Patents, Human Rights, and Access to Medicines

Emmanuel Kolawole Oke

PATENTS, HUMAN RIGHTS, AND ACCESS TO MEDICINES

Patent rights on pharmaceutical products are one of the factors that may contribute to the problem of the lack of access to affordable medicines in developing countries. In this work, Emmanuel Kolawole Oke provides a systematic analysis of the tension between patent rights and human rights law, contending that, in order to preserve their patent policy space and secure access to affordable medicines for their citizens, developing countries should incorporate a model of human rights into the design, implementation, interpretation, and enforcement of their national patent laws. Through a comprehensive analysis of court decisions from three key developing countries (India, Kenya, and South Africa), Oke assesses the effectiveness of national courts in resolving conflicts between patent rights and the right to health, and demonstrates how a model of human rights can be incorporated into the adjudication of patent rights.

Emmanuel Kolawole Oke is a lecturer in International Intellectual Property Law at Edinburgh Law School, University of Edinburgh. His research explores the interface between intellectual property and other branches of international law such as international trade law, international investment law, and international human rights law.

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1

Introduction

1.1 THE PROBLEM OF ACCESS TO AFFORDABLE MEDICINES IN DEVELOPING COUNTRIES

Payment for pharmaceutical products has long been identified as one of the potential causes of poverty in developing countries.[1] Moreover, there is a cyclical relationship between poverty and poor health.[2] In relation to developing countries, the health challenges confronting them is exacerbated by the high incidence of both communicable and non-communicable diseases in these countries. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), as at 2019, it is estimated that about 7.5 million people live with human immunodeficiency virus (HIV) in South Africa[3] and around 1.5 million people live with the same disease in

[1] See Jayashree Watal, 'Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?' (2000) Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, 2, available from www.iatp.org/files/Access_to_Essential_Medicines_in_Developing_Co.pdf (last accessed 21 September 2021), who notes that 'Expenditures on medicines can represent up to 66% of total health spending in developing countries and could be a major cause of household impoverishment, as 50–90% of such expenditures are out-of-pocket expenses.' For a global perspective on out-of-pocket on health generally, see Adam Wagstaff, Patrick Eozenou, and Marc Smitz, 'Out-of-Pocket Expenditures on Health: A Global Stocktake' (2020) 35(2) *The World Bank Research Observer* 123.

[2] See David H. Peters, Anu Garg, Gerry Bloom, Damian G. Walker, William R. Brieger, and M. Hazifur Rahman, 'Poverty and Access to Health Care in Developing Countries' (2008) 1136 *Annals of the New York Academy of Sciences* 161, who noted that, 'Although a lack of financial resources or information can create barriers to accessing services, the causal relationship between access to health services and poverty also runs in the other direction. When health care is needed but is delayed or not obtained, people's health worsens, which in turn leads to lost income and higher health care costs, both of which contribute to poverty … The relationship between poverty and access to health care can be seen as part of a larger cycle, where poverty leads to ill health and ill health maintains poverty.'

[3] UNAIDS, 'South Africa – HIV and AIDS Estimates (2019)', available from www.unaids.org/en/regionscountries/countries/southafrica (last accessed 21 September 2021).

Kenya.[4] Furthermore, in 2020, there were over 1.3 million new cases of cancer in India, over 100,000 new cases in South Africa, and over 42,000 new cases in Kenya.[5] These figures indicate that, in the years to come, poor patients in these and other developing countries will continue to require access to medicines at affordable prices in order to sustain a healthy and productive lifestyle.[6]

It is therefore imperative for the governments of these three developing countries (i.e., India, Kenya, and South Africa), and indeed for the governments of other developing countries facing similar health challenges, to take the necessary steps to facilitate access to medicines at affordable prices for their citizens. However, one crucial impediment that can hinder the ability of governments to make medicines affordable in their countries is the current global system for the protection of intellectual property rights as embodied in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which was signed in Marrakesh, Morocco, on 15 April 1994.[7] By making it mandatory for all WTO members (except the least developed countries) to grant patents on pharmaceutical products, the TRIPS Agreement has encroached on the policy space hitherto enjoyed by countries with regard to the design of their national patent laws.[8]

[4] UNAIDS, 'Kenya – HIV and AIDS Estimates (2019)', available from www.unaids.org/en/regionscountries/countries/kenya (last accessed 21 September 2021).

[5] See International Agency for Research on Cancer (Globocan 2020), 'India', available from https://gco.iarc.fr/today/data/factsheets/populations/356-india-fact-sheets.pdf (last accessed 21 September 2021); International Agency for Research on Cancer (Globocan 2020), 'South Africa', available from https://gco.iarc.fr/today/data/factsheets/populations/710-south-africa-fact-sheets.pdf (last accessed 21 September 2021); International Agency for Research on Cancer (Globocan 2020), 'Kenya', available from https://gco.iarc.fr/today/data/factsheets/populations/404-kenya-fact-sheets.pdf (last accessed 21 September 2021).

[6] Writing in relation to cancer in developing countries, Ellen 't Hoen notes that: 'While death rates from cancer in wealthy countries are slightly declining because of early diagnosis and the availability of treatment, this is not the case in low- and middle-income countries. The rates are rising in low- and middle-income countries, partly because of the [ageing] of the population. Currently 14 million people a year are diagnosed with cancer. That will increase to 19 million by 2025, 22 million by 2030 and 24 million by 2035. More than 60 percent of the world's cancer cases occur in Africa, Asia, and Central and South America … In low- and middle-income countries, however, treatment for cancer is not widely available … Health systems are often unable to deal with cancer treatment. Prevention and early detection programmes are weak or non-existent. This situation is exacerbated by the lack of financing for healthcare and low health insurance and social security coverage … In certain cases, the high cost of treatment and in particular the high cost of cancer medication throws up additional barriers' (Ellen 't Hoen, 'Access to Cancer Treatment: A Study of Medicine Pricing Issues with Recommendations for Improving Access to Cancer Medication', Report Prepared for Oxfam (2015), 4, available from http://oxfamilibrary.openrepository.com/oxfam/handle/10546/344070 (last accessed 21 September 2021).)

[7] Agreement on Trade Related Aspects of Intellectual Property (TRIPS) 1869 UNTS 299, 33 ILM 1197 (1994).

[8] Article 27(1) of the TRIPS Agreement provides, *inter alia*, that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. The TRIPS Agreement provides for transition periods for developing and least-developed countries to implement the

Patent rights on pharmaceutical products can prevent the sale of patented drugs at competitive prices in the market and empowers the patent owner to sell its patented drug at exorbitant prices. The pricing of patented drugs beyond the reach of poor patients in developing countries can further impoverish poor patients in these countries and this invariably perpetuates the deadly cycle of poverty and ill health.[9] It should, however, be noted that, despite the strictures imposed by the current

Agreement. While developed countries were given one year, developing countries were given a period of five years after the entry into force of the Agreement (i.e., from 1995 till 2000) to implement the Agreement. See Article 65(2), TRIPS Agreement. However, developing countries that had no patent protection for pharmaceuticals were given a transition period of ten years from the entry into force of the Agreement to provide patent protection for pharmaceutical products (i.e. from 1995 till 2005). See Article 65(4), TRIPS Agreement. The transition periods for developing countries with regard to the general implementation of the TRIPS Agreement and the provision of patent protection for pharmaceutical products have since expired. Least-developed countries were initially given ten years to implement the TRIPS Agreement (Article 66(1) of the TRIPS Agreement), but this was later extended till 2013. See WTO Council for TRIPS, 'Extension of the Transition Period under Article 66.1 for Least Developed Country Members', Decision of the Council for TRIPS of 29 November 2005, IP/C/40 (30 November 2005). In June 2013, least-developed countries were granted a further extension till July 2021 with regards to the implementation of the TRIPS Agreement. See WTO Council for TRIPS, 'Extension of the Transition Period under Article 66.1 for Least Developed Country Members', Decision of the Council for TRIPS of 11 June 2013, IP/C/64 (12 June 2013). In July 2021, least-developed countries were granted a further extension till July 2034 with regard to the implementation of the TRIPS Agreement. See, WTO Council for TRIPS, 'Extension of the Transition Period under Article 66.1 for Least Developed Country Members', Decision of the Council for TRIPS of 29 June 2021, IP/C/88 (29 June 2021). In 2002, in a separate arrangement, least-developed countries were granted a further extension till 2016 with respect to the provision of patent protection for pharmaceutical products. See WTO Council for TRIPS, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products', Decision of the Council for TRIPS of 27 June 2002, IP/C/25 (1 July 2002). Furthermore, in November 2015, least-developed countries were granted a further extension till January 2033 with regard to the provision of patent protection for pharmaceutical products. See WTO Council for TRIPS, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products', Decision of the Council for TRIPS of 6 November 2015, IP/C/73 (6 November 2015).

[9] On the effect of patents on access to pharmaceutical products in developing countries see, Ellen F. M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond', in Jean-Paul Moatti, Tony Barnett, Benjamin Coriat, Yves Souteyrand, Jérome Dumoulin, and Yves-Antoine Flori (eds.), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries – Issues and Challenges* (ANRS, 2003), 39–57. See also Jean Lanjouw, 'A Patent Policy Proposal for Global Diseases', in Boris Pleskovic and Nicholas Stern (eds.), *Annual World Bank Conference on Development Economics 2001/2002* (World Bank and Oxford University Press, 2002), 193, who stated that, '. . . in a poor country even a small price increase due to such a monopoly can greatly reduce the number of people able to purchase patented drugs and the welfare of those who do. This is particularly so since drug purchases in developing countries are largely paid for directly by consumers, without the benefit of insurance'. See further, Henry Grabowski, 'Patents, Innovation and Access to New Pharmaceuticals' (2002) 5 *Journal of International Economic Law* 849, 856, who stated that, 'In the case of patented drugs, their comparatively higher prices can serve as an additional barrier to many individuals in gaining access to the newest medicines.' But *cf.* Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286 *JAMA* 1886.

global regime on intellectual property rights, developing countries can still secure access to affordable medicines for their citizens by taking steps to preserve their patent policy space.

1.2 ACCESS TO MEDICINES AND PATENT POLICY SPACE

A very apt description of the term 'policy space' that approximates to a definition is provided by the United Nations Conference on Trade and Development (UNCTAD) in the Sao Paulo Consensus document of 2004.[10] In that document, UNCTAD describes 'policy space' as 'the space for national economic policy, i.e. the scope for domestic policies, especially in the area of trade, investment and industrial development'.[11] Policy space is the freedom that a country has to design its national policies, including intellectual property policy, in a manner that suits its needs and level of economic development.

According to Chang, developing countries experienced 'exceptional economic growth during the 1950s to the 1970s'.[12] During this period, developing countries enjoyed a wider policy space, unlike now.[13] This demonstrates the crucial importance of policy space to economic growth and development. However, between the 1980s and 2000s, there was a shrinkage of the policy space available for developing countries.[14] Several factors have been identified as being responsible for this shrinkage of policy space, including the conditionalities attached to the loans obtained from international financial institutions such as the World Bank and the IMF, the aid policies of developed countries, and the establishment of the WTO in 1995.[15]

[10] See UNCTAD, 'Sao Paulo Consensus', UNCTAD TD/410 (25 June 2004).

[11] Ibid., para 8.

[12] Ha-Joon Chang, 'Policy Space in Historical Perspective with Special Reference to Trade and Industrial Policies' (2006) 41 *Economic and Political Weekly* 627, 629. As Chang points out, 'In the 1960s and the 1970s . . . per capita income in the developing world grew at 3 per cent, a rate two to three times higher than what was experienced by the developed countries in the 19th century during their industrial revolution (1–1.15 per cent). Some countries grew much faster than that . . . Per capita income in countries like Japan (then still a developing country by any reasonable definition), South Korea, Taiwan and Singapore grew at 5–6 per cent per year, doubling the income in 12–13 years . . .' (629–30).

[13] Ibid., 629–30.

[14] Ibid., 627. Providing a discussion of policy space from a historical perspective, Chang notes that '. . . the phenomenon of shrinking policy space is in fact not new. In the days of imperialism, the stronger countries were able to restrict the policy space of the weaker countries in the most blatant way . . . Therefore, it may be useful to look at the historical experiences in order to put the current debate on policy space in an appropriate historical context' (628).

[15] Ibid., 627; Alisa DiCaprio and Kevin P. Gallagher, 'The WTO and the Shrinking of Development Space: How Big Is the Bite?' (2006) 7 *Journal of World Investment and Trade* 781, 785. See further, Sheila Page, 'Policy Space: Are WTO Rules Preventing Development?' Overseas Development Institute, Briefing Paper, (January 2007) 1, who notes that 'Perceived extensions to international rules and controls in the 1980s and 1990s included the new rules in the WTO: those on services; the new provisions on patents and copyright, under Trade Related Intellectual Property (TRIPS); and also the strengthened enforcement mechanism. But some

Even after the establishment of the WTO, developed countries have continued to utilize bilateral and regional free trade agreements to further constrain the ability of developing countries to utilize the policy space available to them within the WTO framework.[16] The globalization of neoliberal policies and the attendant shrinkage of policy space in recent decades has, however, not led to increased economic growth in a number of developing countries.[17] It is noteworthy that at the Summit of the Heads of State and Government of the Group of 77 (G77) held in Bolivia in June 2014, the developing countries adopted a declaration which, among other things, called for 'the international trading system to respect and reinforce the policy space of developing countries for the promotion and growth of [their] industrial development and for the design and implementation of [their] industrial strategies'.[18]

One particular area where there has been a significant shrinkage of policy space is the area of intellectual property (especially patent policy). Prior to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), countries (both developed and developing) enjoyed wide policy space with regard to intellectual property rights. Specifically, patent laws have always reflected the stage of technological and economic development of each country.[19] Importantly, the level of patent protection usually depended on whether the country was an innovator or an imitator.[20] It was during this period, prior to the emergence of the TRIPS Agreement, that countries like India were able to deny patent protection for pharmaceutical products, and this was one of the crucial factors that assisted

of the most significant threats were seen in proposals for a Multilateral Agreement on Investment, the environmental conventions, bilateral and regional agreements, and, particularly for indebted developing countries, the increased financial power of the World Bank and IMF.'

[16] Chang, 'Policy Space in Historical Perspective', 628.

[17] According to Chang, '. . . developing countries have been doing much worse in the last quarter of a century than they used to in the two decades . . . during the 1960s and the 1970s . . . Income distribution has worsened in the majority of developing countries, while poverty has increased in many of them. Neoliberal policies may not be totally responsible for such poor performance, but at the least we can say that those policies have failed to deliver their central promise of accelerated growth' (ibid., 630).

[18] Declaration of the Summit of Heads of State and Government of the Group of 77, 'For a New World Order for Living Well' (Santa Cruz de la Sierra, Plurinational State of Bolivia, 14 and 15 June 2014), para 86, available from www.g77.org/doc/A-68-948(E).pdf (last accessed 21 September 2021).

[19] As Shadlen notes, 'National patent regimes have traditionally reflected levels of economic development. Poorer countries, with fewer innovative capacities, have typically made private ownership of knowledge difficult to obtain, and, once granted, the property rights themselves tended to be weaker than in wealthier countries.' Kenneth C. Shadlen, 'Policy Space for Intellectual Property Management: Contrasting Multilateral and Regional-Bilateral Arrangements' (2008) 10 *Economica, Rio de Janeiro* 55, 56.

[20] See also DiCaprio and Gallagher, 'The WTO and the Shrinking of Development Space', 789, who note that 'There are different dynamics between innovators and imitators. Innovators have to worry about how to appropriate returns on their R&D investment. Imitators, on the other hand, are concerned with profitably adapting and adopting different technologies.'

the growth of the Indian generic drugs industry.[21] In addition, countries such as Japan and South Korea also made productive use of the wide policy space available in the area of intellectual property law during this period to permit copying and assimilation of foreign patented technology, and this contributed to their growth and development.[22]

All these developments were possible because the Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention),[23] which preceded the TRIPS Agreement, preserved the policy space of state parties in the field of patent law. Under the Paris Convention, countries were permitted to exclude any invention from patent protection, there was no fixed duration for patent rights, and (in comparison to the TRIPS Agreement) there were fewer restrictions on the grant of compulsory licences.

However, the TRIPS Agreement has significantly reduced the policy space that countries have in the area of intellectual property law.[24] Members of the WTO (except least-developed countries) are now required to design their intellectual property laws in accordance with the minimum standards stipulated in the TRIPS Agreement. For instance, prior to the TRIPS Agreement, more than 40 countries did not provide patent protection for pharmaceuticals and many countries provided only process patents but not product patents for pharmaceuticals.[25] This is however not possible anymore because WTO members (except least-developed countries) are forbidden from denying the grant of patent protection for pharmaceutical products by virtue of Article 27 of the TRIPS Agreement. Thus, the freedom hitherto enjoyed by countries to design their intellectual property laws in a manner that corresponds with their level of economic and technological development has been

[21] See, section 5 of the Indian Patents Act 1970. See also Jean O. Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?"' (1998) NBER Working Paper 6366; Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (Oxford University Press, 2005).

[22] See Carlos M. Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes', in Ronald Labonte, Ted Schrecker, Corinne Packer, and Vivien Runnels (eds.), *Globalization and Health: Pathway, Evidence and Policy* (Routledge, 2009), 265, who notes that, 'In fact, the most successful cases of industrial and technological development in recent history took place in a flexible framework of [intellectual property rights] protection, such as witnessed in Japan and Korea.'

[23] Paris Convention for the Protection of Industrial Property, 1883, as last revised at Stockholm in 1967 and as amended in 1979, 828 UNTS 305.

[24] See Shadlen, 'Policy Space for Intellectual Property Management', 56.

[25] See, WHO, 'Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines' (Health Economics and Drugs, EDM Series No. 11, WHO/EDM/PAR/2002.1, 2002) 15, available from https://apps.who.int/iris/bitstream/handle/10665/67194/WHO_EDM_PAR_2002.1.pdf (last accessed 21 September 2021). According to Correa, 'In many European countries (such as France, Germany, and Switzerland) that are proponents of strong patent protection today, pharmaceutical product patents were only recognized after the 1960s. Portugal, Spain, and the Nordic countries waited until the 1990s' (Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes', 265).

significantly reduced. There has been a shrinkage of intellectual property policy space, including patent policy space.[26]

Though there has been shrinkage of policy space in the general area of intellectual property law, the focus of this book is on the shrinkage of patent policy space. Specifically, the focus is on the effects of the shrinkage of patent policy space on access to medicines in developing countries. It needs to be stressed, however, that, even though intellectual property policy space has been reduced, the TRIPS Agreement does not completely eliminate policy space in the area of intellectual property law.[27] Countries are still free to utilize the limited intellectual property policy space that still exists within the framework of the TRIPS Agreement.

In this regard, it is pertinent to note that the TRIPS Agreement contains certain flexibilities that countries can use to facilitate access to affordable medicines and address the health challenges in their countries. Such flexibilities include the freedom to exclude new forms of known drugs from patent protection, the freedom to adopt the principle of international exhaustion of patent rights to facilitate the parallel importation of drugs (Article 6), regulatory review exemption for producers of generic drugs, research exception, compulsory licences (Article 31), and delinking the grant of marketing approval for generic drugs from the patent status of branded drugs.

However, several developing countries have failed to utilize the available policy space (or flexibilities) in the TRIPS Agreement due to political and economic pressure from certain developed countries.[28] In addition, some developed countries have continued to take steps to ratchet up the current global standards on intellectual property rights through the use of bilateral and regional free trade agreements.[29]

[26] As Sheila Page notes, 'The introduction of rules on patents and copyright in the Uruguay Round was probably one of the most important sources of concern over policy space (and certainly was one of the first subjects where the words were used) … Policy space was indeed reduced: countries needed to change their rules …' (Page, 'Policy Space', 3).

[27] See Shadlen, 'Policy Space for Intellectual Property Management', 56.

[28] See, Rachel Hermann, 'Developing Countries Are Not Making the Most of TRIPS Flexibilities because of Political Pressure' (2011) 343 *British Medical Journal* d7706. It is also possible that some developing countries choose not to exploit the patent policy space available in the TRIPS Agreement due to a perceived need to preserve their international competitiveness. As noted by the United Nations Department of Economic and Social Affairs (UNDESA), '… Global competitive pressures tend to restrict a country's policy choices and often have an adverse effect on social development, since decisions or actions required to advance social policies and social equality are usually perceived as unnecessary costs. Put simply, social development policies are often mistakenly considered to be in conflict with the preservation of a country's international competitiveness … [E]xternal competitive pressures have restricted the ability of some countries to pursue certain aspects of social policy and have therefore undermined the progress of social development.' See UNDESA, '*Report on the World Situation: The Inequity Predicament*' (UNDESA, 2005), 106.

[29] See Meri Koivusalo, Ted Schrecker, and Ronald Labonte, 'Globalization and Policy Space for Health and Social Determinants of Health', in Ronald Labonte, Ted Schrecker, Corinne Packer, and Vivien Runnels (eds.), *Globalization and Health: Pathway, Evidence and Policy*

Developing countries need to muster the political will to preserve and utilize the existing policy space available to them under the TRIPS Agreement and steadfastly resist pressures to implement intellectual property standards that are incongruent with their current state of economic and technological development. In this regard, it is necessary to highlight some of the reasons why developing countries need to preserve their patent policy space.

Firstly, the current shrinkage of patent policy space affects the ability of developing countries to discharge their human rights obligations, especially their right to health obligations.[30] The right to health is recognized in several international instruments, including Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).[31] One of the essential components of the right to health is access to essential medicines.[32] In General Comment No. 14 on Article 12, the UN Committee on Economic, Social, and Cultural Rights (CESCR) explained that state parties are obliged to respect, protect, and fulfil the right to health.[33] The CESCR further noted that one of the core obligations of state parties in relation to the right to health, from which no derogation is permissible,[34] is the provision of essential drugs.[35]

States who are parties to the ICESCR, including developing countries, therefore have an obligation to provide access to essential medicines for their citizens. But, as Carlos Correa rightly points out, the current global regime on intellectual property 'has increasingly limited the room left to countries to exercise their sovereign rights and discharge their obligations in public health, including those subsumed under

(Routledge, 2009), 108–9, who note that 'Bilateral and regional agreements, often between industrialized and developing countries, are increasing in number and importance, particularly as they generally go beyond requirements within WTO agreements. This is notably the case with respect to intellectual property rights.' See also Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes', 264, who notes that 'Negotiating such agreements has allowed the United States to gain concessions on a bilateral basis that were unlikely to be reached in a multilateral framework where developing countries have become increasingly reluctant to support a further elevation of [intellectual property rights] standards.'

[30] See Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes', 263.

[31] See also, The Constitution of the WHO (1946); The Universal Declaration of Human Rights, G.A. Res. 217A (III) (1948), Article 25.

[32] See CESCR, 'General Comment No. 14, The Right to the Highest Attainable Standard of Health' E/C.12/2000/4 (2000), para 12; UN Human Rights Council, 'Access to Medicines in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health', A/HRC/RES/23/14 (2013).

[33] CESCR, 'General Comment No. 14, para 33.

[34] Ibid., para 47.

[35] Ibid., para 43(d). According to the World Health Organization (WHO), essential drugs are drugs that 'satisfy the priority health care needs of the population' and 'are intended to be available within the context of functioning health systems at all times in adequate amounts . . . and at a price the individual and the community can afford'. See, WHO, 'Essential Medicines', available from www.who.int/topics/essential_medicines/en/ (last accessed 21 September 2021).

the right to health'.[36] Patent rights have an impact on the enjoyment of the right to health, especially in developing countries where the monopoly rights conferred by patent law on producers of pharmaceutical products enable them to inflate the price of drugs[37] and prevent competition from producers of cheaper generic drugs. Thus, in order to fulfil their right to health obligations in relation to the provision of access to essential medicines, it is imperative for developing countries to preserve their patent policy space.[38] In this book, it will be contended that developing countries can preserve their patent policy space by incorporating a *model of human rights* into the design, implementation, interpretation, and enforcement of their national patent laws.

Secondly, the current global patent regime primarily serves as an incentive for the production of drugs for diseases affecting patients in rich countries.[39] Thus, developing countries need to think outside the 'patent box' in order to address the problems of neglected diseases affecting poor patients in their countries. The current global patent regime not only impedes access to essential medicines in developing countries, it also fails to incentivize the production of drugs for the treatment of diseases primarily affecting poor patients in developing countries. It could be argued that there would be no new drugs in the absence of patent rights. But this argument, as Sunder rightly points out, 'denies that patents are but one among many alternatives for stimulating and rewarding innovation, including prizes and subsidies. Furthermore, drug companies often benefit from enormous public investment,

[36] Correa, 'Intellectual Property Rights and Inequalities in Health Outcomes', 263. See also Philippe Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79 *International Affairs* 139, 160, who notes that, 'While states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPS directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health. This appears to be unacceptable under the [ICESCR] Covenant and countries in this situation would be expected to give priority to their human rights obligations.'

[37] See Sarah Joseph, 'Trade and the Right to Health', in A. Clapham and M. Robinson (eds.), *Realizing the Right to Health*, Swiss Human Rights Book Series, Vol. 3 (Ruffer & Rub, 2009), 360.

[38] According to para 50 of General Comment No. 14, '. . . the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health; and the failure of the State to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities' constitute a violation of a country's obligation to respect the right to health. See CESCR, 'General Comment No. 14', para 50.

[39] Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan, 2002), 80, who note that, 'The patent system has not . . . stimulated the invention and production of the kind of drugs that developing countries need. Pharmaceutical companies carry out R&D in those markets where the returns are likely to be the greatest. This market rationality explains why only 1 per cent of the new chemical entities marketed between 1975 and 1997 related to tropical diseases.'