Balancing Patent Rights and Public Health: The Case for Compulsory Licensing against 'excessive' pricing in the Netherlands

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List of Abbreviations

AAAQ	Availability, Accessibility, Acceptability, and Quality
ACM	Authority for Consumers and Markets
CBG	Medicines Evaluation Board
CESCR	Committee on Economic, Social and Cultural Rights
DPA	Dutch Patent Act
EC	European Commission
EMA	European Medicines Agency
EU	European Union
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual Property
R&D	Research and Development
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
VWS	Ministry of Health, Welfare and Sport
WHO	World Health Organisation
WTO	World Trade Organisation

List of Legislation

International Instruments and Soft Law
International Covenant on Economic, Social and Cultural Rights
Trade-Related Aspects of Intellectual Property Rights Agreement (WTO)
Doha Declaration on the TRIPS Agreement and Public Health (2001)
General Comment No. 3
General Comment No. 14
General Comment No. 20

European Union Law
Treaty on European Union (TEU)
Treaty on the Functioning of the European Union (TFEU)
Directive 2001/83/EC
Regulation (EC) No 726/2004
Regulation (EC) No 816/2006
Regulation (EU) No 1257/2012

Dutch National Law
Dutch Constitution (Grondwet)
Dutch Patent Act (Rijksoctrooiwet 1995)
Dutch Competition Act (Mededingingswet)
Dutch Medicines Act (Geneesmiddelenwet)
Dutch Medicine Prices Act (Wet Geneesmiddelenprijzen)
Dutch Health insurance Act (Zorgverzekeringswet)
Health Insurance Regulation (Regeling Zorgverzekeringwet)

Chapter 1: Introductory Chapter

1.1 Introduction

In the Netherlands, the rising costs of specialised medical care are largely driven by the continually increasing expenditures on expensive medicines.[1]As a result, less funding is available for other types of specialised care.[2] When healthcare funds allocated to 'high' priced medicines, they cannot be spent on other healthcare services, endangering the provision of high-quality care and undermining the internationally recognised human right to health.[3] Exorbitant or extremely high medicine pricing may not only (either) place new medicine out-of-reach for reimbursement, but may also cause displacement of other forms of healthcare.[4] Hence, such 'excessive' prices, either in terms of affordability or based on competition law principles, jeopardise access to medicines and put pressure on hospital budgets and the overall Dutch healthcare system.[5] Finding a solution to this complex problem is not straightforward considering that the sector's governance is subject to the interplay of various regimes, hence requires strong political determination.[6]

Pharmaceutical companies play a significant role in public health by researching and developing (R&D) new medicines to prevent, treat or cure existing and new diseases. As such, forming an essential actor controlling accessibility of medicines, arguably carrying a societal responsibility due to their impact on health and well-being.[7] This underscores both, the power they wield in ensuring the right to health and raises questions about their responsibility to support governments in realising it.[8] This dependency may become problematic, given that *inter alia* pharmaceutical companies are not subject to the same legally embedded 'duty of care' as the government or other healthcare providers, which may hinder socially acceptable pricing.[9]

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[1] Rijksinstituut voor Volksgezondheid en Milieu (RIVM), 'Verdiepingen Zorguitgaven' (Volksgezondheid Toekomst Verkenning 2018) https://www.vtv2018.nl/verdieping-zorguitgaven accessed 27 May 2025.
[2] Nederlandse Zorgautoriteit, *Stand van de zorg 2024* (8 October 2024) https://www.nza.nl/onderwerpen/stand-van-de-zorg-2024 accessed 27 May 2025, 29.
[3] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant) (2000) E/C.12/2000/4.
[4] Werner Brouwer, Pieter van Baal and Matthijs Verstreegh, 'When is it too expensive? Cost-Effectiveness threshold and health care decision-making' [2018] 20(1) 175, 175-180; Krista Ohlk, et. al, 'Access to Medicines and Human Rights' (2017) *Health and Human Rights* 8.
[5]Algemene Rekenkamer, 'Hogere kortingen op dure medicijnen nodig om verdringing in de zorg te voorkomen' (23 April 2020) https://www.rekenkamer.nl/actueel/nieuws/2020/04/23/hogere-kortingen-op-dure-medicijnen-nodig-om-verdringing-in-de-zorg-te-voorkomen accessed 27 May 2025, K. Perehudoff, B. Toebes & H. Hogerzeil, 'A Human Rights-Based Approach to the Reimbursement of Expensive Medicines', *Bulletin of the World Health Organization* (2016) 1(94), 935-93; L. N. niëns nd W.B.F. Brouwer, 'Measuring the affordability of medicines: Importance and challegenges' [2013] 112(1) *Health Policy* 45, 46.
[6]André den Exter, 'Extreem dure medicijnen verdringen andere vormen van zorg' *Trouw* (24 October 2022) https://www.trouw.nl/opinie/extreem-dure-medicijnen-verdringen-andere-vormen-van-zorg~b98d6095 accessed 27 May 2025; Trudo Lemmens, et al. 'The social contract and human rights bases for promoting access to effective, novel, high-priced medicines- Oslo Medicines Initiative technical Report' (2020) *World Health Organization*
[7] Frans van den Houdt, 'Hoogleraar Carin Uyl-de Groot strijdt tégen hoge prijzen en vóór snellere toegang: Het is onethisch dat een goed middle er niet is voor patiënten' [2019] 154(35)*Pharmaceutisch Weekblad* 9, 9-10; J Ruggie, 'Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)' (2010) 7(9) *PLOS Medicine*; Brigit Toebes, 'The right to health and the privatization of national health systems' [2006] 9(1) *Health and Human Rights* 102, 108; Rosalind Turkie, 'Upholding Human Rights in the Wake of COVID-19: Time to Strengthen Pharmaceutical Accountability' [2022] 24(2) *Health and Human Rights* 205, 205.
[8] R. Turkie, 'Upholding Human Rights in the Wake of COVID-19: Time to Strengthen Pharmaceutical Accountability', *Human Rights and Health Journal* (2022) 2(24), p. 205, 208.
[9] Erasmus University Rotterdam, 'Payback-systeem zorgt voor evenwicht tijdens sluisperiode' (Erasmus University Rotterdam 2024) h https://www.eur.nl/eshpm/nieuws/payback-systeem-zorgt-voor-evenwicht-tijdens-sluisperiode accessed 27 May 2025.

While the regulatory framework governing this sector seeks to strike a balance between competing objectives: offering incentives to innovate and controlling prices to ensure access to medicines; this intricate system, designed to serve both public and private interests, leaves room for strategic exploitation by companies seeking to maximise profits.[10]

Pharmaceutical companies may set medicine prices as they please and are not obliged to be transparent about their pricing, making the industry commercially attractive.[11] Nevertheless, when questioned about their 'high' prices, pharmaceutical companies point to recouping the costly research and substantial investments needed to successfully develop a medicine.[12] They argue that increased pressure on prices reduces incentives to innovate, ultimately harming patients.[13] However, no substantive evidence supporting that claim exists; and importantly, there seems to be a certain discrepancy between R&D costs and the prices.[14] In fact, research has shown that there is no explainable relationship between the price level and R&D costs, suggesting pricing is constructed mainly serving revenue maximisation.[15] *(This tension is further analysed throughout Chapter 3, 4 and 5.)*

Besides this lack of transparency, high prices are explained by the absence of 'typical' market competition. When a pharmaceutical company develops a (new) medicine of which no therapeutic equivalent is available, it applies for a patent, encouraging a *de facto* monopoly, allowing it to freely set prices without competitive restrictions.[16] The Dutch pharmaceutical market is therefore not entirely comparable to a conventional free market. Not only does the Dutch Minister of Health, Welfare, and Sport generally decide which 'extramural' medicines are included in the basic healthcare package; prescribing, procurement and declaration of

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[10] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies- Should competiton law intervene? [2020] 51(1) *ICC Int Rev Ind Prop Copyr Law* 1062, 1065; Marcel Canoy, Jotte Mulder and Wolf Sauter, 'Introduction' in Wolf Sauter, Marcel Canoy and Jotte Mulder (eds), *EU Competition law and pharmaceuticals* (Edward Elgar Publishing Ltd 2022) 6; Claudio Calcano, Antoine Chapsal and Joshua White, 'Economics of 'excessive' Pricing: An Application to the Pharmaceutical Industry' [2019] 10(3) *Journal of European Competition Law and Practice* 166,171.

[11] Robert van den Broek, 'Peperdure medicijnen zijn het resultaat van een verstoord machtsevenwicht' (2021) *Zorginstituut magazine* 1, 19-20; Nora Franzenet al, 'Affordable prices without threatening the oncological R&D pipeline- An economic experiment on transparency', [2022] 2(1) *Cancer Research Communications* 49, 49; Jan-Koen Sluijs and Brigit Toebes, 'Mensenrechten verplichten farmabedrijf transparant te zijn over prijzen' (*Financieele Dagblad*, 11 April 2018) https://fd.nl/opinie/1249287/mensenrechten-verplichten-farmabedrijf-transparant-te-zijn-over-prijzen accessed 27 May 2025.

[12] Nora Franzen et al, 'Improving the Affordability of Anticancer Medicines Demands Evidence-Based Policy Solutions' (2022) 12(2) Cancer Discovery 299, 299-300; Pierluigi Russo, et al, 'Medicine price transparency and confidential managed-entry agreements in Europe: finding from the EURIPID survey' [2021] 125(1) *Health Policy* 1140, 1141.

[13] 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) *Journal of market Access and Health Policy* 1,1; André de Jong, 'Persoonlijke beschouwing over de inzet van de dwanglicenties bij hoge prijzen van medicijnen' (Algemene Bestuursdienst, Ministerie van Buitenlandse Zaken en Koninkrijksrelaties, 2020) 7.

[14] Aylin Sertkaya, 'Costs of drug development and research and development intestity in the US, 2000-2018' [2024] 7(6) *JAMA Network Open* 1,3 Henk Maassen, 'Betaalt de samenleving nog steeds twee keer voor nieuwe geneesmiddelen?' (*Medisch Contact*, 22 February 2023) https://www.medischcontact.nl/actueel/laatste-nieuws/nieuwsartikel/betaalt-de-samenleving-nog-steeds-twee-keer-voor-nieuwe-geneesmiddelen accessed 27 May 2025; Nora Franzen et al, 'Affordable prices without threatening the oncological R&D pipeline- An economic experiment on transparency', [2022] 2(1) *Cancer Research Communications* 49, 49.

[15] Els Torreele, 'Why are our medicine so expensive? Spoiler: Not for the reasons you are being told' [2024] 30(1) *European Journal of General Practice* 1,4; Nora Franzen, e.a., 'Affordable Prices Without Threatening the Oncological R&D Pipeline- An Economic Experiment on Transparency in Price Negotiations', *American Association for Cancer Research* (2022) 1(2), p. 49; https://www.bergjournalistiek.nl/de-marges-op-medicijnen-zijn-gigantisch/

[16] Pieter van Megchelen, 'Vaststellen van een eerlijke prijs is het begin van een gesprek over betaalbare geneesmiddelen' (27 April 2020) *Medisch* Oncologie https://medischeoncologie.nl/artikelen/2020/april/editie-3/vaststellen-van-een-eerlijke-prijs-is-het-begin-van-een-gesprek-over-betaalbare-geneesmiddelen accessed 27 May 2025 ; Irene van den Berg, 'De marges op (nieuwe) medicijnen zijn vaak gigantisch' *AD* (25 April 2020) 18-19.

reimbursement for 'intramural' medicine is consolidated at hospital level.[17] In such absence of true market choice, the government or hospital is often left no choice but to purchase from the patentee or not reimbursing the medicine, risking to fail upholding its obligation to protect the highest attainable standard of health.[18] *(Chapter 3 expands on this structural imbalance.)*

Protecting this right to health, including access to affordable medicine, is primarily a state obligation, irrespective of the considerable influence pharmaceutical companies exert in this domain. Following Article 22 of the Dutch Constitution, the Dutch government is subject to a 'duty of care', encompassing that it should act upon threats to or infringements on the right to health, protected under Article 12 of the International Covenant on Social, Economic and Cultural Rights.[19] Hence, governments must take corrective measures aimed at curbing the growth of pharmaceutical expenditure when these impede the realisation of that right.[20] This requires intervening when third-parties hinder equitable access to medicine, for example by setting 'unfair' or 'excessive' prices. However, this shows to be difficult in practice.[21] *(Chapter 2 discusses these obligations in detail.)*

There seems to be a conflict of interest when relying heavily on private companies to fulfil public health needs.[22] Despite the Dutch government's key role in regulating medicine prices and ensuring access through various bodies and institutions, high costs of patented medicines increasingly strain the system. Between 2017 and 2021, Dutch healthcare spending rose from €62,6 to €77,2 billion, driven in part by rising volumes and technological advances.[23] As expensive medicines and specialised care draw from the same capped budget, the share spent on high-cost medicines increased from 9.4% to 11.6%, putting growing pressure on other essential healthcare services.[24] While efforts are made to negotiate prices by the Minster of Health, health insurers and hospitals, these lack transparency, depict a power-imbalance and are often under pressure given the absence of a therapeutic alternative, making it difficult to gauge their success.[25] *(This is examined in Chapter 3.)*

To address this challenge, a rather controversial measure, yet possibly powerful tool may be considered as a potential solution. A compulsory licensing allows the government to authorise third parties to produce a patented medicine without the consent of the patentee, interfering with its exclusive rights, while protecting the public (health) interest. The Dutch Patent Act 1995 and the Trade-Related Aspects of Intellectual Property Rights Agreement may provide

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[17] 'Pieter van Megchelen, 'Vaststellen van een eerlijke prijs is het begin van een gesprek over betaalbare geneesmiddelen' (27 April 2020) *Medisch* Oncologie https://medischeoncologie.nl/artikelen/2020/april/editie-3/vaststellen-van-een-eerlijke-prijs-is-het-begin-van-een-gesprek-over-betaalbare-geneesmiddelen accessed 27 May 2025.
[18] Klaartje Bax and Niels Rigter, 'Hoe houden we dure geneesmiddelen betaalbaar voor degenen die het nodig hebben?' *De Telegraaf* (28 October 2023) https://www.telegraaf.nl/financieel/1492544247/hoe-houden-we-dure-geneesmiddelen-betaalbaar-voor-degenen-die-het-nodig-hebben accessed 27 May 2025.
[19] Article 22 Dutch Constitution,; UN General Assembly, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 Article 12.
[20] UN Committee on Economic, Social and Cultural Rights. General Comment No. 3, The Nature of States Parties' Obligations. UN Doc. E/C.12/1991/23. 1990 para. 8.
[21] André den Exter, 'Fighting 'excessive' Pharmaceutical Prices: Evaluating the Options' [2021] 28(1) *European Journal of Health Law* 68, 80.
[22] Jillian C. Kohler and Tim K. Mackey, 'Why the COVID-19 pandemic should be a call for action to advance equitable access to medicine' [2020] 18(193) *BMC Medicine* 1,2.
[23] Ministry of Finance, 'Zorguitgaven in volgelvlucht' (*Rijksfinancien)* https://www.rijksfinancien.nl/memorie-van-toelichting/2020/OWB/XVI/onderdeel/d17e52690 accessed 27 May 2025.
[24] 'Nederlandse Zorgautoriteit, *Stand van de zorg 2024* (8 October 2024) https://www.nza.nl/onderwerpen/stand-van-de-zorg-2024 accessed 27 May 2025,
[25] Anton Hagebeek, et. al, 'Fair Pricing of Innovative Medicines: An EHA Position Paper' [2020] 4(5) *HemaSpehere* 1,1-3.

the legal basis for compulsory licensing, but its application remains limited by legal, practical, and political barriers.[26] *(Chapters 5 analyses these barriers in depth.)*

This research aims to explore the legitimacy and effective use of compulsory licensing within the Dutch, European, and international legal frameworks as a tool to regulate medicine prices and ensure access to affordable healthcare. It aims to answer the following research question:

"Does compulsory licensing constitute a legally viable and practically effective instrument for addressing 'excessive' medicine prices and improve access to affordable medicines in the Netherlands?"

To build the answer to the former question, this research will analyse:

1. *How is the accessibility of affordable medicines protected under international law and to which government obligations does this give rise?*
2. *How are medicine prices regulated in the Netherlands, and what mechanisms are in place to control pricing and ensure accessibility within the healthcare system?*
3. *How do patent protection and intellectual property laws influence the pricing of medicines, and can compulsory licensing offer a lawful mechanism to intervene in 'excessive' pricing?*
4. *What challenges hinder the effective implementation of compulsory licensing against 'excessive' medicine prices?*
5. *What reforms are needed to enhance practical application of compulsory licences in ensuring affordable access to medicine?*

The pharmaceutical industry is governed by a complex legal framework that includes patent law, competition law, EU regulations on data and market exclusivity, and national pricing mechanisms. Understanding how these regimes operate and interact in the Dutch context is essential for examining whether and how compulsory licensing can function as a tool to improve affordable access to medicine. By evaluating the current legal and regulatory landscape, this research seeks to identify the legal, practical, and institutional barriers to the implementation of compulsory licences and proposes targeted reforms to improve their feasibility and strategic value. Ultimately, contributing to the broader conversation on how to balance patent rights and public health goals, ensuring that essential medicines remain accessible to all.

[26] Hans Ulrich, 'Mandatory Licensing Under Patent Law and Competition Law: Different Concerns, Complementary Roles' in Reto M. Hilty and Kunch-Chung Liu (Eds), *Compulsory Licensing-Practical Experiences and Ways Forward* (Springer2015) 355.

1.2 Relevance and Methodology

1.2.1 Social Relevance

The rising cost of expensive medicines threatens the sustainability of the Dutch healthcare system. As these medicines consume a growing share of the capped hospital budget, healthcare providers face increasingly difficult trade-offs, risking the displacement of other essential forms of care.

This tension between life-saving innovative medicines on the one hand, and maintaining affordability on the other hand, is likely to increase as technological advancements continue.[27] The increasing cost of medicines may, not only, render them inaccessible but undermine broader public health systems. If unchecked, this pressure may compromise the long-term viability of the system. To guarantee both affordability and accessibility, structural responses must be considered. Compulsory licensing, if effectively implemented, could help mitigate 'excessive' medicines pricing and protect the public interest in a function, equitable healthcare system.

1.2.2 Academic Relevance and Literature Review

In addition, this research may be academically relevant where it complements t existing legal research on the use of compulsory in the Netherlands. This research connects the human rights obligation to the use of compulsory licences as a cost-containment measure or price negotiation tool. In recent years, there has been a renewed interest in compulsory licensing in European Union Member States. Therefore, this research examines the mechanism's viability to strengthen the Dutch government's negotiation position facing pharmaceutical companies; ultimately, addressing 'excessive' pricing causing medicine inaccessibility infringing upon the right to health.

To explore the potential of compulsory licensing as a tool against 'excessive' medicine prices, the Dutch Minister of Health and the Minster of Economic Affairs commissioned a legal review of the relevant framework and its practical implications. Upon this request, André de Jong, chair of the Dutch Compulsory Licence Committee, published a personal review, examining the legal basis for compulsory licensing at the domestic, European, and international levels, estimated practical impact and proposes an *ex-ante* assessment framework as well as further recommendations.[28]

This research builds on his findings regarding the legal ground on which compulsory licensing may be based, while critically considering whether, how and by whom such bases may in fact be invoked against 'excessive' pricing of medicines. It connects earlier findings of flaws in and obstacles stemming from the framework regulating medicine pricing and concerning (developments) competition law. Furthermore, it proposes possible legal enhancements drawn from the assessment framework recommended by de Jong.

Furthermore, this research further explores Lawyer David Mulder's view on the role of competition law to enforce access to legally protected know-how in order to effectively issue

[27] 'André den Exter, 'Extreem dure medicijnen verdringen andere vormen van zorg' *Trouw* (24 October 2022) https://www.trouw.nl/opinie/extreem-dure-medicijnen-verdringen-andere-vormen-van-zorg~b98d6095 accessed 27 May 2025; Pieter van Megchelen, 'Vaststellen van een eerlijke prijs is het begin van een gesprek over betaalbare geneesmiddelen' (27 April 2020) *Medisch* Oncologie https://medischeoncologie.nl/artikelen/2020/april/editie-3/vaststellen-van-een-eerlijke-prijs-is-het-begin-van-een-gesprek-over-betaalbare-geneesmiddelen accessed 27 May 2025.

[28] André de Jong, 'Persoonlijke beschouwing over de inzet van de dwanglicenties bij hoge prijzen van medicijnen' (Algemene Bestuursdienst, Ministerie van Buitenlandse Zaken en Koninkrijksrelaties, 2020).

and employ a compulsory licence.[29] It draws on the work of Ellen 't Hoen, an expert in medicine policy and IP law, particularly her proposals to introduce a formal waiver to data exclusivity. [30] Such reforms are recommended to strengthen the bargaining position in price negotiations with pharmaceutical companies.[31]

Finally, this research builds on the findings of Rivka Shaindla Ajzental's thesis to identify the practical barriers that have emerged in the implementation of compulsory licensing regimes in other national contexts.[32] Based on the gaps or ambiguities in the law, this research will propose legal enhancements inspired by the various authors in Carlos M Correa's and Reto M Hilty's edited book on *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer 2022) as well as several authors in Reto M Hilty's and Kung-Chung Liu's edited book on *Compulsory Licensing: Practical Experiences and Ways Forward* (Springer 2015).

1.2.3 Methodology

This research employs a doctrinal legal methodology, primarily focused on the review and analysis of existing literature, legal texts, and legislative frameworks. A critical approach was taken to assess the effectiveness of existing measures and propose potential legal reforms. The findings extracted from the sources below are analysed qualitatively. The analysis focusses on identifying the strengths and weaknesses of current regulatory frameworks and understanding the practical implications of compulsory licensing. While grounded in legal analysis, this research also draws on interdisciplinary insights from public health and pharmaceutical policy exploring whether and how compulsory licensing offers a viable response to 'excessive' medicine pricing, protecting the right to health.

The research utilises a wide range of primary and secondary sources, including academic literature, legal texts, international treaties, governmental reports, and relevant case law. These sources are essential for understanding the legal and policy frameworks that regulate medicine prices and patent protection.

1. Academic Literature: A thorough review of books, journal articles, and scholarly papers from databases including Elsevier, HeinOnline, Bmcmedicine, BioMed Central, The Lancet, Bju, PubMed Central, JSTOR, Hudoc, Ncbi, the Guardian, Taylor & Francis Online, and Oxford Public International Law was conducted. These sources provided insights into various aspects of pharmaceutical law, international human rights, intellectual property, competition law, and healthcare economics. Furthermore, secondary sources related to pharmaceutical industry practices, including pricing strategies, R&D costs, and transparency in pricing negotiations, drawn from literature were reviewed. Medical and healthcare databases like National Library of Medicine (National Center for Biotechnology Information), Federatie Medisch Specialitsten, Medline, Ovid, and Elsevier were consulted to understand the broader economic impact of pharmaceutical pricing on the Dutch healthcare system.

[29] D.M. Mulder, 'Octroorecht in noodsituties' [2020] 16(3) *IER* 133
[30] Ellen 't Hoen, 'Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of data Exclusivity' in Carlos M. Correa and Reto M. Hilty (Eds.) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property* Law (Springer 2022) 183,194
[31] Ellen F.M. 't Hoen, Pascale Boulet and Brook K. Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: *A proposal for greater coherence in European pharmaceutical legislation*' [2017] 10(19) *Joural of Pharmaceutical Policy and Practice*
[32] R.S. Ajzental, '*Compulosry license: analysis of the effectiveness in providing access to medicines'* (Master Thesis, *Tilburg University*, 2018).

2. Legal Documents and Legislation: The research analyses key international, European and domestic legal documents. The international legal instruments, either binding or non-binding, include the International Covenant on Economic, Social, and Cultural Rights, the Trade-Related Aspects of Intellectual Property Rights Agreement, the Doha Declaration, relevant General Comments. This research focuses on the rights and obligations derived from the ICESCR to narrow down the scope of the right to health. Additionally, relevant Dutch national laws, such as the Dutch Patent Act. Finally, instruments at the European Union level, various Directives and Regulations were reviewed to understand the legal landscape surrounding the right to health, intellectual property law and trade law.
3. Governmental Reports and Institutional Publications: Reports from national health authorities, the Ministry of Health, Welfare, and Sport and the Minister or Economic Affairs and Climate, the World Health Organization (WHO), and other relevant bodies were analysed, providing crucial data on the current state of medicine pricing, access to medicines and healthcare system pressures.

Despite the comprehensive scope of this research, there are limitations. Given the nature of doctrinal legal research, the research is based primarily on secondary sources, such as legal texts and literature, with limited access to empirical data on pharmaceutical companies' investment strategies and internal decision-making processes. While useful case studies from other countries are considered, this research focuses on the Dutch system and its particularities. Moreover, the lack of transparency in pharmaceutical pricing and across the EU, including the limited insight on the pricing negotiations, hinder the ability to estimate the impact of measures.

1.2.4 Use of Artificial Intelligence

I used AI to assist in organising my thoughts for clarity as well as checking the written parts on coherency and refining the language. However, all legal interpretations, analysis of sources and texts as well as (final) conclusions are drawn from my own research, thoughts and analysis.

1.2.5 Structure

This research examines whether compulsory licensing offers a legally viable and practically effective mechanism in the Dutch context to counter ‘excessive’ medicine pricing and ensure affordable access in accordance with international obligations. Chapter 2 outlines the normative framework surrounding the right to medicines under international human rights law, with particular focus on Article 12 of the ICESCR and the corresponding obligations of the Dutch state to ensure the affordable access to essential medicines. Chapter 3 assesses the Dutch national regulatory context surrounding pricing and reimbursement mechanisms, institutional dynamics and growing attention in competition law to pharmaceutical pricing cases. As such, identifying systemic and sector-specific challenges and introduces the option of compulsory licensing to respond to these. Chapter 4 evaluates the legal basis, scope, and operation of compulsory licensing under international, EU, and Dutch law, focusing on its intersection with innovation, intellectual property rights, and public health. Chapter 5 examines the practical and legal feasibility of invoking compulsory licences in the and proposes legal reforms to enhance its viability in offering a legal avenue to counter the specific challenges the current framework’s lacks. The conclusion synthesises the findings and examines compulsory licensing as a tool for promoting equitable access to essential medicines in line with international obligations.

Chapter 2: Access to Affordable Medicines and Obligations under International Law

This Chapter explores the obligations arising under international human rights law underpinning the government's responsibility to ensure affordable access to medicines. It examines how the right to health is given effect through the principles of progressive realisation, the 'tripartite framework', and minimum core obligations and considers how these interact with pricing challenges in a privatised healthcare system. This analysis serves to determine how the accessibility of affordable medicines is protected under international law and to which government obligations this gives rise.

2.1 The Right to health and State Obligations

2.1.1 The Scope of Article 12 ICESCR and the 'Tripartite Framework'

The Netherlands is party to the International Covenant on Economic, Social and Cultural Rights (ICESCR).[33] As a matter of Dutch constitutional law, when the Netherlands becomes a party to an international treaty, the provisions of that treaty are binding upon the government, which is under a legal obligation to comply with its terms in both the international and domestic legal orders.[34] Accordingly, Article 12 ICESCR, as the most authoritative provision on the right to health in international human rights law, creates a direct obligation for the Dutch government to adopt legislation and policy measures to realise this right.[35]

Clarifying the scope of these obligations is essential for this research understand the State's legal responsibility in ensuring affordable access to medicines. This framework enables an analysis of how intellectual property (IP) law, competition law and the right to health intersect, allowing for a more focused evaluation of whether compulsory licensing can be an effective response to 'excessive' medicine prices. International human rights law recognises the right to health and the State obligations to take all necessary steps towards its full realisation. This includes facilitating a system of disease prevention, providing the possibility of treatment and control with access to necessary medicine for everyone. Where the right's realisation is not achieved or where there exist limitations to its exercise, the State must be able to prove this is not arbitrary, unreasonable or discriminatory.[36]

Concretely, the Dutch government is obliged to guarantee *the right of everyone to the highest attainable standard of physical and mental health* must by individually take steps *(…)to the maximum of its available resources, intending to achieve progressively the full realisation of the rights (…) by all appropriate means, including the adoption of legislative measures.*[37] To give proper meaning to and safeguard the positive right to health, State obligations to *protect*, *respect* and *fulfil* arise.[38] This 'tripartite framework' imposes a duty to refrain from harming

[33] OHCHR, 'Ratification Status for the Netherlands https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/Treaty.aspx?CountryID=123&Lang=en accessed 27 May 2025
[34] Dutch Constitution Articles 91 and 93; Explanatory Memorandum to the VCLT Approval Act (*Kamerstukken II*, 1982/83, 17798 (R 1227), nr. 3); Kingdom Act on the Approval and Publication of Treaties Section 15 (1) (3).
[35] Maitetxu San Giorgi, 'The Human Rights to Equal Access to Health Care' (2012) 53 (1) School of Human Rights Research Series 1,11.
[36] UN Commission on Human Rights, The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights (8 January 1987) E/CN.4/1987/17 paras. 48- 51.
[37] UN General Assembly, International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3, Art 2 (1).
[38]UN OHCHR, International Human Rights Law (*UN OHCHR)* https://www.ohchr.org/en/instruments-and-mechanisms/international-human-rights-

human rights through direct, detrimental actions (*respect)*, to prevent and react to human rights harm inflicted by third parties (*protect*), and to take legislative, administrative, budgetary, and judicial measures that create the ability to realise human rights (*fulfil)*.[39] Evidently, providing healthcare at an accepted level requires an established rule-setting institutional framework, with the authority and capacity to investigate abuses of the rights safeguarded .[40]

2.1.2 Progressive Realisation

The full realisation of the right to health and subsequent enjoyment of health-related services and goods is to be fulfilled using 'the maximum of its available resources'.[41] The United Nations Committee on Economic, Social and Cultural Rights' (Committee), the treaty-monitoring body established under the ICESCR, offers authoritative, though non-binding, interpretations of States' obligations. General Comment No. 3 explains that rights must be realised progressively, requiring States to take immediate steps and avoid backsliding.[42] Progressive realisation also requires regular monitoring and making adequate advancements relative to available resource.[43] The Committee emphasises the significance of sound legislation as an indispensable tool to achieve this.[44] Progressive realisation does not imply an immediate right to all treatments for everyone. Rather, it requires States to take deliberate, concrete, and targeted steps to gradually improve access to healthcare.[45]

At a minimum, international human rights law mandates the creation of a clear plan and intentional actions toward the progressive realisation of the right to health.[46] This requires balancing cost-effectiveness, healthcare services and regulating the market. While this flexibility provides discretion regarding the means of implementation, it should not be perceived as an 'escape clause' from treaty obligations.[47] Inevitably, States must enforce a system of prioritisation respecting fair and non-discriminatory provision of treatment, justifiable in the context of progressive realisation of the minimum core obligation. [48] In the

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law#:~:text=The%20obligation%20to%20fulfil%20means,their%20treaty%20obligations%20and%20duties Accessed 27 May 2025

[39] International Commission of Jurists, Maastricht Guidelines on Violations of Economic, Social and Cultural Rights (adopted 26 January 1997, 1 November 1993) para 6; David Jason Karp, 'What is the responsibility to respect human rights? Reconsidering the 'respect, protect, and fulfill' framework' (2020) 12(1) International Theory 83,86; UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para.1, of the Covenant) (14 December 1990) E/1991/23 para 3, 5,7; International Commission of Jurists, '2.3.1. State obligations stemming from international law' (*International Commission of Jurists)* <https://www.icj.org/chapter-2-esc-rights-under-international-law-and-the-role-of-judicial-and-quasi-judicial-bodies-2/2-3-identifying-breaches-of-international-obligations-of-states-pertaining-to-esc-rights/2-3-1-state-obligations-stemming-from-international-law/> Accessed 27 May 2025.

[40] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1 of the Covenant) (14 December 1990) E/1991/23 para 35 in conjunction with UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant) (2000) E/C.12/2000/4, para 16.

[41] (n 37).

[42] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para.1, of the Covenant) (14 December 1990) E/1991/23 para 2 and 9.

[43] Lisa Montel, Naomi Senyonga and Claudia Allemani, 'How should implementation of the human right to health be assessed? A scoping review of the public health literature from 2000 to 2021' [2022] 21(139) *International Journal for Equity in Health* 1,9.

[44] (n 42) para 3.

[45] Katrina Perehudoff, Brigit Toebes and Hans Hogerzeil, 'A human rights-based approach to the reimbursement of expensive medicines' [2016] 94(12) *Bulletin World Health Organisation* 935,935.

[46] Victor Dankwa et al., *The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights*, 20 HUM. RTS. Q. 691, 694 (1998) [hereinafter *Maastricht Guidelines*]; U.N. Comm. on Econ., Soc. & Cultural Rts., *General Comment 14*, para 36.

[47] Brigit Toebes, 'Towards an Improved Understanding of the International Human Rights to Health' (1999) 21(3) 294.

[48] UN Committee on Economic, Social and Cultural Rights (CESCR), 'General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant) (2000) E/C.12/2000/4 para 43.

context of medicines, progressive realisation offers a human rights basis for limiting reimbursement of certain treatments, ensuring fairness by preventing claims to costly therapies solely on individual rights grounds, without considering criteria like cost-effectiveness.[49]

In practice, parties fail to meet its obligations when a significant or rising number of individuals is deprived of essential healthcare due to inadequate allocation of its maximum available resources or the lack of appropriate measures or legislation. A State's failure to meet minimum core obligations may reflect its efforts, including insufficient commitment, inadequate regulatory measures, or inappropriate legislation.[50] To illustrate, in the context of the rising costs of healthcare as a result of increasing medicine prices, may form a substantive obstacle to attaining the highest standard of health as it impedes the possibility to access affordable healthcare.[51] To advance progressing realisation and broaden reimbursement access, States may increase health budgets as part of their duty to use its maximum available resources. However, a more effective strategy is to actively apply available tools, including flexibilities in patent law, to lower medicine prices.[52] Failing to adopt legislation or enforce regulative measures to reduce inequitable distribution of healthcare, may constitute a violation of the right to health.[53]

2.2 Access to Medicine under the Right to Health

2.2.1 The 'AAAQ framework'

The scope of the right to health gives rise to various entitlements including, *preventive, curative, primary, and rehabilitative health services, treatment of prevalent diseases, illnesses (…) the provision of essential drugs*.[54] Given their central role in addressing priority health needs, medicines are an integral and indispensable for the prevention and treatment of disease, the improvement of population health outcomes, and the reduction of health inequalities.[55] Although not explicitly protected as an independent human right, the right to access to medicines can be derived from the right to health, making it a fundamental component for its full realisation.[56] General Comment No.14 interpreting Article 12 ICESCR, prescribes that States, in their legislative efforts must ensure specific safeguards exist to prevent threats to the *availability, accessibility, acceptability* and *quality* (*AAAQ*) of medicines.[57] The right to health falls short of practical meaning without guaranteeing actual access to affordable medicine. In practice, this cannot be ensured 'excessive' pricing impedes access to medicine or other healthcare, posing a substantial barrier to guaranteeing adequate redress for health-related issues.[58] Companies' infringements on the *AAAQ*, may justify expanded State intervention through corrective measures, including patent limitations enabling more affordable access.[59]

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[49] (n 45) 935.
[50] (n 42) para 10; (n 36) para 72.
[51] UN OHCHR, 'Fact Sheet No. 33, Frequently asked questions on Economic, Social and Cultural Rights' (2008) No. 33, 33 https://www.ohchr.org/sites/default/files/Documents/Publications/FactSheet33en.pdf accessed 27 May 2025
[52] (n 45) 935-936.
[53] (n 48) para 52.
[54] (n 48) para 17.
[55] Holger Hestermeyer, 'Access to Medication as a Human Right' [2004] 8(1) *Max Planck Yearbook of United Nations Law* 101, 128.
[56] Katrina Perehudoff, Brigit Toebes and Hans Hogerzeil, 'Essential Medicines in National Constitutions' [2016] 18(1) *Health and Human Rights* 141,142.
[57] (n 48) para 12.
[58] (n 48) paras 33-34 and 37.
[59] (n 48) para 36.

2.2.2 Minimum Core Obligations and Essential Medicines

The Committee explicitly acknowledged that access to essential drugs, as defined by the WHO Action Programme on Essential Drugs, is a part of a state's minimum core obligations under the ICESCR. This means that essential medications are included in each state party's *core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights*.[60] These essential medicines should meet *priority health needs, be selected based on criteria of public health importance, efficacy, safety, and comparative cost-effectiveness, and are intended to be available at all times in functional health systems*.[61]

While General Comment 14 recognises that *the precise nature of the facilities, goods, and services provided as part of the right to health will vary depending on numerous factors*, core obligations are 'non-derogable' and, in many respects, do not depend on a State's level of development.[62] Derogations form the core obligations may be justified by a lack of available resources provided that the State can demonstrate that all efforts have been exploited to realise its obligations.[63] States retain discretion in determining how to ensure access to medicines, whether through financing public health insurance schemes or safeguarding accessibility by addressing 'excessive' pricing, but resource allocation must reflect reasonableness and a genuine effort.[64]

Essential medicines, defined by the WHO as those addressing the priority health care needs, are arguably the most concrete expression of the minimum core obligations. This classification is grounded in the WHO's concept and operationalised through its comprehensive Model List of Essential Medicines.[65] However, this precision is somewhat misleading given that the List is designed to be adapted by national governments to the local context, taking into account factors like disease prevalence, infrastructure, and available resources, which results in a national list that is flexible and responsive to local needs.[66]

Legal scholar Katrina Perehudoff, whose research focuses on regulatory strategies to improve access to medicines for underserved populations, and human rights expert Lisa Forman, known for her interdisciplinary work on the intersection of international human rights law and global health governance, argue that a broader discourse on health rights would show that basic entitlements are more effective in promoting public health goals and human rights when they are flexible rather than rigid. They assert that a fixed list of 'essential medicines', as laid down by the WHO, would be overly specific and inadequate for ensuring the realisation of

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[60] Alicia Ely Yamin, 'Not just a tragedy: Access to medications as a right under international law' [2003] 21(325) *Boston University International Law Journal* 325, 359; (n 48) para 43.
[61] World Health Organization, *Selection of Essential Medicines at Country Level: Using the WHO Model List of Essential Medicines to Update a National Essential Medicines List* (WHO 2020) https://iris.who.int/bitstream/handle/10665/330898/9789241515443-eng.pdf accessed 27 May 2025 3 ;Thomas Piggott, et al., 'Gade Concept 7: Issues and Insights Linking Guideline recommendations to Trustworthy Essential Medicine Lists' [2024] 166(1) *Journal of Clinical Epidemiology* 1,1.
[62] (n 48) para 43 *jo* 47.
[63] (n 48) paras 39, 52 and 53.
[64] (n 48) para 47; (n 42) para 10; (n 55) 143.
[65] World Health Organization, *Selection of Essential Medicines at Country Level: Using the WHO Model List of Essential Medicines to Update a National Essential Medicines List* (WHO 2020) https://iris.who.int/bitstream/handle/10665/330898/9789241515443-eng.pdf accessed 27 May 2025; Katrina Perehudoff and Lisa Forman, 'What constitutes 'reasonable state action on core obligations? Considering a right to health framework to provide essential medicines' (2018) *Rijksuniversiteit Groningen* 29, 35.
[66] WHO Expert Committee on the Selection and Use of Essential Medicines. The selection and use of essential medicines [WHO Technical Report Series, No. 914] [Internet]. Geneva: World Health Organization; 2003 [cited 2018 May 18]. pp. 126. Available from: http://apps.who.int/medicinedocs/en/d/ Js4875e/

rights across different regions and populations facing varying health challenges.[67] Therefore, instead, Perehudoff asserts that the minimum core should be viewed as a concept that is shaped by public health and human rights principles at the domestic level, rather than as a definitive, universal list of medicines.[68] This is particularly relevant for safeguarding affordable access to innovative medicines.[69]

2.2.3 The Duty to *Protect* in a Privatised Healthcare System

Besides the obligation to provide essential medicine, General Comment 14 emphasises that States must ensure that the privatisation of the healthcare sector does not threaten the accessibility of healthcare facilities, goods and services. This underscores States' primary responsibility over the provision of healthcare even when these are mainly controlled or provided by private actors.[70] Namely, States must protect access to and affordability of medicines from direct and indirect interference by pharmaceutical companies and other third parties.[71]

This duty to *protect* becomes particularly relevant in the Dutch context, where significant healthcare reforms were implemented with the 2006 Health Insurance Act (*Zorgverzekeringswet*), effectively introducing a system of regulated competition and shifting a large portion of the provision and financing to private healthcare insurers and providers.[72] The Netherlands relies exclusively on private entities for both healthcare provision and financing, with hospitals bearing direct responsibility for procuring medicines needed for inpatient care and their reimbursement being dependent on the health insurers.[73] Accordingly, the State must control and regulate the market of medicine to prevent actors from infringing upon the right to health.[74] This obligation includes acting or providing remedies against the abuse of patented producers, such engaging in ''excessive' pricing'.[75] Particularly so, as in absence of such efforts and without a functioning regulatory framework to prevent or address infringements, the State may fail to fulfil its international obligations.[76]

While neither international human rights law nor the right to health for that matter, explicitly prohibits high medicine prices, most countries are unable to sustain the escalating costs of pharmaceuticals within finite healthcare budgets.[77] To illustrate, ''excessive' pricing' in the context of medicine should not be understood merely in absolute terms, rather in light of its systemic consequences for the health system. In this sense, high-cost medicines can displace more cost-effective interventions, resulting in a net loss in population health.[78] Such cost-effectiveness analyses, for instance using quality-adjusted life-years (QALYs), offer a methodological tool to assess whether a new treatment provides sufficient health gain relative

[67] Katrina Perehudoff and Lisa Forman, 'What constitutes 'reasonable state action on core obligations? Considering a right to health framework to provide essential medicines' (2018) *Rijks Universiteit Groningen* 29, 35.
[68] *Ibid.*
[69] André den Extrer, 'Fighting 'excessive' Pharmaceutical Prices: Evaluating the Options' [2020] 27(1) *European Journal of Health Law* 1,3.
[70] Brigit Toebes, 'The right to health and the privatization of national health systems' [2006] 9(1) *Health and Human Rights* 103,107.
[71] (n 60) 329, 355 and 367.
[72] (n 70) 107-110.
[73] Wolf Sauter and Illan Akker, 'A Cure for All Ills? The Effectiveness of Therapeutic and Biosimilar Pharmaceutical Competition in the Netherlands' [2020] 4(1) *European Pharmaceutical Law Review* 57, 58.
[74] (n 48) paras 35 and 51.
[75] (n 55) 136.
[76] (n 60) 356.
[77] (n 55) 136.
[78] Karl Claxton, et al., 'Causes for concern: is NICE failing to uphold its responsibilities to all NHS patients?' [2015] 24(1) *Health Economics* 1, 1-4.

to its cost.[79] If the cost per QALY, reflecting a political decision, exceeds the opportunity cost threshold, the price of the new medicine can undermine the efficient allocation of resources.[80] Notably, the term ‘‘excessive’ pricing’ in this context depicts a broader public-health context, whereas competition authorities have developed a specific legal definition through case law.

In any case, ‘‘excessive’ pricing’ whereby costly medicines consume a disproportionate share of the total public healthcare expenditure, either constrains the allocation of funds to other essential healthcare services or places the use of the high-priced medicine out-of-reach.[81] Thus, failure to regulate third parties’ ‘‘excessive’ pricing’ not only affects affordability and accessibility, it may result in budgetary displacements compromising equitable realisation of the right to health.[82] To avoid such infringements, States must take steps to regulate medicine prices or consider alternative indirect price measures, such as under the flexibilities that intellectual property law grants.[83] Regulating medicine prices or implementing control measures contributes to the efficient allocation and utilisation of available healthcare resources. However, such cost-containment measures may be hindered to the pharmaceutical industry’s specific character and the complex sector specific governance.[84] A key regulatory challenge lies in balancing incentives for innovation with ensuring fair and justifiable pricing, requiring both robust enforcement and coherent, rights-based policy frameworks.[85] Dutch regulatory and enforcement mechanisms will be discussed in the following Chapter.

2.3 Conclusion

Article 12 ICESCR outlines the State obligation to safeguard the right to health, including the provision of medicines as supported by General Comment 14. Ensuring access to essential medicines forms part of the core obligations and imposes a government duty to commit to ensuring accessibility of medicines through national policies, including regulatory and legislative measures. Besides the minimum core obligation to provide essential medicine, General Comment 14 stipulates the State obligation to *protect* the population from infringement upon the right to health as a result of actions by private actors involved in the process of guaranteeing the right to health. This is particularly important given the essential role pharmaceutical companies play in the national healthcare system by researching and developing new medicine.[86] Access to medicine is largely controlled by the private sector; and regrettably so, some pharmaceutical companies were unwilling to engage in the collaborative initiatives, including creating greater transparency around the costs and prices of medicine, to work together to identify responsibilities in relation to accessibility of

[79] Leah Z. Rand and Aaron S. Kesselheim, ‘Controversy over using quality-adjusted life-years in cost-effectiveness analyses: A systemic literature review’ [2021] 40(9) *Health Affairs* 1402, 1402.
[80] Joost Johan Godert Wammes, et al. ‘‘Case-Studies of Displacement Effects in Dutch Hospital Care’ (2020) 20 *BMC Health Services Research* 263, 365.
[81] Werner Brouwer, Pieter van Baal and Matthijs Verstreegh, ‘When is it too expensive? Cost-Effectiveness threshold and health care decision-making’ [2018] 20(1) 175, 175-180; Aniek dane, ‘Cost Containment of expensive drugs from a university hospital’s perspective: Discovering new routes to safeguard accessibility to innovative therapies (*Erasmus University of Rotterdam* 2025) 119, 132
[82] Rosalind Turkie, ‘Upholding Human Rights in the Wake of COVID-19: Time to Strengthen Pharmaceutical Accountability’ [2022] 24(2) *Health and human Rights* 205,208.
[83] Katrina Perehudoff and Ellen ’t Hoen, ‘Human rights & intellectual property for universal access to new essential medicines. In: *Babar Z-U-D*, editor. Equitable Access to High-Cost Pharmaceuticals. London: Elsevier Academic Press; 2018 67, 78 and 82-83.
[84] Aniek dane, ‘Cost Containmetn of expensive drugs from a universit hospital’s perspective: Discovering new routes to safeguard accessibility to innovative therapes (*Erasmus University of Rotterdam* 2025) 73.

[86] Rajat Khosla and Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context* (Human Rights Centre, University of Essex 2008) 9,10.

medicines.[87] Notably, international law, binding only those states parties to it and not non-state actors, does not provide a legal avenue to hold the latter directly accountable for failing to uphold the right to health or even obstructing the realisation thereof.[88] Accordingly, the internationally embedded right to (essential) medicine requires States to safeguard this right both at a systemic level by imposing regulatory and legislative measures regulating the pharmaceutical market and controlling medicine expenditure; as well as, at the individual level by ensuring affordable access to specific essential medicines. These two dimensions are closely linked since systemic shortcomings often translate into concrete barriers to individual medicine access. This may require not only entrenching price regulating measures directly through legislative frameworks and ensuring *ex-post* enforcement, but also via indirect intervention that structurally influences pricing over time. To that end, the following Chapter examines the Dutch government's legislative and regulatory efforts to guarantee this right.

[87] Iris R. Joose, et al, 'Evidence on the effectiveness of policies promoting pre transparency- A systemic review' [2023] 134 (1) ; Gaëlle Krikorian and Els Torreele, 'We cannot win the access to medicine struggle using the same thinking the causes the chronic access crisis' [2021] 3291) *Health and Human Rights* 119, 119-120; Nora Franzen, e.a., 'Affordable Prices Without Threatening the Oncological R&D Pipeline- An Economic Experiment on Transparency in Price Negotiations', *American Association for Cancer Research* (2022) 1(2), 49,49.
[88] (n 86) 10.

Chapter 3: The Regulation of Medicine Prices in the Netherlands and Mechanisms to Ensure Affordable Access

This Chapter analyses how the pricing of medicines is regulated in the Netherlands and which mechanisms are in place to ensure affordable access. It outlines the legal framework governing marketing authorisation, price setting and reimbursement decisions, with particular attention to the role of regulatory bodies, the influence of patents and the dynamics of market exclusivity. Furthermore, it examines how competition law is used to address 'excessive' pricing and the challenges posed by asymmetrical power between public purchasers and pharmaceutical companies.

3.1 Market authorisation and pricing of Medicines

Within the European Union (EU), before a medicine may enter the market it must first be granted marketing authorisation through a formal registration process.[89] EU pharmaceutical legislation, largely set out in Directive 2001/83/EC and Regulation (EC) No 726/2004, ensures that all medicines for human use meet strict quality, safety and efficacy requirements.[90] Quality of the medicine must be demonstrated by the pharmaceutical company through documentation, whereas safety and efficacy will be assessed by the competent authorities through the result of clinical trials.[91] In the Netherlands, the competent authority is the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, CBG), at the European level this responsibility lies with the European Commission, advised by the European Medicines Agency (EMA).[92] Market authorisation may be granted if the benefit-risk balance is favourable, stability of both the active substances and the final product is ensured and possesses the claimed therapeutic efficacy.[93]

Following marketing authorisation, the medicinal product is subject to a period of 'data exclusivity' and a subsequent 'market exclusivity'. 'Data exclusivity' refers to a regulatory protection period minimum period of eight years during which third parties are prohibited from relying on the originator's preclinical and clinical data to obtain marketing authorisation for generic equivalents.[94] 'After eight years, regulatory authorities may review a generic application, but due to a two-year market exclusivity period, the product cannot be marketed until ten years have passed since the originator's initial authorisation.[95]

The EMA and CBG only assess the balance between efficacy and safety, without considering cost-effectiveness, allowing pharmaceutical companies to set prices freely after approval.[96] This pricing process starts by the pharmaceutical manufacturer setting an initial price. This pharmacy purchase price is often based on a value-based pricing model, that assumes that medicine pricing cannot be reduced to a straight-forward cost-based pricing method.[97] This initial price is determined by various factors, including incurred research, development and

[89] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use *OJ L 311, 28/11/2001, p. 67–128*, Article 6 an 8
[90] Ibid and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) *OJ L 136, 30.4.2004, p. 1–33*
[91] (n 89) Article 8.
[92] (n 90) Article 1
[93] (n 90) Article 14 and 16
[94] (n 90) Article 14 (11).
[95] Article 9 Dutch Medicines Act and (n 90) Article 14 (11).
[96] (n 95) Article 1.
[97] (n 84) 133.

production costs, anticipated market demand and projected revenues, desired profit margins, comparative clinical effectiveness, prices of similar therapies (if available) and the national market context, including income level and willingness to pay.[98] These internally set prices form the basis for negotiations with national health authorities, including insurance companies, hospitals and the Ministry of Health.[99]

3.2 The legal framework and the Role of Regulatory Bodies

3.2.1 Price regulation following market authorisation

The regulation of medicines in the Netherlands is characterised by a complex and dense legal framework, aimed at safeguarding public health. At the core of this framework lies the Dutch Medicines Act (*Geneesmiddelenwet*), which implements key: European Directive 2001/83/EC and Regulation (EC) No 726/2004.[100] The pricing of medicines in the Netherlands involves an interplay between pharmaceutical companies, government authorities, health insurers and care providers.[101] The legislative and regulatory mechanisms reflect the tension between ensuring access to affordable medicines and incentivising pharmaceutical innovation.[102] However, they also exhibit the power imbalance between public payers and private suppliers, particularly in the context of high-priced, patented medicines.[103]

The Dutch system draws a distinction between in-patient (intramural) and out-patient (extramural) medicine, which are subject to diverging rules regulating the price and the reimbursement. The price of a medicine in the Netherlands is determined by several steps and subject to various rules of which the pharmacy purchase price forms the point of departure. Although pharmaceutical pricing is formally liberalised, technically allowing pharmaceutical companies to set their own prices, a statutory maximum price is medicines with a specific active substance, strength, and pharmaceutical formulation.[104] Following the Medicines Prices Act (*Wet Geneesmiddelenprijzen*) a *maximum price may be imposed on medicine of which availability, in the judgment of the Minister Health, must be guaranteed by the State to ensure accessibility.*[105] The Act aims to safeguard accessibility and affordability of medicines as well as sustainability of healthcare by aligning prices of authorised medicines with the European average price level.[106] This legal maximum price is determined through external reference pricing based on the prices of comparable medicines in Belgium, Germany, the United Kingdom, and France.[107] This international reference pricings should allow

[98] Steven Morgan, et al. 'Pricing of pharmaceuticals is becoming a major challenge for health systems' [2020] 368(1) *BMJ* 1,1-2; Bertalan Németh, et al.' Access to high-priced medicines in lower-income countries in the WHO European Region' (Oslo medicines imitative technical report, 2022); Aniek Dane, Carin Uyl-de Groot and Hugo van der Kuy, 'Unravelling elements of value-based pricings from a pharmaceutical industry's perspective: a scoping review' (2024) *Frontiers in Pharmacology* 1, 1-3; (n 84) 132-133 and 153; Sarah Garner, Andrew Rintoul and Suzane R Hill, 'Value-based pricing: L'Enfant Terrible?' [2017] 36(1) *Pharmacoeconomics* 5,5-6.
[99] Aniek Dane, Carin Uyl-de Groot and Hugo van der Kuy, 'Unraveling elements of value-based pricings from a pharmaceutical industry's perspective: a scoping review' (2024) *Frontiers in Pharmacology* 1, 2.
[100] (n 95) *Inter alia* Article 1 (1), 9, 36, 40 and 42.
[101] W.E.H. Dullaert and others, *An Exploratory Analysis of the Dutch Pharmaceutical Supply Chain* (TKI Dinalog and Vrije Universiteit Amsterdam, January 2021) 11.
[102] Rijksoverheid, 'Betaalbaar houden van medicijnen' (Rijksoverheid.nl) https://www.rijksoverheid.nl/onderwerpen/geneesmiddelen/betaalbaar-houden-van-geneesmiddelen accessed 27 May 2025.
[103] Carin Uyl-de Groot and Emily Dowdalls, 'Payback-systeem zorgt voor evenwicht tijdens sluisperiode' (Erasmus School of Health Policy & Management, 3 May 2024) https://www.eur.nl/eshpm/nieuws/payback-systeem-zorgt-voor-evenwicht-tijdens-sluisperiode accessed 27 May 2025.
[104] (n 95) Article 2 (2) jo Article 1 (1) (c).
[105] (n 95) Article 2 (1).
[106] *Parliamentary Papers II*, 1994/95, 24266, nr. 3, 15.
[107] Article 2 (2) Dutch Medicine Prices Act.

profitability when selling the medicine in the Netherlands, intended to ensure that offering medicine on the Dutch market remains financially attractive.[108] The Act, however, falls short in curbing 'excessive' both initial and post-launch prices of some (patented) medicines given that not all medicines are subject to such maximum price.[109] Moreover, this list is not based on actual transaction prices but on artificial and inflated prices that are kept high by pharmaceutical companies even after generic entry.[110] Thus, maintaining high prices also lies in the strategic efforts by innovative pharmaceutical companies to fragment bargaining powers of hospitals and health insurers, confidential discounts and rebates further obscure pricing, impeding price control and comparability. Moreover, within this current system, various tactics are used to delay effective price competition for as long as possible.[111] Finally, given the absence of strong EU-level coordination, this often results in pricing being anchored to the country with the highest willingness to pay.[112]

3.2.2 Regulation of Reimbursement

For medicines dispensed externally (extramural), the Netherlands applies an internal reference pricing system under the Medicine Reimbursement System (*Geneesmiddelen Vergoedingssysteem*) regulated by the Health Insurance Regulation (*Regeling zorgverzekeringswet*).[113] Whether a medicine qualifies for inclusion in the Reimbursement System list is assessed based on advice from the Scientific Advisory Council (*Wetenschappelijke Adviesraad*) and, where necessary, the Package Advisory Committee (*Adviescommissie Pakket*). Following this assessment, the National Health Care Institute (*Zorginstituut Nederland*) puts out an advice to the Minister of Health, who ultimately decides whether the medicine will be reimburse under basic health insurance in accordance with the insurers preference policy.[114]

Other than extramural, intramural medicines are prescribed by medical specialists in hospitals and are generally reimbursed without separate assessment by the National Healthcare Institute, as long as they meet the legal requirement of 'current scientific and medical practice'.[115] These medicines are not subject to the preference policy. There are three ways in which reimbursement for intramural medicines is obtained. This is either by a substantive assessment done by a health insurance company itself, a joint evaluation between health insurance companies in collaboration with medical specialists through the 'Committee for the

[108] (n 106) 15 and 16.
[109] Mathijs Fijnheer, '*Geneesmidellenprijzen: zijn de regels nog van deze tijd?'* (AKD) https://www.akd.eu/nl/insights/geneesmiddelenprijzen-zijn-de-regels-nog-van-deze-tijd accessed 8 juli 2025.
[110] (n 73) 66.
[111] Lucien Hordkijk, '*Waarom onze dure medicijnen duurder blijven dan de zorgverzekraar wil'* (de Correspondent) https://decorrespondent.nl/4537/waarom-onze-dure-medicijnen-duurder-blijven-dan-de-zorgverzekeraar-wil/1bdff223-1b32-04f0-2671-264c52a2a609 accessed 19 July 2025.
[112] Anton Hagebeek, et. al, 'Fair Pricing of Innovative Medicines: An EHA Position Paper' [2020] 4(5) *HemaSpehere* 1,1-2; Algemene Rekenkamer, *Paardenmiddel of noodverband? Resultaten prijsonderhandelingen geneesmiddelen* (Algemene Rekenkamer 2020) 21; Daan Marselis, 'Geheimzinnigheid troef' (2018) 162 *Nederlands Tijdschrift voor Geneeskunde* https://www.ntvg.nl/artikelen/geheimzinnigheid-troef accessed 27 May 2025.
[113]Zorginstituut Nederland, *Vergoeding van extramurale geneesmiddelen (GVS)* (Zorginstituut Nederland) https://www.zorginstituutnederland.nl/over-ons/werkwijzen-en-procedures/adviseren-over-en-verduidelijken-van-het-basispakket-aan-zorg/beoordeling-van-geneesmiddelen/vergoeding-van-extramurale-geneesmiddelen-gvs accessed 27 May 2025.
[114] Zorginstituut Nederland, *Geneesmiddelen beoordelen: balans tussen zorgvuldigheid en snelheid* (Zorginstituut Nederland) https://www.zorginstituutnederland.nl/over-ons/werkwijzen-en-procedures/adviseren-over-en-verduidelijken-van-het-basispakket-aan-zorg/beoordeling-van-geneesmiddelen/geneesmiddelen-beoordelen-balans-tussen-zorgvuldigheid-en-snelheid accessed 27 May 2025.
[115] Article 10 Health Insurance Act *jo* Article 2.5 Health Insurance Regulation and Article 2.8 Health Insurance Decree.

Assessment of Add-on Medicines of Zorgverzekeraars Nederland' (CieBAG) procedure or by the so-called '*lock'* procedure.[116]

Once a medicine is available for reimbursement, meaning that it has market authorisation and it has been assessed by the relevant institution but not yet has been included in the basic package, healthcare providers (such as hospitals), health insurers, and wholesalers enter a procurement phase. Hospitals bear direct responsibility for procuring medicines for intramural treatment. In general, the determination of purchase prices occurs through negotiations wherein pharmaceutical companies are incentivised to maximise pricing to enhance shareholder value, while hospitals and health insurers, operating within constrained healthcare budgets, seek to minimise expenditure.[117] They negotiate directly with the manufacturer, individually or through purchasing collectives.[118] Insurers often reimburse medicines below list prices, expecting hospitals to secure discounts. Hospitals seek to keep these confidential savings, which can lead to profits or losses depending on reimbursement. This dynamic shapes hospitals' incentives to negotiate prices and fuels ongoing tensions with insurers.[119]

Interestingly, the Dutch government does not operate a uniform definition of 'expensive medicine'. Various institutions apply different thresholds for 'high pricing'. To illustrate, the National Health Care Institution applies a reference value of up to €80.000 per QALY, depending on patient age and disease severity, to assess cost-effectiveness. The Ministry of health considers medicines, in accordance with its 'lock' threshold, 'expensive' if they cost more than €40 million annually in total or more than €50.000 per patient and €10 million annually overall. The Dutch Healthcare Authority (*Nederlandse Zorgauthoriteit*) uses a low threshold of €1.000 per patient per year to classify an add-on medicine 'expensive', particularly for administrative and declaration purposes in hospitals. While this varying threshold framework reflects the diverging institutional responsibilities, it also adds complexity to price regulation and the public debate surrounding medicine prices.

3.2.3 The '*lock'* Procedure

If intramural medicines are expected to have a significant budgetary impact, the Minister of Health may initiate further evaluation and negotiations.[120] A critical management entry tool to that end is the so-called '*lock*' : a temporary reimbursement freeze applied before possible inclusion in the basic package.[121] its purpose is to ensure that new, costly inpatient medicines are only reimbursed if affordable, thereby preventing the displacement of other care.[122] Medicines are placed in the 'lock' if the costs are expected to exceed €20 million, or if a new

[116] *Kamerstukken II,* 2024/25, 29 477, nr. 921, 3; Federatie Medisch Specialisten, *Beoordelingsproces geneesmiddelen vanuit perspectief wetenschappelijke vereniging: Voor het beoordelen van nieuwe geneesmiddelen of nieuwe indicaties voor bestaande geneesmiddelen* (mei 2024) 4-10.
[117] (n 84) 125.
[118] André den Exter, 'De farmapiraat: ondernemerschap in optima forma of een kwalijke zaak?' (Erasmus School of Law, 10 April 2024) https://www.eur.nl/esl/nieuws/de-farmapiraat-ondernemerschap-optima-forma-een-kwalijke-zaak accessed 27 may 2025.
[119] (n 73) 58.
[120] Article 2.4 Health Insurance Decree; Zorginstituut Nederland, 'Sluis voor dure geneesmiddelen' (Zorginstituut Nederland, 2024) https://www.zorginstituutnederland.nl/over-ons/programmas-en-samenwerkingsverbanden/horizonscan-geneesmiddelen/sluis-voor-dure-geneesmiddelen accessed 27 May 2025.
[121] (n 84) 164.
[122] Zorginstituut Nederland, 'Sluis voor dure geneesmiddelen beperkt verdringing andere goede zorg' (Nieuwsbericht, 16 August 2023) https://www.zorginstituutnederland.nl/actueel/nieuws/2023/08/16/sluis-voor-dure-geneesmiddelen-beperkt-verdringing-andere-goede-zorg accessed 27 may 2025.

indication costs over €50,000 per patient and totals at least €10 million annually.[123] As such, the Ministry can selectively manage the admission of high-cost medicines that would otherwise automatically enter the basic package following market authorisation. During this period the National Health Care Institute assess the medicine's effectiveness, necessity cost-effectiveness and compatibility with public health priorities. Based on the advice, the Minister ultimately decides on reimbursement.[124] Even if determined that the medicine is 'excessively' priced' in the sense that there is insufficient cost-effectiveness, the National Healthcare Institute may recommend the Ministry to enter into price negotiations with the manufacturer.[125] While aimed at affordable access, these negotiations may hinder (timely) accessibility or where the pharmaceutical company is unwilling to give an acceptable discount, the medicine will not be included in the basic healthcare package.[126] The Minster holds a relatively weak bargaining position in negotiations concerning innovative medicines that enjoy a monopoly and for which no therapeutic alternatives are anticipated in the near future. If the Minister has successfully negotiated the price and concluded a confidential agreement on appropriate use, the medicine may be released from the 'lock' and included in the basic health insurance package.[127]

The final agreed-upon prices through ministerial negotiations are typically confidential. While this allows governments to secure lower prices, the secrecy leads to inconsistencies nationally and creates significant opacity in international referencing systems.[128] This lack of transparency intended to protect competitive position, limits public scrutiny and undermines efforts to coordinate and evaluate the proportionality of medicine prices at a broader level. This absence of transparency does not only undermine democratic oversight but also perpetuates the power-imbalance between public payers across the EU and pharmaceutical companies.[129]

3.3 The Role of Competition Law and Ensuring Fair Pricing

3.3.1 Competition (law) and the Pharmaceutical Industry

The Dutch legal framework surrounding medicine price regulation, as outlined in the previous section, reveals an imbalance between public purchasers and powerful

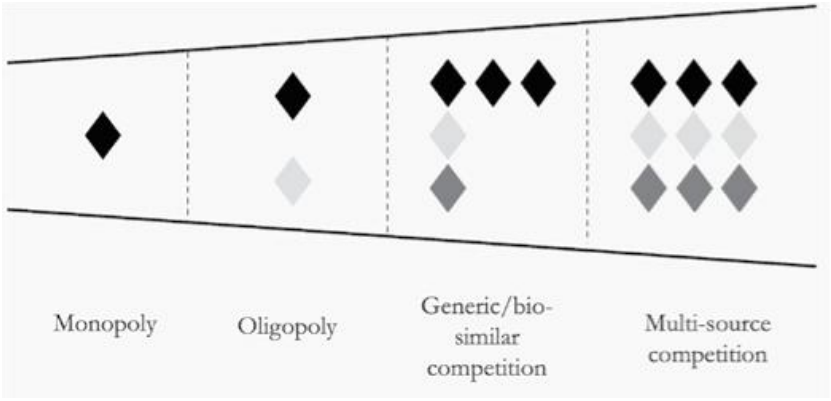
[123] Article 2.4a Health Insurance Decree; Horizonscan Geneesmiddelen, 'Sluis voor dure geneesmiddelen' (Zorginstituut Nederland) https://www.horizonscangeneesmiddelen.nl/over-horizonscan-geneesmiddelen/geneesmiddelsluis accessed 27 may 2025.
[124] Zorginstituut Nederland, 'Beoordeling dure specialistische geneesmiddelen' (Zorginstituut Nederland) https://www.zorginstituutnederland.nl/over-ons/werkwijzen-en-procedures/adviseren-over-en-verduidelijken-van-het-basispakket-aan-zorg/beoordeling-van-geneesmiddelen/beoordeling-dure-specialistische-geneesmiddelen accessed 27 May 2025.
[125] Zorginstituut Nederland, *Beoordelingsprocedure specialistische geneesmiddelen* (11 May 2020) authored by RH Ophuis and FS Diemer, with contributions from Federatie Medisch Specialisten and others, 11.
[126] Maarten van Poll, 'Deze minister houdt poot wél stijf in onderhandelingen over dure geneesmiddelen' (Financieel Dagblad, 16 April 2023) https://fd.nl/samenleving/1473505/deze-minister-houdt-poot-wel-stijf-in-onderhandelingen-over-dure-geneesmiddelen-mqd3caZPDXwN accessed 27 May 2025; Algemene Rekenkamer, *Paardenmiddel of noodverband? Resultaten prijsonderhandelingen geneesmiddelen* (Algemene Rekenkamer 2020).
[127] Jennifer Boer and others, Eindrapport: *Effecten van de sluis: Onderzoek naar de positieve en negatieve effecten van de sluis voor intramurale geneesmiddelen* (*Equalis*, Utrecht, 31 March 2023) 19.
[128] (n 111); Pierluigi Russo, et al., 'Medicine price transparency and confidential managed-entry agreements in Europe: findings from the EURIPID survey' [2021] 125(9) *Health Policy* 1140, 1141; Daan Marselis, 'Geheimzinnigheid troef' (2018) 162 *Nederlands Tijdschrift voor Geneeskunde* https://www.ntvg.nl/artikelen/geheimzinnigheid-troef accessed 27 May 2025.
[129] Redactie Axon Connect, 'Wat maakt een medicijnprijs na geheime onderhandeling aanvaardbaar?' (Axon Healthcare, 6 May 2020) https://www.axonhealthcare.nl/2020/05/06/wat-maakt-een-medicijnprijs-na-geheime-onderhandeling-aanvaardbaar/ accessed 27 May 2025; Katrina Perehudoff, 'European governments should align medicines pricing practice with global transparency norms and legal principles' [2022] 16(1) The *Lancet Regional Health Europe.*

pharmaceutical firms.[130] These dynamics give rise to a broader question of how market power is exercised and regulated in the pharmaceutical market.[131] When national authorities are unable to verify and control the 'fairness' of prices due to *inter alia* opaque price setting, limited insight in other countries' negotiations and regulatory limitations, the risk arises that dominant firms exploit their market position by charging 'excessive' prices.[132] This brings into focus the potential role of competition law as a legal tool to address 'unfair' pricing practices and restore market balance.

Price levels are influenced by various factors, including the degree of market competition but also the generally inelastic demand for medicines. Given the character of the pharmaceutical market, where the purchasing decision-makers, being the prescribing physicians, are not the actors paying for the products. As such, the former may be less sensitive to pricing than customers in other markets.[133] In a competitive market, prices tend to align with the costs, whereas in monopolistic markets encouraged by a patented medicine of which no therapeutic equivalent is available, they may rise to profit-maximising levels.[134] Applying competition law to patented pharmaceutical products, however, may bring risks. The challenge thus lies in determining where legitimate pricing ends and 'excessive' pricing begins.[135]

Competition law and intellectual property (IP) law operate in parallel within pharmaceutical markets. While IP rights incentives innovation by granting temporary exclusivity, they may also limit market entry and suppress price-reducing competition.[136] In some cases, such exclusivity rights-induced, legally granted monopoly cannot be challenged by entries of new competitors, allowing the patentee to charge monopoly prices.[137] While in other instances, competition may still arise, even where exclusivities exist, from therapeutic alternatives using different active ingredients. Nonetheless, true price competition between generics typically only emerges after patent expiry.[138] Each of these four phases of competition pictured below play a role in safeguarding incentives to innovate and are essential to ensure affordability and access. Price reducing market competition requires effective market entry for generics.[139]

[130] Frans van den Houdt, 'Hoogleraar Carin Uyl-de Groot strijdt tégen hoge prijzen en vóór snellere toegang: Het is onethisch dat een goed middel er niet is voor patiënten' [2019] 154(35) *Farmaceutisch Weekblad* 9, 9-10
[131] Mina Hosseini, 'The evolution of EU competition law and policy in the pharmaceutical sector: long-lasting impacts of a pandemic' [2025] 13(1) *Journal of Antitrust Enforcement* 94, 95.
[132] Organisation for Economic Co-operation and Development, ''excessive' Prices in Pharmaceutical Markets: Background Note by the Secretariat' 3 October 2018, DAF/COMP (2018)12.
[133] Claudio Calcagno, Antoine Chapsal and Joshua White, 'Economics of 'excessive' Pricing: An Application to the Pharmaceutical Industry' [2019] 10(3) *Journal of European Competition Law and Practice* 166,169.
[134] (n 132) 5.
[135] Marcel Canoy, Jotte Mulder and Wolf Sauter, 'Introduction' in Wolf Sauter, Marcel Canoy and Jotte Mulder (eds), *EU Competition law and pharmaceuticals* (Edward Elgar Publishing Ltd 2022) 5.
[136] (n 73) 58.
[137] Chris Fonteijn, Ilan Akker and Wolf Sauter, 'Reconciling Competition and IP Law: the case of patented pharmaceuticals and dominance abuse' in Gabriella Muscolo and Mariaanna Tavassi (eds) *The Interplay between Competition Law and Intellectual Property- An international perspective* (Kluwer Law International 2019) 8; Behrang Kianzad, ''excessive' Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law' in K. Mathis and A. Tor (Eds), *New Developments in Competition Law and Economics, Economic Analysis of Law in Legal Scholarships 7,* (Springer Nature Switzerland 2019) 197, 204.
[138] (n 73) 58.
[139] (n 73) 61-62 and 66.



Finding an abuse of dominance is not precluded by the existence of IP rights.[140] In the case of patented medicines, the abusive conduct originates from an asset for which no actual substitute is available on the market, granting the patent holder a dominant position with decisive influence over the relevant market. In such situations, the exclusionary effects of IP protection distort competition as market revenues are allocated based on artificially conferred market power, rather than on competitive market dynamics.[141] While exclusivity rights confer certain economic advantages, they should be balanced against market competitiveness and consumer protection.

Over-enforcement of and stringently regulating the pharmaceutical sector, however, may present challenges, including discouraging investments to innovate.[142] Despite this tension between the objectives of IP law and competition law, which has led to reluctance to enforce competition law to patented pharmaceuticals, an emerging trend towards scrutinising the use of patent rights where pricing practices appear abusive.[143] This gradual rebalancing is exhibited by case law and literature, recognising that patent protection does not grant immunity from competition law. Particularly, where no generic substitute is available and a patent holder abuses its dominance, the inherent friction between the IP law and competition law may not encompass a general impunity from competition law enforcement.

A central and highly contested issue in competition law is whether and how authorities should intervene against prices that are 'too high' or 'excessive' given the practical difficulties in establishing such threshold.[144] It should be recognised that not all 'high' prices are harmful or unlawful from a competition law perspective, considering that some prices may fall after patent expiry due to generic entry or in fact reflect necessary returns on high-risk investments. This represents outcomes aligned with how the patent system is meant to function.[145] While R&D costs may justify some degree of pricing flexibility (see further Section 4.1.2), such justifications cannot shield pharmaceutical firms from competition law scrutiny where prices become abusive and threaten healthcare budgets, displacing more

[140] Ilan Akker and Wolf Sauter, ''excessive' pricing of pharmaceuticals in EU law: balancing competition, innovation and regulation' in Pier Luigi Parcu, Giorgio Monti and Marco Botta (Eds) *The Interaction of Competition Law and Sector Regulation: Emerging trends at the National and EU Level* (Edward Elgar Publishing Ltd 2022) 234, 238.
[141] Behrang Kianzad, ''excessive' Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law' in K. Mathis and A. Tor (Eds), *New Developments in Competition Law and Economics, Economic Analysis of Law in Legal Scholarships 7,* (Springer Nature Switzerland 2019) 197, 209.
[142] Mor Barkhoum, 'Intellectual Property Rights (IPRs), Competition Law and 'excessive' Pricing of Medicines' in Carlos M. Correa and Reto M. Hilty (Eds.) *Implementing Flexibilities Under Intellectual Property* Law (Springer 2022) 277, 294.
[143] Shiju Mazhuvanchery, *Remedies Against 'excessive' Pricing of Patented Medicines Under Competition Law* (Third World Network 2022) 10-12.
[144] Diletta Danieli, ''excessive' pricing in the pharmaceutical industry: adding another string to the bow of EU competition law' [2021] 16(1) 64,66; (n 140) 234.
[145] (n 135) 5.

efficient spending.[146] Furthermore, such claims should not bar enforcement against unlawful pricing, particularly where the risk of unaffordability and inaccessibility of medicine seems more pressing.[147]

3.3.2 'Excessive' and Unfair Prices

In recent years, there has been a notable resurgence of 'excessive' or 'unfair' pricing cases in the EU within the pharmaceutical sector.[148] Such direct exploitation of consumers can occur where price constraints are weak, for instance during the period of exclusivity, where competition is excluded through a patent.[149] Initially competition authorities were hesitant to intervene in pharmaceutical pricing, making 'excessive' pricing cases rare in the sector. However, there has been a notable rise in investigations, particularly targeting off-patent medicines of which prices drastically increased. These included cases against Aspen[150], Pfizer/Flynn[151], Advanz Pharma[152], Auden/Actavis[153] and CD Pharma.[154] More recently, authorities have extended their scrutiny to pricing practices involving patented or exclusivity protected medicines.[155]

Competition law plays increasingly important role, where 'excessive' medicine prices risk undermining access to healthcare. To ensure that pharmaceutical companies that have been admitted to the medicines market comply with the competition law under the Dutch Competition Act (*Mededingingswet*), the independent Authority for Consumers and Markets (ACM) monitors the market and, when it receives indications of anti-competitive practices, initiates an investigation. Article 24 of the Competition Act, prohibits companies from abusing market power.[156] At the EU level, Article 102 on the Treaty on the Functioning of the European Union (TFEU) prohibits abuses of dominance, which may include the direct or indirect imposition of unfair prices.[157]

EU competition case law established that a dominant company's pricing is considered unlawful only if it is both 'excessive' and 'unfair'.[158] Essential to establishing abuse of dominance of a pharmaceutical company in the form of an 'excessive' price, is defining the

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[146] Chris Fonteijn, Ilan Akker and Wolf Sauter, 'Reconciling Competition and IP Law: the case of patented pharmaceuticals and dominance abuse' in Gabriella Muscolo and Mariaanna Tavassi (eds) *The Interplay between Competition Law and Intellectual Property- An international perspective* (Kluwer Law International 2019)13 and Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies- Should Competition law Intervene?' [2020] 51(9) *IIC Int Rev Ind Prop Copyr Law* 1062,1064.

[147] Jaquelyn D. Veraldi, ''excessive' Pricing in Pharmaceuticals under Article 102 TFEU' (2023) *European Journal of Risk Regulation* 1,19-20.

[148] Claudio Calcano, Antoine Chapsal and Joshua White, 'Economics of 'excessive' Pricing: An Application to the Pharmaceutical Industry' [2019] 10(3) *Journal of European Competition Law and Practice* 166,167.

[149] (n 145) 10; (n 146) 12.

[150] *Aspen Italy* [2018], L'Autoritá Garante della Concorrenza e del Mercato, Case A524, 27940/2018 and *Aspen EU* (Case AT.40394) Commission Decision [2021] 724 final.

[151] *Pfizer/Flynn* [2018], Competition Appeal Tribunal, 1275/1/12/17 and 1276/1/12/17, [2018] CAT 11.

[152] *Advanz Pharma Corp v Competition and Markets Authority* [2023] CAT 12, 1422/1/12/21 (Competition Appeal Tribunal).

[153] *Auden/Actavis v Competition and Markets Authority*, 'Hydrocortisone Tablets: 'excessive' and Unfair Pricing and Anti-competitive Agreements' (CMA, Case 50277, 15 July 2021).

[154] *CD Pharma v Competition Council*, Sag BS-3038/2019-SHR (Maritime and Commercial Court, Denmark, 2 March 2020).

[155] 'Decision to fine Leadiant for 'excessive' price of CDCA drug' (*ACM*, 19 July 2021) https://www.acm.nl/en/publications/decision-fine-leadiant-'excessive'-price-cdca-drug accessed 9 July 2025 and Behrang Kianzad, 'Towards Fair Pricing of Medicines? Lessons from the European Commission's Aspen Decision' (2022) 6(1) European Health and Pharmaceutical Law Review 3.

[156] Articles 24 and 2 Dutch Competition Act.

[157] Consolidated version of the Treaty on the Functioning of the European Union (TFEU) [2012] OJ C 236, Article 102 sub a.

[158] (n 148) 166.

relevant market for the medicine at issue. In the context of 'excessive' pricing allegations, the European Commission and National Competition Authorities, have generally defined the markets narrowly, increasing the possibility of finding dominance.[159] Generally, the narrower the relevant market, meaning the fewer substitutes available for a medicine (such as for patented medicines), the more likely dominance and 'excessive' pricing will be established.[160]

In *United Brands*, the Court of Justice clarified that a price is 'excessive' when it bears *no reasonable relation to the economic value of the product*[161], and may be 'unfair' either in itself or in comparison to alternatives.[162] Although neither 'excessiveness' nor 'unfairness' has a precise economic definition, the first limb of this two-step test establishes "*whether the difference between the costs actually incurred and the price actually charged is 'excessive'*". If this question is answered affirmatively, the second limb of the test establishes "*whether a price has been imposed which is either unfair in itself*''.[163] Each step essential to finding a violation. However, again, the specific characteristics of the pharmaceutical sector, such as high R&D costs and market dynamics, can complicate this analysis.[164] Namely, attracting and incentivising appropriate investments in the pharmaceutical industry requires high levels of profitability on successful products.[165] Therefore, 'high' prices cannot inherently be deemed 'excessive'; competition authorities should account for innovation incentives by including the *ex-ante* probability of success in the *United Brands* test.

3.3.3 A Dutch example Involving Regulatory Exclusivity

The two-step approach, established in the *United Brands* case, was successfully applied by Dutch National Competition Authorities, in the *Leadiant* case.[166] The ACM fined the pharmaceutical company for abusing its dominant position by charging and collecting an 'excessive' price for its medicine in the Netherlands.[167] Leadiant's internal rate of return vastly exceeded reasonable benchmarks and that the high prices were unfair, given the low R&D costs, limited commercial risk, and absence of therapeutic innovation or added value compared to its predecessor.[168] The district court of Rotterdam upheld this fine, reaffirming the ACM's assessment of the 'excessiveness and unfairness of Leadiant's price.[169] This case illustrates that 'excessive' pricing assessments require not only economic analysis but also a careful consideration of the broader context, including the nature of the product and its added value. More importantly, this marked the first instance in which a medicine with regulatory exclusivity was found to be 'excessively priced in any jurisdiction.[170]

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[159] Georgios Zacharodimos, 'Growing EU and UK regulatory interest in alleged 'excessive' pricing' (Global Competition Review, 11 October 2024) https://globalcompetitionreview.com/guide/guide-life-sciences/third-edition/article/growing-eu-and-uk-regulatory-interest-in-alleged-'excessive'-pricing Accessed 27 May 2025.
[160] (n 148) 168.
[161] United Brands v Commission of the European Communities [1978], Case 27/76 ('United Brands Judgment') para 9, 250.
[162] (n 161) para 248 and 252-253.
[163] (n 161) 251 and 252
[164] (n 147 2.
[165] (n 148) 170.
[166] *Leadiant Netherlands*, ACM Decision of 19 July 2021.
[167] 'Decision to fine Leadiant for 'excessive' price of CDCA drug' (*ACM*, 19 July 2021) https://www.acm.nl/en/publications/decision-fine-leadiant-'excessive'-price-cdca-drug accessed 9 July 2025.
[168] Murco Mijnlief, 'ACM imposes fine on drug manufacturer Leadiant for CDCA's 'excessive' price' (*ACM* 19 July 2021) https://www.acm.nl/en/publications/acm-imposes-fine-drug-manufacturer-leadiant-cdcas-'excessive'-price accessed 27 May 2025.
[169] District Court of Rotterdam upholds ACM fine on Leadiant for 'excessive' pricing of CDCA, case no ACM/23/185206, 13 February 2025 https://www.acm.nl/nl/zaak/acm/23/185206 Accessed 9 July 2025.
[170] Ilan Akker and Wolf Sauter, ''excessive' pricing of pharmaceuticals in EU law: balancing competition, innovation and regulation' in Pier Luigi Parcu, Giorgio Monti and Marco Botta (Eds) *The Interaction of Competition Law and Sector Regulation: Emerging trends at the National and EU Level* (Edward Elgar Publishing Ltd 2022) 234, 245-46.

3.4 Conclusion

The Dutch pricing regulation strives to balance cost containment with the need to safeguard access to high-priced medicines without displacing other essential healthcare services.[171] This goal may be undermined by a persistent power imbalance between pharmaceutical companies, ambiguously set high prices, and public health institutions, operating under tight budget constraints.[172] The pharmaceutical market is grounded in free-market principles, yet it does not function accordingly in practice. In functioning free market, prices are shaped by open competition and informed consumer demand. By contrast, pharmaceutical markets are heavily regulated and legislated, may offer limited therapeutic substitutes, involve demand that is largely price inelastic and engage in pricing decisions that are disconnected from consumers.[173] Additionally, patents and exclusivity protections legally shield originator companies form competition, enabling monopolistic pricing without the usual market checks. Rather than responding to public health needs, pharmaceutical companies invest in medicines with the highest return of investment. Ideally, in a free market, companies would invest where health gains are the health gains are the greatest. However, in reality, they invest where profit is the greatest, leaving critical public health needs unmet.[174]

Additionally, exists a structural imbalance between the government, hospitals and insurers and pharmaceutical companies. The former are subject to a duty of care towards its population, a responsibility not borne by private firms, which results in a pronounced dependency on the demand side. While such asymmetry is not inherently problematic, it requires a corresponding level of social responsibility on the supply side.[175]

Despite growing calls for pricing transparency, pharmaceutical companies remain reluctant to disclose cost structures.[176] The problem may be particularly acute for patent-induced monopolised medicines, lacking therapeutic alternatives. In such cases, limited competition and patent protections grant pharmaceutical companies disproportionate pricing power, weakening the dependent government's negotiating positions. [177] Furthermore, the 'lock' mechanism, while providing a tool for negotiation which has effectively reduced costs, it may delay access for patients and where price negotiations fail, even prevent the medicine from being reimbursed.[178] Notably, this issue is not limited to newly patented medicines; it also

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[171] *Kamerstukken II*, 2023/24, 29 477, nr. 883, 2.
[172] Robert van den Broek, 'Peperdure medicijnen zijn het resultaat van een verstoord machtsevenwicht' (2021) *Zorginstituut magazine* 1, 19-20;
[173] Frederick M. Abott, ''excessive' Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health' [2016] (6) *UC IRVINE Law Review* 280, 300-302.
[174] Ruben Mersch, 'Als we medicijnen aan de markt overlaten, kan een gewone infectie weer dodelijk worden' (*De Correspondent,* 1 May 2019) https://decorrespondent.nl/9420/als-we-medicijnen-aan-de-markt-overlaten-kan-een-gewone-infectie-weer-dodelijk-worden/fc6f9900-836f-0820-3b24-7cd9e130f0ef acccessed 9 July 2025.
[175] Erasmus University Rotterdam, 'Payback-systeem zorgt voor evenwicht tijdens sluisperiode' (Erasmus University Rotterdam 2024) h https://www.eur.nl/eshpm/nieuws/payback-systeem-zorgt-voor-evenwicht-tijdens-sluisperiode accessed 27 May 2025.
[176] (n 84) 125.
[177] (n 84) 9 ;Erasmus University Rotterdam, 'Payback-systeem zorgt voor evenwicht tijdens sluisperiode' (Erasmus University Rotterdam 2024) hhttps://www.eur.nl/eshpm/nieuws/payback-systeem-zorgt-voor-evenwicht-tijdens-sluisperiode accessed 27 May 2025; Ellen F.M. 't Hoen, Pascale Boulet and Brook K. Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: *A proposal for greater coherence in European pharmaceutical legislation*' [2017] 10(19) *Joural of Pharmaceutical Policy and Practice* 1,1-2.
[178]Charlotte H.C. Bomhof, et l., 'Ethics of access to newly approved expensive medical treatments: multi-stakeholder dialogue in a publicly funded healthcare system', [2024] 14(1) *Frontiers in Pharmacology* 1,1,8-9; Erasmus University Rotterdam, 'Payback-systeem zorgt voor evenwicht tijdens sluisperiode' (Erasmus University Rotterdam 2024) https://www.eur.nl/eshpm/nieuws/payback-systeem-zorgt-voor-evenwicht-tijdens-sluisperiode#:~:text=Meer%20evenwicht,maatschappelijk%20aanvaardbare%20prijs%20wordt%20vergroot. 27 May 2025; CZ en NVMO, 'Medicijnen goed beschikbaar tijdens sluisprocedure' Medische Oncologie (25 October 2021) https://medischeoncologie.nl/artikelen/2021/oktober/editie-8/medicijnen-goed-beschikbaar-tijdens-sluisprocedure accessed

applies to medicines that have been under patent for a longer period of time as well as those that are no longer under patent. In recent years, pharmaceutical companies have generally increased the prices of medicines by hundreds of percent while refusing to disclose the resulting profits.[179] However, for the purpose of this research focus will be on patented medicines.

In cases of abuse of dominance by 'excessive' pricing of a medicine under patent protection or enjoying regulatory exclusivity, it is not the IP right itself that is abused to strengthen a dominant position; rather, the dominant position, underpinned by IP rights, is used to directly exploit consumers.[180] In this context, competition law enforcement may serve as an *ex-post* corrective tool to discipline pharmaceutical companies for charging 'excessive' and 'unfair' prices. The extent of the ACM's competence to remedy violations of competition law may offer a promising route in countering the adverse effects of exclusive market power. For instance, compulsory licensing may exert downward pressure on the price, enabling generic entry to restore competitive pressure without nullifying the patent.

27 May 2025; Féline E.V.Scheijmans, et al., 'Views and op of the general public about the reimbursement of expensive medicines in the Netherlands' [2025] 20(1) PLOS one 1,13; Luc Derijks, Menne Scherpenzeel and Mark Löwenberg, Individuele patiënten de dupe van huidige sluisprocedure' (2 May 2024 *Medisch Contact*) https://www.medischcontact.nl/actueel/laatste-nieuws/artikel/individuele-patient-de-dupe-van-huidige-sluisprocedure accessed 27 May 2025.

[179] See *inter alia* (n 150), (n 151), (n 152), (n 153), (n 154) and European Commission, "Pharmaceutical Strategy for Europe - COM(2020) 761 Final," November 25, 2020; European Union, "'excessive' Pricing in Pharmaceutical Markets - Note by the European Union - OECD Roundtable on 'excessive' Pharmaceutical Pricing - DAF/COMP/WD(2018)112," November 23, 2018.

[180] (n 146) 8; (n 170) 238.

Chapter 4: Intellectual Property Law, Generic Competition and the Role of Compulsory Licensing

This Chapter examines the interplay between intellectual property rights, generic competition, the right to health and the use of compulsory licensing under TRIPS, EU law and Dutch law. It explores how patents on medicines can both incentivise innovation and restrict access through monopoly pricing and considers whether compulsory licensing offers a lawful and effective remedy to improve affordability. Considering increasing concern over 'excessive' pricing, particular attention is given to the Dutch legal framework and the potential of invoking the 'public interest' clause or competition law to justify compulsory licensing. To determine whether compulsory licensing could be a viable strategy to enhance access to medicines in the Netherlands, especially when voluntary price negotiations fail.

4.1 Intellectual Property Protection under TRIPS and Access to Medicines

4.1.1 Pharmaceutical Companies, Intellectual Property Rights and the Right to Health

Policies affecting access to medical products, spanning trade, intellectual property (IP), health, and human rights have developed independently, each with distinct goals and timelines. These frameworks are governed by separate legal and regulatory systems, often imposing obligations that do not necessarily align.[181] Trade and IP regimes were not initially intended to safeguard the right to health, just as human rights frameworks were not designed to promote trade. As a result, policy incoherence can emerge when legitimate economic, social, or political priorities clash with health-related human rights.[182] As previously discussed, upholding the right to health and, by extension, access to medicines, requires deliberate, coordinated governments action across these domains.[183]

Although IP law and human rights law have traditionally evolved on separate tracks, their intersection has been a subject of interest, particularly in the context of access to medicines.[184] Patent protection for (novel) medicines, governed at the national, European or international level, covering both processes and products, can significantly affect access to essential treatments.[185] As discussed in Chapter 3, the legal monopoly limits opportunities for generic production, possibly leading dominance and consequent higher pricing, while simultaneously reinforcing dependence.[186] As such, patented medicines may become unaffordable and inaccessible, obstructing protection of the right to health.[187]

High medicine pricing creates a pressing global access challenge, where patenting has concentrated pricing power in the pharmaceutical industry, limiting government control and restricting access for those in need.[188] This highlights an inherent, fundamental conflict of government obligations under IP law and human rights law, requiring the protection of

[181] Phillipe Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health' [2003] 79(1) *International Affairs* 139, 139.
[182] United Nations, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (2016) 16 http://www.unsgaccessmeds.org/final-report accessed 27 May 2025.
[183] Article 12 ICESCR And General Comment 14.
[184] (n 181) 148.
[185] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) annex 1C of the Marrakesh Agreement Establishing the World Trade Organization 1869 UNTS 299, 33 ILM 1197 (1994) Article 27, Article 2 and 9 Dutch Patent Act 1995, Article 5 A (2) Paris Convention.
[186] (n 181) 141.
[187] (n 181) 151.
[188] Katrina Perehudoff and Ellen 't Hoen, 'Human Rights and intellectual property for universal access to new essential medicines' in Z. Barbar (Eds), *Equitable Access to High-Cost Pharmaceuticals* (Elsevier 2018) 75.

affordable access to medicines, while incentivising research and development.[189] Innovation forms the backbone of the pharmaceutical industry, in which private companies play a key role for the research and development of medicines. Patents related to pharmaceutical medicine and methods of using this form an important part in the economic success of pharmaceutical companies and the industry as a whole.[190] To justify and recover the efforts and substantial investments made to gain market authorisation, pharmaceutical companies rely heavily on IP rights. This protection is regarded as essential to recoup the research and development costs and should stimulate future innovation.[191] Protection of IP safeguards the rights associated with the development of ideas, concepts and inventions and enables the rights holder to benefit economically from their invention, making it one of pharmaceutical companies' most valuable resource.[192]

The establishment of the World Trade Organisation and the subsequent harmonisation of IP law through the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) obliges its Member States to provide a minimum level of protection for IP rights.[193] The Agreement's objective to protect and enforce IP rights to contribute to the promotion of technological innovation (…), to the mutual advantage of producers and users thereof in a manner enabling social and economic welfare, and balancing rights and obligations, establishes a connection with social rights.[194] Article 8 TRIPS is particularly pertinent to the ensuring discussion on human rights and anti-competitive practices, as it provides that Member States may adopt laws aligned with the TRIPS Agreement, to protect *inter alia* public health and promote the public interest or to prevent IP abuse.[195] In this respect, government intervention to protect the right to medicine becomes relevant. Specifically, Article 40 TRIPS, which acknowledges that certain licensing or protection practices related to IP law may restrict competition, obstruct trade and hinder the transfer and dissemination of technology. Consequently, the Article allows Member States to identify such practices in their laws and adopt appropriate measures to prevent or regulate abuses.[196]

4.1.2 The Rationale Behind Patents on Medicines: the Tension between Competition and Innovation

Patents apply broadly to innovative products but are particularly prevalent in the fields of chemistry, pharmaceuticals and technology. Medicines, pharmaceutical products and processes, are patentable insofar as they qualify as inventions, provided they meet the criteria of novelty, inventive step, and industrial applicability.[197] A patent grants legal rights to the inventor or creator to protect their invention or creation for a period of 20 years, conferring an exclusive right to wholly exploit this invention for that given period and prevent others from doing so without their consent.[198] This legally sanctioned market exclusivity constitutes a derogation from the principle of free trade but can be justified following its underlying rationale: the need to reward the inventor and the consequent incentive to innovate. Its

[189] (n 188).
[190] Denise L. Mayfield, 'Medical Patents and How New Instruments or Medications might be patented' [2016] 113(6) *Missouri Medicine* 456, 459.
[191] Chandra Nath Saha and Sanjib Bhattacharya, 'Intellectual property rights: An overview and implications in pharmaceutical industry' [2011] 2(2) *Journal of Advanced Pharmaceutical Technology and Research* 88, 91.
[192] Gorik Ooms and Johanna Hanefeld, 'Threat of compulsory licences could increase access to essential medicines' [2019] 365(1) *BJM* 1, 1.
[193] (n 185) Article 1-3.
[194] (n 185) Article 7.
[195] (n 185) Article 8.
[196] (n 185) Article 40.
[197] (n 185) Article 27.
[198] (n 191) and (n 185) Article 28 (1) (a) and (1) (b) and Article 30

limited duration combined with the obligation to disclose invention, ensures that society at large can benefit from the scientific advancement.[199]

Notably, patents have the potential to facilitate availability of medicine, by rewarding and further incentivising innovation, as well as hinder access to them.[200] As outlined in Chapter 3, IP rights may restrict market competition by granting exclusive control over patented products, limiting price pressure and enabling monopoly pricing. For some medicines, this exclusivity blocks market entry, fostering temporary dominance that affects both innovation and affordability.[201] However, this freedom is not absolute and should be exercised within the bounds of competition law and market principles to prevent anti-competitive practices.[202]

The substantial costs associated with pharmaceutical research and development, result in a corresponding significance of the financial stakes for companies developing new technologies.[203] To guarantee a return of investment, pharmaceutical companies protect the exclusive exploitation of the invention through patenting. Namely, without a patent or once patents of brand-name medicines expire, others may develop generics or therapeutic equivalents of the medicine.[204] Again, market entry of generic competitors fosters price competition, through which it may essentially serve as a pivotal cost-containment-tool, helping reduce public healthcare expenditures and enhancing access to affordable medicine.[205] However, generic price competition does not automatically occur once the exclusivity expires. For generics to enter the market, conditions must be sufficiently attractive to incentivise entry at the end of the patent term.[206]

Notably, the TRIPS Agreement acknowledges that the rights of patent holders must be balanced with their obligations, affirming that limitations on IP rights are an essential part of the system. The Agreement explicitly permits states to implement measures necessary to safeguard public health and advance the public interest, particularly in sectors critical to their socio-economic and technological development.[207]

4.2 Compulsory Licensing under the TRIPS Agreement

The protection of IP has been a subject to controversy specifically where they effectively limit generic competition and hinder access to affordable medicines.[208] While the TRIPS Agreement establishes global minimum standards for patent protection, it also includes a range of safeguards, known as TRIPS 'flexibilities'. Member States may invoke such exceptions to the exclusive rights conferred by a patent to pursue a legitimate third-party

[199] (n 181) 140 and (n 73) 58.
[200] (n 181) 143.
[201] (n 73) 58; (n 142) 284 and Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies- Should competition law intervene? [2020] 51(1) *ICC Int Rev Ind Prop Copyr Law* 1062, 1066.
[202] (n 142) 284-285.
[203] (n 192).
[204] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies- Should competition law intervene? [2020] 51(1) *ICC Int Rev Ind Prop Copyr Law* 1062, 1070; Lucia Gozzo, Filippo Caraci and Filippo Drago, 'Bioequivalence, Drugs with Narrow Therapeutic Index and the Phenomenon of Biocreep: A Critical Analysis of the System for Generic Substitution' [2022] 10(8) *Healthcare MDPI* 1039, 1039.
[205] Lucia Gozzo, Filippo Caraci and Filippo Drago, 'Bioequivalence, Drugs with Narrow Therapeutic Index and the Phenomenon of Biocreep: A Critical Analysis of the System for Generic Substitution' [2022] 10(8) *Healthcare MDPI* 1039, 1039 and (n 181) 141.
[206] (n 142) 288.
[207] (n 185) Article 8 and (n 181) 145.
[208] 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) *Milbank Quarterly* 1280, 1280.

interest.[209] By incorporating these into domestic law, States can *inter alia* respond to public health needs.[210]

4.2.1 Compulsory Licensing under the TRIPS Agreement

Article 31 of the TRIPS Agreement enables a competent government authority to license the use of a patented invention to a third-party or government agency without the consent of the patent holder.[211] Such 'compulsory licences' or 'non-voluntary licences' limit the exclusive rights normally granted by a patent, reducing the patent holder's private power .[212] When used directly by the government, this is known as 'government use' or 'public non-commercial use'; often applied in the context of medicine procurement.[213] This process inherently involves three key stakeholders: the government that authorises the licence; a third-party or a government agency permitted to import, manufacture, use or distribute the originator medicine; and the patent holder, typically a research-based pharmaceutical company, who is entitled to receive compensation in the form of royalties.[214]

Importantly, the TRIPS Agreement grants governments interpretative discretion to determine the grounds on which a compulsory licence may be issued insofar as *such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*.[215] Grounds for issuing may for instance include 'national emergencies', 'other circumstances of extreme urgency', 'public non-commercial use', or against 'anti-competitive' practices.[216]

Following Article 8 (2) TRIPS, appropriate measures may be adopted to prevent abuses of IP rights holders. The Article does not define the 'abuse' of an IP right and whether this should be interpreted following principles of competition law, yet when read in conjunction with Articles 7, 30, 31(k), and 40 (2), the Agreement provides a coherent legal framework for restricting IP rights in cases of anti-competitive conduct, in order to protect public health and remedy market distortions detrimental to competition and consumer welfare.[217] The notion 'anti-competitive practices' remains broad and open to interpretation.[218] Compared to competition law, this undefined broad notion under the TRIPS Agreement offers a rather

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[209] (n 185) Article 30 *jo* Article 8.
[210] (n 185) Article 31 *jo* Article 8; Carlos M. Correa, '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), 1,3.
[211] (n 185) Article 31Article
[212] (n 185) Preamble, Article 27 and 30 and Article 31.
[213] **W**orld Trade Organization, 'TRIPS and Pharmaceutical Patents: Obligations and Exceptions – *Under TRIPS, what are member governments' obligations on pharmaceutical patents?*' (WTO, March 2006) http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#art31 accessed 27 May 2025.
[214] Eduardo Urias and Shayma V Ramani, 'Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence' [202] 3(4) *Journal of International Business Policy* 367, 369.
[215] (n 185) Article 30 and Article 31.
[216] **W**orld Trade Organization, 'TRIPS and Pharmaceutical Patents: Obligations and Exceptions – *Under TRIPS, what are member governments' obligations on pharmaceutical patents?*' (WTO, March 2006) http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#art31 accessed 27 May 2025; Patricia Cappuyns and Jozefien Van Herpe, 'A Licence! Recent developments concerning compulsory licensing for patented pharmaceuticals in the European Union' [2018] 53(2) *Journal of the Licensing Executives Society* 184, 184; Muhammad Zaheer Abbas, 'COVID-19 and the Issue of Affordable Access to Innovative Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option' in Klaus Mathis and Avishalom Tor (eds.), *Law and Economics of the Coronavirus Crisis* (Springer Nature, 2022) 265,265-266.
[217] (n 185) Article 7, Article 8(2), Article 31(k) and Article 40(2) and (n 141) 203.
[218] Xiuqin Lin,' Prior Negotiation and Renumeration for Patent Compulsory Licensing: Practice, Problem and Proposal' in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2105) 165,178.

flexible approach, notably because the issuance does not strictly require dominance nor does it depend on finding abusive conduct within the meaning of competition law.[219]

Alternatively, in cases where a patent holder abuses its dominant market position; for example by refusing to voluntarily license a critical medicine or charging 'excessive' prices, it may be argued that Articles 31 (k) and 40 TRIPS recognise that abusive practices may be remedied through competition law, which is not bound by the same conditions set out by Article 31 TRIPS.[220] Article 40 (1) and (2) TRIPS provide that Member States are free to include in their national legislation what would constitute an abuse of IP rights having an adverse effect on competition as well as laying down measures preventing or controlling such practices.[221] Following this reasoning, it can be argued that national competition law provides an avenue to issue compulsory licences.

The absence of specific restrictions on the grounds for which compulsory licences may be issued, allows member states considerable flexibility to interpret Article 31 and define justifications.[222] Despite the discretion granted regarding the grounds, compulsory licensing is permitted only if specific strict conditions listed in Article 31(a)–(i) are met.

A fundamental requirement is for each application to be assessed on its individual merits.[223] This entails governments are not permitted to issue general or blanket authorisation for compulsory licences covering specific companies. Rather, every application must undergo a case-by-case evaluation to determine whether the statutory criteria are satisfied.[224] Furthermore, prior to non-voluntary licensing the prospective licensee must have made genuine efforts to negotiate a voluntary licence with the rights holder on reasonable commercial terms, reflecting the economic value of the use.[225] This condition does not apply when the licence is issued to address anti-competitive practices.[226] Notably, this requirement may also be waived in situations of national emergency, extreme urgency or for public non-commercial use. Member States have the authority to define what qualifies as a national emergency or other circumstances of extreme urgency or competition violation.[227] While these situations are not preconditions to issue a compulsory licence, removing the obligation to first seek a voluntary licence may simplify the process.[228] Additionally, any compulsory licence must be limited in both scope and duration and terminated once the conditions that justified its issuance no longer exist and are unlikely to reoccur.[229] Additional safeguards include the non-transferability and non-exclusivity of the licence, meaning the licensee cannot prevent the patent holder, as well any third-party the patent-holder allows, from also producing the patented product.[230] The Article, however, limits compulsory licences to domestic use only, preventing countries without manufacturing capacity from importing

[219] (n 218) 178; Quentin B. Schäfer, 'Reconsidering the Limits of EU Competition Law on the IP-Competition Interface' [2024] 15(3) *Journal of European Competition Law &Practice* 188,193.
[220] (n 219) 193-194.
[221] (n 185) Article 40.
[222] (n 185) Article 31 *jo* Article 30 and Article 8; (n 181) 147.
[223] (n 185) Article 31 (a).
[224] (n 185) Article 31 (j).
[225] (n 185) Article 31 31 (b).
[226] (n 185) Article 31 (b) and (k).
[227] (n 185) Article 31 (b) and (k).
[228] Ellen 't Hoen, Pascale Boulet and Brook Baker, 'Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European Pharmaceutical legislation' [2017] 10(19) *Journal of Pharmaceutical Policy and Practice* 1, 7.
[229] (n 185) Article 31 (c).
[230] (n 185) Article 31 (d) and (e).

generics produced under compulsory licences in other countries.[231] Finally, decisions taken regarding compulsory licences are subject to judicial review.[232]

4.2.2 The Doha Declaration

The Doha Declaration explicitly addressed the specific controversies concerning the interface between access to essential medicines and IP protection and explicitly emphasised the applicability of compulsory licences to medicines, particularly in the context of the HIV/AIDS epidemic and the subsequent COVID-19 pandemic.[233] Importantly, this Declaration did not amend the TRIPS Agreement; rather, it sought to clarify acceptable interpretations of its provisions by affirming that the existence of patent rights, should not prevent Member States from taking measures to protect public health.[234] By enlisting compulsory licensing as a tool to produce or purchase lower-priced generics, it marked a first step in recognising that IP rules could not be treated in isolation from pressing global health challenges.[235] It acknowledges the dual role of IP rights in driving pharmaceutical innovation, while also raising concerns about its impact on the affordability of medicines for least-developed nations.[236] Moreover, it bolsters the legal and political position of developing countries and least-developed countries seeking to employ the mechanism.[237] In response, the WTO General Council amended the TRIPS Agreement by initially implemented a temporary waiver for the use of compulsory licences for export purposes, which was later incorporated permanently through Article 31*bis*.[238] The mechanism allows waiving the requirement that compulsory licencing is utilised predominantly for the supply of the domestic market.[239]

While the Doha Declaration played a pivotal role in framing the access to medicine as a legitimate public health concern within international trade law, its practical relevance is limited in developed countries, such as the Netherlands. The Declaration is primarily aimed at shielding developing and least-developed countries from political and legal pressures, which are largely absent in the context of developed countries. Explicating the Declaration is relevant as it constitutes a crucial interpretative milestone for global health equity; specifically, access to affordable medicines. However, it does not provide new tools or essential legal justifications for compulsory licensing in developed, high-income countries.

4.3 Compulsory Licensing at European Union Level and in the Netherlands

4.3.1 Compulsory Licensing at European Union Level

Although compulsory licensing has drawn significant attention as a mechanism aimed at addressing the needs of developing countries, it has been gaining increasing interest from

[231] (n 185) Article 31 (f).
[232] (n 185) Article 31 (i).
[233] World Trade Organization, **'**Declaration on the TRIPS Agreement and Public Health' (20 November 2001); Reed Beal and Randall Kuhn, 'trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' [2012] 9(1) *PloS Medicine* 1,2.
[234] (n 181) 153.
[235] Ellen 't Hoen, Jaqueline Veraldi, Brigit Toebes and Hans Hogerziel, 'Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001-2016' [2018] 96(3) *Bulletin World Health Organization* 185,185.
[236] *Ibid.*
[237] (n 192) 2; Blanka Szupera, 'The Renaissance of compulsory licences (in the pharmaceutical sector) (2023) *Essays of faculty of Law Yearbook University of Pécs, Yearbook of 2021-2022* 191,194; Ellen F.M. 't Hoen, 'Practical implementation of the Doha Declaration on TRIPS and Public Health' in Ellen F.M. 't Hoen (Eds.), *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), 19,30.

developed countries as they explore ways to leverage the system for their own benefit.[240] Its implementation in the Netherlands, as in other EU Member States, takes place within a broader framework of international instruments and European Union level Regulation and Directives. Notably, the EU is a Member of the WTO; consequently, binding itself as well as its Member States to the TRIPS Agreement.[241]

Various instruments governing enhanced cooperation and unity in the area of patent protection, such as Regulation (EU) No 1257/2012 and the 2023 unitary patent system, have introduced a degree harmonisation to the EU patent law, by offering a single legal title that provides uniform protection across all participating Member States.[242] However, neither the Agreement on a Unified Patent System nor Regulation (EU) No 1257/2012 provides substantive rules on compulsory licensing, aside from a general recital noting that compulsory licences for unitary patents should be governed by the national laws of participating Member States.[243] This fragmented approach to compulsory licensing undermines the very purpose of the unitary patent system to *only be limited, transferred or revoked, or lapse, in respect of all the participating Member States* as reiterated in Regulation (EU) No 1257/2012.[244] Namely, if compulsory licences are granted in one Member State but denied or granted under different conditions in another, the supposedly unitary effect of the patent is eroded.[245]

Noteworthy, a specific Regulation (Regulation (EC) No 816/2006) was adopted to establish a compulsory licensing procedure in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products exports to countries with public health problems lacking manufacturing capacity.[246] This Regulation aims to ensure uniform implementation of the Doha Declaration across EU Member States and prescribes to be primarily intended in the context of public health emergencies in low- and middle-income countries.[247] It's limited scope for applications to export-oriented licensing, specifically excluding the use for domestic purposes, precludes the establishment of a comprehensive EU framework for compulsory licensing intended for developed

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[240] (n 228) and Lindor Qunaj, Anna Kaltenoack and Peter B. Bach, 'Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis' [2022] 1001(1) *Milbank Quarterly* 284,286.

[241] European Commission, 'The EU and the WTO' (EU Trade) https://policy.trade.ec.europa.eu/enforcement-and-protection/protecting-eu-creations-inventions-and-designs_en#:~:text=Multilateral%20agreements%3A%20The%20EU%20is,Intellectual%20Property%20Rights%20(TRIPS) accessed 27 May 2025.

[242] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1; European Commission, 'The unitary patent system' (Internal Market, Industry, Entrepreneurship and SMEs, 1 June 2023) https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent-system_en accessed 27 May 2025.

[243] (n 242) para 10.

[244] (n 242) Preamble and para 7; Lamping M and others, Revisiting the Framework for Compulsory Licensing of Patents in the European Union (Max Planck Institute for Innovation & Competition Research Paper No 23-07, 2 March 2023) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381959 accessed 1 June 2025.

[245] Reto M. Hilty and others, The Unitary Patent Package: Twelve Reasons for Concern (Max Planck Institute for Intellectual Property & Competition Law Research Paper No 12-12, 17 October 2012) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2169254accessed 1 June 2025; Lamping M and others, *Revisiting the Framework for Compulsory Licensing of Patents in the European Union* (Max Planck Institute for Innovation & Competition Research Paper No 23-07, 2 March 2023) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381959 accessed 1 June 2025.

[246] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on the granting of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2006] OJ L157/1 Preamble paragraph 1-3 and Article 1.

[247] (n 246) Article 4.

countries facing barriers to medicine access.[248] Thus, compulsory licensing is not harmonised in the sense that there exists no EU-wide compulsory licence apparatus. This fragmentation may cause ineffectiveness in the application of compulsory licenses across the EU.

Notably, in April 2023, the European Commission published a proposal initiating the establishment of a Union-wide compulsory licensing mechanism specifically 'for crisis management', amending Regulation (EC) 816/2006, to alleviate issues related to access to medicine in the EU.[249] The proposal aims to create a coherent and effective EU-level system that can be activated when voluntary agreements fail to ensure timely access to essential products or technologies during EU-recognised emergencies. By introducing this Regulation, the EU seeks to enhance legal certainty, facilitate rapid and equitable access to essential technologies in times of crisis, and overcome the structural shortcomings of relying solely on Member State-level mechanisms.[250] This 'Union compulsory licence' would only be issued after the formal activation of an EU crisis instrument, which is intended to complement existing crisis tools and would ensure that compulsory licensing can cover cross-border supply chains effectively, addressing the limitations of the current patchwork of 27 national regimes.[251] The Union compulsory licence would only 'be granted exceptionally' can thus only be triggered during a declared EU-wide crisis, like COVID-19. This excludes situations where public health concerns exist but do not meet the threshold of a Union emergency. Additionally, it would be inapplicable to crises limited to individual Member States; and more importantly in light of this research, cannot be employed where such crises has not been declared.

4.3.2 Compulsory Licensing in the Netherlands

Based on the legal framework set out above, countries are free to determine the grounds on which a compulsory licence may be issued. In the Netherlands, IP rights are a matter of national patent law, governed by the Dutch Patent Act 1995 (*Rijksoctrooiwet*, DPA).[252] This Act defines the scope and effects of a patent and outlines the applicable exceptions, with Article 57 DPA with key legal provision. As an EU and WTO Member State, Dutch legislation must at the minimum provide the protection to mitigate the risks posed by exclusive exploitation rights in accordance with the latter instruments' standards. However, these frameworks do not form the legal basis for compulsory licensing in Dutch legislation. Compulsory licensing was already laid down in the Dutch Patent Act in 1910.[253]

The original provision in the Dutch Patents Act of 1910 permitted the application for a compulsory licence in the 'public interest', where this was considered desirable in the interest of national industry or for other reasons of public concern.[254] This was further supported in the Explanatory Memorandum describing a compulsory licence as '*an important corrective measure against the harmful consequences of the monopoly conferred by the patent*'.[255] Under the 1977 amendment, the authority to grant a compulsory licence in the public interest

[248] (n 246) Preamble paragraph 5; Ellen 't Hoen, 'Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of data Exclusivity' in Carlos M. Correa and Reto M. Hilty (Eds.) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property* Law (Springer 2022) 183,194.
[249] European Commission, *Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006* COM (2023) 224 final, 27 April 2023.
[250] (n 249) Context for proposal and Preamble paras 1-8.
[251] (n 249) Articles 1-5.
[252] Dutch Patent Act 1995.
[253] *Parliamentary papers II,* 2020/21, 35 809 (R2152), nr. 3 18.
[254] Ch. Gielen, 'Algemeen Belang 'Criterium voor dwanglicenties bij biotechnologische innovatie' [1997] 1(1) *Bijblad Industriële Eigendom* 23, 24.
[255] *Parliamentary papers II,* 1974/75, 13 209 (R 967) nr. 8.

was transferred from the Patent Council (*Octrooiraad*) to 'the Minister'. In this context, 'the Minister' refers to the Minister of Economic Affairs. Noteworthy is that the amendment uses the phrase 'if the public interest requires', suggesting that the provision is not confined to the domain of Economic Affairs. Moreover, the change in terminology from 'desirable' to 'requires' indicates a higher legal threshold for invoking the 'public interest', rendering its application more stringent.

The current Act prescribes, pursuant to Article 57(1), that the Minister of Economic Affairs may, by means of a compulsory licence, if 'the public interest so requires in their opinion', permit a third-party to produce a patented medicine without the consent of the patent holder.[256] Similar to the TRIPS Agreement, such licence may be granted either upon request or *ex officio*.[257] The compulsory licence must be clearly defined in scope and duration, tailored to the specific circumstances that justify its issuance and granted to a designated party.[258] Prior to issuing a compulsory licence, the Minister of Economic Affairs must first assess whether the patent holder is willing to grant a voluntary licence on reasonable terms. To this end, the patent holder shall be given the opportunity to express their views, meaning that the compulsory licence will only be issued where voluntary licensing efforts have failed, unless urgency justifies immediate action.[259] Thus, if the patent holder refuses to licence the invention voluntarily, the Minister of Economic Affairs may enable its dissemination and use by a third-party, effectively compelling the patent holder to tolerate an infringement of their IP rights.[260] Although a compulsory licence may be legally treated as a form of property interference, such interference with the patent may only be exercised by the licensee, unless the patent holder consents to broader use.[261] A compulsory licence constitutes an exceptional legal instrument, of which its use in the 'public interest' is regarded as an *ultimum remedium*.[262]

4.3.2.1 Interpretation of the 'Public Interest'

The law does not provide a precise definition of what constitutes the 'public interest', however, it is generally to be understood as encompassing the objectives pursued by the government in its policymaking.[263] The concept 'public interest' is to be interpreted 'very broadly', determined by the government based on each prevailing circumstances, encompassing general policy goals.[264] The rationale behind this open interpretation is that the understanding of what constitutes 'the public interest' may evolve over time in response to developments or changing societal views, and will therefore, be shaped through jurisprudence.[265]

When the 'public interest' concerns a field that falls outside the competence of the Minister of Economic Affairs, compulsory licensing shall only take place with consultation of the relevant minister. Since the protection of IP in some cases may also be considered a policy objectives, a careful balancing of competing policy goals is required to determine whether

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[256] (n 252) Article 57 (1).
[257] *Kamerstukken II* 2004/05, 27 428, 27 543, nr. 65, 6.
[258] Raoul Soullié, In case of a cure: A compulsory licence as a last resort' (*LeidenLawBlog,* 24 March 2020) https://www.leidenlawblog.nl/articles/in-case-of-a-cure-a-compulsory-licence-as-the-last-resort accessed 27 may 2025.
[259] (n 252) Article 57 (1) and (n 253) 9.
[260] (n 252) Articles 53, 56 and 57 (1).
[261] (n 252) Article 58a (1).
[262] (n 257) 6.
[263] Minister of Economic Affairs 9 januari 1980, *BIE* 198/38 (*Weidepomp*), p. 185 and (n 255) 9.
[264] (n 255).
[265] *Parliamentary papers II*, 2003/04, 27 428, 27 543, nr. 43.

sufficient grounds exist to justify the compulsory licence.[266] To clarify, not only the economic interest of the patent holder but also the rationale underpinning the patent system may thus conflict with the broader 'public interest'.[267] Moreover, when weighing the interest of the users of the patented invention, the focus should lay on balancing the interest of the patent holder against the broader interest of society, including public health, not merely that of a particular interest group.[268] However, it should be borne in mind that a fair balance between the 'public interest' and the individual's right to its property must be struck, meaning that the latter may not bear a disproportionate burden.[269] Importantly, the use of the expression 'so requires' indicates that 'public interest' considerations, other than those underpinning the justification for the patent monopoly, should not be given priority lightly.[270] This may entail that the legal and policy threshold that must be met before overriding a patent encompasses a 'public interest' justification that clearly and compellingly 'requires so'.

Contrary to Article 31 TRIPS, the DPA does not explicate patent restrictions on competition as a justification for issuing a compulsory licence. Nevertheless, this was interpreted through a ministerial decision; particularly, in the *Weidepomp* decision. The decision clarifies that while a patent inherently restricts competition, the 'public interest' in promoting competition can only justify compulsory licensing when accompanied by additional 'public interest' considerations. While the mere existence of a patent does not in itself infringe upon the 'public interest', a price disparity resulting from that patent *may*, depending on the specific circumstances of the case, raise a 'public interest' concern sufficient to justify a compulsory licence.[271] As explained in the previous Chapter, a dominant position rooted in patent exclusivity may enable direct consumer exploitation through 'excessive' pricing. In such cases, where price constraints are weak and market entry is effectively blocked; particularly for patented medicines, affordable access is limited for certain patients while simultaneously placing a strain on public health budgets.[272]

Although it may be argued that the circumstance that a patented product could be marketed by a third-party at a significantly lower price, in itself, forms a substantial 'public interest' justifying the application of Article 57 (1) DPA; the additional circumstances must decide whether a compulsory licence is indeed the most appropriate measure.[273] Evidently, the severity and urgency of 'excessive' pricing undermining access to (essential) medicines, can constitute a compelling ground within the scope of 'public interest'.[274] However, it must subsequently be assessed whether compulsory licensing is a proportionate means to achieve the objective.

4.4 Conclusion

The relationship between IP rights and access to medicines reveals a complex legal and ethical landscape in which competing obligations under intellectual property law and human rights law intersect. While patent protection incentivises innovation, it may also restrict generic competition and create a market dominance, encouraging monopolistic pricing.

[266] (n 257) 8, 9 and 12
[267] (n 257) 8 and 9.
[268] (n 257) 9.
[269] D.M. Mulder, 'Octroorecht in noodsituties' [2020] 16(3) *IER* 133, 136-137.
[270] (n 263) 185.
[271] (n 263) 185-186.
[272] (n146) 10-11.
[273] AvB 19 juli 1972, *BIE* I 1972, p. 236.
[274] André de Jong, 'Persoonlijke beschouwing over de inzet van de dwanglicenties bij hoge prijzen van medicijnen' (Algemene Bestuursdienst, Ministerie van Buitenlandse Zaken en Koninkrijksrelaties, 2020) 32-35.

The TRIPS Agreement aims to embed safeguards to reconcile these tensions through compulsory licensing. The surrounding provisions reflect a recognition that the protection of public interest may at times override the exclusivity of patent rights. The flexibility provided under Article 31, further clarified by the Doha Declaration, has traditionally been utilised by low- and middle-income countries lacking manufacturing capacity to improve access to lower-cost generics. In recent years, however, the growing concern over 'excessive' medicine prices has also prompted increased interest in the use of this mechanism within high-income countries, including the Netherlands.[275] While efforts have been made to promote harmonisation in the EU patent regime, the absence of a unified framework for compulsory licensing leaves regimes across Member States fragmented and inconsistent. This undermines its effectiveness as a cross-border tool to improve access to medicines within the EU but also structurally constraining coordinated, credible threats collectively from Member States to strengthen their negotiation positions.

Where voluntary licensing cannot be reached, threatening with the production or importation of affordable generic medicines via compulsory licensing may enhance the governments' leverage in price negotiations and serve as an effective fallback mechanism when, such negotiations do not yield satisfactory outcomes.[276] Indeed, when the patent holder does not lower prices sufficiently, and is not willing to grant voluntary licenses, allowing generic competition to enter the market via compulsory licensing is the only option.[277] However, whether the measure can legitimately be imposed in the Dutch context is dependent on an examination of the statutory basis particularly in light of 'excessive' pricing. The flexibility inherent in the 'public interest' clause, as illustrated in ministerial interpretations or an alternative route through remedies following competition law, may suggest a potential pathway for intervention.

Neither the TRIPS Agreement nor Dutch legislation explicitly identify compulsory licensing as a tool for price negotiations with pharmaceutical companies nor was compulsory licensing originally intended to directly lower prices. However, the mere threat of generic entry may exert downward pressure on the patentee's price to maintain market share. As such, the mechanism may serve as an interesting price negotiation tool, also in high-income countries such as the Netherlands, where value-based pricing reflects willingness to pay.[278] Nevertheless, the extent to which compulsory licensing forms a viable tool to address 'excessive' pricing in the Netherlands warrants closer examination.[279] The following Chapter will, therefore, examine when and whether compulsory licences can issued in accordance with André de Jong's proposed framework.[280]

Chapter 5: Compulsory Licences as a Remedy for 'Excessive' Pricing in the Netherlands

[275] (n 192) 4; (n 235) 189; (n 240) 284 and Ellen 't Hoen, and Katrina Perehudoff, Ellen't Hoen and Pascale Boulet, 'Override drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too' [2021] 6(1) *BJM lobal Health* 1,2.
[276] (n 228) 1,3 and 7.
[277] (n 214) 369.
[278] (n 240) 306.
[279] (n 253); (n 257) 8 and Parliamentary Papers II, 2023/24, 29 477, nr. 902.
[280] (n 274) 32.

This Chapter assesses whether Dutch law offers an effective legal basis for using compulsory licences to address 'excessive' medicine pricing. It examines when a licence may be justified in the 'public interest', whether high prices alone suffice as grounds for intervention and how such pricing must be assessed in legal and practical terms. The Chapter also explores the complementary role of competition law, the barriers posed by data and market exclusivity, and the feasibility of implementing compulsory licences in practice. Finally, it proposes legal and policy enhancements aimed at improving the instrument's credibility, predictability and effectiveness as a tool to promote access to affordable medicines.

5.1 Reviewing justifications in the Dutch Context

5.1.1 Compulsory Licensing for 'Excessive' Medicines Prices in the 'Public Interest'

In examining the efficacy of compulsory licensing to enhance access to affordable medicine, the premise is that certain patented medicines remain inaccessible due to the high prices and the absence of generic competition. Andre de Jong asserts that although compulsory licenses aimed at reducing prices could serve the 'public interest', particularly where access is at stake, their application requires a careful and structured *ex-ante* assessment.[281]

A rather legally tenable justification, based on 'public interest', for overriding the exclusive exploitation right conferred by a patent may arise in circumstances involving a significant public health need or a shortage of a specific medicine; particularly where the patent holder is unable to ensure adequate supply to meet domestic demands, such as during the COVID-19 crisis.[282] By contrast, invoking compulsory licensing primarily on budgetary grounds, such as to alleviate financial pressure on the healthcare system, presents a more complex and legally contentious justification. Namely, the mere existence of high prices does not form a justification for a compulsory licence, rather the price of the medicine is proven to be unjustifiably high or 'excessive' insofar that it endangers the right to health. Particularly, since high pricing may not raise an issue under 'public interest' where medicines can be acquired or comprehensively financed by the health insurance system.[283] This gives rise to the question as to what threshold of 'too high' or 'excessive' medicine prices this justification should be connected, where this is explicitly not on grounds of anti-competitive conduct.

Following de Jong's proposed framework, it must firstly be determined that the patent in question will continue to block generic competitors from entering the market for a significant period and cannot be circumvented.[284] This criterion is fundamental as a compulsory licence is only meaningful where the patent creates a real and lasting barrier to generic competition. If this question would not be answered affirmatively, the licence would have little practical effect and be deemed unjustifiable and disproportionate.

Additionally, crucial for a compulsory licence to be granted in the 'public interest' is determining whether the licence can be applied effectively, that is whether it is predictable that the licence guarantees a timely, less expensive generic version.[285] Namely, the licence does not operate in a vacuum; its success is dependent on various regimes. This encompasses

[281] (n 274) 32.
[282] (n 269) 136; Sapna Kumar, 'Compulsory Licensing of Patents During Pandemics' [2022] 54(1) *Connecticut Law Review* 57, 59.
[283] (n 55) 136.
[284] (n 274) 32.
[285] Yugank Goyal, 'Economic and Procedural Constraints of Compulsory Licensing for Medicines' in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2105) 437, 439 and 455.

that a licensee must have sufficient manufacturing capacity, that the medicine exists in a viable market where they can recoup their investment and that the licensee has access to additional tacit knowledge needed for industrial scale production.[286] Therefore, before issuing or merely credibly threatening to issue a compulsory license in the 'public interest', it is essential to demonstrate its practical feasibility. Specifically, ensuring the (prompt) availability of the generic version in compliance with safety, quality and efficacy standards.[287] To obtain a marketing authorisation in the Netherlands or the EU, legal requirements of the European Pharmacopoeia must be met, guaranteeing a positive assessment from the CBG or the EMA. Such an assessment is based on the medicine's safety and efficacy, demonstrated through quality studies of the manufacturing process.[288] Both the licensing procedure and those regulatory requirements, such as clinical trials and quality controls, are time-consuming.[289]

If the licensee is unable to produce or import the respective medicine at a reasonable price and within a reasonable timeframe, the compulsory license would ultimately fail to serve the 'public interest' and could therefore not be justified. This indicates that licensee may only be a third-party capable of developing and producing the medicine in compliance with the aforementioned requirements, raising concerns about delays in patient access.[290] This process may be further impeded by the lack of access to the protected know-how, clinical trial data, raising legal and practical barriers to ensuring effective availability of the medicine. Furthermore, this raises budgetary and ethical concerns where re-generating clinical efficacy data is required.[291] Given the anticipated reluctance of patent-holders to voluntarily disclose proprietary know-how, alternative mechanisms must be established to ensure effective implementation of compulsory licences.[292] These procedural and substantive requirements constitute a significant constraint on the (timely) availability of the medicine, undermining its effectiveness and predictability and raise concerns about the proportionality of the measure.[293]

Furthermore, a proportionality assessment must be conducted in relation to the affected patient population. The use of a compulsory licence must be justifiable based on the relative size of the patient population and/or the therapeutic impact of the patented medicine on their health situation.[294] The limitation on the exclusive proprietary rights must be outweighed by the broader societal or 'public interest', raising questions about the legitimacy in the interests of a narrowly defined or individual stakeholder group.[295] This requires assessing whether the price poses a genuine threat access and whether that is sufficiently compelling to take precedent over the interest of both the patent-holder and the underlying patent system.[296] This assessment sheds a light on the question whether reimbursement of the particular medicine leads to the displacement of other essential healthcare services. This approach frames

[286] Richard Li-dar Wang, 'Ancillary Order of Compulsory Licensing and Their Compatibility with TRIPS Agreement' in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2015) 191, 193 and 195.
[287] (n 274) 23.
[288] (n 89) Article 6 an 8 and (n 90).
[289] (n 248) 183.
[290] (n 286) 196 and (n 274) 33.
[291] (n 289) 184.
[292] (n 286) 196.
[293] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory Licence: Why broad Compulsory Licensing is not a Viable Solution to the Access medicine problem' [2013] 38(3) *Brooklyn Journal of International Law* 1191,1202.
[294] (n 274) 33.
[295] *Parliamentary Papers II*, 2004/05, 27 428 and 27 543, nr., 9; Decision Minister of Economic Affairs (Song en Sooho) *Parliamentary Papers* 2004/05, 27 428, nr. 65, Annex *Parliamentary Papers* 2019/20, 29 477, nr. 659.
[296] (n 269) 137.

'excessive' pricing as a threat to the broader 'public interest' rather than the interests of a specific patient group, by asserting that its reimbursement restricts general access to healthcare. However, it may risk advancing the right to health in a potentially discriminatory manner, where clear definition of 'excessive' pricing is not connected to the concept of 'public interest'. Where the company does not hold a dominant position, yet still charges 'excessive' prices the competition law concept will generally not be applicable. To address this, the cost per QALY could be considered as a threshold, allowing comparison across treatments and healthcare spending. However, this raises the question whether any price above this threshold would justify issuing a compulsory license.

Finally, a broader assessment of the potential impact of the licence on the investment and innovation climate must be conducted to justify its issuance in the broader public health interest.[297] Namely, an examination of the broader impact of compulsory licensing reveals further challenges to its implementation and strategic use, including its potential implications for innovation incentives. The underlying rationale of the patent system is to grant exclusive rights to inventors, enabling them to temporarily restrict competition. This legally sanctioned market power is intended to correct potential market failures arising from underinvestment in research and development, by allowing innovators to recoup their investments and thereby stimulate further technological advancement.[298]

Pharmaceutical firms contend that compulsory licensing ultimately harm the consumer by undermining incentives to innovate and prompt patent-owning companies to favour jurisdictions with a more legally accommodating market.[299] Allowing the production of generics through compulsory licences, considering that such licence is non-exclusive, naturally reduces the originator's market power and creates uncertainty about the revenues, threatens their capacity to profitably develop new treatments and pharmaceutical compounds at both the firm and industry level.[300] However, empirical studies have not provided conclusive evidence that compulsory licensing obstructs incentives to innovate.[301] These uncertainties about revenues due to lower prices should however not hinder innovative given that the often value-based pricing not necessarily is connected to R&D costs. Moreover, it should be recognised that patents at times hinder investments in innovation rather than promote it.[302] The value of patents lies not only in enabling patent holders to charge monopoly prices but also in their power to prevent others from producing the patented invention. Paradoxically, such exclusivity may constrain innovation by limiting the dissemination of knowledge and restricting the exchange of production techniques and research findings.[303]

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[297] (n 274) 26-33.
[298] Laura Valterre, 'The interface between patents and regulatory exclusivities and the view on the new EU proposal concerning patent compulsory licensing and regulatory exclusivities' 2023-15 (University of Copenhagen) 1,1-4.
[299] https://www.nber.org/system/files/working_papers/w21442/w21442.pdf p 2
[300] Muhammad Zaheer Abbas, 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments' [2013] 3(3) *International Journal of Social Science and Humanity* 254, 254, 256-257 and Archita Sarmah, Domenico De Giovanni and Pietro de Giovanni, 'Compulsory Licenses in the pharmaceutical industry: Pricing and R&D strategies' [2020] 282(3) 1053, 1057, 1073 and 1080.
[301] (n 285) 455 and S. Frankel and J.C. Lai, 'Recognised and Appropriate Grounds for Compulsory Licenses: Reclaiming Patent Law's Social Contract' in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2105) 149, 162.
[302] Heidi L. Williams, 'How do patents affect research investments' [2017] 9(1) *The Annual Review of Economics* 441 ,443.
[303] (n 204) 1071 and R.L.-d Wang, 'Ancillary Orders of Compulsory Licensing and Their Compatibility with the TRIPS Agreement' in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2105) 191,200.

The perception that compulsory licensing deters innovation is mainly reflects defensive reactions from patent holding pharmaceutical companies. In reality, investment decisions are shaped by various economic factors rather than their desire to 'teach the governments that consider compulsory licensing a lesson'.[304] While such threats are likely to be voiced, in the absence of empirical evidence confirming that companies consistently follow through, this remains uncertain. In fact, carrying out these threats would often result in lost revenue, making them economically irrational in many cases.[305]

Striking a balance between the 'public interest' served by the economic value of the patent and the 'public interest' essentially lies in the broader discussion at a more abstract level regarding the ethical and moral aspects of patent law in relation to human rights law.[306] Compulsory licences infringe upon the IP rights of a pharmaceutical company, but operates as shared global resource constituting a far-reaching measure.[307] To safeguard its legitimacy and effectiveness, the tool must be governed by a transparent, well-calibrated *ex-ante* assessment framework to preserve its credibility and potency as an *ultimum remedium*.[308]

While the pressing issue of 'excessive' medicine prices forms a compelling 'public interest', the absence of a clear guiding framework as to when it is justified may limit the predictable and legally certain use of compulsory licensing as a mechanism to improve access to affordable medicines. Particularly, determining the threshold for what constitutes 'too high' or 'excessive' pricing to justify compulsory licensing in the public interest. Therefore, it may be worth considering an alternative competition law-based route.[309]

5.1.2 Considering a Competition Law-based Justification

While the previous section discussed compulsory licensing in the 'public interest' from a fundamental or human rights perspective, an alternative basis might be found in competition principles. The TRIPS Agreement does not oblige Member States to apply competition law IP related restrictions, meaning that the use of competition law as a flexibility tool remains optional and dependent on the domestic institutional framework.[310] While Article 57a explicitly allows compulsory licensing in cases of anti-competitive conduct, it applies only to semiconductor patents and does therefore not allow the Minister of Economic Affairs to apply this Article to patented medicines.[311] Therefore, compulsory licensing in response to anti-competitive conduct by pharmaceutical companies in the Netherlands will be examined through distinguishment of two separate tracks proposed by André de Jong. The first option considers compulsory licensing issued by the ACM as conditional penalty order remedying a competition law violation. Whereas the second option considers the abuse of a patent as 'anti-competitive conduct' based on an (informal) advice by the ACM, allowing the Minister of Economic Affairs to issue a compulsory licence.[312]

The first route is grounded in competition law, specifically Article 24 of the Dutch Competition Act and falls within the ambit of the ACM following Article 56 (a) of that instrument.[313] In this respect, compulsory licensing is considered a corrective mechanism for

[304] (n 285) 455.
[305] (n 274) 30.
[306] (n 181) 152 and (n 257) 12.
[307] (n 285) 455-456.
[308] (n 274) 33.
[309] (n 274) 34.
[310] (n 142) 280.
[311] (n 252) Article 57a.
[312] (n 274) 34.
[313] Article 56 of the Dutch Competition Act.

anti-competitive conduct. This encompasses that the ACM, independent of patent law, imposes a fine or an order subject to penalty in the form of a compulsory licence whereby it requires the rights holder to take the necessary steps to end the abuse. This path may be triggered when the ACM finds an abuse of dominance, including demanding an 'excessive' price during the 'lock' negotiations.[314]

Compulsory licensing on this ground requires a multi-tiered legal assessment, by which the ACM establishes that the patent holder in fact occupies a dominant position within the relevant market of the patented pharmaceutical and determines that the conduct in question constitutes an abuse.[315] This entails, at least, determining that the price is both 'excessive' and 'unfair', following the two-limb *United Brands* test.[316]

Evidently, compulsory licensing on this ground is only justifiable or even possible for the matter of competition law, if the patentee holds a dominant position, excluding competitors from the market. Whether the patentee is dominant in the relevant market is influenced by and largely dependent on whether the market is defined narrowly, there is high inelastic demand, there is no therapeutic alternative available and competition is genuinely constrained. Notably, IP rights do not generally confer market dominance because the scope of IP rights rarely coincide with the relevant market.[317] Nevertheless, where patent-conferred exclusivities effectively hinder market entry and prices are kept unreasonably high, compulsory licencing may be considered by the ACM to remedy the abuse.

The ever-increasing attention towards pricing investigations of pharmaceuticals, including medicines protected by patents or regulatory exclusivities, as well as growing interest in compulsory licensing as a price-reduction tool, makes the ACM's application of it appear increasingly plausible.[318] Where the ACM finds an abuse, it may impose a fine and/or threaten with a conditional penalty order, possibly including an obligation to grant a licence, to end such abuse.[319] Where such intervention by the ACM indeed leads to the desired conduct, no further government intervention is necessitated.[320]

Other than consumer exploitation through pricing, anti-competitive conduct may also be found where a generic manufacturer has requested, yet been refused a voluntary licence for an essential medicine needed to meet public demand, while the patent holder continues to impose a price that renders the product inaccessible to consumers.[321] This conduct not only suppresses potential innovation by the generic producer but also adversely impacts consumers by denying them access to vital medicines at affordable prices.[322] In such cases, compulsory licensing may through competition law serve as a strategic tool to obtain a licence through legal means against an unwilling patentee.[323] Although no specific precedent of the ACM invoking this measure exists, the growing interest in alleged 'excessive' pricing

[314] (n 274) 34.
[315] *Ibid,* 218.
[316] (n 161).
[317] (n 141) 217.
[318] (n 146) 8; (n 142) 284 and (n 147) 16.
[319] Burton Ong, 'Compulsory Licensing of Pharmaceutical patents to remedy Anti-competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition law Facilitate Access to Essential Medicine, in Reto M. Hilty and Kung-Chung Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways* Forward (Springer 2015) 235,259-260.
[320] (n 274) 34.
[321] Matthias Lamping, 'Refusal to Licence as an abuse of market dominance: from commercial solvents to Microsoft' in R.M. Hilty and K.C. Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (2015 Springer) 121, 127.
[322] (n 146) 8.
[323] (n 322) 140 and (n 219) 193.

also for patented medicines, may pave the way for exploring this intervention in this manner.[324]

While this directly addresses the issue of 'excessive' pricing and its enforcement may deter similar pricing behaviour; the case-by-case approach with lengthy and resource demanding procedures to determine the reasonable pricing may limit the extent to which this forms a structural solution.[325] Notably, intervention by competition authorities has traditionally not been considered to substitute for the absence of *ex-ante* regulatory and legislative measures ensuring fair pricing and equitable access to (patented) medicines.[326] Nonetheless, building upon the newly established *Leadiant* ruling may allow for a more swift procedure for issuing compulsory licences against 'excessive' pricing; and consequently, deter future abusive pricing practices.

However, to tackle this issue André de Jong also proposes a faster yet less formal route, by which the Minister of Health requests an informal advice from the ACM expressing its *thoughts* in the event of a suspicion of 'abusive' behaviour.[327] This would be less resource and time demanding, while a (credible) threat of a subsequent formal investigation by the ACM may by itself drive the pharmaceutical company towards renewed price negotiations or rebating.[328] In situations of high urgency, this option would allow the Minister to issue a compulsory licence based on this informal advice in the 'public interest', rather than the ACM imposing a penalty in the form of a licence aimed at ending the abusive conduct. This would allow compulsory licensing, where 'excessive' pricing constitutes a failure to meet demand on reasonable terms, without necessarily imposing the 'abuse' requirement under competition law. Rather this informal advice framed as a suspicion of 'abuse of patent' may support the instrument's viability to serve as a legal tool to address 'excessive' medicine pricing.[329] In such cases, the *ex-ante* assessment criteria should however be met.

In short, Dutch law provides legal a basis to justify use of compulsory licensing to address 'excessive' medicine pricing.[330] However, its effective justification and application in the 'public interest' is dependent on whether each of the proposed *ex-ante* assessment criteria is met. However, the absence of developed and embedded substantive guidelines and a defined legal threshold for when pricing is 'excessive' in the sense that it justifies compulsory licensing hinders its effective application, as it risks unjustified patent interference and undermines legal certainty.[331]

Given that 'excessiveness' and 'unfairness' of pricing is a well-developed concept in competition law, this may offer a more promising route without such uncertainty. However, this investigation and procedure is rather time and resource demanding and may therefore not serve it desired aim. This is where an informal advice by the ACM would prove useful. Nevertheless, it should be borne in mind that also this route would only provide an actual possibility where the patent-holder in fact holds a dominant market position. Given the

[324] See Chapter 3.
[325] (n 170) 251
[326] (n 170) 253.
[327] (n 274) 34.
[328] (n 274) 34.
[329] (n 219) 193 and 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: Implementing Flexibilities Under Intellectual Property Law 73, 83-84.
[330] Annex *Parliamentary Papers* II 2019/20, 29 477, nr. 659.
[331] (n 293) 1207 and Viviana Munoz Telzez, 'Bolar Exception' in Carlos M. Correa and Reto M. Hilty, Eds.) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property* Law (Springer 2022) 135,136.

growing significance of 'excessive' medicine pricing, Dutch legislation would benefit from the inclusion of and subsequent use of a clearly defined guiding framework in accordance with André de Jong's reflection tailored to address this pressing issue.

5.2 A critical legal Challenge

5.2.1 Data and Market Exclusivity

If the issuance or the mere threat with a compulsory licence against 'excessive' pricing could be justified to improve access to a patented medicine, its practical effectiveness may still be undermined and legally hindered where the originator's product is simultaneously protected by data- and market exclusivity.[332] When applying for such a marketing authorisation, generic manufacturers almost invariably rely on the reference dossier of the originator's medicinal product. Similar to patent rights, data and market exclusivity protect the production of a medicine for a certain period. The rationale behind data exclusivity is comparable to that behind patents.[333] Nevertheless, the exclusivity rules granted by the EMA based on regulatory requirements are separate from patent rights and are not requirements of international IP rights.[334] Data exclusivity is granted automatically via regulatory processes without requiring an application or proof of eligibility, unlike patents, which require examination and must meet criteria such as novelty and inventive step.[335] Other than patents, data exclusivity is not subject to national override where no such waivers are included in domestic legislation.[336] The separate regimes exist independently of one another, yet their application may overlap.

Regulation No 726/2004, laying down procedures for the authorisation and supervision the use of pharmaceutical data, prohibits the use of the originator's pre-clinical and clinical rest data in the processing of a marketing authorisation for generic medicine for a period of eight years.[337] Only after this period of enjoyment of 'data exclusivity', derived from clinical trials that demonstrate the efficacy and safety of the reference medicine, has passed, the regulatory authorities will process the application for market authorisation of generic medicinal products by other pharmaceutical companies. However, even after approval the generic product cannot enter the market until ten years have passed since the original product's approval. This period of restricted market entry is called market exclusivity.[338] An extra year may be added if the originator gains approval for a significant new therapeutic use, forming the so-called 8 + 2 + 1 rule.

This does not prohibit generic companies from generating their own data, yet it blocks a generic manufacturer from relying solely on bioequivalence data to apply for marketing authorisation until the eight-year period has ended. Instead, they would need to conduct their own pre-clinical and clinical trials, something generic companies rarely undertake; rather they rely on the original data filed with regulators. As previously raised, duplicating such studies is generally unnecessary and raises ethical concerns.[339] As a result, data exclusivity regimes establish de facto monopolies that are automatically conferred and discreetly upheld by the pharmaceutical regulatory system, often without meaningful exceptions or limitations.[340] These regulatory exclusivity, delay such use of existing data until the

[332] (n 228) 3.
[333] (n 248) 185.
[334] (n 90) Article 14.
[335] (n 248) 185.
[336] (n 248) 183.
[337] (n 90) Article 14 (11).
[338] (n 90) Article 14 (11).
[339] (n 228) 1-3 and (n 248) 184.
[340] *Ibid.*

exclusivity period expires and thereby significantly delay the registration and market entry of generic medicines.[341]

While compulsory licensing allows the provision of a generic version of a patented medicine aimed at protecting public health, data exclusivity forms an obstacle to its registration and block its entry into the market.[342] This regulatory exclusivity prevents timely regulatory approval of a generic medicine.[343] Effective implementation of compulsory licenses therefore requires an exception to data- and market exclusivity rules. Neither the Dutch Medicines Act nor the relevant higher-level European legislation currently provides for an exception to such exclusivities in the context of a marketing authorisation application based on a compulsory license.[344] This legal gap significantly undermines the prompt and practical use of compulsory licensing as a public health tool to access lower-priced medicines from generic competitors. This structural flaw reflects a lack of proper public health safeguards in European pharmaceutical legislation; particularly, considering the growing recognition that EU Member States lack sufficient bargaining power in price negotiations for (patented) medicines.[345] Notably, Article 18(2) of Regulation (EC) No 816/2006, provides an exception to the exclusivity rules. However, this waiver applies exclusively to medicines designated for export to countries facing public health problems.[346] In this context, it would be desirable to introduce explicit data and market exclusivity waivers into national or European legislation, reflecting the pressing need for tools to strengthen government's negotiating position. Nonetheless, it is useful to explore alternative solutions to this legislative gap to make compulsory licensing a viable response to the current medicine inaccessibility. Most notably, the application of competition law, as a more immediate and flexible means to address 'excessive' pricing and ensure access to affordable medicines.

5.3 Recommendations

Despite the rationale behind the open interpretation, allowing adaption to societal circumstances and judicial interpretation, the absence of developed, embedded assessment guidelines towards the implementation and evidentiary thresholds renders the issuance of compulsory licences justified by a 'public interest' unfavourably, unpredictable. Additionally, barriers, including lack of access to protected manufacturing know-how and EU level data- and market exclusivity limit the mechanism's practical effectiveness. Thus far, these factors resulted in a reluctance to invoke the measure, hindering the development of jurisprudence.[347] Nevertheless, considering the growing strain that 'excessive' medicine prices place on national healthcare budgets, exploring targeted, legal enhancements and recommendations appears both relevant and appropriate.

Having examined these existing challenges surrounding the use of compulsory licensing, valuable insights have emerged to inform legal improvements. Without reform, the Netherlands may remain constrained in its ability to respond to the power-imbalance in its price negotiations for patented medicines and the consequent rising costs of healthcare and may ultimately not live up to its international obligations under the ICESCR. Therefore, the

[341] (n 90) Article 14 (11).
[342] (n 248) 190.
[343] (n 248) 190.
[344] (n 269) 138.
[345] (n 248) 193.
[346] (n 246) Article 18(2).
[347] Annex to *Parliamentary Papers* II 2019/20, 29 477, nr. 659; Geertrui van Overwalle, 'Fair Use: A workable Concept in European Patent Law?, in R.M. Hilty and K.C. Liu (Eds.), *Compulsory Licensing: Practical Experiences and Ways Forward* (2015 Springer) 421,429.

Dutch government should explore practically and legally viable licensing and the strategic use of compulsory licensing in line with the UN Secretary-General's High Level Panel on Access to Medicines 2016 recommendation:

> *Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines.*[348]

5.3.1 Clarify and Strengthen the Assessment Framework

Compulsory licensing and government use provisions may function both as essential safeguards against the abusive exercise of intellectual property rights and as mechanisms to facilitate public access to affordable medicines.[349] To enhance their effectiveness and legal certainty, Dutch law should further develop and implement interpretative guidelines for conducting an *ex-ante* assessment based on literature and practical experiences from other states, preferably codified by secondary legislation or an annex to the Dutch Patent Act.[350] These evaluate whether a compulsory licence is both proportionate and practically feasible, following de Jong's proposed framework. To promote legal certainty and facilitate its legitimate use, this should include a clear uniform evidentiary thresholds for what constitutes ''excessive' pricing' to issue a compulsory licence in the 'public interest'.[351] Consistent and strict adherence to this checklist of criteria to justify the intervention, creates legal certainty and potentially discipline or deter pricing behaviour even if not actually used.

André de Jong additionally recommends institutionalising closer coordination between the Ministry of Health and the ACM to enable both informal and formal scrutiny of anti-competitive conduct and include the possibility of issuing a compulsory licence as a remedy under competition law. While the growing attention to 'excessive' pricing cases in the pharmaceutical industry may enlarge chances of the competition authority issuing compulsory licences to end such abuses, such formal enforcement applying the *united Brands* test comes with lengthy and resource intensive procedures. To alternatively enhance the effectiveness of compulsory licensing as a prompt response to 'excessive' medicine pricing, it is recommended to enable greater reliance on informal mechanisms. In this context, the Minister of Health is empowered to request informal advice from the ACM in cases where a *prima facie* suspicion of anti-competitive or exploitative conduct exists. This route provides a time-efficient alternative to formal abuse proceedings and strengthens the mechanism's credibility as a bargaining tool, while still being grounded in legal authority.

5.3.2 Access to Protected Know-how

The lack of specific (protected) know-how, including manufacturing data and technology, may form an obstacle to generic production through compulsory licensing. Without such know-how, compulsory licensing by itself would be inadequate as patentees are not required to disclose information beyond what is contained in the patent specifications.[352] Confidential manufacturing knowledge often supplements patent and data exclusivity protections, limiting the ability of a compulsory licensee to produce a high-quality generic solely on the basis of

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[348] United Nations, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines' (2016), http://www.unsgaccessmeds.org/final-report accessed 27 May 2025.
[349] (n 330) 74.
[350] (n 274) 37.
[351] (n 81) 179.
[352] 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 and practice* 1242, 1248.

publicly available information or regulatory filings. Essential to enhancing the practical feasibility of compulsory licensing, is developing and implementing robust mechanisms that guarantee access to critical protected know-how and undisclosed clinical trial data.[353]

To ensure access to affordable medicine, the compulsory licence should be complemented by mechanisms that allow the use of the originator's regulatory and technical data to circumvent obstruction by lengthy procedures at the EMA or CBG. The ACM could play a crucial role by investigating refusals to share such essential know-how or data as potential abuses of dominance. Where appropriate, competition law may thus serve as an alternative or complementary tool to enforce access and remedy 'excessive' pricing frustrating the public health objectives of compulsory licensing.[354]

Assuming that permission to use know-how is indispensable for bringing a medicine to market and such a permission is withheld by the right holder, rendering a compulsory licence ineffective; it may be contended that access to this indispensable know-how qualifies as an 'essential facility' and could therefore be subject to a mandatory access obligation under competition law.[355] As such, refusing to share such essential know-how is treated an abuse of market power, in accordance with the 'essential facilities doctrine'.[356] Consequently, the ACM may impose measures to share such information with the respective third-party, eliminating the anti-competitive conduct.

5.3.3 Coherence with Data and Market Exclusivity Rules

Finally, at EU level, it is crucial to advocate for regulatory reform that permits exceptions to data and market exclusivity rules in the context of compulsory licensing. Some scholars contend that a compulsory licence issued in the 'public interest' entails an obligation for the patent holder to also explicitly waive regulatory exclusivities as a refusal by a dominant firm to grant access to regulatory data may constitute an abuse under competition law.[357] Ellen 't Hoen, expert in medicines policy and IP law, contests this claim holding that this view may trigger prolonged legal disputes and further delayed access.[358]

Consequently, 't Hoen emphasises the urgent need for greater coherence within EU law to enable the effective use of compulsory licensing as a tool serving the 'public interest', such as guaranteeing access by addressing 'excessive' medicine prices. Particularly, there is a need to provide a data exclusivity waiver that permits derogation from data protection under Article 14(11) of Regulation 726/2004. Such waiver would allow generic producers to effectively use their rights through the compulsory licence for the purpose of granting access to and use of pharmaceutical test data in the 'public interest'. Without such reform, the practical effect of such licences remains limited, despite their legal availability.

Therefore, to achieve legal coherence in the useful issuing of compulsory licences, 't Hoen proposes to adopt the following provision into the EU Regulation:[359]

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[353] (n 286) 191
[354] (n 269) 138.
[355] (n 269) 138.
[356] (n 322) 139.
[357] Valérie Junod, 'The interface between patent protection and data exclusivity: The issue of compulsory licensing in the public interest under Swiss law'
[358] (n 248) 196.
[359] (n 228) 1-3.

'The protection periods set out in article 14 (11) of Regulation 726/2004 shall not apply in cases where it is necessary to allow access to and the use of pharmaceutical test data to register a generic of a reference medicinal product, which is or has been authorised under article 6 of Directive 2001/83/EC, for reasons of public interest including public health, in case of compulsory licensing of patents, including for public non-commercial use, and in situations of national emergency or extreme urgency'.

5.4 Conclusion

Legal and practical constraints continue to limit the effectiveness of compulsory licensing as a response to 'excessive' medicine pricing. Importantly, indiscriminate or politically expedient use of compulsory licensing risks undermining its legitimacy and diminishing its long-term operability. For the instrument to be deployed or credibly threatened with, predictability and legal certainty are essential. From an *ex-ante* perspective, a clearly defined assessment framework, articulating robust thresholds and evidentiary standards for invoking the public interest, is pivotal to ensure such legal certainty and safeguard investment climates.[360] Such framework strengthens the government's credibility as it communicates to pharmaceutical companies a justified, legally grounded and non-arbitrary use. To strengthen this utility and legal certainty various enhancements may be considered.

The operationalisation of a legal decision-making framework, preferably internationally coordinated, may strengthen the government's negotiation position in price negotiations, while simultaneously increasing the practical enforceability of compulsory licensing as a remedial mechanism. In the event of unsuccessful negotiations, closer coordination between the ACM and minister of Health may allow the nudge the patentee towards price reduction. Additionally, furthering transparency in price negotiations and expanding coalition between like-minded EU countries should be pursued to strengthen bargaining power and increase leverage. Finally, to prevent delays in application of compulsory licences, the Dutch government should continue urging the EU to revise its exclusivity policies.

Absent such reforms, the instruments risks remaining legally available yet practically ineffective. Robust legal and policy enhancements are therefore essential to ensure that compulsory licensing can serve as a credible and implementable response to market failures, including 'excessive' pricing, that undermine access to medicines and threaten the right to health. While legal amendments may offer a promising route to strengthen the effectiveness of the Dutch compulsory licence regime, both at national and EU level such processes typically require extensive procedures and great political will and institutional support. Without a clear commitment from policymakers to prioritise public health over commercial interests, even well-crafted legal proposals may fail to materialise.

[360] (n 285) 455.

Chapter 6: Conclusion

This research set out to examine if compulsory licensing can serve as a viable legal mechanism to counter 'excessive' medicine prices and ensure access to affordable medicines in the Dutch context. It reveals that while Dutch and international law provide a foundation for such intervention, the current framework remains fragmented and underdeveloped, limiting its practical enforceability. While meaningful conclusions have been drawn, the complexity, the length, the specific nature of the subject, lacunae in the law and the lack of specific precedent make this study far from exhaustive. It aimed to provide a foundational analysis of legal conditions, exhibit shortcomings and institutional dynamics surrounding the mechanism and propose enhancements, rather than providing a comprehensive solution.

The key issues explored include: (i) the protection of access to medicines under international human rights law and corresponding State obligations; (ii) the Dutch regulatory mechanisms to manage medicine prices and their limitations; (iii) the intersection between innovation incentives and the influence of patent law and competition (law) on medicine pricing, (iv) the legal framework surrounding compulsory licensing and the justification framework under the Dutch Patent Act; (v) the practical and legal barriers to legitimate issuance of compulsory licences; and (vi) potential national and EU legal and institutional reforms to increase its feasibility and strategic value.

While it can be argued that pharmaceutical companies have a duty to ensure that the fruits of science are made available and affordable to all in need of them as a legally protected entitlement, the State holds primary responsibility for ensuring access medicines, even where provision is largely delegated to private actors.[361] This duty encompasses also the protection against interferences by pharmaceutical companies. This obligation is reinforced by the Committee's recognition that access to essential medicines prescribed by the WHO's List, forms part of the non-derogable minimum core obligations. Ultimately, ensuring equitable access to affordable medicines, whether following or beyond the essential medicines list, is fundamental to safeguarding the right to health. This requires the implementation of legislatives and regulatory measures, as well as oversight to prevent and enforce against infringements by private actors.

The Dutch medicine pricing framework contains several regulatory instruments, aimed at promoting affordability and accessibility. However, these do not succeed in constraining all medicine prices, permitting a degree of market autonomy that allows companies to determine prices freely, after market authorisation. Moreover, the relative inelastic nature of medicine demand amplifies the risk of 'excessive' pricing and ultimately places a disproportionate burden on public health budgets or displaces other forms of specialised medical care. Therefore, *post hoc* instruments such as the 'lock' procedure provide a platform for price negotiations, yet the Minister of Health's bargaining position is structurally weak, especially when dealing with patent encouraged monopoly medicines for which no therapeutic alternatives is available. This negotiation-based model is further weakened by a lack of transparency across countries within the EU. European governments have increasingly acknowledged their limited bargaining power in negotiating medicine prices, despite evidence from competition authorities' investigations demonstrating that many patented medicines can be produced at a fraction of their market price. Furthermore, the absence of a readily enforceable 'duty to care' binding pharmaceutical companies to which healthcare providers and the government is subject.

[361] (n 188) 83.

Compulsory licensing offers a potential counterbalance to the negative effects of exclusivity granted by pharmaceutical patents, such as 'excessive' pricing. It reflects an acknowledgement within the IP system itself, that under specific circumstances the protection of public health may justify restrictions on proprietary rights. Despite this rather controversial intrusion on the core principle of patent exclusivity, the tool may offer strategic value in addressing accessibility issues. Considering the premise that 'excessive' pricing also results from patent protection, where no therapeutic alternative is available, the tool could theoretically strengthen the government's bargaining position in the negotiations with pharmaceutical companies by threatening of or enabling a generic market entry to reduce prices. However, its viability in the Dutch context is hindered by various legal challenges and practical hurdles.

While Article 57(1) of the Dutch Patent Act 1995 permits compulsory licences in the 'public interest', their effective application requires a structured, *ex-ante* framework that balances public health imperatives with legal certainty and innovation incentives. Legitimacy depends not merely on high prices but on demonstrating 'excessive' pricing that jeopardises access and the broader 'public interest'. To this end, de Jong proposed an *ex-ante* assessment framework provides guidance in determining whether the issuance is effective in order to ultimately render it proportionate to the aim pursued. This requires at least affirming that 1) the patent in fact poses a non-circumventable barrier to competition; 2) the use serves a justifiable size of patient group and concerns a medicine with proven therapeutic impact 3) the medicine can be reproduces or imported at a reasonable price and within a reasonable timeframe; 4) there are no other legal or regulatory obstacles such as EMA standards, that impede market authorisation for the licence.

Without clear thresholds or guidelines, however, the measure risks unpredictability, undermining its strategic use and legitimacy as a last-resort tool. Therefore, a threshold should be determined for when pricing becomes 'excessive' to justify the use or the threat of a compulsory licence in the 'public interest', outside of the competition law context. In the context of the two last criteria, the lack of access to protected know-how and regulatory data significantly limit its feasibility, which obstructs successfully justifying the intervention. The ACM could play a key role by investigating refusals to share critical data as abuses of dominance, including ordering data disclosure.

Considering these legal and evidentiary uncertainties surrounding the application of compulsory licensing for 'excessive' pricing on 'public interest' grounds, it may appear that a competition law-based approach offers a more concrete and structured legal framework. In particular, 'excessive' pricing by a dominant patent-holder may constitute an abuse of competition law, justifying compulsory licensing as a remedy. In this respect, two tracks grounded in competition principles can be considered. Importantly, both routes require the patent holder to hold a dominant market position to be applicable.

The first route allows the ACM to issue a compulsory licence as a conditional penalty to remedy a proven abuse of dominance under Dutch competition law. This path, while legally robust, requires a complex and resource-intensive assessment of market dominance and unfair pricing based on *United Brands* case law. Nonetheless, given the growing and ground-breaking attention towards 'excessive' pricing cases in the pharmaceutical industry, also for medicines protected by exclusivity rights as seen in the frontier *leadiant* case, this route may become increasingly promising. The second option involves a more flexible route, whereby

the Minister of Health requesting an informal advice from the ACM when there is a *prima facie* suspicion of anti-competitive conduct. When credible this 'threat' of investigation of an abuse could in principle bring a pharmaceutical company towards rebating or renegotiating its prices without a formal abuse finding. This route provides a faster and more pragmatic alternative yet is unsuitable for urgent access needs. Finally, in urgent cases the government could even decide to justify a compulsory licence on this informal advice. Notably, in such cases, the *ex-ante* assessment framework for issuance in the 'public interest' must be adhered to.

Bearing in mind those recommendations, compulsory licensing under Dutch legislation may offer a tailored response to the pressing issue of 'excessive' pricing. However, compulsory licensing is often undermined by barriers related data and market exclusivity at the EU level. These regulatory exclusivities reinforce monopolistic control beyond the exclusionary effects of the patent. Unlike patents, data exclusivity is automatically granted, enforced through regulatory systems and not subject to scrutiny for novelty or public interest considerations. As such, it prevents generic or biosimilar manufacturers from relying on existing clinical data for marketing authorisation. Even when a compulsory licence is granted allowing the production of a generic version of a patent-protected medicine, data and market exclusivity bars reliance on the reference dossier and entry into the market for up to eleven years. This legal incoherency, rendering Dutch compulsory licensing provisions ineffective for EMA approved products, undermines the utility of compulsory licensing to address 'excessive' medicine prices in the Netherlands but also EU-wide.

To overcome these legal challenges, targeted reforms are needed at the EU level. To that effect, 't Hoen proposes a built-in waiver to data and market exclusivity under Regulation 726/2004. Such measure would introduce predictability, reduce procedural delays, and ensure that compulsory licences can be implemented swiftly and proportionately, in accordance with the UN Secretary-General's 2016 High-Level Panel's recommendations. Given the mounting pressure on national health budgets and its consequent adverse effects on the realisation of internationally protected the right to health, explicit waivers to override these regulatory exclusivities for compulsory licensing for public health concerns should be included in EU law. The absence of such waiver means that the Netherlands, and other EU Member States, lack effective remedy to address 'excessive' pricing of patented medicines, risking falling short of their (international) legal obligations to ensure affordable access to essential medicines.

While incentive to innovate remains a concern in the context of compulsory licensing, this research finds no conclusive evidence that judicious, public-health driven use of such licenses structurally undermines pharmaceutical innovation. It notes that overly rigid exclusivity regimes may even deter it by limiting access and dissemination of knowledge. This tension between innovation incentives and equitable access underscores the significance of a calibrated legal framework that ensures that patents serve their social function.

Ultimately, while compulsory licensing holds legal potential to address 'excessive' medicine pricing in the Netherlands, its current framework lacks clarity, coherence and institutional support required to function as an effective and predictable mechanism. From a legal and strategic perspective this research finds the mechanism could become workable if:

- A structured e*x-ante* framework is operationalised and codified;
- Clear evidentiary thresholds and proportionality criteria are adopted;

- Protected know-how and regulatory data can be accessed or disclosed;
- Competition law procedures, formal or informal, are embedded into the enforcement strategy;
- Coherent EU-level reforms introduce waivers to data and market exclusivities in public interest cases.

However, achieving such reforms require not only legal innovation but also a political and institutional commitment. In the absence of coordinated action at the national and EU level and between EU Member States and political will to address the structural power imbalances in pharmaceutical regulation, compulsory licensing risks remaining a theoretical mechanism with limited practical effect. Ultimately, failing to fulfil its potential as an accessible and predictable tool to promote equitable access to essential medicines following obligations under the right to health.

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