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Access to Medicine in Developing Countries: Instituting State Obligation over Corporate Profit

Abstract

This paper investigates the divergence between the objectives of the State in ensuring the right to health of citizens and the profit maximization objective of pharmaceutical corporations in relation to access to, and supply of, medicine. This is pertinent given the rising cost of medicines and unmet needs, particularly in developing countries. This paper analyses the contention between pharmaceutical corporations' profit drive and the State's welfare obligation. There is a need to bridge the gap between business and human rights and this can be achieved by combining the concepts of 'business ethical responsibility' and corporation's contributions to 'common good' with the jurisprudence on the right to health. This is imperative in view of the impact of the business of pharmaceutical corporations on vulnerable populations particularly in, but not limited to, developing countries.

Keywords: Human rights, International Law, Pharmaceutical Companies, Business Ethics, Access to Medicines,

Introduction

It is critical to bridge the gap between business and human rights on the accessibility of medicines through the combination of a human rights perspective¹ and ethico-economics theory to ensure individual and social wellbeing. Both human rights and ethico-economics converge on a conceptual approach—that places people over profit. The theoretical approach offered by the conjunction of these two sources provides a normative basis for advocating a change in the current operating framework of pharmaceutical corporations where the profit motive dominates human well-being. Arguably, with the experience of the COVID-19 pandemic, at no time in contemporary history is the need for this change more pertinent than now.

¹ Moon, S. (2013) Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry, *Health and Human Rights*, Vol. 15, No. 1, pp. 32-43.

With reference to the experience of the COVID-19 pandemic, the Committee for Economic, Social and Cultural Rights (CESCR)² has noted that ‘Inadequate public goods and social programmes also deepen global income and wealth inequalities.’³ The ‘public goods’ referred to by the CESCR includes medicines, and we adopt that position in this paper.⁴ In particular, the CESCR has restated the need for States to adopt ‘regulatory measures...to prevent profiteering’ for, among other critical items, ‘essential medicines and supplies.’⁵ This is particularly pertinent, given the negative impact of the rising cost of medicines, and unmet needs across the globe but particularly, in developing countries.⁶ As a joint report by the three principal organisations responsible for global health, regulation of intellectual property and trade, observed that

Affordable prices are a critical determinant of access to medicines, especially in countries where public health sector is weak and where those with most limited means are often required to secure medicines at market prices.⁷

It has also been noted in that regard that while there are ‘significant advances in overall health outcomes’, it remains the current reality too that ‘the benefits’ have been ‘distributed inequitably.’⁸ This is because the advances in global health have been largely devoid of ‘justice’ with the result that equal enjoyment of the current strides ‘remains

² The United Nations committee of independent experts responsible for monitoring the pre-eminent treaty on economic, social and cultural rights, the International Covenant on Economic, Social and Cultural Rights. See, Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights <https://www.ohchr.org/Documents/Publications/FactSheet16rev.1en.pdf>

³ Committee on Economic, Social and Cultural Rights ‘Statement on the Covid-19 Pandemic and Economic, Social and Cultural Rights’ (2020) 9 *International Human Rights Review* 135, 137, paragraph 6. See also Committee on Economic, Social and Cultural Rights ‘Statement on the coronavirus disease (COVID-19) pandemic and economic, social and cultural rights’ E/C.12/2020/1 adopted by the Committee on 6 April 2020, para. 6. available at: <https://www.gi-escr.org/esc-rights-updates-geneva/cescr-april-2020>.

⁴ Ibid. see for instance paragraphs 1, 2, 4, 5, 13, 17, 21 and 22; variously referring to the ‘right to health’, ‘essential medicines and supplies’, ‘health care resources’, ‘medicines’, ‘vaccines’, ‘medical supplies’, ‘health care systems’ among other deemed public goods or essentials.

⁵ Committee on Economic and Social Rights at 139, para. 17.

⁶ Erika George, *The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines*, 18 *IND. J. GLOBAL LEGAL Stud.* 167 (2011).

⁷ World Health Organization, World Intellectual Property Organization and World Trade Organization *Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade* (2013)

⁸ Lawrence O. Gostin & Eric A. Friedman (2020), *Imagining Global Health with Justice: Transformative Ideas for Health and Well-Being While Leaving No One Behind*, 108 *GEO.L.J.* 1535, 1541.

seemingly over the horizon'.⁹ The poor access to medicines, a matter sometimes going all the way back to colonial arrangements,¹⁰ is a key factor in that picture.

While there is no 'magic bullet' for eradicating disease¹¹ or ensuring enjoyment of the highest attainable standard of physical and mental health, access to medicines is, at the least, one of the core components of ensuring this.¹² A human rights lens is particularly relevant for exploring the issue of access to medicines since most countries are parties to, at least, one international human rights treaty that guarantees the right to health.¹³ This article builds on the view that it has become critical in today's world to build bridges across interdisciplinary and analytical levels to overcome existing gaps in order to achieve global equity on health matters.¹⁴

Health sector issues are essentially a matter for state-policy, but corporations continue to dominate the production of drugs and their availability which are critical to healthcare as well as individual and communal well-being. The situation constitutes corporations into critical non-State actors on an issue in which the State has primary obligation.¹⁵ The production of medicines, from the perspective of pharmaceutical corporations, is a business activity. However, it has a direct impact on individuals' well-being, public health and the common good. This is because the accessibility of medicine is at the core of the delivery of medical care that forms part of the fundamental right to health.¹⁶ International

⁹ Lawrence O. Gostin and Eric A. Friedman (2020), *Imagining Global Health with Justice: Transformative Ideas for Health and Well-Being While Leaving No One Behind*, 108 *GEO.L.J.* 1535, 1541.

¹⁰ Danwood M. Chirwa, *Access to Medicines and Health Care in Sub-Saharan Africa: A Historical Perspective*, 31 *Maryland J. INT'L L.* 21 (2016) 21-43, 26-29.

¹¹ Jackson, E. (2012). *The Law and Regulation of Medicines*, Oxford: Hart Publishing Oxford, 1-5.

¹² Edward Halle, "Access to Essential Medicine as Part of the Right to Health in Africa: Access to Essential Medicine under International Human Rights Law, the Case of Kenya and South Africa," *Asia Pacific Journal of Health Law & Ethics* 11, no. 3 (July 2018): 105-138

¹³ Marks, S.P. (2016) *Normative Expansion of the Right to Health and the Proliferation of Human Rights*, *The George Washington International Law Review*, 49: 97 – 141; Hogerzeil, H.V., Samson, M., Casanovas, J.V. and Rahmani-Ocora, L. (2006) 'Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?' 368 *Lancet* 305-311; Hogerzeil, H.V. (2006) 'Essential medicines and human rights: what can they learn from each other?' 84 *Bulletin of the World Health Organization* 371-375.

¹⁴ Frenk, J. & Chen, L. (2011). *Overcoming gaps to advance global health equity: A symposium on new directions for research. Health Research Policy and Systems*, 9 (11), 1 - 3.

¹⁵ Paul O. Ogendi, *Pharmaceutical Trade Policies and Access to Medicines in Kenya*, 19 *AFR. HUM. Rts. L.J.* 698 (2019).

¹⁶ *Ibid.* 699; Erika George, *The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines*, 18 *IND. J. GLOBAL LEGAL Stud.* 167 (2011).

law, principally through the International Covenant for Economic and Social Rights (ICESCR),¹⁷ guarantees the right to health and, health is considered fundamental to human dignity.¹⁸

Legal scholarship has laid emphasis on the human rights responsibilities of pharmaceutical companies as part of the broader discussion of corporations and human rights.¹⁹ On their part, business and management scholars have focused on ethical concerns,²⁰ medicine patenting,²¹ medicine-pricing²² and corporate social responsibility.²³ Relevantly, Ahen advocates for 'deeper and broader discussions about the limitless opportunities of cross-fertilization of International Business and other

¹⁷ Adopted and opened for signature, ratification and accession by General Assembly Resolution 2200A (XXI) of 16 December 1966 (entry into force 3 January 1976).

¹⁸ George P. Smith II, Dignity in Living and in Dying: The Henry H. H. Remak Memorial Lecture (2018) *Indiana Journal of Global Legal Studies* 25 *Ind. J. Global Legal Std* 413, 434; Da Silva, Michael The International Right to Health Care: A Legal and Moral Defense *Michigan Journal of International Law*, Vol. 39, Issue 3 (Fall 2018), pp. 343-384, 364.

Office of the United Nations High Commissioner for Human Rights (2008). The right to health' Fact Sheet No. 31. (New York, Geneva) 1.

¹⁹ Lee, J.Y. & Hunt, P. (2012). Human rights responsibilities of pharmaceutical companies in relation to access to medicines. *Journal of Law, Medicine & Ethics*, 40 (2), 220 – 233.

Gathii, J.T. (2003). The structural power of strong pharmaceutical patent protection in U.S. foreign policy. *Journal of Gender Race & Justice*, 7(2), 267 – 314; Gathii, J.T. (2002). Rights, patents, markets and the global AIDS pandemic. *Florida Journal of International Law*, 14, 261- 352.

²⁰ Sah, S. (2003). *Essays on conflicts of interest in medicine. Business & Society*, 52 (4), 666 – 678; Weber, L.J. (2006) *Profits before people? Ethical standards and the marketing of prescription drugs*. Bloomington, Indiana: Indiana University Press.

Santoro, M.A. and Gorrie, T.M. (2005). *Ethics and the Pharmaceutical Industry, Cambridge*: Cambridge University Press; Reisel, W.D. and Sama, L.M. (2003). The distribution of life-saving pharmaceuticals: Viewing the conflict between social efficiency and economic efficiency through a social contract lens. *Business and Society Review*, 108 (3), 365 – 387.

²¹ Sophie Loveridge, Would Limiting Compulsory Licensing Availability under TRIPS to a List of Eligible Diseases Increase Access to Medicine in the Developing World, 2017BLR 28 (2017); Horner, R. (2015) 'Responding to the rising power "threat": Pharmaceutical MNEs and the intellectual property "institutional void"', *Critical Perspectives on International Business*, 11 (3/4): 285 – 300; Oppenheimer, M. LaVan, H., & Martin, W.F. (2015). A framework for understanding ethical and efficiency issues in pharmaceutical intellectual property litigation. *Journal of Business Ethics*, 132 (3), 505-524; Ghosh, S. (2014). *Identity, invention, and the culture of personalized medicine patenting*. Cambridge: Cambridge University Press; Owen, T. (2013). From "Pirates" to "Heroes": News, discourse change, and the contested legitimacy of generic HIV/AIDS medicines. *The Harvard International Journal of Press/Politics*, 13 (8), 259 – 280; Byrne, S., Davey, P., McFarlane, K., O'Brien, J. & Templeton, C. (2006). Patent rights or patent wrongs? The case of patent rights on AIDS drugs. *Business Ethics: A European Review*, 15 (3): 299–305.

²² Brennan, R. & Baines, P. (2006). Is there a morally right price for anti-retroviral drugs in the developing world? *Business Ethics: A European Review*, 15 (1) 29–43; Buckley, J. & O Tuama, S. (2005). International pricing and distribution of therapeutic pharmaceuticals: An ethical minefield. *Business Ethics: A European Review*, 14 (2), 127 – 141.

²³ Trullen, J and Stevenson, W.B. (2006). Strategy and legitimacy: Pharmaceutical companies' reaction to the HIV crisis *Business & Society*, 45, 178-210; Bolton, P.L. (2008). Corporate responses to HIV/AIDS: Experience and leadership from South Africa. *Business and Society Review*, 113 (2) 277–300; Grigore, G., Adi, A. & Theofilou, A. (2015). Digital reflections of pharmaceutical companies and their CSR communication strategies, in A. Adi, G. Grigore & D. Crowther (Eds.) *Corporate Social Responsibility in the Digital Age*, London: Emerald Group Publishing Limited, 221 – 239.

disciplines' in matters relating to global health.²⁴ This study responds to that call by combining insights from (International) Law, (Ethico-) Economics and (Critical) Management to elucidate the challenge inherent in the obligation of the State (which has the duty to deliver the right to health) and the sometimes inordinate drive for profit by some transnational corporations (TNCs) with specific focus on pharmaceutical corporations.

The next section examines the significance of the right to health in the international system, as well as its jurisprudence in international and comparative perspectives. It discusses the obligation of the state for access to medicines as a critical aspect of the right to health and pharmaceutical corporations' business of producing and making medicines available. It then further frames the case for regulating the operations of pharmaceutical corporations in the light of the special nature of their business to ensure their ethical responsibility to society while preserving their business interest. Section III examines the tension between the State's obligation to ensure enjoyment of the right to health and pharmaceutical corporations' business approach, driven as it were, by the profit motive like other corporations. It then argues the case for regulating the operations of pharmaceutical corporations to ensure their ethical responsibility to society while preserving their business interest. The article concludes that it is imperative to engage more closely with the duty of the State, particularly in developing countries, to regulate the operations of pharmaceutical corporations for social well-being across the globe.

Right to Health, Access to Medicine and Business Ethics: A Theoretical Framework

Access to Medicines in International and Comparative Law

As Matiangai has noted, international law is particularly useful for framing issues of global relevance as it

increasingly addresses almost every type of human activity, including those typically considered within the exclusive domestic jurisdiction of states-like health. States turn to international law and institutions to achieve common aims,

²⁴ Ahen, F. (2019), Global health and international business: new frontiers of international business research, *Critical Perspectives on International Business*. 15(2/3): 158-178

solve shared problems, promote compliance with norms, reduce transaction costs, provide information, and coordinate orderly and peaceful dispute resolution.²⁵

A useful starting point is to highlight the framing of the right to health, and especially access to medicines as an integral part of the development project in the international system. The 1946 Constitution of the World Health Organisation (WHO)²⁶ which is the first international legal instrument that recognised the right to health defines health as ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’.²⁷ To underscore its significance, the preamble of the WHO Constitution emphasises that the enjoyment of the highest possible standard of health is a fundamental right.

The inclusion of access to medicines in the United Nations Millennium Declaration²⁸ clearly demonstrates its significance. Goal No.8 was the ‘development of global partnerships for development’.²⁹ One of the targets of this goal was to provide access to affordable but quality essential drugs in developing countries, in cooperation with pharmaceutical companies. However, the MDGs Gap Task Force found that there continues to be ‘major gaps...in reducing vulnerabilities for many developing countries’ while ‘access to essential medicines at affordable prices remains highly problematic, with many households squeezed out of the market due to high prices and limited availability’.³⁰ Profit considerations made ‘capable pharmaceutical enterprises’ abstain, with few exceptions, from ensuring access to affordable but quality, essential medicines, especially in public institutions in developing countries.³¹

²⁵ Matiangai Sirleaf, *Ebola Does Not Fall from the Sky: Structural Violence & International Responsibility*, 51 *VAND. J. Transnat'l L.* 477 (2018). Gathii, J.T. (2005). How necessity may preclude State responsibility for compulsory licensing under the TRIPS agreement. *North Carolina Journal of International Law* 31 (4) 943 – 970, 489.

²⁶ The WHO Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948.

²⁷ World Health Organisation (2009) *Basic Documents* (47th edition WHO Press Geneva 2009) 1 available at: http://apps.who.int/iris/bitstream/10665/44192/1/9789241650472_eng.pdf.

²⁸ United Nations Millennium Declaration, Resolution 55/2 adopted by the General Assembly on 8 September 2000, A/RES/55/2.

²⁹ United Nations (2015). *Millennium Development Goal 8: Taking Stock of the Global Partnership for Development- MDGs Gap Task Force Report 2015*, New York: United Nations, i – 75.

³⁰ United Nations (2015). *Millennium Development Goal 8: Taking Stock of the Global Partnership for Development- MDGs Gap Task Force Report 2015*, New York: United Nations, i – 75, iii.

³¹ United Nations (2015). *Millennium Development Goal 8: Taking Stock of the Global Partnership for Development- MDGs Gap Task Force Report 2015*, New York: United Nations, i – 75, 2.

The Sustainable Development Goals (SDGs) launched by the United Nations in September 2015 as the successor programme to the MDGs reaffirms the significance of the access to medicine in the considerations of the international system.³² Goal No.3 of the SDGs is to 'ensure healthy lives and promote well-being for all at all ages.' One of the targets of this goal is to provide 'access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all'.³³

A major issue regarding the accessibility of medicines is the high cost of drugs arising, ostensibly, from the need to ensure pharmaceutical corporations³⁴ are able to recover their investments in drug research and development.³⁵ Although one of the Sustainable Development Goals involves access to medicine, the WHO has not moved aggressively enough to develop ways of delinking research into drug therapies from economic incentives. Consequently, from 1995 onwards, the operation of the Agreement on Trade-Related Intellectual Property Rights (TRIPs Agreement)³⁶ of the World Trade Organisation (WTO) has affected the accessibility of medicines. TRIPS is the widest ranging multilateral agreement on intellectual property. It essentially imposes some requirements on members of the WTO to put in place legal and institutional arrangements in place in their national jurisdictions through legislation. Its main aim, according to its preamble, is to 'reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of

³² United Nations General Assembly (2015). Transforming our world: The 2030 agenda for sustainable development, United Nations A/RES/70/1 adopted by the General Assembly on 25 September 2015 available at:

http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E paragraph 2.

³³ United Nations General Assembly (2015). Transforming our world: The 2030 agenda for sustainable development, United Nations A/RES/70/1 adopted by the General Assembly on 25 September 2015 available at:

http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E at 8.

³⁴ Quentin A. Palfrey, Expanding Access to Medicines and Promoting Innovation: A Practical Approach, 24 (2) GEO. JOURNAL OF POVERTY L. & POL'Y 161 (2017), 166-167, Sophie Loveridge, Would Limiting Compulsory Licensing Availability under TRIPS to a List of Eligible Diseases Increase Access to Medicine in the Developing World, 2017BLR 28 (2017), 28.

³⁵ Margo A. Bagley, The Morality of Compulsory Licensing as an Access to Medicines Tool, 102 MINN. L. REV. 2463 (2018) 2643; Jackson, E. (2012). *The Law and Regulation of Medicines*, Oxford: Hart Publishing Oxford, Gathii, J.T. (2005). How necessity may preclude State responsibility for compulsory licensing under the TRIPS agreement. *North Carolina Journal of International Law* 31 (4) 943 – 970.

³⁶ Agreement on Trade Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, vol.31, 33 I.L.M 81 (1994).

intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.’

Article 27 of the TRIPs Agreement provides 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.’ This imposes an obligation on countries to provide, at least, 20 years of patent protection in virtually all fields of technology including the pharmaceutical industry (except the ‘least developed countries’), as a measure to incentivise investment in innovation. Pharmaceutical corporations are thus able to maintain exclusive worldwide patent rights on newly developed medicines for 20 years and sell at prices they dictate even where pandemics like HIV/AIDS or the Ebola crisis leads to millions of deaths, or threatens whole regions.³⁷

It was envisaged that the TRIPs Agreement will ensure a win-win situation for access to medicines (especially for the otherwise disempowered billions of people in the developing countries) and ensure returns to investment for pharmaceutical corporations as patent holders. As Article 7 which articulates the objective of the treaty states

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

This is desirable to ensure a critical balance between the interest in availability of medicines and required investment in the research and development of medicines. As Melat notes a ‘balanced intellectual property system can allow for the promotion of access to medicines for developing countries and protection of intellectual property rights for pharmaceutical companies.’³⁸ Hence, the inclusion of the Compulsory Licencing in the TRIPs Agreement to facilitate better access to medicines in developing countries,

³⁷ Matiangai Sirleaf, *Ebola Does Not Fall from the Sky: Structural Violence & International Responsibility*, 51 *VAND. J. Transnat'l L.* 477 (2018); Michael Kirby, *Human Rights and Global Pharma Converge*, (2018) 18 (21) *QUT L. REV.* 163, 166; Gathii, J.T. (2005). How necessity may preclude State responsibility for compulsory licensing under the TRIPS agreement. *North Carolina Journal of International Law* 31 (4) 943 – 970.

³⁸ Arega Melat *Defending Local Working American University Intellectual Property Brief*, Vol. 10, Issue 2 (2019), pp. 28-61, 60; Kirby *supra* 37 at 170

to achieve a balance between the imperative of fulfilling their obligations of the right to health of their citizens under international law, and uphold the rights of patent holders.³⁹

Nonetheless, the application of Compulsory Licencing to facilitate access to medicines has been stoutly resisted and stifled by a wide range of interests including notably pharmaceutical corporations, the EU and the World Trade Organisation.⁴⁰ In the aftermath of the TRIPS, global access to drugs due costs, have become more difficult.⁴¹ Some leading western nations – the home countries of giant pharmaceutical corporations – and in particular, the United States, have been in the vanguard of insisting on an interpretation of the TRIPs Agreement that provides virtually impenetrable protection to commercial rights of those pharmaceutical corporations.⁴² Thus, the aim of allowing countries waiving patents rights to allow the production of even deemed essential medicines have been met with considerable objection and referred to as ‘theft’,⁴³ and ‘expropriation’.⁴⁴

The position of the United States on access to medicine based on ‘free trade’⁴⁵ is of particular concern. The United States has a complicated intellectual property scheme and legal regulations that in general, protect pharmaceutical companies at the expense of its citizens, to say nothing of residents of other countries. Critics note that the regulatory position on patents is a ‘one-size-fits-all’⁴⁶ in which all inventions satisfying ‘the standards of patentability are eligible for patent protection, without regard to their social effects, their costs, or the technologies used in the innovation process.’⁴⁷ Medicines are

³⁹ Melat *supra* 38 at 31.

⁴⁰ Sophie Loveridge, Would Limiting Compulsory Licensing Availability under TRIPS to a List of Eligible Diseases Increase Access to Medicine in the Developing World, 2017BLR 28 (2017) at 31.

⁴¹ Lisa Forman, Ifrah Abdillahi and Jeannie Samuel, Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health, *Laws* 5 (4) (2016): 1-11, 2-3.

⁴² Siobhan Elizabeth Stade Murillo, Fair or Fraud: Has the Protocol Amending TRIPS Flourished or Failed, 27 IND. INT’L & COMP. L. REV. 191 (2017); Erika George, The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines, 18 IND. J. GLOBAL LEGAL Stud. 167 (2011) at 180-181, Gathii, J.T. (2003). The structural power of strong pharmaceutical patent protection in U.S. foreign policy. *Journal of Gender Race & Justice*, 7(2), 267 – 314, 267;

⁴³ Bagley *supra* 35 at 2467-2474.

⁴⁴ *Ibid.* at 2467-2468.

⁴⁵ Ruth Lopert; Deborah Gleeson, ‘The High Price of Free Trade: U.S. Trade Agreements and Access to Medicines’ *Journal of Law, Medicine and Ethics* 41, no. 1 (Spring 2013): 199-223.

⁴⁶ Elif Kavusturan, Reforming U.S. Patent Law to Enable Access to Essential Medicines in the Era of Artificial Intelligence, 18 NW. J. TECH. & INTELL. PROP. 51, 53 (2020).

⁴⁷ *Ibid.* at 53.

not treated as a public utility⁴⁸ warranting government intervention to ensure that pharmaceutical companies charge (affordable) prices that reflect the critical nature of medicines in healthcare.⁴⁹ It has been further observed that at the ‘heart’ of the regulatory framework of the pharmaceutical industry, is the balance of ‘conflicting interests—the interest in innovation and the interest in competition.’⁵⁰

Thus, there is a major tension between the US policy approach to the issue of access to medicines and international law perspectives on the right to health.⁵¹ In this regard, the U.S is not party to most treaties that reinforce a human rights perspective on the right to health including the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child.⁵² This state of affairs has profound effect on healthcare costs in the United States and beyond. For instance, consumers pay more for pharmaceutical products in the US than any other high income country,⁵³ or indeed, any other country in the world⁵⁴ leading to serious concerns on the implications in the country.⁵⁵ As a country with some of the foremost pharmaceutical companies like Johnson and Johnson, Pfizer, Moderna, AbbVie and Abott,⁵⁶ this has a major negative effect on the international outlook and practice on affordability of medicines.

⁴⁸ Sarah Kliff The true story of America’s sky-high prescription drug prices Vox (10 May 2018) <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> (accessed 12 March 2021)

⁴⁹ Kavusturan *supra* 46 at 65.

⁵⁰ Kevin Hickey and Katherine B. Armstrong ‘Patent Law: A Primer and Overview of Emerging Issues’ *Congressional Research Service* (21 September 2017) 22.

⁵¹ Mary Gersich Health Care As a Human Right *ABA Human Rights Magazine* 46 (3) 2018 available at: https://www.americanbar.org/groups/crsi/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/health-care-as-a-human-right/

⁵² Working Group on the Universal Periodic Review, National report submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21 - United States of America, (36th Session 4-5 May 2020) A/HRC/WG.6/36/USA/1, 4 <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G20/204/16/PDF/G2020416.pdf?OpenElement> (accessed 14 March 2021).

⁵³ Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, Health Care Spending in the United States and Other High-Income Countries, 319 *JAMA* 1024, 1031 (2018); Robert Langreth, Drug Prices (Updated on 5 February 2019, 15:39 GMT) *Bloomberg* <https://perma.cc/QUd5-9HT6> (accessed 12 March 2021).

⁵⁴ Monique Dabbous, Cyprien Milea, Steven Simoens, Clement François, Claude Dussart, Lyliya Chachoua, Borislav Borissov, and Mondher Toumi Why “American Patients First” is likely to raise drug prices outside of the United States *JOURNAL OF MARKET ACCESS & HEALTH POLICY* 7, 1, 2 (2019)

⁵⁵ Nathan E Wineinger, Yunyue Zhang, Eric J Topol, Trends in Prices of Popular Brand-Name Prescription Drugs in the United States *JAMA Netw Open*. 2019 May 3; 2(5) 1 (2019)

⁵⁶ Majority of them are important players in the global quest to develop COVID-19 vaccines for instance. See *Pharmaceutical Technology Top Ten Pharma Companies in 2020* <https://www.pharmaceutical-technology.com/features/top-ten-pharma-companies-in-2020/> (accessed 07 March 2021).

The United States - before and after the coming into effect of the TRIPS agreement -, has resisted efforts by some countries to benefit from the provisions that allow countries to use the flexibilities of the agreement (like compulsory licensing and related measures) to make crucial drugs available to combat diseases of major concern, and situations like epidemics.⁵⁷ In this regard, the United States has been noted for actively seeking to protect the intellectual property claims of its pharmaceutical companies, thereby seeking to achieve what it failed to do through the TRIPS negotiations.⁵⁸ For instance, the United States Trade Representative stoutly resisted efforts of Thailand to utilize compulsory licensing for medicines for heart diseases.⁵⁹ The United States even sued South Africa to stop that country from deploying generic AIDS medicine at a time the country was a battling with an epidemic of the disease.⁶⁰ More recently, the 2018 United States-Mexico-Canada Agreement (USMCA)⁶¹ contains heightened provisions on pharmaceutical patents beyond those of the TRIPS Agreement.⁶² The USMCA has serious negative implications for pharmaceutical policy and access to medicines, including substantial higher costs in the short and long term in Canada and Mexico and even other countries.⁶³

Given the policy preferences of the United States, it is no surprise that the situation regarding access to medicines have scarcely moved beyond high-policy declarations. This is despite the Doha Declaration that sought to ameliorate the strictures in the TRIPS in relation to access to medicines,⁶⁴ and the more recent United Nations Secretary General

⁵⁷ Kevin Outterson, "Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases," *American Journal of Law & Medicine* 34, no. 2 (2008): 279-330.

⁵⁸ Lopert and Gleeson *supra* 45 at 199-200.

⁵⁹ Outterson *supra* 57 at 282.

⁶⁰ Outterson *supra* 57 at 281.

⁶¹ *Agreement Between the United States of America, the United Mexican States, and Canada* 12/13/19 Text, <https://ustr.gov/tradeagreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between>. (accessed 14 March 2021). This agreement replaces the 1994 North American Free Trade Agreement (NAFTA).

⁶² Tolulope Anthony Adekola, Regional Mechanism under Doha Paragraph 6 System – The Largely Untested Alternative Route for Access to Patented Medicines, 15 *Asian J. WTO & INT'L HEALTH L & POL'y* 61, 71-72 (2020).

⁶³ Ronald Labonté, Eric Crosbie, Deborah Gleeson and Courtney McNamarat, *USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health*, 15 *GLOBALIZATION & HEALTH* 1, 2-3(2019).

⁶⁴ It affirms that members, 'recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' Paragraphs 3 and 4. The Doha Declaration, adopted on 14 November 2001

commissioned high level panel report.⁶⁵ Rather, the ‘thicket of global policy has had almost no impact on primary barriers to affordability: TRIPS-plus intellectual property rights are not only expanding but are getting stricter...Global access to affordable medicines is more, not less, threatened.’⁶⁶

It is important to recall that Article 12 of the ICESCR provides that the States Parties to the ICESCR recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It is also significant that, at least, over hundred national constitutions,⁶⁷ or high-level legislation make provisions for the right to health an obligation of governments to their citizens and residents.⁶⁸ This is in line with the significant number of ratification of the ICESCR by State Parties, which stands at 171 countries.⁶⁹ Several other important international law instruments equally protect the right to health.⁷⁰

Usefully, the United Nations’ Committee on Economic, Social and Cultural Rights (CESCR), which is responsible for monitoring and interpreting the ICESCR, provides ample guidance on the obligation of states and how to handle the inherent tension between the fulfilment of the right to health by the state, and private commercial interest in profit. In General Comment 17 on intellectual property rights, the CESCR stated that intellectual property is ‘a social product’ with ‘a social function’ and State Parties have a duty to ‘prevent unreasonably high costs’ of essential medicines from ‘undermining’ the right to health of the majority of the population. It is also the duty of State Parties to ‘prevent the

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 14 March 2021).

⁶⁵ *Report of the Secretary General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (2016) <http://www.unsgaccessmeds.org/final-report> (accessed 14 March 2021).

⁶⁶ Lisa Forman *The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries* (2016) 31 *Maryland J. Int’l L.* 8-20, 20.

⁶⁷ *Report of the Secretary General’s High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies* (2016) 7 <http://www.unsgaccessmeds.org/final-report> (accessed 14 March 2021).

⁶⁸ Bustreo, F. (2012). Statement by the World Health Organisation’, 19th Session of the Human Rights Council, (2012) available at: http://www.who.int/hhr/news/adg_speech_hrc.pdf. (accessed 11 March 2021)

⁶⁹ Status of Ratification Interactive Dashboard: International Covenant on Economic Social and Cultural Rights <https://indicators.ohchr.org/> (as at 9 February 2021).

⁷⁰ These include Articles 12 and 14 of the Convention on the Elimination of All Forms of Discrimination Against Women, 1979; Article 5 of the Convention on the Rights of the Child (1989), Article 5 of the Convention on the Elimination of All Forms of Racial Discrimination, 1965. These are complemented by quite a number of regional human rights treaties like the European Social Charter, 1961; the African Charter on Human and Peoples’ Rights, 1981; Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (the Protocol of San Salvador), 1988 among others.

use of scientific and technical progress for purposes contrary to human rights and dignity' including the right to health. The MDGs Gap Task Force has similarly noted the dire need to 'resolve remaining tensions' between the protection of intellectual property for medicines and international human rights obligations of States for public health.⁷¹

Comparative Law – National Courts and the Right to Health

Various national courts have adopted the foregoing views with regard to access to medicines. The decision of the Kenyan High Court in *Patricia Asero Ochieng and 2 Others v. the Attorney General & Another (Ochieng)*⁷² adopted the views of the CESCR. The petitioners who are living with HIV-AIDs and dependent on the use of retroviral drugs, challenged the constitutionality of Kenya's Anti-Counterfeit Act of 2008 (ACA). The petitioners alleged that sections 2, 32 and 34 of the ACA affect or were likely to affect their access to affordable and essential drugs and medicines including generic drugs and medicines. This was because the government, in passing the ACA, failed to acknowledge, and specifically exempt, generic drugs and medicines from the definition of counterfeit goods. This meant the provisions proscribed their right to purchase the generic drugs they required for their treatment. They argued the law violated their fundamental right to life, human dignity and health, protected by Articles 26 (1), 28 and 43 of the Constitution of Kenya as well as Article 12 of the International Covenant on Economic, Social and Cultural Rights. The government contended that the intention of the ACA was to protect the lives of Kenyans from those few individuals who would deal with counterfeit goods, including drugs, for profit. The High Court ruled in favour of the petitioners. It recognised the socio-economic context in which HIV poses a potent challenge to the society with most of those infected with HIV being vulnerable, poor, and unemployed people who were not able to afford the high costs of branded medicines and dependent on cheap, accessible, generic anti-retroviral medication.

Relevant to the core of the discussion here, the Kenyan High Court demonstrated a progressive view on the balance between the right to intellectual property, and the right to health. On the right of everyone to benefit from the protection of the moral and

⁷¹ United Nations (2015). *Millennium Development Goal 8: Taking Stock of the Global Partnership for Development- MDGs Gap Task Force Report 2015*, New York: United Nations, i – 75, 64

⁷² Petition No. 409 of 2009

material interests resulting from their scientific, literary or artistic product, the court referred with approval to the CESCR's observation in General Comment No. 17 (mentioned above). The CESCR had stated that 'States parties thus have a duty to prevent unreasonably high costs for access to essential medicines.' Based on this, the court held that the fundamental right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders' medicines.⁷³

In *Ochieng v Attorney General*, the Kenyan High Court had also cited with approval, the South Africa's Constitutional Court (the apex judicial authority in that country) in the case of *Minister of Health and Others -v- Treatment Action Campaign and Others* (TAC).⁷⁴ The context of the case was that South Africa was experiencing a HIV/AIDS pandemic. The Constitutional Court of South Africa (Constitutional Court) noted that the country's health authorities had declared it as 'an incomprehensible calamity' and 'the most important challenge facing South Africa since the birth' of her democracy.⁷⁵ Combating the scourge was categorised as a 'top priority' because it had claimed 'millions of lives, inflicting pain and grief, causing fear and uncertainty, and threatening the economy.'⁷⁶ In 2000, manufacturers of the anti-retroviral drug, *Nevirapine*, offered to provide it free to the Government of South Africa for five years. The drug offered has the potential of preventing the HIV/AIDS infection of an estimated 30,000 – 40,000 children per year by curtailing Mother-To-Child-Transmission (MTCT), which was one of the ways the HIV virus was rapidly spreading in the country. However, the South African Government announced it would introduce the drug only in certain pilot sites and thereby imposed restrictions on the availability of *Nevirapine* in the public health sector. The applicants were a number of associations and members of civil society concerned with the treatment of people with HIV/AIDS and with the prevention of new infections. The applicants contended that these restrictions were unreasonable and violated Sections 27 and 28 of the Constitution of South Africa, which provides for the right to health. The High Court ruled in favour of the applicants, holding among others, that the government was obliged to make *Nevirapine* available to pregnant women with HIV who give birth in the public health sector and their babies. The government appealed to the Constitutional Court, the

⁷³ Ibid. paragraph 86.

⁷⁴ (2002) 5 SA 721 (CC)

⁷⁵ Ibid at 2

⁷⁶ Ibid at 2

highest judicial authority in the country. The Constitutional Court rejected the government's appeal.

Similarly, the constitutional division of the Supreme Court of Venezuela also upheld the link between the right to health and the right to life in *López, Glenda y otros c. Instituto Venezolano de los Seguros Sociales*.⁷⁷ The petitioners in the case, a group of people who were living with HIV, filed an *amparo* action (constitutional writ of protection); an extraordinary judicial remedy, to request regular and consistent supply of triple-therapy medicines and other drugs they needed to treat opportunistic diseases due to AIDS. They further requested that the *Instituto Venezolano de Seguros Sociales* (Venezuelan Institute for Social Security, IVSS) cover the expenses of necessary medical tests. The petitioners requested that these be extended to all those who were HIV-positive. The Court held in favour of the petitioners, holding that the failure, which led to their action, was, among others, a violation of their right to health as well as a threat to their right to life, contrary to provisions of the Constitution of Venezuela and international human rights treaties. A recent decision of the Supreme Court of Justice of the Nation in Mexico upheld a similar claim for HIV patients against the country's National Institute of Respiratory Diseases (INER).⁷⁸

In *Free Legal Assistance Group and Others v. Zaire*,⁷⁹ the petitioners invited the African Commission on Human and People's Rights (African Commission) to consider various claims of gross violations of human rights by the government of the Democratic Republic of Congo (formerly Zaire) by four non-governmental organisations. A key part of the claims was the gross mismanagement of public finances by the government resulting in degrading conditions, shortages of medicine, education and basic services. The claimants averred that these failures of government impaired the ability of the people to obtain adequate medical treatment, among other difficulties. On this, the African Commission held that shortage of medicine constitutes a violation of the right to enjoy the best state

⁷⁷ Expediente 00-1343. Judgment No. 487 (18 December 1997) available at: <https://www.escri-net.org/docs/i/412539> (accessed 14 March 2021).

⁷⁸ Case 'Special Care Unit 13' (Pabellón 13) regarding patients with HIV-AIDS brought against the National Institute of Respiratory Diseases (INER) and other authorities (AR 378/2014) <https://www.escri-net.org/node/365700> (accessed 13 March 2021).

⁷⁹ *Free Legal Assistance Group and Others v. Zaire, African Commission on Human and Peoples' Rights*, Comm. No. 25/89, 47/90, 56/91, 100/93 (1995) available at: http://hrlibrary.umn.edu/africa/comcases/25-89_47-90_56-91_100-93.html (accessed 14 March 2021).

of physical and mental health guaranteed by Article 16 of the African Charter on Human and Peoples' Rights.⁸⁰

It has been noted that the courts in the United States, and in particular, the Supreme Court, have been playing a critical role in patents law.⁸¹ This is of particular significance as there is an incipient judicial approach to patents in some recent decisions of the Supreme Court of the United States that may lead to better access to medicines. One such case is the 2017 case, *Impression Products, Inc. v. Lexmark International, Inc.*,⁸² on domestic and international patent exhaustion.⁸³ Lexmark International Incorporated (Lexmark), a company that designs, manufactures, and sells toner cartridges to consumers in the United States and abroad. The company owns a number of patents that cover components of those cartridges and how they are used. At the point of sale, Lexmark gives consumers two options: the first is buy a toner cartridge at full price and no restrictions; the second option is for the customer to buy a cartridge at a discount through the company's 'Return Program.' On the second option, the customer must sign a contract agreeing to use the cartridge only once, to return them to Lexmark and not transfer the cartridge to anyone else.⁸⁴ Other companies obtain empty Lexmark toner cartridges — including Return Program cartridges — from purchasers in the United States and overseas, refill them with toner, and then resell them, hence they are referred to as remanufacturers. Lexmark sued a number of these remanufacturers, including Impression Products, Incorporated (Impression Products), for infringement of their patent for both group of cartridges.⁸⁵ The defense of Impression Products was that Lexmark's sales, both in the United States and abroad, exhausted its patent rights in the cartridges, so Impression Products was free to refurbish and resell them, and to import them if acquired abroad.

To understand the issue in the case, it is important to state that in the United States, a patent holder is by law, entitled to 'exclude others from making, using, offering for sale, or selling [its] invention throughout the United States or importing the invention into the

⁸⁰ Adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986.

⁸¹ Hickey and Armstrong *supra* 50 at 2.

⁸² 137 S. Ct. 1523 (2017)

⁸³ *Ibid.* 1529

⁸⁴ *Ibid.* at 1525

⁸⁵ *Ibid.* at 1525

United States.⁸⁶ Consequently, anyone who engages in any of the stated acts without the authority of the patent holder may be liable for patent infringement.⁸⁷ The District Court ruled in favour of Lexmark on the cartridges sold in the United States but rejected the claim for cartridges sold abroad. Both parties appealed the decision. On appeal, the full bench of the Federal Circuit Court (Federal Circuit) decided in favour of Lexmark with respect to both groups of cartridges.⁸⁸ Impression products appealed to the Supreme Court.

The Supreme Court held that while the Patent Act grants patent holders the right to exclude others from making, using, offering for sale, or selling [their] invention, the doctrine of patent exhaustion has imposed a limit on that right to exclude. It stated that once a patentee sells an item, that product is no longer within scope of the patent monopoly.⁸⁹ Rather, the item becomes the 'private, individual property' of the purchaser.⁹⁰ A claim of this nature may succeed in contract (as a breach) but not in patent law. According to Justice Roberts

Lexmark cannot bring a patent infringement suit against Impression Products to enforce the single-use/no-resale provision accompanying its Return Program cartridges. Once sold, the Return Program cartridges passed outside of the patent monopoly, and whatever rights Lexmark retained are a matter of the contracts with its purchasers, not the patent law.⁹¹

While the case arose from a dispute regarding printer toners, it has been noted that the case has important implications for the pharmaceutical corporations in the United States.⁹² This decision bodes well for the accessibility to medicines as it can be extended to loosen the vice-like grip of pharmaceutical companies on medicine patents to ensure profit maximization. As Hickey and Armstrong have noted, the decision has a strong

⁸⁶ 35 U.S.C. § 154(a)

⁸⁷ § 271(a)

⁸⁸ *Impression Products, Inc. v. Lexmark International, Inc.* *supra* 82 at 1526

⁸⁹ *Ibid.* at 1532

⁹⁰ *Ibid.* at 1531

⁹¹ *Ibid.* at 1533.

⁹² Hickey and Armstrong *supra* 50 at 22.

potential to drive down drug prices in the international market.⁹³ The decision, applied to the pharmaceutical companies, balances the concern of the pharmaceutical companies in their legitimate quest to secure returns on their research and production costs, but opens the leeway for generic production of medicines that would otherwise be priced beyond the reach of millions of people even in the event of a pandemic.

In sum, access to medicines constitutes a vital aspect of the right to health. In recognition of this, the United Nations Human Rights Council has declared that access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health is fundamental. In a 2009 resolution, it stated that States should ensure that ‘the application of international agreements is supportive of public health policies that promote broad access to safe, effective and affordable medicines’.⁹⁴ In the light of this, the continuing deference, lax, or complete non-regulation of the activities of pharmaceutical corporations by quite a number of countries, especially with regard to the affordability of medicines, is not only ethically problematic, but also legally untenable. The issue here then is whether a conception of business can accommodate the right to access to medicine, particularly in the light of limited resources in many parts of the world. The ethical approach to economics offers a useful approach for resolving the challenge.

Business Ethics

From the ethical perspective, the core question is: how do pharmaceutical corporations demonstrate a positive degree of ethical consideration for society in the light of the huge profits they make?⁹⁵ In this regard, Windsor identifies three approaches to the responsibilities of corporations to society namely: ethical responsibility theory, economic responsibility theory and corporate citizenship.⁹⁶ The ethical responsibility theory draws parallels between the results of corporations that are morally sensitive to the

⁹³ Hickey and Armstrong *supra* 50 at 29-30.

⁹⁴ Human Rights Council (2009). Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. UN Resolution A/HRC/RES/12/24, Twelfth Session, 12 October 2009.

⁹⁵ Smith, A.D. (2008). Corporate social responsibility practices in the pharmaceutical industry. *Business Strategy Series*, 9 (6), 306 – 315; Resnik, D.B. (2001). Developing drugs for the developing world: An economic, legal, moral and political dilemma. *Developing World Bioethics*, 1 (1) 11 – 32.

⁹⁶ Windsor, D. (2006). Corporate social responsibility: Three key approaches. *Journal of Management Studies*, 43(1): 93 – 114, 94-96.

predicaments of stakeholders and those that are not. In order to cater for stakeholders' interests, the approach places 'welfare outcomes more broadly to include expanded duties, rights, and just consequences'⁹⁷ while advocating three fundamental principles of strong corporate self-restraint, genuine corporate altruism duties and expansive public policy. Self-restraint is the corporation's moral choice to avoid 'exploiting market opportunities left legally unregulated'⁹⁸; altruism is the corporation's voluntary, uncompensated or costly contributions to society and stakeholders; while expansive public policy is viewed from the moral compass perspective.

Windsor's foregoing ethical conception aligns well with the analysis of Garriga and Melé.⁹⁹ They identify four different but related dimensions of social reality – economics, politics, social integration and ethics.¹⁰⁰ The economics dimension regards the corporation as a vehicle for creating individual wealth and indirectly contributing towards national income. The politics dimension emphasises the social power of the corporation with which it influences vital political decisions, national legislation and foreign policies. The social interaction dimension stresses the need for corporations to integrate social demands; while the ethical dimension advocates that the interaction between business and society should be based on strong ethical values.¹⁰¹

The capitalist foundation and orientation of pharmaceutical corporations place strong emphasis on their profit maximisation and long-term financial stability. However, the overarching rationale of the State is the socio-economic well-being of its people. Therefore, the healthcare delivery obligation of the State faces a challenge because of the divergent motivations of these two principal actors. It is useful to recall however that, historically, economics as a discipline was considered a branch of ethics, as it was unrealistic to separate 'the study of economics from that of ethics and political philosophy'.¹⁰² Proponents of ethico-economics have advocated the dimension of

⁹⁷ Ibid at 96.

⁹⁸ Ibid at 96.

⁹⁹ Garriga, E. & Mele', D. (2004). Corporate social responsibility theories: Mapping the territory. *Journal of Business Ethics*, 51-71, 53.

¹⁰⁰ Ibid; Mele', D. (2008). Corporate social responsibility theories.' In Andrew Crane et al. (Eds.) *The Oxford Handbook of Corporate Social Responsibility Oxford*: Oxford University Press.

¹⁰¹ Garriga *supra* 99.

¹⁰² Sen, A. (1987). *On ethics and economics*. Oxford: Blackwell 2-3; Hicks, S. (2003). Ayn Rand and contemporary business ethics. *Journal of Accounting, Ethics & Public Policy*, 3(1), 1 - 26.

'common good' in the profitmaking objective of corporations.¹⁰³ On this view, it is important to moderate the profit maximisation paradigm with humane, moral and ethical philosophy – a natural tendency for human-driven endeavours to contribute to the common good and wellbeing of their environments and their constituents, especially people. However, the modern approach to economics is tending more towards the positivist orientation than normative and such a trend can only separate economics from moral or religious values, deferring rather to the laws of economic behaviour. As Braybrook and Mofid observe, 'modern economics has deliberately divorced itself from all moral and ethical considerations in the belief that it needs to be a value-free science'¹⁰⁴. To its advocates, what matters is 'maximising profits and cutting costs – any other considerations are irrelevant'.¹⁰⁵ In this regard, Sen argues that the distance that has developed between modern economics and ethics has 'impoverished' the former.¹⁰⁶

The ethico-economics approach considers the efficiency and equity objectives of the firm as being of equal importance for its long-term success.¹⁰⁷ As such, 'productive investment is to be judged with reference to the twin criteria of economic viability and socio-moral desirability' with the latter taking precedence, as 'the morality of economic agents influences economic outcomes'.¹⁰⁸ As Islahi points out, the ethico-economic school rejects the assumptions that man is a rational maximiser, competitive, selfish and with insatiable 'wants' – an acquisitive animal.¹⁰⁹

Ethico-economics offers an alternative view to utilitarianism and materialism, which provided the logical rationale for the single-minded pursuit of wealth and bodily satisfaction, by emphasising 'values' and 'virtues'. The former 'is a good to be achieved or a standard of right to be followed', while the latter 'is a character trait that enables one to

¹⁰³ Alam, M. (1987). 'A Study of ethico-economics in the general equilibrium field.' *International Journal of Social Economics*, 3/4/5, 207 – 218; Logsdon, J.M. & Palmer, D. R. (1988). Issues management and ethics, *Journal of Business Ethics* 7, 191 – 198; Bakan, J. (2005). The corporation: The pathological pursuit of profit and power. London: Constable; Braybrook, M. and Mofid, K. (2005) *Promoting the common good: Bringing economics and theology together again*. London: Shephard-Walwyn Ltd; Banerjee, S.B. (2008). Corporate social responsibility: The Good, the bad and the ugly. *Critical Sociology* 34 (1), 51 - 79.

¹⁰⁴ Braybrook and Mofid *supra* 103 at 3.

¹⁰⁵ Braybrook and Mofid *supra* 103 at 3.

¹⁰⁶ Sen, *supra* 102 at 7.

¹⁰⁷ Islahi, A.A. 'Ethico-economics, the future system (2003). In D. S. Uma (Ed.) *Economics and ethics* New Delhi: Deep and Deep Publications, 122-129.

¹⁰⁸ *Ibid.*

¹⁰⁹ *Ibid.*

achieve the good or act rightly'.¹¹⁰ In this context, the current operations of pharmaceutical corporations are typically not in line with ethico-economics approach. For example, pharmaceutical corporations have been accused of not exploring the price discrimination mechanism in the sales of their products (medicines) to developing or poor countries at cheaper prices.¹¹¹

State Obligation versus Corporate Profits: Resolving the Tension

Obligation versus Profit

The nature of the pharmaceutical industry's business stands it out as performing 'highly distinctive functions' since its activities directly affect the lives and well-being of 'countless individuals and communities' across the world.¹¹² The distinctiveness of the pharmaceutical industry justifies a special regulatory framework that stands apart from other corporations.¹¹³ Healthcare is typically a core issue in national governance agenda. For instance, this was recently brought to the fore by the widespread concern generated by the allegation that access to the UK's National Health Service (NHS) would form part of a trade deal between the UK and the United States in the context of the United Kingdom exiting the European Union.¹¹⁴

From the perspective of pharmaceutical corporations, charging the full price for medicines is justifiable given the costs involved in starting up, staffing, operating and researching in pharmaceutical outfits.¹¹⁵ Besides, providers of capital should expect, and

¹¹⁰ Hicks, S.R.C. (2008). 'Ethics and economics' in *The Concise Encyclopaedia of Economics* (2nd Edition) available at:

<http://www.econlib.org/library/Enc/EthicsandEconomics.html>

¹¹¹ Leisinger, K.M. (2005). The corporate social responsibility of the pharmaceutical industry: Idealism without illusion and realism without resignation. *Business Ethics Quarterly*, 15 (4) 577-594; Chang, P.L. (2006). Who's in the business of saving lives? *Journal of Medicine and Philosophy*, 31(5), 461-482; Nussbaum, A.K. (2009). Ethical corporate social responsibility (CSR) and the pharmaceutical industry: A happy couple? *Journal of Medical Marketing* 9 (1), 67 - 76.

¹¹² Lee, J.Y. & Hunt, P. (2012). Human rights responsibilities of pharmaceutical companies in relation to access to medicines. *Journal of Law, Medicine & Ethics*, 40 (2), 220 - 233, 224.

¹¹³ Jackson, E. (2012). *The Law and Regulation of Medicines*, Oxford: Hart Publishing Oxford.

¹¹⁴ Hill, A 'How to protect the NHS in a post-Brexit trade deal with the US' *The Conversation* (2 December 2019) available at: <http://theconversation.com/how-to-protect-the-nhs-in-a-post-brexit-trade-deal-with-the-us-128020> (accessed 1 March 2021).

¹¹⁵ Kavusturan *supra* 46 at 71-73.

are reasonably entitled to, decent returns on their investment just as shareholders in any other industry.¹¹⁶

Nonetheless, it remains a major cause for concern that the ethical and human rights dimensions that should regulate the conduct of the activities of the industry have arguably been accorded unacceptably diminished relevance.¹¹⁷ Furthermore, State authorities have sometimes accused pharmaceutical corporations of profiteering. For instance, the Competition and Markets Authority (the UK's competition watchdog) accused Pfizer and Flynn Pharma of 'charging excessive and unfair prices for an anti-epilepsy drug', *Phenytoin sodium capsules*.¹¹⁸ Another relevant example is the two-year standoff between Novartis and the UK government over the provision of a meningitis vaccine, *Bexsero*, which latter deemed overpriced at the proposed £75 per dose. Eventually, the government that GlaxoSmithKline (GSK) provides the vaccine for £20 per dose.¹¹⁹ These two examples underscore the cloud over the justification of prices pharmaceutical corporations charge for medicines, particularly when it is considered that they are one of the 'top five, often top two, most profitable industries in the world'.¹²⁰

The claim by pharmaceutical corporations that their prices are tied to research costs they incur in the process of research and development of medicines should not be tenable in the event that the information on such costs are not in the public domain. Governments need to require pharmaceutical corporations to make drugs' research and development costs available at least to it (if not the general public) as this will form the basis of assessing the fairness of drug prices to the consumers (the public). Since scarce public resources are involved, government, on behalf of the people, needs to ensure transparency and accountability to dispel the current opaque regime of drugs pricing. That way, government maintains a balance between the legitimate interest of business in making profits, and ensuring justifiable use of public resources.

¹¹⁶ Kavusturan *supra* 46 at 78.

¹¹⁷ Kavusturan *supra* 46 at 69-70.

¹¹⁸ BBC (2015). Pfizer and Flynn Pharma accused of overcharging by CMA. <http://www.bbc.co.uk/news/business-33799495> (accessed 12 March 2021).

¹¹⁹ Sagonowsky, E. (2015). GSK finally seals U.K. Bexsero deal for £20 per dose. *Fierce Markets Online*, 30, March 2015, <https://www.fiercepharma.com/vaccines/gsk-finally-seals-u-k-bexsero-deal-for-%C2%A320-per-dose-report-says> (accessed 12 March 2021).

¹²⁰ Bagley *supra* 35 at 2481.

In a report compiled by Bluestone et al., Oxfam, Save the Children, and VSO advocated that pharmaceutical corporations should be compelled to 'have policies on access to treatment for developing countries which include the five priorities of: pricing; patents; joint public private initiatives (JPPIs); research and development (R&D); and the appropriate use of drugs'.¹²¹ Of these five priorities, pricing stands out as an area of 'critical challenge'.¹²² The report stresses further, that 'systematic approach to drugs pricing could lower prices sustainably if delivered through an efficient system; it would also strengthen the industry's potential to improve global health with little effect on profits'.¹²³ While acknowledging and commending some price reduction offers by a few pharmaceutical corporations, the report asserted that such reduction offers, 'cannot achieve the predictability, sustainability and efficiency necessary to meet the needs of developing countries'.¹²⁴ The report also highlights the inflexible approach of pharmaceutical corporations to the interpretations of intellectual property rights (patents). Such inflexibility often leads to higher prices of medicine in developing countries, which in turn limits access to medicine.

Resolving the Tension

Aligning the profit motive with the critical nature of the accessibility of medicines remains a vexed one.¹²⁵ With the persisting ethical deficits in pharmaceutical industry, a lingering question is whether State regulation should play a greater role in embedding ethical values in the industry. Miller has noted, in this regard, that 'market forces can be harnessed to recognize and promote better bioethical performance' by pharmaceutical corporations through sound systems of accreditation, certification, or rating.¹²⁶ He suggests that these mechanisms will enhance pharmaceutical corporations' bioethical

¹²¹ Bluestone, K., Heaton, A. and Lewis, C. (2002) Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World, A Joint Report by Oxfam, Save the Children and VSO <https://oxfamilibrary.openrepository.com/bitstream/handle/10546/111964/beyond-philanthropy-pharmaceutical-industry-010702-en.pdf;jsessionid=FB58064420B5D1DCF88B8663B1F0C9DE?sequence=1> 5.

¹²² Ibid., [1](#)

¹²³ Ibid.

¹²⁴ Ibid.

¹²⁵ Gagnon, M.A. (2013). Corruption of pharmaceutical markets: Addressing the misalignment of financial incentives and public health. *Journal of Law, Medicine & Ethics*, 41(3), 571 – 680.

¹²⁶ Miller, J.E. (2013). From bad pharma to good pharma: Aligning market forces with good and trustworthy practices through accreditation, certification, and rating. *Journal of law, Medicine & Ethics*, 41 (3), 601-610, 603-604.

performance and reputation with stakeholders (including potential consumers, investors, civil society actors, employees, business-partners and regulatory agencies).¹²⁷ For these assessment mechanisms to be effective, stakeholders should have the willingness and ability to boycott (the purchase of products for some other alternative ones) or sanction the pharmaceutical corporations. However, in the context of essential drugs whose supply are limited to one or very few pharmaceutical corporations, the applicable stakeholders are powerless (in terms of boycott or holding pharmaceutical corporations to account). The situation is even worse in the case of many developing countries characterised by poverty, corruption and weak governance mechanisms.

There are provision gaps in developing countries that require substantial intervention by government. Based on their evaluation of the endogenous and exogenous factors that have contributed to the underdeveloped pharmaceutical market and its attendant limitation of access to medicine in Africa, Ahen and Salo-Ahen argue that, with conscious and strategic efforts by leaders of African countries, certain governance and macro-economic variables can be combined to 'create the market and institutional conditions to spur innovations for improving access to medicine'.¹²⁸ Similarly, Callaghan advocate a resistance against 'a global paradigm of inequality in access to the outcomes of pharmaceutical development' which is a result of a lopsided power relationship.¹²⁹ According to Callaghan, this lop-sidedness in the power relationship has to be addressed in order 'to ensure more equitable outcomes for those in society that are most vulnerable to innovation failure' in the industry.¹³⁰

In developed countries, the government usually have agencies in charge of monitoring the supply and accessibility of essential medicines such as vaccines. In the UK for instance, the Joint Committee on Vaccination and Immunisation recommends a vaccine only if it is considered cost effective. However, according to Christensen *et al.*, the committee's 'consideration of *Bexsero* is the first time the committee has used the guidance from the Working Group on Uncertainty in Vaccine Evaluation and Procurement

¹²⁷ Ibid.

¹²⁸ Ahen, F. and Salo-Ahen, O. M. H. (2018) Governing pharmaceutical innovations in Africa: inclusive models for accelerating access to quality medicines. *Cogent Medicine*. 5(1): 1-22, 1.

¹²⁹ Callaghan, C. (2019), "Critical perspectives on international pharmaceutical innovation: Malthus, Foucault and resistance", *critical perspectives on international business*, 15(1): 68-86, 68.

¹³⁰ Ibid.

to assess the cost effectiveness of vaccination, including the provision for quality of life and cost adjustment factors'.¹³¹

As discussed above,¹³² with respect to most developing economies, the State has a legal obligation under international and domestic law to cater for the wellbeing of people. However, due to the dominance of private commercial entities in the pharmaceutical industry, the State's duty of care has been constrained and this has been to the detriment of the poor and vulnerable majority.

[insert Table 1 about here]

The table above draws a parallel between the supply-obligation chains of two essential products, oil (fuel) and medicines (pharmaceutical drugs). Oil has become an important aspect of modern living as we depend on it for power generation for domestic, commercial and industrial use. In the context of liberal economic practice, price determination mechanism is essentially a matter for the market, yet, in the case of oil, despite the absence of legal obligations from the State, the State often intervenes in price determination because of the direct impact the price of oil has on the economy. Indeed, the drive for its acquisition and control by national governments has led to disputes and sometimes war.¹³³

Two common mechanisms used by governments are the provision of subsidy and the imposition of tax. On the other hand, in most developing countries, the price determination mechanism of medicines (an essential part of health care and wellbeing) is largely left to market forces (between demand and supply) despite the State's legal obligation. Therefore, in developing countries, the poor, weak individual (victim of an ailment) is left at the mercy of their meagre savings (if any) and those of their close

¹³¹ Christensen, H., Trotter, C.L., Hickman, M. & Edmunds, W.J. (2014). Re-evaluating cost effectiveness of universal meningitis vaccination (Bexsero) in England: Modelling study. *British Medical Journal*, 349 1-18, 5 (Published 10 October 2014) <http://www.bmj.com/content/349/bmj.g5725> (accessed 14 March 2014).

¹³² In Section II.

¹³³ Yergin, D. (1991). *The prize: The epic quest for oil, money and power*. New York: Simon and Schuster.

relatives and friends to buy the medicines they need. This unbridged economic chasm between the victim (individual citizen) and the ultimate provider of relief (pharmaceutical corporations) in most developing countries leaves individuals to suffer and possibly die as the relief they get is often too little, too late.

Arguably, it amounts to a violation of the duty of the State to ensure the enjoyment of the right to health as provided under international law and many domestic constitutional instruments. Consequently, as it is the case with petroleum products and as obtained in most developed countries (with price control systems), it is the argument here that the State, as the legal duty bearer (at least under international law and indeed in many domestic systems), ought to intervene in the manufacture and supply of pharmaceutical products in less developed economies.

One relevant step in this regard is the requirement for transparency in drugs pricing as is currently the case, for example, in the energy market in the United Kingdom where suppliers set out the proportions and categories of their costs. As alluded to earlier, this will contribute to a more accountable approach to drugs pricing. Further, the emerging call for an enforceable model of transnational corporations' accountability based on an international mechanism should be helpful in reigning in the excesses of such pharmaceutical giants.¹³⁴

Second, there is also the need for the State to consider investing in pharmaceutical research so as to dilute the dominance of the current pharmaceutical giants whose sole *raison d'être*, understandably, is profit maximisation. Alternatively, the state can engage in a joint venture or partnership with pharmaceutical corporations in pharmaceutical research and or the production of key medicines as these will bring down their prices, thereby making them affordable to consumers, without compromising quality. The obvious challenge to this idea is 'the opportunity cost' of such investments by the State in these developing economies, given their limited resources and the huge costs involved in

¹³⁴ Simons, P. (2004). Corporate voluntarism and human rights: The adequacy and effectiveness of voluntary self-regulation regimes. *Industrial Relations*, 59 (1), 101 – 141; Seppala, N. (2009). Business and the international human rights regime: A comparison of UN initiatives. *Journal of Business Ethics*, 87, 401 – 417; De Jonge, A. (2011). Transnational corporations and international law: Bringing TNCs out of the accountability vacuum. *Critical Perspectives on International Business*, 7 (1), 66 – 89; Fasterling, B. & Demuijnck, G. (2013). Human rights in the void? Due diligence in the UN guiding principles on business and human rights. *Journal of Business Ethics*, 116, 799 – 814; Omoteso, K. and Yusuf, H.O. (2017). Accountability of Transnational Corporations in the Developing World: The Case for an Enforceable International Mechanism', *Critical Perspectives on International Business*, 13(1): 54 – 71.

such ventures. However, the public-private-partnership initiative (PPP) that is gaining acceptance across the developed economies may provide a good platform for the actualisation of this idea.¹³⁵ To be sure, the PPP concept has its drawbacks. For example, Richter has pointed out that the safeguards which the WHO put in place since 1998 to ensure an effective PPP system in the health sector and protect public interests are grossly inadequate.¹³⁶ A major reason for this is the conflict of interest of government officials involved in the partnerships. Similarly, Buse and Harmer identify contributions as well as substantive factors that negatively affect the effectiveness of such a scheme including wasting of resources and poor harmonisation between the partners.¹³⁷

Third, national governments in developing economies may consider the use of fiscal measures to reduce the inaccessibility of medicines to the people. One such measure is reducing the corporate tax rates of pharmaceutical corporations in exchange for reduced prices of certain essential medicines. The danger with this idea is the temptation for the pharmaceutical corporations to doctor their financial statements through creative accounting systems. Nonetheless, a sound tax accounting system with inbuilt control mechanisms should be able to mitigate this risk.

A closely related mechanism to the foregoing is to directly subsidise the cost of such essential medicines by a certain percentage. In such an arrangement, the government pays part of the cost of a medicine (to the pharmaceutical company) in order to make it affordable to the people, in the right quality. It could be argued that, as most of the countries concerned are poor, embarking on the subsidy option will put further strains on their tight budgets. However, if access to medicine is given the priority it deserves in the scheme of good governance and considered an essential of life, the government in

¹³⁵ Hodge, G.A. and Greve, C. (2007). Public-Private partnerships: An international performance review. *Public Administration Review*, 67 (3) 545 – 558; Crotty, J. (2009). Structural causes of the global financial crisis: A critical assessment of the “new financial architecture”. *Cambridge Journal of Economics*, 33 (4), 563 – 580; Demirag, I., Khadaroo, I., Stapleton, P. & Stevenson, C. (2011). Risks and the financing of PPP: Perspectives from the financier. *The British Accounting Review*, 43(4), 294 – 310; Yang, Y., Hou, Y. and Wang, Y. (2013). On the development of public-private partnerships in transitional economies: An explanatory framework. *Public Administration Review*, 73 (2), 301 - 310.

¹³⁶ Richter, J. (2004) Public-Private Partnership and Health for All: How Can WHO Safeguard Public Interests? Globalism and Social Policy Programme Policy Brief, No. 5 <http://www.aaci-india.org/Resources/Public-Private-Partnerships-and-Health-for-All.pdf> (accessed 14 March 2021)

¹³⁷ Buse, K. and Harmer, A.M. (2007) Seven Habits of Highly Effective Global Public-Private Health Partnerships: Practice and Potential, *Social Science and Medicine*, 64: 259 – 271, 259-261.

developing countries will not hesitate to subsidise its prices as they do for oil or agriculture.

Public subsidies for the cost of medicines in order to guarantee people's right to health is a major health investment in most developed countries, as they generate excellent dividends even from the economic point of view. In economic terms, generally, the costs of ill-health are substantial. It impedes economic production, growth and development, given its deleterious effects, ranging from workforce absences to poor production skills arising from substantial absences at education and training points.¹³⁸ The costs of ill-health are quite high and impact most acute in low and medium income countries. There is also the tendency to perpetuate the 'vicious circle of poverty' due to the common absence of mitigating measures like social welfare and insurance policies built into the socio-welfare systems of many high-income countries.¹³⁹

In sum, combining an ethico-economic approach to the business of pharmaceutical corporations (developing and producing medicines) with the State's obligation to deliver the right to health (under international and domestic legal instruments) holds much promise for achieving higher accessibility to medicines, an important element required for individual and societal well-being across the globe. It creates opportunity for establishing an optimal framework for regulation and management of a critical issue relevant for socio-economic development, preserving human dignity and fostering peace given the close connection between disease, poverty and violence.¹⁴⁰

Conclusion

There is the need for holding pharmaceutical corporations to high ethical and human rights standards. This remains deficient in the current global business environment. There is also a case for engaging more closely with duty of the State to regulate the operations of pharmaceutical corporations, particularly in developing countries. While

¹³⁸ Global Forum for Health Research (2006). The 10/90 Report on Health Research 2003–2004. Geneva: Global Forum for Health Research 3-4.

¹³⁹ Ibid. at 3-7.

¹⁴⁰ Yusuf, H.O. (2013). Harvests of violence - Neglect of basic rights and the *Boko Haram* insurgency in Nigeria. *Critical Studies on Terrorism*, 6 (3), 371 – 391.

recognising the legitimate right of pharmaceutical corporations to operate profitably and accrue decent returns for their owners, they should conduct their business in an ethical responsible way. The required standards can be achieved through a closer engagement with the duty of the State to regulate the operations of pharmaceutical corporations through appropriate legislation, robust oversight, credible investment model and effective economic policies.


The approach of developing countries' governments to pharmaceutical corporations has generally been one of considerable, arguably, undue deference. One of the main reasons for this is the need to protect commercial interests in exploiting intellectual property arising from investment in the scientific research on, and production, of medicines. However, balanced against the nature of the business of pharmaceutical companies – producing and making available medicine to people suffering from sometimes debilitating ailments that reduce their quality of life or even terminate it-, State deference is inappropriate. In contrast with corporations operating in other industries in which the argument of protecting commercial interests may hold, governments, especially those of developing countries, must regulate and moderate the operations and profit drive of pharmaceutical corporations.

Like any other business, it is the legitimate right of pharmaceutical corporations to operate profitably and accrue decent returns for their owners and investors but there is a need for governments of developing countries to moderate their profit drive. The agitation for securing human rights (including right to health) has been on the increase worldwide while the clamour for corporations to exhibit ethical and social responsibilities in their business activities has never been louder.¹⁴¹

¹⁴¹ This is reflected, among others, in the United Nation's Guiding Principles on Business and Human Rights (Guiding Principles) on the duty of states and responsibility of TNCs and other business enterprises transnational adopted by the UN Human Rights Council in 2011. The Guiding Principles expect corporations as critical players in contemporary society to respect human rights. See Human Rights Council Resolution 17/4, 'Human Rights and Transnational Corporations and Other Business Enterprises,' UN Doc. A/HRC/RES/17/4, June 16, 2011. The Guiding Principles on Business and Human Rights are annexed to the Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie, UN Doc. A/HRC/17/31, March 21, 2011.

Table 1: A Comparison of the Supply-Obligation Chain between Oil and Pharmaceutical Companies

Industry	End-User	Proximate Duty Bearer	Legal Duty Bearer	Provider of Relief (product)
Oil	Individuals and Businesses	Not applicable	Not applicable	Oil companies
Pharmaceutical	Individuals (usually poor and weak)	Family and friends	The State	Pharmaceutical corporations



An Unbridged Gap

