regulations 2023 Available: https://wipolex-resources-eu-central-1-358922420655.s3.amazonaws.com/edocs/lexdocs/laws/en/gb/gb594en_1.pdf
[681] Richards and Hudson (n 663) 1473.
[682] Bently *et al.,* (n 41) 699.
[683] Patents Law, Law 16(1) 1998, Sections 49- 56.
[684] Patents Law, Law 16(1) 1998, Sections 49- 56.

#### 3.3.2.1. Compulsory licensing

In Cyprus, the legal framework for compulsory licensing is established under Patents Law, Law 16(1) of 1998, as amended between 1998 and 2006.[685] It incorporates provisions from the EPC and PCT. Sections 49 to 56[686] of the law outline the issuance of compulsory licenses, primarily in cases where a patented invention is not being commercially exploited, demand for a patented product is unmet or the refusal to grant a license unfairly restricts market competition or industrial development.

Although EU Regulation 816/2006[687], which governs compulsory licensing for the export of pharmaceutical products to countries facing public health challenges, is applicable in Cyprus, the national law does not explicitly reference it.[688] The Patents Law 1998 No. 16(1), particularly Sections 49 to 56, provides the legal framework for non-voluntary licenses and governmental use of patents.[689] These licenses are granted by the government when the patent holder is unable or unwilling to make the invention available for public use under reasonable terms.[690] The government can authorize third parties to use the invention under specific conditions, ensuring access to essential technologies in situations such as public health crises or, emergencies.[691]

The Registrar of Patents is the primary authority for granting compulsory licenses, while the Council of Ministers may issue licenses in cases of national security or public safety.[692] Decisions on compulsory licensing can be reviewed by the Administrative Court with further appeals possible before the Supreme Court. To date, one case involving the compulsory licensing of a medication for a genetic condition has been recorded, however the decision was not contested, leaving no established legal precedent.

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685 Patents Law, 1998, 16(1) as amended to 2006 (hereinafter PL).
686Patents Law 16(1)/1998, Sections 49-56.
687 Regulation (EC) No. 816/2006 of the European Parliament and the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2006] OJ L 157/1 (9 June 2006).
688 Regulation (EC) No, 816/2006 (n 687). This implements TRIPS, Article 31*bis*. The required number of ratifications of TRIPS, Article 31*bis* for it to come into force was only reached in January 2017.
689 Patents Law 16(1)/1998, Sections 49-56.
690 Patents Law 16(1)/1998, Sections 49.
691 Patents Law 16(1)/1998, Sections 49.
692 Patents Law 16(1)/1998, Section 55.

#### *3.3.2.2. Exhaustion of patent rights*

The drug development process is strictly regulated, including the need for originators to secure special approval from the relevant state in order to market a drug. These marketing authorizations are granted only if the originators can demonstrate the drug's safety and effectiveness, usually through long and costly clinical trials.[693] This regulation ensures that medicines authorized in one EU member state are recognized for sale in other member states, thereby facilitating broader access to essential treatments. In addition, Directive 2001/83/EC provides a comprehensive legal framework for the authorization and distribution of medicinal products, further supporting the parallel importation system within the EU.[694]

Parallel importation can play a significant role in improving access to medicines for treating NCDs in Cyprus. By allowing the import of medicines already authorized in other EU Member States, it helps reduce costs, increase market competition and ensure the availability of essential treatments for conditions such as diabetes, cardiovascular disease, and cancer. This system permits the importation of medicinal products that have a marketing authorization both in Cyprus and another EU Member State.[695] The parallel import system in Cyprus aligns with EU regulations, ensuring adherence to safety and quality standards while facilitating market access within the EU/EEA.[696]

## 4. Exceptions on patentability

Patent protection plays a crucial role in incentivizing innovation by granting exclusive rights to inventors. However, recognizing that strict enforcement of patent rights could sometimes hinder scientific progress, public health (access to medicines) and technological development, legal frameworks at the international, regional and national levels include various exceptions.[697] These exceptions aim to balance the rights of patent holders with broader

[693] Medicines can only be sold once they have been approved through national or community marketing authorisation procedures, that ensure their safety and effectiveness. The procedure is regulated by Regulation (EC) No. 726/2004 'Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicine Agency' and Directive 2004/27/EC amending Directive 2001/83/ EC (n 655).
[694] Directive 2001/83/EC as amended by Directive 2004/27/EC (n 655).
[695] Directive 2001/83/EC as amended by Directive 2004/27/EC (n 655).
[696] Directive 2001/83/EC as amended by Directive 2004/27/EC (n 655).
[697] Marta Radelli, 'Patent Evergreening: Technological advancement and abusive commercial practices. Availability of essential medicines in the case of access to insulin' (2021) 2(66) QMLJ 71.

societal interests, such as scientific research, education and public welfare. Among these, exceptions for research and private use are particularly significant. They allow researchers, educational institutions and even individuals to use patented inventions in specific circumstances without the patent holder's authorization. The scope of these exceptions varies across different legal systems. At the international level is TRIPS Agreement (Article 30) which will be explored in the next section. At the regional level agreements such as the EPC offer further guidance, and finally national laws specifically for the UK and CY determine the specific conditions under which these exceptions apply.

### 4.1. International rules on exceptions from patentability

Under the TRIPS Agreement Article 30[698] provides WTO member states the ability to introduce limited exceptions to patent rights conferred by patent.[699] However, these exceptions must satisfy three cumulative criteria: firstly it must be 'limited', secondly it must not unreasonably conflict with normal exploitation of the patent, and lastly the exception must not unreasonably prejudice the legitimate interests of third parties.[700] These criteria aimed to strike a balance between protecting patent holders' exclusive rights and allowing flexibilities that serve the public interest, such as scientific research, education, and public health. If any of the three criteria are not met the Article 30 exception is disallowed.[701]

The interpretation of Article 30 of the TRIPS Agreement has been analysed in WTO dispute settlements, particularly in the *Canada Pharmaceutical Patents* (DS114) case.[702] This case examined whether two exceptions under Canadian law, particularly the regulatory review exception and the stockpiling exception complied with the criteria under Article 30 TRIPS.[703] The regulatory review exception, often referred to as the 'Bolar exception', permits competitors to use a patented invention without the authorization of the patent holder for the purposes of obtaining marketing approval. The WTO panel upheld this exception,

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[698] TRIPS Agreement, Article 30. Gervais (n 93) 474 subsection 3.431.
[699] TRIPS Agreement, Article 30. Gervais (n 93) 474 subsection 3.431.
[700] TRIPS Agreement, Article 30. Gervais (n 93) 474 subsection 3.431.
[701] TRIPS Agreement, Article 30. Gervais (n 93) 474 subsection 3.431.
[702] Kennedy (n 163) 429.
[703] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R < https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed 25 March 2025. See also Kennedy (n 163) 429.

reasoning that without it competitors would face delays in market entry as they would have to wait until patent expiration to begin regulatory approval. Since this exception only facilitated regulatory approval without undermining the patent holder's market exclusivity, it was deemed consistent with Article 30.[704]

In contrast, the stockpiling exception which allow competitors to manufacture and stockpile patented pharmaceuticals for sale immediately upon expiration of the patent, was found inconsistent with TRIPS.[705] The WTO panel concluded that it could undermine the exclusive rights of patent holders by allowing competitors to build up large quantities of generic medicines before the patent expired, with no restrictions on the quantities involved.[706] Since Article 30 requires all three conditions to be met cumulatively, the failure of the stockpiling exception to satisfy these standards led to its rejection.[707]

While Canada argued that the exception served public interest by ensuring immediate access to generics upon patent expiration, the WTO panel applied a strict legal interpretation of Article 30.[708] It concluded that the stockpiling exception did not qualify as a 'narrow' exception to patent rights, prioritizing the legal criteria over broader policy considerations.

The WTO panel's ruling reaffirmed the limited scope of permissible exceptions under TRIPS. It demonstrated that public interest alone is insufficient to justify broad exceptions unless they strictly comply with all Article 30 conditions.[709] The case also highlights the tension between patent protection and public health needs, particularly in ensuring access to affordable medicines. While the regulatory review exception was upheld, the panel's strict interpretation of Article 30 set a precedent that restricts the WTO members' ability to introduce patent flexibilities. This in turn reinforced the strength of pharmaceutical patent protection, shaping future discussions on balancing intellectual property rights with public health concerns.

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[704] TRIPS Agreement, Article 30. See also Kennedy (n 163) 430.
[705] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 983) 1.3.[3]. See also Gervais (n 93) 476 subsection 3.436.
[706] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.5. [10].
[707] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.2. [1]. In response to Canada, considers that it will achieve compliance with its obligations under TRIPS Agreement, by revoking the regulations essential to the existence of the stockpiling exception.
[708] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.4. [7].
[709] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.2. [1].

This case is directly relevant to IP-SJ requirement because it directly impacts access to medicines, particularly for vulnerable populations.[710] The TRIPS framework and its exceptions determine how patent laws can be adapted to serve public health needs, aligning with social justice principles that advocate for equitable access to essential medicines. The WTO panel's strict interpretation of Article 30 demonstrates the challenge of balancing patent rights with the public interest, often favouring pharmaceutical companies over broader social justice concerns. Regarding NCDs, this case is also relevant because patents play a crucial role in the pricing and availability of treatments for conditions such as cancer, diabetes, and cardiovascular diseases. Many life-saving treatments for NCDs remain under patent protection, making them expensive and inaccessible in low-and middle-income countries. The rejection of the stockpiling exception limits the ability of generic manufacturers to prepare affordable alternatives immediately after patent expiration, potentially delaying access to essential medicines for NCD patients.

Unlike communicable diseases, which have received more policy attention, the high cost of patented NCD treatments such as insulin for diabetes or targeted cancer therapies poses a significant barrier to public health.[711] Therefore the strict interpretation of Article 30 TRIPS, as seen in Canada-Pharmaceutical Patents (DS114)[712] limits governments' ability to introduce flexibilities that allow for earlier production and stockpiling of essential NCD medicines. This reinforces the inequities in global health access as many low and middle-income countries struggle to afford patented treatments for chronic diseases. Thus while Article 30 remains a critical tool for balancing patent rights and public health, its narrow interpretation by the WTO panel[713] means that NCD-related medicines remain largely under patent control, restricting timely and affordable access for populations that need them most, especially for conditions such as cancer, diabetes, cardiovascular diseases and chronic respiratory illnesses.

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[710] Mtima 2024 (n 28) 80 and Mtima 2019-2020 (n 49) 407.

[711] Dean T Jamison *et al.,* 'Cost-Effective Strategies for Noncommunicable Diseases, Risk Factors, and Bahaviors' in Dean T Jamison and others (eds), *Priorities in Health,* (The International Bank for Reconstruction and Development/ The World Bank, 2006) 97.

[712] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.3. [3].

[713] Canada-Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R (n 703) 1.2. [2].

Therefore one major consequence is the delayed entry of generic NCD medicines, as generic manufacturers are unable to produce or stockpile drugs before patent expiry, prolonging high prices and restricting availability.[714] This in turn places a greater financial burden on healthcare systems, particularly in low-and middle-income countries (LMICs) where international agreements like the Doha Declaration have facilitated compulsory licensing and other flexibilities, NCDs have received less policy attention, worsening global health inequalities.

In particular, the narrow interpretation of Article 30 also limits government policy options, making it difficult for countries to introduce early generic competition for essential NCD medicines. This reinforces pharmaceutical patent protection at the expense of public health needs, leaving many populations unable to access life-saving medications. Addressing these challenges will be crucial in ensuring that the growing burden of NCDs does not escalate into even greater public health crises. This issue will be further examined in Chapter Five, where recommendations will be provided to enhance affordable access to NCD treatments while balancing patent rights.

### 4.2. Regional rules on exceptions from patentability

At the regional level, patent laws across European jurisdictions aim to strike a balance between protecting intellectual property rights and ensuring the timely availability of medicines. Exceptions and restrictions to patent rights are designated to respect the freedom of research under Article 13 of the EC Charter.[715] Among the most notable exceptions are the Bolar and research exemptions.[716]

The Bolar exemption was originally established in the United States in Hatch-Waxman Act in 1984.[717] The exemption allows generic manufacturers to seek regulatory approval for

[714] Kerstin Noelle Vokinger *et al*., 'Strategies That Delay Market Entry of Generic Drugs' (2017) 177(11) JAMA 1665.
[715] EU Charter of Fundamental Rights, Article 13.
[716] Liz Cohen and Laura Peirson, 'The UK Research and 'Bolar' exemptions: broadening the scope for innovation? (2013) 8(11) Journal of Intellectual Property Law 837. See also Michael J Carroll, 'The importance of regulatory data protection or exclusive use and other forms of intellectual property rights in the crop protection industry' (2016) 72 Pest Management Science 4316. See also Marco Stief, 'The European Research and Bolar Exemptions – Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation' 73(9) 2024 GRUP International 824.
[717] The Hatch-Waxman Act is formally known as the 'Drug Price Competition and patent Term Restoration Act'. See also Stief (n 716) 827.

medicines before a patent expires, enabling them market to enter the market immediately after patent expiration.[718] Enshrined in Article 10(6) of Directive 2001/83/EC[719], the Bolar exemption enables quicker market access for generic medical products.[720] However, the application of the Bolar exemption is inconsistent across EU countries.[721] In some countries, the exemption is broad, covering trials for new, generic and biosimilar medicines, and even studies for non-EU regulatory approval.[722] In others the exemption is more limited, focusing solely on regulatory approval within the EU and primarily for generics and biosimilars.[723]

To address these inconsistencies the European Commission proposed amendments to the Bolar exemption through the 'EU Pharma Package' on April 26, 2023.[724] The proposal seeks to expand the scope of the exemption to explicitly cover trials and data generation for generic, biosimilar, hybrid[725] and bio-hybrid medicines[726], as well as health technology assessment (HTA), pricing and reimbursement procedures under Regulation (EU) 2021/2282.[727] These changes aim to harmonize the exemption across EU member states and enhance access to affordable medicines.

One of the key amendments includes the inclusion of third-party beneficiaries such as suppliers and contract research organization (CROs) which previously faced legal uncertainty in some EU jurisdictions.[728] Additionally, the exemption extends to the manufacture of test quantities for regulatory trials. However, it is important to note that while these test quantities can be manufactured for the purpose of regulatory trials, the commercial sale or market use

[718] Stief (n 716) 824.
[719] Article 10(6) of Directive 2001/83/EC, as amended by 2004/27/EC.
[720] Stief (n 716) 828.
[721] Stief (n 716) 826.
[722] Stief (n 716) 826.
[723] Stief (n 716) 826.
[724] Stief (n 716) 826.
[725] Ankit Kumar Singh *et al.*, 'Concept of Hybrid Drugs and Recent Advancements in Anticancer Hybrids' (2022) 15(9) Pharmaceuticals 1071. Hybrid is a medicine that is similar to an authorised medicine containing the same active substance, but where there are certain differences between the two medicines such as in their strength, indication or pharmaceutical form.
[726] A follow-on product to a biological reference product, but in contrast to a biosimilar product it may differ in strength, pharmaceutical form or route of administration. More information can be found in Salcher P *et al.,* 'HPR149 Bio-Hybrid Medicinal Products: Widening Access or Product Differentiation?' (2023) 26(12) Value in Health 279.
[727] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24EU.
[728] Stief (n 716) 834.

of these products before patent expiration remains strictly prohibited.[729] Notably, the proposed changes do not extend to clinical trials for new innovative medicines, meaning research on patented drugs beyond generics and biosimilars still require national-level research exemptions. The reform is still under discussion in the European Parliament, with final adoption expected in the coming years.[730]

## 4.3. National rules on exceptions from patentability

This section addresses exceptions to patent rights, specifically under the UK and Cyprus patent law frameworks. Cyprus follows much of the EPC system. These exceptions provide specific deviations from the exclusive rights granted to patent holders, aiming to balance intellectual property protection with broader public and scientific interests. The following sections will examine these exceptions in more details, focusing on the relevant provisions and their application within each jurisdiction.

### 4.3.1. United Kingdom

As the Patent Act 1977 provides the strongest protection for patent holders, the exceptions are very limited.[731] The first exception is the private use, defined under Section 60(5)(a) and the second is experimental use defined under Section 60(5)(b) Patent Act 1977.[732]

The private use exception provides for acts done privately and not for commercial purposes. While private uses must be secret or confidential, they must also be 'for the person's own use.'[733] This is demonstrated in the case of *SKF Laboratories*[734] which owned a patent for a specific process used to produce a pharmaceutical compound. *Evans Medical's* process infringed this patent as it involved steps substantially similar to those described in the patented method. The main issue was whether *Evans Medical's* process fell within the scope

[729] Hans-Rainer Jaenichen and Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' (2015) 5(2) Cold Spring Harb Perspect Med 7.
[730] Stief (n 716) 837.
[731] Patent Act 1977 provides two exceptions: the private use Section 60(5)(a) and experimental use Section 60(5)(b).
[732] Patent Act 1977, Section 60(5)(a) and Section 60(5)(b).
[733] *SKF Laboratories* v *Evans Medical* [1989] FSR 513, 518; *McDonald* v *Graham* [1994] RPC 407.
[734] *SKF Laboratories* v *Evans Medical* (n 733) 518.

of SKF's patent claims, specifically regarding the interpretation of the patent specifications and the doctrine of equivalent. Notably, there is no defence for public health or human rights.

In the UK, the experimental use exemption[735] allows certain activities to be conducted without infringing patent rights[736], ensuring scientific development is not hindered by patent protections. This exception serves multiple policy objectives, most notably ensuring that the patent monopoly does not inhibit scientific developments.[737] This exemption is particularly significant in biotechnology, as it interacts with 'pure' scientific research conducted within universities and other academic institutions.[738] To invoke this exception, a defendant must demonstrate that the act was carried out for experimental purposes and was directly related to the invention's subject matter.[739]

In *Monsanto Co* v *Stauffer Chemical Co*[740] the court ruled that the UK "experimental use" exemption applies to activities aimed at generating genuinely new information but does not extend to those intended to verify existing knowledge.[741] In this case it was held that field trials carried out in order to discover something unknown, test a hypothesis, find out whether something that is known to work in specific conditions would work in different conditions, or see if the experimenter could manufacture commercially in accordance with the patent could "fairly be regarded as experiments".[742] However, trials conducted solely to demonstrate a product's effectiveness to a third party such as a regulatory body or customer do not qualify as experimental purposes.[743] The critical question in each case is whether the studies or tests are designed to advance scientific knowledge and establish something new. If they meet this criterion, they should be exempt under Section 60(5)(b) of the UK Patent Act[744] provided they relate to the invention's subject matter. According to the *Monsanto* decision, this would cover:

735 Bently *et al*., (n 41) 682. See also Jaenichen and Pitz (n 729) 7.
736 Patents Act 1977, Section 60(5).
737 Patents Act 1977, Section 60(5).
738 Elizabeth A Rowe, 'The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment? (2007) 59(2) Maine Law Review 284. See also Eyal H Barash, 'Experimental Uses, Patents and Scientific Progress' (1997) 91(2) Nw UL Rev 667 (recommending expansion of experimental-use defence for non-profit research).
739 Patents Act 1977, Section 60(5).
740 *Monsanto Co* v *Stauffer Chemical Co.* (1985) RPC 515 [2].
741 *Monsanto Co* v *Stauffer Chemical Co.* (1985) (n 740) 522 [25] and [30].
742 Jaenichen and Pitz (n 729) 7.
743 *Monsanto Co* v *Stauffer Chemical Co.* (1985) (n 740). See also Jaenichen and Pitz (n 729) 7.
744 Patent Act 1977, Section 60(5)(b).

> "Experiments directed to the patented invention as such, experiments such as testing whether a patented product can be made, or a patented article made to work, as described in the patent specification, or experiments to see whether the patented invention can be improved or testing the effect of the modification in some particular to see whether it is an improvement or not. But the limitation would…exclude from the exemption… use of a patented article or process in experiments to test or evaluate some other product or process."[745]

Beyond the experimental use exception, other exceptions are equally crucial, particularly the medical regulatory use defence which provides a safeguard for researchers conducting studies, tests or trials aimed at making medicinal products.[746] This defence was significantly reinforced through a 2014 amendment which expanded protections to clinical trials, field trials, and health technology assessments.[747] The new Section 60(6D)[748] clarifies that activities undertaken for the purposes of obtaining regulatory approval or health technology assessment for drugs fall within the scope of Section 60(5)(b) of Patent Acts 1977.[749] However, this provision does not extend to the commercial use of patented medical products, ensuring that the balance between research freedom and patent protection is maintained.[750]

A well-defined Bolar exemption is crucial for accelerating the availability of generic and biosimilar drugs, reducing healthcare costs and ensuring faster access to affordable treatments. However, continued legal uncertainties such as cross-border regulatory approvals and trials for innovative drugs, suggests that further refinements to the Bolar exemption may still be necessary.

The research exemption allows third parties to use patented inventions for research purposes without infringing on the patent holder's rights.[751] This exemption aims to strike a balance between protecting the IPRs of patent holders and promoting scientific and technological

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[745] *Monsanto Co* v *Stauffer Chemical Co.* (1985) (n 740) 522 [20].
[746] Patents Act 1977, Section 60(5)(i).
[747] Legislative Reform (Patents) Order 2014, cl. 2 introduction new PA 1977, Section 60(6D) -(6G) (with effect, 1 Oct. 2014).
[748] Patent Act 1977, Section 60(D) – F10
[749] Patents Act 1977, Section 60(5)(b).
[750] UK IPO, Changes to patent legislation made by the Legislative Reform (Patents) Order 2014 from 1 October 2014. Bently et al., (n 41) 683.
[751] Stief (n 716) 824.

progress.[752] By enabling the study, analysis and testing of patented technologies under certain conditions, the research exemption helps drive innovation without unduly restricting the patent holder's basic exploitation monopoly.[753]

The exemption is designated to encourage new discoveries and advancements in fields like medicines, technology and engineering, where research is vital to progress. However, the scope and criteria of the research exemption vary across jurisdictions. In some cases, the criteria for its application and the specific activities allowed can differ significantly.[754]

These exceptions play critical roles in advancing medical research and innovation. Allowing researchers to study patented inventions without facing legal barriers fosters innovation and contributes to the broader goal of improving access to medicines. In the context of public health, such defences help strike a balance between the rights of patent holders and the need to ensure that essential medicines remain accessible and affordable. Ultimately, these legal provisions support global health initiatives and promote equitable distribution of treatments, particularly in areas where patent restrictions might otherwise hinder medical advances.

### 4.3.2. Cyprus

Under the Patents Law 1998[755] Cyprus has provisions similar to those in the UK Patents Act 1977. Section 27(3) of the Patents Law 1998[756] states that the patent owner has no right to prevent third parties from performing certain acts without authorization. Specifically, under Section 27(3)(i), if a product has been placed on the market by the patent owner or with their explicit consent, its subsequent use does not constitute patent infringement provided these acts occur after the product's lawful introduction into the Cypriot market.[757]

However, Cyprus also provides exceptions to patent protection, similarly to the UK, including the right of the patent holder to prevent unauthorized use except in cases where the act is

[752] Stief (n 716) 824.
[753] Stief (n 716) 824.
[754] Jaenichen and Pitz (n 729) 7.
[755] Patents Law 16(1)/1998.
[756] Patents Law 16(1)/1998, Section 27(3).
[757] Patents Law 16(1)/1998, Section 27(3)(i).

private and non-commercial, in which case it must not significantly harm the patent holder's economic interest.[758] This exception serves as a safeguard for small-scale, non-commercial use, balancing intellectual property rights with individual freedoms.

A particularly important defence under Cypriot patent law is the exception allowing the use of a patented invention for experimental purposes or scientific research.[759] This provision is especially relevant in pharmaceutical and medicines, as it enables researchers to study, test, and refine medical innovations without infringing patent rights.[760] While this is similar to the UK Patent Act 1977[761] the question arises as to whether Cyprus aligns more closely with EU regulations. EU law broadly upholds research exemptions, particularly under Directive 2001/83/EC[762] (the "Bolar exemption") which allows for testing and regulatory approval activities.

From an IP-SJ perspective, Cyprus seeks to balance innovation incentives with public access, particularly in health-related fields. The research exemption is critical in fostering medical progress and is particularly significant for NCDs. Given the global rise in NCDs ensuring broad research access without patent barriers is essential for developing new treatments. Unlike communicable diseases where patents on vaccines and antiviral treatments often raise urgent access issues, NCDs require sustained long-term research and investment. Thus, the Cypriot legal framework plays a crucial role in facilitating ongoing drug development while maintaining patent protection by allowing research exemptions.

Comparatively, Cyprus adheres to EU norms in balancing patent rights with access considerations whereas the UK's approach, though historically aligned, could evolve differently post-Brexit. Evaluating through an IP-SJ lens, Cyprus' legal stance appears to support innovation without overly restricting access, particularly in the NCD space where continuous pharmaceutical advancements are necessary for public health.

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[758] Patents Law 16(1)/1998, Section 27(3)(ii).
[759] Patents Law 16(1)/1998, Section 27(3)(iii).
[760] Patents Law 16(1)/1998, Section 27(3)(iii).
[761] Patent Act 1977 (n 530).
[762] Directive 2001/83/EC, as amended by 2004/27/EC (n 655).

## 5. TRIPS Waiver

Despite Covid-19 vaccines being the fastest developed in history, global access remained uneven.[763] Access to vaccines and other health technologies was deeply unequal worldwide.[764] Most vaccines approved for use were developed by firms in the United States, Europe, China and Russia, but the Western-made mRNA vaccines such as those by Pfizer-BioNTech and Moderna proved to be the most effective and in highest demand.[765] The wealth of Western nations, along with the geographic distribution of mRNA vaccine production, enabled high-income countries to secure large supplies early in the pandemic, effectively shutting out lower-income nations. This disparity disproportionately affected low and middle-income countries, raising concerns about human rights, particularly the right to health and the right to benefit from scientific advancements as outlined in Article 12 and 15 of the International Covenant on Economic, Social and Cultural Rights.[766] As a result, the relationship between intellectual property rights (IPRs) and public health re-emerged as a major topic of global debate.

Citing this disparity, many developing nations called on the international community to waive TRIPS intellectual property protections for Covid-19 vaccines, arguing that allowing broader production would increase supply and improve global vaccine access. In October 2020 South Africa and India submitted a formal proposal to the WTO seeking a waiver of certain provisions under the TRIPS Agreement. This proposal gained support from over 100 lower-income countries, as well as international organizations like the WHO and various NGOs. However, high-income countries, including the United States, the European Union and Switzerland initially opposed the waiver, arguing that it would undermine innovation, compromise drug quality and discourage investment in pharmaceutical research. It is important to note that this section focuses solely on explaining what the TRIPS waiver is, while the numerous responses from academic and other circles are discussed in Chapter Four.

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[763] Olivier J Wouters *et al.*, 'Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment' 397 (10278) 1023-1034 Health Policy 1023.
[764] Jillian Kohler *et al.,* (n 18) 159.
[765] Wouters *et al.,* (n 763) 1029.
[766] International Covenant on Economic, Social, and Cultural Rights, Article 12 and 15.

Negotiations over the waiver continued for nearly two years, reflecting the deep divide between wealthier and lower-income countries. By June 2022, WTO members finally reached an agreement but by this time, over 12 billion vaccine doses had already been administered globally and high-income countries had already secured sufficient supplies. The final waiver was narrower than originally proposed, applying only to vaccines, with discussions still going about expanding it to treatments and diagnostics.

The waiver was designed as a temporary emergency measure allowing countries to override certain patent restrictions on Covid-19 vaccines without the risk of WTO legal disputes. However, it faced strong opposition from the pharmaceutical industry which argued that patents drive innovation by ensuring that companies can recover their research and development costs. Critics contended that the waiver could discourage future investment in vaccine development and harm voluntary licensing programs such as those established during the pandemic for technology transfers and licensing agreements.

The European Union proposed a compromise, suggesting that instead of a broad suspension of IP rights, voluntary licensing, technology transfer and more flexible patent-sharing mechanisms should be prioritized to expand vaccine access. Meanwhile, organizations like WHO and Médecins Sans Frontières (MSF) strongly supported the waiver, arguing that patents posed significant barriers to public health and that eliminating these barriers was essential in responding to a global crisis.

Ultimately the real issue was not just patents but broader inequalities in global health systems. Within academic discourse, the TRIPS waiver was a pivotal moment in the ongoing debate between intellectual property protection and global public health priorities. Scholars offering diverse perspectives on its effectiveness, scope and long-term implications for the global IP system. The next chapter will then shift to the private interest in patent law.

## 6. Conclusion

As was discussed in this chapter, the international level TRIPS Agreement provides a comprehensive framework for protecting intellectual property rights, including the patenting of new drugs. The TRIPS Agreement offers flexibilities such as compulsory licensing and parallel imports and has been further clarified in the Doha Declaration which highlights the importance of public health over patent rights. Particularly, a variety of mechanisms exist for improving access to affordable generic medicines of assured quality, including compulsory licensing, parallel importation and the WTO's production for export system under Article 31*bis*.[767] The burden in developing countries is made worse by limited access to skilled medical care and to medicines that are easily available to developed countries.[768] However, a key obstacle is the complex intellectual property systems including patents, high medicine prices and data and marketing exclusivity rules which together delay the availability of affordable generic medicines.

While pharmaceutical companies argue that flexibilities like compulsory licensing undermine incentives for innovation, it is essential to balance the public health needs with the protection of intellectual property rights. Indeed, patents play a critical role in providing financial rewards for developing new medicines and excessive weakening of patent protections risks reducing investments in research and development. Without the promise of financial returns, companies may find it less interesting to undertake the costly and uncertain process of developing new medicines. However, public health emergencies such as the Covid-19 pandemic have demonstrated the importance of flexible patent mechanisms like those under the TRIPS waiver proposal. These ensure that life-saving treatments can reach the world's most vulnerable populations without excessively risking incentives for innovation.

Finally, addressing the barrier to access those medicines requires a comprehensive global cooperation. Strengthening healthcare systems is pivotal to developing countries, promoting technology transfer and ensuring the global intellectual property framework evolves to meet both innovation needs and public health priorities. To strike this balance it is important to achieve equitable access to medicines and address the dual burden of communicable and non-communicable diseases on a global scale. Recommendations will be presented in Chapter Five.

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[767] Igbokwe and Tosato (n 610) 49. See also Brook K Baker, 'Process and Issues for Improving Access to Medicines' (2004) DFID Health Systems Resource Centre 24.
[768] Baker (n 767) 24.

For the national levels, the UK patent system is well-developed, offering strong protection for pharmaceutical innovations. Obtaining a patent for a new drug requires indicating that the invention is novel, involves an inventive step and is capable of industrial application. The process aligns with the EPC standards and TRIPS requirements. The system in the UK strongly supports innovation, particularly for multinational pharmaceutical companies, but it also imposes strict timelines and legal barriers for challenging patents or implementing flexibilities such as compulsory licenses. For example, although compulsory licensing is theoretically allowed under the UK law, it is seldom applied in practice, with significant emphasis placed on protecting the commercial interests of patent holders.

In Cyprus, the patent system is similarly aligned with the international level through its incorporation of key international treaties and EU regulations, but it operates within a smaller economic and industrial background. It follows similar procedural requirements to obtain a patent for a new drug as the UK law, but the country's dependence on imported medicines makes the practical relevance of TRIPS flexibilities, such as compulsory licensing or parallel imports, more significant. However, the practical application of these mechanisms remains limited, highlighting the absence of adequate institutional infrastructure to implement them effectively.

The central issue in both countries is the balance between incentivizing through patent protection and ensuring affordable access to essential medicines. While patents provide financial rewards for pharmaceutical companies, they also contribute to the high cost of drugs and delay the availability of generics. It is evident from the Covid-19 pandemic, where global debates over the TRIPS waiver highlighted the barriers that patents pose to equitable access. The UK as a high-income country has less incentive to rely on TRIPS flexibilities, focusing instead on voluntary licensing or fostering innovation through incentives. In contrast, Cyprus as a smaller market, faces greater challenges in accessing affordable medicines and might benefit from more active use of TRIPS flexibilities.

While compulsory licenses have played crucial roles in improving access to medicines for communicable diseases, their potential for addressing the growing burden of NCDs remains underutilized. In the context of NCDs the high cost of essential medications often limits access, particularly in low- and middle-income countries. By expanding the application of compulsory licensing to include NCDs governments could significantly lower the cost of treatment, making life-saving drugs more affordable to the larger population. This expansion could be crucial in addressing the rising incidence of NCDs globally. Chapter Five explores a range of specific recommendations aimed at addressing the rising burden of NCDs, including the potential role of compulsory licenses.

The debate over the TRIPS flexibilities is not consistent for both countries. Particularly for the UK, the focus is less on flexibilities and more on fostering innovation with the framework of strong patent protection, while for Cyprus the flexibilities have better potential to influence discussions over access to medicines, but this requires a stronger institutional capacity and legal framework. Therefore while TRIPS and its flexibilities are critical tools for addressing public health concerns, their practical application in the UK and Cyprus differ significantly due to differences in economic priorities, pharmaceutical markets and legal infrastructure. Addressing the challenges of balancing innovation with public health require both the UK and Cyprus to adapt their policies to their unique context while remaining responsive to global developments in intellectual property law. These debates should also take into account the growing burden on NCDs, the need for equitable access to medicines, and the role of international cooperation in achieving these goals.

Building on these findings, this chapter highlights the need for a more balanced approach, one that supports innovation while prioritizing public health and the right to access affordable medicines. The next chapter will focus on the private interest in patent law, providing a detailed examination of patent rights and their role in the pharmaceutical sector.

## CHAPTER FOUR: PRIVATE INTERESTS IN PATENT LAW

### 1. Introduction

To address the research question, '*To what extent does patent law affect the right to health and access to medicines for non-communicable diseases*', this chapter provides a detailed explanation of patent law and the extent of private interests. It examines the nature and extent of property rights in the pharmaceutical sector with a focus on how patents serve private interest. A significant issue results from the conflict between the interests of the pharmaceutical industry and government objectives. While governments aim to protect public health, pharmaceutical companies often charge high prices for patented drugs, making many essential medicines unaffordable to a large part of the population, which can result in preventable deaths.

This chapter explores the legal frameworks and regulations governing patents at the international, regional, and national levels. At the international level, it examines key agreements that impact patent rights on a global or regional scale, including the Paris Convention for the Protection of Industrial Property[769] and the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[770] At the regional level, the chapter discusses the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC)[771], which harmonize patent rules across member states. Additionally, the regional section considers the roles of the European Patent Office (EPO)[772], the Unified Patent Court (UPC)[773] and the Supplementary Protection Certificates (SPC)[774]. While the UPC

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769 Paris Convention for the Protection of Industrial Property (Signed 20 March 1883, Paris as revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at the Hague on 6 November 1925, at London 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967, and as amended on 28 September 1979) <https://www.wipo.int/treaties/en/ip/paris/> accessed 25 March 2025. (Paris Convention).

770 Junaid Subhan, 'Scrutinized: The TRIPS Agreement and Public Health' (2006) 9 (2) Journal of Medicine 152.

771 European Patent Convention, 'Convention on the Grant of European Patents' (*European Patent Convention* 2024) Available: https://www.epo.org/en/legal/epc/2020/EPC_conv_20240401_en_20240401.pdf

772 European Patent Office (EPO) 'The EPO provides high-quality patents and efficient services that foster innovation, competitiveness and economic growth' <https://www.epo.org/en>accessed 25 March 2025.

773 Unified Patent Court, 'About the Unified Patent Court' (*Unified Patent Court* 2025) <https://www.unified-patent-court.org/en> accessed 25 March 2025.

774 European Commission, 'Supplementary protection certificates for pharmaceutical and plant protection products' <https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en> accessed 25 March 2025.

is not applicable in the UK[775], it is applicable in Cyprus[776] which is within the scope of this thesis. At the national level, the chapter examines patent legislation in the UK and Cyprus, focusing on how patents are granted, protected and enforced in each jurisdiction, with reference to specific cases.

Over time, several different justifications have been given in support of the patent system.[777] Proponents of patent protection have at times highlighted the natural rights of inventors to the products of their mental labour[778], while others believe that fairness requires recognition of an inventor's contribution through the grant of a reward.[779] Although some commentators have occasionally drawn on natural rights to justify the granting of patents, the most prevalent argument focuses on the public benefits derived from patent monopolies.[780] Despite evolving over time, these arguments share the core belief that the public should accept the potential harm caused by granting a patent only if there is a corresponding public benefit. This perspective has significantly influenced discussions on the purpose of the patent system since the nineteenth century.[781]

However, the failure of major intellectual property systems to address critical issues from the unaffordability of patented drugs to the exploitation of marginalized communities' traditional knowledge highlights a significant gap in meeting the needs of the most vulnerable people.[782] As intellectual property continues to play a critical role in everyday life, it is increasingly clear that there is a need for a more socially equitable and responsive theoretical framework.[783] This framework would better align IP protection with its social function and ensure that it serves the broader needs of global society in the context of political and economic inequalities.

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[775] European Parliament, 'The Unified Patent Court after Brexit' (*European Union* 2020). Available: https://www.europarl.europa.eu/RegData/etudes/ATAG/2020/649575/IPOL_ATA(2020)649575_EN.pdf
[776] Unified Patent Court, 'UPC Member States' (Unified Patent Court 2025) (*Unified Patent Court* 2025) <https://www.unified-patent-court.org/en/organisation/upc-member-states> accessed 25 March 2025.
[777] Robert P Merges, *Justifying Intellectual Property* (Harvard University Press, 2011). See also Bently *et al.,* (n 41) 413. See also Victoria C Onyeagbako, 'Justifications for Copyrights and Patent protections' (2020) ssrn doi: 10.2139/ssrn.3596193.
[778] Bently *et al.,* (n 41) 413. See also Fritz Machlup and Edith Penrose, 'The Patent Controversy' (1950) 10 (01) The Journal of Economic History 11.
[779] Machlup and Penrose (n 778) 11.
[780] Bently *et al.,* (n 41) 413.
[781] Bently *et al.,* (n 41) 413.
[782] Lateef Mtima 2024 (n 28) 78.
[783] Lateef Mtima 2024 (n 28) 78.

While several justifications exist for the protection of intellectual property rights[784], this thesis adopts the Intellectual Property and Social Justice (IP-SJ) approach, which explicitly considers social justice principles in its theoretical foundation. The IP-SJ framework calls for a reimaging of patent law and IP policies to account for values such as access, inclusion and empowerment for all individuals impacted by the IP regime.[785] It stresses that intellectual property protection should not simply privilege private interests but should also ensure fair and equitable outcomes for society.[786]

In the context of patents and access to medicines, patent law can affect health outcomes by controlling who can produce, sell and access life-saving medications.[787] Patents grants private rights under the IP law, but these rights are not absolute and must be considered in relation to public health concerns, particularly the right to health.[788] While patents provide exclusivity, preventing others from making, using or selling the patented product without the patent holder's permission, the IP-SJ framework emphasizes that these private rights come with ethical and legal considerations that prioritise social good over unmitigated private control.

This chapter examines private rights in patent law. While the analysis focuses on the doctrinal requirements for patent protection, it is framed through the IP-SJ perspective. This lens highlights how rules designed to incentivise innovation can also create barriers to access, particularly for medicines to public health. From an IP-SJ perspective, patent rights should not undermine access to essential goods such as medicines, especially when they affect health.[789] The exclusive nature of patents can create monopolies that lead to exorbitant prices, thereby restricting access to essential medicines and exacerbating health inequities.[790] The IP-SJ perspective should not only encourage innovation, but also ensure fair distribution of its

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784 For more detailed discussion on various justifications for protecting intellectual property rights See Chapter Introduction: Theoretical Framework.
785 Mtima and Jamar (n 58) 15.
786 Mtima and Jamar (n 58) 15.
787 Brigitte *et al.,* (n 19) 1.
788 Emmanuel Kolawole Oke, 'Incorporating a right to health perspective into the resolution of patent law disputes' (2013) 15(2) Health Hum Rights 97.
789 Mtima 2024 (n 28) 78.
790 Levon M Khachigian, 'Pharmaceutical patents: reconciling the human right to health with the incentive to invent' (2020) 25(7) Drug Discovery Today 1135.

benefits.[791] In addition, the IP-SJ calls for a more nuanced approach where patent rights are balanced with broader social and human rights goals, such as the right to health and the right to access affordable medication.[792] Thus, this chapter examines the specific rules of patent law and the extent of private rights in the pharmaceutical sector, with a particular focus on the conditions for patent protection.

## 2. Protectable subject matter: defining how to get a patent

This section explores the key frameworks and instruments that govern patent protection at the international, regional, and national levels. It examines the influence of international treaties such as the Paris Convention and TRIPS Agreement, as well as regional harmonization efforts through regional agreements like the PCT and EPC. Additionally, it reviews national patent laws in the UK and Cyprus. By analysing these regulations, this section provides a comprehensive understanding of how patent law operates across different jurisdictions.

### 2.1. International

#### 2.1.1. The Paris Convention for the Protection of Industrial Property (1883)

Before the establishment of an international framework for industrial property, securing protection across multiple countries was challenging due to differing national laws.[793] In the nineteenth century, several countries particularly those with strong intellectual property exports, began to explore ways of protecting the rights of their authors, designers, inventors, and trade mark owners. These agreements allowed nationals of one country to claim protection under another's laws.[794]

Towards the late nineteenth century, the need for broader international cooperation led to the adoption of two key multilateral treaties: the Paris Convention for the Protection of Industrial Property of 1883[795] and the Berne Convention for the Protection of Literary and

[791] Mtima 2024 (n 28) 78.
[792] Mtima 2024 (n 28) 78. See also Ellen 't Hoen, 'Private Patents and Public Health' (*Health Action International* 2016) Available: https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf
[793] World Intellectual Property Organization, 'WIPO national seminar on intellectual property' (*World Intellectual Property Organization* 2003) WIPO/IP/CAI/1/03/2.
[794] Bently *et al.,* (n 41) 7.
[795] Paris Convention 1883 (n 769).

Artistic Works of 1886.[796] Both treaties established the principle of 'national treatment', which ensures that foreign nationals receive the same intellectual property protections as domestic citizens. The principle allows countries the autonomy to develop and enforce their own laws[797] while meeting the demands for international protection.[798]

The Paris Convention, the first international agreement dedicated to industrial property, marked a major milestone.[799] One of its key achievements was the national treatment[800] principle requiring member countries to grant the same industrial property protections to foreign nationals as they do to their own citizens.[801] Additionally, the Convention established the priority date principle allowing the inventor to file a patent application in one member state without affecting their right to file in another member state, provided that subsequent applications are filed with a specific time.

The expansion of international arrangements for the protection of intellectual property continued throughout the twentieth century and into the twenty-first.[802] Both Conventions have undergone multiple revisions, with its membership expanding, particularly as former colonies achieved independence and a number of new treaties have been formulated.[803] Most international intellectual property treaties have been developed and administered by the World Intellectual Property Organization (WIPO)[804], headquartered in Geneva and WIPO remains the leading forum for developing and overseeing intellectual property initiatives at the international level.[805]

Over time, efforts to simplify industrial property protection continued, with new mechanisms introduced to reduce administrative burdens, particularly in the patent system. While the

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796 Berne Convention for the Protection of Literary and Artistic Works (signed 9 September 1886, entered into force 5 December 1887).
797 Bently *et al.,* (n 41) 8.
798 Sam Ricketson (n 83) 128. See also Bently *et al.,* (n 41) 8.
799 Paris Convention for the Protection of Industrial Property (n 769).
800 Bently *et al.,* (n 41) 7.
801 Paris Convention 1883, Article 2 ('National Treatments for Nationals of Countries of the Union').
802 Peter Drahos, 'The universality of intellectual property rights: origins and development' (1999) Intellectual Property and Human Rights. Geneva: World Intellectual Property Organization 13, 13-41.
803 Bently *et al.,* (n 41) 8.
804 WIPO, 'About WIPO' <https://www.wipo.int/about-wipo/en/> accessed 25 March 2025.
805 Sam Ricketson (n 83)

Paris Convention introduced essential principles for industrial property protection[806], the growing complexities of international trade and technological advancements in the twentieth century highlighted the need for a more robust and enforceable framework, which eventually led to the development of the TRIPS Agreement under the World Trade Organization (WTO).[807] The following section will further elaborate on these principles and their impact on international industrial property protection.

### 2.1.2. World Trade Organization (WTO) and the TRIPS Agreement

International agreements play a critical role in establishing consistent standards for patent rights across borders, allowing inventors to protect their innovations globally and promoting fair competition.[808] The World Trade Organization (WTO) serves as the legal and institutional foundations for its 164 member countries,[809] succeeding the General Agreement on Tariffs and Trade (GATT), a multilateral trade agreement established in 1947.[810] The WTO aims to promote equal and balanced international trade, that elevates living standards worldwide.

One of the WTO key agreements, the Trade-Related Aspects of Intellectual Property Protection (TRIPS) Agreement[811] signed in Marrakesh in April 1994 and came into force in 1995.[812] As the first major agreement to formally introduced the concept of 'intellectual property' TRIPS has played a critical role in placing the concept of intellectual property at the forefront of policymaking, while establishing essential protections for patents.[813]

The TRIPS Agreement has had an important effect on the general development of intellectual property law since it came into force on 1 January 1995.[814] The Agreement sets minimum standards for intellectual property protection, while allowing countries to provide additional

806 Paris Convention for the Protection of Industrial Property 1883 (n 769) 128.
807 Bently *et al.,* (n 41) 9.
808 Stephen Ezell and Nigel Cory, 'The way forward for Intellectual Property Internationally' (*Information Technology & Innovation Foundation* 2019) 18. Available: https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally/
809 For details about WTO See Chapter Four on International subsection 2.1.2 ('World Trade Organization (WTO) and the TRIPS Agreement').
810 General Agreement on Tariffs and Trade (GATT 1947).
811 Gervais (n 93) 55. Daniel Gervais analysing the life of TRIPS Agreement.
812 TRIPS Agreement (n 63). See also Gervais (n 93) 55.
813 Gervais (n 93) 55, 56.
814 TRIPS Agreement (n 63). See also Bently *et al.,* (n 41) 9.

protection if they wish.[815] For instance, with the entry of the TRIPS Agreement in 1995, patent protection for drug compounds became a new global standard.[816] While this change was beneficial for inventors and pharmaceutical companies, it also created tensions for countries that previously produced generic medicines but were restricted from doing so under the new rules.

Furthermore, the Agreement is the first major agreement to introduce the concept of 'intellectual property' as a defining element of its scope, and it has been pivotal in elevating intellectual property to a central focus in policy discussions.[817] It outlines 'intellectual property' by referencing the rights explicitly stated or those indirectly included through provisions that require WTO members to recognize the existing standards of protection within the Berne and Paris Convention.[818] While TRIPS stands as the most significant development in international intellectual property law over the past four decades[819], it has not diminished WIPO's role. On the contrary, WIPO continues to shape the field through new intellectual property treaties and initiatives.[820] Other WIPO initiatives, particularly in relation to traditional knowledge and standardization of patent law, will continue to play a significant role in intellectual property law.[821]

The TRIPS Agreement introduces a shift from the provisions in the Paris Convention.[822] Prior to 1995, patentability standards for pharmaceutical inventions varied. Before TRIPS some countries did not grant patents for pharmaceuticals, which meant allowing them to freely manufacture and distribute cheaper generic versions of drugs.[823] However, with enforcement of the TRIPS Agreement the situation changed. Under Article 27(1)[824], patents must be

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[815] TRIPS Agreement (n 63). Gervais (n 93) 429.
[816] Gervais (n 93) 429.
[817] Gervais (n 93) 429 subsection 3.385.
[818] Gervais (n 93) 429 subsection 3.385.
[819] Gervais (n 93) 429. See also Bently *et al.,* (n 41) 11.
[820] This included the 1966 WIPO Copyright Treaty, the 1966 WIPO Performances and Phonograms Treaty. The Beijing Treaty on Audiovisual Performances, the Marrakesh Treaty for the Visually Impaired, and the revised Geneva Act of Lisbon Treaty on Appellations of Origin.
[821] Bently *et al.,* (n 41) 9.
[822] Gervais (n 93) 443 subsection 3.400. TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or process, in fields of technology without discrimination.
[823] Gervais (n 93) 40. The transition from the Paris Convention to TRIPS was enormous.
[824] TRIPS Agreement, Article 27(1). See also Gervais (n 93) 429 and 443 subsection 3.400. TRIPS Article 27, which is cast in terms of non-discrimination, should be interpreted to permit 'differential treatment'.

available for any invention, whether products or a process, in all fields of technology.[825] Members had to grant patents in all fields of technology including pharmaceuticals[826], as a result making harder for countries to produce generic versions before the 20-year patent expiry.[827]

Article 27 of the TRIPS Agreement[828] establishes new international rules on patentable subject matter, setting the criteria for patentability. It ensures that an invention meeting the requirements of novelty, inventive step and industrial applicability is eligible for protection.[829] If an application fails to meet any one of the criteria, a patent will not be granted. If a patent has already been granted but later found to violate these criteria, it may be revoked.[830] In addition, under Article 27(1) of TRIPS patents shall be available and patent rights enjoyable without discrimination.[831] Specifically, the Article 27(1) states that 'patents shall be available and patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.'[832]

Therefore, TRIPS expanded and tightened the rules around patents, including for pharmaceuticals, impacting countries' ability to produce or access affordable generic drugs as they could before.[833] All member countries are required to provide patents protection for inventions that meet the requirements regardless of the industry from which they originate. This means that even if a pharmaceutical product is imported from another country, its patent rights should still be recognized and enforced in the importing country.

Beyond international treaties such as the Paris Convention and TRIPS Agreement, regional frameworks also play a crucial role in patent law. The following section examine mechanisms that streamline patent applications across multiple jurisdictions, ensuring greater consistency in patent protection.

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[825] TRIPS Agreement, Article 27(1). See also Gervais (n 93) 429 subsection 3.385.
[826] Gervais (n 93) 56, section 2.02.
[827] On the history and negotiations process proceedings the singing of TRIPS Duncan Matthews, *Globalising Intellectual Property. The TRIPS Agreement* (Routledge, 2002) 216.
[828] Gervais (n 93) 429 subsection 3.385. Article 27 TRIPS Agreement. See also Matthews (n 827) 216.
[829] Gervais (n 93) 429 subsection 3.385. For Article 27(2) see Gervais (n 93) 429 subsection 3.385.
[830] Bently *et al.,* (n 41) 467.
[831] TRIPS Agreement, Article 27(1). See also Gervais (n 93) 429 subsection 3.385.
[832] Gervais (n 93) 429 subsection 3.385.
[833] Matthews (n 827) 216.

### 2.2. Regional Framework

While the patent system operates on a global scale through frameworks such as the Patent Cooperation Treaty (PCT), the EU has developed its own regional mechanisms to facilitate patent protection.[834] Several European initiatives such as the European Patent Convention (EPC) operate independently of the European Union and are therefore unaffected by Brexit.[835] The European patent system is built on three main elements: the European Patent Convention (EPC) which establishes a unified procedure for granting patents[836], the European Patent Office[837] which serves a central body for patent examination and grant, and the Unified Patent Court (UPC)[838] which provides a unified judicial system for handling patent disputes across participating member states. This section will also discuss the SPC which was introduced by the European Union to extend the protection of patented pharmaceutical beyond the standards of the 20-year patent term.[839]

#### 2.2.1. Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty (PCT) was signed in 1970[840] and came into operation since 1978.[841] It is administered by the World Intellectual Property Organization[842] and it offers a system for international patent applications and early examination. With 158 contracting states, the PCT allows applicants to file a single international application and receive an international search and preliminary examination.[843] However, the final decision to grant a

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834 WIPO, 'The PCT now has 158 Contracting States' <https://www.wipo.int/pct/en/pct_contracting_states.html> accessed 25 March 2025. The European Union has established a regional mechanism for patent protection through the European Patent Convention (EPC), which provides a centralized application process for patent protection in multiple countries. Countries such as Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Montenegro, Netherland, North Macedonia, Norway, Poland, Portogul, Republic of Moldova, Romania, San Marino, Serbia, Sweden, Switzerland, Turkey, United Kingdom (No longer an EU member but remains an EPC member), Bosnia and Herzegovina.

835 Bently *et al.,* (n 41) 416.

836 The European Patent Convention (EPC), signed in Munich in October 1973. See Bently *et al.,* (n 41) 416.

837 European Patent Office (EPO) provides high-quality patents and efficient services that fosters innovation, competitiveness and economic growth. See Bently *et al.,* (n 41) 416.

838 Bently *et al.,* (n 41) 425.

839 European Parliament, 'Revision of the Supplementary Protection Certificate Regulations for medicinal and plant protection products' (*European Union* 2023) 1. Available: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/740258/EPRS_BRI(2023)740258_EN.pdf

840 Bently *et al.,* (n 41) 426

841 Bently *et al.,* (n 41) 426.

842 WIPO, 'Patent Cooperation Treaty (PCT)' <https://www.wipo.int/treaties/en/registration/pct/> accessed 25 March 2025.

843 WIPO, 'The PCT now has 158 Contracting States' <https://www.wipo.int/pct/en/pct_contracting_states.html> accessed 25 March 2025.

patent remains with the national patent offices[844] which can use the international search and examination findings to guide their decisions. The centralized procedure is particularly useful for countries where the patent office is not capable of carrying out its own examination. One key benefit of the PCT is the reduction of fees payable and extended time, usually at least 18 months[845], between the initial international application and its submission to national offices. This extra time allows applicants to assess whether the invention is likely to be successful enough to warrant the translation costs that arise when the application is transferred to the national offices.[846]

The PCT plays a crucial role in improving access to medicines for NCDs by facilitating the international patenting process for medical innovations. By allowing inventors to file a single international application, the PCT enables them to cover multiple jurisdictions with one filing, helping to ensure that new treatments or technologies are protected in a wide range of markets.[847] This is particularly important for NCDs, which require global access due to their widespread impact on health.

Additionally, innovating in the field of NCD often involves high costs, especially in the R&D. The PCT system helps manage these expenses by offering a cost-effective way to delay significant costs such as translation and national filing fees. The additional 18 months before national filings are due provides applicants with the opportunity to evaluate the commercial viability of the invention, making it easier for innovators especially those from resource constrained settings to make informed decisions.[848]

Another significant way the PCT supports NCD innovations is through facilitating technology transfer, which is crucial for improving access to medical innovation in low-and middle-income countries. By allowing inventors to establish patent rights internationally, the PCT can help

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[844] World Intellectual Property Organization, 'Protecting your inventions abroad: Frequently asked questions about the Patent Cooperation Treaty (PCT) (*WIPO Publication* No. 433E, April 2006) 12. Available: https://innovation.ox.ac.uk/wp-content/uploads/2019/05/faqs_about_the_pct1.pdf

[845] Bently *et al*., (n 41) 426.

[846] World Intellectual Property Organization, 'Protecting your inventions abroad: Frequently asked questions about the Patent Cooperation Treaty (PCT) (n 844).

[847] World Intellectual Property Organization, 'Protecting your inventions abroad: Frequently asked questions about the Patent Cooperation Treaty (PCT) (n 844).

[848] Bently *et al.,* (n 41) 426.

attract global partnerships that are necessary for scaling up production and distribution of NCD related medicines in varied regions. Moreover, the PCT allows licensing agreements that make medicines more affordable or accessible which can help bridge the gap in healthcare access for underserved populations.[849]

Despite its benefits, the PCT provides an efficient mechanism for applicants seeking patent protection in multiple jurisdictions through a single international application. This system is particularly relevant in the context of essential medicines for NCDs, as widespread patent filings can affect how treatments are distributed globally. This issue is especially important in developing countries, where the cost of patented medicines can often be prohibitive. The debate about how to balance innovation incentives with public health needs is ongoing. For countries such as Cyprus, extending a PCT international application requires validation through a European Patent system[850], further highlighting the diverse ways in which the PCT interacts with national and regional patent system to ensure protection across borders.

### 2.2.2. European Patent Convention (EPC) and the European Patent Office (EPO)

The European Patent Convention (EPC) was established as an intergovernmental treaty in Munich in 1973 and came into effect on 7 October 1977.[851] It provides a unified framework for granting European patents across multiple jurisdictions. Initially, it was based on the existing patent laws of member states and was separate from the European Union, allowing non-EU countries to participate. In 2022, the EPC had 39 member states.[852]

The European Patent Office (EPO) headquarters are located in Munich, Germany, created to administer the EPC by providing a centralized patent application and granting process. Rather than applying separately in multiple European countries, applicants could submit a single

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849 Bently *et al.,* (n 41) 426.

850 Maria Kyriacou and Ramona Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016). Available: https://www.neocleous.com/publications/download/manual-of-industrial-property.pdf

851 European Patent Office, 'Legal foundations' <https://www.epo.org/en/about-us/foundation/legal-foundations> accessed 25 March 2025. Bently *et al.,* (n 41) 417.

852 As of 1 January 2022, the 38 members were Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, former Yugoslav Republic of Macedonia, Malta, Monaco, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tukey, and the United Kingdom. In addition, there are two extension states: Bosnia and Herzegovina, and Montenegro, and four validation states: Cambodia, Republic of Moldova, Morocco, and Tunisia (these are countries where a European patent can be validated). See also Bently *et al.,* (n 41) 416.

application to the EPO which would then result in a bundle of national patents enforceable in participating states. Legal issues of broader significance could be referred to the Enlarged Board of Appeal (EBA).[853]

A key principle behind the EPC was the harmonization of core patentability standards among member states to ensure consistency in patent granting.[854] However, while the EPC governs validity and examination, enforcement, infringement disputes, and revocation remain subject to national laws, leading to potential inconsistencies in how a granted patent is interpreted across jurisdictions.[855] Efforts to minimize such problems include annual meetings between EPO examiners and national judges, as well as the Protocol on the Interpretation of Article 69 of the EPC.[856] This Article will be examined later in this chapter.

By the 1990s, advancements in technology and shifts in legal and political landscapes led to demands for updating the EPC.[857] In response, a conference in Munich in 2000 initiated a modernization effort, culminating in the adoption of the EPC 2000 which replaced the original EPC 1973 on 13 December 2007.[858] The revised Convention aligned with international agreements such as TRIPS and considered future developments like the Community patent and regulations concerning biotechnological inventions.[859]

During the formulation of the EPC, it was decided that for there to be an effective single granting process, it was necessary for member states to harmonize the basic rules of patent law.[860] This was particularly the case in relation to the rules of patentability and validity. Lord Walker, spoke of the 'importance of UK patent law aligning itself, so far as possible, with the

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[853] Birs *et al., Terrell on the Law of Patents* (18th edn, Sweet & Maxwell, 2016) 1, 1-8. See also Bently *et al.,* (n 41) 417.
[854] Bently *et al.,* (n 41) 417.
[855] European Patent Office, 'European Patent Convention' <https://www.epo.org/en/legal/epc> accessed 25 March 2025. See also Bently *et al.,* (n 41) 417.
[856] Protocol on the Interpretation of Article 69 European Patent Convention (EPC) 2000.
[857] Bently *et al.,* (n 41) 418.
[858] European Patent Office, 'Notice from the European Patent Office dated 20 September 2007 on implementation of the transitional provisions of the EPC 2000 applicable during the transition from the EPC 1973 to the EPC 2000' Official Journal EPO 10/2007 504. Available: https://www.epo.org/xx/legal/official-journal/2007/10/p504/2007-p504.pdf
[859] Rule 27 Patentable biotechnological inventions EPC 2000. European Patent Office 'Examination in the field of biotechnology at the EPO – PART I' 9. Available: https://www.wipo.int/edocs/mdocs/pct/en/wipo_ip_mnl_19/wipo_ip_mnl_19_t8.pdf See also Bently *et al.,* (n 41) 418.
[860] European Patent Office, 'European Patent Convention' (n 858). See also Bently *et al.,* (n 41) 417.

jurisprudence of the EPO (especially decisions of the EBA').[861] Jacob LJ took this one step further when he said that the Court of Appeal could, but was not bound to, depart from its own precedent if there was a 'settled view' of European patent law at the EPO that was inconsistent with earlier Court of Appeal decisions. [862] While in some areas such as patentable subject matter and inventive steps, the UK approach differs from that at the EPO, in other areas such as sufficiency and novelty, they are very similar.

The UK and the EPO have different approaches to determining the patentable subject matter, particularly regarding inventive step. The UK applies the structured Windsurfing/Pozzoli test, which involves identifying the inventive concept, the relevant common general knowledge, and assessing whether the invention would have been obvious to a skilled person.[863] In contrast, the EPO uses the Problem-Solution Approach, which starts by identifying the closest prior art, the objective technical problem, and assessing whether the claimed invention would have been obvious.[864] These different approached can lead to different outcomes in the grant of pharmaceutical patents, which is significant when evaluating the protection of medicines for NCDs. A drug that may be deemed obvious under one test could still succeed under the other, potentially influencing access depending on jurisdiction.

With regard to novelty, both the UK and the EPO apply an absolute novelty standard, requiring that any public disclosure anywhere in the world before the filing date will destroy novelty. This is particularly relevant in the context of second medical use claims, common in the pharmaceutical industry where an existing drug is patented for a new therapeutic use. While second medical use claims can drive innovation, they can also be used strategically to extend market exclusivity, affecting the timely availability of cheaper generics versions. These issues are directly relevant to this thesis, as they impact how patent law interacts with access to essential medicines for non-communicable diseases. These aspects will be discussed in more detail in the following sections.

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[861] *Generics (UK)* v H *Lundbeck* [2009] UKHL 12, [2009] RPC (13) 407, [35]. See also *Conor Medysystems* v *Angiotech Pharmaceuticals* [2008] UKHL 49, [2008] RPC (28) 716, [3]; *Human Genome Sciences* v *Eli Lilly & Co* [2011] UKSC 51, [2012] RPC (6) 102, [83]-[95].

[862] *Actavis UK* v *Merck* [2008] EWCA Civ 444, [2008] RPC (26) 631, [107].

[863] Bently *et al.,* (n 41) 594.

[864] Bently *et al.,* (n 41) 594.

### 2.2.3. Supplementary protection certificate (SPCs)

Supplementary protection certificates (SPCs) are a complex area of patent law that first saw intervention from the European Union, particularly regarding the duration of patent protection.[865] With delays in regulatory approval for products like pharmaceuticals, patent holders argued that the effective time to exploit their patents was shorter than the intended 20-year period.[866] To address this, the EU introduced the SPC which extends patent protection if the patent holder was not able to fully utilize their rights due to regulatory delays.[867]

SPCs specifically aim to compensate the owner where they have not been able to market the patent product because of delays in seeking regulatory approval.[868] This extension can last up to five years, and in some cases, up to five and a half years.[869] Notably, an SPC is considered a distinct right from the original patent, so it does not conflict with the maximum term set by the European Patent Convention (EPC 2000). In 1995, a challenge from the Spanish government against the regime was dismissed by the Court of Justice.[870] The UK also implemented a similar SPC system which continues even after Brexit.[871]

SPCs are directly relevant to this thesis because they exemplify how intellectual property rules can restrict access to medicines, a central concern of the IP-SJ approach. From an IP-SJ perspective, SPCs extend patent monopolies beyond the standard term, delaying the entry of affordable generics and keeping prices high. This is especially problematic for NCDs, which

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[865] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

[866] Term of protection which shall not end before the expiration of a period of twenty years counted from the filing date, Article 33 of TRIPS Agreement. See also Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

[867] European Parliament, 'Revision of the Supplementary Protection Certificate Regulations for medicinal and plant protection products' 6 (n 839). See also Bently *et al.,* (n 41) 422.

[868] European Parliament, 'Revision of the Supplementary Protection Certificate Regulations for medicinal and plant protection products' 6 (n 839). See also Bently *et al.,* (n 41) 423.

[869] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. See also Birka Lehmann, 'Regulation (EC) no 1901/2006 on medicinal products for paediatric use & clinical research in vulnerable populations (2008) 2(37) Child Adolesc Psychiatry Ment Health 3.

[870] This was on the grounds that the Community as it then did not have competence to legislate a new patent right and that intervention could not be justified by reference to the need to harmonize laws for the internal market. Specific case C-350/92 *Spain* v *Council of the European Union* [1995] ECR I-1985.

[871] Bently *et al*., (n 41) 724. For SPC applications filed after 1 January 2021, applicants require a UK patent granted by either the EPO or the UK IPO, as was the case under the EU regime. They must also have a marketing authorization valid in the United Kingdom granted by either the UK Medicines and Healthcare Products Regulatory Agency or the EU European Medicines Agency.

require long-term treatments and place heavy financial pressures on patients and health systems. By prolonging exclusivity, SPCs risk worsening existing health inequities, particularly in lower-income settings where access to life-saving medicines is already limited. In this way, SPCs illustrate the tension between rewarding innovation and upholding the IP-SJ principles of inclusion, access, and empowerment that underpin this thesis.

The Court of Justice of the European Union (CJEU) adopted a restrictive approach to the SPCs, holding that an SPC could only be granted for a product that is protected by a basic patent, has undergone the process of regulatory authorization and has not been marketed before such authorization.[872] However, on 19 July 2012, the CJEU issued a landmark ruling in the *Neurim Pharmaceuticals*[873] which broadened the scope of SPC eligibility by allowing SPCs for new therapeutic applications of previously authorized active ingredients under certain conditions.[874]

The court ruled that a prior marketing authorization for a pharmaceutical product intended for veterinary use does not prevent the granting of an SPC for a different use of the same product for which a marketing authorization was granted, provided that this new use is within the scope of the basic patent which was relied upon for the SPC application.[875]

In a recent decision issued on 19 December, 2024[876] the CJEU addressed two joint cases, C-119/22 and C-149/22, providing clarification on the interpretation of Article 3 of the EU Regulation No.469/2009 concerning Supplementary Protection Certificates (SPCs).[877] The central issue was whether an SPC could be granted for a combination of two active ingredients when one ingredient was already protected by an existing SPC and the other was part of the prior art.[878]

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[872] C-195/09 *Synthon BV* v *Merz Pharma GmbH & Co KG* [2011] ECR 1-7011. See also CJEU, C-427/09 *Generics (UK)* v *Synaptech* [2011] ECR 1-7099.
[873] C-130/11 *Neurim Pharmaceuticals (2012) ECLI:EU:C:2012:489.*
[874] C-130/11 *Neurim Pharmaceuticals* (n 873) [2].
[875] EU Regulation No. 469/2009 (n 865) Article 13(1) 'Duration of the certificate'.
[876] C-119/22 *Teva BV and Teva Finland Oy* v *Merck Sharp & Dohme LLC* [2023] ECLI:EU:C:2023 and C-149/22 *Merck Sharp & Dohme Corp* v *Clonmel Healthcare Limited* [2023] ECLI:EU:C:2023.
[877] EU Regulation No. 469/2009 (n 865) Article 3 'Conditions for Obtaining a certificate.'
[878] *Merck Sharp & Dohme Corp* v *Clonmel Healthcare Limited* (n 876). See also Bently *et al.,* (n 41) 422 section on Supplementary Protection Certificates.

The cases involved two combination drugs where one active ingredient had an existing SPC, and the other one was a known compound. In the first case, C-199/22 involved *Merck's* diabetes medication, Janumet, which combines sitagliptin and metformin. *Merck* held a patent (EP 1412357) covering sitagliptin alone and in combination with metformin, a well-known compound. *Merck* had an existing SPC for sitagliptin (marketed as Januvia). *Teva* challenged the SPC for Janumet, arguing that it violated Article 3(c) of the SPC for the same product.[879] *Teva* also contended that the combination did not meet the requirements of Article 3(a) as the patent did not specifically protect the combination of sitagliptin and metformin.[880] *Merck* argued that Article 3(c) allows multiple SPCs for the same active ingredient if the subsequent product differs from the first.[881]

In the second case, *Merck Sharp & Dohme*[882]*,* the case concerned *Merck's* cholesterol lowering drug, Inegy, combining ezetimibe and simvastatin. *Merck's* patent (EP 0720599) covered ezetimibe alone and its combinations with statins, including simvastatin, which was already known. *Merck* had an existing SPC for ezetimibe (marketed as Ezetrol). *Clonmel* challenged the SPC for Inegy, asserting that the combination product was not protected by the basic patent under Article 3(a)[883] and that granting a second SPC violated Article 3(c).

Despite the differences in patent scope and arguments, both cases raised a broader legal question of whether an SPC can be granted for a combination drug when one compound is already protected and the other is prior art. The CJEU emphasized that the term 'product' must be interpreted consistently across all requirements in Article 3(a)[884] and Articl3 (c)[885] of the SPC Regulation.[886] Specifically, "product" must be understood according to its definition in Article 1(b)[887] of the SPC Regulation, which defines products as the active ingredients or combinations of active ingredients.[888] The Court stresses that the interpretation of "product"

[879] EU Regulation No. 469/2009 (n 865) Article 3(c) the product has not already been the subject of a certificate.
[880] EU Regulation No. 469/2009 (n 865) Article 3(a) the product is protected by a basic patent in force.
[881] EU Regulation No. 469/2009 (n 865) and (n 879) for Article 3(c).
[882] C-119/22 (n 876) and C-149/22 (876).
[883] C-121/17 *Teva UK Ltd and Others* v *Gilead Sciences Inc* [2018] ECLI:EU:C:2018:585.
[884] EU Regulation No. 469/2009 (n 865) and (n 880) for Article 3(a).
[885] EU Regulation No. 469/2009 (n 865) and (n 879) for Article 3(c).
[886] EU Regulation No. 469/2009 (n 865).
[887] EU Regulation No. 469/2009 Article 1(b) 'product means the active ingredient or combination of active ingredients of a medicinal product.
[888] EU Regulation No. 469/2009 (n 865).

must remain consistent. It also clarified that the criteria for Article 3(a)[889] such as whether an active ingredient is protected by the basic patent are irrelevant when assessing compliance with Article 3(c).[890] These are separate legal considerations. Additionally, the CJEU clarified a key procedural aspect that the assessment of an SPC for a combination product should be based solely on the specific provisions of the SPC Regulation (Article 1(b) and 3(c)) without considering the examination criteria of the basic patent.[891]

Additionally, the decision revisited the "Teva test" from the earlier *Teva* v *Gilead*[892] case, which provides guidance on whether a product is a considered protected by a basic patent under Article 3(a).[893] However, the CJEU clarified that the Teva test does not apply when determining compliance with Article 3(c).[894]

This ruling is significant as it provides guidance on the eligibility of combination products for SPCs, especially when one compound is already protected or known, impacting pharmaceutical patent strategies and the scope of supplementary protection in the EU. Therefore, the CJEU's decision on SPC for combination drugs could have significant implications for access to medicines for NCDs, particularly due to the potential extension of market exclusivity and delayed entry of generics. By allowing SPCs for drug combinations where one compound is already known, pharmaceutical companies may effectively prolong their monopolies, keeping drug prices high and limiting affordability, especially for patients in low-and middle-income countries. This practice, often referred to as "evergreening"[895], can lead to extended patent protection without necessarily representing a breakthrough

889 EU Regulation No. 469/2009 (n 865) and (n 880) for Article 3(a).
890 EU Regulation No. 469/2009 (n 865) and (n 879) for Article 3(c).
891 EU Regulation No. 469/2009 (n 865) and (n 879) for Article 3(c) and (n 887) for Article 1(b).
892 *Teva UK Ltd and Others* v *Gilead Sciences Inc* (n 883) [3].
893 EU Regulation No. 469/2009 (n 865) and (n 880) for Article 3(a). See also *Teva UK Ltd and Others* v *Gilead Sciences Inc* (n 883) 3.
894 EU Regulation No. 469/2009 (n 865) and (n 879) for Article 3(c).
895 Evergreening generally refers to the extension of the duration of an existing temporary monopolistic or market dominant position. Scholars have written on evergreening such as Ove Granstrand and Frank Tietze, 'IP strategies and policies for and against evergreening' (*Centre for Technology Management working paper series* No. 1 2015) 2. Available: https://www.ifm.eng.cam.ac.uk/uploads/Research/CTM/working_paper/2015_01_Granstrand_Tietze.pdf. See also Ali A Alkhafaji *et al.,* 'Impact of evergreening on patients and health insurance: a meta analysis and reimbursement cost analysis of citalopram/escitalopram antidepressants' (2012) 10 (142) BMC Medicine 1. Scholar Ali defines the evergreening as a practice that allows owners of pharmaceutical products using several strategies, such as patent laws and minor drug modifications, to extend their monopoly privileges on the drug. See also Roger Collier, 'Drug patents the evergreening problem' (2013) 185(9) CMAJ 385 (defining evergreening as a practice in the pharmaceutical industry where brand-name companies patent slight modifications of existing drugs and present them as new inventions. This strategy is primarily used to extend market exclusivity and maintain revenue streams, often without offering significant therapeutic improvements).

innovation, making it harder for healthcare systems to provide cost effective treatments. Given that many NCDs require lifelong medication such as diabetes, cardiovascular diseases, and cancer, the prolonged exclusivity of combination therapies could place a significant financial burden on both patients and public health programs. While intellectual protection is critical for incentivizing pharmaceutical innovation, excessive delays in generic competition can hinder equitable access to essential medicines, highlighting the need for a balanced approach in SPC regulation.

Another case from the CJEU concerning SPCs for medicinal products is the *Actavis Group PTC EHF* v *Sanofi.*[896] The case addressed whether *Sanofi* could obtain an SPC for a combination product (CoAprovel) when an SPC had already been granted for the core patented ingredient. The CJEU ruled that a second SPC for the combination product was not allowed if the first SPC already covered the core innovation.[897] The validity of the SPC for CoAprovel which was a combination of drugs was challenged by *Actavis*, arguing that an SPC was invalid because it covered a combination of active ingredients that did not correspond to a new active ingredient protected by the initial patent. The CJEU ruled that SPCs should not be granted for combination products if the initial patent already covers the core ingredient and a prior SPC has been granted.[898] Thus this case is relevant to patent law and access to medicines because it balances patent exclusivity with ensuring access to affordable medicines, particularly in the case of NCDs. The ruling prevents the extension of exclusivity beyond what the original patent covers.

## 3. National Framework

This section examines patent legislation in the UK and Cyprus, focusing on how patents are granted, protected, and enforced for each jurisdiction. In the UK, the Patent Act 1977[899] serves as the primary legal framework for patent protection, aligning with international agreements such as TRIPS and the European Patent Convention (EPC). In addition in the UK patents can be

[896] *Actavis Group PTC* EHF & Anor v *Sanofi Pharma Bristol-Myers Squibb SNC* [2012] EWHC 2545 (Pat), [2013] RPC 24.
[897] *Actavis Group PTC* v *Sanofi* (n 896) [59].
[898] *Actavis Group PTC* v *Sanofi* (n 896) [73].
[899] Patent Act 1977 (as amended).

granted by two authorities: the UK Intellectual Property Office and the European Patent Office (EPO).[900]

In Cyprus patent law follows a similar structure closely to the UK's, reflecting the EPC, with the Cyprus Department of Registrar of Companies and Official Receiver monitoring patent fillings and granting.[901] Therefore, this section examines the criteria required for a patent to be granted: the invention must be novel, involve an inventive step, and be capable of industrial application. This analysis will first cover the UK, followed by Cyprus.

### 3.1. UK patent provisions of the Patent Act 1977

The Patent Act 1997 is the main legislation for patent protection in the UK, setting out the essential provisions for both the granting and enforcement of patents. Based on the European Patent Convention (EPC), the 1977 Act introduced a range of significant changes to British patent law both substantively and procedurally.[902] The provisions of the Act are aligned with the EPC and the Act stipulates that these provisions should be interpreted in a way that aligns with the EPC and the decisions made under it.[903] The Patent Act 1977 covers important aspects of patent law, including patent eligibility criteria, requirements for obtaining a patent and the rights granted to patent holders. As such, it is crucial to examine the specific provisions of the Act that govern the application and enforcement of patents in the UK.

#### 3.1.1. Inventor

The term inventor under section 13 of the Patent Act 1977[904] is generally regarded as the person who made the invention, the individual who created the new idea and innovative concept that is being patented.[905] As illustrated in the case of *Thaler* v *Comptroller – General of Patents, Designs and Trademarks* (2021),[906] the UK Supreme Court addressed the legal questions of whether an artificial intelligence (AI) system can be named as the inventor on a

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900 Bently *et al.,* (n 41) 447.
901 The Patents Law 16(1)/1988.
902 Bently *et al.,* (n 41) 421.
903 Bently *et al.,* (n 41) 421.
904 Patent Act 1977, Section 13.
905 Patent Act 1977, Section 13.
906 *Thaler* v *Comptroller – General of Patents, Designs and Trademarks* [2023] UKSC 49.

patent application. This case concerns two British patent applications for two inventions that the appellant Dr. Stephen Thaler claimed were applications created by an AI system known as DABUS in the absence of a traditional human inventor. The UK Intellectual Property Office (UKIPO) rejected these applications, asserting that a non-human entity cannot be designated as an inventor under the Patent Act 1977. The statement of inventorship was held not to satisfy section 13(2) of the Patent Act 1977[907] which requires that inventors must be natural persons.[908]

The *Thaler* case has important implications for patent law, particularly in fields like medicines and the development of treatments for NCDs. As AI systems become increasingly involved in the invention process, this could impact the way inventions in fields such as pharmaceuticals, medical technologies and specifically treatments for NCDs are patented. AI is now frequently used in drug discovery to identify promising compounds, optimise molecular structures, and even repurpose existing drugs all of which can accelerate the development of therapies for non-communicable diseases. The role of AI in creating innovative solutions for NCDs such as cancer, cardiovascular diseases, or diabetes, has grown substantially. Nevertheless, based on the Thaler case, even if an AI is generating a significant part of the innovation, it cannot be named as an inventor. Instead, the inventor must still be a human under the Patent Act 1977.

From an IP-SJ perspective, this raises important questions about who owns and controls AI-created inventions in healthcare. If AI can help find important new treatments, but only a few people or companies control the results, it could make it harder for others to access those medicines. Making sure that AI-driven medical discoveries are shared fairly is important for improving global health and equity.

### 3.1.2. Subject matter, capable of patent protection

This section examines the subject matter eligible for patent protection as regulated under the Patent Act 1977.[909] More specifically, it will discuss the criteria required for a patent to be granted.

[907] Patent Act 1977, Section 13(2).
[908] *Thaler* v *Comptroller* (n 906) [56-59].
[909] Bently *et al.,* (n 41) 413.

### 3.1.3. An invention

The Patent Act 1977 Section 1 (1)[910] sets out the requirements for patentability in the UK. The three essential requirements that every invention has to meet are outlined in this section: the invention must be new; it has to have an inventive step, and the invention is capable of industrial application.[911]

The case of *Generics (UK)* v *Lundbeck*[912] is an important case in patent law, particularly concerning the patentability of pharmaceutical products under the Patent Act 1977 and the standards for granting patents for new products, specifically enantiomers of known compounds. In this case Lord Scott stated that Section 1(1) of the Patent Act 1977 lays down four conditions that must be satisfied if a patent for an invention is to be granted. In the case of *Generics* Lord Scott is reflecting on the complexities surrounding patenting chemical products, especially in the context of generics. What he seems to be addressing is how the requirement of 'newness' for a patent might apply to a chemical product, like the (+) enantiomer of citalopram, which is essentially a refined or specific form of an already known compound.[913]

In this case, the underlying issue is whether the (+) enantiomer of citalopram qualifies a 'new' or sufficiently innovative, given that citalopram as a whole is already known and its chemical properties are established. The existing patent for citalopram has expired and generics manufacturers can produce and sell citalopram. But now, someone is seeking to patent just one specific enantiomer of citalopram, which raises the question of whether this specific form constitutes a truly new invention or whether it is merely a natural variation of an existing, known substance. Lord Scott's difficulty seems to lie in determining how 'new' needs to be

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[910] Patent Act 1977, Section 1.
[911] Patent Act 1977, Section 1(1).
[912] *Generics (UK)* v *H Lundbeck* [2009] (n 861) [3].
[913] *Generics* v *Lundbeck* (n 861) [2]. See also Justine Pila, *The Requirement for an Invention in Patent Law* (Oxford University Press, 2010) 3. In the UK, s 125(1) Patent Act requires that the scope of protection conferred by a patent be determined with reference to the "invention" specified by the patentee in the claims. It provides: "For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly."

understood when the invention is a chemical product where much of the molecular structure and characteristics are already in the public domain due to the prior expiration of the original patent.

Justine Pila has noted that the definition of an invention is not always straightforward, and is in fact subject to interpretation within legislative frameworks, case law and international agreements.[914] Justine Pila argues that there is a pressing need for a robust and meaningful definition of an invention, one that can provide clear guidance in complex cases such as the current case of *Generics* which is about chemical products.[915] Both the Patent Act 1977 and the EPC specify that an invention must be new and involve an inventive step.[916] This means that an invention is not a matter of creating something unfamiliar, but of creating something that offers new technical solutions to the technical problem and that were not obvious to a person skilled in the art.

In the context of chemical products, the invention often becomes more difficult to apply. Justine Pila emphasizes that a new chemical composition or a slight modification of an existing product can still constitute an invention as long as it meets the positive requirements of patentability.[917] Specifically, it must be novel, non-obvious to the person skilled in the art, and the invention must be capable of industrial application. For instance, the isolation of the (+) enantiomer of citalopram might seem like a small change to the compound, but if it brings distinct advantages such as a greater efficacy or fewer side effects, it could still qualify as a legitimate invention even if the underlying structure of citalopram is already known.

### 3.1.4. Novelty

In the context of the Patent Act 1977, when evaluating whether an invention is patentable, the court does not immediately proceed to the novelty assessment. Rather, it follows a structured approach that first ensures that invention is eligible for patent protection based on its technical nature. The courts then move on to assess whether the invention meets the

914 Pila (n 913) 1.
915 *Generics* v *Lundbeck* (n 861) [2].
916Bently *et al.,* (n 41) 554. See also Patent Act 1977, Section 1(1)(a); European Patent Convention, Article 52(1). See also Pila (n 913) 1. Article 52(2) and (3) of the European Patent Convention (EPC) defines what constitutes an invention.
917 Pila (n 913) 1.

requirements for novelty, inventive step and industrial applicability. While the way an invention is characterized often plays a key role in shaping the novelty examination and influencing the outcome of many patent applications[918], this aspect has not been extensively explored in case law.[919]

Patents are granted protection once registered. An invention must be new in order to qualify for patent protection, a requirement further defined in Section 2(1).[920] Various factors justify the novelty requirement for the grant of patents. An invention is considered new if it does not form part of the 'state of the art,' which includes all matter available anywhere in the world before the priority date of the invention, as defined in Section 2(2) of the UK Patents Act 1977.[921] In assessing novelty, several factors must be considered: what the invention requires, the existing knowledge of experts in the relevant field, and what constitutes the state of the art.[922] The critical determination is whether the invention has already been disclosed in the state of the art or whether it represents something new and previously unknown.

The rational of novelty requirement comes from the case *Bristol Myers Company (Johnson's) Application*, in which proceedings were based on a several grounds including insufficiency.[923] The application in question related to a novel, anhydrous form of ampicillin, characterized by a specific infrared absorption spectrum, and to a process for preparing this form.[924] The claim concerned a process using an acid addition salt of ampicillin as the starting material, with a preference for salts disclosed in an earlier specification of the applicants.[925] The opponents argued that the specification was insufficient, claiming that even when using the anhydrous salt as the starting material, the process did not yield the desired result.[926] There was a conflict of expert evidence regarding this objection.[927] The hearing officer, having found in favour of the opponents on these sufficiency issues, led the applicants to appeal to the Patents Appeal

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918 *Glaverbel* v *British Coal* [1994] RPC 443; [1995] RPC 255 (CA); CIPA, [2.03]. See also Bently *et al.,* (n 41) 557.
919 Bently *et al.,* (n 41) 557.
920 The first patentability requirement is novelty. Patent Act 1977, Section 2.
921 Patent Act 1977, Section 2(2).
922 *Merrell Dow Pharmaceutical Inc and Another* v *H. N. Norton & Co. Ltd. and Others* [1996] R.P.C, para [88]. (emphasis added). Lord Hoffman acknowledged that legal definitions of novelty depend on the law's answer to the question, '*what does it mean to know something, so that it can be part of the state of the art?*'
923 *Bristol-Myers Company (Johnson's) Application* [1973] RPC 147.
924 *Bristol Myers Company* (n 923) [10].
925 *Bristol Myers Company* (n 923) [15].
926 *Bristol Myers Company* (n 923) [20].
927 *Bristol Myers Company* (n 923) [20].

Tribunal. Before the appeal was heard the applicants proposed amendments, including a disclaimer to limit the process claims to those using the anhydrous form of salt.[928]

A patent will not be granted if an invention is disclosed or anticipated by the state of the art. The novelty requirement means the invention must be quantitively different from what has been previously disclosed: the technical information provided by the patent must not already be available to the public.[929] The public is willing to bear costs or the monopoly profits of patenting only if they gain access to new information that would not otherwise have been available.[930] To determine whether the invention is already part of the state of the art, the principles established in the case of *Synthon* v *SmithKline Beecham*[931] are applied. As a rule, patent law stipulates that the state of the art includes only material available in the public domain before the priority date of the invention. However, an exception exists for patent applications that are published after the priority date of the application in question.[932]

The *Synthon* v *SmithKline Beecham* case established a two-step approach to determine the novelty of an invention: there must be a prior disclosure, and it must be an enabling disclosure. The House of Lords (as it was then known, before the establishment of the Supreme Court in 2009) as articulated by Lord Hoffmann, set out two requirements: it is crucial to analyse prior disclosure and enablement as conceptually distinct and separate requirements.[933] If the prior disclosure is enabling, the novelty of the invention is destroyed, rendering the patent application unsuccessful. This approach tests whether the invention is indeed novel. An enabling disclosure is one where a person skilled in the art can make the invention work based on the information provided.[934]

According to the case of *Synthon* v *SmithKline Beecham*[935] an enabling disclosure is tested against the standard of an ordinary skilled person who would perform the invention.[936] The

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[928] *Bristol Myers Company* (n 923) [25].
[929] Bently *et al.,* (n 41) 556.
[930] Bently *et al.,* (n 41) 556.
[931] *Synthon* v *SmithKline Beecham* [2005] UKHL 59; [2006] 1 All ER 685; [2006] RPC 10; (2005) 86 BMLR 130.
[932] *Synthon* v *SmithKline* (n 931) See also Bently *et al.,* (n 41) 559.
[933] *Synthon* v *SmithKline* (n 931) [2].
[934] Bently *et al.,* (n 41) 557.
[935] *Synthon* v *SmithKline* (n 931) [14].
[936] *Synthon* v *SmithKline* (n 931) [14].

first disclosure involves information shared with the public. If this information reveals subject matter that if performed would necessarily result in an infringement of the patent, it constitutes enabling disclosure.[937] In this case, *Synthon* sought to revoke *SmithKline Beecham's (SkB's)* patent for a process for producing paroxetine salts on the grounds of lack of novelty. *Synthon* relied on an earlier patent application of its own, claiming that it contained a prior disclosure of the process covered in *SkB's* patent.

The Court of Appeal initially held that a skilled person would not obtain a paroxetine salt by following the teaching of the Application alone; additional experiments would be needed.[938] Therefore, the Application did not disclose the same invention as claimed under *SkB's* patent, which remained valid.[939] However, the House of Lords overturned this decision, ruling that the application did invalidate the patent, as the disclosure in the prior art enabled an ordinary skilled person to perform the invention.[940]

In *Synthon* v *SmithKline Beecham* case, a patent for paroxetine methanesulfonate in crystalline form was deemed invalid due to enabling disclosure in a prior application that had been filed but not published before the priority date.[941] The plaintiff pharmaceutical company appealed against this decision which held that the patent for paroxetine salt owned by the respondent pharmaceutical company, *SmithKline Beecham*, was invalid.

The claimant filed an international patent application claiming a broad class of sulfonic acid salts including paroxetine methanesulfonate.[942] The objective of the invention was to highlight the unique characteristics of this particular form of paroxetine methanesulfonate compared to other crystalline forms. After the claimant had filed this application but before it was published, the respondant, *SmithKline Beecham (SkB)*, filed a document that established priority for a United Kingdom patent application specifically claiming a particular form of crystalline paroxetine methanesulfonate.[943]

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[937] *Synthon* v *SmithKline* (n 931) [15].
[938] *Synthon* v *SmithKline* (n 931) [55].
[939] *Synthon* v *SmithKline* (n 931*)* [55].
[940] *Synthon* v *SmithKline* (n 931).
[941] *Synthon* v *SmithKline* (n 931*)* [13].
[942] *Synthon* v *SmithKline* (n 931*)* [3].
[943] *Synthon* v *SmithKline* (n 931*)* [2].

Following this, the claimant (S) initiated proceedings to revoke *SmithKline Beecham's* (B's) patent on the grounds that it lacked novelty. S argued that B's patent was part of the state of the art as defined by Section 2(3) of the Patents Act 1977, because it had been disclosed in S's own patent application.[944] The court held that disclosure and enablement are distinct concepts, each with its own criteria.[945] To determine disclosure, the prior art must reveal an invention that if performed would necessarily infringe the patent in question.[946]

Once the subject matter of the invention had been disclosed in the prior art it was necessary to determine whether it enabled an ordinary skilled person to perform the invention.[947] It was assumed that the skilled person would be willing to undertake some research to make it work.[948] The judge correctly found that disclosing a crystalline form of paroxetine methanesulfonate implied that it would be the form described in the patent even if a person attempting to recreate it might believe they were making something different.[949] There was no dispute that the disclosure enabled the skilled person to make paroxetine methanesulfonate.[950] The issue was whether they could successfully crystallize it. The judge's decision that the patent was invalid was therefore upheld.[951]

The *Synthon* case highlights the crucial role of novelty and enablement in determining patentability, particularly in the pharmaceutical industry, which plays a central role in the development of treatments for NCDs. In the case of *Synthon,* the court determined that a prior disclosure could destroy the novelty of a patent, even if the disclosure had not been published. In the context of NCD treatments, it is vital that patents are granted only for inventions that provide genuine new knowledge that is not already available to the public. This ensures that patents do not block access to existing ideas or technologies, which would hinder progress in the field. The *Synthon* further illustrates how patent law incentivizes

[944] *Synthon* v *SmithKline* (n 931*)* [12] and [13].
[945] *Synthon* v *SmithKline* (n 931) [20] and [33]. Disclosure and enablement are distinct concept. Both need to be met in order to prove lack of novelty.
[946] *Synthon* v *SmithKline* (n 931) [25].
[947] *Synthon* v *SmithKline* (n 931) [14].
[948] *Synthon* v *SmithKline* (n 931) [14].
[949] *Synthon* v *SmithKline* (n 931) [16].
[950] Patent Act 1977, Section 14(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.
[951] *Synthon* v *SmithKline* (n 931) [25].

research and development in the pharmaceutical sector while also preventing the evergreening of patents where minor modifications to existing treatments could otherwise block access to treatments. This balance between private rights and public access is particularly important in the treatment of NCDs, where effective, affordable solutions are crucial to global health challenges.

Another relevant case that applies for novelty is *Generics (UK) Ltd* v *Daiichi Pharmaceutical Co Ltd*.[952] This case involves a dispute over the validity of a patent under the European Patent Convention (EPC).[953] In this case, the defendant was the proprietor of a European Patent (UK) for an antidepressant drug called escitalopram, marketed under the brand name 'Cipralex.' The claimants brought three separate claims for revocation, which were heard together by the Patent Court. The evidence from each claim was considered collectively, with the appellants using a single set of experts. The challenges to validity were based on the prior art drug citalopram. The respondent contended that claims 1,3, and 6 of the patents had independent validity. However, it was also argued that these claims were invalid due to obviousness in light of the 193 and 884 patents and common general knowledge.[954]

The House of Lords ruled that the patent had novelty.[955] Although levofloxacin was present in the prior art, it was not disclosed individually as a distinct substance.[956] Isolating levofloxacin was a separate discovery that constituted a new product.[957] Moreover, in the Patent Courts, the judge rejected the grounds based on lack of novelty and inventive step but found claims 1 and 3 for insufficiency.

In summary, the *Generics (UK) Ltd* v *Daiichi Pharmaceutical*[958] case is significant for the pharmaceutical industry because it highlights how patent validity, particularly concerning novelty and inventive step (covered in the next section) can influence the market for branded and generic medicines. Strong patents, as in this case, can delay generics from entering the

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[952] *Generics (UK) Ltd* v *Daiichi Pharmaceutical Co Ltd* [2009] UKHL 12, [2009] RPC 13.
[953] European Patent Convention, Article 54(1), an invention shall be considered novel if it does not form part of the "state of the art."
[954] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952).
[955] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952).
[956] *Generics (UK) Ltd* v *Daiichi pharmaceutical* (n 952) [H9].
[957] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952) [46].
[958] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952).

market, potentially keeping drug prices high, while for patients this means that access to affordable versions of the medicines may be delayed. It affects the balance between innovation through patent protection and access to cheaper versions as generic medicines. For pharmaceutical companies having a well-written patent is key to maintaining control over its product and market.

This led to an insufficiency of disclosure argument which was informed by the principles established in *Biogen* v *Medeva* case.[959] In *Biogen*, the claims covered a class of products but the patent was deemed insufficient because it did not instruct the skilled person on how to make all the products in the class.[960] However, this principle does not apply to 'normal product claims' where a patent is generally considered sufficient if it discloses at least one method for making the product to the person skilled in the art.[961] In the present case the patent only disclosed a single method for producing the enantiomer, which was held to be insufficient and thus invalid.[962]

While as general rule, patent law provides that the state of the art only includes material in the public domain before the priority date of the invention, an exception is made in relation to patent application that are published after the priority date of the application in suit.[963] In addition to the matter published before the priority date of the invention, the state of the art also includes applications for other patents that are published after the priority date of the invention but nonetheless have a priority date earlier than the application in question. This can be defined under Section 2(3)[964] of the Patent Act 1977.

There are two situations where material in the public domain is not taken into account when assessing novelty of inventions. The first is where the information was obtained unlawfully or

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[959] *Biogen Inc* v *Medeva plc* [1997] RPC 1, [1996] UKHL 18, (1997) 38 BMLR 149. The disclosure in the specification must enable a person skilled in the art to manufacture the invention or, in Lord Hoffman's words, that there must be an 'enabling disclosure.' The following case, the court found that the patent did not adequately disclose how to make the invention, in result failing the enablement requirements, this can be found in the case of *Asahi Kasei Kogyo* [1991] RPC 485 (HL) 536 (Lord Oliver), 547 (Lord Jauncey); *Eli Lilly* v *Janssen Alzheimer Immunotherapy* [2013] EWHC 1737 (Pat), [2014] RPC 1, [248]-[254].
[960] *Biogen Inc* v *Medeva Plc* (n 959) [12].
[961] *Biogen Inc* v *Medeva Plc* (n 959) [12] and [13].
[962] *Biogen Inc* v *Medeva Plc* (n 959) [12].
[963] Bently *et al.,* (n 41) 559.
[964] Paten Act 1977, Section 2(3). The test for novelty under Section 2(3) of the Patent Act 1977 is the same as under Section 2(2) *SmithKline Beecham plc's Patent* [2002] EWCA Civ 116, [2003] RPC 6 114, [19] – [37] CA.

was disclosed as a result of a breach of confidence[965] and this reaffirms the old principle that material is only available to the public. The second situation where information is excluded from the state of the art is where the disclosure was due to or made in consequence of the inventor displaying the invention at an 'international exhibition'.[966]

The current patent laws on novelty emphasizes that while the patent system grants monopolies only for new inventions, the definition of 'new' in the pharmaceutical industry can be influenced by interpretations of prior disclosure and enablement. Consequently, pharmaceutical compounds already known and used by the public, may still be deemed novel if a skilled person cannot reproduce them using common general knowledge.

Novelty plays a crucial role in determining whether a pharmaceutical invention, including a second medical use of a known compound, can receive new patent protection.[967] This is particularly important for access to medicines for NCDs, as second medical use patents can extend the period of market exclusivity beyond the original patent term, delaying the availability of cheaper generic alternatives and potentially limiting access for patients.

### 3.1.5. Inventive step

Inventive step is the second requirement for patentability.[968] It ensures that an invention is not just new but also represents a non-obvious development in its field. There is no an explicit definition of the person skilled in the art. The concept has developed through case law and judicial interpretation rather than being specifically defined in the statute itself.

According to the inventive step requirement, "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of Section 2(2) above (and disregarding section 2(3) above)".[969] This means that the technical invention described in the patent

[965] Patent Act 1977, Section 2(4)(a)(b).
[966] Patent Act 1977, Section 2(4)(c).
[967] Bently *et al.,* (n 41) 574.
[968] Patent Act 1977, Section 3.
[969] Patent Act 1977, Section 2(2) and 2(3). See also Bently *et al.,* (n 41) 587.

application must not be obvious to an expert in the field. Therefore, it is crucial to identify the person skilled in the art and evaluate whether the invention would be considered obvious to them based on the state of the art.[970] The skilled person refers to a hypothetical person who is knowledgeable and experienced in the specific field of technology relevant to the patent, but not exceptionally inventive.[971] The person also is assumed to possess a standard level of skill rather than extraordinary expertise.[972]

English courts have generally remained separate from and resistant to the adaptation of the problem- and solution approach[973] which is used by the European Patent Office to assess inventive step. Instead, when interpreting an inventive step, they have relied on the approach set out in *Windsurfing* decision.[974]

In *Windsurfing International* v *Tabur Limited,*[975] the dispute centred on a patent held by *Windsurfing International* for a wind-propelled vehicle, specifically a sailboard with a Bermuda rig sail, a universal joint and wishbone-shaped booms.[976] *Windsurfing International* claimed that *Tabur* had infringed this patent, but *Tabur* defended itself by arguing that the invention lacked novelty and it was obvious in light of prior public use.[977]

In support of this claim, *Tabur* cited a sailboard created in 1958 by Peter Chilvers which featured a basic universal joint and booms, as well as a 1966 article by Darby outlining a similar sailboard design.[978] The court accepted this as prior art, determining that the invention was indeed obvious. *Windsurfing International* attempted to amend the patent by restricting their

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[970] *Teva UK Ltd & Ors* v *AstraZeneca AB* [2012] EWHC 655. See also *Bayer* v *Teva* [2021] EWHC 2690 and *Actavis Group PTC EHF and other*s v *ICOS Corporation and another* [2017] EWCA Civ [54]. Cases will be explored in this section after applying *the Windsurfer/Pozzoli.*
[971] Bently *et al.,* (n 41) 588.
[972] Bently *et al.,* (n 41) 588. The person skilled in the art should be presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date.
[973] Inventive steps appear to be an area in which British courts have taken little notice of EPC pretendents and therefore an area in which harmonization seems at its most embryonic: *Hallen* v *Brabantia* [1991] RPC 195, 212; *Hoechst Celanese* v *BP Chemicals* [1997] FSR 547, 567, 572.
[974] *Windsurfing International* v *Tabur Limited* [1985] RPC 59 (CA), followed in *Lux Traffic* v *Pike Signals* [1993] RPC 107; *Hallen* v *Brabantia* (n 973); *Mannheim* v *Genzyme* [1993] FSR 716, 724; *PLG Research* [1995] FSR 116; A. Griffiths, '*Windsurfing* and Inventive Step' [1999] IPQ 160.
[975] *Windsurfing International* v *Tabur Limited* [1985] RPC 59. The importance of the way in which an invention is interpretated is illustrated in *Genentech's Patents* [1989] RPC 147.
[976] *Windsurfing International* v *Tabur Limited* (n 975) [15].
[977] *Windsurfing International* v *Tabur Limited* (n 975) [20].
[978] *Windsurfing International* v *Tabur Limited* (n 975) [35].

claims but the court refused.[979] This case is particularly significant because it established the *Windsurfing* test, a structured four-step approach to assessing inventive step under Section 3 of the Patent Act 1977.[980] The *Windsurfing* test was widely used in UK patent law until it was later refined in *Pozzoli SPA* v *BDMO SA[981],* which improved the structure and clarity of the analysis.

Although the *Windsurfing* test provided a structured approach it had certain limitations in defining the inventive concept clearly. The test did not always distinguish between common general knowledge and specific prior art, sometimes leading to hindsight bias in assessing obviousness. Recognizing these issues, the Court of Appeal in *Pozzoli SPA* v *BDMO SA[982]* refined the test to improve clarity and structure.

To evaluate inventive step, the UK applies a four-step test which involves several key stages. First, it identifies the inventive concept embodied in the patent in suit, the person skilled in the art and what their relevant common knowledge encompasses.[983] Second, it identifies the inventive concept of the claim in question or, if this is not readily done, construes the claim to determine its scope and inventive aspect.[984] Third, it examines what differences if any exist between the matter cited as forming part of the "state of the art" and the inventive concept.[985] Finally, without any knowledge of the alleged invention claimed, it assesses whether those differences constitute steps that would have been obvious to the person skilled in the art.[986]

Courts determine what is considered obvious in the context of patents. The quality of an invention has been described by Lord Hoffmann in the *Societe Technique de Pulverisation Step* v *Emson Europe Ltd.*[987] According to Lord Hoffmann "the words 'obvious' and 'inventive step' involve questions of fact and degree which must be answered in accordance with the general policy of the Patents Act to reward and encourage inventors without inhabiting improvements

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[979] *Windsurfing International* v *Tabur Limited* (n 975) [40].
[980] Patent Act 1977, Section 3. See also Bently *et al.,* (n 41) 587.
[981] *Pozzoli SpA* v *BDMO SA and others* [2007] EWCA Civ 588, [2007] FSR (37) 872.
[982] *Pozzoli SpA* v *BDMO SA* Civ 588 (n 981) [15]-[19].
[983] *Pozzoli SpA* v *BDMO SA* Civ 588 (n 981) [60] (6) (i).
[984] *Pozzoli SpA* v *BDMO SA* Civ 558 (n 981) [60] (6) (ii).
[985] *Pozzoli SpA* v *BDMO SA* Civ 558 (n 981). [60] (6) (ii).
[986] Bently *et al.,* (n 41) 583.
[987] *Société Technique de Pulverisation (STEP)* v *Emson* [1993] RPC 513.

of existing technology by others. The question is therefore whether in accordance with this policy the patent discloses something sufficiently inventive to deserve the grant of monopoly."[988] The courts, assisted by experts, will examine the description of the invention to determine if it meets the quality required to be rewarded with a monopoly.

In the *Pozzoli* approach, the courts must first identify the person skilled in the art as of the priority date, effectively determining who the expert is. They then assess any differences between the inventive concept and the existing knowledge of the expert. The courts must ask whether, viewed without any knowledge of the alleged invention, these differences constitute steps that would have been obvious to the skilled person or if they require any degree of invention. The critical question is whether the differences between the invention described in the application and the expert's prior knowledge would have been obvious to the person skilled in the art.[989]

The UK courts take a different approach to assess obviousness by first determining the person skilled in the art and their common knowledge at the time of the invention. The *Pozzoli* test then identifies the inventive concept of the patent and compares it to the prior art, looking at the differences between the two.[990] This helps to objectively assess whether the differences would have been obvious to a person skilled in the art, rather than framing the issue as a problem and solution.

While *Generics (UK) Ltd* v *Daiichi Pharmaceutical Co. Ltd,*[991] was initially discussed in the context of novelty, where the court assesses whether levofloxacin was sufficiently distinct from the prior art, the case also delivers valuable insights into the assessment of inventive step.[992] Moving beyond novelty, the court further evaluated whether the claimed invention, involving the separation of enantiomers of ofloxacin, represented a non-obvious technical advance. *Daiichi Pharmaceutical Co Ltd* held a patent for levofloxacin, claimed that as a new, more effective treatment for bacterial infections, emphasizing that it was superior to the

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988 *Société Technique de Pulverisation v Emson* (n 987) [25].
989 *Pozzoli SpA* v *BDMO SA* Civ 588 (n 981).
990 Bently *et al*., (n 41) 587.
991 *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952).
992 *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952) [24].

racemic mixture (ofloxacin). However, *Generics (UK)* challenged the patent's validity arguing that the separation of enantiomers was a routine process known to a skilled person and therefore, there was no inventive step involved.[993] *Daiichi* argued that the benefits of the isolated enantiomer were unexpected and not obvious. Ultimately, the Court of Appeal ruled in favour of *Generics*, finding the patent invalid for lack of inventive step as the separation of enantiomers was considered obvious to a skilled person in the light of prior art.[994]

In this case, the court relied on the *Windsurfing/Pozzoli* test to assess the inventive step (obviousness) or whether it is merely an obvious extension of prior knowledge. The court found that the separation of enantiomers (levofloxacin from ofloxacin) was a routine process known to a skilled person and thus lacked an inventive step. The case highlights the strict application of the obviousness standard in pharmaceutical patents which may undermine incentives for drug innovation. While the *Windsurfing/Pozzoli* test ensures consistency, its strict application here overlooks the complexities of enantiomer separation and the potential unpredictability of improved pharmacological effects. The court's assumption that a skilled person would have naturally pursued the separation of levofloxacin may have set the inventive step threshold too high, limiting patentability for incremental but valuable pharmaceutical advancements. Although this ruling supports generic competition and affordability, it also risks discouraging investment in enantiomer research, where smaller molecular refinements can produce significant therapeutic benefits. A more nuanced approach, considering scientific unpredictability and real-world pharmaceutical innovation, may better balance patent protection with public health interests.

Another case which concerns inventive step is the *Richardson-Vicks Inc's Patent.*[995] The case involved a pharmaceutical patent and addressed inventive step particularly regarding drug combinations. The case involved a European Patent relating to a mixture of an analgesic from a class of drugs known as non-steroidal anti-inflammatory drugs (NSAIDs) and a decongestant, intended for over-the-counter self-medication of coughs and colds.[996] The appeal highlighted

[993] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952) [H11] and [H19] and [34].
[994] *Generics (UK) Ltd* v *Daiichi Pharmaceutical* (n 952) [34].
[995] *Richardson- Vicks Inc's Patent* also known as *Reckitt & Colman Products Ltd* v *Richardson-Vicks Inc* [1995] RPC 568,579-80.
[996] *Richardson- Vicks Patents* [1995] RPC 561 (n 995) [35].

the challenges of assessing inventive step in pharmaceutical patents.[997] It considers whether replacing older NSAIDs like aspirin and paracetamol with newer ones like ibuprofen in a drug combination would have been obvious to a person skilled in the art. The key issues seem to be whether a skilled pharmaceutical team would reject the combination due to regulatory concerns rather than scientific unpredictability.[998] The judge allowed the amendment but held that the amended claims were invalid, stating that whether a mixture could be expected to receive regulatory approval had nothing to do with obviousness: consequently the proprietor appealed.[999] As the case was decided in the UK it is more likely that the court applied the *Windsurfing/Pozzoli* test, rather than the EPO's problem-solution approach. As mentioned earlier, the *Pozzoli* test follows four step-tests.

*Richardson-Vicks Inc's Patent* is relevant on this research work, as it raises public health concerns regarding incremental innovation, particularly drug combinations. It also highlights tensions between patent law and access to medicines, especially for NCD treatments in several ways. First, the case questioned whether a combination of known drugs NSAIDs and decongestant should be patentable, which is a key issue in incremental innovation in pharmaceuticals.[1000] If such combinations receive patent protection without truly inventive step, they extend market exclusivity on existing drugs, delaying the entry of cheaper generic alternatives that improve access to medicines. Second, the proprietor argued that a skilled pharmaceutical team would reject the drug combination due to regulatory concerns, implying that this made the invention non-obvious. However, the court rejected this argument, stating that whether a drug could gain regulatory approval had nothing to do with obviousness under patent law. This ruling suggests that patent law should focus on technical innovation rather than regulatory challenges, reinforcing that regulatory barriers cannot justify extending monopolies on medicines. Lastly, it indeed impacts on NCDs treatments as many treatments for NCDs such as cardiovascular diseases and diabetes rely on combinations of existing drugs. If minor modifications can easily receive new patents that could lead to evergreening, where pharmaceutical companies keep extending patent protection without offering significant

[997] *Richardson- Vicks Patents* [1995] RPC 561 (n 995)
[998] *Richardson- Vicks Patents* [1995] RPC 561 (n 995) [10].
[999] *Richardson- Vicks Patents* [1995] RPC 561 (n 995) [45].
[1000] *Richardson- Vicks Patents* [1995] RPC 561 (n 995) [45].

innovation. Additional pharmaceutical cases with explanations are provided to further illustrate this point.

Following the Court of Appeal's decision in *Angiotech* v *Conor*,[1001] the approach has shifted towards being more favourable to patents. In this case, Jacob LJ confirmed the importance of 'obvious to try' doctrine in assessing inventive step. He clarified that 'the notion of something being obvious to try was useful only in a case where there was a fair expectation of success.[1002] How much of an expectation would be needed depended on the particular facts of the case'.[1003] Some authors argued that the decision demonstrated a significant shift in the analysis on follow-on inventions under the 'obvious to try test' in favour of patentees, which required that the skilled person had known that the inventions would almost certainly work.[1004]

*Angiotech* v *Conor* deals with the assessment of secondary patents, those that involve minor modifications or combinations of existing technologies and it also highlights the tension between promoting incremental innovation and preventing the extension of patent rights for trivial improvements.[1005] The court applied a test similar to *Windsurfing/Pozzoli* test, which involves identifying the closest prior art, determining the technical problem, and assessing whether the solution would have been obvious to a person skilled in the art. The decision highlights how secondary patents, especially in the pharmaceutical and medical devices field, can be challenged on the grounds of obviousness if they are seen as insufficiently inventive.[1006] This case also illustrates the balance courts strive to strike between encouraging innovation and preventing the evergreening of patents, which could potentially hinder access to medicines. Therefore, *Angiotech* v *Conor* serves as a key example of how inventive step is assessed in the context of pharmaceutical and medical device patents, offering insights into both legal standards applied and the policy implications for public health.[1007]

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[1001] *Angiotech Pharmaceutical Inc* v *Conor Medsystems Inc* [2007] EWCA Civ 5; [2008] UKHL 49.
[1002] *Angiotech v Conor* [2008] UK HL 49 (n 1001) [42].
[1003] *Angiotech* v *Conor* [2008] UKHL 49 (n 1001) para 19. The House of Lords subsequently set aside the decision of Jacob LJ, because there was no requirement in patent law that the patentee must demonstrate that the invention works.
[1004] Paul England, 'Saint Gobain- patron of pharmaceutical patentees?' (2007) 2(8) Journal of Intellectual Property & Practice, 532.
[1005] *Angiotech v Conor* [2008] UK HL 49 (n 1001).
[1006] *Angiotech v Conor* [2008] UK HL 49 (n 1001) [62].
[1007] *Angiotech v Conor* [2008] UK HL 49 (n 1001) [34].

A recent case, *Sandoz* v *BMS*[1008] it addresses the tension between two key aspects of patent law. First is the inventive step and sufficiency of disclosure, while the second aspect is plausibility. The plausibility requirement is central to the case and plays an important role in both the EPO's approach to assessing patents and that taken by UK courts.

The concept of plausibility is as a key indicator for the sufficiency of a patent's disclosure and whether the claimed invention has the potential to solve the stated technical problem.[1009] In the EPO, plausibility is treated as a signal to assess whether the claims are supported by credible evidence, ensuring that the invention can be practically worked and that the patent is not based on speculative claims. In this context the EPO's treatment of plausibility is linked to both sufficiency disclosure (Article 83 EPC)[1010] and inventive step (Article 56 EPC).[1011] This means that a patent will not satisfy the sufficiency requirement if the invention's claimed technical effects are not plausible, which consequently also affects the assessment of its inventive step.[1012] The EPO insists that for an invention to be considered non-obvious the technical effect claimed must be plausible, meaning there must be some substantiation or reasonable expectation that the claimed effect can be achieved. In this way the EPO's treatment of plausibility ensures that patents are not granted for inventions that are too speculative or lacking in a sound technical basis.

Conversely in the UK courts the principles governing plausibility have become somewhat conflated with both sufficiency and inventive step, making the legal test for patentability somewhat more complicated. This blending of doctrines was illustrated in *Sandoz* v *BMS*[1013], where the UK court took a broader view of plausibility. Rather than treating plausibility as a separate consideration under sufficiency and inventive step, the court examines it as part of the broader inventive step analysis. This approach seems to suggest that the presence of

[1008] *Sandoz* v *BMS* [2022] EWHC 822 (Pat) [2023] EWCA Civ 472.
[1009] Luke McDonagh, 'An impressive overview of European patent law in the UPC era' (2024) Journal of Intellectual Property Law & Practice doi. org/10.1093/jiplp/jpae113. See also *Sandoz* v *BMS* [2022] (n 1008) [1].
[1010] Article 83 of the European Patent Convention. The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
[1011] Article 56 of the European Patent Convention. An invention shall be considered as involving an inventive step, if having regard to the state of the art, it is not obvious to a person skilled in the art.
[1012] The principle that a patent must satisfy the sufficiency requirement by making the claimed technical effects plausible, thereby impacting the assessment of inventive step, was central to the case *Sandoz* v *BMS* (n 1008) [6].
[1013] *Sandoz* v *BMS* (n 1008) [4].

plausible technical effects is crucial for assessing whether the invention is inventive or obvious, irrespective of whether those effects are sufficiently disclosed in the patent.

To incorporate plausibility in patent law raises complex issues regarding the balance between promoting innovation and ensuring that patent claims are genuinely inventive. While the EPO uses plausibility as a signal for sufficiency under Article 83 and inventive step under EPC Article 56, the UK courts have conflated the two doctrines, making the test for inventive step potentially more rigid. This approach could have both positive and negative implications. On the one hand, requiring plausible technical effects ensures that patents are not granted for inventions based on speculative or unsupported claims. On the other hand, this could create obstacles for innovators whose breakthrough may appear implausible at first but prove to be valuable with further research. The challenges lie in balancing the need for solid evidence to support claims while not stifling innovation, particularly in fields where scientific advances are incremental and often initially uncertain.

A case with indirect implications for NCDS is *Eli Lilly and Co Human Genome Sciences Inc*[1014], due to the nature of the patent in question which involves a gene sequence potentially linked to therapeutic applications in immune-related diseases and other conditions that fall under the broader category of NCDs.[1015] In this case *Eli Lilly* applied to revoke a European Patent (UK) held by the defendant Human Genome Sciences.[1016] The patent disclosed the nucleotide and amino acid sequence of a novel member of the TNF ligand superfamily called Neutrokine-α.[1017] The defendant identified the protein using bioinformatics, claiming industrial applicability and therapeutic potential, while *Eli Lilly* argued that the patent lacked industrial applicability, emphasizing that it was speculative and unsupported by experimental data.[1018]

Although this case primarily focuses on industrial applicability which is addressed in a separate section, it is relevant to inventive step because such early-stage patents in the pharmaceutical and biotechnology sectors often involve potential treatments for various diseases, including

[1014] *Eli Lilly and Co* v *Human Genome Sciences Inc* [2008] RPC 29 also known as *Human Genome Sciences Inc* v *Eli Lilly and Company* [2010] EWCA Civ 33.
[1015] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014) [120].
[1016] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014) [H3].
[1017] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014) [H3].
[1018] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014) [H15] and [H17]

NCDs. The court ruled in favour of Human Genome Sciences, upholding the patent on a gene sequence associated to with Neutrokine- α despite the lack of experimental data to prove its functions in treating diseases.[1019] This decision highlights the tension between granting early patents in the pharmaceutical field and the need for solid evidence to support practical applications. While the case itself is not specifically about NCDs, the technology could eventually contribute to the development of treatments for these diseases. Therefore, it serves as an important example of how patent law might impact the future development of medicines for NCDs. The case underscores the delicate balance patent law must strike between encouraging innovation and ensuring that essential health solutions remain accessible to the public.[1020] If patents are granted prematurely, without sufficient evidence of clinical utility they can create barriers to affordable, effective treatments in patients in need.

A 2021 decision of the English High Court in *Bayer* v *Teva*[1021] illustrates how the UK courts have found a pharmaceutical invention to be the obvious outcome of routine drug development.[1022] In this case the patent in question was directed to the salt form of sorafenib and its use in the treatment of cancer.[1023] The claim in contention related to sorafenib tosylate salt.[1024] In the Supreme Court decision *Actavis* v *ICOS* the court found a drug dose selection obvious in view of what was considered to be the obvious route that the skilled person would take through the drug development decision tree.[1025] The High Court in *Bayer* v *Teva* followed a similar reasoning to find the clinical formulation of *Bayer's* cancer drug, sorafenib, obvious in view of the preliminary phase I clinical trial results for the drug.

*Teva* sought to revoke *Bayer's* patent, arguing that the development of sorafenib tosylate was a predictable outcome of routine pharmaceutical research. Following *Windsurfing/Pozzoli* test, the team skilled in the art in *Bayer* v *Teva* was found to include a person skilled in drug formulation: 'the Skilled Formulator.' The court identified a Phase I clinical trial which motivated skilled persons to further investigate sorafenib.[1026] According to the expert witness

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[1019] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014) [H15].
[1020] *Eli Lilly and Co* v *Human Genome Sciences Inc* (n 1014).
[1021] *Bayer Healthcare LLC* v *Teva Pharmaceutical Industries Ltd & Anor* [2021] EWHC 2690 (Pat).
[1022] *Bayer* v *Teva* (n 1021) [4].
[1023] *Bayer* v *Teva* (n 1021) [7].
[1024] *Bayer* v *Teva* (n 1021) [7].
[1025] *Bayer* v *Teva* (n 1021). See also *Actavis Group PTC EHF and others* v *ICOS Corporation and another* [2017] (n 970) [1].
[1026] *Bayer* v *Teva* (n 1021) [5].

for the patentee, the skilled person would have found overcoming the very low solubility of sorafenib 'to be an extremely challenging project'.[1027] Ultimately, the court found that a skilled formulator would have tested tosylate in the salt screen for sorafenib, making *Bayer's* patent invalid for lack of inventive step.[1028] The ruling followed a similar logic to *Actavis* v *ICOS*, emphasizing practical drug development processes over hindsight arguments. *Bayer* also failed to uphold its patent in Germany and many appeals in the UK.[1029] The ruling in *Bayer* v *Teva* highlights the increasing difficulty of patenting pharmaceutical formulations that follow standard and routine considerations.[1030]

This requirement is particularly relevant in the pharmaceuticals field for non-communicable diseases. If the inventive step standard is too broad or weak, it can lead to patents being granted for minor improvements. This may delay the entry of generic medicines and limit access to affordable treatment, raising important concerns regarding intellectual property, social justice, and the right to health.

### 3.1.6. Industrial application

The last patentability requirement found in Section 4 of the Patent Act 1977.[1031] Section 4 specifies that an invention is considered capable of industrial application if it can be made or used in any kind of industry.[1032] While often seen as a technical formality, this requirement serves a critical public interest function, it ensures that patents are granted only for inventions that offer tangible, functional outcomes. In the context of pharmaceutical innovation for non-communicable diseases, this requirement acts as a safeguard against speculative patents that lack proven therapeutic utility. For example, an anti-obesity drug must demonstrate a plausible mechanism of action or clinical pathway to be considered industrially applicable.[1033]

From an IP-SJ perspective, industrial application requirement is a crucial checkpoint for equitable innovation. It ensures that exclusive rights are granted only where the invention has

[1027] *Bayer* v *Teva* (n 1021) [127].
[1028] *Bayer* v *Teva* (n 1021) [227] and [234].
[1029] *Bayer* v *Teva* (n 1021) [184].
[1030] *Bayer* v *Teva* (n 1021) [85].
[1031] Patent Act 1977, Section 4.
[1032] Patent Act 1977, Section 4.
[1033] Timo D Müller *et al*., 'Anti-obesity drug discovery: advances and challenges' (2021) 21(3) Nature Reviews Drug Discovery.

the potential to contribute to public welfare. Without this requirement pharmaceutical companies could secure patents for underdeveloped or unproven therapies, potentially excluding others from pursuing more effective or accessible treatments for NCDs. Highlighting how granting such patents may lead to 'patent thickets' or evergreening, impeding access to affordable treatments for NCDs.

The case of Ozempic, initially developed for type 2 diabetes but increasingly used off-label for obesity, the industrial applicability of its active compound had to be demonstrated for its original indication. However, the secondary use raises questions about whether expanded therapeutic claims also meet the threshold of industrial applicability, especially when demand increases, and access is compromised.

Industrial application is essential to prevent unjustified monopolies that hinder access to essential medicines. This is particularly important for NCDs where treatments are often needed long-term and at scale. A failure to enforce this standard can lead to unnecessary market exclusivity for ineffective or marginal innovations, exacerbating in healthcare access.

### 3.1.7. Sufficiency of disclosure

Sufficiency of disclosure is relevant for the pharmaceutical innovations. In addition, meeting the patentability requirements, the application must fully disclose the invention. A patent application must provide enough information about the invention which would enable the person skilled in the art to work it. The application must include an abstract, a description and claims. According to Patent Act 1977 Section 14(3)[1034], "the specification of the application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."[1035] This means that the invention must be described in a manner that is understandable to an expert in the field.[1036] Failing to meet this requirement may lead to the revocation of the patent.[1037] The aim of this

[1034] Patent Act 1977, Section 14(3).
[1035] Patent Act 1977, Section 14(3).
[1036] Bently *et al*., (n 41) 607.
[1037] Patent Act 1977, Section 72(1)(c).

requirement is to guarantee that the claimed invention has made an 'actual technical contribution to the art' and that 'it justifies the grant of a patent monopoly'.

A case that concerning the validity of patent claims under European patent law is the case of *Generics (UK) Ltd (T/A Mylan)* v *Research and Development Company*.[1038] The case focused on clarity, sufficiency of disclosure and entitlement to priority. The dispute revolved around a patent held by *Yeda Research* for a formulation of copolymer 1, used in the treatment of multiple sclerosis.[1039] *Generics (UK) Ltd* challenged the validity of *Yeda's* patent, arguing that the patent was insufficiently disclosed, meaning the invention was not described in enough detail for the person skilled in the art, and *Yeda* was not entitled to priority because the priority claim relied on an earlier application that did not disclose the invention sufficiently.[1040] The Supreme Court ruled in favour of *Mylan*, upholding the Court of Appeal's decision to revoke *Yeda's* patent.[1041] The patent was found insufficient because the description did not enable a skilled person to produce the claimed copolumer-1 composition with the specified molecular weight and, the patent lacked clear guidance on how to achieve the molecular weight range required for the claimed invention.[1042]

The case highlights key patent law issues, including clarity, sufficiency of disclosure, and priority entitlement, which directly impact both pharmaceutical innovation and generic drug accessibility. The patent was found to be insufficiently disclosed, a flaw that can unfairly extend market exclusivity, delaying generic alternatives and restricting access to affordable treatments for NCDs like multiple sclerosis. This outcome demonstrates how a lack of sufficient disclosure can be sued as a strategic tool to maintain control over high-cost medicines, even when the scientific contribution is unclear or limited. In doing so, it undermines the fundamental principle of the patent bargain, exclusive rights in exchange for public knowledge and shifts the balance away from equitable access innovation. This especially harmful in the case of NCDs, where long-term treatments are essential, and affordability is critical for health equity.

[1038] *Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* [2017] EWHC 2629 (Pat), [2018] R.P.C (2) 101.
[1039] *Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* (n 1038) [H3].
[1040] *Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* (n 1038) [191].
[1041] *Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* (n 1038) [2].
[1042] *Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* (n 1038) [196].

For a patent to be valid, it must provide sufficient technical information to allow generic manufacturers to reproduce the invention once the patent expires. However, the lack of transparency in patent description is often used as a strategy by pharmaceutical companies to block generic competition and maintain high drug prices. This case highlights the ongoing tension between pharmaceutical patents and public health needs, reinforcing the argument that patent law should strike a balance between incentivizing innovation and ensuring access to affordable medicines.

From an IP-SJ perspective, sufficiency of disclosure is not only a technical threshold, but also a tool for advancing equity of public health. It reinforces the transparency obligation at the heart of the patent system, ensuring that inventors do not withhold essential technical information while enjoying exclusive commercial rights. In the context of NCDs, this is especially important because patients suffering from chronic illnesses rely on sustained access to affordable medication, and inadequate disclosure can delay or obstruct the production of generics, which are critical for healthcare equity. IP-SJ requires that legal mechanisms like sufficiency serve not just innovation, but also inclusion, empowerment, and the right to health.

### 3.2. Cyprus patent provisions of the Patents Law 16(1)/1998

Cyprus may not have a solid tradition of patent litigation disputes, nevertheless it has established a robust legal framework for the protection of intellectual property through both national laws and international treaties that have been endorsed domestically.[1043] The primary legislation governing patents in Cyprus is the Patents Law 16(1)/1998[1044], which has been amended several times since its enactment in 1998 to align with European and international standards.

[1043] A G Paphitis & Co Law Firm, 'The rise of patent litigation in Cyprus after Brexit' (*Lawyers in Cyprus* 2022) <https://www.lawyersincyprus.com/news/articles/the-rise-of-patent-litigation-in-cyprus-after-brexit> accessed 25 March 2025.

[1044] Patents Law 16(1)/1998.

A thorough examination of relevant case law before the Cypriot courts has been conducted, alongside a review of Cypriot legal scholarship.[1045] Given that Cypriot legal texts, particularly those written in Greek, frequently cite EPO case law as authoritative, the same approach has been adopted in this research. This ensures consistency with established legal discourse in Cyprus while maintaining a broader European perspective.

The Patents Law 16(1)/1998 does not explicitly define the term 'invention'[1046], but it sets out the criteria for patentability. The applicant must demonstrate that the invention which is to solve a technical problem is novel (Section 6)[1047], involves an inventive step (Section 7)[1048] and is industrially applicable (Section 8).[1049] A patent in Cyprus is granted for a period of twenty years from the filing date subject to the payment of annual maintenance fees.[1050] In certain cases such as pharmaceutical patents the term may be extended up to twenty-five years[1051], with an additional six-months extension available for paediatric pharmaceutical products.[1052]

Patent protection in Cyprus is territorial, meaning that a Cypriot patent only provides exclusive rights within the Republic of Cyprus.[1053] The law follows the 'first to file' principle, granting patent rights to the first person who submits a valid application.[1054] A patent can cover either a product or a process if it introduces a new way of doing something or offers new technical knowledge.[1055] Additionally, the patent application must include sufficient disclosure of the invention to enable the public to understand and reproduce it.[1056]

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1045 Philippe Jougleux, *European Intellectual Property Law* (Sakkoulas Publications, 2020) 367.
1046 Patents Law 16(1)/1998.
1047 Patents Law 16(1)/1998. Supplementary Protection Certificates (SPC); Regarding pharmaceutical patents, the law provides for the possibility of extending the standard 20-year protection period up to 25 years through the SPC. This extension compensates for the time taken to obtain regulatory approval for pharmaceutical products, ensuring adequate effective protection.
1048 Patents Law 16(1)/1998.
1049 Patents Law 16(1)/1998, Art. 5(1). See also Jougleux (n 1045) 367.
1050 Patents Law 16(1)/1998, Section 26.
1051 Patents Law 16(1)/1998.
1052 European Commission, 'Supplementary protection certificates for pharmaceutical and plant protection products' (n 774).
1053 European Commission, 'Supplementary protection certificates for pharmaceutical and plant protection products' (n 774).
1054 Patents Law 16(1)/1998, Section 10(2). ('Where two or more applications have been filed by different persons in respect of the same invention and the inventors concerned the invention independently of each other, the right to a patent for that invention shall belong to the applicant whose application has the earliest filing date or, where priority is claimed, the earliest priority date, as long as his application is not withdrawn or abandoned or rejected.'
1055 Patents Law 16(1)/1998, Section 5 (1). ('Patents shall be available for any invention, whether products or process in all fields of technologies.') The European Patent Convention has also reproduced this text of the TRIPS Agreement in Article 52 EPC stating that European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
1056 Patents Law 16(1)/1998, Section 15. ('The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art').

Although these provisions are primarily technical in nature, they have wider implications for IP-SJ. By determining how pharmaceutical patents are granted and protected in Cyprus, they influence the availability of affordable medicines for non-communicable diseases and therefore, directly affect the right to health.

### 3.2.1. Inventor

Under Cyprus Patents Law 16(1)/1998, Section 12[1057] an inventor is defined as the person who has made the invention, specifically the individual who conceived the new idea and developed the innovative concept[1058], similar to the definition under the UK Patent Act 1977.[1059] While Cyprus Patent Law does not have a widely known landmark case that specifically defines an inventor within its jurisdiction, general principles from European and UK case law influence Cypriot patent law due to alignment with the European Patent Convention and the EU directives. In European patent applications the designated inventor must be a natural person.[1060]

The European Patent Office Legal Board of Appeal recently dismissed appeals in cases J 8/20[1061] and J 9/20[1062], reaffirming the EPO's decision to reject two patent applications in which an artificial intelligence (AI) system was designated as the inventor. The EPO confirmed that only human beings can be recognized as inventors on patent applications. The ruling is another obstacle for the AI system DABUS, whose creator Dr. Stephen Thaler has been attempting to secure patents with AI as the inventor. The decision aligns with similar rulings worldwide, reinforcing the principle that legal rights related to inventions remain tied to human individuals.[1063]

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1057 Patents Law 16(1)/1998, Section 12.
1058 Patents Law 16(1)/1998, Section 12.
1059 For the UK's inventor see Chapter Four - National Framework, 3.1.1 ('Inventor').
1060 Article 81 of the European Patent Convention. The European patent application shall designate the inventor. If the applicant is not the inventor or the only inventor, the designation must include a statement specifying the origin of the right to the European patent.
1061 In the case of the European Patent Office (EPO), the decision of the Examination Division was appealed to the EPO Board of Appeal. Case J 0008/20, Decision of 21 December 2021, ECLI:EP:BA:2021:J000820.20211221 – Designation of inventor/DABUS.
1062 In the case of the European Patent Office (EPO), J 0009/20 (Designation of inventor/DABUS II) 21-12-2021.
1063 Fernando Cerdà Belda, 'EPO rules only humans can be inventors- another blow to the DABUS patents' (*Clifford Chance* 2022) <https://www.cliffordchance.com/insights/resources/blogs/talking-tech/en/articles/2022/03/epo-rules-only-humans-can-be-inventors-another-blow-to-dabus-a.html> accessed 25 March 2025.

### 3.2.2. Subject matter capable of patent protection

This section examines the subject matter eligible for patent protection as regulated under the Patents Law 16(1)/1998.[1064] More specifically, it will discuss the criteria required for a patent to be granted: the invention must be novel, involve an inventive step, and be capable of industrial application.[1065]

### 3.2.3. An invention

The Patents Law of 1988 in Cyprus, as amended, requires that an invention must fullfil three key criteria to qualify for patent protection.[1066] It must be novel, involve an inventive step and be capable of industrial application.[1067] A patent grants exclusive rights to an invention, which can be either a product or a process that introduces a new way of doing something or offers a new technical solution to a problem. To secure a patent, the inventor is required to disclose the invention's technical information in a patent application.[1068] As a member of the EU, Cyprus, aligns its patent system with the EPC, ensuring consistency with broader European standards.[1069]

This system of protection allows inventors to commercially exploit their inventions for a limited period, typically 20 years[1070], in exchange for the public disclosure of the invention's technical information. The exclusive right to the invention is typically held by the inventor, granting them the ability to control its use, manufacture and sale. This right allows the inventor to prevent others from using the invention without permission.

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[1064] Patents Law 16(1)/1998.
[1065] Patents Law 16(1)/1998, Section 5(1).
[1066] Patents Law 16(1)/1998, Section 5(1).
[1067] Patents Law 16(1)/1998, Section 5(1).
[1068] Patents Law 16(1)/1998.
[1069] Article 52(1) of the European Patent Convention (2000) (EPC). European patents shall be regarded for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
[1070] Patents Law 16(1)/1998, Section 26. See also Article 63 (1) EPC is the term of the European patent; the term of the patent shall be twenty years from the date of filing of the application.

### 3.2.4. Novelty

The first requirement for obtaining a patent in Cyprus is novelty. According to Cyprus Patents Law 16 (1)/1998 as amended ("the Law")[1071], an invention is considered novel if it does not form part of the state of the art.[1072] As defined in Section 6 of the Law, novelty means that an invention is new if it does not form part of the prior art.[1073] The prior art includes everything that was available before the filing date of the patent, application or, where priority is claimed.[1074]

Similarly, Article 54 EPC defines the first patentability requirements.[1075] An invention shall be considered new if it does not form part of the 'state of the art.'[1076] The state of the art, which constitutes a potential barrier to the novelty of an invention, includes specific categories of prior disclosures. First, national Cyprus patent applications with an earlier filing or priority date are considered part of the state of the art[1077], provided that the application or the patent granted thereon has been published by the Office of the Registrar. Second, European patent applications for which a European patent valid in Cyprus is sought and for which the requisite designation fee for Cyprus has been duly paid, also fall within the state of the art to the extent that such applications or the patents granted are published by the Office of the Registrar.[1078] Third, international patent applications filed under the Patent Cooperation Treaty (PCT) that designate the EPO for a European patent extending to Cyprus are included in the state of the art, assuming the original phase of such applications has been properly entered and the application or the resulting patent has been published by or on behalf of the Office of the Registrar.[1079]

Once granted, a Cypriot patent provides the owner the exclusive right to utilize the invention for a period of up to twenty years from the filing date of the application, contingent upon the

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[1071] Patents Law 16(1)/1998.
[1072] Patents Law 16(1)/1998, Section 6(1).
[1073] Patents Law 16(1)/1998, Section 6(1).
[1074] Patents Law 16(1)/1998, Section 6(2). The priority date of the application claiming the invention, has been made available to the public in a written or other graphic form, by an oral description, by use or any other way anywhere in the world.
[1075] Article 54 European Patent Convention.
[1076] Article 54(1) European Patent Convention. ('An invention shall be considered new if it does not form part of the state of the art').
[1077] Kyriacou and Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016) (n 850).
[1078] Kyriacou and Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016) (n 850).
[1079] Kyriacou and Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016) (n 850).

annual payment of renewal fees.[1080] This protection extends to European patents valid in Cyprus, provided the Cyprus designation fee has been paid[1081], as well as to PCT applications that designate the EPO and extend to Cyprus, as long as the regional phase is properly entered, and the application or resulting patent is published by the Office of the Registrar.[1082]

While there are currently no specific pharmaceutical cases in Cyprus focusing on novelty under the Patents Law 16 (1)/1998[1083], this is likely due to the limited number of publicly available case reports or the relatively small number of patent litigation cases in Cyprus. In the absence of specific Cypriot case law and given that Cyprus is a member of the EU and adheres to the EPC, legal professionals in Cyprus typically rely on EPO case law for guidance.

The EPO provides a well-established framework for interpreting novelty. Specifically, the 'state of the art' includes everything that has been made available to the public by means of a written or oral description, by use, or in any other way anywhere in the world before the priority date of the patent application.[1084] Therefore when assessing whether an invention is new or part of the prior art, it is important to determine whether it has been disclosed to the public. An invention is considered to have been made available to the public if a skilled person using their general knowledge in the relevant technical field at the time, could reproduce it based on the disclosed information, and this is known as 'enabling disclosure.'[1085] However, even if an invention has been previously disclosed, it will not be considered part of common knowledge if it can only be found through an extensive search and is not readily accessible as part of the disclosure.[1086]

Since Cyprus follows EPC principles, legal professionals in Cyprus often refer to EPO case law, particularly in complex areas such as pharmaceutical patentability. Therefore although there

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[1080] Patents Law 16(1)/1998, Section 26(3).
[1081] Article 79(2) European Patent Convention. ('The designation of a Contracting State may be subject to the payment of a designation free').
[1082] Kyriacou and Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016) (n 850).
[1083] Patents Law 16(1)/1998.
[1084] Article 54(2) European Patent Convention. ('The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application').
[1085] EPO, 'Guidelines for Examination in the European Patent Office' (November 2017 edn) Part G, Ch, VII, Section 3.
[1086] EPO Guidelines (n 1085) Part G – Chapter IV-2 Section 2.

may not be specific Cypriot case law on pharmaceutical novelty, EPO decisions are crucial in shaping how patents, including pharmaceutical patents, are assessed in Cyprus.

In the context of pharmaceutical inventions, enabling disclosure is crucial aspect of novelty. Even if a compound has been previously mentioned in prior art, making it seemingly lacking in novelty, this legal concept can still preserve its novelty. This occurs in cases where prior art reveals the existence of a product but does not disclose details such as its manufacturing process, starting materials or precise chemical composition.[1087] For example, in the EPO decision, T 206/83 *ICI/Pyridine Herbicides*[1088] the Board of Appeal ruled that the prior art reference does not constitute an enabling disclosure of the claimed invention if it fails to provide sufficient information for a skilled person to synthesize it.[1089] This is particularly the case when essential starting materials or intermediates are not readily available or derivable from common knowledge. In the current case, the prior art merely described the compound without providing a detailed method for its preparation. As a result, the claimed invention remains novel as the cited reference does not meet the requirements for an enabling disclosure under Article 54 EPC.[1090]

### 3.2.5. Inventive step

While novelty is assessed based on the measurable differences between the claimed invention and prior art, inventive step evaluates the qualitative aspects of those differences.[1091] According to Section 7 of the Patents Law 16 (1)/1998[1092], an invention shall involve an inventive step if, considering the prior art is defined in Section 6(2), it is not obvious to a specialist in the field.[1093] Similarly, at the European level, Article 56 of the EPC[1094] establishes that an invention involves an inventive step if it is not obvious to a person skilled in the art. However, Cypriot law does not provide further definitions or detailed explanations of key concepts related to the inventive step, such as the notion of a “person skilled in the art” or

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[1087] Richard Davis *et al.,* Tritton on Intellectual Property in Europe (5th edn, Sweet & Maxwell, 2018) 91.
[1088] T 206/83 *ICI/Pyridine Herbicides* [1986] E.P.O.R. 232 para [11].
[1089] T-206/83 [1986] (n 1088) para [11].
[1090] Article 54 European Patent Convention.
[1091] Bently *et al.,* (n 41) 578.
[1092] Patents Law 16(1)/1998, Section 7.
[1093] Patents Law 16(1)/1998, Section 6(2).
[1094] Article 56 European Patent Convention. (‘An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art’).

"prior art." Due to the lack of clear legislative guidance, the interpretation of the inventive step in Cyprus is likely to be shaped primarily by judicial decisions, placing a greater responsibility on the courts in determining the scope of patentability.[1095]

The term 'prior art' encompasses all information that has been made available to the public before the filing date of a patent application, whether through oral description, written form, or any other means. An invention may meet the requirement of inventiveness[1096] if, considering the prior art, it is not obvious to a person skilled in the relevant field. Furthermore, an invention must also satisfy the criterion of industrial applicability. As outlined in Section 8 of the Patents Law 1998, an invention is considered capable of industrial application if it can be manufactured or utilized in any industry.[1097]

While specific Cypriot case law on the inventive step in pharmaceutical patents is not readily available, Cyprus's alignment with European standards means that European case law and guidelines often influence its patent examination practices. Therefore, decisions by the EPO and interpretations of the EPC can be relevant when assessing inventive steps in pharmaceutical inventions within Cyprus.

As discussed in the context of inventive step in the UK[1098], the *Pozzoli* test originated from UK case law is used by UK courts to assess inventive step. However, the EPO applies a different method, the so-called 'problem-and-solution approach'[1099] to determine whether an invention would have been obvious to a person skilled in the art.[1100] This approach ensures consistency and predictability in patent examination. It consists of three key stages.[1101] The first identifies the closest prior art, the second defines the technical problem the invention seeks to solve, and the third assesses whether the claimed invention, starting from the closest prior art and identified technical problem, would have been obvious to a person skilled in the

[1095] Patents Law 16(1)/1998, Section 6(2).
[1096] Patents Law 16(1)/1998, Section 7.
[1097] Patents Law 16(1)/1998, Section 7.
[1098] Patent Act 1977, Section 3 defines the inventive step.
[1099] EPO Guidelines (n 1085). The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant filed of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date.
[1100] EPO Guidelines (n 1085). See also European Patent Convention, Article 56. See also *Bayer/Corbonless Copying Paper*, where the problem and solution is established and is approach used by the EPO.
[1101] Bently et *al.,* (n 41) 585.

art. By understanding and structuring the analysis in this way, the EPO aims to provide a systematic and objective assessment of inventive step.[1102] The difference with the EPO test lies mainly in the necessity of finding the 'hypothetical problem' in the EPO 'problem-solution' approach, which some authors claim has added an additional step, as opposed to the English analysis.[1103]

### 3.2.6. Industrial application

The last patentability requirement is that the invention shall be considered industrially applicable if it can be made or used in any kind of industry.[1104] This interpretation aligns with the broader understanding of industrial applicability including the EPC[1105] and the UK Patents Act 1977[1106] which similarly extends the concept to various sectors beyond conventional industry.

### 3.2.7. Sufficiency of disclosure

The description of the invention must be presented in a manner that is sufficiently clear and complete to enable a person skilled in the art to carry out the invention.[1107] The claims must define the scope of the invention for which patent protection is sought.[1108] Specifically, the claims must be clear and concise[1109], supported by the description[1110], and presented in the prescribed format.[1111] The abstract of the invention serves solely as technical information and should not be used for interpreting the claims.[1112]

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[1102] Bently *et al.,* (n 41) 585.
[1103] Philip W Grubb *et al., Patents for Chemicals, Pharmaceuticals, and Biotechnology. Fundamentals of Global Law, Practice and Strategy* (6th edn, OUP, 2016) 74.
[1104] Patents Law 16(1)/1998, Section 8(1). The term 'industry' shall be understood in its broadest sense, encompassing not only traditional manufacturing sectors but also handicraft, agriculture, fishery, and services.
[1105] Article 57 European Patent Convention. ('An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture').
[1106] UK Patent Act 1977, Section 4.
[1107] Patents Law 16(1)/1998, Section 15. See also Article 83 European Patent Convention. ('The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art').
[1108] Patents Law 16(1)/1998, Section 16(1).
[1109] Patents Law 16(1)/1998, Section 16(2).
[1110] Patents Law 16(1)/1998, Section 16(3).
[1111] Patents Law 16(1)/1998, Section 16(4).
[1112] Patents Law 16(1)/1998, Section 17.

4. Scope of protection

Patent protection grants exclusive rights to inventors over their inventions for a limited period, typically 20 years from the filing date. These rights allow the patent holder to prevent others from making, using, selling or importing the patented invention without the patent's consent.[1113] This monopoly is intended to incentivize innovation by allowing inventors to recover R&D costs. However, in industries such as pharmaceuticals, the exercise of patent rights can also have significant implications for access to essential medicines.

Patent infringement is an extremely complex area of law[1114] which, occurs when a third party, without authorization, engages in activities that fall within the scope of protection defined by the patent claims. In the pharmaceutical sector, infringement disputes often arise when generic manufacturers seek to enter the market before patent expiration. Courts assess infringement based on whether the accused product or process directly or indirectly reproduces the patent invention. Some jurisdictions also apply the doctrine of equivalence, and that will be discussed in the next sections.[1115]

Understanding patent protection and infringement is essential for evaluating the balance between innovation and public health. While strong patent rights discourage infringement in drug development, they also contribute to high drug prices and delayed access to generics, particularly in low and middle-income countries.[1116] The ability of pharmaceutical companies to enforce broad patent rights, extend monopolies and use infringement claims influences not only market competition but also the availability of affordable treatments for life-threatening conditions. Legal mechanisms such as compulsory licensing and parallel imports are frequently used to balance intellectual property protection with public health interests. The role and effectiveness of these mechanisms in ensuring access to medicines were examined in previous chapter.

[1113] European Patent Convention, Article 63. The term of the European patent shall be 20 years from the date of filing of the application.
[1114] Bently *et al*., (n 41) 647.
[1115] See section 4 'Scope of Protection' subsection 4.3.1. for United Kingdom.
[1116] Kevin J Hickey and Erin H Ward, 'The Role of Patents and Regulatory Exclusivities in Drug Pricing' (2024) (*Congressional Research Service*) 34. Available: https://www.congress.gov/crs-product/R46679

### 4.1. International

As discussed earlier in this chapter, the TRIPS Agreement came into force in 1995.[1117] Notably, TRIPS represents a far stronger treaty than any prior intellectual property (IP) agreement.[1118] Article 28 of the TRIPS Agreement defines the scope of protection granted by a patent and establishes the rights conferred to a patent holder as well as the circumstances under which patent infringement occurs.[1119] Under Article 28(1) of the TRIPS Agreement, patent owners are granted exclusive rights[1120] to prevent third parties from making, using, offering for sale, selling or importing a patented product without the owner's consent.[1121] In cases where a patent covers a process, the owner can prevent others from using that process as well as from using, offering for sale, or importing products directly obtained from that process.[1122]

This exclusivity leads to high prices for patented drugs, a challenge that highlights in his analysis of the intersection between intellectual property law and access to healthcare.[1123] Pharmaceutical companies holding patents on life-saving medications can control both production and pricing, exacerbating the issue of unaffordable medicines, particularly in low- and middle-income countries.[1124]

Gervais emphasizes[1125] that the exclusive rights granted under Article 28 TRIPS created barriers for generic drug manufacturers, preventing them from producing affordable alternatives during the 20-year patent period. This restriction contributes to the unaffordability of essential medicines, conflicting with fundamental rights such as the right to health. The tension between patent law and public health, as analysed by Gervais, underscores the need for flexibility within the TRIPS framework to ensure that access to medicines is not excessively hindered.

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[1117] Gervais (n 93) 55 subsection 2.01.
[1118] Gervais (n 93) 55 subsection 2.01.
[1119] Gervais (n 93) 461 subsection 3.412. Article 28 TRIPS ('Rights Conferred').
[1120] Gervais (n 93) 461 subsection 3.412.
[1121] Gervais (n 93) 461 subsection 3.412.
[1122] Gervais (n 93) 462 subsection 3.412.
[1123] Gervais (n 93) 130 subsection 2.76. and 129 subsection 2.75.
[1124] Gervais (n 93) 130 subsection 2.76.
[1125] Gervais (n 93) 130 subsection 2.76.

While Gervais provides a comprehensive analysis of access to medicines, his work does not specifically focus on NCDs.[1126] However, his commentary on TRIPS Agreement and its impact on healthcare includes discussions on diseases like HIV/AIDS which face similar challenges regarding access to affordable treatments. He highlights how patent exclusivity creates barriers for individuals in need of life-saving medications, particularly in low- and middle-income countries, and examines how this issue played out during the HIV/AIDS crisis.[1127] The experience of HIV/AIDS serves as a key example of the broader implications of intellectual property law on public health, which is critical when considering access to medicines for both CDs and NCDs.[1128] This relationship between patent exclusivity and high drug prices directly impact access to medicines, which is central to the concerns addressed in this thesis.

However, Article 28 of TRIPS[1129] plays a crucial role in the availability and affordability of essential medicines, particularly in developing countries. Patent holders' exclusive rights mean that generic manufacturers cannot produce cheaper alternatives until the patent expires (typically 20 years), keeping drug prices high. Many low- and middle-income countries rely on generic medicines for affordable healthcare and patent monopolies can severely limit access to life-saving treatments, including HIV/AIDS and cancer medications. While patents incentivize research and development, they also restrict competition, reinforcing high drug prices.

For people with chronic diseases, Article 28 of TRIPS presents significant challenges in accessing affordable medications. Patent exclusivity prevents the production of generic alternatives leading to high costs for treatments related to diabetes, cancer, and cardiovascular diseases. This disproportionately affects low-income regions where patients depend on generic alternatives. The lack of competition strengthens pharmaceutical monopolies, further exacerbating global healthcare inequalities.

While much commentary on TRIPS and public health has focused on Article 28.1, it is important to recognise that the Agreement provides a broader range of flexibilities that

[1126] Gervais (n 93) 130 subsection 2.76.
[1127] Gervais (n 93) 130 subsection 2.76.
[1128] Gervais (n 93) 130 subsection 2.76.
[1129] Gervais (n 93) 461-426 subsection 3.412 explains Article 28 TRIPS Agreement.

remain under-utilised. Articles 6, 27.1, 30, 31 and 39.3 TRIPS collectively allow WTO Members significant discretion in balancing patent protection with public health needs. Measures such as parallel imports, limited exceptions to patent rights, compulsory licensing, and flexible approaches to regulatory data all present opportunities for states to promote the right to health and improve access to medicines for non-communicable diseases. Yet, these mechanisms are often neglected in favour of narrower interpretations of TRIPS obligations, which restrict their potential as tools of Intellectual Property and Social Justice.

### 4.2. Regional

Article 69 of the European Patent Convention links the scope of protection conferred by a patent to its claims.[1130] The Protocol on the Interpretation of Article 69 EPC[1131] clarifies that courts should interpret claims in a way that balances fair protection for patentees with legal certainty for third parties.[1132] In this perspective, the claims should neither be interpreted too strictly nor treated as mere guidelines. National courts have taken different approaches to applying Article 69 and harmonizing these interpretations will be crucial for the Unified Patent Court, which seeks to create a consistent approach to determining the scope of protection.[1133]

This includes addressing how national courts consider equivalents, the importance of the literal wording of claims, and the influence of prosecution history on claim interpretation. While the EPC governs the grant of European patents, enforcement infringement, revocation and litigation remain matters of national law.[1134] Article 2 of the Protocol on the interpretation of article 69 of the EPC[1135] states "*For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in claims.*"[1136]

[1130] England (n 1004) 689.
[1131] Article 69 European Patent Convention. ('The extend of the protection conferred by a European patent or a European patent application shall be determined by the claims').
[1132] Article 69 European Patent Convention (n 1131).
[1133] England (n 1004) 689.
[1134] Bently *et al.,* (n 41) 417.
[1135] Article 69 European Patent Convention (n 1131).
[1136] Art. 2 of the Protocol on the Interpretation of Art. 69 European Patent Convention.

This interpretive approach, while technical, also has important implications for IP-SJ. The way in which patent claims are construed under the EPC can determine the scope of exclusivity afforded to pharmaceutical patents, which in turn influences the availability of generic medicines for NCDs and impacts the equitable realization of the right to health.

### 4.3. National

The scope and enforcement of patent protection vary across different legal frameworks, ranging from international agreements to regional systems and national laws. While international treaties like the TRIPS Agreement establish fundamental principles for patent rights, regional agreements such as the European Patent Convention, provide additional harmonization. At the national level, countries such as the UK and Cyprus implement their own patent laws, which define how patents are protected, enforced, and infringed.

This section examines the scope of patent infringement under the national patent laws of the UK and Cyprus. In both jurisdictions, patent infringement is governed by Section 60 of the UK Patent Acts 1977[1137] and Section 60 of the Cyprus Patents Law 1998[1138]. Both legal systems distinguish between direct and indirect infringement, setting out different criteria for liability. The following subsections provide a detailed analysis of the infringement provisions in each jurisdiction.

In both the UK and Cyprus, the construction of patent claims is not only a matter of legal technique but also a determinant of access. Broader or narrower interpretations directly affect the ability of competitors to develop affordable alternatives. From an IP-SJ perspective, this raises significant questions about whether claim construction should prioritize public health considerations, particularly in the field of NCDs where long-term access to essential medicines is vital to the right to health.

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[1137] Patent Act 1977, Section 60.
[1138] Patents Law 16(1)/1998, Section 60.

### 4.3.1. United Kingdom

Patent infringement is a highly complex area of law.[1139] The scope of a patent should not be limited to situations where infringement act takes place in relation to a product or process that is the same as the patented invention. While broadening the patent's reach beyond a strict interpretation of its claims helps protect the patent holder's rights, it also raise a new questions, such as how a patent can be extended and how much of an invention must be used for infringement to occur.[1140] These uncertainties make infringement analysis even more challenging.

The complexity of infringement is closely tied to the UK's involvement in the European Patent Convention (EPC).[1141] When the EPC was established in 1973, it was agreed that national courts, rather than a central authority, would handle patent infringement cases. This arrangement has led to challenges because patent validity and infringement are so closely intertwined. Decisions made by the EPO, particularly in a relation to novelty, have had a profound impact on UK patent law. The situation has been further complicated by the lack of a unified tribunal to handle infringement cases, making the process even more burdensome and inconsistent.[1142]

Despite complexities, determining infringement generally involves three key steps. First it is necessary to determine the types of activity that constitute an infringement. Next, it is necessary to ascertain whether the activity complained of falls within the scope of the patent monopoly, and finally it needs to be determined whether the defendant can make use of any of the defences that are available to them.[1143]

It is also important to note that there are two types of infringement: direct and indirect. The key distinction between them is that direct infringement involves some immediate engagement with the patented product or process[1144] such as manufacturing or selling a

[1139] Bently *et al*., (n 41) 647.
[1140] Bently *et al.,* (n 41) 647.
[1141] Bently *et al.,* (n 41) 647.
[1142] Bently *et al.,* (n 41) 647.
[1143] Bently *et al.,* (n 41) 647.
[1144] Patent Act 1977, Section 60(1).

patented invention without authorization. In contrast, indirect infringement applies where a party facilitates the act of infringement[1145] in effect, patent law's version of aiding and abetting.[1146]

Thus for a patentee to succeed in an infringement claim, they must show on the balance of probabilities that the defendant engaged in an activity falling within the patent owner's exclusive rights.[1147] The rights given to a patent owner are outlined in the Patent Act 1977, which covers a wide range of actions, including making, using, selling or importing a patented product or process. As a result, most, if not all, commercially valuable activities fall within the owner's control.[1148]

Direct infringement and the rights given to patent holders are listed in Section 60 of the Patent Act 1977.[1149] In the realm of pharmaceutical innovation, the holder of patent rights possesses exclusive authority over the production, distribution and commercialization of a patented product.[1150] This includes the right to manufacture, use, offer for sale, import and retain the product, whether for commercial purposes or otherwise.[1151] For instance, a pharmaceutical company that has developed a drug for a specific disease can control its production and distribution, thereby determining market access and pricing strategies. This exclusivity, while fostering innovation, also raises critical questions regarding equitable access to essential medicines, particularly in low-income regions.

The extent of these rights depends on whether the patent protects a product, a process, or a product obtained directly from a process. Except in cases where an infringer uses or 'offers a process for use' under Section 60(1)(b), direct infringement occurs regardless of the defendant's knowledge.[1152] This means that for product patents or products derived from a patented process, liability is absolute, and the patentee is not required to prove that the

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[1145] Patent Act 1977, Section 60(2); CPC, Art. 26. Patent Act 1977 also contains provisions on contributory infringement.
[1146] Bently *et al*., (n 41) 648.
[1147] Patent Act 1977, Section 60(1)-(2). See also Bently *et al.,* (n 41) 648.
[1148] Bently *et al.,* (n 41) 648.
[1149] Patent Act 1977, Section 60. Defines the scope of patent monopoly.
[1150] Patent Act 1977, Section 60(1)(a). See also Bently *et al*., (n 41) 647.
[1151] Patent Act 1977, Section 60(1)(a).
[1152] Patent Act 1977, Section 60(1)(b).

defendant was aware of the infringement. Even if the invention was created independently, accidentally, or unintentionally, it would still constitute an infringement.[1153]

Indirect infringement is established under Section 60(2) of the Patent Act 1977.[1154] A person other than the proprietor of the patent also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor[1155], he supplies or offers to supply in the UK a person other than a licensee or other person entitled to work the invention with any of the means[1156] relating to an essential element of the invention, for putting the invention into effect when he knows[1157], or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect, in the UK.[1158]

Once a patent is granted and the rights conferred under Section 60 of the Patent Act 1977[1159], it is necessary to determine the scope of protection and what is covered by the patent. UK courts have examined cases to clarify the extent of protection.

The history of patent claim interpretation in the UK typically begins with Lord Diplock's 1982 House of Lords judgment in *Catnic* v *Hill and Smith*[1160], which introduced the purposive interpretation approach.[1161] This means that, rather than limiting the meaning of a claim to a literal or strict meaning, it is necessary to interpret claims from the perspective of the person skilled in the art.[1162] This approach evolved with the *Improver* Questions and was later modified by the *Actavis* v *Eli Lilly* case[1163], which is the leading authority.

The specific mention of equivalents in Article 2 of the Protocol on the Interpretation of Article 69 EPC was a source of interest in the UK because a 'doctrine of equivalents' had never been

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1153 Bently *et al.,* (n 41) 648.
1154 Patent Act 1977, Section 60(2).
1155 Patent Act 1977, Section 60(2).
1156 Manimaran R and Sheik S, 'A Guide to Patent Infringement: A Global Perspective 2019-2020' (2019) 6 Court Uncourt 2.
1157 Manimaran and Sheik (n 1156) 2.
1158 Manimaran and Sheik (n 1156) 2.
1159 Patent Act 1977, Section 60.
1160 *Catnic* v *Hill and Smith* [1982] RPC 183.
1161 *Catnic* v *Hill and Smith* [1982] (n 1160) 241.
1162 *Catnic* v *Hill and Smith* [1982] (n 160) 241.
1163 *Actavis UK Ltd* v *Eli Lilly & Co* [2017] UKSC 48, [2017] RPC (21) 957 [8].

considered part of English law.[1164] However, even before this provision came into force in the UK, the House of Lords ruled in *Kirin-Amgen* that Article 69 EPC ‘shuts the door on any doctrine, which extends protection outside the claims’.[1165] Thus the scope of a patent must be limited by the extent of the claims and no further.[1166] Although Article 69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean.[1167]

Since *Kirin-Amgen*, the Court of Appeal has sought to organize the principles laid down by the House of Lords in a list of eleven guidelines.[1168] Notably, the ninth guideline explicitly states that there is no general doctrine of equivalents. However, more recent decisions by the Court of Appeal clarify that this does not mean equivalents are irrelevant to claim construction. Instead, English law recognises that if equivalents do not materially affect how an invention works, they can influence how a skilled person interprets the scope of a claim.[1169] This recognition aligns with the Protocol Questions[1170] which at the time had been little considered for ten years.

The evolution of patent claim interpretation in the UK law began with *Catnic* v *Hill* and *Smith*[1171]*,* where Lord Diplock’s 1982 judgment established the principle of ‘purposive’ construction, meaning that the claims should be interpreted not by their strict literal wording but from the perspective of a person skilled in the art[1172] considering the inventor’s intended purposes. This approach was further refined in *Improver* v *Remington*[1173], where the court introduced the *Improver* questions, a three-step test to determine whether a variant of a patented invention could still constitute infringement despite not being identical.[1174]

[1164] England (n 1004) 689.
[1165] *Kirin-Amgen Inc* v *Hoechst Marion Roussel Ltd* [2004] UKHL, 46; [2005] RPC 9.
[1166] *Kirin-Amgen Inc* v *Hoechst Marion Roussel Ltd* (n 1165) [49].
[1167] England (n 1004) 690. It expressly provided by the new Article 2 added to the Protocol by the Munich Act revising the EPC.
[1168] The Court of Appeal modified these principles to take into account the amended language of the EPC 2000.
[1169] *Actavis UK Ltd* v *Eli Lilly & Co* (n 1163) [41] and [43].
[1170] *Improver Corporation* v *Remington Consumer Products Ltd* [1990] FSR 181.
[1171] *Catnic Components Ltd* v *Hill & Smith Ltd* [1982] (n 1160) 241.
[1172] *Catnic Components Ltd* v *Hill & Smith Ltd* (n 1160) 241.
[1173] *Improver Corporation* v *Remington Consumer Products Ltd* (n 1170). Bently *et al.*, (n 41) 674.
[1174] Bently *et al.,* (n 41) 674.

The *Improver* Questions are as follows:

1. Does the variant have a material effect on the way in which the invention works? If yes, the variant is outside the claim. If no:
2. Would this (i.e. that the variant has no material effect) have been obvious to a reader skilled in the art at the date of the publication of the patent? If no, the variant is outside the claim. If yes:
3. Would a reader skilled in the art nevertheless have understood from the language of the claim that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.[1175]

Over time, courts have attempted various approaches to answering these questions. A key turning point was the 2017 Supreme Court decision in *Actavis* v *Eli Lilly*[1176], which held that patents can be infringed even if the infringement does not include all of the feature of an independent claim but instead has one or more features that are equivalent to the future in the claim.[1177] While *Actavis* represents an important reformulation of the test of the scope of protection because the decision builds on some of the important decisions that preceded it, it may be helpful to outline the judicial and legislative background.[1178] Therefore, the doctrine of equivalence now exists because of *Actavis* v *Eli Lilly*[1179] case.

The UK patent is part of the EPC, and the element specified in the claim was the use of antifolate pemetrexed disodium. Therefore, if a party creates a similar invention by substituting a different element for one specified in the original patent claim such as using a different ingredient in a drug, as in the case of *Actavis* v *Eli Lilly*, the substituted element may be considered equivalent.[1180]

[1175] *Improver Corporation* v *Remington Consumer Products Ltd* (n 1170). Bently *et al*., (n 41) 674.
[1176] *Actavis UK Ltd* v *Eli Lilly & Co* [2017] UKSC 48 (n 1163) [2].
[1177] *Actavis UK Ltd* v *Eli Lilly* (n 1163) [8].
[1178] Bently *et al.,* (n 41) 667.
[1179] *Actavis UK Ltd* v *Eli Lilly* (n 1163) [45].
[1180] *Actavis* v *Elil Lilly* [2017] UKSC 48 (SC): the doctrine of equivalents in the UK, France and Germany.

The *Actavis* v *Eli Lilly* and its doctrine of equivalence is arguably meeting the standards of the EPC and the requirements of the Protocol provision.[1181] The case of *Actavis* v *Eli Lilly* was an infringement action concerned a chemotherapy drug patented by *Eli Lilly*.[1182] *Eli Lilly's* patent covered the use of antifolate pemetrexed disodium in the manufacture of a medicament for use in combination with vitamin B12 (and optionally folic acid) for cancer treatment, which overcomes the side effects of earlier antifolates.[1183] *Actavis* wanted to manufacture a medicament combining antifolates with vitamin B12 but using different forms of pemetrexed disodium.[1184]

*Actavis* was found to be in breach of *Eli Lilly's* patent by developing a similar chemotherapy drug where one of the salts in the production process was replaced. While drugs can produce the same therapeutic effect through different chemical reactions, the issue in this case centred on whether *Actavis's* modification fell within the scope of *Eli Lilly's* patent.[1185] Therefore, under the doctrine of equivalents, a party may be liable for infringement even if the exact terms of the patent claim are not literally met provided that the alternative method or ingredient achieves the same results. *Actavis* argued that by using a different antifolate compound, they were not infringing *Eli Lilly's* patent.[1186] However, the court applied a purposive interpretation and determined that *Actavis's* drug, despite the chemical modification, was essentially the same as the patented invention.[1187] Therefore, it fell within the monopoly granted by the original patent, and *Actavis* was found to have infringed *Eli Lilly's* patent.

The *Actavis* v *Eli Lilly* case marks a significant shift in the UK patent law, reinforcing the doctrine of equivalents and broadening the scope of protection in pharmaceuticals. While this strengthens patent owners' rights, particularly in the pharmaceutical industry, it also raises concerns about access to affordable medicines as it makes it more difficult for generic manufacturers to introduce alternative formulations. This decision aligns the UK's approach

1181 Protocol on the Interpretation of Article 69 EPC 2000. See also *Actavis* v *Elil Lilly* (n 1163) [31].
1182 *Actavis UK Ltd* v *Eli Lilly* (n 1163) para [8] and [9].
1183 *Actavis UK Ltd* v *Eli Lilly* (n 1163) para [8].
1184 *Actavis UK Ltd* v *Eli Lilly* (n 1163) [69].
1185 *Actavis UK Ltd* v *Eli Lilly* (n 1163) [7].
1186 *Actavis UK Ltd* v *Eli Lilly* (n 1163) [27].
1187 *Actavis UK Ltd* v *Eli Lilly* (n 1163) [41] and [43].

more closely with European patent standards, potentially influencing future patent disputes. However, it also highlights the ongoing tension between intellectual property rights and public health needs, a central issue in global debates on pharmaceutical patents and medicine accessibility.

The *Actavis* v *Eli Lilly* decision is a landmark case that expands patent protection in the UK. This case highlights the need for a balanced approach that protects innovation while ensuring life-saving medicines remain accessible to those who need them most. This case is also relevant because the doctrine of equivalents can broaden the scope of protection, making it harder for generic drug manufacturers to introduce alternative versions of patented medicines.

### 4.3.2. Cyprus

Under the Patents Law 16(1)/1998, Section 60(1) and Section 60(2) defined acts of infringement for Cyprus.[1188] The performance of any act referred to in Section 27(1)[1189], (2)[1190] and (4)[1191] of this Law in Cyprus by a person other than the owner of the patent, without the consent of the latter, in relation to a product or process falling within the scope of protection of the patent shall constitute an infringement of the patent.[1192] Under Section 60(2) of the Patents Law 1998, the performance of any act referred to in Section 27(1), (2) and (4) of this Law in Cyprus by a person other than the applicant, and without the consent of the applicant, in relation to a product or process falling within the scope of provisional protection conferred on a published patent application shall constitute an infringement of that provisional protection.[1193]

There are two rights that allow the proprietor to prevent third parties from using the invention without their consent.[1194] Article 25 of the EPC outlines the right to stop the direct use of the

[1188] Patents Law 16(1)/1998, Section 60(1) and Section 60(2).
[1189] Patents Law 16(1)/1998, Section 27(1).
[1190] Patents Law 16(1)/1998, Section 27(2).
[1191] Patents Law 16(1)/1998, Section 27(4).
[1192] Patents Law 16(1)/1998, Section 60(1).
[1193] Patents Law 16(1)/1998, Section 60(2).
[1194] Jougleux (n 1045) 380.

invention.[1195] This include preventing a third party from making, offering, marketing, using, importing or storing a product that is covered by the patent.[1196] The patent also gives the proprietor the right to stop third parties from using a patented process without consent or offering the process for use in the Contracting Member States in which that patent has effect.[1197] Additionally, it prevents third parties from offering, placing on the market, using, importing or storing for those purposes a product obtained directly by a process which is the subject matter of the patent.[1198]

Article 26 of the EPC provides the right to prevent the indirect use of the invention.[1199] A patent grants its owner the right to stop any third party who does not have the owner's consent, from supplying or offering to supply within the territory of the Contracting Member States in which that patent has effect. This applies to anyone other than those authorized to use the patented invention, with means, relating to an essential element of that invention, of putting into effect therein, when the third party knows or should have known that those means are suitable and intended for putting that invention into effect.[1200] Article 26(2)[1201] of the EPC, in other words, states that the protection is extended to means that are essential to the implementation of the invention.[1202] Indirect infringement may be seen as a counterpart to the right of discovery of the mechanism of ethical autonomy and collaboration. For this reason, liability for indirect infringement of the proprietor's right is accompanied by safety provisions. First actual, or substantiated knowledge of the infringement is required. Second, liability is not invoked when the means are common commercial products.[1203]

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1195 Article 25 European Patent Convention. ('Right to prevent the direct use of the invention').
1196 Article 25(a) European Patent Convention ('A patent gives its owner the right to stop others, without consent, from making, offering, placing on the market or using a product which is the subject matter of the patent, or importing or storing the product for those purposes').
1197 Article 25(b) European Patent Convention. ('A patent gives its owner the right to stop others, without consent, from using a process which is the subject matter of the patent or, where the third party knows, or should have known, that the use of the process is prohibited without the consent of the patent proprietor, offering the process for use within the territory of the Contracting Member States in which that patent has effect').
1198 Article 25(c) European Patent Convention. ('A patent gives its owner the right to stop, without consent from offering, placing on the market, using, or importing or storing for those purposes a product obtained directly by a process which is the subject matter of the patent').
1199 Article 26 European Patent Convention. ('Right to prevent the indirect use of the invention').
1200 Article 26(1) European Patent Convention. ('A patent gives its owner the right to stop others from providing or offering to provide, within the relevant Member States, any means related to an essential part of the invention to unauthorized persons. This applies if the third party knows or should know that these means are meant to use the invention').
1201 Article 26(2) European Patent Convention. ('Subsection 1 from Article 26 does not apply to stable commercial products, unless the third part encourage the recipient to carry out actions forbidden by Article 25 of the European Patent Convention').
1202 Article 26(2) European Patent Convention (n 1201).
1203 Article 26(2) European Patent Convention (n 1201. See also Jougleux (n 1045) 381.

## 5. Conclusion

This chapter examined the private face of patent law, focusing on its role in the pharmaceutical sector within the context of the UK and Cyprus. Through this analysis, several critical insights have emerged, highlighting the complex interplay between protections, innovation incentives and public health needs.

The legal frameworks governing patent protection at international, regional, and national levels, highlighting how patents serve private interests while raising significant concerns about access to essential medicines, particularly for NCDs. While patent law is designed to incentivize innovation by granting exclusive rights to inventors, it can simultaneously create significant barriers to affordable access to life-saving treatments, especially in low-and middle-income countries. The high prices associated with patented drugs disproportionately affect low-income patients in both the UK and Cyprus. To mitigate these impacts, key agreements such as the TRIPS Agreement, the European Patent Convention and national legislation in the UK and Cyprus reveals the extent to which patent rights are enforced and the challenges they present for public health. The Intellectual Property and Social Justice also highlights the need for a balanced framework that not only protects the private interest but also ensures equitable access to medicines.

Taken together, these findings demonstrate how the legal framework of patent protection often prioritizes private economic interests, creating tensions with the social imperative of safeguarding public health. This tension is central to the thesis as it illustrates the ongoing need to critically assess and reform intellectual property law to achieve a more equitable balance between innovation incentives and access to essential medicines.

Furthermore, case law demonstrated a clear and detailed analysis of patent rules and their interaction with the pharmaceutical sector, focusing on the criteria for patentability, ensuring that inventions are novel, involve an inventive step and are capable of industrial application. However, concerns remain over evergreening and the potential misuse of patents to extend market exclusivity without substantial innovation. Within the UK, the robust intellectual property regime fosters pharmaceutical innovation but also presents affordability challenges for essential medicines, particularly for NCDs. Conversely, Cyprus with its smaller healthcare infrastructure and narrow cases reliant on EU frameworks, faces difficulties in balancing compliance with international obligations while ensuring equitable medicine access.

Finally, this chapter establishes that while patents are a vital tool for fostering medical advancements, they must be regulated in a way that aligns with broader social justice goals. Building on these findings, this next chapter will present targeted recommendations aimed at bridging this gap, proposing legal and policy interventions that can reconcile the dual goals of incentivizing innovation and ensuring public health for all.

## CHAPTER FIVE: ANALYSIS AND POLICY RECOMMENDATIONS FOR NCD MEDICINEs

### 1. Introduction

This chapter explores the challenges surrounding access to medicines for non-communicable diseases (NCDs) and provides recommendations for improving the international, UK and CY frameworks. With the research question, "*To what extent does patent law affect the right to health and access to medicines for non-communicable diseases?",* this chapter not only examines how existing legal frameworks impact the right to health and access to medicines for NCDs but also offers strategies for reform to enhance affordability and accessibility.

The two case studies examined in this chapter, Ozempic and Imatinib (Gleevec), were chosen for their relevance in highlighting the challenges and potential solutions related to access to life-saving treatments for chronic conditions. Ozempic (Semaglutide) is a brand-name medication that remains under patent protection, preventing the availability of generic versions and raising concerns about affordability, particularly for patients with type 2 diabetes and obesity. In contrast, Imatinib (Gleevec) was originally a patented drug but its patent has expired in many countries, allowing the production of generic versions. This has significantly improved accessibility and affordability for patients worldwide, particularly for those with chronic myeloid leukaemia.[1204]

Ozempic, as a patented drug, demonstrates the challenges associated with patent protection, pricing, and the impact of the intellectual property law on access to medicines. In the contexts of the UK and Cyprus, this case study will examine how patent regulations influence the availability and accessibility of essential NCD treatments. Furthermore, the discussion will explore how the absence of generic alternatives affects healthcare costs and access to medicines for individuals with type 2 diabetes and obesity.

[1204] Abdülkadir Erçalışkan *et al.,'*Current evidence on the efficacy and safety of generic imatinib in CML and the impact of generics on health care costs' (2021) 5(17) Blood Adv 3344-3353. See also Larry Gorkin and Hagop Kantarjian, 'Targeted therapy Generic imatinib-impact on frontline and salvage therapy for CML' (2016) 13(5) Nat Rev Clin Oncol 270. See also Maria Gemelli *et al.,'*Use of generic imatinib as first-line treatment in patients with chronic myeloid leukaemia (CML): the GIMS (Glivec to Imatinib Switch) study' (2020) 55(3) Blood Research 139-145. See also A Hochhaus *et al.,* 'European Leukaemia Net 2020 recommendations for treating chronic myeloid leukaemia' (2020) 34 Leukaemia 966-984.

Conversely, the case of Imatinib (Gleevec), where the patent has expired and generic versions are widely available, demonstrates how generic competition can reduce costs and improve access to life-saving NCD treatments such as leukaemia. However, despite its patent expiry, challenges remain, including differences in national regulations and policy barriers that lead to inconsistent access to generics across different healthcare systems. These disparities will be analysed in the context of the UK and Cyprus to access the role of patent laws in shaping access to medicines for NCDs.

This research exposes several critical barriers to access and affordable medicines for NCDs. Key findings include the impact of the TRIPS Agreement, which enforces patent protections on essential drugs and limits the availability of generics. While the Doha Declaration provides flexibilities to prioritize public health, the application of these provisions remains inconsistent. The case of Imatinib (Gleevec) illustrates how generic availability significantly enhances treatment access, yet variations in national regulatory frameworks continue to create obstacles.

In both the UK and Cyprus, national institutions play a crucial role in supporting healthcare access. However, gaps persist in policies that ensures equitable access to new, patented NCD treatments. These findings highlight the need for policy reforms at both international and national levels, advocating for greater flexibility in intellectual property laws, stronger public health protections, and improved policies to enhance the accessibility and availability of essential medicines for NCDs.

To critically assess the impact of patent law on access to NCD medicines, this section applies the Intellectual Property-Social Justice (IP-SJ) framework. NCDs, such as cancer, diabetes, and cardiovascular diseases, differ significantly from communicable diseases like HIV/AIDS in their nature and the challenges they present for healthcare systems and patent law. NCDs requires a long ongoing treatment, often with expensive medication.[1205] In addition, NCDs can span a lifetime, leading to significant economic burden on individuals and healthcare systems.[1206]

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[1205] Details for NCDs can be found in Chapter Two: Health Framework - section 2.2. ('Non-Communicable Diseases NCDs').
[1206] Taulant Muka *et al.,* 'The global impact of non-communicable diseases on healthcare spending and national income: a systematic review' (2015) 30(4) Eur J Epidemiol 251.

Given the disparities in medicine affordability and accessibility to medicines for NCDs, IP-SJ provides a lens through which the tension between patent protection and public health can be analysed. The IP-SJ framework emphasizes the integration of social justice principles into intellectual property law, ensuring that patent protections do not undermine access to life-saving treatments. This perspective is particularly relevant for NCDs, where the high cost of medications can create inequities in healthcare access.[1207] In the case of NCDs, the monopolistic nature of patents can be especially detrimental, as it leads to sustained high prices for medications that are required for ongoing treatment, in contrast to the shorter treatment durations required for many communicable diseases.

## 2. Case studies

The following cases of Ozempic and Gleevec illustrate critical issues at the intersection of patent law, public health and social justice. These examples highlight the broader challenges and implications of intellectual property protection on the availability and affordability of treatment for NCDs. The IP-SJ framework is particularly relevant here as it highlights the need to balance innovation incentives with equitable access to essential medicines. Both cases illustrate how patent protections influence drug pricing and accessibility, affecting patients' ability to obtain life-saving medications. Therefore, applying an IP-SJ framework to these cases provides insights into how patent law can be restructured to prioritize public health while fostering medical advancements.

### 2.1. Ozempic case

Ozempic (semaglutide) offers a compelling case study in the management of type 2 diabetes, illustrating both the potential and challenges of contemporary therapeutic innovations.[1208] As a GLP-1 receptor agonist, Ozempic has demonstrated significant efficacy in improving glycaemic control and promoting weight loss, supported by extensive clinical trials that

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[1207] Mtima and D Jamar (n 58) 1-18. See also Mtima (n 49) 403.
[1208] Shaunta Chamberlin and William Dabbs, 'Semaglutide (Ozempic) for Type 2 Diabetes Mellitus' (2019) 100 (2) Am Fam Physician 116-117.

highlight its benefits over traditional treatments.[1209] Despite its clinical success, the drug's market entry has been marked by high pricing and accessibility issues, which raise concerns about affordability for patients, especially in lower-income regions. The impact of Ozempic on health policy is evident in the evolving treatment guidelines and reimbursement strategies, reflecting its integration into diabetes management protocols.[1210]

Ozempic is now increasingly prescribed by some doctors to individuals seeking rapid weight loss, including those without obesity or diabetes.[1211] This trend has sparked a surge in demand exacerbated by people ordering the drug online at cheaper prices, sometimes without proper medical supervision. Many individuals taking Ozempic are not clinically obese or diabetic but are using the drug for cosmetic weight loss. This has significantly driven up demand, as healthy individuals influenced by social media and weight-loss trends are seeking rapid results.[1212] This change in how the drug is being used raises both ethical and practical issues, especially when it comes to ensuring that people with conditions like diabetes can still get the medication they need.[1213]

Growing demand has resulted in shortages, leaving diabetes patients and the original group of people who really needed this drug struggling to access their necessary medication.[1214] The NHS is currently facing significant challenges related to Ozempic as this unexpected demand, coupled with its patent protection, has contributed to a shortage leaving many diabetes patients struggling to access their necessary treatment.[1215] The NHS is working to address these challenges, but the ongoing shortages emphasize the need for more robust strategies in managing drug availability and prescription practices in the face of rising demand.

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[1209] Chamberlin and Dabbs (n 1208) 116-117. See also Deepa Jahagirdar and Quenby Mahood, 'Semaglutide for Type 2 Diabetes (2 mg)' (2023) 3 (10) CADTH Health Technology Review 1-18.
[1210] Chamberlin and Dabbs (n 1208) 116-117. See also Jahagirdar and Mahood (n 1209) 1-18.
[1211] Chamberlin and Dabbs (n 1208) 116-117.
[1212] BBC News, 'Weight loss injection hype fuels online black market' (*BBC* 2023) <https://www.bbc.co.uk/news/health-67414203> accessed 25 March 2025.
[1213] Chamberlin and Dabbs (n 1208) 116-117. See also Jahagirdar and Mahood (n 1209) 1-18. See also Christine Blank, 'High Demand Keeps Some Diabetes Medications in Short Supply: Pharmaceutical companies are experiencing supply chain disruptions and shortages because of the popularity of diabetes drugs used for weight loss' (2023) 167 (2) Health and Medicine 16.
[1214] BBC News, 'Diabetes patients struggling without 'wonder drug' (*BBC* 2024) < https://www.bbc.co.uk/news/uk-england-hampshire-68083710> accessed 25 March 2025.
[1215] Blank (n 1213) 16. See also Joanna Mitri and Osama Hamdy, 'Diabetes medications and body weight' (2009) 8 (5) Expert Opinion on Drug Safety 573.

Contributing to this problem is the fact that Ozempic is protected by patents, preventing the production of generic alternatives that could alleviate the supply strain. Ozempic is protected by multiple patents, with the most critical one in the UK and EU set to expire on June 21, 2033.[1216] This patent specifically covers the 'use of long-acting GLP-1 peptides', which is key to the drug's prolonged effect in controlling blood sugar and facilitating weight loss.[1217] Additionally, Ozempic benefits from market exclusivity rights granted by regulatory agencies. Some of these exclusivity protections have already expired: the 'New Chemical Entity' exclusivity ended in December 2022 while the last outstanding exclusivity granted for a 'New Dosing Schedule' expired in March 2025. The patent protections prevent the production of cheaper, generic drugs which has contributed to drug shortages by limiting supply to Novo Nordisk's production capacity.[1218]

This situation highlights the complexities of intellectual property in pharmaceutical innovation.[1219] While Ozempic's global availability varies, it underscores the need for equitable access solutions and highlights ongoing research aimed at enhancing its therapeutic profile.[1220] Governments can address affordability and supply challenges by implementing compulsory licensing in cases of high prices or shortages, enabling the production of generic alternatives while ensuring fair compensation to patent holders. Compulsory licensing aligns with social justice principles by ensuring that patents do not create health inequities. It emphasizes that intellectual property law should be structured in a way that prioritize public health rather than merely protecting the commercial interests of pharmaceutical companies seeking to protect their patents on medicines. Within this framework, governments should have greater flexibility to issue compulsory licenses when drug prices become prohibitively high. In addition, adopting differential pricing models, where drug prices are adjusted based on country's income level can improve affordability without discouraging innovation. Promoting generic competition through streamlined regulatory approvals and voluntary licensing agreements can further enhance access once a patent expires. Finally, leveraging

[1216] Mitri and Hamdy (n 1215) 573.
[1217] Rasha Alhiari *et al.,* 'Patents and regulatory exclusivities on GLP-1 receptor agonists' (2023) 330 (7) JAMA 650-657.
[1218] Alhiari *et al.,* (n 1217) 650-657.
[1219] Alhiari *et al.,* (n 1217) 650-657.
[1220] Tina K Reddy *et al.,* 'Achieving equitable access to incretin-based therapies in cardiovascular care' (2024) 46 (100455) American Heart Journal Plus: Cardiology Research and Practice' 1-7.

TRIPS flexibilities and supporting global patent reforms will help align intellectual property rights with public health priorities, ensuring life-saving treatments remain accessible to all.

This case study not only provides insights into Ozempic's clinical and economic impact but also serves as a lens through which broader issues of drug accessibility and health policy can be examined. Regulating pharmaceuticals in the context of NCDs requires a balanced approach that fosters both innovation and equitable access. Patent policies should incorporate mechanisms like compulsory licensing and stronger generic competition to mitigate barriers for affordability.[1221] As Ozempic remains under patent protection, no generic alternatives yet are available. However, ensuring the timely introduction of generics post-patent expiration is critical, particularly in low-and middle-income countries where the burden of NCDs is high. Ensuring transparency in drug pricing and regulatory oversight can further help control costs, making essential medicines more affordable while still encouraging innovation.

At the same time, the legitimate interests of patent holders must be considered. Pharmaceutical companies invest significant time and resources in developing drugs such as Ozempic, relying on patent protections to recoup R&D costs and fund future innovations. A compulsory license, while aimed at improving affordability, can weaken these incentives by allowing competitors to produce the drug at lower price without the patents' holders' consent. In this case, the unfair burden on the patent holder arises because increased demand and subsequent price pressures are driven not only by medically necessary use but also by individuals using it for non-crucial purposes such as weight loss. This raises the question of whether it is fair for the patent holder (the pharmaceutical company) to bear financial losses due to how society chooses to use the drug especially when some individuals are using it for non-medical reasons. A fair approach might involve targeted pricing regulations or government subsidies rather than overriding patent protections entirely.

[1221] Urias and Ramani (n 123) 367-384.

### 2.2. Imatinib (Gleevec) for Chronic Myeloid Leukaemia (CML)

Imatinib, marketed as Gleevec, is an innovative cancer drug developed to treat Chronic Myeloid Leukaemia (CML), a non-communicable disease caused by a genetic mutation[1222] known as the Philadelphia chromosome. CML affects the bone marrow and blood. Imatinib was developed in the late 1990s with the first clinical trial taking place in 1998, and it received Food and Drug Administration (FDA) approval in May 2001.[1223] In Europe, Imatinib was approved by the European Medicines Agency (EMA) in November 2001, shortly after its approval in the United States. Following the expiration of its patent a competitive market for generic versions of imatinib emerged, significantly reducing costs and improving access for patients. In contrast, the ongoing patent protection for Ozempic, which is expected to last until 2033, limits the availability of affordable alternatives, highlighting the different implications for patient access and healthcare economics.

In addition to CML, Imatinib has been approved for treating other NCDs such as Gastrointestinal Stromal Tumour (GIST) and Philadelphia chromosome-positive Acute Lymphoblastic Leukaemia (Ph+ALL). The drug has also shown effectiveness in treating other cancers and conditions driven by similar tyrosine kinase abnormalities, such as Hypereosinophilic Syndrome (HES) and Systemic Mastocytosis.[1224] These conditions are different types of cancers, but they are not linked to lifestyle factors like obesity or poor diet. Instead, they are caused by genetic changes or problems with certain types of blood cells.

While Imatinib has been a commercial success, generating billions in revenue for its manufacturer, it has also raised questions about its pricing as the cost of the drug has significantly increased over the years.

In low-and middle-income countries, the high cost of patented medicines often limits access for those in need. This has been the case with Imatinib (Gleevec), which remains prohibitively expensive in many developing countries, restricting access for patients with CML. Similarly,

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[1222] Nida Iqbal and Naveed Iqbal, 'Imatinib: a Breakthrough of Targeted Therapy in Cancer' (2014) 2014(357027) Chemotherapy Res Pract 1-9.
[1223] David W Woessner *et al.,* 'Development of an effective therapy for chronic myelogenous leukaemia' (2011) 17(6) Cancer J 477-86.
[1224] Iqbal and Iqbal (n 1222) 1-9.

other patented medicines such as HIV/AIDS treatments have faced criticism for their high prices, which hinder affordability in LMICs. The impact of costly cancer medications is also seen in high-income countries, for example in the UK access to life-extending drugs like Enhertu has been rejected.[1225] These high costs pose significant challenges to healthcare systems and patients, limiting the availability of essential NCD medications and raising concerns about the balance between pharmaceutical innovation and equitable access.

Over time, the introduction of generic versions of Imatinib have become available, offering more affordable options while maintaining similar efficacy. Following the expiration of the patent in 2016 several pharmaceutical companies including Mylan, Teva and Sun Pharma launched generic formulations, leading to a considerable reduction in treatment costs. For example, the average monthly price for imatinib decreased from around $12,106 to approximately $9,316 after generics entered the market.[1226] This price drop illustrates how increased competition among manufacturers enhance affordability and improves patient access to essential medications. However, when generic imatinib was first introduced in the U.S. it entered the market at nearly the same price as the branded version, highlighting significant pricing issues. This situation contrasts sharply with Ozempic, which remains under patent protection until 2033, thereby maintaining higher prices and limiting patient access.[1227]

The case of Gleevec underscores the complex relationship between IP-SJ, particularly in the realm of access to life-saving medicines. While patents on drugs such as Gleevec allow pharmaceutical companies to recoup R&D costs and incentivize future innovation, they also create significant affordability barriers, especially in LMICs. The high price of Gleevec during its patent period restricted access for many patients, raising ethical concerns about whether essential medicines should be treated purely as commercial products. In response, countries such as India, rejected Novarti's patent application, allowing generic competition to reduce

[1225] Mustaqeem Siddiqui and S Vincent Rajkumar, 'The High Cost of Cancer Drugs and What We Can Do About It' (2012) 87 (10) Mayo Clin Proc 935. See also CADTH Reimbursement Review, 'Trastuzumab Deruxtecan (Enhertu)' (2023) 3 (1) Clinical Review Pharmacoeconomic Review 10.
[1226] Kristina Jenei *et al.,* 'CostPlus and implications for generic imatinib' (2022) 13(100317) The Lancet Regional Health-American 1-3.
[1227] Ravinder Gabble and Jillian Clare Kohler, 'To patent or not to patent? The case of Novartis' cancer drug Glivec in India' (2014) 10(3) Globalization and Health 1-6.

prices and improve accessibility.[1228] This case illustrates the tension between rewarding innovation through IP protection and ensuring equitable access to medicines as a matter of social justice. It also highlights the need for policy mechanisms such as compulsory licensing and pricing regulations to balance pharmaceutical incentives with public health priorities.

## 3. The Role of International Legal and Policy Frameworks in Access to Medicines for NCDs

In the global effort to balance patent protection with the right to health, particularly in relation to NCDs, international legal and policy frameworks play a crucial role. These frameworks establish the legal obligations of states, guide the implementation of national policies and influence the availability and affordability of essential medicines. By shaping how intellectual property laws interact with public health priorities, these mechanisms define the extent to which life-saving treatment remain accessible. The following sections examine key international agreements and policies that impact access to NCD medicines, assessing their effectiveness and potential areas for reform.

### 3.1. The TRIPS Agreement: Challenges and the Need for Reform

The TRIPS Agreement, as discussed in Chapter Four, aims to promote innovation through patent protection. However, it also poses significant barriers to accessing affordable medicines, particularly for NCDs. The intersection of intellectual property law and the right to health presents a complex challenge, where the benefits of patent protection often clash with the urgent need for equitable access to life-saving treatments.[1229]

While the TRIPS Agreement establishes minimum standards for intellectual property protection, it also includes flexibilities such as compulsory licensing and parallel imports to safeguard public health.[1230] However, the implementation of these flexibilities varies significantly across countries as states retain sovereignty in shaping their public health policies. The disparity is particularly evident in developing nations, where the demand for affordable medicines is most pressing. Factors such as different health priorities, resource

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[1228] Sophie Arie, 'Indian Supreme Court rejects Novartis's appeal on drug patent' (2013) 346 (f2099) BMJ 1. See also William J Bennette, 'Indian Pharmaceutical Patent Law and the Effects of Novartis Ag Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v Union of India' (2014) 13 (3) Indian Pharmaceutical Patent Law 535.
[1229] Tenni *et al*., (n 19) 1-40.
[1230] Correa and Hilty (n 522) 1. See also TRIPS Agreement Gervais (n 93) 55 subsection 2.01.

constraints and legal frameworks can influence how effectively governments utilize TRIPS provisions. However, in the context of the UK and Cyprus, the issue is slightly different. It is not necessarily about a lack of resources but rather about how patent laws, pricing regulations and market exclusivity affect access to affordable medicines for NCDs.

For instance, in the UK, as discussed earlier[1231], while the NHS provides coverage for many essential medicines, high drug prices driven by patent protections can strain healthcare budgets leading to rationing or restricted access to newer treatments, particularly for NCDs. The case of Ozempic, used for type 2 diabetes and obesity, illustrates how affordability concerns can delay approval and limit availability for patients who require long-term treatment. In Cyprus, the challenges are more pronounced due to its smaller market size and reliance on parallel imports. Although the country follows EU regulations as well as TRIPS provisions, medicine shortage and pricing issues continue to hinder access to treatments for chronic diseases, further exacerbating healthcare inequalities.

Although the TRIPS Agreement allows for public health-driven exceptions, challenges in implementation such as lack of technical expertise, regulatory barriers and limited international support from bodies such as the WTO and WHO often hinder their full realization.[1232] This inconsistency highlights the need for clearer international guidelines and stronger mechanisms to ensure that patent laws align with public health imperatives. The following section examines the key issues raised by the TRIPS Agreement and explores potential reforms to enhance access to essential medicines for NCDs.

### 3.1.1. Overview of the Issues Raised by TRIPS Agreement

The TRIPS Agreement while intended to drive innovation, often imposes stringent intellectual property protections that hinder access to essential medicines for NCDs, particularly among marginalized populations. From an IP-SJ perspective, this imbalance highlights the social injustice inherent in global intellectual property regimes, where the economic interest of pharmaceutical companies often take precedence over public health needs. The IP-SJ

[1231] For NHS details, see Chapter Two: Health Framework – section 4 ('National Health Law and Rules').
[1232] Junaid Subhan, 'Scrutinized: The TRIPS Agreement and Public Health' (2006) 9 (2) Mcgill J Med

framework argues that patent law must be structured in a way that prioritizes equitable access to life-saving treatments, ensuring that innovation does not come at the expense of human rights.[1233]

A major concern is that developing countries often struggle to implement TRIPS flexibilities, such as compulsory licensing and parallel imports due to legal, political, and economic pressures. While these mechanisms are permitted under TRIPS, wealthier nations and pharmaceutical industries frequently challenge their use, limiting their effectiveness in improving medicine accessibility.[1234] The IP-SJ perspective critiques this disparity as a form of structural inequality, where lower-income countries face systemic barriers to exercising their rights within the global IP framework. For instance, the threat of trade sanctions or political pressures discourages many nations from using compulsory licensing even when public health concerns justify such measures. A more just approach would ensure that countries can utilize TRIPS flexibilities without external pressure, reinforcing that intellectual property rights should serve the well-being of people rather than corporate profits.

Additionally, the pricing strategies of pharmaceutical companies under TRIPS protections often lead to significant affordability gaps, particularly for chronic conditions requiring long-term treatment. NCDs such as diabetes, cardiovascular disease and cancer disproportionately affect low-and middle-income countries, yet essential medications remain financially out of reach for many patients. The IP-SJ lens critiques this dynamic, arguing that patent laws must be restructured to prevent excessive monopolistic pricing.[1235] Alternative models, such as publicly funded drug research, tiered pricing based on income levels and stronger price regulations could help realign patent policies with social justice principles, ensuring that medicines serve a broader humanitarian purpose rather than being treated as commercial goods.[1236]

[1233] Mtima 2024 (n 28) 77.
[1234] Diependaele *et al.,* (n 632) 11-21.
[1235] Mtima and Jamar (n 58) 420.
[1236] Mtima and Jamar (n 58) 420.

TRIPS flexibilities have played a vital role in improving access to medicines for communicable diseases, particularly through compulsory licensing.[1237] This mechanism allowed countries to bypass patent protections in the public interest, significantly reducing costs and increasing access to life-saving treatments. The success of this approach is evident in the HIV/AIDS[1238] crisis, where nations like South Africa, Brazil and Thailand issued compulsory licenses to produce or import generic versions of antiretroviral drugs, which were initially priced out of reach due to patent protections.[1239] By leveraging this TRIPS flexibility, these countries scaled up treatment programs and saved millions of lives. International organizations including the WHO and UNAIDS, strongly supported these efforts emphasizing the importance of prioritizing public health over IP enforcement.[1240]

However, compulsory licensing has been less effective for NCDs due to multiple barriers. As discussed in the previous chapter, the literature highlights that unlike the HIV/AIDS crisis, were global urgency and advocacy from NGOs and international organizations drove the use of TRIPS flexibilities, NCDs do not provoke the same immediate global concern. As a result, there is less political momentum and weaker institutional support for their inclusion under compulsory licensing. Additionally, pharmaceutical companies and high-income nations exert economic and trade pressures that discourage the use of compulsory licensing. Even when compulsory licenses are issued, their impact is limited by the high costs and complexity of manufacturing essential NCD treatments such as insulin and cancer biologics. These factors create systemic obstacles, making it more difficult for low-and middle-income countries to implement compulsory licensing for NCD medicines without facing significant challenges.

The WHO is crucial in advocating for more equitable access to medicines. Through initiatives like the Global NCD Action Plan, the WHO has urged governments to use TRIPS flexibilities more effectively, emphasizing that affordability and accessibility must take precedence over rigid IP enforcement. Additionally, the WHO facilitates technology transfers and promotes voluntary licensing agreements through initiatives such as the Medicines Patent Pool, which

[1237] Nicol and Owoeye (n 147) 533.
[1238] 'T Hoen *et al.,* (n 140) 12.
[1239] Eduardo Urias, 'The potential synergies between industrial and health policies for access to medicines: insights from the Brazilian policy of universal access to HIV/AIDS treatment' (2019) 9(2) Innovation and Development 245-260.
[1240] Avafia and Mullapudi (n 92) 9-10.

has been successful in expanding the production of generic alternatives in lower-income countries. However, the effectiveness of these initiatives depends on stronger global cooperation, as well as political commitment from both developing and developed nations.

The success of compulsory licensing in the HIV/AIDS context provides valuable lessons for improving access to medicines for NCDs. While challenges exist, strengthening TRIPS flexibilities and expanding global support mechanisms could make their use more viable. A key strategy involves shifting the global narrative so that NCDs are recognized as a pressing public health emergency rather than just a chronic disease burden. If international organizations, policymakers, and governments unite around this goal, they can generate greater pressure to ensure that TRIPS flexibilities are applied equitably across all areas of disease treatment. The UK, with its strong pharmaceutical sector and post-Brexit policy independence, is well-positioned to take a leading role in advancing equitable access to medicines while also navigating the interests of the pharmaceutical sector. Cyprus, as an EU member with a smaller healthcare market, could benefit from a more flexible approach to compulsory licensing, ensuring affordable access to essential NCD treatment. Therefore, by aligning their policies with global efforts to expand TRIPS flexibilities, both countries can contribute to a fairer and more sustainable approach to medicine accessibility.

The next section will provide recommendations on how TRIPS flexibilities can be strengthened and more effectively implemented to ensure equitable access to essential medicines for NCDs while maintaining a balance between innovation and public health needs.

#### 3.1.2. Recommendations for addressing NCDs within the TRIPS

States have a responsibility to protect and promote access to medicines. To deliver on this, they need to use all available resources. Countries should be encouraged to fully utilize the flexibilities provided under the TRIPS Agreement. This includes using mechanisms such as compulsory licensing, which allows for the production or importation of generic versions of patented medicines to meet public health needs without undermining incentives for pharmaceutical innovation. Additionally, international organisations such as the WTO and WHO should play a crucial role in providing technical assistance to help developing countries effectively navigate and implement these flexibilities. By doing so, organizations can ensure that countries can access and produce affordable medicines while remaining compliant with international intellectual property standards.

To improve access to medicines for NCDs, it is crucial to strengthen the flexibility of data exclusivity regulations.[1241] Data exclusivity can delay the entry of affordable generic medicines into the market even after the patent has expired by preventing generic manufacturers from using the original clinical trial data to gain regulatory approval. This delay disproportionately affects low-and middle-income countries, where NCDs are increasingly prevalent exacerbating the challenge of accessing affordable treatments. Therefore, by advocating for a reduction in the duration of data exclusivity or introducing exceptions for essential medicines, it can facilitate a timelier introduction of generics. This would ensure that affordable medicines would become available sooner. Enhancing flexibility in data exclusivity regulations would balance the need to protect pharmaceutical innovation with the urgent public health needs of populations suffering from NCDs, ultimately improving global health outcomes and equity in access to essential medicines.

Another recommendation that has not been thoroughly analysed is voluntary licensing. From an IP-SJ perspective, voluntary licenses can be a mechanism for achieving greater health equity by balancing patent rights with the urgent need for affordable medicines.[1242] Unlike compulsory licensing, which is imposed by governments, voluntary licensing reflects a collaborative approach where IP holders authorize generic manufacturers to produce and distribute patented medicines in specified low- and middle-income countries. While this approach has primarily been applied to communicable diseases like HIV and Covid-19, expanding it to NCDs presents significant opportunities for both public health and business sustainability.[1243]

The terms of voluntary licensing for NCDs would likely differ from those for communicable diseases due to the distinct nature of NCD treatments. While the basic principle of providing

[1241] For 'data exclusivity' See Chapter Three, section 3 on Limitations.
[1242] Charles Gore *et al.,* 'Negotiating public-health intellectual property licensing agreements to increase access to health technologies: an insider's story' (2023) 8 (9) BMJ Global Health 1-8.
[1243] Gore *et al.,* (n 1242) 1-8. See also Budreviciute *et al.,* (n 1) 1-11. See also Urias and Ramani (n 123) 367-284.

affordable medicines through generic manufacturers would remain, voluntary licensing on NCD should be nuanced, considering distinguished pricing, long-term treatment needs, local manufacturing, and the need to incentivize innovation. By adapting the voluntary licensing model to the specific challenges posed by NCDs, it can foster both public health improvement and business sustainability.

For example, the Medicines Patent Pool (MPP) has successfully negotiated voluntary licenses for HIV treatments, reducing costs and expanding access in resource-limited settings.[1244] A similar approach could be taken for NCDs, particularly for high-cost treatments such as Ozempic for diabetes and Imatinib (Gleevec) for chronic myeloid leukaemia.[1245] Despite its primary role in managing diabetes, Ozempic has been explored for potential benefits in cancer treatments. However extensive patent disputes have delayed the entry of generic versions in several markets. By applying voluntary licensing to this treatment, patients in developing nations could gain earlier and more affordable access to life-saving medicines.

Therefore, from an IP-SJ perspective, voluntary licensing should not only be seen as a business strategy but as a moral and legal imperative that aligns innovation incentives with social justice goals.[1246] Governments, international organizations, and pharmaceutical companies must work together to expand voluntary licensing for NCDs, ensuring that essential medicines are not treated solely as commercial commodities but as public health necessities.[1247]

In addition, the MPP report, published in May 2024, highlights how voluntary licensing advances global health while being commercially viable for biopharmaceutical companies.[1248] The World Intellectual Property Organization along with the Government of Canada presented evidence that voluntary licensing is indeed an effective mechanism for addressing global health disparities and proven to help expand access to medicines.[1249] While the MPP primarily

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[1244] Lobna Gaayeb *et al.,* 'Voluntary licensing of long-acting HIV prevention and treatment regimens: using a proven collaboration- and competition-based mechanism to rapidly expand at-scale, sustainable, quality-assured and affordable supplies in LMICs' (2023) 26 (Suppl 2) J Int AIDS Soc 77.
[1245] Gaayeb *et al.,* (n 1244) 77.
[1246] Mtima and Jamar (n 58) 671-684.
[1247] Rafaella Ravinetto *et al.,* 'Shaping the future of global access to safe, effective, appropriate, and quality health products' (2024) 9(1) BMJ Global Health 1-6.
[1248] Gaayeb *et al.,* (n 1244) 77.
[1249] Gaayeb *et al.,* (n 1244) 77.

targets low and middle-income countries, its model has indirect relevance for the UK and Cyprus. The UK, despite not being covered by MPP licenses, faces challenges with high drug prices, as seen with Ozempic, and could benefit from voluntary licensing models to ease NHS budgets constraints. Cyprus, as a small EU market reliant on parallel imports, also struggles with medicine affordability. Expanding MPP's voluntary licensing to certain middle-income European nations could improve access to lower-cost generics, highlighting the need for broader application of such initiatives beyond LMICs.

### 3.2. Doha Declaration

The Doha Declaration reaffirmed the right of WTO members to use the flexibilities within the TRIPS Agreement[1250] such as compulsory licensing and parallel imports to address public health crises. These mechanisms grounded in IP law and linked to the territorial nature of IP rights provide countries with important tools to bypass patent restrictions when necessary to ensure access to essential medicines. While the Doha Declaration applies to all public health challenges, its impact has been more pronounced in addressing communicable diseases like HIV/AIDS, tuberculosis and malaria, leading to increased access to essential medicines for these conditions. In contrast, its application to NCDs has been more limited, largely due to weaker political momentum and the absence of a sense of global urgency.

#### 3.2.1. Overview of the issues raised by the Doha Declaration

The Doha Declaration raised the following key issues. One of the most significant concerns is the global shift from communicable to non-communicable diseases, with conditions such as diabetes, cardiovascular diseases, chronic respiratory diseases, and cancer now being the leading causes of death worldwide.[1251] Despite this shift, the Doha Declaration primarily emphasized acute public health emergencies, particularly those caused by communicable diseases. While this focus was crucial at the time to address crises like HIV/AIDS, tuberculosis and malaria it resulted in less attention to the growing burden of NCDs.[1252] The mechanisms it strengthened such as compulsory licensing and parallel importation were designed to

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[1250] Doha Declaration Racital [4].
[1251] Anthony Maher and Devi Sridhar, 'Political priority in the global fight against non-communicable diseases' (2012) 2(2) J Glob Health 1-19.
[1252] Luna and Luyckx (n 74) 5-25.

respond to urgent, short-term health threats, where rapid intervention can prevent disease spread or save lives. However, these tools are less effective in ensuring long-term affordability and accessibility of medicines for NCDs.[1253]

A significant challenge related to the Doha Declaration is the continued barrier to accessing NCD medications. Unlike short-term treatments for communicable diseases, NCD management requires lifelong access to affordable medicines. However, the high cost of these drugs, particularly newer biologics, and personalized therapies such as targeted cancer treatments, remains a major obstacle even with the flexibilities provided by TRIPS. For example, South Africa issued a compulsory license for HIV/AIDS medications in the early 2000s, allowing the production of generic antiretrovirals at a lower cost.[1254] Similarly, India and Thailand have used compulsory licenses for hepatitis C treatments to make the drugs affordable.[1255] The duration of such licences is typically temporary, tied to the duration of the public health need or emergency.[1256] Once the crisis diminishes or generic alternatives are sufficiently available the licenses usually expire, allowing patent holders to regain control. While compulsory licensing has been used successfully applied to HIV/AIDS drugs, its use for NCD treatments remains legally complex and uncertain, largely due to political and economic pressures from pharmaceutical companies and high-income nations seeking to protect patent rights.[1257]

Pharmaceutical companies, particularly those in high-income countries, often hold the patents for essential NCDs medications such as treatments for diabetes, cancer and cardiovascular diseases.[1258] These companies, protected by strong patent law in their countries, often push against rules that allow others to sell their drugs without permission either with compulsory licensing or with parallel imports.[1259] Pharmaceutical companies worried about losing their intellectual property rights and profits, especially as NCD

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[1253] Budreviciute *et al.,* (n 1) 1-11.
[1254] E L Saslow, 'Compulsory licensing and the AIDS epidemic in South Africa' (1999) 13 (10) AIDS Patient Care STDS 577-84. See also 'T Hoen *et al*., (n 140) 36-38. See also Usher (n 216) 1790.
[1255] Mohga Kamal-Yanni 'Hepatitis C drug affordability' (2015) 3 (2) Global Health 73.
[1256] Urias and Ramani (n 123) 367-384. See also Saslow (n 1254) 1790.
[1257] Urias and Ramani (n 123) 367-384.
[1258] Khachigian L M, 'Pharmaceutical patents: reconciling the human rights to health with the incentive to invent' (2020) 25(7) Drug Discovery Today 1135.
[1259] Khachigian (n 1258) 1135. See also Tenni *et al.,* (n 19) 1-40.

treatments are long-term, requiring patients to purchase medications for years or even decades.[1260] It has led to a situation where, despite the significant global burden of NCDs, these diseases remain under-prioritized in the global intellectual property landscape.[1261] TRIPS flexibilities which have been successful in increasing access to medicines in communicable diseases remain largely ineffective for NCDs due to these barriers.[1262]

### 3.2.2. Recommendations for addressing NCDs within the Doha Declaration

Given the limitations mentioned above, it is crucial to recommend adaptations to the Doha Declaration framework to better address the challenges posed by NCDs. Firstly, the focus should be on the strengthening the flexibilities within the TRIPS Agreement for NCDs such as broadening the scope of compulsory licensing. Building on the examples of India and Thailand[1263], a key recommendation would be to expand the scope of compulsory licensing to better address the unique challenges posed by NCDs, ensuring that public health needs can be prioritized over patent protections.

In the UK, while the NHS negotiates drug prices, compulsory licensing could serve as an additional mechanism for cases where patented NCD medications remain unaffordable. Moreover, voluntary licensing agreements could be encouraged to facilitate generic production and lower costs. By leveraging both compulsory and voluntary licensing mechanisms a more flexible, adaptive system can be created, ensuring that essential NCD medications remain accessible and affordable. These two mechanisms can complement each other, with compulsory licensing serving as a safeguard when urgent public health needs arise, and voluntary licensing ensuring long-term, sustainable access to medicines. Together, they could provide a balanced solution that promotes public health while respecting intellectual property rights.

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[1260] Tenni *et al.,* (n 19) 1-40. See also Anna Lanzoszka, 'The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries' (2003) 24(2) International Political Science Review 181-197.

[1261] Ana Teresa Santos *et al.,* 'Analysis the Influence of WHO Initiatives on the Scientific Discourse of Noncommunicable Diseases through a Bibliometric Approach' (2023) 20(18) Int J Environ Res Public Health 6714.

[1262] Heller *et a.,* (n 140) 370-383.

[1263] Jakkrit Kuanpoth, 'Compulsory Licenses: Law and Practice in Thailand' (2014) 25(22) Compulsory Licensing 61-77. See also Jianhao Shu and Jin Weifeng, 'Prioritizing non-communicable diseases in the post-pandemic era based on a comprehensive analysis of the GBD 2019 from 1990 to 2019' (2023) 13 (13325) Sci Rep 1-17.

Additionally, the framework should encourage parallel importation[1264] of NCD medications, particularly in countries within limited manufacturing capacity such as Cyprus. By allowing Cyprus to source medicines from countries where they are sold at lower prices, parallel importation could improve affordability ad accessibility. Strengthening these mechanisms would ensure that Doha flexibilities effectively support equitable access to essential medicines for NCDs, aligning patent protections with public health priorities.

To address NCDs challenges more effectively, it is crucial to enhance international cooperation through targeted initiatives. One promising approach is the establishment of a global fund specifically dedicated to NCDs, like the Global fund for HIV/AIDS, tuberculosis and malaria, which could provide financial support to low- and middle-income countries for acquiring essential medications needed to combat NCDs. Such a model has proven successful for communicable disease and could be equally beneficial for addressing NCDs, offering much-needed resources for countries facing significant NCD burdens. Thus, international organizations such as the WHO, could spearhead efforts in partnership with regional and national authorities, as well as through public private collaboration. From an IP-SJ perspective, the approach should focus on striking a balance between protecting intellectual property rights and ensuring affordable access to essential medicines, with an emphasis on equity, fairness and long-term sustainability in addressing the NCDs.

Furthermore, fostering collaborative research and development initiatives through public private partnerships should focus on developing affordable, high-impact treatments for NCDs.[1265] Such collaborations should prioritize open access models to ensure that resulting medications are accessible to a wider population.[1266] By facilitating the sharing of research, intellectual property and distribution, this partnership can help create affordable treatments and improve access to medicines.[1267] Finally, by improving global coordination for medicine

[1264] For parallel importation See Chapter Three, section 3.1.2. ('Parallel imports').
[1265] Nadia Amin Somani *et al.,*'Evaluation of frameworks demonstrating the role of private sector in non-communicable disease management and control: a systematic review and thematic synthesis' (2023) 13(3) BMJ Open 1-11. See also Adnan A Hyder *et al.,* 'Strengthening evidence to inform health systems: opportunities for the WHO and partners to accelerate progress for non-communicable diseases' (2023) 8(1) BMJ Journals 1-4.
[1266] Hyder *et al.,* (n 1265) 1-4.
[1267] Hilde Stevens and Isabelle Huys, 'Innovative Approaches to Increase Access to Medicines in Developing Countries' (2017) 4(218) Frontiers in Medicine 1-6.

distribution and resource allocation, the framework could more effectively address the rising global burden of NCDs.[1268] This improved cooperation would contribute to more equitable distribution of essential medicines, ensuring that patients worldwide have their treatments on time, specifically in low-income regions.[1269]

Unlike communicable diseases, NCDs often require long-term treatment, which involves different considerations in terms of access, affordability and healthcare infrastructure.[1270] Encouraging the production of generic medications for NCDs can play a crucial role in reducing costs and strengthening accessibility.[1271] This can be achieved by providing financial incentives from the government to manufacturers, such as tax breaks, as well as by streamlining regulatory processes to accelerate the availability of generics.[1272] For instance, Brazil has implemented a successful model where the government actively supports the production of generics through public procurement policies and regulatory pathways that prioritize affordability.[1273] Similarly, China has made significant strides in reducing drug approval times and has adopted a fast-track process for essential medications, which could serve as a useful reference for the UK and Cyprus.[1274]

In the UK and Cyprus, adapting the successful models of Brazil and China for generics would involve optimizing existing healthcare and regulatory frameworks. Instead of directly supporting local production, the UK and Cyprus could focus on integrating generics into national health systems, streamlining approval processes for essential NCD medications, and fostering public-private partnerships to negotiate lower prices.

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[1268] Ndumwa *et al.,* (n 14) 77. See also Syed Massud Ahmed *et al.,* 'Delivering non-communicable disease services through primary health care in selected south Asian countries: are health systems prepared?' (2024) 12(10) The Lancet Global Health 1706.

[1269] Ndumwa *et al.,* (n 14) 77.

[1270] Ojewale and Mukumbang (n 204) 2.

[1271] Manoj Kumar Pati *et al.,* 'Improving access to medicines for non-communicable diseases in rural primary care: results from a quasi-randomized cluster trial in a district in South India' (2021) 21(770) BMC Health Serv Res 1-11.

[1272] Association of Medical Research Charities, 'Facilitating adoption of off-patent, repurposed medicines into NHS clinical practice' (*Amrc* 2017) Available: https://www.amrc.org.uk/blog/facilitating-adoption-of-off-patent-repurposed-medicines-into-nhs-clinical-practice

[1273] Elize Massard da Fonseca and Kenneth C Shadlen, 'Promoting and regulating generic medicines: Brazil in comparative perspective' (2017) 41(e5) Rev Panam Salud Publica 1-6.

[1274] Xingyue Zhu and Yang Chen, 'Bridging the new drug access gap between China and the United States and its related policies' (2024) 14(1296737) Frontiers in Pharmacology 1-10.

Particularly in the UK, further incentives for local manufacturing and faster approval pathways for generic NCD medicines could improve affordability. Strengthening policies that encourage domestic production while ensuring that NHS procurement prioritizes cost-effective generic alternatives would be a key improvement. In contrast, Cyprus has a smaller pharmaceutical industry and relies heavily on imports, making affordability a greater challenge. In this case, policies should focus on parallel importation to bring in lower-cost generics from other EU markets while also simplifying regulatory approvals to encourage competition. Additionally, public procurement policies could play a crucial role in negotiating better prices for NCD medicines.

Additionally, adapting national patent laws to include specific provisions for NCDs, such as extended exemptions for essential treatments or simplified procedures for compulsory licensing can help overcome patent barriers and ensure that necessary medications are available at affordable prices. These polices are essential for filling the gap in access to treatments for NCD and for supporting the long-term management of these conditions, especially in resource-limited settings. For instance, Brazil has adopted a proactive approach by issuing compulsory licenses for essential medicines, primarily for communicable diseases.[1275] While its focus was initially on HIV/AIDS and other infectious diseases[1276], Brazil's legal framework allows for the potential expansion of compulsory licensing to NCD treatment when public health justifies it. This approach could serve as a model for countries seeking to enforce compulsory licensing for essential NCD medications that are otherwise inaccessible or unaffordable.

Some other countries such as India, China, South Africa, and Thailand have also made changes to their national patent laws or regulatory policies to help improve access to treatments for

[1275] Carlos M Correa, 'Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing' (*South Centre* 2011) Available: https://www.thaidrugwatch.org/download/rp_41_pharm_complice_ccorrea.pdf The report provides a perspective on Brazil's compulsory licensing policy within the broader framework of patent law reforms aimed at improving access to essential medicines. It also applies to a broader health crisis, includes non-communicable diseases. Brazil's 2007 compulsory license for an HIV drug called 'efavirenz' market a turning point, as the government negotiated with pharmaceutical companies to reduce prices for essential medications.

[1276] Nunn *et al.,* (n 500) 131. Brazil's 2007 compulsory license for an HIV drug called 'efavirenz' market a turning point, as the government negotiated with pharmaceutical companies to reduce prices for essential medications.

NCDs.[1277] India's its patent laws include extensive provisions for compulsory licensing, particularly to meet public health needs. In 2012, the Indian government granted a compulsory license on sorafenib, a drug used to treat kidney and liver cancers.[1278] At the time, Bayer's patented version of the drug cost approximately $5,500 per month, making it unaffordable for most patients. The license was awarded to the India generic manufacturer Natco Pharma, allowing it to sell the drug at a drastically reduced price, around $175 per month, provided that a percentage of royalties was paid to Bayer. This landmark case demonstrated how a strong compulsory licensing framework can effectively reduce costs and expand access to life-saving NCD treatments. India's approach serves as a valuable model for other countries to consider similar measures to ensure affordable access to essential medicines.

To adapt India's compulsory licensing model for the UK and Cyprus, several adjustments would be necessary due to differences in legal systems, healthcare infrastructure and economic context. While India's experience highlights the potential of compulsory licensing to make life-saving medicines affordable, the UK and Cyprus would need to ensure that any implementation is fair to patent holders, encourages innovation and fits within the existing healthcare systems. Therefore, adapting India's framework for compulsory licensing in the UK and Cyprus offers valuable potential to address access to life-saving NCD treatments, but would require careful adaptation to the specific legal, economic and healthcare systems of these countries.

Implementing a robust monitoring and accountability mechanism is crucial for ensuring that application of TRIPS flexibilities in addressing NCDs from an IP-SJ perspective. National regulatory bodies should be at the forefront of tracking the use of TRIPS provisions to ensure that they are used effectively, equitably and in a way that aligns with the public health needs of the population. Additionally, from an IP-SJ viewpoint, countries should be encouraged to regularly report on their use of compulsory licensing and other TRIPS flexibilities, including

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[1277] Tahir Amin and Aaron S Kesselheim, 'A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness' (2022) 59 The Journal of Health care Organization, Provision and Financing 1-6.

[1278] Talha Khan Burki, 'Indian government awards compulsory license for sorafenib' (2012) 13(4) The Lancet Oncology 146. See also Lauren McGivern, 'Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation' (2023) 101 (4) 1280 -1313.

data on the availability affordability, and effectiveness of NCD medications and their impact on public health outcomes. IP-SJ principles should guide this process, ensuring that transparency leads to accountability in promoting equitable access to medicines. Furthermore, IP-SJ emphasizes the need for a collaborative approach where national bodies not only oversee the use of IP flexibilities but also work in concert with international frameworks to ensure the access to essential NCD treatments is prioritized, while still respecting the role of IP in fostering innovation.

## 4. UK Framework for NCD

Having examined the global context, it is essential to consider how these issues are addressed within national frameworks, beginning with the UK. As explored in previous chapters, several critical challenges arise at the intersection of patent law, access to medicines and the right to health concerning NCDs.

### 4.1. Overview the Issues Raised by the UK Framework

Patent protections significantly impact drug prices, making essential medicines for NCDs, such as diabetes and cancer treatments, less affordable. The financial strain affects not only patients but also the NHS, which is responsible for delivering these treatments. While the UK government and its agencies regulate patent protections and influence drug pricing through frameworks like the Pharmaceutical Price Regulation Scheme (PPRS), these policies play a key role in the accessibility and affordability of medicines.[1279] The NHS incorporates strategies such as personalized care and preventive services to manage NCDs. However, these efforts can be impacted by the high costs of certain patented medications, especially those not covered under existing cost control mechanisms.

UK patent law, which aligns with international agreement like the TRIPS Agreement, can also limit the availability of generic alternatives that could otherwise reduce drug prices. This creates disparities in access to treatment, disproportionately affecting marginalized and

[1279] Joe Collier, 'The Pharmaceutical Price Regulation Scheme' (2007) 334 (7591) BMJ 435-436. See also NHS England, 'Summary of Pharmaceutical Price Regulation Scheme/Medicines Optimisation National Roadshows' (*NHS England* 2015) Available: https://www.england.nhs.uk/wp-content/uploads/2014/06/pharmaceutical-price-regulation-scheme-mo-roadshows.pdf. See also Huseyin Nac, 'Pharmaceutical Policy in the UK' (*The Health Foundation* 2023) Available: https://www.health.org.uk/sites/default/files/2023-03/report_3_pharmaceutical_policy_in_the_uk_final.pdf lower-income populations who struggle to afford necessary medications. Additionally, pharmaceutical companies often engage in practices such as patent evergreening, where minor modifications to existing drugs extend exclusive periods, delaying the introduction of lower-cost generics or biosimilars into the market. This results in prolonged high prices and restricted access to affordable treatment options.

Another challenge arises from the dual focus in NHS policies on communicable and non-communicable diseases. While the NHS takes a proactive approach in managing infectious diseases through vaccination programs and outbreak containment, its strategy for NCDs revolves around long-term management, including lifestyle interventions and chronic diseases treatment. However, the financial burden imposed by high-cost patented medicines can strain NHS resources, making sustained NCD care more difficult to implement effectively.

Furthermore, the creation of the UK Health Security Agency (UKHSA) in 2021 raised concerns regarding the prioritisation of health resources. While the agency's primary mandate is to manage infectious disease threats, there is growing concern that this focus might come at the expense of long-term strategies for addressing NCDs, particularly in ensuring equitable access to affordable medicines. This transition from Public Health England to the UKHSA has also led to uncertainties regarding its ability to coordinate effectively with NHS England and the pharmaceutical industry. Questions remain about how well the agency can address barriers to NCD treatment access, including high drug prices and restrictive patent protections.

To address these challenges, the UKHS should recognise that its focus on infectious diseases should not overshadow the need for equitable access to treatments for chronic conditions like diabetes. Ozempic's high cost, patent protections and raised demand highlight the urgent need for better coordination between the UKHSA, NHS England and the pharmaceutical industry. Without a unified approach, access to essential medicines will remain a significant barrier, particularly for underserved populations. The UKHSA must balance its infectious disease priorities with long-term strategies that ensure affordability and accessibility of life-saving treatments for NCDs.

These challenges highlight the need for a more balanced approach that considers both innovation and public health, ensuring that the UK's patent framework does not hinder the accessibility of affordable treatments for NCDs.

#### 4.1.1. Recommendations for addressing NCDs within UK Framework

To strengthen the UK framework for NCDs, it is essential to address key barriers to medicine accessibility, particularly those arising from patent protections. A multi-faceted approach is required, integrating reforms in patent law to ensure equitable access to treatment.

The UK should review its patent framework to prevent strategies that delay the entry of generics and biosimilar, such as evergreening.[1280] Strengthening patent examination criteria and imposing stricter regulations on secondary patents will help promote timely availability of lower-cost alternatives. Additionally, the UK government should expand the use of compulsory licensing provisions, as permitted under the TRIPS Agreement, to authorise generic production of essential medicines when affordability becomes a public health concern. Government use licenses should be leveraged to ensure that NHS programmes can access high-cost patented medicines when necessary. To further enhance affordability, the UK government should promote patent pooling and voluntary licensing by encouraging pharmaceutical companies to participate in international patent pools, such as the MPP. These mechanisms facilitate generic production while ensuring fair compensation for patent holders, ultimately improving access to affordable NCD treatments.

## 5. Cyprus Framework for NCDs

Cyprus with a small market still faces significant barriers to medicine accessibility due to its national patent laws and regulatory framework. Patent Law No. 16(1) 1998[1281] plays a crucial role in shaping this landscape, influencing drug pricing, availability, and market competition. The following section will explore the issues raised, then suggest recommendations.

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[1280] Evergreening been discussed in Chapter Four, section 2.2.3. (Supplementary protection certificate SPCs). Evergreening of patents is a process by which patent holders can extend the life of their patents and maximize their profits.
[1281] Patents Law 16(1)/1998.

### 5.1. Overview the issues raised by the Cyprus Framework

Patent Law No. 16(1) of 1998 in Cyprus significantly affects access to medicines for NCDs due to its provisions on patent protection and exclusivity, which contributes to high drug prices and delayed availability of lower-cost alternatives. The twent-year patent term grants exclusive rights to pharmaceutical companies, preventing the sale of generic versions during this period.[1282] Additionally, some companies engage in evergreening by filing secondary patents on slight modifications of existing drugs, extending exclusivity beyond the original twenty years. As a result the introduction of cheaper generic and biosimilar alternatives is often delayed, keeping essential NCD treatments costly.

While the law includes provisions for compulsory licensing in cases of public health necessity, such measures are rarely used due to complex administrative procedures and restrictive eligibility criteria. The reluctance to issue compulsory licenses means that Cyprus remains dependent on expensive patented medicines, limiting affordability even when high drug prices create barriers to treatment access.[1283] This underutilization of compulsory licensing prevents the government from taking effective measures to ensure equitable access to essential NCD drugs when affordability becomes a public health concern.

Cyprus adherence to the principle of international exhaustion of patent rights means that once a patented medicine is sold in any EU member state the patent holder’s control over distribution is exhausted across the entire EU. This allow for parallel imports of medicines from other EU countries where they may be sold at a lower price, potentially improving access to more affordable treatments. However, despite this, varying prices across EU countries and the control pharmaceutical companies have over pricing still contribute to high medicine costs in Cyprus, limiting access to essential treatments for NCDs.

Moreover, the high cost of patent filing and maintenance in Cyprus discourages local pharmaceutical companies from producing generic alternatives. The lack of domestic

[1282] Charalampous *et al.,* (n 8) 1-12. See also Maria Kyprianidou *et al.,* ‘Prevalence and sociodemographic determinants of selected noncommunicable diseases among the general population of Cyprus: A large population-based cross-sectional study’ (2023) 9(3) Chronic Dis Transl Med 222-237.

[1283] Olivier J Wouters and Panos G Kanavos, ‘Transitioning to a national health system in Cyprus: a stakeholder analysis of pharmaceutical policy reform’ (2015) 93(9) Bull World Health Organ 606-613.

pharmaceutical competition means that the market remains dominated by high-cost patented medicines, further restricting affordability for patients who rely on continuous treatment for chronic conditions. Even after patents expire the regulatory approval process for generics in Cyprus is often slow and complex, causing further delays in making lower-cost treatments available. Unlike some EU countries that have accelerated pathways of generic approvals, Cyprus lacks a fast-track mechanism, meaning that patients continue to pay high prices for patented medicines longer than necessary.

Collectively, these patent related barriers significantly impact access to medicines for NCDs in Cyprus. The combination of prolonged market exclusivity, restricted generic competition, limited use of compulsory licensing, restrictions on parallel imports and regulatory delays in generic approvals creates substantial challenges in ensuring affordable access to essential NCD treatments. Addressing these issues within the patent framework is crucial for improving medicine affordability and reducing health inequalities among NCD patients in Cyprus.

#### 5.1.1. Recommendations for addressing NCDs within CY Framework

To improve access to medicines for NCDs in Cyprus, reforms to the country's patent framework are essential.[1284] The current patent system creates barriers to affordability and availability, particularly due to prolonged market exclusivity, restrictive importation policies, and underutilization of key legal mechanisms that could facilitate greater access to essential treatments.[1285] Addressing these challenges requires targeted reforms to ensure a balance between incentivizing pharmaceutical innovation and safeguarding public health.

While Cyprus has a legal framework for compulsory licensing under the Patents Law (Law No.16(1)/1998[1286] its application remains limited due to procedural complexities and restrictive criteria. Currently, a compulsory license can only be applied for after four years from the grant of a patent, creating delays in addressing urgent public health needs. Strengthening this framework by reducing the waiting period and explicitly incorporating public health

[1284] Wouters and Kanavos (n 1283) 606-613.
[1285] Wouters and Kanavos (n 1283) 606-613. The current patent system creates barriers to affordability and availability, particularly due to prolonged market exclusivity, restrictive importation policies, and underutilization of key legal mechanisms that could facilitate greater access to essential treatments.
[1286] Patents Law (Law No.16(1)/1998, Section 49-56.

emergencies, excessive pricing and drug shortages as valid grounds for issuing licenses would enable more timely intervention for essential medicines for NCDs.[1287] Additionally, as NCDs have remained a major public health challenge since 1990[1288], the implementation of early detection and screening programmes is needed to reduce occurrence and exacerbation of leading NCDs causes within the Cypriot population.

Moreover, limiting patent evergreening through stricter patent examination criteria is crucial. Many pharmaceutical companies extend market exclusivity by filing secondary patents on minor modifications of existing drugs, delaying the entry of generics and biosimilars. Cyprus should adopt stricter patentability criteria, ensuring that secondary patents are granted only for significant therapeutic advancements rather than minor changes.[1289] This would prevent unjustified patent extensions while maintaining incentives for genuine pharmaceutical innovation.

Additionally, enhancing parallel import policies within the EEA would help Cyprus benefit from lower-priced medicines available in other EU countries. While Cyprus adheres to the principle of international exhaustion which allows parallel imports, variations in pricing and market dynamics still limit the full potential of this practice. Aligning more closely with other EU nations that facilitate parallel imports could increase competition and reduce medicine prices, improving affordability for patients with chronic conditions.

Furthermore, streamlining the regulatory approval process for generics is essential to ensure that lower-cost alternatives can enter the market without unnecessary delays. Cyprus could consider adopting an accelerate approval pathway for generics, like models in other EU countries, or relying more on European Medicines Agency approvals rather than requiring separate national approvals. This would reduce reliance on high-cost patented medicines and expand treatment options for NCDs.

[1287] Patents Law (Law No.16(1)/1998, Section 49.
[1288] Wouters and Kanavos (n 1283) 606-613.
[1289] Livio Garattini and Bruno Finazzi, 'Pharmaceutical Patents in Europe: Radical Reforms Rather than Getting Rid?' (2021) 20(4) Appl Health Econ Health Policy.

Lastly, the government should encourage voluntary licensing and participation in patent pooling initiatives. By promoting agreements with initiatives such as the MPP, Cyprus can facilitate the local production and distribution of affordable generic medicines for NCDs while ensuring that patent holders receive fair compensation. These agreements can provide a balanced solution that supports both pharmaceutical innovation and public health interests.

Implementing these reforms within the patent law framework will significantly enhance medicine accessibility in Cyprus, ensuring that patients suffering from NCDs can obtain the treatments they need without facing financial difficulty. By modernizing this approach to patents and pharmaceutical regulation, Cyprus can strike a sustainable balance between protecting intellectual property rights and prioritizing public health needs.

This approach aligns with the principles of IP-SJ, which emphasizes that patent laws should serve the broader public good rather than solely protecting commercial interest. Social utility in Cyprus's patent law would ensure that IP frameworks promote equitable access to medicines, particularly patients with NCDs, by enabling parallel imports, generic competition and differential pricing. By integrating IP-SJ principles, Cyprus can create a patent system that fosters innovation while safeguarding public health, ensuring that life-saving treatment remain accessible and affordable for all.

## 6. Conclusion

The intersection of patent law and the right to health poses significant challenges in ensuring access to medicines for NCDs.[1290] As NCDs increasingly contribute to the global disease burden, it is crucial to address the issues that patent protection impose on the availability and affordability and accessibility of essential treatments. The two case studies of Ozempic and Imatinib (Gleevec) demonstrate the complexities of balancing intellectual property rights with public health needs. While patents incentivize innovation, they also create monopolies that can result in high drug prices and limited access, particularly in low-and-middle-income countries.

[1290] Tenni *et al.,* (n 19) 1-40.

International frameworks such as the TRIPS Agreement and the Doha Declaration provide mechanisms to balance these interests, yet their implementation often falls to address the unique challenges of NCDs. TRIPS flexibilities such as compulsory licensing have been underutilized for NCDs due to legal, political, and economic pressures. Moreover, the Doha Declaration's focus on communicable disease has left a gap in addressing the chronic conditions and the lifelong treatment needs for NCDs patients.

National frameworks, including those in the UK and Cyprus, further reflect these challenges. In the UK, patent laws aligned with international agreements can restrict access to affordable NCD medications, exacerbating health inequalities. Cyprus faces similar issues, where patent protections under national law contribute to high costs and delayed availability of generics, despite the presence of a comprehensive health system.

To address these issues, a multifaceted approach is necessary. Strengthening the use of TRIPS flexibilities, promoting generic competition, revising patent laws to prevent evergreening and enhancing international cooperation through organizations such as the WHO, WTO, UN, WIPO, Global Fund to Fight AIDS, Tuberculosis and Malaria, Non-Governmental Organizations (NGOs) and Public-Private Partnerships (PPPs) are critical steps. Additionally, there is a need for robust monitoring and accountability mechanisms to ensure that global and national policies align with public health goals, particularly in making NCD treatments accessible and affordable.

By integrating principles of social justice into intellectual property law as discussed in Lateef's work it is possible to create a more equitable healthcare system that prioritizes the right to health over commercial interests. This requires determined effort from international bodies, national governments and stakeholders across the healthcare and pharmaceutical sectors to ensure that advancements in medical treatment benefit all populations, specifically those most vulnerable to the burden of NCDs.

Global Health agencies such as the WHO can play crucial roles in lowering research and development costs, thereby ensuring broader access to essential treatments for NCD. Strengthening international agreements like TRIPS, with provisions that prioritize public health over intellectual property along with global monitoring and accountability mechanism, is essential for equitable access.[1291] Additionally, offering incentives for research into neglected NCDs and developing targeted access programmes for marginalized populations are vital steps towards ensuring that all patients benefit from advancements in treatment.[1292] Finally, education and awareness campaigns for the public and healthcare providers can highlight ethical issues around drug access and prescription practices, helping to prevent misuse and shortages. Through this comprehensive regulatory approach, it is possible to address the current NCD crisis and establish a more equitable global health system.[1293]

This chapter has outlined practical and policy-oriented measures to strengthen access to essential medicines for NCDs, drawing on doctrinal analysis, comparative insights, and case studies. Together, these proposals demonstrate how patent law can be better aligned with social justice and the right to health. The final chapter concludes the thesis by synthesizing the key findings, reflecting on their broader implications, and identifying areas for further research.

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[1291] Katrina Perehudoff *et al.*, 'A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology' (2022) 7(e009709) BMJ Global Health 1-5.
[1292] Ndumwa *et al.,* (n 14) 77.
[1293] Kruk *et al*., (n 469) 1196.

# CHAPTER SIX: CONCLUSION

## CONCLUSION

This thesis explored the complex relationship between patent law and the right to health, with a particular focus on access to medicines for non-communicable diseases. Guided by the research question, '*To what extent does patent law affect the right to health and access to medicines for non-communicable diseases?*', it has demonstrated that while patent law plays a crucial role in incentivizing pharmaceutical innovation, it also creates significant barriers to accessing affordable medicines, particularly for those suffering from NCDs.

Patent protection, by granting exclusive rights to pharmaceutical companies, often leads to high drug prices and restricted availability of essential medicines. Although intellectual property rights are designated to reward innovation, they can also limit competition and delay the entry of affordable generic alternatives. This has a particularly adverse impact on NCDs, which require long-term treatment, making affordability a critical issue.

A major finding of this thesis is that existing international frameworks, such as the TRIPS Agreement and the Doha Declaration, provide legal flexibilities such as compulsory licensing to balance intellectual property protection with public health priorities. However, these mechanisms have primarily been utilized and have been underutilized for NCDs. The lack of political will and the influence of the pharmaceutical industry contribute to this imbalance.

By conducting a comprehensive analysis of the UK and Cyprus legal frameworks, the thesis identified both similarities and differences in how patent laws are structured and enforced. The UK, with its established intellectual property system, has faced challenges in ensuring affordability despite a strong National Health Service (NHS). Cyprus, as a smaller EU member state, operates within the broader EU framework but also encounters access issues due to pharmaceutical pricing and patent policies.

The tension is particularly pronounced for NCDs, which require long-term and often costly medical interventions. The research is based in the Intellectual Property and Social Justice (IP-SJ) approach, analysing international agreements, national legal frameworks and specific case studies to reveal the challenges and find the solutions. This chapter synthesizes the findings from the previous chapters and outlines the implications for policy and future research.

Therefore the methodology and theoretical framework is supported by doctrinal analysis and the IP-SJ approach. It provides analysis of primary legal sources, including statutes, case law, and secondary sources. The IP-SJ approach was fundamental as it evaluates whether patent law align with principles of equity, inclusion, and access. More specifically, by applying case studies and comparative analysis of legal frameworks, this research highlights the disproportionate impact of patent protections on the affordability and availability of medications for long-term diseases (NCDs). For instance, using case studies of Ozempic and Imatinib (Gleevec) illustrates the implications of patent protection on access to essential medicines. Imatinib (Gleevec) demonstrates how generic competition improves affordability post-patent expiry, whereas Ozempic illustrates the challenges of patent monopolies in creating access barriers. Moreover, the critical examination of international agreements such as TRIPS and the Doha Declaration that this research work undertook has provided a robust foundation for understanding and addressing the challenges posed by patent law.

Chapter One presents a detailed literature review tracing the historical relationship between patent law and access to medicines. It began with the Paris Convention, which allowed nations the flexibility to design their own intellectual property rights regimes. This flexibility enabled countries to prioritize public health over intellectual property rights, including exclusions for pharmaceutical patents. The establishment of the TRIPS Agreement marked a turning point as it standardized patent protection globally, significantly reducing national flexibilities to address public health needs. It was during the TRIPS negotiations that pharmaceutical patents became a central point of debate, with concerns emerging about their impact on drug affordability and accessibility. This shift created barriers to the affordability and availability of essential medicines, particularly of chronic diseases. Following this, the Doha Declaration attempted to reaffirmed public health safeguards within TRIPS yet debates on NCDs remained secondary compared to communicable diseases. The literature review highlighted the growing disparity between the global organization of communicable diseases and the relative neglect of NCDs in the public health policies.

Overall, global health policies prioritize and focus on communicable diseases over NCDs. For instance, compulsory licensing has successfully used in addressing communicable diseases like HIV/AIDS, as seen in Brazil and India, and offers viable pathways for enhancing access to NCD treatment. This neglect led to undeveloped mechanisms for addressing access to NCD medicines within the global patent framework. In addition, the importance of TRIPS flexibilities such as compulsory licensing and the Doha Declaration offer pathways to balance patent rights with public health. However, the practical application of these provisions has been limited, especially for NCD treatments. In addition, promoting voluntary licensing agreements where pharmaceutical companies allow generic manufacturers to produce patented drugs in exchange for royalties, can equitably balance public health needs and innovation incentives.

This work reinforces the core argument that while patent law is essential for fostering innovation, it is also creates significant barriers to access and affordability of medicines, specifically for non-communicable diseases (NCDs) in low- and middle-income countries. This tension between incentivizing pharmaceutical advancements and ensuring broad access to innovations highlights critical gaps in the current topic of the impact of patent law, which affects the regulation of NCDs and the accessibility of treatments. Effective regulation of patent law is essential to ensure that life-saving medicines are not only developed but are also accessible and affordable for those in need. More specifically, Chapter One identified the key lessons for the intersection between patent law and access to medicines for non-communicable diseases.

In Chapter Two established the health framework. It highlighted the increasing global burden of NCDs and the inherent tension between intellectual property rights and public health needs. The purpose of this chapter was to define the role of key organizations such as the Word Trade Organization (WTO), World Health Organization (WHO) and explore the global policy priorities for NCDs. This chapter highlighted the disproportionate historical focus on communicable diseases which has left gaps in the legal and regulatory mechanisms addressing NCDs treatments. It highlighted the importance of integrating public health needs into intellectual property system to ensure equitable access to medicines.

Chapter Three explored the public interest in patent law, focusing on exceptions, limitations, and exclusions within international framework, regional and national particularly for UK and Cyprus. It also analysed the Doha Declaration and compulsory licensing provisions, revealing their underutilization in addressing NCD challenges. Chapter Three highlights the importance for a more harmonized approach to applying these flexibilities to promote public health needs. Conversely, Chapter Four provided in depth analysis of private interest in patent law, focusing on its regulatory framework at international, regional, and national levels including UK and Cyprus. It examined the TRIPS Agreement and its provisions, presenting how patent protection enforces exclusivity and can restrict the availability of affordable medicines, with specific cases. This chapter introduced key legal mechanisms such as compulsory licensing and discussed their potential to mitigate these challenges, although with limited practical application for NCDs.

The key findings of this work suggest a clear roadmap for addressing the challenges at the intersection of patent law and the right to health. This is illustrated in Chapter Five: to overcome these barriers, it concluded this thesis with recommendations for this problem. First, TRIPS flexibilities are crucial to enhancing the use of such flexibilities like compulsory licensing to address NCD medicine access. Secondly, the literature review's identification of regular gaps in addressing NCDs informs the recommendation for tailored reforms in the UK and Cyprus. These include promoting generics and strengthening public health protections. Furthermore the WTO along with the other partners at WHO and WIPO have to support the efforts to better prevent, control and treat on NCDs.

All the nongovernmental international organizations must continue to work together, strengthen dialogue, leverage complementary mandates in health, IP and trade to promote policy coherence to address the urgent challenges for the NCDs. International organizations must promote generic competition and greater international cooperation to ensure that medical innovations are accessible and affordable for all prioritizing the right to health over the commercial interests. Organizations such as WHO Global NCD Action Plan provide ideal platforms for integrating these reforms and prioritizing access to generics. Drawing on the literature review in Chapter One, where the global health system is discussed, Chapter Five advocates for a more inclusive Global NCD Action Plan that prioritizes equity, resource redistribution and generic medicine availability. In addition, aligning these reforms with the IP-SJ framework ensures that access to medicines remains a fundamental human right, placing public health at the forefront of legal and economic consideration. These efforts not only bridge the gap between innovation and access but also create a sustainable proposal for addressing the growing burden of NCD worldwide.

This work answered its primary research question by establishing that while patent law incentives innovation, it can also create significant barriers to affordable access to medicines for NCDs, particularly in low-and middle-income countries. For instance, while international agreements such as TRIPS offer mechanisms such as compulsory licenses, practical implementation is often hindered by economic or political challenges. TRIPS sets minimum standards for countries and creating barriers to affordability and availability of access to medicines. However, the Doha Declaration in 2001 reaffirmed the rights of WTO member states to prioritize public health over intellectual property protections. Therefore the Doha Declaration enables countries to adopt mechanisms such as compulsory licensing and parallel importing to ensure access to medicines during public health crises. However, this research confirms that while the Doha Declaration was instrumental in allowing lower-income countries to access generic versions of lifesaving drugs in the HIV/AIDS pandemic, it has not been fully leveraged for non-communicable diseases therefore highlighting the need for greater international support and domestic implementation.

It is clearly stated that the inability of the current health innovation and access ecosystem to provide equitable access to lifesaving technologies has never been so clear.[1294] While the rapid development of vaccines demonstrated potential in the Covid-19 pandemic, it also exposed extreme inequities in access, disregarding human dignity and the right to health.[1295] The key points suggested by Dr. Krikorian and Dr. Torreele were to rebalance power dynamics from private to public priorities in medical innovation, ensuring transparency across the production chain. Moreover, policy alignment, policies designed to meet public health needs equitably, and embracing the idea that one size does not fit all are all necessary. Diversification,

[1294] Gaelle Krikorian and Els Torreele, 'We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis' (2021) 23(1) Health and Human Rights Journal 125.
[1295] Krikorian and Torreele (n 1294) 125.

deconcentration and devolution of health innovation and manufacturing must be catalysed, allowing for locally and regionally driven solutions adapted to specific health needs and contexts, and fostering countries' agency, resilience and autonomy in improving the health of their own communities.[1296]

Public health initiatives such as the WHO's Global NCD Action Plan align with TRIPS flexibilities support affordable access. However, this alignment requires stronger implementation and broader application as explored in Chapter Three which examined the public face of patent law. Examining the global response to HIV/AIDS, particularly the use of TRIPS flexibilities and voluntary licensing, provides valuable insights. Therefore, the current international and national legal framework inadequately address the unique challenges posed by NCDs, and reforms are essential to ensure that innovation aligns with public health necessities.

Concluding the recommendation made in the Chapter Five, several reforms are needed to address to these challenges. The use of TRIPS flexibilities such as compulsory licensing and parallel imports particularly for NCD treatments needs to be expand. It also needs to prevent evergreening. By doing so, national frameworks can dismantle barriers to generic competition, ensuring that NCD medicines become affordable and accessible particularly for populations unable to afford high-cost treatments. International cooperation must be strengthened, including revising the WHO Global NCD Action Plan to emphasize equity and generic medicine availability and adopting the IP-SJ framework to prioritise the right to health, a fundamental right above commercial interest. The findings call for immediate action by governments, international organizations and stakeholders to reform patent systems and prioritize the right to health. By addressing the barriers posed by patent law, the global community can take significant strides toward achieving equity for all, particularly in the face of the growing NCD burden.

The intersection of intellectual property rights in patent law and public health is a dynamic, ongoing challenge. By highlighting inequities in access to medicines for NCDs, this research advocates a reimagining of patent laws to prioritize social justice and the right to health. To

[1296] Krikorian and Torreele (n 1294) 125.

achieve this balance, consistent support is required from policymakers, international organizations, and civil society. As the global burden of NCDs continues to rise, the urgency of such reforms cannot be overstated. The next step involves further research to evaluate the practical implementation of these recommendations.

**BIBLIOGRAPHY**

# BOOKS

Ballin E H, *Advanced Introduction to Legal Research Methods* (Edward Elgar, 2020).

Banatvala S, Akselrod S, Bovet P and Mendis S, *The WHO Global Action Plan for the Prevention and Control of NCDs 2013-2030* (Routledge, 2023).

Bentley L, Sherman B, Gangjee D and Johnson P, *Intellectual Property Law* (6th edn, Oxford, 2022).

Bessen J and Meurer M J, *Patent Failure: How Judges, Bureaucrats and Lawyers Put Innovators at Risk* (Princeton University Press, 2008).

Birss C, Austem T and Baran S, *Terrell on the Law of Patents* (18th edn, Sweet and Maxwell, 2016).

Busse R, Blumel M, Kreinsen D S and Zentner A, *Tackling Chronic Disease in Europe* (European Observatory on Health Systems and Policy, 2010).

Correa C M and Hilty R M, *Access to medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

Correa C M, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, (Reprinted edition, Zed Books Ltd, 2000).

Correa C M, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd edn, Oxford University Press, 2007).

Davis R, Quintin T S and Tritton G, *Tritton on Intellectual Property in Europe* (5th edn, Sweet & Maxwell, 2018).

Fisher M, *Fundamentals of Patent Law: Interpretation and Scope of Protection* (Hart Publishing, 2007).

Fisher W W and Syed T, *Infection: The Health Crisis in the Developing World and What We Should Do About It* (Stanford University Press, 2017).

Gervais D J, *Fairness, Morality and Ordre Public in Intellectual Property* (Edward Elgar, 2020).

Gervais D, *The TRIPS Agreement* (4th edn, Sweet and Maxwell, 2012).

Gervais D, *The TRIPS Agreement: Drafting History and Analysis* (5th edn, Sweet and Maxwell, 2021).

Grabowski H, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (2nd edn, Taylor and Francis Group, 2006).

Grubb P W, Thomsen P R, Wright G and Hoxie T, *Patents for Chemicals, Pharmaceuticals, and Biotechnology. Fundamentals of Global Law, Practice and Strategy* (6th edn, OUP, 2016).

Hovenkamp H, Janis M D, Lemley M A, Leslie C R, Carrier M A, *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (Wolters Kluwer Legal & Regulatory U.S., 2016).

Johnson P, *Privatised Law Reform: A History of Patent Law through Private Legislation* (Routledge, 2017).

Jougleux P, *European Intellectual Property Law* (Sakkoulas Publications, 2020).

Kennedy M, *WTO Dispute Settlement and the TRIPS Agreement, Applying the Intellectual Property Standards in a Trade Law Framework* (Cambridge University Press, 2016).

Khor M, *Patents, compulsory licenses and access to medicines: some recent experience* (2nd edn, Third World Network, 2009).

Matthews D and Torremans P, *European Patent Law: The Unified Patent Court and the European Patent Convention* (De Gruyter, 2023).

Matthews D, *Globalising Intellectual Property. The TRIPS Agreement* (Routledge, 2002).

Mercurio B, Adekola T A and Tsega C F, *Pharmaceutical patent law and policy in Africa: a survey of selected SAD member state* (Cambridge University Press, 2023).

Merges R P, *Justifying Intellectual Property* (Harvard University Press, 2011).

Monateri P G, *Advanced Introduction to Comparative Legal Methods* (Edward Elgar, 2021).

Okediji R L and Bagley M A, *Patent Law in Global Perspective* (Oxford, 2014).

Pila J, *The Requirement for an Invention in Patent Law* (Oxford University Press, 2010).

Ragavan S and Vanni A, *Intellectual Property Law and Access to Medicine. TRIPS Agreement, Health, and Pharmaceuticals* (Routledge, 2012).

Ricketson S, *The Paris Convention for the Protection of Industrial Property*: *A Commentary* (Oxford University Press, 2015).

Shiva V, *Patents Myths & reality* (Penguin Books, 2001).

Sterckx S and Cockbain J*, Exclusions from Patentability* (Cambridge University Press, 2015).

Takenaka T, *Research Handbook on Patent Law and Theory* (2nd edn, Edward Elgar, 2019).

Taubman A, Wager H and Watal J, *A handbook on the WTO TRIPS Agreement* (Cambridge University Press, 2012).

## Chapters in Edited Collections

Azam M, 'The Experiences of TRIPS-compliant Patent Law Reform in Brazil, China, India and South Africa—Lessons for Bangladesh' in Monirul Azam (ed), *Intellectual Property and Public Health in the Developing World* (Cambridge, 2017).

Bonadio E, ‘Patents as a tool to encourage the production of healthier food’ in Alberto Alemanno and Enrico Bonadio (eds), *The New Intellectual Property of Health; Beyond Plain Packaging* (Edward Elgar, 2016).

Calboli I, ‘Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review’ in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines* (Springer, 2022).

Correa C M, ‘Interpreting the Flexibilities Under the TRIPS Agreement’ in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines*: *Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

Davies L, ‘Compulsory Licensing: an effective tool for securing access to Covid-19 vaccines for developing states?’ in Lowri Davies (ed), *Legal Studies* (Cambridge University Press, 2022).

Dobinson I and Johns F, ‘Qualitative Legal Research’ in Mike McConville and Wing Hong Chui, (eds), *Research Methods for Law* (Edinburgh University Press Ltd, 2007).

El Said M, ‘The Impact of ‘TRIPS-Plus’ Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges’ in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

Filho C S and Ido V H P, ‘Courts and Pharmaceutical Patents: From Formalist Positivism to Emergence of a Global Law’ in Carlos M Correa and Reto M Hilty (eds), *Access to medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

Fisher W, ‘Theories of Intellectual Property’ in Stephen R Munzer (ed), *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, 2001).

Helfer L R, ‘Mapping the interface between human rights and intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar,2015).

Hestermeyer H, 'Conflict between Patents and Access to Medicine' in Hestermeyer Holger (ed), *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2008).

Ho C M, ‘A new approach to the compulsory license conundrum’ in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (Oxford, 2014).

Jamison D T, Breman J G, Measham A R, ‘Cost-Effective Strategies for Noncommunicable Diseases, Risk Factors, and Bahaviors’ in Dean T Jamison, Joel G Breman, Anthony R Measham, George Alleyne, Mariam Cleason, David B Evans, Prabhat Jha, Anne Mills, and Philip Musgrove (eds), *Priorities in Health* (The International Bank for Reconstruction and Development/ The World Bank, 2006).

Jha P, MacLennan, Chaloupka F J, Yurekli A, Ramasundarahettige C, Palipudi K, Zatonski W, Asma S, Gupta C, Gelband H, Jha P, Sankaranarayanan R and Horton S, ‘Global Hazards of Tobacco and the Benefits of Smoking Cessation and Tobacco Taxes’ (2015) in Hellen Gelband, Prabhat Jha, Rengaswamy Sankaranayanan and Susan Horton (eds) *Cancer* (3rd edn, World Bank Group, 2015).

John R T, ‘Pharmaceutical patents’ in Toshiko Takenaka (ed), *Research Hnadbook on Patent Law and Theory* (2nd edn, Edward Elgar, 2019).

Khor M, ‘Rethinking Intellectual Property Rights and TRIPS’, in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights—Knowledge, Access and Development* (Palgrave Macmillan, 2002).

Kim S, Barnett A and Fry C, ‘Essential Medicines, Pharmaceutical Policy and Global Health’ in Stella R. Quah (ed) *International Encyclopedia of Public Health* (3rd edn, Elsevier, 2024).

Laurence R Helfer, ‘Mapping the Interface Between Human Rights and Intellectual Property’, in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar, 2016).

Matthews D, ‘Access to CRISPR Genome Editing Technologies: Patents, Human Rights and the Public Interest’ in Carlos M Correa and Reto M Hillty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Spring, 2022).

Matthews D, ‘Intellectual Property, Human Rights and the Right to Health’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar, 2010).

McConville M and Chui W H, ‘Introduction and Overview’ in Mike McConville and Hong Chui Wing, (eds), *Research Methods for Law* (Edinburgh University Press Ltd, 2007).

Menell P S, ‘Intellectual Property: General Theories’ in Boudewijn Bouckaert (ed), *Encyclopedia of Law & Economics* (Edward Elgar, 2000).

Menell P S, ‘Mapping the Intellectual property social justice frontier’ in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024).

Mtima L ‘Intellectual Property Social Justice: A Theoretical Rationale’ in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024).

Mtima L and Jamar S D, ‘Introduction: Intellectual Property Social Justice Theory: History, Development, and Description’ in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024).

Mtima L and Jamar S D, ‘Researching Social Justice Aspects of Intellectual Property’ in Irene Calboli and Maria Lilla Montagnani (eds), *Intellectual Property Research: Lenses, Methods, and* Perspectives (Oxford University Press, 2021).

Mtima L, ‘Prolusion: What is the Intellectual Property (And Why Should You Care About It Anyway?) – A layperson’s Guide to Intellectual Property in Steven D Jamar and Lateef Mtima (eds), *Intellectual Property and Social Justice* (Cambridge University Press, 2024).

Mtima L, ‘From Swords to Ploughshares: Towards a Unified Theory of Intellectual Property Social Justice’, in Lateef Mtima (ed), *Intellectual Property, Entrepreneurship and Social Justice* (Elgar Law,2015).

National Academies of Sciences, Engineering, Medicine, Health and Medicine Division, Board on Population Health and Public Health Practice, Committee on Community-Based Solutions to Promote Health Equity in the United States, Braciu A, Negussie Y and Geller A, ‘The Root causes of health inequity’ in National Academies of Sciences, Engineering, Medicine (eds) *Communities in Action: Pathways to Health Equity* (National Academies Press, 2017).

Richardson M, 'Intellectual Property and Privacy Law' in in Irene Calboli and Maria Lilla Montagnani (eds), *Handbook of Intellectual Property Research* (Oxford, 2021).

Sellin S, 'Access to Medicines: The Problem' in Sellin J (ed), *Access to Medicines: The Interface between Patents and Human Rights: Does One Size Fit All?'* (School of Human Rights Research Intersentia, 2014).

Shaffer G and Shell G K, 'Transnational Legal Ordering and Access to Medicines' in Ruth L Okedji and Margo A. Bagley (eds), *Patent Law in Global Perspective* (OUP, 2014).

Vawda Y A, 'Compulsory Licenses and Government Use: Challenges and Opportunities' in Carlos M Correa and Reto M Hilty (eds), *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer, 2022).

Wood U, 'The Case for a Qualified Veto System of Adverse Possession in Ireland: A Doctrinal Approach with Bells and Whistles' in Laura Cahillance and Jennifer Schweppe (eds), *Case Studies in Legal Research Methodologies* (Clarus Press, 2019).

Yu P K, 'Intellectual property, human rights, and methodological reflections' in Irene Calboli and Maria Lilla Montagnani (eds), *Handbook of Intellectual Property Research* (Oxford, 2021).

## Articles

Abbas M Z, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' (2013) 3(3) International Journal of Social Science and Humanity.

Abbott F M and Reichman F H, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amendment TRIPS Provisions' (2007) 10(4) Journal of International Economic Law.

Ahmed S M, Krishnan A, Karim O, Shafique K, Naher N, Sanjida Ahmed Srishti, Raj A, Ahmed S, Rawal L and Adams A, 'Delivering non-communicable disease services through primary health care in selected south Asian countries: are health systems prepared?' (2024) 12(10) The Lancet Global Health.

Ajigboye M O and Olubiyi I, 'Impact of TRIPs Agreement on access to immunosuppressant drugs: another challenge in kidney transplantation and treatment in developing countries' (2021) 29(2) African Journal of International and Comparative Law.

Alderwick H and Dixon J, 'The NHS long term plan' (2019) 346 (184) BMJ.

Alhiari R, Kesselheim A S, Gabriele S, Beall R, Tu S S and Feldman W B, 'Patents and regulatory exclusivities on GLP-1 receptor agonists' (2023) 330 (7) JAMA.

Alkhafaji A A, Trinquart L, Baron G, Desvarieux M and Ravaud P, 'Impact of evergreening on patients and health insuarance: a meta analysis and reimbursement cost analysis of citalopram/escitalopram antidepressants' (2012) 10 (142) BMC Medicine.

Amin T and Kesselheim A S, 'A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness' (2022) 59 The Journal of Health care Organization, Provision and Financing.

Amini H, Habibi S, Islamoglu A H, Isanejad E, Uz C and Daniyari H, 'COVID-19 pandemic-induced physical inactivity: the necessity of updating the Global Action Plan on Physical Activity 2018-2030' (2021) 26 (32) Environmental Health and Preventive Medicine.

Amy Kapczynski and Aaron S Kesselheim, 'Government Patent Use': A Legal Approach to Reducing Drug Spending' (2016) 35(5) Health Aff (Millwood).

Arie S, 'Indian Supreme Court rejects Novartis's appeal on drug patent' (2013) 346 (f2099) BMJ.

Arifin H, Chou K R, Ibrahim K, Rifa'actul F S U, Pradipta R O, Rias Y A, Sitorus N, Wiratama B S, Setiawan A, Setyowati S, Kuswanto H, Mediarti D, Rosnani R, Sulistini R, Pahria T, 'Analysis of Modifiable, Non-Modifiable,and Physiological Risk Factors of Non-Communicable Diseases in Indonesia: Evidence from the 2018 Indonesian Basic Health Research' (2022) 15 Journal of Multidisciplinary Healthcare.

Augusto G F, 'Cuts in Portugal's NHS could compromise care' (2012) 379 (9814) World Report.

B D'Angelo A, Grov C, Johnson J and Freudenberg N, 'Breaking Bad *Patents*: Learning from HIV/AIDS to make COVID-19 treatments accessible' (2021) 16(10) Glob Public Health, An International Journal for Research, Policy and Practice.

Bagley M A, 'The Morality of Compulsory Licensing as an Access to Medicines Tool' (2018) 102(2463) Emory Law Scholarly Commons.

Baker P, Kay A and Walls H, 'Trade and investment liberalization and Asia's noncommunicable disease epidemic: a synthesis of data and existing literature' (2014) 10(66) Globalization and Health.

Barash E H, 'Experimental Uses, Patents and Scientific Progress' (1997) 91(2) Nw UL Rev.

Barnard B 'In the High Court of South Africa, Case No 4138/98: The Global Politics of Access to Low-Cost AID Drugs in Poor Countries' (2002) 12(2) Kennedy Institute of Ethics Journal.

Bell D and Hansen K S, 'Relative Burdens of the Covid-19, Malaria, Tuberculosis, and HIV/AIDS Epidemics in Sub-Saharan Africa' (2021) 105(6) Am J Trop Hyg.

Bennette W J, 'Indian Pharmaceutical Patent Law and the Effects of Novartis Ag Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v Union of India' (2014) 13 (3) Indian Pharmaceutical Patent Law.

Beran D, Pedersen H B and Robertson J, 'Noncommunicable diseases, access to essential medicines and universal health coverage' (2019) 12(1) Global Health Action.

Bhattacharya S, Heidler P and Varshney S, 'Incorporating neglected non-communicable diseases into the national health program- A review' (2023) 10(1093170) Front Public Health.

Blank C, ‘High Demand Keeps Some Diabetes Medications in Short Supply: Pharmaceutical companies are experiencing supply chain disruptions and shortages because of the popularity of diabetes drugs used for weight loss’ (2023) 167 (2) Health and Medicine.

Boles A, Kandimalla R and Reddy P H, ‘Dynamics of diabetes and obesity: Epidemiological perspective’ (2017) 1863 (5) Biochimica et Biophysica Acta.

Bollyky T J, ‘Access to drugs for Treatment of Non-communicable diseases’ (2013) 10(7) Plos Med.

Bonadio E and Baldini A, ‘COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health’(2020) 11(2) European Journal of Risk Regulation.

Boutayeb A and Boutayeb S, ‘The burden of non-communicable diseases in developing countries’ (2005) 4 (2) International Journal for Equity in Health 1.

Budreviciute A, Damiati S, Damiati S, Sbir S K, Onder K, Goetzburg P S, Plakys G, Katileviciute A, Khoja S and Kodzius R, ‘Management and Prevention Strategies for Non-communicable Diseases (NCDs) and Their Risk Factors’ (2020) 8(574111) Front Public Health.

Bull F C and Bauman A E, ‘Physical Inactivity: The “Cinderella” Risk Factor for Noncommunicable Disease Prevention’ (2011) 16(sup2) Journal of Health Communication.

Burki T K, ‘Indian government awards compulsory license for sorafenib’ (2012) 13(4) The Lancet Oncology 146.

Busfield J, ‘Globalization and the pharmaceutical industry revisited’ (2003) 33(3) International Journal of Health Services.

CADTH Reimbursement Review, ‘Trastuzumab Deruxtecan (Enhertu)’ (2023) 3 (1) Clinical Review Pharmacoeconomic Review.

Calcaterra C and Zuccotti G, ‘Non-Communicable Diseases and Rare Diseases: A Current and Future Public Health Challenge within Pediatrics’ (2022) 9 (10) Children.

Carroll M J, ‘The importance of regulatory data protection or exclusive use and other forms of intellectual property rights in the crop protection industry’ (2016) 72 Pest Management Science.

Chamberlin S and Dabbs W, ‘Semaglutide (Ozempic) for Type 2 Diabetes Mellitus’ (2019) 100 (2) Am Fam Physician.

Charalambous P, Pallari E, Tyrovolas S, Middleton Nm, Economou M, Devleesschauwer B and Haagsma J A, ‘Burden of non-communicable diseases in Cyprus 1990-2017 findings from the Global Burden of Disease 2017 study’ (2021) 79(138) Archives of Public Health.

Charnovitz S, 'The Legal Status of the Doha Declarations' (2002) 5(1) Journal of International Economic Law.

Chattu V K, Singh B, Pattanshetty S and Reddy S, ‘Access to medicines through global health diplomacy’ (2023) 13(1) Health Promot Respect.

Chaudhary T and Chaudhary A, 'TRIPS waiver of COVID-19 vaccines: Impact on pharmaceutical industry and what it means to developing countries' (2021) 24 The Journal of World intellectual Property.

Chien C V, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation' (2003) 18(853) Berkeley Technology Law Journal.

Choudhury J H, Chowdhury T I, Nayeem A and Jahan W A, 'Modifiable and Non-Modifiable Risk Factors of Stroke: A Review Update' (2015) 1(1) Journal of National Institute of Neurosciences Bangladesh.

Cohen J C, Lutterodt M G, Torpey K, Esmail L C and Kurokawa G, 'TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana' (2005) 1(17) Globalization and Health.

Cohen L and Peirson L, 'The UK Research and 'Bolar' exemptions: broadening the scope for innovation? (2013) 8(11) Journal of Intellectual Property Law.

Collier J, 'The Pharmaceutical Price Regulation Scheme' (2007) 334 (7591) BMJ.

Collier R, 'Drug patents the evergreening problem' (2013) 185(9) CMAJ.

Correa C M, 'The use of compulsory licenses in Latin America' (2013) 71 South Bulletin.

Cullet P, 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79(1) International Affairs.

Curtice M, 'Article 8 of the Human Rights Act 1998: implications for clinical practice' (2009) 15 Advances in psychiatric treatment.

Cuschieri S, Hatziyianni A, Karayiannis P, Haagsma J A, Wyper G M A, Kontraris M, Theodorou and Pallari E, 'Re-engineering the Cypriot General Healthcare System for Syndemics' (2022) 10 (734796) Frontiers in Public Health.

D'Angelo A B, Grov C, Johnson J and Freudenberg N, 'Breaking Bad Patents: learning from HIV/AIDS to make COVID-19 treatments accessible' (2021) 16(10) Glob Public Health.

Da Fonseca E M and Shadlen K C, 'Promoting and regulating generic medicines: Brazil in comparative perspective' (2017) 41(e5) Rev. Panam Salud Publica.

Danawala S and Zhang Z, 'Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower- and Middle-Income Countries' (2013) 1(1) GSTF International Journal of Nursing and Health Care (JNHC).

De Vos P F, Stefanini A, Ceukelaire W D and Schuftan C, 'A human right to health approach for non-communicable diseases' (2013) 381(9866) The Lancet.

Del Castillo F A, 'Temporary waiver of intellectual property on Covid-19 vaccines: toward the creation of a better, pot-pandemic society' (2021) 19(2) Journal of Public Health.

Demir E and Stamhuis E, 'Patenting biological materials and data: balancing the reward of innovation with the ordre public and morality exception' (2023) 18 (7) Journal of Intellectual Property Law & Practice.

Desai M A, ‘Compulsory licensing: Procedural requirements under the TRIPS agreement’ (2016) 18 Pharmaceuticals Policy and Law.

Diependaele L, Cockbain J and Sterckx S, ‘Raising the Barriers to Access to Medicines in the Developing World-The Relentless Push for Data Exclusivity’ (2017) 17(1) Developing World Bioethics.

Druedahl L C, Minssen T and Price W N, ‘Collaborations in times of crisis: A study on Covid-19 vaccine R&D partnerships’ (2021) 39 (42) Vaccine.

Duran M G, ‘Untangling the International Responsibility of the European Union and Its Member States in the World Trade Organization Post-Lisbon: A Competence/ Remedy Model’ (2017) 28(3) EJIL.

E L Saslow, ‘Compulsory licensing and the AIDS epidemic in South Africa’ (1999) 13 (10) AIDS Patient Care STDS.

England P, ‘Saint Gobain- patron of pharmaceutical patentees?’ (2007) 2(8) Journal of Intellectual Property & Practice.

England P, ‘The scope of protection of patent claims in Europe and the UPC’ (2016) 11(9) Journal of Intellectual Property Law & Practice.

Erçalışkan A, Erdogan D S, Eskazan A E, ‘Current evidence on the efficacy and safety of generic imatinib in CML and the impact of generics on health care costs’ (2021) 5(17) Blood Adv.

Excler J L, Saville M, Privor-Dumm L, Gilbert S, J Hotez P, Thompson D, Abdool-Karim S and H Kim J, ‘Factors, enablers and challenges for COVID-19 vaccine development’ (2023) 8(6) BMJ Glob Health.

Feldman J, ‘Compulsory Licenses: The Dangers Behind the Current Practice’ (2009) 8(1) Journal of International Business and Law.

Feldman R C, Hyman D A, Price W N and Ratain M J, ‘Negative innovation when patents are bad for patients’ (2021) 39(8) Nature biotechnology.

Ferreira L, ‘Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations’ (2002) 71 (3) Fordham Law Review.

Flaherty G T, Hession P, Liew C H, Lim B C W, Lim V, Sulaiman L H, ‘COVID019 in adult patients with pre-existing chronic cardiac, respiratory, and metabolic disease: a critical literature review with clinical recommendations’ (2020) 6(16) Tropical Diseases Travel Medicine Vaccines.

Ford N, Wilson D, Chaves G C, Lotrowaska M and Kijtiwatchakul K, ‘Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand’ (2007) Suppl 4:S21-9 AIDS.

Frankel S and Gervais D, ‘Plain packaging and the Interpretation of the Trips Agreement’ (2013) 46(5) Vanderbilt Journal of Transnational Law.

Gaayeb J, Das A, Murthy I J R, Nobre S, Burrone E and Morin S, ‘Voluntary licensing of long-acting HIV prevention and treatment regimens: using a proven collaboration- and competition-based mechanism to rapidly expand at-scale, sustainable, quality-assured and affordable supplies in LMICs’ (2023) 26 (Suppl 2) J Int AIDS Soc.

Gabble R and Kohler J C, ‘To patent or not to patent? The case of Novartis’ cancer drug Glivec in India’ (2014) 10(3) Globalization and Health.

Ganju A, Goulart A C, Ray A, Majumdar A, Jeffers B W, Llamosa G, Canizares H, Canizares I J R, Fadhil I, Subramaniam K, Lim L L Bizri L E, Ramesh M, Guilford M, Ali R, Devi R D, Malik R A, Potkar S and Wang Y P, ‘Systemic Solutions for Addressing Non-Communicable Diseases in Low- and Middle-Income Countries’ (2020) 13 Issue Journal of Multidisciplinary Healthcare.

Garattini L and Finazzi B, ‘Pharmaceutical Patents in Europe: Radical Reforms Rather than Getting Rid?’ (2021) 20(4) Appl Health Econ Health Policy.

Gavurova B, Kosciova K and Sopko J, ‘Health system efficiency in OECD countries: dynamic network DEA approach’ (2021) 11 (40) Health Econ Rev.

Gemelli M, Elli E M, Elena C, Iurlo A, Intermesoli T, Maffioli M, Pungolino E, Carraro M C, D’Adda M, Lunghi F, Anghileri M, Polverselli N, Rossi M, Bacciocci M, Bono E, Bucelli C, Passamonti F, Antolini L, Passerini C G, ‘Use of generic imatinib as first-line treatment in patients with chronic myeloid leukemia (CML): the GIMS (Glivec to Imatinib Switch) study’ (2020) 55(3) Blood Research.

George E, ‘The Human Rights to Health and HIV/AIDS: South Africa and South-South Cooperation for Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines’ (2011) 18(1) Indiana Journal of Global Legal Studies.

Gillat A, ‘Compulsory licensing to regulated licensing: effects on the conflict between innovation and access in the pharmaceutical industry’ (2003) 58(4) Food Drug Law Journal.

Glantz S and Gonzalez M, ‘Effective tobacco control is key to rapid progress in reduction of non-communicable diseases’ (2013) 379(9822) Lancet.

Goodman B, Buscics A, Bonanno P V, Oortwijn W, Rothe C C, Ferrario A, Bosseli S, Hill A, Martin S S, Kurdi A, Gad M, Gulbinovic J, Timoney A, Bochenek T, Salem A, Hoxha I, Sauremann R, Massele A, Guerra Jr A A, Petrova G, Mitkova Z, Achniotou G, Laius O, Sermet C, Selke G, Kouraalos V, Yfantopoulos J, Magnusson E, Joppi R, Oluka M, kwon H Y, Jakupi A, Kalemeera F,Fadare J O, Melien O, Pomorski M, Wladysiuk M, Markovic-Perkovic V, Mardare I, Meshkov D, Novakovic T, Furst J, Tomek D, Zara C, Diogene E, Meyer J C, Malmstrom R, Wettermark B, Matsebula Z, Campbell S and Haycox A, ‘Barriers for Access to New Medicines: Searching for the Balance Between Rising Costs and Limited Budgets’ (2018) 6(328) Frontiers in Public Health.

Goodman B, Massele A, Fadare J,Kwon H Y, Kurdi A, Kalemeera F, Hussain S, Pisana A and Meyer J C, ‘Barriers for Access to New Medicines: Searching for the Balance Between Rising Costs and Limited Budgets’ (2018) 6(328) Frontiers in Public Health.

Gordon W J, ‘A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property’ (1993) 102 YALE LJ.

Gore C, Morin S, Rottingen J A and Kieny M P, ‘Negotiating public-health intellectual property licensing agreements to increase access to health technologies: an insider’s story’ (2023) 8 (9) BMJ Global Health.

Gorkin L and Kantarjian H, ‘Targeted therapy Generic imatinib-impact on frontline and salvage therapy for CML’ (2016) 13(5) Nat Rev. Clin Oncol.

Grabowski H, ‘Patents, Innovation and Access to New Pharmaceuticals’ (2002) 5(4) Journal of International Economic Law.

Gravely S, Giovino G A, Craig L, Commar A, D’Espaignet E T, Schotte and Fong G T ‘Implementation of key demand-reduction measures of the WHO Framework Convention on Tobacco Control and change in smoking prevalence in 126 countries: an association study’ (2017) 2 (4) The Lancet Public Health.

Grosios K, Gahan P B and Burbidge J, ‘Overview of healthcare in the UK’ (2010) 1(4) EMPA J.

Guennif S, ‘Evaluating the Usefulness of Compulsory Licensing in Developing Countries: A Comparative Study of Thai and Brazilian Experiences Regarding Access to Aids Treatments’ (2017) 17(2) Dev World Bioeth.

Guennif S, ‘Is compulsory Licensing Bad for Public Health? Some Critical Comments on Drug Accessibility in Developing Countries’ (2017) 15 Applied Health Economics and Health Policy.

Gurgula O ‘Strategic Patenting by Pharmaceutical Companies- Should Competition Law Intervene?’ (2020) 51 International Review of Intellectual Property and Competition Law.

Gurgula O and Hull J, ‘Compulsory licensing of trade secrets: ensuring access to Covid-19 vaccines via involuntary technology transfer’ (2021) 16(11) Journal of Intellectual Property Law & Practice.

Haileamlak A, ‘Physical Inactivity: The Major Risk Factor for Non-Communicable Diseases’ (2019) 29(1) Ethiop J Health Sci.

Halbert D, ‘Moralized Discourses: South Africa’s Intellectual Property Fight for Access to AIDS Drugs’ (2002) 1(2) Seattle Journal for Social Justice.

Hassan S U N, Zahra A, Parveen N, Khatoon F, Bangi N A and Hosseinzadeh H, ‘Quality of Life and Adherence to Healthcare Services During the COVID-19 Pandemic: A Cross-Sectional Analysis’ (2022) 16 Patient Prefer Adherence.

Hastings G, ‘Why corporate power is a public health priority’ (2012) 345(e5124) BMJ.

Heller O, Somerville C, Suggs L S, Lachat S, Piper J, Pastrana N A, Correia J C, Miranda J J and Beran D,‘The process of prioritization of non-communicable diseases in the global health policy arena’ (2019) National Library of Medicines (2019) 34(5) Health Policy Plan.

Ho C M, ‘Should All Drugs Be Patentable? A Comprehensive Perspective’ (2015) 17 (2) Vanderbilt Journal of Entertainment & Technology Law.

Hochhaus A, Baccarani M, Silver R T, Schiffer C, Apperley J F, Cervantes F, Clark R E, Cortes J E, Deininger M W, Guilhot F, Hjorth-Hansen H, Hughes T P, Janssen J J W M, Kantarjian H M, Kim D W, Larson R A, Lipton J H, Mahon F X, Mayer J, Nicolini F, Niederwieser D, Pane F, Radich J P, Rea D, Richter J, Rosti G, Rousselot P, Saglio G, Saußele S, Soverini S, Steegmann J L, Turkina A, Zaritskey A and Helmann ‘European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia’ (2020) 34 Leukemia.

Hogerzeil H V, ‘The concept of essential medicines: lessons for rich countries’ (2004) 13(329) BMJ.

Hogerzeil H V, Liberman J, Wirtz V J, Kishore S P, Selvaraj S, Monroe R K, Powell F N M and Angerer T V S, 'Promotion of access to essential medicines for non-communicable diseases: practical implications of the UN political declaration' (2013) 23(381) Lancet.

Holman C M, 'In Defence of Secondary Pharmaceutical Patents: A response to the UN's Guidelines for Pharmaceutical Patent Examination' (2017) 50 (759) Ind. L. Rev.

Holman C M, Minssen T, and Solovy E M, 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report.

Hunt P, 'Interpretating the International Right to Health in a Human Rights-Based Approach to Health' (2016) 18(2).

Hunter D J and Reddy K S, 'Non communicable diseases' (2013) 369(64) N Engl J Med.

Hunter D J, Littlejohns P and Weale A, 'Reforming the public health system in England' (2022) 7(9) The Lancet Public Health.

Hutchinson T and Duncan N J, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17(1) Deakin Law Rev.

Hyder A A, Rylance S, Saegh A A, Feign V L, Kataria I and Laatikainen T, 'Strengthening evidence to inform health systems: opportunities for the WHO and partners to accelerate progress for non-communicable diseases' (2023) 8(1) BMJ Journals.

Igbokwe E M and Tosato A, 'Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31*bis*' (2022) 91 (5) Fordham Law Review.

Iqbal N and Iqbal N, 'Imatinib: A Breakthrough of Targeted Therapy in Cancer' (2014) 2014(357027) Chemotherapy Res Pract.

Ismail H, Marshall Vincent D, Patel Minal, Tarqi Madiha and Mohammad R A, 'The impact of the COVID-19 pandemic on medical conditions and medical adherence in people living with chronic Diseases' (2003) 62(3) J Am Pharmacists Association.

Jaenichen H R and Pitz J, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' (2015) 5(2) Cold Spring Harb Perspect Med.

Jahagirdar D and Mahood Q, 'Semaglutide for Type 2 Diabetes (2 mg)' (2023) 3 (10) CADTH Health Technology Review.

Jamar S D and Mtima L, 'The Centrality of Social Justice for an Academic Intellectual Property Institute' (2011) 64 Southern Methodist University Law Review.

Jenei K, Lythgoe M P and Prasad V, 'CostPlus and implications for generic imatinib' (2022) 13(100317) The Lancet Regional Health- American.

Ji G, Li L, Lin C and Sun S, 'The impact of HIV/AIDS on families and children – a study in China' (2007) 21(Suppl 8) AIDS.

Jimenez F L, Almahmeed W, Bays H, Cuevas A, Angelantonio D, Roux C W le, Sattar N, Sun M C, Wittert G, Pinto F J and Wilding J P H, 'Obesity and cardiovascular disease: mechanistic insights and management strategies. A joint position paper by the World Heart Federation and World Obesity Federation' (2022) 29 (17) European Journal of Preventive Cardiology.

Kabir A, Karim M N and Billah B, 'Health system challenges and opportunities in organizing non-communicable diseases services delivery at primary healthcare level in Bangladesh: A qualitative study' (2022) 10(1015245) Front Public Health.

Kar S S Pradhan H S and Mohanta G P, 'Concept of Essential Medicines and Rational Use in Public Health' (2010) 35 (1) Indian Journal of Community Medicine.

Khachigian L M, 'Pharmaceutical patents: reconciling the human rights to health with the incentive to invent' (2020) 25(7) Drug Discovery Today.

Kianzad B and Wested J, 'No-one is Safe Until Everyone is Safe' – Patent Waiver, Compulsory Licensing and COVID-19' (2021) 5(2) European Pharmaceutical Law Review.

Kishore P K, Kolappa K, Jarvis J, Park P H, Belt R, Balasubramaniam T and Monroe R K, 'Overcoming Obstacles to Enable Access to Medicines for Noncommunicable Diseases in Poor Countries' (2015) 34(9) Health Aff (Millwood).

Koh K H, Geller A C and VanderWeele J T, 'Deaths From COVID-19' (2021) 325 (2) JAMA Network.

Kohler J, Wong A and Tailor L, 'Improving Access to Covid-19 Vaccines: An analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders' (2022) 24(2) Health and Human Rights Journal.

Kovacevic A, Rancic N, Segrt Z and Simic V D, 'Pharmaceutical Expenditure and Burden of Non-communicable Diseases in Serbia' (2016) 7(373) Front Pharmacol.

Kreuter M W, Thompson T, McQueen A and Garg R, 'Addressing Social Needs in Health Care Settings: Evidence, Challenges, and Opportunities for Public Health' (2021) 42 Annu Rev. Public Health.

Krikorian G and Torreele E, 'We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis' (2021) 23(1) Health and Human Rights Journal.

Kruk M E, Dage A D, Arsenault C, Jordan K, Leslie H H, Roder-DeWan S, Adeyi O, Barker P, Daelmans B, Doubova S V, English M, Garcia-Elorrio E, Guanais F, Gureje O, Hirschhorn L R, Jiang L, Kelley E, Lemango E T, Lijestrand J, Malata A, Marchant T, Matsoso M P, Meara J G, Mohanan M, Ndiaye Y, Norheim O F, Reddy K S, Rowe A K, Salomon J A, Thapa G, Twum-Danso N A Y and Pate M, 'High-quality health systems in Sustainable Development Goals era: time for a revolution' (2018) 6 (1) The Lancet Global Health.

Kuanpoth J, 'Compulsory Licenses: Law and Practice in Thailand' (2014) 25(22) Compulsory Licensing.

Kyle M, Strategic Responses to Parallel Trade' (2011) 11(2) Industrial Organization and Healthcare.

Kyprianidou M, Panagiotakos D, Makris k C, Kambanaros M, Christophi C A and Giannakou K, 'Prevalence and sociodemographic determinants of selected noncommunicable diseases among the general population of Cyprus: A large population-based cross-sectional study' (2023) 9(3) Chronic Dis Transl Med.

Lachat C, Otchere S, Roberfroid D, Abdulai A, Seret F M A, Milesevic J, Xuereb G, Candeias V and Kolsteren P, 'Diet and Physical Activity for the Prevention of Noncommunicable Diseases in Low- and Middle-Income Countries: A Systematic Policy Review' (2013) 10(6) PLOS Medicine.

Lai C C, Shih T P, Ko W C, Tang H J and Hsueh P R 'Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges' (2020) 55 (3) Int J Antimicrob Agents.

Laing R, Waning B, Gray A, Ford N and 't Hoen E, '25 years of the WHO essential medicines lists: progress and challenges' (2003) 361(9370) Lancet.

Lanzoszka A, 'The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries' (2003) 24(2) International Political Science Review.

Latten T, Westra D, Angeli F, Paulus A, Struss M and Ruwaard D, 'Pharmaceutical companies and healthcare providers: Going beyond the gift- An explorative review' (2018) 13(2) PLos One.

Le L K D, Faller J, Chatterton M L, Perez J K, Chiotelis O, Tran J N Q, Sultana M, Hall N, Lee Y Y, Chapman C, Newton N, Slade T, Sunderland M, Teesson M and Mihalopoulos C, 'Interventions to prevent alcohol use: systematic review of economic evaluations' 2023 9(4) BJPsych Open.

Lee J Y, 'A human rights framework for intellectual property, innovation and access to Medicine' (2015) 11(2) Journal of Intellectual Property Law & Practice.

Lehmann B, 'Regulation (EC) nO 1901/2006 on medicinal products for paediatric use & clinical research in vulnerable populations (2008) 2(37) Child Adolesc Psychiatry Ment Health.

Lemley M A, 'Rational Ignorance at the Patent Office' (2001) 95(4) Northwester University Law Review 1495.

Lopez A D, Williams T N, Levin A, Tonelli M, Singh J A, Burney P GJ, Rehm J, Volkow N D,Koob G and Ferri C, 'Remembering the forgotten non-communicable diseases' (2014) 12(200) BMC.

Luna F and Luyckx V A, 'Why have non-communicable diseases been left behind?' (2020) 12(1) Asian Bioeth Rev.

Machlup F and Penrose E, 'The Patent Controversy' (1950) 10(01) The Journal of Economic History.

Mackey T K and Liang B A, 'Patent and Exclusivity Status of Essential Medicines for Non-Communicable Diseases' (2012) 7(11) PLos One.

Magnusson R S and Patterson D, 'The role of law and governance reform in the global response to non-communicable diseases' (2014) 10(44) Globalization and Health.

Maher A and Sridhar D, 'Political priority in the global fight against non-communicable diseases' (2012) 2(2) J Glob Health.

Manimaran R and Sheik S, 'A Guide to Patent Infringement: A Global Perspective 2019-2020' (2019) 6 Court Uncourt.

Mansfield E 'Patents and Innovation: An Empirical Study' (1986) 32(2) The Institute of Management Sciences.

Marmot M and Bell R, 'Social determinants and non-communicable diseases: time for integrated action' (2019) 364 (Suppl 1) BMJ.

Martin R, 'Law and Public Health Policy' (2008) 26 International Encyclopaedia of Public Health.

Masupe T, Mashalla Y, Seloilwe E, Jibril H and Medhin H, 'Integrated management of HIV/NCD knowledge, attitudes, and practices of health care workers in Gaborone, Botswana' (2019) 19(3) African Health Sciences.

Matthews D, 'Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation' (2004) 1 Law, Social Justice & Global Development Journal**.**

Matthews D, 'WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: a solution to the access to essential medicines problem?' (2004) 7(1) J Int Econ Law.

McDonagh L, 'An impressive overview of European patent law in the UPC era' (2024) Journal of Intellectual Property Law & Practice doi. org/10.1093/jiplp/jpae113.

McGivern L, 'Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation' (2023) 101 (4) Milbank Q.

McGowan D, 'Copyright Nonconsequentialism' (2004) 69(1) Missouri Law Review.

McPherson J, 'Article 25 Changed my life: How the Universal Declaration of Human Rights Reframed my Social Work Practice' (2016) 22 (2) Reflections: Narratives of Professional Helping.

Mendis S, Fukino K, Cameron A, Laing R, Jr A F, Khatib O, Leowski J and Ewen M, 'The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries' (2007) 85(4) Bull World Health Organ.

Mercurio B, 'The IP waiver for COVID-19: bad policy, bad precedent' (2021) 52(8) International Review of Intellectual Property and Competition Law.

Mitchell A and Voon T, 'Implications of the World Trade Organization in combating non-communicable diseases' (2011) 125(12) Public Health.

Mitchell A D and Voon T, 'Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law' 43(3) Journal of World Trade.

Mitri J and Hamdy O, 'Diabetes medications and body weight' (2009) 8 (5) Expert Opinion on Drug Safety.

Montana M, 'COVID-19 and India's and South Africa's attempt to reopen the TRIPS Pandora's box: a proposal made in vain? (2021) 43(6) E.I.P.R.

Moreno S G and Epstein D, 'The price of innovation- the role of drug pricing in financing pharmaceutical innovation. A conceptual framework' (2019) 7(1) J Mar Access and Health Policy.

Moser P, 'Patents and Innovation: Evidence from Economic History' (2013) 27 (1) Journal of Economic Perspectives.

Mossoff A, 'Patents as Constitutional Private Property: The Historical Protction of Patents Under the Takings Clause' (2007) 87(689) Boston University Law Review.

Motari M, Nikiema J B, Kasilo O M J, Kniazkov S, Loua A, Sougou A and Tumusiime P, 'The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement' (2021) 21(490) BMC Public Health.

Moyo E, Moyo P, Murewanhema G, Mhango M, Chitungo I and Dzinamarira T, 'Key populations and Sub-Saharan Africa's HIV response' (2023) 10 (3389) Frontiers in Public Health.

Mtima L, 'IP Social Justice Theory: Access, Inclusion and Empowerment' (2019-2020) 55 Gonzaga Law Review.

Muka T, Imo D, Jaspers L, Colpani V, Chaker L, Van der Lee S, Mendis S, Chowdhury R, Bramer W M, Falla A, Pazoki R and Franco O H, 'The global impact of non-communicable diseases on healthcare spending and national income: a systematic review' (2015) 30(4) Eur J Epidemiol.

Mulkey S B, Bearer C F and Molloy E J, 'Indirect effects of the Covid-19 pandemic on children related to the child's age and experience' (2023) 94 Pediatr Res.

Murthy D, 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health' (2002) 17(6) The American University International Law Review.

Ncayiyana D J, 'Antiretroviral therapy cannot be South Africa's first priority' (2001) 164(13) CMAJ.

NCD Countdown, 'NCD Countdown 2030: efficient pathways and strategic investments to accelerate progress towards the Sustainable Development Goal target 3.4 in low-income and middle-income countries' (2022) 399 (10331) Health Policy.

Ndubuisi N E, 'Noncommunicable Diseases Prevention in Low and Middle-Income Countries: An Overview of Health in All Policies (HiAP) (2021) 58 Inquiry: The Journal of Health Care Organization.

Ndumwa H P, Amani D E, Ngowi N, Njiro J, Munishi C, Mboya E A, Mloka D, Kikula A I, Balandya E, Ruggajo P, Kessy A T, Kitambala E, Kapologwe N, Kengia J T, Kiologwe J, Ubuguyu O, Salum B, Kamuhabwa A, Ramaiya K and Sunguya B F, 'Mitigating the Rising Burden of Non-Communicable Diseases through Locally Generated Evidence-Lessons from Tanzania' (2023) 89(1) Ann Glob Health.

Nicol D and Owoeye O, 'Using TRIPS flexibilities to facilitate access to medicines' (2013) 91(7) Bull World Health Organ.

Nunn A, Fonseca E M, Bastos F I and Gruskin S, 'Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil' (2009) 4 (2) Glob Public Health.

Nuno M, ‘A Fair Return Approach to Pharmaceutical Compulsory Licensing’ (2016) 48(1) Case Western Reserve Journal of International Law.

O Gostin L, ‘Global Health Law’ (2015) 93(1) The Milbank Quarterl.

Ojewale L Y and Mukumbang F C, ‘Access to healthcare services for people with non-communicable diseases during the COVID-19 pandemic in Ibadan, Nigeria: a qualitative study’ (2023) 23(1231) BMC Health Ser Res.

Oke E K, ‘Incorporating a right to health perspective into the resolution of patent law disputes’ (2013) 15(2) Health Hum Rights.

Ola K, ‘COVID-19 strategic global north-south divide: access to knowledge quadrants, imperatives for granting the WTO waiver’ (September 2021) European Intellectual Property Review doi.org/10.2139/ssrn.3927721.

Ooms G and Hanefeld J, ‘Threat of compulsory licenses could increase access to essential medicines’ (2019) 365(1298) BMJ.

Oturu K, O’Brien O and Ozo-Eson P I, ‘Barriers and enabling structural forces affecting access to antiretroviral therapy in Nigeria’ (2024) 24(105) BMC Public Health.

Ozdemir S, Fernandez de Arroyable J C, Sena V and Gupta S, ‘Stakeholder diversity and collaborative innovation: Integrating the resource-based view with stakeholder theory’ (2023) 164(113955) Journal of Business Research.

Pallari E, Lewison G, Pallari C T, Samoutis G, Begum M and Sullivan R, ‘The contribution of Cyprus to non-communicable diseases and biomedical research from 2002 to 2013: implications for evidence-based health policy’ (2018) 16(82) Health Research Policy and Systems.

Pammolli F, Orsenigo L and Magazzini L, ‘The Intensity of Competition After Patent Expiry in Pharmaceuticals. A Cross-Country Analysis’ (2002) 99 *Revue d'Economie Industrielle.*

Parry C D, Patra J and Rehm J, ‘Alcohol consumption and non-communicable diseases: epidemiology and policy implications’ (2012) 106(10) Addiction.

Pati M K, Bhojani U, Elias M A, Srinivas P S, ‘Improving access to medicines for non-communicable diseases in rural primary care: results from a quasi-randomized cluster trial in a district in South India’ (2021) 21(770) BMC Health Serv Res.

Petersen P E, ‘World Health Organization global policy for improvement of oral health – World Health Assembly 2007’ (2008) 58(3) International Dental Journal.

Petrou P, ‘The 2019 introduction of the new National Healthcare System in Cyprus’ (2021) 125(3) Health Policy.

Piggott T, Moja L, Huttner B, Okwen P, Raviglione M C B, Kredo T and Schünemann H, ‘WHO Model list of essential medicines: visions for the future’ (2024) 102 (10) Bull World Health Organ.

Piovani D, Nikolopoulos G K and Bonovas S, ‘Non-Communicable Diseases: The Invisible Epidemic’ (2022) 11 (19) J Clin Med.

Powell-Wiley T M, Poirier C P, E Burke L E, Despres J P, Gordon-Larsen P, Lavie C L, Lear S A, Ndumele C E, Neeland I J, Sanders P, St-Onge M P, 'Obesity and Cardiovascular disease' (2021) 143(21) HHS Public Access.

Ramakrishnan M, Poojari P G, Rashid M, Nair S, Chandran V P, Thunga G, 'Impact of COVID-19 pandemic on medicine supply chain for patients with chronic diseases: Experiences of the community pharmacists' (2023) 20(101243) Clinical Epidemiology and Global Health.

Ravinetto R, Henriquez R, Srinivas P S, Bradley H, Coetzee R, Ochoa T J, Ngabonziza J C S, Mazarati J B, Damme W V, Va de Pas R, Vandaele N and Torreele E, 'Shaping the future of global access to safe, effective, appropriate, and quality health products' (2024) 9(1) BMJ Global Health.

Reddy T K, Villavaso C D, Pulapaka A V and Ferdinand K C, 'Achieving equitable access to incretin-based therapies in cardiovascular care' (2024) 46 (100455) American Heart Journal Plus: Cardiology Research and Practice'.

Resnki D B, 'Embryonic Stem Cell Patents and Human Dignity' (2007) 15(3) Health Care Anal.

Reubi D, Herrick C, Brown T, 'The politics of non-communicable diseases in the global South' (2016) 39 Health & Place.

Richards N and Hudson I, 'UK medicines regulation: responding to current challenges' (2016) 82(6) BBr J Clin Pharmacol.

Robinson H M and Hort K, 'Non-communicable diseases and health systems reform in low- and-middle-income countries' (2012) National 18(1) Pac Health Dialog.

Rogowska K J and Mieczan A W, 'Initiatives to Reduce the Content of Sodium in Food Products and Meals and Impove the Population's Health' (2023) 15 (10) Nutrients.

Rowe E A, 'The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment? (2007) 59(2) Maine Law Review.

Rowley J, 'Using Case Studies in Research' (2002) 25(1) Management Research News.

Ruger J P and Yach D, 'The Global Role of the World Health Organization' (2014) 2(2) Glob Health Gov.

Salako A O, Odubela O O, Ohwodo H O, Opaneye B, Ojuko S O, Nwankwo N L, Eliga Q E, David A N, Ezechi O C and Salako B L, 'Challenges of Accessing Care in Art Clinic during COVID-19 Lockdown in Lagos' (2022) 25(1) Niger J Clin Pract.

Sanders A K, 'Compulsory Licensing and Public Health' (2004) 11(4) Sage Journals.

Santos A T, Costa C M, Marquez L D and Banheiro R M, 'Analysis the Influence of WHO Initiatives on the Scientific Discourse of Noncommunicable Diseases through a Bibliometric Approach' (2023) 20(18) Int J Environ Res Public Health.

Santosa A, Rocklöv J, Högberg U and Byass P, 'Achieving a 25% reduction in premature non-communicable disease mortality: the Swedish population as a cohort study' (2015) 13(65) BMC Medicine.

Sarvestani A S and Sienko K H, 'Medical device landscape for communicable and non-communicable diseases in low-income countries' (2018) 14(65) Globalization and Health.

Schneider P, Maximilian S K, Stefan F, Bettina H, Claudia H, 'HPR149 Bio-Hybrid Medicinal Products: Widening Access or Product Differentiation?' (2023) 26(12) Value in Health.

Schug M K, 'Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa within the Framework of International Intellectual Property Law' (2001) 19(2) Minnesota Journal of Law & Inequality.

Schwartz J I, Muddu M, Kimera Isaac, Mbuliro M, Ssennyonjo R, Ssinabulya I and C Semitala F C, 'Impact of a COVID-19 national lockdown on integrated care for Hypertension and HIV' (2021) 16(1) Global Heart.

Shallcross L J and Davies S C, 'The World Health Assembly resolution on antimicrobial resistance' (2014) 69 (11) Journal of Antimicrobial Chemotherapy.

Shaw S, Muir S, Strommer S, Crozier S, Cooper C, Smith D, Barker M and Vogel C, 'The interplay between social and food environments on UK adolescents' food choices: implications for policy' (2023) 38(4) Health Promotion International.

Shu J and Weifeng Jin, 'Prioritizing non-communicable diseases in the post-pandemic era based on a comprehensive analysis of the GBD 2019 from 1990 to 2019' (2023) 13 (13325) Sci Rep**.**

Siddiqui M and Rajkumar S V, 'The High Cost of Cancer Drugs and What We Can Do About It' (2012) 87 (10) Mayo Clin Proc.

Singh A K, Kumar A, Sigh H, Sonawane P, Paliwal H, Thareja S, Pathak P, Grishina M, Jaremko M, Emwas A H, Yadav J P, Verma A, Khalilullah H and Kumar P, 'Concept of Hybrid Drugs and Recent Advancements in Anticancer Hybrids' (2022) 15(9) Pharmaceuticals (Basel).

Singh B, Chattu V K, Kaur J, Mol R, Gauttam P and Singh B, 'COVID-19 and Global Distributive Justice: 'Health Diplomacy' of India and South Africa for the TRIPS waiver' (2023) 58(5) Journal of Asian and African Studies.

Singh K, Reddy K S and Prabhakaran D, 'What are the Evidence Based Public Health Interventions for Prevention and Control of NCDs in Relation to India?' (2011) 36(Suppl1) Indian J Community Med.

Singhal T, 'A review of Coronavirus Disease-2019 (COVID-19)' (2010) 87(4) The India Journal of Pediatrics.

Somani S N, Marshall K, Durrani H, Tang K, Moglizevski R and Bhutta Z,'Evaluation of frameworks demonstrating the role of private sector in non-communicable isease management and control: a systematic review and thematic synthesis' (2023) 13(3) BMJ Open.

Sridhar D, 'Improving Access to Essential Medicines: How Health Concerns can be Prioritised in the Global Governance System' (2008) 1(2) Public Health Ethics.

Stevens H and Huys I, 'Innovative Approaches to Increase Access to Medicines in Developing Countries' (2017) 4(218) Frontiers in Medicines.

Stief M, 'The European Research and Bolar Exemptions – Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission's New Draft Directive for the Reform of Pharmaceutical Legislation' (2024) 73(9) GRUR International.

Stirner B and Thangaraj H, 'Leaning from practice: compulsory licensing cases and access to medicines' (2013) 2(2) Pharmaceutical Patent Analyst.

Stolbrink M, Ozoh O B, Halpin D M G, Nightingale R, Meghji J, Plum C, Allwood B W, Jayasooriya S and Mortimer K, 'Availability, cost and affordability of essential medicines for chronic respiratory diseases in low-income and middle-income countries: a cross-sectional study' (2024) 79 Open Access.

Subhan J, 'Scrutinized: The TRIPS Agreement and Public Health' (2006) 9 (2) Mcgill J Med.

Sudheer N and Bhadoria G, 'The Intersection of Intellectual Property Rights (IPR) and Sustainable Development Goals (SDGs): Examining how the Former can either Hinder or Facilitate Progress towards achieving the Latter' (2024) 7(2) International Journal of Law Management & Humanities.

Suhrcke M, Stuckler D, Suk J E, Desai M, Senek M, McKee M, Tsolova S, Basu S, Abubakar I, Hunter P, Rechel B and Seenza J C, 'The Impact of Economic Crises on Communicable Disease Transmission and Control: A Systematic Review of the Evidence' (2011) 6 (6) Plos one.

Sun H, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health' (2004) 15(1) European Journal of International Law.

Sykes A O, 'TRIPS, Pharmaceuticals, Developing Countries, and the Doha Solution' (2003) 3 Chicago Journal of International Law.

'T Hoen E and Passarelli C A, 'The role of intellectual property rights in treatment access: challenges and solutions' 8 (1) 70 Curr Opin HIV AIDS.

'T Hoen E F M, 'TRIPS Pharmaceutical Patents and Access to Medicines: Seattle, Doha and Beyond' (2003) 11(8) MSF Access Campaign.

'T Hoen E F M, Kujinga T and Boulet P, 'Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region' (2018) 11(31) Journal of Pharmaceutical Policy and Practice.

'T Hoen E Fm, Veraldi J, Toebes B and Hogerzeil H V,'Medicine procurement and the use of flexibilities in the Agreement on Trade- Related Aspects of Intellectual Property Rights, 2001-2016' (2018) 96(3) Bull World Health Organ.

'T Hoen E, Berger J, Calmy A and Moon S, 'Driving a decade of change: HIV/AIDS, patents and access to medicines for all' (2011) 14(15) Journal of the International AIDS Society.

'T Hoen Ellen F M, Kujinga T and Boulet P, 'Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region' (2018) 11(31) Journal of Pharmaceutical Policy and Practice.

Taillie L S, Busey E, Stoltze F M and Carpentier F R D, 'Governmental policies to reduce unhealthy food marketing to children' (2019) 77 (11) Nutr Rev.

Tenni B, Moir H V J, Townsend B, Killic B, Farrell A M, Keegal T, Gleeson D, 'What is the impact of intellectual property rules on access to medicines? A systematic review' (2022) 18(40) Globalization and Health.

Thakur J S, Garg R, Narain J P and Menabde N, 'Tobacco Use, A major Risk Factor for noncommunicable Diseases in South-East Asia Region' (2011) 55(3) Indian Journal of Public Health.

Thakur J S, Nangia R and Singh S, 'Progress and challenges in achieving noncommunicable diseases targets for the sustainable development goals' (2021) 3(8) FASEB Bioadv.

Thow A M, Downs S M, Mayes C, Trevena H and Waqanivalu J C, 'Fiscal policy to improve diets and prevent noncommunicable diseases: from recommendations to action' (2018) 96(3) Bull World Health Organ.

Tranby E P, Heaton L J, Tomar S L, Kelly A L, Fager G L, Backley M and Frantsve-Hawley J, 'Oral cancer Prevalence, Mortality, and Costs in Medicaid and Commercial Insurance Claims Data' (2022) 31(9) Cancer Epidemiol Biomarkers Prev.

Tsakalidou A, 'The Intricacies of Partly New Inventions: Should We Grant Patentability' (2015) 3 Legal Issues J.

Urias E and Ramani S V, 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' (2020) 3(4) National Library of Medicines.

Urias E, 'The potential synergies between industrial and health policies for access to medicines: insights from the Brazilian policy of universal access to HIV/AIDS treatment' (2019) 9(2) Innovation and Development.

Usher A D, 'South Africa and India push for COVID-19 patents ban' (2020) 396(10265) The Lancet Summit.

Victoria C Onyeagbako, 'Justifications for Copyrights and Patent protections' (2020) ssrn doi: 10.2139/ssrn.3596193.

Vokinger K N, Kesselheim A S, Avorn J and Sarpatwari A, 'Strategies That Delay Market Entry of Generic Drugs' (2017) 177(11) JAMA.

Wagner K H and Brath H, 'A global view on the development of non-communicable diseases' (2012) 54(1) Preventive Medicine.

Wakely J, 'Compulsory licensing under TRIPS: an effective tool to increase access to medicines in developing and least developed countries?' (2011) 33(5) European Intellectual Property Law.

Waxman A, 'WHO global strategy on diet, physical activity and health' (2004) 25(3) Food Nutr. Bull.

Whyatt S B, Winters RN K P and Dubbert P M, 'Overweight and Obesity: Prevelance, Consequences, and Causes of a Growing Public Health Problem' (2006) 33(4) The American Journal of the Medical Sciences.

Witek K, Wydra K and Filip M, 'A High-Sugar Diet Consumption, Metabolism and Health Impacts with a Focus on the Development of Substance Use Disorder: A Narrative Review' (2022) 14(14) Nutrients.

Woessner D W, Lim C S and Deininger M W, 'Development of an effective therapy for chronic myelogenous leukemia' (2011) 17(6) Cancer J.

Wong H, 'The case for compulsory licensing during COVID-19' (2020) 10(1) J Glob Health.

Wouters O J, Shadlen K C, Konrad M S, Pollard A J, Larson H J, Teerawattananon Y and Jit M, 'Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment' 397 (10278) 1023-1034 Health Policy.

Wouters O J and Kanavos P G, 'Transitioning to a national health system in Cyprus: a stakeholder analysis of pharmaceutical policy reform' (2015) 93(9) Bull World Health Organ.

Wu S, Xu W, Guan C, Lv M, Jiang S and Jinhua Z, 'Global burden of cardiovascular disease attributable to metabolic risk factors, 1990-2019: an analysis of observational data from a 2019 Global Burden of Disease study' (2023) 13(5) BMJ Open.

Wu T, Yang F, Lok Chan W W, Kuen Lam C L and Ho Wong C K, 'Healthcare utilization and direct medical cost in the years during and after cancer diagnosis in patients with type 2 diabetes mellitus' (2020) 11(6) Journal of Diabetes Investigation.

Xu C and Zhu D, 'On Conflicts between Pharmaceutical Patent Protection and the Right to Life and Health Based on a Stackelberg Game' (2021) 18(3) Int J Environ Res Public Health.

Yang J S, Mamudu H M and John R, 'Incorporating a structural approach to reducing the burden of non-communicable diseases' (2018) 66 Globalization and Health.

Yanni M K 'Hepatitis C drug affordability' (2015) 3 (2) Global Health.

Yu P K, 'Intellectual Property and Human Rights' (2019) 53(1375) University of Richmond Law Review.

Zakumumpa H, Tumwine C, Milliam K and Spicer N, 'Dispensing antiretrovirals during COVID-19 lockdown: re-discovering community-based ART delivery models in Uganda' (2021) 21(692) BMC Health Services Research.

Zaman K and Islam M R, 'The proposal to the WTO for a new patent waiver on COVID-19 vaccines and pharmaceuticals: is it necessary under TRIPS? (2021) 43(10) European Intellectual Property Review.

Zhu X and Chen Y, 'Bridging the new drug access gap between China and the United States and its related policies' (2024) 14(1296737) Frontiers in Pharmacology.

Zinnah M A, Uddin B, Hasan T, Das S, Khatun F, Hasan H, Udonsom R, Rahman M and Ashour H, 'The Re-Emergence of Mpox: Old Ilness, Modern Challenges' (2024) 12(7) Bomedicines.

# List of Treaties and Statutes (Chronological)

## International

Paris Convention for the Protection of Industrial Property (Signed 20 March 1883, Paris as revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at the Hague on 6 November 1925, at London 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967, and as amended on 28 September 1979) <https://www.wipo.int/treaties/en/ip/paris/> accessed 25 March 2025. (Paris Convention).

Berne Convention for the Protection of Literary and Artistic Works (signed 9 September 1886, entered into force 5 December 1887).

Universal Declaration of Human Rights, GA res. 217A (III), UN Doc A/810 at 71 (1948) (UDHR).

Treaty on the Functioning of the European Union (TFEU) (signed on 25 March 1959).

Vienna Convention on the Law of Treaties (adopted 23 May 1969) 1155 UNTS 331 (VCLT).

WIPO Performances and Phonograms Treaty 1966.

International Covenant on Economic, Social, and Cultural Rights, Adopted by UN General Assembly on 16 December 1966 (ICESCR) (General Assembly Resolution 2200A (XXI), 16 December 1966).

Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (adopted 17 November 1988, entered into force 1999).

Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994) 1869 UNTS 299 (TRIPS).

General Agreement on Tariffs and Trade 1994, Annex 1A: Multilateral Agreements on Trade in Goods of the WTO Agreement (GATT) 1867 UNTS 187.

European Patent Convention 2000 (EPC).

Council of Europe, 'Human rights and health' (Council of Europe, 2025).

## EU

Directive 2004/27/EC of the European Parliament and the Council of 31 March 2994 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

Regulation (EC) No. 469/2009 Concerning the supplementary protection certificate for medicinal products.

Regulation (EC) No. 726/2004 Laying down Community procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicine Agency.

Regulation (EC) No. 816/2006 On compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24EU on health technology assessment.

UK Amendment Regulation 2023 (SI 2023/1287).

## Legislation

### United Kingdom

Patent Act 1977 (as amended).

### Cyprus

Patents Law 16(1)/1998 (as amended).

Patents Law 1998, 16(1) as amended to 2006 (hereinafter PL).

### Other Jurisdictions

Indian Patent Act 1970 (as amended in 2005).

## Case Law

### Cases of the ECtHR

*Passannante* v *Italy* (1998) ECHR (Admissibility Decision) Application no. 32647/96 1st July.

### Court of Justice of the European Union

Judgment of 31 October 1974, *Centrafarm BV and Adriaan De Peijper* v *Winthrop BV*, C-16/74, ECLI:EU:C:1974:115.

Judgment of 13 July 1995, *Spain* v *Council*, C-350/92, ECLI:EU:C:1995:237.

Judgment of 11 July 1996, *Bristol Myers Squibb and Other* v *Paranova*, C-427/93, ECLI:EU:C:1996:282.

Judgment of 11 January 2007, *Aikaterini Stamatelaki* v *NPDD Organismos Asfaliseos Eleftheron Epangelmation (OAEE),* C-444/05, ECLI:EU:2007:24.

Judgment of 28 July 2011, *Synthon BV* v *Merz Pharma GmbH & Co. KGaA,* C-195/09, ECLI:EU:C:2011:518

Judgment of 28 July 2011, *Generics (UK)*, C-427/09, ECLI:EU:C:2011:520.

Judgment of 18 October 2011, *Oliver Brüstle v Greenpeace eV, C-34/10, ECLI:EU:C:2011 1-09821*

*Judgment of 24 November 2011, Medeva, C-322/10, ECLI:EU:C:2011:773.*

*Judgment of 19 July 2012, Neurim Pharmaceuticals (1991), C-130/11, ECLI:EU:C:2012:489.*

Judgment of 12 December 2013, *Actavis Group PTC and Actavis UK*, C-443/12, ECLI:EU:C2013:833.

Judgment of 7 December 2017, *Merck Shar,* C-567/16, ECLI:EU:C:2017:948.

Judgment of 25 July 2018, *Teva UK and Others*, C-121/17, ECLI:EU:C:2018:585.

Judgment of 19 December 2024, *Teva BV and Teva Finland Oy* v *Merck Sharp & Dohme LLC* (Joined cases C-119/22 and C-149/22), ECLI:EU:C:2024:1039.

## EPO case law

*Harvard College* v *European Patent Office* T 0318/97 [2003] OJ EPO 101.

*Abbott Respiratory/Dosage regime* (G 2/08) [2010] OJ EPO 456.

*MEDI-PHYSICS/Treatment* by Surgery G 1/07 [2010] E.P.O.R. 25; (2010) 116 B.M.L.R. 1.

*EISAI/Second medical indication* (G5/83) [1979-85] E.P. O. R. B241.

J0008/20 Board of Appeal, EPO, (Designation of inventor/DABUS) 21-12-2021

J0009/20 Board of Appeal, EPO, (Designation of inventor/DABUS II) 21-12-2021.

MEDI-PHYSICS/Treatment by surgery (G 1/07) [2010] E.P.O.R. 25; (2010) 116 B.M.L.R. 1.

*EISAI/Second medical indication* (G5/83) [1979-85] E.P.O.R. B241.

*Harvard/OncoMouse* [2003] OJ EPO 473 (Opp Div).

*ICI/Pyridine Herbicides* (T-206/83) [1986] E.P.O.R. 232.

T800/01 Carbonless copying paper/Bayer [2003] EPOR 4 (EPO BoA).

## UK Case law

*Hallen Co and Anr* v *Brabantia (UK) Ltd* [1991] RPC 195.

*Boehringer Mannheim GmbH* v *Genzyme Ltd* [1993] FSR 716.

*PLG Research Ltd and Another* v *Ardon International Ltd and Others* [1995] FSR 116.

*Angiotech Pharmaceutical Inc* v *Conor Medsystems Inc* [2007] EWCA Civ 5.

*Generics (UK) Ltd (t/a Mylan)* v *Yeda Research and Development Company* [2017] EWHC 2629 (Pat), [2018] R.P.C (2) 101.

*Biogen* Inc v *Medeva Plc* [1997] RPC 47.

*Actavis UK Ltd* v *Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186.

*Generics (UK)* v H. *Lundbeck* [2009] UKHL 12 [2009] Bus. L.R. 828.

*Human Genome Sciences* v *Eli Lilly & Co* [2011] UKSC 51, [2012] RPC (6) 102.

*Actavis Group PTC* EHF & Anor v *Sanofi* Pharma Bristol-Myers Squibb SNC [2012] EWHC 2545 (Pat), [2013] RPC 24.

*Thaler* v *Comptroller – General of Patents, Designs and Trademarks* [2023] UKSC 49.

*Glaverbel* v *British Coal* [1994] RPC 443; [1995] RPC 255 (CA); CIPA, [2.03].

*Synthon* v *SmithKline Beecham* [2005] UKHL 59; [2006] 1 All ER 685; [2006] RPC 10; (2005) 86 BMLR 130.

*Synthon BV* v *SmithKline Beecham Plc (No.2) [2003] EWCA Civ 861.*

*Generics (UK) Ltd* v *Daiichi Pharmaceutical Co Ltd* [2009] UKHL 12; [2009] RPC 13.

*Asahi Kasei Kogyo KK's Application* [1991] RPC 485.

*Eli Lilly* v *Janssen Alzheimer Immunotherapy* [2013] EWHC 1737 (Pat), [2014] RPC 1.

*Biogen Inc* v *Medeva plc* [1997] RPC 1, [1996] UKHL 18, (1997) 38 BMLR 149.

*Teva UK Ltd & Ors* v *AstraZeneca AB* [2012] EWHC 655 (Pat).

*Bayer* Healthcare LLC v *Teva* Pharmaceutical Industries Ltd & Anor [2021] EWHC 2690 (Pat).

*Hallen Co and Another* v *Brabantia (UK) Ltd* [1991] RPC 195 (CA).

*Hoechst Celanese* v *BP Chemicals Ltd* [1997] FSR 547

*Lux Traffic Controls* v *Pike Signals* [1993] RPC 107.

*Windsurfing International Inc.* v *Tabur Marine (Great Britain) Ltd* [1985] RPC 59.

*Lux Traffic Controls Limited* v *Pike Signals Ltd* [1993] RPC 107.

*Pozzoli SpA* v *BDMO SA* [2007] FSR 37

*Société Technique de Pulverisation (STEP)* v *Emson* [1993] RPC 513.

*Richardson- Vicks Inc's Patent* also known as *Reckitt & Colman Products Ltd* v *Richardson-Vicks Inc* [1995] RPC 568.

*Sandoz* v *Bristol Myers Squibb* [2023] EWCA Civ 472.

*Eli Lilly and Company* v *Human Genome Sciences Inc* [2008] RPC 29

*Human Genome Sciences Inc.* v *Eli Lilly and Company* [2011] UKSC 51.

*Bayer* Pharma AG v *Teva UK Ltd & Anor* [2021] EWHC 2690 (Pat).

*Actavis Group PTC EHF and others* v *ICOS Corp* [2017] EWCA Civ 1671; (2018) 159 B.M.L.R. 108.

*SmithKline French Laboratories Ltd* v *Evans Medica Ltd* [1989] FSR 513.

*McDonald* v *Graham* [1994] RPC 407.

*Regeneron Pharmaceuticals* v *Kymab* [2020] UKSC 27, [2020] RPC (22) 900.

*Kirin-Amgen Inc* v *Hoechst Marion Roussel Ltd* [2004] UKHL, 46; [2005] RPC 9

*Actavis UK Limited & Ors* v *Eli Lilly & Company* [2015] EWCA Civ 555.

*Actavis Group PTC* v *Sanofi* [2012] EWHC 2545 (Pat).

*Improver Corporation* v *Remington Consumer Products Ltd* [1990] FSR 181

*Catnic Components Ltd* v *Hill & Smith Ltd* [1982] RPC 183.

*Actavis UK Ltd* v *Eli Lilly & Co* [2017] UKSC 48, [2017] RPC (21) 957.

*John Wyeth & Brother Ltd's Application* [1985] RPC 545.

*Generics (UK) Ltd (t/a Mylan)* v *Warner- Lambert* [2015] EWHC 2548 (Pat), [2016] RPC 1.

*Griffiths Andrew, Windsurfing* and Inventive Step [1999] IPQ 160.

*Monsanto Co* v *Stauffer Chemical Co* (1985) RPC 515.

## WTO Dispute Settlement

### Panel Reports

*Canada – Patent Protection of Pharmaceutical Products (7 April 2000) WT/DS114/R < https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed 4 March 2025 (Canada-Pharmaceutical Patents).*

## REPORTS

Amendment Regulation 2023 (SI 2023/1287) Statutory Instruments, 'The Intellectual Property (Exhaustion of Rights) (Amendment) Regulations 2023. Available: https://wipolex-resources-eu-central-1-358922420655.s3.amazonaws.com/edocs/lexdocs/laws/en/gb/gb594en_1.pdf

Chartered Institute of Environmental Health, 'Call for Evidence: Roles and Responsibilities for Heath Protection in England' (*Chartered Institute of Environmental Health* 2024). Available: https://www.cieh.org/media/ohndni3n/cieh-submission-to-ukhsa-call-for-evidence-on-the-future-of-the-health-protection-system-fhps.pdf

Dele Abegunde, 'Essential Medicines for Non-Communicable Diseases (NCDs)' (*World Health Organization* 2006). Available: https://www.iccp-portal.org/system/files/resources/UNHLM-2011_WHO-EssentialMedicinesforNCDs.pdf

Duncan Matthews and Carlos Correa, 'The Doha Declaration Ten Years on and its Impact on Access to Medicines and the Right to Health' (United Nations Development Programme 2011). Available: https://qmro.qmul.ac.uk/xmlui/bitstream/handle/123456789/3109/MATTHEWSTheDohaDeclaration2011FINAL.pdf?sequence=2
Ellen 't Hoen, 'Private Patents and Public Health' (*Health Action International* 2016). Available: https://haiweb.org/wp-content/uploads/2016/07/Private-Patents-Public-Health.pdf

Ellen F M 't Hoen, 'The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation, and the Application of the WTO Doha Declaration on TRIPS and Public Health' (*AMB* 2009). Available: https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf

European Chronic Disease Alliance *et al.,* 'Towards an EU Strategic Framework for the Prevention of Non-communicable Diseases (NCDs)' (*European Public Health Alliance* 2019). Available: https://easl.eu/wp-content/uploads/2019/05/Final-NCD-Paper-full-version.pdf

European Commission, 'Commission Implementing Decision -Annex 1' (*European Commission* 2022). Available: https://ec.europa.eu/assets/sante/health/funding/wp2022_en.pdf

European Commission, 'Health at a Glance: Europe 2022: State of Health in the EU cycle' (*European Union* 2022). Available: https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/12/health-at-a-glance-europe-2022_b73a1698/507433b0-en.pdf

European Commission, 'Healthier Together: EU Non-Communicable Diseases Initiative' (*European Commission* 2022). Available: https://health.ec.europa.eu/system/files/2022-06/eu-ncd-initiative_publication_en_0.pdf

European Commission, 'Pharmaceutical Strategy for Europe' (*Pharmaceutical Strategy for Europe* 2020). Available: https://health.ec.europa.eu/document/download/92714c9c-6880-4708-b649-287ee9e86670_en

European Court of Human Rights Court, 'Guide on Article 2 of the European Convention on Human Rights' (*European Court of Human Rights* 2024). Available: https://ks.echr.coe.int/documents/d/echr-ks/guide_art_2_eng

European Court of Human Rights, 'European Convention on Human Rights' (2022). Available: https://www.echr.coe.int/documents/d/echr/convention_ENG

European Parliament, 'Revision of the Supplementary Protection Certificate Regulations for medicinal and plant protection products' (*European Union* 2023). Available: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/740258/EPRS_BRI(2023)740258_EN.pdf

European Parliament, 'The Unified Patent Court after Brexit' (*European Union* 2020). Available: https://www.europarl.europa.eu/RegData/etudes/ATAG/2020/649575/IPOL_ATA(2020)649575_EN.pdf

European Parliament, 'The Unified Patent Court after Brexit' (*European Union* 2020). Available: https://www.europarl.europa.eu/RegData/etudes/ATAG/2020/649575/IPOL_ATA(2020)649575_EN.pdf

European Patent Convention, 'Convention on the Grant of European Patents' (*European Patent Convention* 2024). Available: https://www.epo.org/en/legal/epc/2020/EPC_conv_20240401_en_20240401.pdf

European Patent Office, 'Notice from the European Patent Office dated 20 September 2007 on implementation of the transitional provisions of the EPC 2000 applicable during the transition from the EPC 1973 to the EPC 2000' Official Journal EPO 10/2007. Available: https://www.epo.org/xx/legal/official-journal/2007/10/p504/2007-p504.pdf

HM Government, 'National Risk Register' (*HM Government* 2023). Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1175834/2023_NATIONAL_RISK_REGISTER_NRR.pdf

House of Commons Library, 'Work for the Council of Europe' (*Work for the Council of Europe* 2023). Available: https://researchbriefings.files.parliament.uk/documents/CDP-2023-0119/CDP-2023-0119.pdf

Huseyin Nac, 'Pharmaceutical Policy in the UK' (*The Health Foundation* 2023). Available: https://www.health.org.uk/sites/default/files/2023-03/report_3_pharmaceutical_policy_in_the_uk_final.pdf

Katharine Stephens, 'Brexit Exhaustion of Intellectual Property Law' (*Bird & Bird* 2021). Available: https://www.twobirds.com/en/insights/2019/uk/exhaustion-of-intellectual-property-rights-post-brexit

Kevin J Hickey and Erin H Ward, 'The Role of Patents and Regulatory Exclusivities in Drug Pricing' (2024) (*Congressional Research Service*). Available: https://www.congress.gov/crs-product/R46679

Maria Kyriacou and Ramona Livera, 'Patents and Trademarks' (*Arnold & Siedsma* 2016). Available: https://www.neocleous.com/publications/download/manual-of-industrial-property.pdf

Office of the United Nations High Commissioner for Human Rights, 'The Right to Health' (*Office of the United Nations High Commissioner for Human Rights* 2008). Available: https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf

Ove Granstrand and Frank Tietze, 'IP strategies and policies for and against evergreening' (*Centre for Technology Management working paper series* No. 1 2015). Available: https://www.ifm.eng.cam.ac.uk/uploads/Research/CTM/working_paper/2015_01_Granstrand_Tietze.pdf

Rule 27 Patentable biotechnological inventions EPC 2000. European Patent Office 'Examination in the field of biotechnology at the EPO – PART I'. Available: https://www.wipo.int/edocs/mdocs/pct/en/wipo_ip_mnl_19/wipo_ip_mnl_19_t8.pdf

Sarah Galbraith-Emami, 'Public Health Law and Non-communicable Diseases' (*UK Health Forum* 2013) 5. Available: https://www.rsph.org.uk/static/uploaded/18165127-73a3-4c7a-8eb01fd5b791e5b1.pdf

Scott L Greer, *et al.,* 'Everything you always wanted to know about European Union heath policies but were afraid to ask' (*Health Policy Series* 2019). Available: https://www.ncbi.nlm.nih.gov/books/NBK551086/pdf/Bookshelf_NBK551086.pdf

World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (2023) CDIP/30/14. Available: Available: https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_30/cdip_30_14.pdf

Sixty-Sixth World Health Assembly, 'Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases' (*World Health Organization* 2013) WHA66.10. Available: https://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R10-en.pdf?ua=1

Stephen Ezell and Nigel Cory, 'The way forward for Intellectual Property Internationally' (*Information Technology & Innovation Foundation* 2019). Available: https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally/

United Nations, 'Vienna Convention on the Law of Treaties 1969' (2005) 1155 United Nations, Treaty Series. Available: https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf

Universal Declaration of Human Rights Adopted and proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948, G.A. Res217A (III) 3 U.N. GAOR (Resolutions, part 1) at 71, U.N. Doc. A/810 (1948). Available: https://www.ohchr.org/en/resources/educators/human-rights-education-training/universal-declaration-human-rights-1948

Varsha Venkatesh, 'Exclusions of Methods of Medical Treatment from Patentability: A Global Perspective' (2021) 14 Acclaims. Available: http://www.penacclaims.com/wp-content/uploads/2021/02/Varsha-Venkatesh.pdf

WIPO, 'Intellectual property offices and sustainable innovation, Implementing the SDGs in national intellectual property systems' (*WIPO* 2023). Available: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-10-en-intellectual-property-offices-and-sustainable-innovation.pdf

World Health Organization and United Nations Development Programme, 'What Legislators Need to Know' (*World Health Organization* 2018). Available: https://iris.who.int/bitstream/handle/10665/272640/WHO-NMH-NMA-18.96-eng.pdf?sequence=1

World Health Organization, 'Global action plan for the prevention and control of noncommunicable diseases 2013-2020' (*World Health Organization* 2013). Available: https://iris.who.int/bitstream/handle/10665/94384/9789241506236_eng.pdf?sequence=1

World Health Organization, 'Promote Health Keep the World Save the Vulnerable' (*World Health Organization* 2019) WHO/PRP/18.1. Available: https://iris.who.int/bitstream/handle/10665/324775/WHO-PRP-18.1-eng.pdf

World Health Organization, 'The Right to Health' (*Office of the United Nations High Commissioner for Human Rights* 2008). Available: https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf

World Health Organization, 'WHO European Regional Obesity Report 2022' (*World Health Organization* 2022). Available: https://iris.who.int/bitstream/handle/10665/353747/9789289057738-eng.pdf?sequence=1

World Health Organization, WHO Model List of Essential Medicines -23rd list, 2023-Web Annex A' (*World Health Organization* 2023). Available: https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1

World Intellectual Property Organization, 'Committee on Development and Intellectual Property (CDIP)' (2023) CDIP/30/14. Available: https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_30/cdip_30_14.pdf

World Intellectual Property Organization, 'Protecting your inventions abroad: Frequently asked questions about the Patent Cooperation Treaty (PCT) (*WIPO Publication* No. 433E, April 2006). Available: https://innovation.ox.ac.uk/wp-content/uploads/2019/05/faqs_about_the_pct1.pdf

World Obesity, 'Cyprus: Policies, Interventions and Actions' (*World Obesity* 2025). Available: https://data.worldobesity.org/country/cyprus-53/actions.pdf?utm_source=chatgpt.com

## WEBPAGES (All the webpages were checked on 25 March 2025)

The Commonwealth, 'Strengthening health policies and systems' (*The Commonwealth* 2025) <https://thecommonwealth.org/strengthening-health-policies-and-systems>accessed 25 March 2025.

World Health Organization, 'TB cases and deaths linked to HIV now at alarming levels in Africa' (*World Health Organization* 2025) <https://www.who.int/news/item/22-03-2005-tb-cases-and-deaths-linked-to-hiv-now-at-alarming-levels-in-africa>accessed 25 March 2025.

World Health Organization, 'Obesity' (*World Health Organization* 2025) <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3420#:~:text=Rationale%3A,caused%20by%20overweight%20or%20obesity>accessed 25 March 2025.

BBC News, 'Obesity: Study of 2.8 million shows increased disease and death risks' (*BBC* 2019) <https://www.bbc.co.uk/news/health-48088391>accessed 25 March 2025.

Gov.uk, 'Junk food ad ban legislation progresses to curb childhood obesity' (*Gov.uk* 2024) <https://www.gov.uk/government/news/junk-food-ad-ban-legislation-progresses-to-curb-childhood-obesity#:~:text=Children%20will%20no%20longer%20be,plans%20to%20curb%20childhood%20obesity>accessed 25 March 2025.

BBC News, 'Ban on junk food TV adverts before 9pm to come in next year' (*BBC* 2024) < https://www.bbc.co.uk/news/articles/cx2n2g5wze4o>accessed 25 March 2025.

World Health Organization, 'Who we are' <https://www.who.int/about/who-we-are> accessed 25 March 2025.

World Health Organization, 'World Health Assembly'(*World Health Organization* 2025) <https://www.who.int/about/governance/world-health-assembly#:~:text=The%20World%20Health%20Assembly%20is,prepared%20by%20the%20Executive%20Board>accessed 25 March 2025.

World Health Organization, 'Commemorating Smallpox Eradication- a legacy of hope for COVID-19 and other diseases' (*World Health Organization* 2025) <https://www.who.int/news/item/08-05-2020-commemorating-smallpox-eradication-a-legacy-of-hope-for-covid-19-and-other-diseases>accessed 25 March 2025.

World Health Organization, 'Working together for equity and healthier populations; Sustainable multisectoral collaboration based on Health in All Policies approaches' (*World Health Organization* 2023) <https://iris.who.int/bitstream/handle/10665/372714/9789240067530-eng.pdf>accessed 25 March 2025.

World Health Organization, 'What we do' <https://www.who.int/about/what-we-do#:~:text=WHO%20works%20worldwide%20to%20promote,better%20health%20and%20well%2Dbeing>accessed 25 March 2025.

World Health Organization, 'Universal health coverage (UHC), (*World Health Organization* 2023) <https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)>accessed 25 March 2025.

World Health Organization, Sustainable Development Goals' (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals>accessed 25 March 2025.

World Health Organization, 'Transforming our world: the 2030 Agenda for Sustainable Development' <https://sdgs.un.org/2030agenda>accessed 25 March 2025.

World Health Organization, 'Updated Appendix 3 of the WHO Global NCD Action Plan 2013-2030' (*World Health Organization* 2022) <https://cdn.who.int/media/docs/default-source/ncds/mnd/2022-app3-technical-annex-v26jan2023.pdf>accessed 25 March 2025.

World Health Organization, 'Implementation roadman 2023-2030 for the Global action plan for the prevention and control of NCDs 2013-2030' (*World Health Organization* 2025) <https://www.who.int/teams/noncommunicable-diseases/governance/roadmap>accessed 25 March 2025.

European Union, 'Global' <https://health.ec.europa.eu/internationalcooperation/global-health_en>accessed 25 March 2025.

European Council, 'EU health policy' <https://www.consilium.europa.eu/en/policies/eu-health-policy/>accessed 25 March 2025.

European Parliament, 'Report on non-communicable diseases (NCDs)' (*European Parliament* 2023) <https://www.europarl.europa.eu/doceo/document/A-9-2023-0366_EN.html>accessed 25 March 2025.

European Parliament, 'Public Health' (*Fact Sheets on the European Union* 2024) <https://www.europarl.europa.eu/erpl-app-public/factsheets/pdf/en/FTU_2.2.4.pdf>accessed 25 March 2025.

European Commission, 'EU Action on Antimicrobial Resistance' <https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en>accessed 25 March 2025.

European Commission, 'EU4Health programme 2021-2027- a vision for a healthier European Union' <https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en>accessed 25 March 2025.

European Commission, 'Health promotion' <https://health.ec.europa.eu/other-pages/basic-page/health-promotion_en#:~:text=The%20EU%20is%20required%20to,ensuring%20good%20health%20and%20healthcare>accessed 25 March 2025.

European Commission, 'Health monitoring programme' <https://health.ec.europa.eu/other-pages/basic-page/health-monitoring-programme_en>accessed 25 March 2025.

European Commission, 'Speech by Andriukaitis at the Plenary Session of the United Nations General Assembly High-Level Meeting on the Prevention & Control of Non-Communicable Diseases' (*European Commission* 2018) <https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_18_5929>accessed 25 March 2025.

ESC, 'A new European Heart Health Charter for a new Europe' (*European Society of Cardiology* 2023) <https://www.escardio.org/The-ESC/Press-Office/Press-releases/a-new-european-heart-health-charter-for-a-new-europe>accessed 25 March 2025.

European Commission, 'ECIS - European Cancer Information System' <https://ecis.jrc.ec.europa.eu>accessed 25 March 2025.

European Commission, 'International organizations' (*European Commission*) <https://health.ec.europa.eu/internationalcooperation/international-organisations_en>accessed 25 March 2025.

WIPO, 'WHO, WIPO, WTO Trilateral Cooperation on Public Health, IP and Trade' <https://www.wipo.int/web/global-health/trilateral_cooperation#:~:text=The%20World%20Health%20Organization%20(WHO,property%20(IP)%20and%20trade>accessed 25 March 2025.

World Health Organization, 'Trilateral cooperation on intellectual property and public health' (*World Heath Organization* 2025) <https://www.who.int/teams/health-product-policy-and-standards/medicines-selection-ip-and-affordability/cooperation>accessed 25 March 2025.

United Nations, 'Universal Declaration of Human Rights' (*United Nations* 2023) <https://www.un.org/en/about-us/universal-declaration-of-human-rights>accessed 25 March 2025.

Local Governments for Sustainability, ‘From MDGs to SDGs: What are the Sustainable Development Goals?’ (*Local Governments for Sustainability* 2015) <https://www.local2030.org/library/251/From-MDGs-to-SDGs-What-are-the-Sustainable-Development-Goals.pdf>accessed 25 March 2025.

Sustainable Development Goals Fund, ‘Millennium Development Goals’ (*Sustainable Development Goals Fund*) <https://www.sdgfund.org/mdgs-sdgs>accessed 25 March 2025.

World Health Organization, ‘Sustainable Development Goals’ (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals>accessed 25 March 2025.

World Health Organization, ‘Millennium Development Goals (MDGs)’ (*World Health Organization* 2018) <https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals-(mdgs)>accessed 25 March 2025.

Sustainable Development Goals, Target 3.b. Development assistance and vaccine coverage: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases < https://www.who.int/data/gho/data/themes/topics/indicator-groups/indicator-group-details/GHO/sdg-target-3.b-development-assistance-and-vaccine-coverage>accessed 25 March 2025.

NCD Alliance, ‘NCDs and the Millennium Development Goals’ (*The NCD Alliance* 2017) <https://ncdalliance.org/ncds-and-the-millennium-development-goals#:~:text=Home%20%2F%20NCD%20Facts%20%2F%20NCDs%20and%20the%20Millennium%20Development%20Goals&text=As%20a%20result%2C%20three%20of,malaria%2C%20and%20other%20diseases>accessed 25 March 2025.

Sightsavers, ‘What are the Sustainable Development Goals?’ (*Sightsavers* 2025) <https://www.sightsavers.org/policy-and-advocacy/global-goals/?gclid=Cj0KCQjw6sHzBRCbARIsAF8FMpVevntGJnxGZSf2PvRC3aeolmuqHwLUrijeFE_xm9jEn6VcxksUAykaAvA-EALw_wcB>accessed 25 March 2025.

World Health Organization, ‘Targets of Sustainable and Development Goal 3’ (*World Health Organization* 2025) <https://www.who.int/europe/about-us/our-work/sustainable-development-goals/targets-of-sustainable-development-goal-3>accessed 25 March 2025.

United Nations, ‘SDG 10: Reduced Inequalities’ (United Nations) <https://sdgs.un.org/goals/goal10>accessed 25 March 2025.

SDG Goals, ‘Goal 17: Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development’ (*United Nations* 2025) < https://unstats.un.org/sdgs/report/2017/goal-17/>accessed 25 March 2025.

WIPO, ‘The Impact of Innovation, WIPO and the Sustainable Development Goals’ <https://www.wipo.int/sdgs/en/story.html>accessed 25 March 2025.

SDG Knowledge Hub, ‘WIPO illustrates How Innovation, Intellectual Property Can Support SDGs’ (October, 2018) < https://sdg.iisd.org/news/wipo-illustrates-how-innovation-intellectual-property-can-support-sdgs/>accessed 25 March 2025.

World Health Organization, ‘Essential noncommunicable disease medicines and basic technologies to treat major noncommunicable diseases’ (*World Health Organization* 2025) <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3421>accessed 25 March 2025.

World Health Organization, ‘Essential medicines’ (*World Health Organization* 2024) <https://www.who.int/news-room/fact-sheets/detail/essential-medicines>accessed 25 March 2025.

World Health Organization, ‘WHO endorses landmark public health decisions on Essential Medicines for Multiple Sclerosis’ (*World Health Organization* 2023) <https://www.who.int/news/item/26-07-2023-who-endorses-landmark-public-health-decisions-on-essential-medicines-for-multiple-sclerosis>accessed 25 March 2025.

European Patent Office (EPO) ‘The EPO provides high-quality patents and efficient services that foster innovation, competitiveness and economic growth’ <https://www.epo.org/en>accessed 25 March 2025.

Unified Patent Court, ‘About the Unified Patent Court’ (*Unified Patent Court* 2025) <https://www.unified-patent-court.org/en>accessed 25 March 2025.

European Commission, ‘Supplementary protection certificates for pharmaceutical and plant protection products’ <https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en>accessed 25 March 2025.

Unified Patent Court, ‘UPC Member States’ (Unified Patent Court 2025) (*Unified Patent Court* 2025) <https://www.unified-patent-court.org/en/organisation/upc-member-states>accessed 25 March 2025.

WIPO, ‘About WIPO’ <https://www.wipo.int/about-wipo/en/>accessed 25 March 2025.

WIPO, ‘Patent Cooperation Treaty (PCT)’ <https://www.wipo.int/treaties/en/registration/pct/>accessed 25 March 2025.

WIPO, ‘The PCT now has 158 Contracting States’ <https://www.wipo.int/pct/en/pct_contracting_states.html>accessed 25 March 2025.

European Patent Office, ‘Legal foundations’ <https://www.epo.org/en/about-us/foundation/legal-foundations>accessed 25 March 2025.

European Patent Office, ‘European Patent Convention’ <https://www.epo.org/en/legal/epc>accessed 25 March 2025.

Unified Patent Court, ‘UPC Member States’ (*Unified Patent Court* 2025) <https://www.unified-patent-court.org/en/organisation/upc-member-states>accessed 25 March 2025.

Unified Patent Court, ‘A single patent court for Member States of the European Union’ (*Unified Patent Court* 2025)<https://www.unified-patent-court.org/en/news/unified-patent-court-opens-its-doors>accessed 25 March 2025.

Fernando Cerdà Belda, ‘EPO rules only humans can be inventors- another blow to the DABUS patents’ (*Clifford Chance* 2022) <https://www.cliffordchance.com/insights/resources/blogs/talking-

tech/en/articles/2022/03/epo-rules-only-humans-can-be-inventors-another-blow-to-dabus-a.html>accessed 25 March 2025.

European Commission, 'European Economic Area (EEA) Agreement' <https://trade.ec.europa.eu/access-to-markets/en/content/european-economic-area-eea-agreement#:~:text=The%20European%20Economic%20Area%20(EEA,%2C%20economic%20and%20monetary%20cooperation)>accessed 25 March 2025.

Morrison and Foerster, 'UK Expands Export Controls to Semiconductor and Other Emerging Technologies' (*Morrison and Foerster* 2024) <https://www.mofo.com/resources/insights/240314-uk-expands-export-controls-to-semiconductor>accessed 25 March 2025.

WIPO, 'Summary of the Paris Convention for the Protection of Industrial Property (1883)' <https://www.wipo.int/treaties/en/ip/paris/summary_paris.html>accessed 25 March 2025.