Patents & Access to Health-Technologies in Everyday Healthcare Contexts for Rare Diseases: Implications and Limitations of the Right to Health at the National Level?

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Abstract

Patent rights enable rightsholders to exclude others from using a technology for typically 20 years. The exclusionary nature of patents mean they can be used to incentivize certain technological developments, including health-technologies. On the other hand, this exclusionary role also means that patents can be used in ways that can create barriers for access to technologies. For patents over health-related technologies, such as medicines, vaccines and medical devices, this can have significant health implications for patients. Thus, it is sometimes argued that the right to health could be used to mobilize greater access to patented health-technologies.

This chapter analyses the role of the right to health, focusing on Article 12(1) International Covenant on Economic, Social and Cultural Rights 1966, as an avenue to be used within national States to obtain greater access to patented health-technologies. Against the backdrop of increasing costs of medicines globally, within high-income and low- and middle-income States, this chapter focuses on the role of the right to health in *everyday* healthcare contexts. It examines whether and to what extent, the right to health can be leveraged at the national level within States – by individual patients and/or their families, and by States - to offer effective avenues to address access issues posed by certain uses of IPRs over health-technologies. It also analyses various limitations of the right to health in such contexts.

The chapter argues that for the right to health to offer an effective avenue in national contexts to appropriately balance patients' interests with intellectual property rightsholders' interests, States must show greater willingness to engage with the right to health in a proactive manner,

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including using this right to support targeted policy and legislative reform. A key element of this is the need for greater State recognition and engagement with the collective dimension of the right to health. Moreover, it argues- that the more States which adopt such approaches, the greater likelihood that the right to health can offer effective avenues to address these issues. [329 words]

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Introduction

Patents enable rightsholders to exclude others from using a patented technology (typically for 20 years). The exclusionary nature of patents means they can be used to incentivize certain technological developments, including health-technologies. This is because, aside from limited exceptions, where a technology is patented within a State, third parties must seek permission from rightsholders to use such patented technologies. Permission (in the form of a license) can be granted by rightsholders to third parties for such use of the technology, often in return for monetary payment. This enables rightsholders to develop an income stream. On the other hand, this exclusionary role means that patents can be used in ways that can impede access to such technologies.[2] For patents over health-related technologies, such as medicines, vaccines and medical devices, this can have implications for patients' access to healthcare,[3] and for patients' broader human rights and interests. Accordingly, it is sometimes argued that the right to health could be used to mobilize greater access to patented health-technologies.[4]

This chapter analyses the role of the right to health, focusing specifically on the right as protected under Article 12(1) of the *International Covenant of Economic, Social and Cultural Rights,* and how this right could be used within national States as an avenue to secure broader access to patented health-technologies. There is a considerable body of literature that focuses on how the right to health can be used to temper the effects of IPRs over access to health-technologies in *health-emergency* contexts. For example, there is considerable literature examining the role of patents over access to medicines during the HIV/AIDS crisis in 1990s/2000s where patents were used in ways that significantly impacted access to anti-

[2] For a discussion of the double-edged nature of the exclusionary role that patents can play, *see*: Aisling McMahon, *Accounting for Ethical Considerations in the Licensing of Patented Biotechnologies and Health-Related Technologies: A Justification* in *Patenting Biotechnological Innovation: Eligibility, Ethics and Public Interest* (Naomi Hawkins ed., Edward Elgar Publishing, 2022).

[3] How patents, and other IPRs are used over health-related technologies, can have a range of implications for patient autonomy, dignity and broader bioethical interests, *see* discussion in: Aisling McMahon, *Patents Over Technologies Related to how we Treat, Use and Modify the body: An Urgent Need for Greater Bioethics Scrutiny* Med. L. Rev. (2025)33(3) 1-28.

[4] For example, *see* discussions in: Duncan Matthews, *Right to Health and Patents* in *Research Handbook on Human Rights and Intellectual Property* (Christophe Geiger ed., Edward Elgar 2015); Alicia Ely Yamin, *Not Just a Tragedy: Access to Medicines as a Right Under International Law* 21 B.U. Int'l L.J. (2003); Emmanuel Kolawole Oke, *Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes*, 15(2) Health & Hum. Rts. (2013); Duncan Matthews & Carlos Correa, *The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health*, New York: United Nations Development Programme (2011).

retrovirals (ARVs) with significant implications for the right to health.[5] The impact of patents (and other IPRs) on access to health again came under scrutiny during the COVID-19 pandemic, including concerns around how IPRs impacted access to COVID-19 medicines, vaccines and diagnostics.[6] Both the HIV/AIDs and the COVID-19 context constituted emergency situations involving communicable diseases which threatened public health. However, IPRs are also being used in ways which impact access to health-technologies for everyday healthcare contexts and non-communicable diseases (NCDs), such as cancers. Innovative health-technologies that have the potential to provide more effective treatment options for various NCDs or address unmet needs of patients for whom no viable treatment previously existed, are increasingly entering the market. However, in some cases such emerging health-technologies are inaccessible for patients due to high costs.[7] We acknowledge that the high prices of emerging health-technologies are not solely caused by IPRs. Nonetheless, as will be discussed in this chapter, IPRs are a key factor in enabling rightsholders to set high prices which significantly contributes to such issues.[8] Due to the high prices of health-technologies, challenges around access to health-technologies is increasingly an issue for low and middle income countries (LMICs) and high income countries (HICs), in health emergency and everyday healthcare contexts.[9]

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[5] For a discussion of the impact of patents on the right to health during the HIV/AIDs crisis *see*: Barbara Cochrane Alexander, *Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health*?, 8(3) Hum. Rts. Brief (2001); Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 Berkeley J. Int'l L. (2005); Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, The Right to Health, and AIDS Drug*s, 6(2) UCLA J. Int'l L.& Foreign Affs. (2001-2002). For a more general discussion, *see*: Ellen 't Hoen, et al, *Driving a decade of change: HIV/AIDS, patents and access to medicines for all* 14(15) J. of Int'l AIDS Society (2011).

[6] For a discussion of the impact of IPRs on access to COVID-19 health-technologies, *see*: Aisling McMahon, *Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance* 47 J. Med. Ethics 142-148 (2021); For a discussion of the right to health in the COVID-19 context, *see*: Ichiro Nakayama, *Intellectual property rights and the right to health in pandemic times* in *The Interface of Intellectual Property Law with other Legal Disciplines*, 113-128 (Christoph Geiger ed., Edward Elgar 2025); Sharifah Sekalala et al, *Decolonising Human Rights: How Intellectual Property Laws Result in Unequal Access to the COVID-19 Vaccine* 6 BMJ Glob. Health (2021).

[7] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* 4, 5 (Health Action International 2016); Oriel Güell, *The Most Expensive Drug Ever Approved: A Gene Therapy That Cures Butterfly Skin and Could Cost $20 Million Per Patient*, El Pais (12 Mar. 2025). http://www.english.elpais.com/science-tech/2025-03-12/the-most-expensive-drug-ever-approved-a-gene-therapy-that-cures-butterfly-skin-and-could-cost-20-million-per-patient.html

[8] *See* also discussion in: Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 4-5 (Health Action International 2016).

[9] For discussion, *see*: Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* 4-5 (Health Action International 2016); Tenni, B., Moir, H.V.J., Townsend, B. *et al. What is the impact of intellectual property rules on access to medicines? A systematic review*. Glob. Health 18, 40 (2022); Katrina Perehudoff, Ellen 't Hoen, Pascale Boulet, *Overriding Drug and Medical Technology Patents for Pandemic Recovery: A Legitimate Move for High-Income Countries, too*, 6 BMJ Glob. Health (2021). Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Human. J. (2019); Levon M Khachigian, *Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent*, 25 (7) Drug Discov.

There has been a significant increase in national healthcare spending in many States, and this is expected to continue on an upwards trajectory, with cancer drugs and medicines for the treatment of rare diseases reported as the primary drivers of expenditure.[10] For example, the cost of new cancer medications is increasing faster than public and private health system spending in HICs which is impacting patients and healthcare systems.[11]

Against this backdrop of increasing costs of medicines globally in everyday health contexts, this chapter examines whether and to what extent, the right to health can be leveraged at the national level by patients within States and by States themselves (or national courts) to offer effective avenues to address access issues posed by how patents (and other IPRs) can be used over health-technologies. It also explores limitations of such approaches. In doing so, the chapter highlights a tension that can arise between how individual patient needs and broader population and public health needs can be met by a human rights-based approach, focusing on the right to health. For instance, in certain contexts, the right to health can be used by individual patients who lack access to health-technologies to seek this access. However, where such challenges are successful and certain patients or patient groups are provided with access to such technologies at market prices, (depending on States' approaches), it may reduce overall funds within healthcare budgets in the State thereby impacting the public within a State. This is because if States provide health-technologies at high costs within finite public health budgets it may mean that other treatments cannot be funded in that State. Such scenarios give rise to complex bioethical questions related to opportunity costs which can arise. Moreover, individually framed uses of the right to health do not necessarily address the systemic issues around high costs medicines which may have contributed to, or caused, the lack of access in the first place. Thus, without further policy and strategic changes to tackle high prices, such

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Today 20 (2020); Mari Eccles, *Drug Prices in Europe are Soaring – and are only Expected to Rise*, Politico (14 Oct. 2024). http://www.politico.eu/article/drug-medicine-price-europe-rising-big-pharma-europe/; European Social Insurance Platform (ESIP), Medicine Evaluation Committee (MEDEV), *Trends in Pharmaceutical Expenditure* (Oct. 2024). http://www.politico.eu/wp-content/uploads/2024/10/11/Trends-in-Pharmaceutical-Expenditure_ESIP-MEDEV_2024.pdf>

[10] For discussion, *see*: Mari Eccles, *Drug Prices in Europe are Soaring – and are only Expected to Rise* Politico (14 Oct. 2024). http://www.politico.eu/article/drug-medicine-price-europe-rising-big-pharma-europe/; European Social Insurance Platform (ESIP), Medicine Evaluation Committee (MEDEV), *Trends in Pharmaceutical Expenditure* (October 2024). http://www.politico.eu/wp-content/uploads/2024/10/11/Trends-in-Pharmaceutical-Expenditure_ESIP-MEDEV_2024.pdf.

[11] Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 5 (Health Action International 2016).

actions often do little to address - and may exacerbate - the underlying access to medicine challenges at a population level.

Accordingly, the chapter argues that whilst addressing individual patient needs via the right to health can deliver on short-term needs for patients and is an important legal avenue for patients to have, however, for the right to health to offer an effective avenue to address underlying access to health issues, States must engage with the right to health in a targeted and strategic manner that seeks longer term change, including via legislative reform. As will be discussed, individual challenges using the right to health can act as a catalyst for States to address the broader policy issues around access to health-technologies, however, States should be engaging further with the collective dimension of the right to health, taking pre-emptive actions to maximise access to medicines for all patients who need them within health systems.[12]

The chapter is structured as follows: Part I offers an overview of the right to health under international law focusing on the International Covenant on Economic, Social and Cultural Rights (ICESCR), and related instruments. Part II outlines the tension that can arise between incentivizing the development of new health-technologies by protecting IPRs over health-technologies and how such IPRs can impact patient access to health-technologies, with implications for the *accessibility* and *availability* components of the right to health. Part III then uses the recent litigation in India in relation to access to Risdiplam, a drug used in treatment of spinal muscular atrophy (SMA), as a case study to highlight the tensions between IPRs and patient access. This case study also illustrates various aspects of how the right to health can be used in legal challenges related to access to high-cost health-technologies.

Building upon this analysis, Part IV examines pathways for the right to health to offer an avenue to: 1) *individual patients* (and their families) to secure access to patented health-technologies, and limitations of such approaches at the national level; and 2) how this right can be used by *States* (and judicial bodies within these) as a means to provide greater access to emerging health-technologies. Part V concludes by arguing that for the right to health to offer an effective avenue to balance IPRs with patient needs around access to health-technologies, States must take proactive strategic policy action, including legislative measures, underpinned

[12] In this context, as discussed below, we draw on Audrey Chapmans work on the collective dimension of right to health, *see*: Audrey R. Chapman, *Global Health, Human Rights and the Challenges of Neoliberal Policies*, 55-59 (Cambridge University Press 2016).

by the right to health. Ideally, such approaches should be adopted by as many national States as possible and supported by the international community to normalize the use of the right to health in this way in everyday healthcare contexts.

Part I: Article 12(1) of the International Covenant on Economic, Social and Cultural Rights: Availability & Accessibility Dimensions of the Right to Health

An early iteration of the right to health at an international level can be found within the World Health Organisation's (WHO) Constitution, adopted in 1946 and which came into force in 1948.[13] The protection of the right to health was subsequently confirmed within Article 25(1) of the Universal Declaration of Human Rights (UNDHR) adopted in 1948,[14] and under Article 12(1) of the International Covenant on Economic, Social and Cultural Rights 1966 (ICESCR). Article 12(1) ICESCR states that:[15]

> *'The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'*

The ICESCR is an international treaty adopted for the purpose of the protection of economic, social and cultural rights which creates obligations on ratifying States to integrate this Covenant and principles within it into their domestic legal order. State Parties must interpret current legislation in a manner compatible with such obligations, in line with the Vienna Convention on the Law of Treaties (1980).[16] The ICESCR is ratified by 173 States worldwide.[17] Article 12(1) of the ICESCR has become a central element to the general protection for the right to health at an international level. Thus, this chapter focuses on Article 12(1) ICESCR and the extent to which it can be used by individual patients and States to secure access to patented health-technologies. Nonetheless, whilst the focus here is on Article 12(1) ICESCR, it should

[13] The WHO's Constitution states that: 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.' World Health Organisation (WHO), Constitution of the World Health Organisation 1946 (adopted on 22 Jul. 1946, entered into force 07 Apr. 1948).
[14] Universal Declaration of Human Rights 1948 (adopted 10 Dec. 1948 UNGA Res 217 A (III)(UDHR), Art. 25(1).
[15] International Covenant on Economic, Social and Cultural Rights 1966, (adopted 16 December 1966, entered into force 3 Jan. 1976) (XXI) UNTS (ICESCR), Art. 12(1).
[16] Art. 26, Art. 27, Vienna Convention on the Law of Treaties 1980 (adopted 23 May 1969, entered into force 27 Jan. 1980) UNTS (VCLT).
[17] United Nations Treaty Collection, *Chapter IV: Human Rights: International Covenant on Economic, Social and Cultural Rights* (10 Jul. 2025). https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&clang=_en

be noted that the right to health is also articulated in a range of international/regional instruments and protected in over 100 national constitutions worldwide.[18]

Given the centrality of Article 12(1) of the ICESCR in enshrining a general protection for the right to health at an international level, it is useful to examine key elements of the right to health in terms of how this right may be impacted by how patents (and other IPRs) operate. State obligations under the ICESCR have been developed and clarified by various General Comments issued by the UN Committee on Economic, Social and Cultural Rights,[19] and developed by the Special Rapporteur on the Right to Health,[20] which offer further guidance in such contexts.

General Comment 14 of the UN Committee on Economic, Social and Cultural Rights (CESCR) (2000) is particularly relevant here. It provides that States Parties that have ratified the ICESCR

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[18] *See* discussion in: Eric A. Friedman, Lawrence O. Gostin, *Imagining Global Health with Justice: In Defence of the Right to Health*, 23 Health Care Anal, 319 (2015); For example, at a regional level, the right to health (or a variation of this) is protected within: Art. 11 of the Council of Europe European Social Charter of 1961(opened for signature 18 Oct. 1961, entered into force 26 Feb. 1965) ETS No.035, Art.16 of the African (Banjul) Charter on Human Rights and Peoples' Rights of 1981(adopted 17 Jun. 1981, entered into force 21 Oct. 1986). CAB/LEG/67 rev. 5, ILM 58, Art. 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights 1988 (Protocol of San Salvador) (adopted 17 Nov. 1988, entered into force 16 Nov. 1999); Art. 35 of the Charter of Fundamental Rights of the European Union 2000 (adopted 07 Dec. 2000, entered into force 01 Dec. 2009) (2000/C 364/01)(CFR); Art. 3 of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1997 (Oviedo Convention) (opened for signature 04 Apr. 1997, entered into force 01 Dec. 1999) ETS No. 164. The right to health could also be suggested to be protected by some articles of the Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights 1950) (ECHR) such as Art. 2 – the right to life, and Art. 8 – the protection of private and family life.
Furthermore, the right to health is provided in a range of specific contexts such as in the context of women under Art. 11(1)(f) and Art. 12(1) of the Convention on the Elimination of all Forms of Discrimination against Women 1979 (adopted 18 Dec. 1979, entered into force 03 Sept. 1981) UNTS (CEDAW); in the context of children, under Art. 24 of the Convention on the Rights of the Child 1989 (adopted 20 Nov. 1989, entered into force 02 Sept. 1990) UNTS (CRC); Art. 5 (e)(iv) of the International Convention on Elimination of all forms of Racial Discrimination 1965 (adopted 21 Dec. 1965, entered into force 04 Jan. 1969) UNTS (XX)(ICERD). *See also* general discussion on right to health and intellectual property rights in: Lauren Kane, *30 years of the TRIPS Agreement: The Need to Balance Intellectual Property Rights with the Right to Health,* Ideas in All Blog (09 May 2025). *https://www.ideasinall.com/30-years-of-global-patent-rules-what-it-means-for-patients-and-access-to-medicines/*

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

[20]For example, *see*: UNCHR, *Report of the UN Special Rapporteur on the Right to Health, Paul Hunt* (2007) (A/HRC/4/48); UNCHR, *Report of the UN Special Rapporteur on the Right to Health, Paul Hunt* (2008) (A/HRC/7/11); UNCHR, *Report of the Special Rapporteur on the Right to Health, Anand Grover* (2010) (A/HRC/14/2). *See also* discussion in Paul O' Connell, *The Human Right to Health in an Age of Market Hegemony* in *Global Health and Human Rights: Legal and Philosophical Perspectives*, 3 (John Harrington and Maria Stuttaford eds., Routledge 2010); A.M. Gross, *The Right to Health in an Era of Privatisation and Globalisation: National and International Perspectives* in *Exploring Social Rights: Between Theory and Practice*, 300 (Barak-Erez and Gross eds.,Oxford, Hart 2007); Eric A. Friedman, Lawrence O. Gostin, *Imagining Global Health with Justice: In Defence of the Right to Health*, 23 Health Care Anal, 319 (2015); Oliver Bartlett, Anja Naumann, *Reinterpreting the Health in all Policies Obligation in Article 168 TFEU: The First Step Towards Making Enforcement a Realistic Prospect* 16 Health Econ., Pol'y & L. 10 (2021); Paul O' Connell, *The Human Right to Health and the Privatisation of Irish Health Care*, 11(2) Med. Leg. J. Ireland, 77 (2005).

are required to respect, protect and fulfil the right to health.[21] States are obliged to offer a *progressive realisation* of this right (as set out within Article 2(1) ICESCR),[22] within the limits of their individual resources.[23] Accordingly, State obligations under the right to health are resource dependent, however, there are minimum 'core obligations' under Article 12(1) ICESCR which States have a duty to meet regardless of their resources.[24] These include State obligations around the provision of essential primary health care and *essential drugs* which are set out in a list defined by the WHO Action Programme on Essential Drugs.[25]

Furthermore, paragraph 12 of General Comment No. 14 outlines four key inter-related elements of the right to health, namely, ensuring: availability, accessibility, acceptability and quality in the health context.[26] Under the availability dimension, General Comment No. 14 states that: 'Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party.'[27] In terms of 'accessibility', General Comment No. 14 states that: 'Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party.'[28]

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[21] Art. 33 of General Comment 14 states that: 'The right to health, like all human rights, imposes three types or levels of obligations on States parties: the obligations to respect, protect and fulfil.'

[22] Art. 2(1) states that: '1. Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.' International Covenant on Economic, Social and Cultural Rights 1966, (adopted 16 Dec. 1966, entered into force 3 Jan. 1976) (XXI) UNTS (ICESCR) Art. 2(1).

[23] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health E/C.12/2000/4 (2000), para. 33; *See* discussion in: Emmanuel Kolawole Oke, *The Right to Health in Pharmaceutical Patent Disputes* Research Paper, No 145, South Centre, Geneva, 2 (2022); Eric A. Friedman, Lawrence O. Gostin, *Imagining Global Health with Justice: In Defence of the Right to Health*, 23 Health Care Anal, 319 (2015); Oliver Bartlett, Anja Naumann, *Reinterpreting the Health in all Policies Obligation in Article 168 TFEU: The First Step Towards Making Enforcement a Realistic Prospect* 16 Health Econ., Pol'y & L. 10 (2021).

[24] This is confirmed by General Comment No. 14, para. 43.

[25] *See* General Comment No. 14, para. 43. For a discussion, *see*: Lisa Forman, *Trade Rules, Intellectual Property and the Right to Health*, 21(3) Ethics & Int'l Affs, 6 (2007); Melissa McClellan, *'Tools for Success": The TRIPS Agreement and the Human Right to Essential Medicines*, 12(1) Wash. & Lee J. Civ. Rts. & Soc. Just. 153, 167 (2005); Sharifah Sekalala, Katrina Perehudoff, Michael Parker, Lisa Forman, Belinda Rawson, Maxwell Smith, *An Intersectional Human Rights Approach to Prioritising Access to COVID-19 Vaccines*, 6 BMJ Glob. Health (2021); CESCR General Comment No. 3, The Nature of States Parties' Obligations, UN Doc No. E/C.12/1991/23, (1990).

[26] CESCR General Comment No.14, para. 12. *See* discussion in: Paul O' Connell, *The Human Right to Health in an Age of Market Hegemony* in *Global Health and Human Rights: Legal and Philosophical Perspectives*, 3 (John Harrington and Maria Stuttaford eds., Routledge 2010).

[27] CESCR General Comment 14, Para. 12(a).

[28] CESCR General Comment 14, Para. 12(b).

Four overlapping dimensions of accessibility are set out under paragraph 12(b) of General Comment No. 14, including '*economic accessibility'* defined as:[29]

> Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.[30]

The availability and accessibility dimensions of the right to health relate directly to the supply, affordability and availability of health goods and services, which includes medicines, vaccines and other health-technologies.[31] As the next section will consider, IPRs, including patents, and how these rights are used over health-technologies, can impact access, development and use of health-technologies. This can have implications for the available supply of health-technologies with repercussions for the availability and accessibility dimensions of the right to health.

Part II: Implications of Intellectual Property Rights for the Availability and Accessibility Dimensions of the Right to Health: A Double-Edged Sword.

Intellectual property rights (IPRs) such as patents enable rightsholders to exclude others from using patented technologies for commercial purposes, including developing that technology for sale or supply, for the patent term.[32] Depending on how patents are used, they can impact both the *availability* and *accessibility* of health-technologies. For instance, if we consider patented medicines, rightsholders can refuse permission (by refusing a patent license) to others to produce that patented medicine (or component of it). This could enable that rightsholder(s)

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[29] *See* para. 12(b) (iii) CESCR General Comment 14, as discussed in: Holger Hestermeyer, *Access to Medicine as a Human Right in the WTO Order Human Rights and the WTO: The Case of Patents and Access to Medicine*, 136 (Oxford University Press 2008).

[31] *See* more general discussion of this right in: Genevieve Wilkinson, *Finding a Healthy Balance: Evaluating Models for Change to International Intellectual Property Laws Affecting Global Access to Medicine and Realisation of the Human Right to Health*, 5 Deusto J. Hum. Rts. 145,146 (2008).

[32] Patents are typically granted for a minimum of 20 years, this twenty-year term of protection is set out under Art. 33 of the TRIPS Agreement, as amended. For a discussion of the private governance role of IPRs in the health context, *see*: Aisling McMahon, *Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance*, 47 J. Med. Ethics 142-148 (2021).

to become the sole producer of the patented medicine in the State. Depending on the rightsholder's ability to produce and supply the product to meet patient demand, their refusal to license others to produce or supply a technology can curtail the *availability* of that product within a market. This is because in such circumstances the supply (for the duration of time that the patent exists) will be limited to what that rightsholder can produce. Indeed, it could be more desirable economically for rightsholders to maintain lower supplies of a product than the amount of demand for the product, as this could drive competition between parties (including between States) for access to patented health-technologies. Uses of patents (and other IPRs) in such ways can contribute to limits on the supplies of patented health-technologies. Where States cannot obtain sufficient supplies of health-technologies to meet patient demand, this could impact States' ability to fulfil the *availability* component of the right to health.[33]

Relatedly, where a rightsholder becomes the sole provider of a patented technology they can exercise monopoly functions within that market – as no alternative supplier(s) or similar products may be available to address patient needs. This increases the likelihood that rightsholders can obtain high prices for access to health-technologies as States compete to gain access to limited supplies.[34] Such uses of IPRs can impact the affordability of patented health-technologies thereby impacting the *economic accessibility* dimension of the right to health.

Nonetheless, as noted, patents act as a double-edged sword, as patents (and other IPRs) can have an important role in incentivizing health-technologies by providing an income stream for industry to recoup costs of investment. Abbott has argued that: '[c]onsumers pay high prices for on-patent drugs, but this must be understood in the context that high prices are the mechanism for funding long-term R & D, thus yielding an offsetting social good.'[35] Some commentators argue that under the current health innovation system, without patent protection, there would be limited investment in developing new health-technologies.[36] Khachigian describes this problem as the 'unresolved paradox in reconciling the human right to health with

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[33] For an example of this, *see* discussion of role of IPRs as a factor which contributed to lack of access to COVID-19 vaccines during the pandemic, as discussed in: Siva Thambisetti, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang, Graham Dutfield, *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic*, LSE Legal Studies Working Paper No. 06/2021 (May 24, 2021). SSRN: https://ssrn.com/abstract=3851737.

[34] For a discussion, more generally, *see*: Sarah Joseph, *TRIPS and the Right to Health* in *Blame it on the WTO? A Human Rights Critique*, 214, 215 (Sarah Joseph ed., Oxford University Press 2011); Jennifer Heaven Mogekwu Mike, *Re-evaluating the Relationship Between Patent Rights and Human Rights for the Enhancement of Access to Essential Medicines* 3(2) African J. L.& Hum. Rts, 93 (2019).

[35] Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO* 5(2) J. of Int'l Econ. L., 472, 473 (2002).

[36] *See* discussion in: Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny* 25 Hum. Rts. Q., 432 (2003).

the incentive to invent,' highlighting that the development of novel and more effective medicines can be driven by IPRs, but IPRs can increase cost and reduce accessibility for patients.[37]

When considering such arguments in relation to the right to health, we recognize that the effects of patents (and other IPRs) are not the same for all States or for all patients within these States. For instance, patents are typically more effective as incentives for the development of health-technologies where there is a high purchasing power for that technology within a State. Thus, patents are often better incentives for products directed at conditions affecting high income countries where there is higher purchasing power of patients, insurers or public health systems to pay high costs for access to such health-technologies. IPRs offer a more limited incentivizing role for health-technologies to address diseases that primarily impact low-income countries. Indeed, a recent UN Report of the Office of the High Commissioner for Human Rights, *Comprehensive Report on Access to Medicines, Vaccines and Other Health Products in the Context of the Right to the Highest Attainable Standard of Physical and Mental Health* (2025) (hereafter 'UN High Commissioner, Comprehensive Report on Access to Medicines 2025'), discussed further below, found that:

> Inadequate investment in research and development for diseases, for which the market provides little financial return, has led to reduced availability, and even unavailability, of products to address the health needs of those with little purchasing power, in particular those in vulnerable and marginalized situations. [38]

Patents are also historically of limited incentivizing effect for certain technologies, such as vaccines.[39]

Furthermore, it is sometimes argued that the potential impacts that patents have on access to health-technologies are time-limited because patents are temporary rights (existing typically for 20 years), and such temporary impacts on access to health are outweighed by their incentivizing role on the development of health-technologies as patients will gain access after the 20-year patent term. However, caveats must be noted on these points. First, at an individual

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[37] Levon M Khachigian, *Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent*, 20;25(7) Drug Discov. Today 1138, 1139 (2020).
[38] UNHRC, *Comprehensive Report on Access to Medicines, Vaccines and Other Health Products in the Context of the Right to the Highest Attainable Standard of Physical and Mental Health* (2025) A/HRC/59/29, para. 8.
[39] *See* for example discussion in: Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 Mich. L. Rev. Online 170 (2020); Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. Rev. 1200, 1203 (2018); Douglas Lichtman, *The Central Assumptions of Patent Law*, 65 UCLA L. Rev. 1268 (2018).

patient level, most patients need health-technologies promptly. Depending on the disease individual patients are often unable to wait until the end of a patent term to gain access, their health may significantly deteriorate in that time. In some cases, lack of access to medicines will be fatal. Moreover, even if such patients could wait for access, or if the argument being made was that future patients may benefit from access to such health-technologies, rightsholders can adopt strategies to bundle IPRs over health-technologies, or may be able to apply for an extension of the patent protection, (e.g. by using the supplementary protection certificate system in the EU), thereby increasing their protection over a technology. This in turn means even after the patent term has ended, rightsholders may be able to rely on other IPRs (or other avenues to extend legal exclusivities), to maintain high costs.[40]

Nonetheless, for all the potential negative repercussions certain uses of patents (and other IPRs) have in the health-innovation context, they are currently one of the main innovation models for health-technologies. Thus, from a pragmatic perspective, there is a need to consider how the right to health and IPRs are balanced in this context. Accordingly, prior to delving into the role of the right to health, it is important to consider how the international intellectual property system operates and existing tools within it to balance IPRs with the need for access to health-technologies and the right to health.

[A] *TRIPS, Minimum Standards: Heightened Tensions for IPRs and the Right To Health?*

Under Article 27(2) of TRIPS Agreement patents must be made available in all technological fields, including health.[41] Participation in the TRIPS Agreement and compliance with its standards is mandatory for States to be party to the World Trade Organization (WTO) system. Thus, post-TRIPS, WTO States have limited discretion to tailor national patent systems to address national needs including in the health context. For example, States cannot offer a blanket prohibition on patents on pharmaceuticals, where access issues arise.[42] Accordingly,

[40] For a discussion of this in the medical device and IPR context, *see* Aisling M. McMahon, Opeyemi I. Kolawole, *Intellectual Property Rights Over 'Integrated' Medical Devices: The Potential Health Impacts and Bioethical Implications of Rightsholders' Control*, 33, 1-25, Med. L. Rev. (2025).

[41] Agreement on Trade Related-Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) (adopted 15 Apr. 1994, entered into force 01 Jan. 1995) TRT/WTO01/001, Art. 27(2).

[42] The intellectual property and human rights law regimes were previously distinct/independent of each other, however, Helfer highlights how they have become increasingly intertwined over time, *see*: Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5(1) Minn. Intell. Prop. Rev., 47 (2003); *See* also discussion in: Peter K. Yu, *Reconceptualising Intellectual Property Interests in a Human Rights Framework*, 40 U.C. Davis L. Rev. (2007); Jennifer Heaven Mogekwu Mike, *Re-evaluating the Relationship Between Patent Rights and Human Rights for the Enhancement of Access to Essential Medicines* 3(2) African J. L.& Hum. Rts., 92 (2019).

since the TRIPS Agreement came into force, the tensions arising in the relationship between human rights and IPRs have been subject to significant debate.[43]

Several provisions within the TRIPS Agreement address the potential impact of IPRs on health. For example, Article 8 of the TRIPS Agreement enables States to take steps to ensure protection of health and promote the public interest in certain contexts.[44] The TRIPS Agreement also makes provision for so-called 'TRIPS flexibilities' which are measures that can be adopted by States to limit the role of IPRs in certain contexts, including for the protection of public health. Such flexibilities include the ability of States to grant compulsory licences, parallel importation, etc. However, after the adoption of TRIPS, many LMICs faced uncertainties around using such flexibilities, including, sometimes facing trade sanctions (or the threat of sanctions) from HICs for seeking to use compulsory licensing.[45]

Uncertainties around States ability to use TRIPS flexibilities were demonstrated during the HIV/AIDs crisis in the 1990s/2000s.[46] In response to these difficulties, the Doha Ministerial Declaration of 14 November 2001 was adopted. [47] The Doha Declaration re-iterated States ability to adopt various national measures including 'the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.'[48] Nonetheless,

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[43] *See* discussion in: Jakob Cornides, *Human Rights and Intellectual Property: Conflict or Convergence*, 7(2) J. World Intell. Prop. 135 (2004); Gabriele Spina Ali, *Intellectual Property and Human Rights: A Taxonomy of Their Interactions*, 51 IIC (2020); Peter Drahos, *Intellectual Property and Human Rights*, 3 Intell. Prop. Q. (1999); Philippe Cullet and Hu Yuanquiong, *Medical Patents and the Right to Health: From Monopoly Control to Open Access Innovation and Provision of Medicines*, 61 German Yearbook Int'l L. (2018); Robert L. Ostergard Jr. & Shauna E. Sweeney *Give Me Property or Give Me Death: Reconciling Intellectual Property Rights and the Right to Health*, 10(3) J. Hum. Rts. (2011); Thomas Pogge, *Pharmaceutical Patents and Economic Inequality*, 25(2) Health & Hum. Rts. J. (2023); Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42(3) Geo. J. Int'l L. (2011); Mirela V. Hristova, *Are Intellectual Property Rights Human Rights? Patent Protection and the Right to Health*, 93 J. Pat. & Trademark Off. Soc'y (2011).

[44] Agreement on Trade Related-Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) (adopted 15 Apr. 1994, entered into force 01 Jan. 1995) TRT/WTO01/001, Art. 8.
See discussion in: Geertrui van Overwalle, *Gene Patents and Human Rights* in *Intellectual Property Law and Human Rights*, 28, 29 (Paul L.C. Torremans ed., Kluwer Law International, 3rd edn, 2015).

[45] For a discussion, *see*: Barbara Cochrane Alexander, *Lack of Access to HIV/AIDS Drugs in Developing Countries: Is There a Violation of the International Human Right to Health?*, 8(3) Hum. Rts. Brief (2001); Sisule F. Musungu, Cecelia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (Apr. 2006, South Centre Paper); Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, The Right to Health, and AIDS Drugs*, 6(2) UCLA J. Int'l L. & Foreign Affs. (2001-2002).

[46] *See* discussion in: Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, Chicago J. Int'l L. Vol. 3: No. 1, Article 6 (2002); Aisling McMahon, *Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance* J.Med. Ethics ;47**:**142-148 (2021); Geertrui van Overwalle, *Gene Patents and Human Rights* in *Intellectual Property Law and Human Rights*, 29 (Paul L.C. Torremans ed., Kluwer Law International, 3rd edn, 2015).

[47] Ministerial Conference, Fourth Session, Doha, 9–14 Nov. 2001, Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (14 Nov. 2001) WT/MIN(01)/DEC/2, para. 4 (hereinafter referred to as 'Doha Declaration')

[48] Doha Declaration, Para. 5.

despite the Doha Declaration, patents (and other IPRs) continue to create barriers for access to health-technologies, which has implications for the right to health.[49]

[B] UN Bodies Reports: Tension between IPRs and Right to Health: Landscape Post-Doha

To address such tensions between IPRs and health, around the time of the Doha Declaration, and since its adoption, various UN bodies have adopted reports and resolutions which have re-iterated State obligations under the right to health. [50] In some cases, such reports have also set out recommendations seeking to ensure IPRs do not unreasonably restrict access to health and hinder the right to health.[51]

The cost of patented medicines was emphasized as a key area where change was needed by the UN High Commissioner for Human Rights Report (2023)[52] which noted that '[t]he trend towards the high pricing of patented new medicines undermines access in both wealthier and poorer countries'(paragraph 7). It recognized the role of IPRs in enabling the pharmaceutical industry recoup investments in the development of health-technologies, however, it also highlighted the double-edged nature of IPRs, as follows:

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[49] *See* discussion in: Caitlyn Morrison, *The Human Rights Perspective Behind Patent Laws*, 3(7) Paideia (2016); Carlos Correa and Duncan Matthews, *The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health, Discussion Paper*, United Nations Development Programme, 20 December 2011; Ellen 't Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond* in Economics of AIDS and Access to HIV-AIDS Care in Developing Countries: Issues and Challenges (Paul Moatti et al eds., Paris: ANRS 2003); Duncan Matthews, *The Covid-19 Pandemic: Lessons for the European Patent System*, Queen Mary Law Research Paper No. 377/2022, (January 31, 2022) Forthcoming in the European Intellectual Property Review, March 2022, Available at SSRN: https://ssrn.com/abstract=4022509.

[50] For example, in 2001 around the time of adoption of the Doha Declaration *see*: UN Sub-Commission (UNSC), Resolution 2001/21 on Intellectual Property and Human Rights'(2001) E/CN.4/Sub.2/RES/2001/21; UNSC, Res 2001/21 on Intellectual Property and Human Rights; Report of the High Commissioner, (2001) UN Doc. No.E/CN.4/Sub.2/2001/13; and UNSC Commission on the Promotion and Protection of Human Rights, Res 2000/7 (2000) E/CN.4/Sub.2/2000/SR.25. *See* discussion in: Aurora Plomer, *Patents, Human Rights and Access to Science*, 58 (Edward Elgar 2015);
For an example of relevant reports after 2000/2001, *see*: UNGA, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, (2008) (A/63/263); UNGA, Report of the Special Rapporteur in the Field of Cultural Rights, Farida Shaheed, (2015) (A/70/279); UNGA, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, A/HRC/11/12 (31 March 2009), para. 27.

[51] For example: On State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities; *See*: UNCHR, ICESCR, General Comment No. 24: State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities (2017) E/C.12/GC/24, Para. 23, Para. 24; UNSC, Res 2001/21 on Intellectual Property and Human Rights; Report of the High Commissioner, (2001) UN Doc. No.E/CN.4/Sub.2/2001/13.

[52] UNCHR, Economic, Social & Cultural Rights, *Report of the UN High Commissioner for Human Rights* (2023) (E/2023/74), para. 5. https://docs.un.org/en/E/2023/74

> …the effective monopoly created by patents for essential medicines can allow manufacturers to set the price for new pharmaceuticals at price points that solely maximize returns on investment, even when this entails avoidable deaths.[53] The practical impacts on the rights of millions of human beings is often neglected in pricing decisions, with prices frequently unrelated to the value of the product or the cost of research and development.[54]

More recently, the UN Office of the High Commissioner published a comprehensive report on access to medicines, vaccines and other health-technologies at the 59th session of the Human Rights Council in June 2025.[55] This Report stated that:

> Medical innovation rooted in the patent system has undoubtedly contributed to improving the health and lives of millions globally. However, it has also had its limitations in terms of ensuring equitable access.[56]

The report stated that since its adoption, the TRIPS Agreement has raised 'concerns regarding its potential inconsistency with States' obligations under the right to health to ensure access to medicines, vaccines and other health products.'[57] It acknowledged that States have experienced difficulties in using TRIPS flexibilities such as compulsory licensing (CL), including retaliatory actions from other States/third parties, and lack of manufacturing capacity to use CL.[58] Alongside this, the report highlighted difficulties caused by bilateral trade and investment agreements conducted between States which often impose higher protections for IPRs than those outlined in the TRIPS Agreement, so-called TRIPS-plus standards.[59] It emphasized the

[53] *See* Cecilia Oh, *Patents and Monopoly Prices*, TWN, https://twn.my/title/twr131b.htm.
[54] UNCHR, *Report of the UN High Commissioner for Human Rights* (2023) (E/2023/74), para. 10.
[55] UNHRC, *Comprehensive Report on Access to Medicines, Vaccines and Other Health Products in the Context of the Right to the Highest Attainable Standard of Physical and Mental Health* (2025) A/HRC/59/29. https://www.ohchr.org/en/hr-bodies/hrc/regular-sessions/session59/list-reports This report was informed by detailed background work, For this background work *see*: UNHRC, Res 50/13 (2022) (A/HRC/RES/50/13); UNHRC, *Report of the High Commissioner* (2023) (A/HRC/53/50); OHCHR *Analytical Study on Key Challenges in Ensuring Access to Medicines, Vaccines and other Health Products* (HRC Resolution 50/13) (2023); UN, *Expert Workshop on New Developments in Ensuring Access to Medicines, Vaccines and Other Health Products*, UN (21 Jan. 2025) http://www.ohchr.org/en/events/events/2025/expert-workshop-new-developments-ensuring-access-medicines-vaccines-and-other
[56] *Ibid*, para.8.
[57] *Ibid*, para.13
[58] *Ibid*, para. 18.
[59] *Ibid*, para. 19-20

role for the right to health (and the right to science)[60] both at an international and national level to address such tensions stating that:

> International legal frameworks on intellectual property, trade, investment and finance should be interpreted and applied against the obligations of States to ensure effective access to medicines, vaccines and other health products.
>
> The right to enjoy the benefits of scientific progress and its applications requires that States align intellectual property regulations with human rights, ensuring that patents do not block access to life-saving medicines and impede the enjoyment of the right to health.[61]

The report concluded by stating that: 'The right to health provides an actionable framework for States to enhance the availability, accessibility, acceptability and quality of medicines, vaccines and other health products.'[62] It made recommendations to achieve such aims which we return to in Part IV. Given the emphasis placed on the right to health in providing an actionable framework for access to health-technologies, the chapter now considers this right. In doing so, we focus on whether and to what extent, the right to health can be used by individual patients and States to obtain better access to medicines, and the challenges remaining.

Part III: Right to Health and Access to Patented Health-Technologies: A Case Study of Recent Indian Litigation around Access to Risdiplam

The tensions that can arise between the protection of IPRs and patients' need for access to patented health-technologies are increasingly evident in a range of contexts, including for high-

[60] The discussion of the right to science is beyond the scope of this chapter. For a discussion on this, *see* for example: Aurora Plomer, *The Human Rights Paradox: Rights of Access to Science and Intellectual Property Rights* Human Rights Quarterly, 35(1) 143-175 (2013); Aurora Plomer, *Patents, Human Rights and Access to Science* (Edward Elgar 2015); Peter K. Yu, *Can the Right to Science Reduce the Tensions Between Intellectual Property and Human Rights?* in *A Human-centred approach to health innovations: Reconciling Intellectual Property with Human Rights*, (Lisa Biersay, Thomas Pogge and Peter K. Yu eds, Cambridge University Press, Forthcoming 2025); Peter K Yu, *The Complex Interplay Between Intellectual Property and the Right to Science*, 104 B.U. L. Rev. 705 (2025).
[61] *Ibid*, para. 60-61
[62] Para. 70.

priced cancer therapies,[63] emerging gene therapies,[64] and rare disease contexts etc.[65] This section focuses on recent litigation in India related to access to *Risdiplam* (and its generic version), a drug used in treatment of spinal muscular atrophy (SMA). This litigation is used as a case study as it provides an exemplar of how IPRs can impact access to health, and how patients can invoke this right in cases related to the enforcement of IP rights which may impact access to medicines. It also highlights a range of tensions between individual patients and broader public health considerations around the right to health. Moreover, medicines for SMA (and other rare diseases) are some of highest priced medicines currently.[66] This is due to a range of factors including the limited patient populations for recovery of investments in the research and development process for such medicines, hence developers sometimes argue in such contexts that high costs must be charged.[67] Accordingly, in certain contexts, medicines may be produced which are simply inaccessible by a significant cohort of patients who would clinically

[63] For example, *see* discussion in: Phyllis Ocran Mattila, Rabbiya Ahmad, Syed Shahzas Hasan, Zaheer-Ud-Din Babar, *Availability, Affordability, Access, and Pricing of Anti-Cancer Medicines in Low-and-Middle-Income Countries: A Systematic Review of the Literature*, 9 Pub. Health Pol'y. (2021); G Vassel et al, *Access to essential anticancer medicines for children and adolescents in Europe*, 32(4) Annals of Oncology, 560 – 568 (2021); Wilking et al, *1588MO_PR A comparative study on costs of cancer and access to medicines in Europe*, 31 Annals of Oncology, S1197 (2020).

[64] For example, *see*: Oriel Güell, *The Most Expensive Drug Ever Approved: A Gene Therapy That Cures Butterfly Skin and Could Cost $20 Million Per Patient*, El Pais (12 Mar. 2025); Jacob S. Sherkow, *CRISPR, Patents, and the Public Health*, 90 Yale J. Bio. Med. 667-672 (2017); Fergus Walsh, *UK's Most Expensive Drug Libmeldy Saved Teddy Shaw, But It Is Too Late For Her Sister*, BBC (15 Feb. 2023). https://www.bbc.com/news/health-64629680; Oriel Güell, *Skysona: The Gene Therapy That Saved Darius' Life Cannot Help Any More European Children*, El Pais (26 Nov. 2023). https://english.elpais.com/science-tech/2023-11-26/skysona-the-gene-therapy-that-saved-darius-life-cannot-help-any-more-european-children.html; http://www.english.elpais.com/science-tech/2025-03-12/the-most-expensive-drug-ever-approved-a-gene-therapy-that-cures-butterfly-skin-and-could-cost-20-million-per-patient.html;

[65] *See* generally: J. Mestre-Ferrandiz, et al, *An analysis of orphan medicine expenditure in Europe: is it sustainable?* Orphanet J Rare Dis, 14 (1) 287 (2019); Sibren van den Berg, et al, *Twenty-Four Years After the Launch of the EU Orphan Regulation: Analyzing Dutch Price Dynamics, Biosimilars, and Generics for Orphan Medicinal Products* 28(5)Value in Health 692-698 (2025); Rebecca Robbins, Stephanie Nolen, *A Dilemma for Governments: How to Pay for Million-Dollar Therapies*, New York Times (24 Jan. 2023). https://www.nytimes.com/2023/01/24/health/gene-therapies-cost-zolgensma.html

[66] Philippe Pakter, *Rare disease care in Europe – Gaping unmet needs*, 2 Rare (2024); Steven Simoens, *Pricing and Reimbursement of Orphan Drugs: The Need for More Transparency*, 17;6;42 Orphanet J. Rare Dis. (2011). https://pmc.ncbi.nlm.nih.gov/articles/PMC3132155/; Oriel Güell, *The Most Expensive Drug Ever Approved: A Gene Therapy That Cures Butterfly Skin and Could Cost $20 Million Per Patient*, El Pais (12 Mar. 2025) https://www.english.elpais.com/science-tech/2025-03-12/the-most-expensive-drug-ever-approved-a-gene-therapy-that-cures-butterfly-skin-and-could-cost-20-million-per-patient.html; Mari Eccles, *Drug Prices in Europe are Soaring – and are only Expected to Rise* Politico (14 Oct. 2024). https://www.politico.eu/article/drug-medicine-price-europe-rising-big-pharma-europe/; European Social Insurance Platform (ESIP), Medicine Evaluation Committee (MEDEV), *Trends in Pharmaceutical Expenditure* (Oct. 2024). https://www.politico.eu/wp-content/uploads/2024/10/11/Trends-in-Pharmaceutical-Expenditure_ESIP-MEDEV_2024.pdf

[67] This is where such treatments exist, as another challenge for patients in rare disease contexts is lack of any available treatments - Philippe Pakter, *Rare Disease Care in Europe – Gaping Unmet Needs* 2 Rare (2024).

benefit from them. Similar challenges are increasingly evident for other emerging medicines such as high-priced cancer medicines.[68] Thus, this timely case study provides lessons for a range of high-priced medicines.

Challenges around access to medicines for rare disease contexts are an everyday health context worldwide. Whilst a specific rare disease, by definition, will only affect small numbers of patients, collectively, there are many rare diseases which impact significant numbers of people globally.[69] For example, within the EU, a rare disease is typically defined as a condition that affects less than 5 people in 10,000 of the population,[70] however, on estimate there are over 6,000 different rare diseases. Indeed, it is estimated that over 30 million people in the EU have a rare disease,[71] and between 6-8% of the global population have a rare disease.[72] This is a global issue, as high-priced medicines for rare disease and other non-communicable diseases (such as cancer), affect both LMICs and HICs, and IPRs are a significant factor enabling such high prices.

(i) Litigation related to Risdiplam in India

Since 2021, there have been numerous legal challenges in Indian courts in relation to access to Risdiplam (marketed by Roche as EVRYSDI®), a drug used to treat Spinal Muscular Atrophy (SMA).[73] SMA is a rare genetic disease which leads to muscular weakness and

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[68] For discussion, *see*: S Devi, '*Rising costs of cancer medicines'*, The Lancet Oncology, Volume 25, Issue 10, 1262 (2024).

[69] Stéphanie Nguengang Wakap, Deborah M. Lambert, Annie Olry, Charlotte Rodwell, Charlotte Gueydan, Valérie Lanneau, Daniel Murphy, Yann Le Cam, Ana Rath, *Estimating Cumulative Point Prevalence of Rare Diseases: Analysis of the Orphanet Database*, 28:165-173 Eur. J. Hum. Genetics (2020). https://www.nature.com/articles/s41431-019-0508-0; Aryan Chaudhary, Vidyapati Kumar, *Rare Diseases: A Comprehensive Literature Review and Future Directions*, 4(33) J. Rare Dis. (2025) https://link.springer.com/article/10.1007/s44162-025-00099-6 ; The Lancet, *The Landscape for Rare Diseases in 2024*, 12(3) Lancet Glob. Health (2024).https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(24)00056-1/fulltext

[70] European Commission, *European Rare Diseases Day: Top Facts on EU Action*, European Commission (2015). https://health.ec.europa.eu/system/files/2016-11/2015_factsheet_en_0.pdf ; Thomas Hofmarcher, Caroline Berchet, Guillaume Dedet, *Access to Oncology Medicines in EU and OECD Countries*, OECD Health Working Papers No.170 (DELSA/HEA/WD/HWP(2024)6) OECD (19 Sept. 2024). https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/09/access-to-oncology-medicines-in-eu-and-oecd-countries_6cf189fe/c263c014-en.pdf

[71] European Commission, *European Rare Diseases Day: Top Facts on EU Action*, European Commission (2015). https://health.ec.europa.eu/system/files/2016-11/2015_factsheet_en_0.pdf

[72] Stéphanie Nguengang Wakap, et al, *Estimating Cumulative Point Prevalence of Rare Diseases: Analysis of the Orphanet Database*, 28:165-173 European J. Hum. Genetics (2020). https://www.nature.com/articles/s41431-019-0508-0

[73] For example, *see*: Access to Medicines India, *Supreme Court Order Risks Interrupting Treatment for Young Woman with Spinal Muscular Atrophy*, Access to Medicines India, (27 Feb. 2025). https://www.accesstomedicinesindia.wordpress.com/2025/02/27/press-statement-28-february-2025-rare-diseases-day-supreme-court-order-risks-interrupting-treatment-for-young-woman-with-spinal-muscular-atrophy/ ; *F.Hoffman-La Roche AG & Anr v Natco Pharma Limited* (Neutral Citation:2025:DHC:1907); *Arif v the State of*

eventual wastage.[74] SMA affects approximately 1 in 10,000 live births globally, and 1 in 7,744 live births in India.[75] SMA is a leading cause of infant mortality globally.[76] Risdiplam is an oral medicine produced by Roche, aimed at reducing patients' symptoms and slowing down disease progression.[77] This drug must be taken regularly for the life-time of the patient.

Risdiplam is one of three treatment options currently used to treat SMA, the other two treatment options are Spinraza and Zolgensma. All three therapies are high cost, and present significant affordability and access issues globally.[78] Zolgensma (Onasemnogene abeparvovac) is a gene therapy that must be taken by infants under 2 years of age,[79] so it cannot be used for older patients with SMA. It is not currently available in India.[80] Spinraza (Nusinersen) is indicated for the treatment of SMA in children and adults, however, it is also not currently available in India.[81] Risdiplam is the lowest cost of the three therapies currently, but it is still priced at a

Kerala (21 Jan. 2022) WP (C) No. 7984 of 2021; *Master Medhansh Jhawar @ Madhav Through … v Rajesh Bhushan & Ors.* (4 Oct. 2024); *Master Arnesh Shaw v Union of India & Anr.* (15 May 2023); *Sahir Chawla v Union of India & Ors.* (5 Jan. 2024).

[74] *See* discussion in: Spicy IP, *Right To Health and the Issue of Compulsory Licensing for Exorbitantly Priced Risdiplam, Spicy IP* (11 Mar. 2025). https://spicyip.com/2025/03/right-to-health-and-the-issue-of-compulsory-licensing-for-exorbitantly-priced-risdiplam.html

[75] *See*: Verhaart I. E. C., et al. *A Multi-Source Approach to Determine SMA Incidence and Research Ready Population*. J. Neurol. 264, 1465–1473 (2017); Arkblad E, Tulinius M, Kroksmark AK, Henricsson M, Darin N., *A population-based study of genotypic and phenotypic variability in children with spinal muscular atrophy*. Acta Paediatr.;98(5):865–872 (2009). *See* also: Roche, *Rare Diseases* (2025). https://www.rocheindia.com/solutions/focus-areas/rare-diseases accessed 25 August 2025. For an overview of how the drug works, *see*: European Medicines Agency, *Evrysdi (Risdiplam)*, EMA. https://www.ema.europa.eu/en/medicines/human/EPAR/evrysdi

[76] Mitchell R Lunn, Ching H Wang, *Spinal Muscular Atrophy*, 371 Lancet, 2120-33 (2008).; Matthew E R Butchbach, *Genomic Variability in the Survival Motor Neuron Genes (SMN1 and SMN2): Implications for Spinal Muscular Atrophy Phenotype and Therapeutics Development*, 23;22 (15) Int'l J. Mol. Sci. (2021).

[77] *See*: European Medicines Agency, *Evrysdi (Risdiplam)*, EMA. https://www.ema.europa.eu/en/medicines/human/EPAR/evrysdi

[78] Ryan Flinn, *SMA Treatments Save Lives and Money, But Economic Barriers Hinder Access*, Managed Healthcare Executive (19 Jul. 2024). https://www.managedhealthcareexecutive.com/view/sma-treatments-save-lives-and-money-but-economic-barriers-hinder-access; S Madipalli, *Spinraza: The Patient Perspective*, 24 Gene Therapy, 501-502 (2017); Rebecca Robbins, Stephanie Nolen, *A Dilemma for Governments: How to Pay for Million-Dollar Therapies*, New York Times (24 Jan. 2023). https://www.nytimes.com/2023/01/24/health/gene-therapies-cost-zolgensma.html; *Muscular Dystrophy Ireland, Campaign Update: Equal Access to Treatments for SMA Adult*s, MDI (6 Jun. 2025). https://www.mdi.ie/all-news-articles/campaign-update-equal-access-to-treatments-for-sma-adults

[79] Zolgensma, *How Zolgensma Works* (2025). https://www.zolgensma.com/how-zolgensma-works

[80] It was made available to some eligible patients under Novartis Global Managed Access Programme which commenced in 2020, however, this programme was closed in 2024, *see*: Novartis, *Zolgensma Global Managed Access Program (gMAP)* https://www.novartis.com/healthcare-professionals/managed-access-programs/zolgensma-global-managed-access-program-gmap

[81] CureSMA, *About SMA*, (2023). https://www.curesmaindia.org/about-sma/#treatment ; Spinraza was made available to a small number of selected patients in India through an Individual Patient Humanitarian Access Program. *See discussion in*: R Suthar & AN Pati, *Spinal Muscular Atrophy Therapeutics in India: Parental Hopes and Despair!* Ann Neurosci. Jul;28(3-4):112-113 (2021).

level unaffordable by many globally, including in India.[82] However, it has been suggested that Risdiplam is the most likely of the three therapies to be able to be offered as a lower cost generic version in LMICs.[83]

Several recent legal challenges have arisen in India around access to Risdiplam or a generic version of this medicine for SMA patients, as a key issue is the high cost of Risdiplam (discussed further below) which makes it inaccessible for many patients. [84] In March 2025, the Indian High Court issued a decision refusing an application filed by Hoffmann-La Roche (hereafter Roche) (the plaintiffs) who produce Risdiplam, where Roche were seeking an interim injunction against Natco Pharma Limited (hereafter Natco) to halt production of its planned generic version of Risdiplam in India, as part of a broader action whereby Roche, alleged that Natco was infringing their patents over Risdiplam.[85] Natco planned to offer the generic version at a significantly lower cost, reportedly at 80-90% lower than the cost of Roche's price for Risdiplam.[86] If this interim injunction was granted, this would halt Natco's ability to produce the generic version, pending the final determination of the case on the question of IP infringement. In response to the infringement challenge, Natco challenged the validity of Roche's patent including alleging that Roche engaged in evergreening behaviour,[87] and on several other grounds, arguing that Roche's patents could be susceptible to revocation in such contexts. In addition, Natco raised a point around Risdiplam being imported by Roche into India and not made by Roche in India, Natco argued that this amounted to failure to work

[82] Finshots, *Risdiplam & the Cost of Survival: Is Pharma Playing Fair?* Finshots (1 Apr. 2025). https://finshots.in/archive/is-pharma-playing-fair-risdiplam-the-cost-of-survival-evrysdi-la-roche-natco-pharma/

[83] Knowledge Ecology International, *Proposal for the Addition of Risdiplam to the WHO Model List of Essential Medicines for the Treatment of Children and Adults with Spinal Muscular Atrophy*, KEI, 11 (1 Nov. 2024). https://cdn.who.int/media/docs/default-source/2025-eml-expert-committee/addition-of-new-medicines/a.24_risdiplam.pdf?sfvrsn=a0920ef9_9 ; Melissa Barber, *Submission to WHO EML Secretariat and Expert Committee on the Selection and Use of Essential Medicines: Subject: Risdiplam, Spinal Muscular Atrophy*, Harvard T.H. Chan School of Public Health (6 Apr. 2023). https://cdn.who.int/media/docs/default-source/essential-medicines/2023-eml-expert-committee/public-comments/a40_risdiplam_barber.pdf?sfvrsn=28a26d21_1 ; Md Saheeh Ahmad, *A Rare Invocation for a Rare Disease? Government Urged to Invoke Section 100, Patents Act for Rare Disease Medicine*, Spicy IP (20 Jan. 2025). https://spicyip.com/2025/01/a-rare-invocation-for-a-rare-disease-government-urged-to-invoke-section-100-patents-act-for-rare-disease-medicine.html

[84] *See*: Spicy IP, *Right To Health and the Issue of Compulsory Licensing for Exorbitantly Priced Risdiplam, Spicy IP* (11 Mar. 2025). https://spicyip.com/2025/03/right-to-health-and-the-issue-of-compulsory-licensing-for-exorbitantly-priced-risdiplam.html

[85] *F.Hoffman-La Roche AG & Anr v Natco Pharma Limited* (Neutral Citation:2025:DHC:1907).

[86] Ariana Schouten, *Risdiplam Comment: Tablet Formulation and New Clinical Evidence*, Knowledge Ecology International (KEI) (2 Apr. 2025). https://cdn.who.int/media/docs/default-source/2025-eml-expert-committee/addition-of-new-medicines/a.24_risdiplam_update_april2025.pdf?sfvrsn=eb1ad9ce_1

[87] Narula R, *Public Interest Prevails: Roche Denied Injunction in Patent Dispute*, The Patent Lawyer, (08 Apr. 2025). http://www.patentlawyermagazine.com/public-interest-prevails-roche-denied-injunction-in-patent-dispute/

the patent. Furthermore, Natco argued that Roche's approach of producing the product elsewhere and importing it into India is increasing the cost of production of Risdiplam, which it claimed could be produced at a lower price if made in India.

As part of the hearing on whether an interim injunction should be granted to halt the generic production of the product by Natco pending the final determination of the IP infringement/validity issues, the potential impact of an injunction on third parties (patients) was highlighted, and two interveners joined the case.[88] Both interveners were patients with SMA who were seeking access to the generic version of Risdiplam in India, namely: Ms Purva Mittal and Ms Seba P.A. In their interventions, they highlighted that despite Roche offering Risdiplam at a discounted price in India, it was still inaccessible to many patients. The National Centre for Rare Disease in India, offers 50 Lakhs per year to those with a rare disease who require access to medicines for their condition, however, as Risdiplam reportedly costs 6.2 Lakhs per bottle, and patients over 20kg require approx. 36 bottles per year, this fund does not cover the costs of ongoing access to patients.[89] On behalf of Ms. Seba P.A., it was submitted that 'the court ought to balance the public interest, and the constitutionally protected right to health of patients and balance them against the exorbitant price of the drug.' [90]

In considering the application for the interim injunction against the production of the generic version of Risdiplam, the court considered if there was an arguable case, and whether it could be remedied by damages if infringement was found in the full hearing. In addition, the court considered the potential impact on third parties. In this latter context, the court emphasized the importance of the public interest in access to medicines, and the broader public health context, it stated that:

> This Court also takes note of the submissions made on behalf of the interveners, wherein, it has been brought forth that SMA is a debilitating disease and there is no cure for the same. The approved drug, i.e., Risdiplam, which is marketed under the name Evrysdi, is not available at reasonably affordable prices in India. Thus, *if a party*

[88] It is also notable that various NGO and patient advocacy groups have been petitioning for broader access to SMA therapies in India, including: CureSMA, *About SMA*, (2023) https://www.curesmaindia.org/about-sma/#treatment

[89] IPEssentia, *Roche v Natco – Genus vs. Species Patent Dispute over Risdiplam*, IPEssentia (27 Mar. 2025). http://www.ipessentia.com/roche-vs-natco-genus-vs-species-patent-dispute-over-risdiplam/ ; *See also* discussion in: Spicy IP, *Right To Health and the Issue of Compulsory Licensing for Exorbitantly Priced Risdiplam, Spicy IP* (11 Mar. 2025). https://spicyip.com/2025/03/right-to-health-and-the-issue-of-compulsory-licensing-for-exorbitantly-priced-risdiplam.html - Patients weighing up to 20kg are reported to require 1 bottle per month (6.2 lakh per bottle) which costs approx. 72 lakhs per year.

[90] *F.Hoffman-La Roche AG & Anr v Natco Pharma Limited* (Neutral Citation:2025:DHC:1907) para. 13.7.

is able to manufacture the drug and make it available at an affordable price, in such a case, the public interest would have to outweigh the need for grant of injunction.

In relation to pharmaceuticals, which not just borders on the public good, but brings about the foremost good of the public, i.e. health, is not something that should be dealt with lightly. *A drug which is the only one available for treatment in India, for a rare disease, its availability to the public at large at very economical and competitive prices, is a material factor which a Court will consider at the time of dealing with an application for interim injunction. Besides, the plaintiffs can be compensated by way of damages. However, there exists no right for the public to lessen or compensate itself.* [Paragraphs 106-107] [Emphasis added][91]

Accordingly, the court refused the interim injunction against Natco finding there was a prima facie case raised, and that the balance of convenience lay against granting the interim injunction. This case highlights how the public interest, and included within this, broader public health factors including the access to health needs of patients, was a factor which the courts considered at this interim injunction stage. The interveners framed their access to health interests in terms of the right to health implications this had for them in not being able to access Risdiplam or a generic version. This highlights how individual patients can use the right to health to support arguments against interim IP enforcement remedies which may impact access to health.

Nonetheless, we acknowledge that this case is, at time of writing awaiting final hearing, when the issues related to IP infringement and validity will be decided on their merits (see further updates discussed below). We also acknowledge that patients may have a greater opportunity to raise the right to health in such contexts in India, as compared to other jurisdictions. For context, the right to health in India has been recognised as falling under the constitutional right to life (Article 21), and as part of the right to live with human dignity. This arguably strengthens the foundational basis of the right to health in India. It may also strengthen Indian courts' willingness to consider the right to health at a domestic level in disputes relating to IPRs. Moreover, there is a history of such cases in India.[92] India also has significant domestic

[91] *F.Hoffman-La Roche AG & Anr v Natco Pharma Limited* (Neutral Citation:2025:DHC:1907) Para. 106, Para. 107.

[92] For example, see also: *Bayer v. Union of India & Others,* OA/35/2012/PT/MUM, decision of the Indian Intellectual Property Appellate Board, (4 March 2013); *Mohd. Ahmed (Minor) v. Union of India and others* W.P.(C) 7279/2013 (Decision of the High Court of Delhi at New Delhi, 17 April 2014); VK Shrama, *Right to Health: A Constitutional and Human Right Perspective in India*, IOSR J. Humanities Soc. Science 29(3) (2024).

manufacturing capacity for generic production, which makes it more likely that a case like this, involving a generic manufacturer wishing to produce a generic would come before the courts.[93]

Following this case, in April 2025, it was reported that Natco Pharma was expected to launch its generic version for a cost of $190.80 USD compared to Roche's price for Risdiplam of $7,440 USD per bottle.[94] However, in May 2025 on appeal the divisional High Court restrained Natco from launching its generic version until the next hearing.[95] On the 9th of October 2025 the division bench of the Delhi High Court upheld the March 2025 decision to allow generic production of Risdiplam by Natco Pharma.[96] Roche subsequently appealed this decision on the interim injunction to the Supreme Court, and on the 17th October 2025, the Supreme Court again refused an interim injunction to restrain Natco from selling the generic version of Risdiplam pending the final determination of this case.[97] At the time of writing, we await the full hearing which will decide the substantive issues raised in this case.[98]

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[93] For a discussion of the development of Article 21 of the Indian Constitution, *see*: Arghya Sen, *Expanding Horizons of the Right to Life with Dignity Under Article 21*, Nat. J. Leg. Research & Innovative Ideas 3(3) (2023).

[94] Navlin Daily, *Natco to Launch Generic Risdiplam in India for SMA at USD 190.80*, Navlin Daily (15 Apr. 2025). https://www.navlindaily.com/article/25715/natco-to-launch-generic-risdiplam-in-india-for-sma-at-usd-190-80

[95] Himani Pandey, Shukadev Khuraijam, *Delhi High Court Division Bench Overturn Injunction Ruling Amid Genus and Species Patent Controversy*, IAM, (7 May 2025). https://www.lexology.com/library/detail.aspx?g=3493513f-60d1-41ab-a855-96826e2b1955

[96] *F. Hoffman-La Roche Ag & Anr v Natco Pharma Limited* (09 October 2025:DHC). For a discussion and reactions to this case, *see*: Knowledge Ecology International, *Delhi High Court Rejects Roche's Appeal, Paving Way for Affordable Generic Risdiplam*, KEI (10 Oct. 2025). https://www.keionline.org/41023; Third World Network, *Indian Court Rules Against Roche and Allows Generic SMA* Drug, TWN (10 Oct. 2025). https://www.twn.my/title2/intellectual_property/info.service/2025/ip251002.htm#:~:text=This%20Thursday%20%289%20October%29%2C%20a%20Delhi%20High%20Court,NATCO%20for%20patent%20infringement%20of%20the%20drug%20risdiplam.

[97] Economic Times Pharma, *Roche Challenges Natco's Risdiplam Generic Launch in SC,* Economic Times Pharma (15 Oct. 2025) https://pharma.economictimes.indiatimes.com/news/pharma-industry/roche-challenges-natcos-risdiplam-generic-launch-in-supreme-court/124565308; Krishna Yadav, Jessica Jani, *SC Refuses to Restrain Natco from Selling Generic Version of Roche's Risdiplam*, Mint (7 Oct. 2025). https://www.livemint.com/news/india/supreme-court-clears-natco-generic-spinal-muscular-atrophy-drug-india-roche-natco-pharma-risdiplam-patent-ruling-11760686204050.html ; For a reaction to the case, *see*: Krishna Yadav, Jessica Jani, *SC Refuses to Restrain Natco from Selling Generic Version of Roche's Risdiplam*, Mint (7 Oct. 2025). https://www.livemint.com/news/india/supreme-court-clears-natco-generic-spinal-muscular-atrophy-drug-india-roche-natco-pharma-risdiplam-patent-ruling-11760686204050.html which highlights Roche's statements following the case; Working Group on Access to Medicines and Treatment, *Working Group on Access to Medicines and Treatment on Rejection of Roche's Interim Injunction Plea at the Supreme Court: Press Release*, Working Group on Access to Medicines and Treatment (17 Oct. 2025). https://accesstomedicinesindia.wordpress.com/wp-content/uploads/2025/10/press-release-supreme-court-sma.pdf which highlights statements of patient interveners following decision.

[98] This is correct at time of writing, 30th October 2025.

Nonetheless, these decisions open the door for Natco to start manufacturing a generic version of Risdiplam ('Natsmart').[99] It has been reported that, once available, Natsmart will cost 179 USD per bottle, 97% less than Roche's Risdiplam ('Evrysdi').[100] This could improve patient access through India's National Policy for Rare Diseases, alleviating some of the funding constraints which have limited access through this scheme to date.[101] Additionally, Natco Pharma have announced plans to launch a patient access programme to extend discounts to eligible patients.[102] At the time of writing, it remains to be seen how this will develop.[103]

(ii) Risdiplam Litigation: Tensions around Private & Public Interests in Development/Access to Emerging Therapies

This litigation highlights the tension between the enforcement of IPRs and the right to health. Generic production of drugs like Risdiplam as proposed by Natco Pharma, can offer more affordable medicines for patients and healthcare systems. However, depending on the context, production of generics could infringe applicable patents. Thus, courts can face difficult legal questions around the balance between enforcing IPRs and facilitating patient interests around access to medicines which goes to the core of the appropriate balance between IPRs and the right to health. Notably, the cases discussed above, related to applications for interim injunction pending final determination of the case, at that stage a range of factors are considered, including consideration of the adequacy of damages as a remedy should the final determination find IP infringement, if the interim injunction is not granted.

Alongside the cases discussed, which related to the patent aspects and interim injunction remedies applicable in such contexts, the cap of 50Lakhs towards payment for Risdiplam

[99] Indian Organization for Rare Diseases (IORD), *Natco Wins Patent Battle, Makes SMA Drug Affordable in India*, IORD (12 Oct. 2025). https://www.rarediseases.in/natco-wins-patent-battle-makes-sma-drug-affordable-in-india/

[100] Knowledge Ecology International, *Delhi High Court Rejects Roche's Appeal, Paving Way for Affordable Generic Risdiplam*, KEI (10 Oct. 2025). https://www.keionline.org/41023; Indian Organization for Rare Diseases (IORD), *Natco Wins Patent Battle, Makes SMA Drug Affordable in India*, IORD (12 Oct. 2025). https://www.rarediseases.in/natco-wins-patent-battle-makes-sma-drug-affordable-in-india/

[101] Trading View, *Roche Faces Setback as Delhi High Court Clears Natco Pharma's Low Cost Generic Risdiplam*, TV (09 Oct. 2025). https://www.tradingview.com/news/moneycontrol:2bcf4b897094b:0-roche-faces-setback-as-delhi-high-court-clears-natco-pharma-s-low-cost-generic-risdiplam/

[102] Parthika Patel, *Natco Gets SC Nod to Launch Generic Risdiplam at 80% Lower Price, Roche Appeal Dismissed*, Medical Dialogues (18 Oct. 2025). https://medicaldialogues.in/news/industry/pharma/natco-gets-sc-nod-to-launch-generic-risdiplam-at-80-lower-price-roche-appeal-dismissed-157173

[103] 30 October 2025.

offered by the Indian National Center for Rare Disease is also being legally challenged.[104] This latter case is expected to be heard by the Indian Supreme Court in the coming months.[105] If this cap is raised this would allow more funds for individual patients which could potentially mean patients may be able to obtain greater quantities of Risdiplam. If generic production of Risdiplam by Natco commences and reduces the costs of the medicine this could have a significant impact on patient access (however, much will depend on the outcome of the final full hearing in this case).

Nonetheless, in the absence of policy avenues to lower the cost of a medicine (such as via generic version or negotiating with rightsholders), a challenge to the amount of funding provided for individual treatments under public health systems is an important avenue for such patients. We recognise that it is important that patients pursue any legal avenues possible to gain greater access to such medicines. However, providing additional funds to pay for commercial costs of patented products typically only addresses short-term access to medicines issues for specific patients, as such funds will usually come from the overall national public health budget. Over time, dedicating more funds to certain medicines could mean that less funds are available for other medicines, creating difficult resource allocation questions for States. Such avenues do not, on their own, address the systemic issues around how to reduce the costs of high-priced medicines to levels affordable to patients and States. Instead, policy changes are needed to structure legal frameworks in ways that can better balance the need to incentivize the development of emerging therapies for rare diseases through IPRs (including patents) and other tools, with the need to also ensure that therapies if developed are accessible for patients who need them.

Accordingly, the Risdiplam example epitomizes some of the key tensions that arise between the use of IPRs to incentivize the development of medicines, including for rare diseases, [106] and the impact that IPRs can have on downstream medicine pricing and ultimately access to

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[104] *F.Hoffman-La Roche AG & Anr v Natco Pharma Limited* (Neutral Citation:2025:DHC:1907); Law Trend, *Supreme Court to Review Rs 50 Lakh Cap on Government Aid for Rare Diseases*, Law Trend (Apr. 09 2025) https://lawtrend.in/supreme-court-to-review-rs-50-lakh-cap-on-government-aid-for-rare-diseases

[105] The Hindu, *Supreme Court to Hear Pleas Over 50 Lakh Cap on Centre Aid for Rare Diseases*, The Hindu (09 Apr. 2025). https://www.thehindu.com/sci-tech/health/supreme-court-to-hear-pleas-over-50-lakh-cap-on-centre-aid-for-rare-diseases/article69430451.ece

[106] *See also* discussion in: Access to Medicines India, *Supreme Court Order Risks Interrupting Treatment for Young Woman with Spinal Muscular Atrophy*, Access to Medicines India (27 Feb. 2025). https://www.accesstomedicinesindia.wordpress.com/2025/02/27/press-statement-28-february-2025-rare-diseases-day-supreme-court-order-risks-interrupting-treatment-for-young-woman-with-spinal-muscular-atrophy; Ellen ‘t Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 119, 121 (Health Action International 2016).

medicines for patients, and for States in fulfilling their obligations as part of the right to health.[107] It remains to be seen how these cases in relation to Risdiplam will be decided. Nonetheless, this example, gives us pause to reflect on how the right to health can be used at the national level by patients and States (or judicial actors within States) in cases related to access to healthcare which we now turn to consider in more detail.

Part IV: Leveraging the Right to Health Towards Access to IP Protected Health-Technologies: Avenues for Individual Patients and States

The obligations under the right to health as set out within Article 12(1) ICESCR are obligations imposed on States. Thus, it is important to reflect on how individual patients can use, and States implement (and use) this right at the national level to increase accessibility and availability of patented health-technologies. This section will argue that in practice, whether the right to health contributes to the fulfilment of the highest attainable standard of health in everyday healthcare contexts, including for rare diseases, is often determined by whether there is an effective national avenue to use this right. It will also depend on whether and to what extent, the right is implemented or used in a proactive manner by States to develop longer term strategies to deliver access to IP protected health-technologies.[108]

This section focuses on how the right to health can be used by individuals and by States at a *national level* to secure and/or deliver better access to patented health-technologies. This focus is taken for pragmatic reasons, as due to a range of factors, including issues around its enforceability at a supranational level, the right to health often has more limited teeth when used at a supranational level to secure access to health-technologies. An examination of the limitations of the right to health when used at a supranational level are beyond the scope of this chapter but are considered elsewhere.[109] Nonetheless, in taking this focus, we are not suggesting supranational actions are not important in terms of the right to health. Supranational

[107] Access to high costs medicines for rare diseases creates difficult challenges for developing countries, *see*: UNCHR, Report of the UN High Commissioner for Human Rights (2023) (E/2023/74), para. 15.
[108] *See* discussion in: Carlos M Correa, *Mitigating the Impact of Intellectual Property in Developing Countries Through the Implementation of Human Rights* in *Research Handbook on Human Rights and Intellectual Property*, 201 (Christophe Geiger ed., Edward Elgar 2015).
[109] For example, *see* discussion in: Lawrence O. Gostin, *Global Health Law*, 61-64, 252-260 (Harvard University Press, 2014); Olasupo Ayodeji Owoeye, *Patents and the Obligation to Protect Health: Examining the Significance of Human Rights Considerations in the Protection of Pharmaceutical Patents*, 21(4) J.L.Med. 906 (2014); Aisling M. McMahon, *Intellectual Property Rights & Global Access to Health-Technologies During Pandemics: Reflecting on Vaccine Nationalism, COVID-19 & the WHO Pandemic Agreement Negotiations – The Need for Institutional Change & Collective Action,*J. of L. Med. Ethics (2025) (forthcoming).

actions across states, are important to bolster, encourage and support national actions in using the right to health to address access issues posed by IPRs.[110]

(i) Use of the Right to Health at a National level to Secure Access to IP Protected Health-Technologies

Considering first how individual patients (and/or their families) can use the right to health to secure access to health-technologies at a national level, in such contexts, much depends on whether there is a justiciable avenue to use the right to health within national legal systems. For example, where there is a national constitutional protection for the right to health, if an affected person who needs access to health-technologies has legal standing (and financial resources where needed) to take a case in the domestic courts, they could use the right to health to challenge the national State's failure to provide specific health-technologies to meet their health needs. However, using the right to health in this way is generally only possible in countries which have a justiciable right to health at the domestic level. Whilst the ICESCR is not directly enforceable in domestic legal systems, it may nonetheless provide support in such cases in relation to a State's international human rights obligations.[111] In certain contexts, individuals may also seek to use other rights, such as the right to life, if that is constitutionally (or otherwise) protected in the State as a legal avenue to seek access to health-technologies, such as where lack of access to health-technologies could be potentially fatal or shorten their life-span. It should however be noted, that in some jurisdictions, courts will adopt a high level of deference to governments on decisions around resource allocation including how healthcare spending is allocated within a State given the finite national health budgets, and high thresholds may be applied in some jurisdictions before courts will intervene.[112]

These types of legal actions grounded in a justiciable right to health are more common in middle income countries, where the right to health is frequently 'judicialized' i.e. used

[110] Genevieve Wilkinson, Evana Wright, *Unblocking the Human Right to Access the Benefits of Science in the Covid-19 Era* in Jens Schovsbo (ed), *Intellectual Property Rights in Times of Crisis,* 59-82 (Edward Elgar 2024).
[111] Hans V. Hogerzeil, Melanie Samson, Jaume Vidal Casanovas, Ladan Rahmani-Ocora, *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* 368 Lancet 307 (2006).
[112] For a discussion of this in the UK context, which does not have a justiciable right to health per se, but where other human rights have been argued to seek access to health, *see* Keith Syrett, *Law, Legitimacy and the Rationing of Health Care* (Cambridge University Press, 2007) 166-167. Rights based arguments under the Human Rights Act 1998 have been argued in several UK cases by patients seeking access to healthcare, for example *see*: *R (on the application of Condliff v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910 which focus on Art. 8 (ECHR) private and family life.

domestically to seek access to medicines through litigation.[113] In contrast, such approaches are less common in low-income countries, or high-income countries. This is at least in part likely due to different contexts. For instance, low-income countries often lack the resources to provide access to health-technologies at commercial prices, and high-income countries have - in many cases - been slow to incorporate a justiciable right to health, [114] including due to public policy concerns around resources and the potential for litigation. Indeed, the majority of domestic right to health litigation has taken place in middle-income countries, such as Brazil.[115] Such litigation provides an avenue for individual patients to seek access to specific health-technologies to meet their needs. Accordingly, the right to health as used by patients in countries with national legal protections for this right exist can offer an important and effective avenue for individuals to obtain access to patented health-technologies in certain contexts.

Ensuring a justiciable right to health at the national level is a key recommendation of the UN High Commissioner for Human Rights, Comprehensive Report on Access to Medicines 2025.[116] Paragraph 71 (a) of this Report recommends that Member States would: '(a) Ensure that universal and effective access to essential medicines, vaccines and other health products is protected as a right under domestic legal frameworks'. Alongside this, Paragraph 71 (f) recommends Member States would 'Ensure the availability of monitoring and accountability mechanisms, including human rights indicators; the justiciability of the right to health, under domestic legal systems; and access to remedy, including through non-judicial mechanisms.'[117] Thus, it is vital that States which do not have a justiciable right to health consider the adoption

[113] For an analysis and discussion of this *see*: Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism* Humanity Journal (2019); Everaldo Lamprea, *The Judicialization of Health Care: A Global South Perspective*, 13 Annual Rev. L. Soc. Sci. 442 (2017); Everaldo Lamprea, Lisa Forman, Audrey Chapman, *Structural Reform Litigation* in *Comparative Law and Regulation*, 342-45 (Francesca Bignami, David Zaring eds., Edward Elgar 2016).

[114] Colleen M. Flood, Bryan Thomas, *Justiciability of Human Rights for Health* in *Foundations of Global Health and Human Rights*, 184 (Lawrence O. Gostin, Benjamin Mason Meier eds., Oxford University Press 2020).

[115] Colleen M. Flood, Bryan Thomas, *Justiciability of Human Rights for Health* in *Foundations of Global Health and Human Rights*, 187 (Lawrence O. Gostin, Benjamin Mason Meier eds., Oxford University Press 2020); Holger Hestermeyer, *Access to Medicine as a Human Right in the WTO Order* in *Human Rights and the WTO: The Case of Patents and Access to Medicine*, 136 (Oxford University Press, 2008).

[116] UNHRC, *Comprehensive Report on Access to Medicines, Vaccines and Other Health Products in the Context of the Right to the Highest Attainable Standard of Physical and Mental Health* (2025) A/HRC/59/29, para. 71 (a),(f).

[117] Human rights indicators can be important tools for accountability and monitoring, depending on how they are developed and used. We do not consider this in full due to space constraints. For a discussion, *see*: Paul Hunt, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. E/CN.4/2006/48, March 3, 2006; Paul Hunt, Gillian MacNaughton, *A Human Rights-Based Approach to Health Indicators* in *Economic, Social, and Cultural Rights in Action* (Mashood Baderin, Robert McCorquodale (eds.), Oxford University Press, 2007); Andrea Boggio, Brian Gran, *A Proposal for Indicators of the Human Right to Science* in *The Right to Science Then and Now* (Helle Porsdam and Sebastian Porsdam Mann (eds), Cambridge University Press, 2021).

of one, to provide patients (and their families) an avenue to petition for access to health-technologies where these are inaccessible to them in the State, particularly where lack of access can prove life-limiting.

Having said this, whether a justiciable right to health at the national level creates positive and/or negative implications for the population at a whole within a State, is often dependent on how it is interpreted and utilized in practice by the State.[118] A justiciable right to health in the national State can sometimes act as a double-edged sword, as in some cases, it can potentially bolster the ability of commercial providers to charge high prices for patented medicines, and other health-technologies. For example, based on analysis of the use of the right to health in Colombian and Brazilian courts, both countries where there has been extensive right to health litigation, Kapczynski writing in 2019 suggested that decisions to provide expensive patented drugs in fulfilment of this right for individuals was having an adverse impact on the overall health budget, likely contributing to inequality for others.[119] Kapczynski noted that, for example, in Brazil, estimates suggested that over 40,000 persons per year litigate for access to medicines or other health services, with a success rate of between 80-90% at that time.[120]

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[118] Katharine Young, Julieta Lemaitre, *The Comparative Fortunes of the Right to Health: Two Tales of Justiciability in Colombia and South Africa* 26 Harvard Hum. Rts. J. 179 (2013); Octavio Luiz Motta Ferraz, *The Right to Health and the Courts of Brazil: Worsening Health Inequities?* 11(2) Health Hum. Rts. 33 (2009). *See also* discussion which makes the case for a constitutional right to health in Ireland, in: Ollie Bartlett, *Does Ireland Need a Constitutional Right to Health After the Covid-19 Pandemic?* 73(2) N.I. Legal Q. 373 (2022).

[119] Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Hum. J. 85 (2019); Colleen M. Flood, Bryan Thomas, *Justiciability of Human Rights for Health* in *Foundations of Global Health and Human Rights,* 187 (Lawrence O. Gostin, Benjamin Mason Meier eds.,Oxford University Press 2020); A recent example of such issues in Brazil is the right to health litigation which has ensued in relation to access to 'Zolgensma' a gene therapy used for the treatment of SMA. In this instance, the Brazilian drug pricing authority approved a maximum price which was 77% lower than the manufacturer's (Novartis) intended price. In response, the manufacturer decided not to commercialise Zolgensma in Brazil. However, families of children with SMA sued the government for immediate access on the grounds of the right to health, which resulted in the court directing the Ministry of Health to fund the treatment of numerous patients, at an average cost of over $1.7 million per patient. This has meant the Ministry of Health must fund the importation of Zolgensma, with knock-on implications for the health budget. *See:* Adriana Mitsue Ivama-Brummell, Anita K Wagner, Vera Lúcia Edais Pepe, Huseyin Naci, *Ultraexpensive Gene Therapies, Industry Interests and the Right to Health: The Case of Onasemnogene Abeparvovec in Brazil*, 7 BMJ Glob. Health (2022).

[120] Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Hum. J. 83, 84 (2019); Octavio L. Motta Ferraz, *Brazil: Health Inequalities, Rights, and Courts: The Social Impact of the Judicialisation of Health* in *Litigating Health Rights* (Alicia Ely Yamin, Siri Gloppen eds., Harvard Law School 2011); Daniel Wei L. Wang, *Right to Health Litigation in Brazil: The Problem and the Institutional Responses* 15(4) Hum. Rts. L. Rev. (2015); *see* also discussion of Colombian context in: Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Hum. J. 85 (2019);
Everaldo Lamprea, *The Judicialization of Health Care: A Global South Perspective*, 13 Annual Rev. L. Soc. Sci., 442 (2017); Everaldo Lamprea, Lisa Forman, Audrey Chapman, *Structural Reform Litigation* in *Comparative Law and Regulation*, 342-45 (Francesca Bignami, David Zaring eds., Edward Elgar 2016).
See also discussion more broadly around health justice and right to health in: Eric A. Friedman, Lawrence O. Gostin, *Imagining Global Health with Justice: In Defence of the Right to Health*, 23 Health Care Anal 319 (2015).

Indeed, Kapczynski has previously argued that such uses of human rights is contributing to the emergence of neoliberal regimes and inequality.[121] In addition to such tensions between delivering individual patient and broader societal healthcare needs, questions of equality between patients within a State can arise. For instance, often it is individuals with the highest socio-economic disadvantage in society that are likely to have the least access to judicial processes. This in turn means that where there is potential to engage in right to health litigation at the national level, this is likely something that only individuals who have more financial means can pursue, further contributing to health inequity.[122]

In highlighting such issues, we recognize that access to high-cost health-technologies is often vital for the individual patients affected. It cannot be overstated that lack of access to such medicines may have devastating consequences for a patient's quality of life. In some cases, lack of access to medicines will be fatal for patients. Given such individual health needs, this analysis is not seeking to criticise in any way individuals or their families for using the right to health to seek access to health-technologies. Nonetheless, considered from a population level, such individually framed uses of the right to health could be seen as a short-term mechanism to address individual patient needs. In the longer term, a more sustainable approach is needed to address root causes of high-cost medicines and tackle these issues from a public health perspective, so that patients do not face such difficulties.

Such longer-term State strategies are directly implicated by the right to health particularly if greater emphasis is placed on the collective as opposed to individual dimension of the right to health. This collective dimension of the right to health is discussed by Chapman and others.[123]

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[121] Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Hum. J. 85 (2019); Everaldo Lamprea, *The Judicialization of Health Care: A Global South Perspective*, 13 Annual Rev. L. Soc. Sci. 442 (2017); Everaldo Lamprea, Lisa Forman, Audrey Chapman, *Structural Reform Litigation* in *Comparative Law and Regulation* 342-45 (Francesca Bignami, David Zaring eds., Edward Elgar 2016).

[122] Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism*, Hum. J. 85 (2019); Everaldo Lamprea, *The Judicialization of Health Care: A Global South Perspective* 13 Annual Rev. L. Soc. Sci., 442 (2017); Everaldo Lamprea, Lisa Forman, Audrey Chapman, *Structural Reform Litigation* in *Comparative Law and Regulation* 342-45 (Francesca Bignami, David Zaring eds., Edward Elgar 2016); Luiz Motta Ferraz, *The Right to Health in the Courts of Brazil: Worsening Health Inequities?* 11(2) Health Hum. Rts. (2009).

[123] Audrey R. Chapman, *Global Health, Human Rights and the Challenges of Neoliberal Policies*, 55-59 (Cambridge University Press 2016); Wilkinson also discusses the relationship between public health and the right to health (for individuals), highlighting how the right to health can be used to strengthen public health at a population level, *see* discussion in for example: Genevieve Wilkinson, *The Human Rights (Parliamentary Scrutiny) Act 2011 (Cth) and the Increasingly Visible Intersections Between the Human Right to Health and Intellectual Property in Australia*, Intellectual Property Forum, 47 (2016).

For instance, in terms of the collective dimension of the right to health, Chapman points to footnote 30 of General Comment 14, which states that:[124]

> Regardless of whether groups as such can seek remedies as distinct holders of rights, States parties are bound by **both the collective and individual dimensions** of article 12. **Collective rights are critical in the field of health**; modern public health policy relies heavily on prevention and promotion which are approaches directed primarily to groups. [Emphasis added]

This is a recognition of the collective nature of healthcare, we as individuals benefit from population level functioning healthcare systems. This collective nature of healthcare is particularly evident in public health campaigns such as around vaccination, where the more people that are vaccinated, the more effectively public health strategies may eradicate transmissible diseases. Nonetheless, particularly in the current era of rising costs of medicines, the collective dimension of the right to health is critically important and could be used to bolster State strategies to reduce costs of health-technologies. This is because, if States must pay high costs for medicines this reduces funds for other therapies/medicines for other patients. Thus, it is in our collective interest that States would develop health care systems which offer more affordable medicines/therapies, so that more people can benefit from health-care technologies and ultimately, so that more therapies/medicines can be provided to all people. Such longer-term solutions focusing on the collective dimension of the right to health, should also mean that patients do not need to raise legal challenges to secure access to health-technologies, which places significant burdens on patients and their families, often at a difficult time for them.

In terms of broader strategies, the UN High Commissioner for Human Rights, Comprehensive Report on Access to Medicines 2025, recommended the advancement of a 'human rights economy' which would entail ensuring the maximum available financial budget resources for public health, which could include the adoption of tax measures to increase relevant fiscal space for the realisation of the right to health.[125] If States adopt such recommendations, this could help to provide additional funds towards national health budgets to enable States to better deliver access to health-technologies and hence comply with their right to health obligations. However, the adoption of such measures by States will arguably only deliver better overall

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[124] Audrey R. Chapman, *Global Health, Human Rights and the Challenges of Neoliberal Policies*, 58 (Cambridge University Press 2016).

[125] UNHRC, *Comprehensive Report on Access to Medicines, Vaccines and Other Health Products in the Context of the Right to the Highest Attainable Standard of Physical and Mental Health* (2025) A/HRC/59/29, para. 71 (e).

access to healthcare, if States also engage with and develop mechanisms to reduce the high cost of patented health-technologies. In the absence of such mechanisms, directing greater State resources towards funding patented health-technologies at commercial prices could maintain the status quo. Indeed, one could question whether such measures would unintentionally drive up the high costs of medicines if there is a perceived availability of increased resources in the longer term, thus negating potential short-term gains in relation to access to medicines.

In short, a justiciable right to health at the national level is a vital tool for individual patients. However, given the issues highlighted, we argue that litigation by individual patients should encourage States to take longer term actions to facilitate strategies which deliver sustainable systems to reduce costs of health-technologies and maximise the availability of these to address the collective dimension of the right to health. In the longer term, more systematic approaches to reducing costs of high-priced medicines are critical to delivering on the right to health for everyone, including by tackling the ways certain uses of IPRs enable high costs, whilst balancing the incentives provided by IPRs.

ii) Right to Health & States Actions to deliver right to health: Balancing IPRs with Access to Health-Technologies

The right to health can be engaged with by States in a proactive way as an avenue to support States in taking legislative or other policy measures to address public health needs impacted by how IPRs are used.[126] Here, we focus on recent examples in India and other contexts, whereby the right to health has been engaged with by States (or judicial/legislative bodies within States) in a proactive manner which aims to facilitate access to health-technologies in cases where IPRs have the potential to impede access. We focus on three avenues in such contexts,[127] namely: a) use of the right to health by States to support its use of TRIPS flexibilities, including compulsory licensing (CL) to deliver access to health-technologies; b) use of the right to health within national courts in deciding whether a remedy related to the enforcement of IPRs will be

[126] *See* also analysis in: Holger Hestermeyer, *Conflict Between Patents and Access to Medicine* in *Human Rights and the WTO: The Case of Patents and Access to Medicine*, 208 (Oxford University Press 2008); Duncan Matthews, *Right to Health and Patents* in *Research Handbook on Human Rights and Intellectual Property,* 499 (Christophe Geiger ed., Edward Elgar 2015).

[127] This builds upon the conception set out by: Duncan Matthews, *Right to Health and Patents* in *Research Handbook on Human Rights and Intellectual Property*, 499 (Christophe Geiger ed., Edward Elgar 2015) where Matthews argues that a right to health and rights based discourse, has been engaged with by States in such contexts via approaches to policy change, legislative change and judicial interpretation.

granted if this could impact right to health, and c) use of the right to health by States as a driver (and defense where challenged) to the adoption of legislative or other policy measures which aim to offer greater balance of IP rightsholders interests with access to health needs.

A) Right to Health: Justification/Defense for Issuance of a compulsory license (or other TRIPS Flexibility)

In terms of avenues under which the right to health could be used to address access issues for high-priced medicines, one route is through the use and grant of CLs. The right to health could be used as a justification for the use of a CL where a legal challenge is raised against the CL. For example, the right to health was used to justify a CL in the Indian decision in *Natco v. Bayer, Compulsory License Application No.1 of 2011,* (Decision of the Indian Controller of Patents, 9 March 2012), which involved the drug called 'Sorafenib' (trade name 'Nexavar'). This drug is used to treat kidney and liver cancer. In the case, Natco sought a voluntary license to produce the drug from Bayer, the patent holder, but this was refused, and a CL was subsequently sought.[128] The CL was granted by the comptroller for patents, and upheld on appeal to the Indian IP Appellate Board which concluded that 'public health and access to medicine, a facet of [the] right to life'.[129] In the case, access to the technology was framed as not just impacting the right to health, but rather as impacting the right to life, as without access to the medicine, the condition could prove fatal.

In such cases, Oke argues that:

> By incorporating the right to health into the adjudication of patent disputes, national courts in developing countries can play a crucial role in improving access to medicines at affordable prices. The incorporation of the right to health into the adjudication of disputes involving pharmaceutical patents does not necessarily imply that patent rights will no longer be recognized and respected, it only means that courts should not permit patent rights to be exercized and enforced in a manner that impedes access to medicines and the enjoyment of the right to health.[130]

[128] As discussed in Emmanuel Kolawole Oke, *The Right to Health in Pharmaceutical Patent Disputes* Research Paper, No 145, South Centre, Geneva, 29 (2022).
[129] *Bayer v. Union of India & Others, OA/35/2012/PT/MUM, decision of the Indian Intellectual Property Appellate Board,* (4 Mar. 2013), para. 20; As cited by and discussed in Emmanuel Kolawole Oke, *The Right to Health in Pharmaceutical Patent Disputes* Research Paper, No 145, South Centre, Geneva, 29 (2022).
[130] Emmanuel Kolawole Oke, *The Right to Health in Pharmaceutical Patent Disputes* Research Paper, No 145, South Centre, Geneva 30 (2022).

This approach is supported by statements of the former Special Rapporteur on the Right to Health, Anand Grover, who stated in their (2009) report that States should employ TRIPS flexibilities including CL where needed to fulfil the right to health.[131]

Nonetheless, there are practical and legal challenges with using CLs. At a practical level, States' ability to effectively use a CL is contingent on there being sufficient domestic manufacturing capacity for a generic manufacturer to produce a product under CL in that State. India has a very strong domestic drug manufacturing system and thus, will have greater ability to use CLs than other States.[132] Therefore, developing domestic manufacturing capacity is essential in the context of making use of existing TRIPs flexibilities to improve access to medicines.

Article 31 bis to the TRIPS Agreement, provides an avenue to waive the requirement under Article 31(f) of TRIPS that product made under CL are authorised '… predominantly for the supply of the domestic market of the Member authorizing such use'. Article 31 bis, provides for limited circumstances, in which products can be made under CL for export to a State which has insufficient manufacturing capacity to produce that product itself under CL.[133] Nonetheless, the provision has been used only once to date.[134] In practice, Article 31bis is often seen as ineffective for a range of reasons, including the limited incentives to produce a product under CL for use in another State, and due to procedural and other legal hurdles involved in using this provision.[135] Thus, developing domestic manufacturing capacity, is critical to effective operation of CLs under the TRIPS framework, in the current context.

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[131] UNGA, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, A/HRC/11/12 (31 March 2009), para. 27.

[132] Olasupo Ayodeji Owoeye, *Compulsory Patent Licensing and Local Drug Manufacturing in Africa*, Bull. World Health Organ. (2014).

[133] Art 31 bis was introduced as an amendment to the TRIPS Agreement on a temporary measure in August 2003, it was subsequently proposed as an amendment to TRIPS in 2005, and finally adopted within TRIPS following ratification by the required number of WTO States in 2017. General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), WT/L/540/Corr. 1 (1 September 2003); WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641, 8 Dec. 2005
See discussion, in Aisling M McMahon, *Patents, access to health and COVID-19 – The role of compulsory and government-use licensing in Ireland*, 71(3) Northern Irish Legal Quarterly 331-358 (2020).

[134] For a discussion and critique of Art 31(bis) *see*: Ezinne Mirian Igbokwe and Andrea Tosato, *Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis,* 91 Fordham L. Rev. 1791 (2023).

[135] *See* recent discussion of Art 31bis in: Ezinne Mirian Igbokwe and Andrea Tosato, *Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31bis*, 91 Fordham L. Rev. 1791 (2023).; *See also*: Nicholas G. Vincent, *TRIP-ING Up: The Failure of TRIPS Article 31bis*, Gonzaga J. Int'l. L. 24(1) (2020).

Nonetheless, there are also several legal and other obstacles with using CLs in domestic settings,[136] these include: LMICs may fear utilising the TRIPS flexibilities, including CL, due to risks of trade retaliation including trade sanction being imposed by HICs.[137] For example, Correa and Matthews refer to Thailand's 2007 decision to issue a CL for a drug used to treat NCDs, based on the constitutional protection of the right to health wherein Thailand took the view that NCDs represent an equally serious a threat to health as communicable diseases and issued a CL for Plavix (used to treat heart disease).[138] However, Thailand's action in issuing CLs for this and other NCDs, provoked backlash from the EU and the United States (US), including, at that time, the US placing Thailand on its Priority Watch List under the Special 301 procedure.[139]

This example raises a related question around the role of HICs and regions in supporting other States ability to fulfil their obligations under the right to health. In this context, the UN High Commissioner's, *Comprehensive Report on Access to Medicines* (2025) stated in paragraph 72(a) that in line with States obligations of international co-operation and assistance, it recommended that Member States: '[e]nsure that intellectual property rights are not invoked and applied in a manner inconsistent with the right to access medicines, vaccines and other health products or with the exercise of States of the flexibilities of the TRIPS Agreement.' This could be read to imply States should avoid challenging other States use of CL if IPRs are impacting the right to health in that other State. As a corollary, this statement reinforces the importance of a right to health argument being invoked by States in justifying uses of CL particularly where challenges arise.

There are some albeit more limited instances of HICs issuing a CL for medicines used to treat NCDs.[140] For example, Italy issued a CL in 2005 for 'Imipenem/Cilastatin,' an antibiotic used to treat serious bacterial infections.[141] It also issued a CL for 'Finasteride' in 2007, a drug used

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[136] *See* discussion in: Aisling McMahon, *Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance*, 47 J. Med. Ethics 142-148 (2021).
[137] *See* discussion in: Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 136 (Health Action International 2016).
[138] Carlos Correa, Duncan Matthews, *The Doha Declaration Ten Years on and its Impact on Access to Medicines and the Right to Health*, 27 (UNDP Discussion Paper, Dec. 2011).
[139] Carlos Correa, Duncan Matthews, *The Doha Declaration Ten Years on and its Impact on Access to Medicines and the Right to Health*, 28 (UNDP Discussion Paper, Dec. 2011).
[140] *See* discussion in: Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 54-58 (Health Action International 2016); Medicines Law and Policy, *The TRIPS Flexibilities Database*, Medicines Law and Policy https://www.tripsflexibilities.medicineslawandpolicy.org
[141] *See*: Medicines Law and Policy, *The TRIPS Flexibilities Database*, Medicines Law and Policy https://www.tripsflexibilities.medicineslawandpolicy.org; *AGCM Case A364, Merck-Principi Attivi* (2005), Provvedimento n. 14388;); Third World Network, *Italy Forces Drug Firms to Give Licences for Generics Rivals*,

to treat prostatic hyperplasia.[142] More recently, several HICs have initiated the process of issuing CLs for NCDs, however in many cases these CLs were not executed, including in some cases because voluntary agreements were reached on a price discount. Examples of recent CL discussions by HICs for NCDs, include CL applications related to; 'Pertuzumab,' a drug used to treat breast cancer (Scotland 2018) and 'Orkambi' a drug used to treat cystic fibrosis in the UK in 2019.[143] In such cases, CLs were threatened but not issued, due to a later price negotiation. These examples show that a State's threat to using a CL can act as leverage to obtain more favourable voluntary licensing terms. Where successful this may lead to lower prices for the medicines in that State, thereby enabling States to provide access to such medicines to greater patient numbers and to vindicate the accessibility/availability components of the right to health. Nonetheless, for CLs to be an effective lever in such contexts, there must be a real possibility for States to use a CL to ensure generic production of the health-technology in question which is contingent, amongst other aspects, on State's domestic manufacturing capacity.

In short, this chapter argues that States should actively use TRIPS flexibilities where needed to provide access to health-technologies in the national State to vindicate the right to health. States should ensure national systems offer feasible and appropriate legal avenues to apply for a CL in the national State, and that the grounds for grant of a CL at the national level include public interest and health considerations.[144] Arguably, the greater the number of States including HICs that use CL, the more normalised such practices become, and such practices could link with States international co-operation obligations. This in turn could assist in achieving a better balance between protection of IPRs and the right to health, particularly, around access to emerging health-technologies. Alongside this, it is critical that domestic manufacturing

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TWN (2007). https://www.twn.my/title2/health.info/twninfohealth086.html ; James Packard Love, *Knowledge Ecology International Research Note 2007: Recent Examples of Compulsory Licensing of Patents*, KEI (8 Mar. 2007) https://www.keionline.org/book/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents

[142] Medicines Law and Policy, *The TRIPS Flexibilities Database*, Medicines Law and Policy, https://www.tripsflexibilities.medicineslawandpolicy.org/; *AGCM Case A364, Merck-Principi Attivi* (2005), Provvedimento n. 16597;

[143] Medicines Law and Policy, *The TRIPS Flexibilities Database*, Medicines Law and Policy https://www.tripsflexibilities.medicineslawandpolicy.org/; Just Treatment Campaign, *Technical Submission: Enacting a Crown Use Licence to Secure Access to Affordable Pertuzumab for Scottish Breast Cancer Patients*, Just Treatment Campaign (13 Apr. 2018); Ellen t'Hoen, *Cystic Fibrosis Medicines Wars in Europe,* Medicines Law and Policy, (03 Feb. 2025). https://www.medicineslawandpolicy.org/2019/02/cystic-fibrosis-medicines-wars-in-europe/ ; This Orkambi campaign also highlights the important role of civil society groups in such context, *see also*: Just Treatment, *Patient Power Works – Here's the Proof*, Just Treatment (14 Nov. 2019). https://www.justtreatment.org/news/2019/11/12/we-won.

[144] *See discussion in:* Aisling M McMahon*, Patents, access to health and COVID-19 – The role of compulsory and government-use licensing in Ireland*, 71(3) Northern Irish Legal Quarterly 331-358 (2020).

capacity be developed across States including in LMICs, as this will over time enable States to develop a sustainable supply of domestic products, and provide avenues to use CL, where legally possible and required for public health reasons.

b) *Right to Health: Consideration by Courts including in challenges related to enforcement of IPRs which could impact third parties' right to health*

The right to health can also be a factor that is considered by national courts in deciding on whether to enforce IPRs, and other legal remedies in certain contexts. For example, in the 2008 case of *F. Hoffman-La Roche Ltd. And Anr. v. Cipla Ltd*, as Correa highlights the right to health successfully prevailed against an attempt to obtain an injunction against the generic manufacturer of a lung cancer drug ('Tarceva'), on the basis that it would be incompatible with the right to access life-saving medication.[145] In this case, Justice Ravindra Bhat considered the right to health in the reasoning (as part of Article 21 of the Constitution which offers protection for the right to life) and stated that:

> […] India entered into the TRIPS regime, and amended her law to fulfil her international obligations, yet… the Court cannot be unmindful of the right of the general public to access life-saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erloticip are concerned. *F. Hoffman-La Roche Ltd. and Anr. Vs. Cipla Limited*, paragraph 85.[146]

[145] Carlos M Correa, *Mitigating the Impact of Intellectual Property in Developing Countries Through the Implementation of Human Rights* in *Research Handbook on Human Rights and Intellectual Property,* 212, 213 (Christophe Geiger ed., Edward Elgar 2015).
[146] *See* discussion in: Carlos M Correa, *Mitigating the Impact of Intellectual Property in Developing Countries Through the Implementation of Human Rights* in *Research Handbook on Human Rights and Intellectual Property,* 212, 213 (Christophe Geiger ed., Edward Elgar 2015).

This case demonstrates how the right to health can be used within judicial reasoning to support the refusal of injunctive relief where IP enforcement has the potential to impact access to medicines in certain contexts.

As discussed above, more recently, a similar approach was evident in the Risdiplam case involving Roche's application for an interim injunction against Natco to produce a generic version of Risdiplam. In that case, the court highlighted the importance of the public interests at stake including health needs of patients and thus, refused the interim injunction. We acknowledge here that Indian jurisprudence has a long history of engaging with the right to health (as part of the right to life) which will likely mean Indian courts are more inclined to engage with such arguments. Moreover, national courts can only address such issues if relevant cases come before them. India's significant pharmaceutical manufacturing capacity makes it more likely that challenges such as those outlined will come before Indian courts as generic pharmaceutical companies in India may be more likely to seek to produce a domestic generic product. Such cases provide courts an opportunity to intervene based on the right to health. These types of actions are arguably not as likely in many other States, such as where there are limited domestic manufacturing capacity, or where there are strong originator pharmaceutical companies (such as in many HICs) and more limited generic producers.

Nonetheless, where such cases do arise, arguably, national courts should actively consider the impact of IP remedies on other human rights including the right to health, where possible within the national legal framework. This could also form part of moves within the national legal system to better balance the right to IPRs with other rights at stake, including the right to health, a point we return to below.

c) Right to Health: National Legislative Measures Balancing Rightsholder Interests with Right to Health

Arguably, approaches such as making greater use of TRIPS flexibilities, and national courts having greater recourse to the right to health within cases related to IP enforcement, are likely to primarily facilitate short-term access to health-technologies. Thus, alongside such approaches, it is critical that States use the right to health to actively devise and support policies including legislative measures which seek to better balance IPRs and access to health. States can do this in several ways, some of which we highlight in this section.

One avenue is by States considering national patent legislation and adopting references within this to human rights, for example, the right to health and other relevant human rights could be referenced in the preamble or object clauses to national intellectual property legislation.[147]This could provide further impetus for national courts to engage with such rights. However, it should be noted that depending on the national level framework, for example, where there is constitutional protection for private property (and where IPRs are construed as falling under this protection) this may give rise to challenges. Thus, careful consideration is needed.

In addition, States could consider how the patentability criteria are being interpreted in national States, and ensuring thresholds adopted for these criteria offer an appropriate balance between providing incentives for the development of novel health-technologies and ensuring patents are not provided to overly broad subject-matter or in cases where there are minimal advancements to existing technologies. For example, we can consider Section 3(d) of the Indian Patents Act 1970, as amended by the Indian Patents (Amendment) Act 2005 and how this has been interpreted within India in certain cases to align with right to health. For instance, in 2013, the right to health was used to indirectly support continued access to 'Glivec' (a targeted cancer therapy for use in treatment of chronic myeloid leukemia (CML)) in *Novartis v India*.[148] Novartis had applied for patents related to Glivec which were refused in India, based on Section 3(d) of the Indian Patents Act 1970, as amended by the Indian Patents (Amendment) Act 2005. This provision states that; 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' shall not be considered a patentable invention. As such, medicines or health-technologies must demonstrate enhanced 'efficacy,' which has been interpreted by the Madras High Court as 'therapeutic efficacy,' to be patentable.[149] This provision was introduced via national legislation in 2005[150] and aims to

[147] We are particularly grateful to Dr Genevieve Wilkinson for her insights on earlier drafts in this context; For a discussion in the Australian context, *see*: Genevieve Wilkinson, *The Human Rights (Parliamentary Scrutiny) Act 2011 (Cth) and the Increasingly Visible Intersections Between the Human Right to Health and Intellectual Property in Australia*, IP Forum: J. Intellectual & Industrial Prop. Soc. Aus. N.Z. 105 (2016).
[148] *Novartis AG V Union of India & Others* (2013) 6 SCC 1. For a discussion of the role of Médecins San Frontier in this case, *see*: Eduard Grebe and Marcus Low, *Transnational mobilisation on access to medicines*:*The global movement around the imatinib mesylate case and its roots in the AIDS movement,* Centre for Social Science Research, University of Capetown, Working Paper No. 349 (December 2014) available at : https://humanities.uct.ac.za/sites/default/files/content_migration/humanities_uct_ac_za/1380/files/WP%2520349.pdf
[149] *Novartis AG & Ors. .v. Union of India & Ors*. AIR 2013 SC 1311; *See* discussion in: Vasishtan P & Samhitha Reddy, *Rethinking the Need for Defining 'Efficacy' In The Indian Patent Regime*, 1(1) E-Journal of Academic Innovation Research Int'l Prop. Assets, 107 (2020).
[150] Indian Patents Act 1970, s.3(d) as amended by the Indian Patents (Amendment) Act 2005.

restrict the patenting of medicines to 'new chemical entities,' the purpose of which was to prevent 'evergreening.'[151]

Novartis challenged the refusal to grant a patent over 'Glivec', however, the Supreme Court of India held that Glivec did not meet the criteria for patentability. In coming to this conclusion, the Supreme Court considered several factors, which included human rights obligations underpinning this provision. Oke has argued that:

> The Supreme Court's discussion of the legislative history behind section 3(d) indicates that the lawmakers who enacted the provision incorporated a *model of human rights* into the design of section 3 (d). The goal of the lawmakers was to ensure that the implementation and enforcement of the Indian Patents Act would not impede the enjoyment of the right to have access to essential medicines at affordable prices…[152]

This case highlights the role of judicial interpretation in giving effect to the human right to health at the national level even where there is no explicit constitutional protection of this right.[153]

The practical impact of this case and approach more generally in India for the right to health of such patients should not be understated. 't Hoen has noted that the cost of the generic version of this product in India was 176 USD (Natco) or 167 USD (Cipla) per patient per year, whereas the cost of Novartis's patented version in India was approx. 2,222 USD per patient per year.[154] Kapczynski previously argued that such legislative measures may encourage beneficial innovation which could advance the right to health, through incentivizing investment in research which leads to significant innovation, rather than incremental innovation.[155] In terms

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[151] *See* discussion in: Duncan Matthews, *Right to Health and Patents* in *Research Handbook on Human Rights and Intellectual Property*, 502 (Christophe Geiger ed., Edward Elgar 2015).

[152] *See* discussion in: Emmanuel Kolawole Oke, *Patents, Human Rights, and Access to Medicines*,151 (Cambridge University Press, 2022). *See also*: Olasupo Ayodeji Owoeye, *Patents and the Obligation to Protect Health: Examining the Significance of Human Rights Considerations in the Protection of Pharmaceutical Patents*, 21(4) J. L. Med 917 (2014); Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 135 (Health Action International 2016).

[153] *See* discussion in: Duncan Matthews, *Right to Health and Patents* in *Research Handbook on Human Rights and Intellectual Property*, 499 (Christophe Geiger ed., Edward Elgar 2015).*See also* discussion of the role of judicial interpretation in such contexts, *see*: Olasupo Ayodeji Owoeye, *Patents and the Obligation to Protect Health: Examining the Significance of Human Rights Considerations in the Protection of Pharmaceutical Patents*, 21(4) J. L. Med. 918 (2014); *See* also discussion of the case by Marta Radelli, *Patent Evergreening: Technological Advancement and Abusive Commercial Practices: Availability of Essential Medicine in the Case of Access to Insulin*, (2) Queen Mary L.J. 73 (2021).

[154] Ellen 't Hoen, *A victory for global public health in the Indian Supreme Court*, J. Pub. Health Pol'y 34, no. 3 (2013): 370-374, figure 1. *See also*: Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, 109 (Health Action International 2016), figure 7.

[155] Amy Kapczynski, *Engineered in India – Patent Law 2.0* , N. Eng. J. Med. 2,3 (2013).

of the impact of section 3(d) in India more generally, a 2017 report highlighted that it 'was raised in 69% of cases where the exceptions to patentability were cited indicating its use as a policy tool by the Indian Patent Office (IPO) in rejecting applications that fell within the exceptions.'[156] Despite this, a 2018 report analysing the pharmaceutical drug patents granted between 2009 and 2016 in India suggested that up to 72% of secondary patents were granted by the Indian Patent Office (IPO) in contravention of section 3 of the Indian Patents Act, where objections such as anti-evergreening and other rejections were overcome by the patentee, and not raised by the IPO.[157] Indeed, section 3(d) is sometimes criticized as being 'ambiguous,' owing to the absence of a definition for the term 'efficacy.'[158] However, as the term 'efficacy' may be interpreted either narrowly or broadly, the lack of a definition could also be viewed positively, as it provides greater discretion to the courts and Controller of the Patents and thus could potentially act as a useful policy lever.[159] This highlights the importance of not just legislative measures, but also the judicial interpretation of such measures, in creating a balance between IPRs and protecting the right to health.[160]

Yet such moves by India, have been met with a degree of backlash from some other states. For instance, India consistently features on the United States Trade Representative (USTR) Special 301 report 'priority watch list,' with reference often made to the restrictions on patent eligible subject matter created by section 3(d) of the Indian Patents Act.[161] Such consequences can deter

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[156] Feroz Ali, Sudarsan Rajagopal, Mohamed Mustafa, Chinnasamy Prabhu, *Rejected in India: What the Indian Patent Office Got Right on Pharmaceuticals Patent Applications (2009-2016)* 8 (Azim Premji University, Dec. 2017).

[157] Feroz Ali, Sudarsan Rajagopal, Venkata S. Raman, Roshan John, *Pharmaceutical Patent Grants in India: How Our Safeguards Against Evergreening Have Failed, and Why the System Must Be Reformed*, 34 (Azim Premji University, Apr. 2018).

[158] Vasishtan P & Samhitha Reddy, *Rethinking the Need for Defining 'Efficacy' In The Indian Patent Regime* 1(1) E-J. Academic Innovation Research Int'l Prop. Assets 103(2020); Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d*), 5(2) SCRIPTed 258 (2008).

[159] Vasishtan P & Samhitha Reddy, *Rethinking the Need for Defining 'Efficacy' In The Indian Patent Regime* 1(1) E-J. Academic Innovation Research Int'l Prop. Assets 111(2020); Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)* 5(2) SCRIPTed 260, 261 (2008); *See* D L Burk & M A Lemley, *Policy Levers in Patent Law,* 89 Va. L. Rev. (2003).

[160] Although beyond the scope of this chapter, concerns have been raised around how the recent Patents (Amendment) Rules 2024 in India may impact access to affordable medicines in this and other contexts. *See*: Indian Patent (Amendment) Rules 2024, Rule 55, Rule 66, Rule 131; For example, *see* discussion in: Durgesh Mukharya, *New Indian Patents (Amendment) Rules 2024: What You Need to Know: Significant Changes to Benefit Patent Applicants and Owners*, K&S Partners (25 Mar. 2024) https://www.lexology.com/library/detail.aspx?g=f3f88ba0-9791-48d1-a959-eebab9cb63da ; G Naga Sridhar, *Patent (Amendment) Rules 2024 May Increase Litigation, Impact Health Safety of Global South: Experts*, The Hindu Business Line (20 Apr. 2025). https://www.thehindubusinessline.com/economy/patent-amendment-rules-2024-may-increase-litigation-impact-health-safety-of-global-south-experts/article69468238.ece

[161] Office of the United States Trade Representative, *2025 Special 301 Report* , 54-55 (2025). https://www.ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf

States from utilising TRIPS flexibilities due to fear of retaliation, creating a chilling effect. These issues may act as less of a deterrent for India than other countries, as India has a significant pharmaceutical manufacturing industry, including for generic medicines. For instance, prior to the introduction of the TRIPS Agreement, India had become a leading producer of generic drugs (many of which were exported to developing countries), often described as the 'pharmacy of the developing world.'[162] Therefore, India may be less concerned about impacts related to the supply of other pharmaceuticals to the country (as a possible retaliation measure by companies in such contexts is the threat to refuse to supply that country with pharmaceuticals), as it has manufacturing capacity itself and could produce its own supply of medicines if necessary.[163] Nonetheless, this example also highlights the need for States to consider their international co-operation obligations under the right to health, and where possible to support other States in their use of TRIPS flexibilities and adoption of other policies (provided these are compliant with TRIPS) which seek to better shape a national IP framework that can deliver on the right to health.[164]

Aside from legislative measures related to the patentability of health-technologies, States could also look to other policy changes to better balance IPRs and the right to health. Arguably States have an obligation under the collective dimension of the right to health to take strategic action in such contexts. Indeed, paragraph 43(f) of General Comment No. 14 (discussed above) imposes the following obligation on States:

> To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely

[162] Timothy Bazzle, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines* 42(3) Georgetown J. Int'l L. 785 (2011).
[163] Kristen Jakobsen Osenga, *Get the Balance Right!: Squaring Access With Patent Protection*, 25 Pacific McGeorge Glob. Bus. Development L. J. 320 (2012); Genevieve Wilkinson, *Finding a Healthy Balance: Evaluating Models for Change to International Intellectual Property Laws Affecting Global Access to Medicine and Realisation of the Human Right to Health*, 5 Deusto J. Hum. Rts. 149 (2008); Caitlyn Morrison, *The Human Rights Perspective Behind Patent Laws*, 3(7) 19 Paideia (2016).
[164] For discussion of such international co-operation obligations, *see*: Genevieve Wilkinson, Evana Wright, *Unblocking the Human Right to Access the Benefits of Science in the Covid-19 Era* in Jens Schovsbo (ed), *Intellectual Property Rights in Times of Crisis, 59-82* (Edward Elgar 2024).

> monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.[165]

Any plan of action should address the accessibility and availability dimensions of the right to health, and as part of this, States could take strategic action by adopting a range of policy levers which may give States greater leverage to negotiate better prices for patented technologies.

Moreover, as noted, under the ICESCR and relevant General Comments, provision of essential medicines (as defined by the WHO Essential Medicines list) is a minimum obligation of States in protecting the right to health. States cannot use a resource-based argument to justify failure to provide essential medicines. One way to impose stronger requirements on States to facilitate the right to health would be for the WHO list of essential medicines to be reviewed and to add more medicines. If a drug is on that list, States have an obligation under the right to health to provide access to such medicines. In a similar vein, the UN High Commissioner on Human Rights *Comprehensive Report on Access to Medicines* (2025) recommended at paragraph 71(c) that Member States:

> Adopt national essential medicines lists, determined and regularly updated through an evidence-based, transparent and participatory process, which reflect the national health context and the particular needs of groups at risk; such lists should guide social protection, procurement, pricing and manufacturing policies.

Having said this, adding a medicine to the WHO list or creating a national list of essential medicines, without also having a national strategy towards ensuring sustainable prices for such medicines, could further entrench inequity as it could simply mean States purchase such essential drugs at commercial prices from rightsholders. This could perpetuate high-priced medicines, and lead to less funds being available for medicines not on that list. Nonetheless, States could use the WHO essential medicines list or national essential medicines lists (where applicable) to better leverage the right to health to negotiate for better pricing of such medicines with rightsholders. Relatedly, where affordable pricing is not available, States could invoke the right to health as a justification to employ TRIPS flexibilities including CLs, or threats of using these unless a reasonable and more affordable price can be obtained, to leverage better access to such medicines, or generic versions of these. If States were to act together as a bloc around essential medicines, this would lend strength in numbers and would arguably enable them to

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

negotiate for better access to such patented medicines. Such approaches would also serve to normalise the use of TRIPS flexibilities in cases where access cannot be achieved.

Part V: Concluding Reflections: The Right to Health & Intellectual Property Rights over Health-Technologies : Balancing Individual and Collective Needs towards person centred approaches

Increasingly, health systems all over the world, in HICs and LMICs are on brink of collapse due to rising costs of medicines and other emerging health-technologies. Many medicines are simply unaffordable to provide within public health contexts for all patients who need them. Lack of access to medicines can have a devastating impact on patients and their families, including impacting patients' quality of life. While, in some cases, lack of access to medicines can be the difference between life and death. The right to health is directly impacted in such contexts, as there are increasing constraints on both the accessibility and availability of health-technologies in all States. IPRs are not the only factor leading to high-priced medicines, but they are one key factor which can impact prices and hence, States' ability to deliver on their right to health obligations.

Having said this, patents (and other IPRs) play an important role in incentivizing development of emerging health-technologies within the current health innovation model. Thus, a nuanced consideration is needed around how to deliver more affordable pathways to access to IP protected health-technologies. Nonetheless, given the current crisis facing many States, deeper scrutiny is needed over the current balance being struck around how IPRs are being used over health-technologies, and the impact of IPRs on the accessibility and availability dimensions of the right to health.

This chapter has focused on how the right to health can be used at a national level by both individuals and States to seek greater access to patented health-technologies in everyday healthcare contexts. At an individual patient level, we have highlighted examples of how patients have used the right to health as the basis for legal challenges to petition for access to health-technologies to meet their individual healthcare needs. Such avenues can provide effective avenues for individual patients, and States should be encouraged to ensure there is a justiciable right to health for patients.

Nonetheless, individual uses of the right to health poses challenges. For patients, having to take a legal action to secure access to medicines is challenging, particularly, where access to such medicines may be the only potential treatment avenue for their clinical needs. Such legal challenges come with significant uncertainty as challenges may not be successful, and could cause significant stress for patients and their families. Legal action can also be time-consuming and can involve high legal costs Furthermore, at a population level, even where such challenges are effective, if the State does not adopt longer term strategies or pathways to offer medicines at lower costs, these challenges may mean there is a priority of finite resources directed to meeting access needs of individual patients which could impact funds available for other health-technologies. This in turn could exacerbate access to health issues at the national level. In making such arguments, we are not suggesting individual patients should be discouraged from taking such legal challenges where these are available to them. At an individual patient level, patients who need health-technologies to vindicate their right to health should be encouraged to use every means accessible to them to achieve this. However, at a policy level, such individualized framing of right to health should be seen only as a short-term solution to address individual access to health needs, often such approaches on their own do not address the broader systematic causes of high-priced medicines. Instead, such legal actions should encourage States to consider the collective dimension of the right to health and use this to develop longer term strategies to address access issues identified and reduce costs of health-technologies.

In this regard, States have considerable potential to use the right to health to support proactive measures. This chapter has discussed three key avenues for States (or national judicial bodies) to take to readdress the balance between IPRs and the right to health, namely: 1) greater State use of TRIPS flexibilities including CLs to address public health needs, including for NCDs. To enable this, States need to ensure national CL legislation offers an effective avenue for use of CL to facilitate ease of use of CL. Moreover, steps should be taken within States and at an international level, to build domestic manufacturing capacity within all States so States have practical manufacturing ability to use CLs. The right to health could be used as a justification (or defence) to support the grant (or challenge) of CLs; 2) National courts could engage more with the right to health where cases arise related to IPRs and access to health, including for example in cases involving the enforcement of IPRs (in assessing applications for injunctions, damages etc). Where appropriate, national courts could engage with the right to health to

highlight the need for States to adopt longer term strategies to deliver a greater balance between IPRs and access to health-technologies, in vindication of this right; and 3) in the longer term, it is vital that States take strategic actions to deliver avenues that will reduce the costs of medicines, including by considering national patent laws (and legislation) with reference to the right to health– to better balance IPRs and access to health whilst remaining in compliance with international obligations within the TRIPS Agreement for WTO States. This could be achieved, by ensuring the right to health is referenced in national patent (or other IPR) laws. Moreover, States could consider adopting national laws enforcing stricter patentability criteria around the application of novelty, and inventive step requirements which consider the broader societal benefits of the proposed technologies, and minimize risks of evergreening. However, as discussed, alongside adopting such laws, for these to offer effective avenues to vindicate the right to health, they must be implemented including via judicial interpretation with this aim in mind.

Finally, whilst this chapter has focused on national States as they bear the obligation under the ICESCR in terms of the right to health, nonetheless, the international community also has a key role to play in such contexts. [166] The more States and regional entities, such as the European Union, work together in tackling the access to health issues we all face, the greater the likelihood of success. Collective, regional and multi-lateral action is needed to support States who take such approaches, as the more such practices are normalized, arguably the greater likelihood of rights-based approaches having teeth in such contexts. The 21st century has brought transformative scientific developments in the health field, including new medicines and therapies for conditions that were previously untreatable. However, for us to realise the full benefits of such scientific advancements, as a global community, we must work together to adopt strategies and systems to ensure that those who need access to such health-technologies, can access them. This does not just have benefits for others, it also benefits each of us. The human condition means that everyone needs access to healthcare at some stage. Anyone could have or could develop a condition within their lifetime which requires access to novel health-technologies. Thus, having effective healthcare systems which promotes the development of novel health-technologies and ensures the accessibility of these for those who need them, is in all our collective interests, As Dr Martin Luther King Jr. put it:

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[166] *See* discussion in: Genevieve Wilkinson, Evana Wright, *Unblocking the Human Right to Access the Benefits of Science in the Covid-19 Era* in Jens Schovsbo (ed), *Intellectual Property Rights in Times of Crisis,* 59-82 (Edward Elgar 2024).

> We are tied together in the single garment of destiny, caught in an inescapable network of mutuality. And whatever affects one directly affects all indirectly.[167]

The right to health can be a key mechanism to enable us to reimagine the current framework within health innovation to deliver a system which better balances tools to incentivise the development of new health-technologies with ensuring that we can deliver access to these for all people who need them. However, this can only be achieved, if there is a greater willingness by all States and people within such States to achieve this, and to ensure greater attention is placed on delivering upon the collective dimension of the right to health.

[167] Dr Martin Luther King Jr., *Remaining Awake Through a Great Revolution* Speech Delivered at the National Cathedral, Washington, D.C., on 31 March 1968. Congressional Record, 9 April 1968.