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Lisa Forman

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The Inadequate Global Policy Response to Trade-Related Intellectual Property Rights: Impact on Access to Medicines in Low- and Middle-Income Countries

LISA FORMAN†

Access to medicines in low- and middle-income countries is arguably one of the most explicit examples of how economic and trade rules can derogate from the rights to health and life protected in international human rights treaties.[1] Despite multiple efforts to address access to medicines, material access gains outside of HIV/AIDS are so negligible as to suggest that the primary determinants of the drug gap are not being responded to. This article suggests that this lack of progress is partly a result of obstacles created by the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property[2] (TRIPS Agreement) and the proliferating use of bilateral and free trade agreements (FTAs).[3] In this light, the global drug gap provides a signal of the extent to which international actors are willing

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† Canada Research Chair in Human Rights and Global Health Equity, Assistant Professor, Dalla Lana School of Public Health, Director, Comparative Program on Health and Society, Munk School of Global Affairs, University of Toronto. I thank Peter Danchin for inviting me to participate in the Symposium on Clinical Trials and Access to Essential Medicines in African Countries at the University of Maryland School of Law. I also thank the Editors for their helpful insights on this paper.

1. *See, e.g.*, G.A. Res. 2200 (XXI) A, annex, International Covenant on Economic, Social and Cultural Rights, at 51 (Dec. 16, 1966) (recognizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" in Article 12); G.A. Res. 2200 (XXI) A, annex, International Covenant on Civil and Political Rights, at 53 (Dec. 16, 1966) (recognizing the "inherent right to life" and associated rights in Article 6).

2. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

3. *See infra* Part II.

to give teeth to fundamental human rights like health when powerful commercial and trade interests point in other directions. This paper surveys this landscape, outlining the inaccessibility of essential medicines due to pricing, the impact of trade-related intellectual property rights on pricing, and the trade law and global health policy responses to the affordability and access challenges posed by intellectual property rights protections under the TRIPS Agreement and FTAs. It concludes that existing policy initiatives have failed to adequately respond to the impact of trade-related intellectual property rights on access to medicines, and that bolder measures are required, including suspending the application of trade-related intellectual property rights to essential drugs for low- and middle-income countries.

I. ACCESS TO MEDICINES AND PRICING

The centrality of medicines to realizing human rights, development, and health system imperatives is illustrated in multiple domains: essential medicines are understood as a core obligation of states under the right to health,[4] are recognized as a fundamental building block of health care systems capable of providing universal health coverage,[5] and are included within global development policies like the Millennium Development Goals (MDG) and Sustainable Development Goals.[6]

Yet despite a plethora of international initiatives designed to improve access in low- and middle-income countries,[7] two billion people still cannot access essential medicines,[8] either because there are

4. United Nations [U.N.] Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social, and Cultural Rights), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter General Comment No. 14].

5. *See* World Health Organization [WHO], Monitoring the Building Blocks of Health Systems: A Handbook of Indicators and Their Measurement Strategies, at vi, 59–69 (2010), http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_full_web.pdf.

6. *Goal 8: Develop a Global Partnership for Development*, U.N., http://www.un.org/millenniumgoals/global.shtml (last visited Apr. 19, 2016); G.A. Res. 70/1, Transforming Our World: The 2030 Agenda for Sustainable Development, at 16 (Sept. 25, 2015). The Millennium Development Goals are development goals adopted globally in 2000 to guide global development policy to 2015. *Millennium Summit (6–8 September 2000)*, U.N., http://www.un.org/en/events/pastevents/millennium_summit.shtml (last visited Apr. 19, 2016). The Sustainable Development Goals aim to replace the MDGs with a new fifteen year development agenda. G.A. Res. 70/1, *supra*, at 1.

7. For example, the MDGs and the WHO Global Strategy and Plan of Action discussed below. *See infra* Part IV.

8. WHO, WHO MEDICINES STRATEGY 2004–2007: COUNTRIES AT THE CORE, at 3, WHO

not enough drugs available in public health systems or because the drugs that are there or in the private sector are priced out of reach or not covered by health insurance.[9] As a United Nations (U.N.) report monitoring compliance with the MDG on medicines illustrates that "essential medicines remain unaffordable and insufficiently available in developing countries."[10] This finding is reiterated in a 2015 report which found that "medicine availability is poor in many countries (particularly in the public sector), prices are high, and treatments, especially those for noncommunicable diseases, are unaffordable for those on low wages."[11]

Affordability is thus a key determinant of drug access, alongside rational selection and use; sustainable financing; and adequate infrastructure.[12] However, the influence of affordability is amplified in low- and middle-income countries, where drugs are one of the largest out-of-pocket expenditures for the poor and one of the largest health care expenditures consuming anywhere from 25–70 percent of national health-care expenditures.[13] Indeed, multiple studies confirm that low availability and unaffordable prices exacerbate illness and death and impoverish people.[14] This situation leaves people to make terrible

Doc. WHO/EDM/2004.5 (2004), http://apps.who.int/medicinedocs/pdf/s5416e/s5416e.pdf. The WHO defines essential medicines as medicines "that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness." *Essential Medicines*, WHO, http://www.who.int/topics/essential_medicines/en (last visited Apr. 10, 2016). The importance of essential medicines is underscored by the fact that they are designated as core—and hence prioritized—obligations under the right to health. *See* General Comment No. 14, *supra* note 4, ¶ 12.

9. *See* U.N. MILLENNIUM DEVELOPMENT GOAL GAP TASK FORCE, MDG GAP TASK FORCE REPORT 2014: THE STATE OF THE GLOBAL PARTNERSHIP FOR DEVELOPMENT, at 53–59, U.N. Sales No. E.14.I.7 (2014), http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2014/2014GAP_FULL_EN.pdf [hereinafter MDG Gap Task Force Report 2014]; U.N. MILLENNIUM DEVELOPMENT GOAL GAP TASK FORCE, MDG GAP TASK FORCE REPORT 2015: TAKING STOCK OF THE GLOBAL PARTNERSHIP FOR DEVELOPMent, at 53–58, U.N. Sales No. E.15.I.5 (2015), http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2015/2015GAP_FULLREPORT_EN.pdf [hereinafter MDG Gap Task Force Report 2015].

10. MDG GAP TASK FORCE REPORT 2014, *supra* note 9, at 53.

11. MDG GAP TASK FORCE REPORT 2015, *supra* note 9, at 58.

12. *See* WHO, *supra* note 8, at 4–5.

13. *Id*. at 4.

14. WHO, THE WORLD MEDICINES SITUATION 2011: MEDICINE PRICES, AVAILABILITY AND AFFORDABILITY, WHO Doc. WHO/EMP/MIE/2011.2.1 (2011); Laurens M. Niëns et al., *Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World*, 7 PLOS MED., Aug. 31, 2010, at 6–7, http://journals.plos.org/plosmedicine/article/asset?id=10.1371%2Fjournal.pmed.1000333.PDF.

choices: between food and no health care, or health care and impoverishment. To the extent that access to essential medicines is a core obligation of states under the right to health, the inaccessibility of such medicines would constitute a prima facie violation of the right to health.

The issue of affordability came to prominence around inaccessible antiretroviral medicines (ARVs) for HIV/AIDS,[15] with early access campaigns focused on drugs for infectious diseases such as HIV/AIDS, tuberculosis, and malaria.[16] While infectious diseases are a pressing problem in low- and middle-income countries, the need for accessible drugs to treat noncommunicable diseases is no less great, especially as developing countries increasingly shoulder the "double burden" of communicable and noncommunicable diseases.[17] Yet many essential medicines for both communicable and noncommunicable disease remain unaffordable. For example, a 2010 study found that drugs for asthma, diabetes, hypertension, and adult respiratory infection in sixteen low- and middle-income countries were so unaffordable as to be impoverishing.[18] Moreover the early focus on infectious disease remains narrow: as a prominent example, medicines for hepatitis C remain unaffordable, resulting in very low treatment rates in low-income countries where prevalence may be highest.[19] These examples underscore the need for affordable medicines across the health domains, and not simply in relation to prominent infectious diseases.

II. TRIPS AND INTELLECTUAL PROPERTY RIGHTS

Generic medicines policies are broadly recognized as a key policy intervention to control health budgets and make medicines more

15. *See* Ellen 't Hoen et al., *Driving a Decade of Change*: *HIV/AIDS, Patents and Access to Medicines for All*, 14 J. INT'L AIDS SOC'Y, Mar. 27, 2011, at 1–2, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/pdf/1758-2652-14-15.pdf. ARVs for HIV/AIDS were priced at approximately USD $10–15,000 per person per annum, a prohibitive cost in low- and middle-income countries where the vast majority of people with HIV/AIDS live. *Id*. at 1.

16. *See generally* Lisa Forman et al., *Human Rights and Global Health Funding: What Contribution Can the Right to Health Make to Sustaining and Extending International Assistance for Health?*, 6 GLOBAL HEALTH GOVERNANCE (2012), at 2–8, http://blogs.shu.edu/ghg/files/2012/12/VOLUME-VI-ISSUE-1-FALL-2012-Human-Rights-and-Global-Health-Funding-What-Contribution-Can-the-Right-to-Health-Make-to-Sustaining-and-Extending-International-Assistance-for-Health_-.pdf

17. I. C. Bygbjerg, *Double Burden of Noncommunicable and Infectious Diseases in Developing Countries*, 337 SCIENCE 1499 (2012).

18. Niëns, *supra note* 14, at 5.

19. *See* MDG GAP TASK FORCE REPORT 2015, *supra* note 9, at 61.

affordable.[20] Yet the policy space for countries to provide affordable medicines is bound sometimes wholesale by trade rules around intellectual property rights. The introduction in 1995 of the TRIPS Agreement required countries acceding to the World Trade Organization (WTO) to give patent protection to pharmaceuticals, something that around 50 countries had not done previously.[21] Even in countries providing patents, the requirement of 20-year patents conferring exclusive rights to prevent nonconsensual use was unprecedented. The introduction of patents of this nature resulted in monopolistic pricing that saw sometimes dramatic increases in drug prices, as in Malaysia where drug prices increased by 28 percent per year between 1996 and 2005.[22]

TRIPS has flexibilities to give governments policy space to meet public health and social welfare imperatives. These include delaying the onset of the agreement for the least developed countries (LDC); tailoring patent criteria or excluding patents for inventions to protect health and life; and permitting countries to manufacture or import generic versions of patented drugs or import cheaper versions of patented drugs under measures like compulsory licenses and parallel imports (albeit strictly limited).[23] Global debates focus on these flexibilities because they allow policymakers to ensure that high prices resulting from exclusive patenting rights do not negatively impact public health imperatives. Pharmaceutical companies countered that use of these mechanisms in low and middle incomes countries negatively impacts their incentives to continue producing new medicines,[24] an argument decisively countered in the 2006 report of the

20. WHO, WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO] & WORLD TRADE ORGANIZATION [WTO], PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE, at 156 (2012), https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.

21. Sandra Bartelt, *Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INTELL. PROP. 283, 285 (2003).

22. Richard D. Smith, Carlos Correa & Cecilia Oh, *Trade, TRIPS and Pharmaceuticals*, 373 LANCET 684, 689 (2009).

23. *See generally* TRIPS Agreement, *supra* note 2, art. 6, 30, 31, 41, 65. Parallel importing allows countries to import cheaper versions of patented medicines. Compulsory licensing allows governments to manufacture generic versions of patented medicines without corporate consent during national emergencies or other circumstances of extreme urgency, for public non-commercial use, or where usage is intended to remedy a practice determined after judicial or administrative processes to be anti-competitive. *See The Doha Declaration on the TRIPS Agreement and Public Health*, WHO, http://www.who.int/medicines/areas/policy/doha_declaration/en (last visited May 13, 2016).

24. *See, e.g.*, *The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals*, at 12–17 (2000), http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf.

WHO Commission on Intellectual Property, Innovation and Health [CIPIH Report] which held that where "the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market."[25]

Yet global debates focus on TRIPS flexibilities because their use continues to attract staunch opposition from companies and their host governments in the form of litigation, drug removals, trade sanctions, and diplomatic pressures.[26] More or less at the same time, regional and bilateral FTAs are restricting TRIPS flexibilities in ways that extend monopoly pricing and limit market entry for generic medicines with stark impacts on affordability. For example, "TRIPS-plus rules," so called because they exceed the standards in the TRIPS agreement, restrict the grounds on which compulsory licenses can be issued; prohibit parallel imports; restrict autonomy to decide patent criteria; limit patent exclusions; limit market approval for generic drugs; extend data exclusivity requirements and patent terms; and enable "ever-greening" provisions (the practice of taking out new patents on existing medicines in order to maintain monopolies).[27]

The price impacts on medicines can be stark: in 2007, Oxfam found that after its introduction the US-Jordan FTA resulted in a 20 percent increase in drug prices.[28] Trade-related intellectual property rights have therefore discernibly increased medicine prices in many low- and middle-income countries and considerably reduced policy space to respond to these restrictions.

III. THE DOHA DECLARATION AND THE 'PARAGRAPH 6' SYSTEM

The impact of trade-related intellectual property rights on access to medicines came most prominently to public attention in 2001 when activist and media attention focused on corporate litigation in South Africa, which aimed to prevent the government from passing

25. WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS, at 22 (2006), http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

26. *See* Lisa Forman, *Trade Rules, Intellectual Property and the Right to Health*, 21 ETHICS & INT'L AFF. 337 (2007).

27. Lisa Forman & Gillian MacNaughton, *Moving Theory into Practice with Human Rights Impact Assessment of Trade-Related Intellectual Property Rights*, 7 J. HUM. RTS. PRAC. 109, 114 (2015).

28. *See* OXFAM INT'L, ALL COSTS, NO BENEFITS: HOW TRIPS-PLUS INTELLECTUAL PROPERTY RULES IN THE US-JORDAN FTA AFFECT ACCESS TO MEDICINES 2 (2007), http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf.

affordable medicines legislation despite the fact millions were dying annually from lack of access to medicines for diseases like HIV/AIDS.[29] This caused a tremendous public outcry and contributed to enabling African countries at the Doha round of WTO negotiations to push through the Doha Declaration on the TRIPS Agreement and Public Health to give legal clarity to states' use of these flexibilities.[30] The Doha Declaration explicitly endorsed the right of WTO members to protect public health and promote access to medicines for all and to use TRIPS flexibilities to the fullest to do so.[31] It specified that these flexibilities included the right to grant compulsory licenses and to use parallel importing.[32] It also asked the TRIPS council to find a solution to the inability of WTO members with insufficient or no manufacturing capacity to effectively use compulsory licensing and to extend the LDC waiver from applying TRIPS to pharmaceuticals to 2016.[33]

This request prompted the development of the "Paragraph 6 System," so called because of its location within the Doha Declaration. The system aimed to enable countries to export drugs to LDC without domestic manufacturing capacity, since TRIPS restricts the use of compulsory licenses to supplying the domestic market, leaving countries without domestic manufacturing capacity without a means to export generic pharmaceuticals made elsewhere. In 2005, the TRIPS Council proposed to incorporate the system as a permanent TRIPS amendment when it was accepted by two-thirds of WTO members (with a deadline of 2007 extended to December 31, 2015, in 2013, and then to December 2017 in 2015).[34]

However the system has been used only once, when in 2007, a Canadian generic manufacturer exported ARVs to Rwanda.[35] The cost and complexity of the Canadian experience suggest why the Paragraph

29. *See* Lisa Forman, *"Rights" and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?*, 10 HEALTH & HUM. RTS. 37, 43–45 (2008).

30. *See* Ellen 't Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L. L. 27, 38–42 (2002).

31. WTO, Declaration on the TRIPS Agreement and Public Health, ¶ 4, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration].

32. *Id*. ¶ 5.b.

33. *Id*. ¶¶ 6, 7.

34. *See* General Council Decision, Amendment of the TRIPS Agreement – Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement, WTO Doc. WT/L/965 (Dec. 2, 2015).

35. *See* Richard Elliott, *Managing the Market for Medicines Access: Realizing the Right to Health by Facilitating Compulsory Licensing of Pharmaceuticals—A Case Study of Legislation and the Need for Reform*, in ACCESS TO MEDICINES AS A HUMAN RIGHT: IMPLICATIONS FOR PHARMACEUTICAL INDUSTRY RESPONSIBILITY 151, 156–57 (Lisa Forman & Jillian Clare Kohler eds., 2012).

6 System is used so infrequently: over six years, the manufacturer made two drug shipments and declined to renew the license,[36] and industry opposition saw legislative efforts to streamline the process voted down twice in parliament.[37]

Another reason countries are not using the system is because they are buying from countries that do not need to issue compulsory licenses, like India, which Ghana did in 2005 instead of importing from Canada where the drugs were patented.[38] That India's role in providing access to affordable generics is of crucial importance globally is shown clearly with ARVs, the greatest success of the global access campaigns. Of the 13.6 million people accessing ARVs in 2014,[39] it is estimated that 80 percent are dependent on Indian generics to do so.[40] India has this generic manufacturing capacity because it took full advantage of the transition periods in TRIPS that all low- and middle-income countries have when acceding to it.

However the introduction in 2005 of pharmaceutical patents means India will no longer be able to supply generics of newer ARVs and other drugs other than through the use of TRIPS flexibilities. The Indian Government has incorporated these flexibilities into law, including by curtailing "ever-greening" by refusing patents if companies cannot show clear novelty or efficacy.[41] The Indian Government used this flexibility when it denied a patent to Novartis on a new formulation of Gleevec, a blood cancer drug, which it contended lacked novelty. This decision was upheld in 2013 by the Supreme Court of India.[42] While the Doha Declaration is explicit that

36. *See, e.g.*, APOTEX INC., SUBMISSION TO THE STANDING COMMITTEE ON INDUSTRY, SCIENCE AND TECHNOLOGY: BILL C-393, AN ACT TO AMEND THE PATENT ACT (DRUGS FOR INTERNATIONAL HUMANITARIAN PURPOSES) AND TO MAKE A CONSEQUENTIAL AMENDMENT TO ANOTHER ACT (Oct. 26, 2010), http://www.apotex.com/global/docs/submission_order_en.pdf; Gloria Galloway, *Tories Block Bid to Make Cheaper Medicines for Poor Nations*, GLOBE & MAIL (Nov. 28, 2012), http://www.theglobeandmail.com/news/politics/tories-block-bid-to-make-cheaper-medicines-for-poor-nations/article5759286.

37. *See* Galloway, *supra* note 36.

38. *See* WHO, WIPO, & WTO, *supra* note 20, at 178.

39. JOINT U.N. PROGRAMME on HIV/AIDS, FAST TRACK: ENDING THE AIDS EPIDEMIC BY 2030, at 7 (2014), http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf.

40. *See* Brenda Waning et al., *A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries*, 13 J. INT'L AIDS SOC'Y, Sept. 14, 2010, at 3, 5, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/pdf/1758-2652-13-35.pdf.

41. *See* Patralekha Chatterjee, *India's Patent Case Victory Rattles Big Pharma*, 381 LANCET 1263 (2013).

42. Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

states can use flexibilities like compulsory licenses to ensure access to medicines, India has faced corporate litigation over patent denials,[43] and a full range of U.S. diplomatic and trade pressures, with worrying signs that these might be prompting intellectual property policy reform.[44] These kinds of reforms may threaten India's central role as supplier of generic medicines to much of the developing world.

IV. UNITED NATIONS RESPONSES TO TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS

The U.N. system's policy response to the affordability of medicines has been mixed. Access to medicines was first included as an objective in the original MDGs largely because of immense social pressures, which turned the issue into a focal point for political actors.[45] However, its location and formulation in the text of the MDGs reflects an institutional mindset at the time of its drafting that was very reluctant to upset the political and commercial interests at stake. For example, MDG 8.e aims to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies,[46] an approach that seemed to preclude ostensibly "uncooperative" measures like compulsory licenses. While the inclusion of this goal in the MDGs brought global access to medicines within the scope of annual progress monitoring of the MDGs, the goal failed to quantify a target or timeframe and did not speak of TRIPS flexibilities even in general. This response took at face value corporate arguments that strict intellectual property rights in developing countries were critical to protect the innovation cycle that produced new medicines.[47] However, studies and reports since then confirm that patents in developing countries do not stimulate research and

43. *See, e.g.*, Bayer Corp. v. Union of India, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai, 2013).

44. *See, e.g.*, Ben Wolfgang, *Modi Pressed to Address Intellectual Property Reforms*, WASH. TIMES (Sept. 29, 2014), http://www.washingtontimes.com/news/2014/sep/29/indias-narendra-modi-pressed-to-address-intellectu.

45. For example, the analysis of how activist mobilization around corporate litigation to prevent the South African government from adopting an affordable medicines law influenced political responses to HIV/AIDS medicines. *See generally* Forman, *supra* note 29. (I forget if it's small caps or not)

46. *Goal 8: Develop a Global Partnership for Development*, *supra* note 6; G.A. Res. 55/2, United Nations Millennium Declaration, ¶ 20 (Sept. 18, 2000) (resolving to "encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries").

47. *See, e.g.*, Henry Grabowski, *Patents, Innovation, and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849 (2002).

development of new medicines.[48] The timidity of global policy initiatives like the MDGs in naming practices like compulsory licenses therefore appears to be misplaced.

The 2006 CIPIH report prompted the most comprehensive global policy response yet in the Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health (GSPA) produced by a WHO intergovernmental working group between 2006 and 2008 and adopted by the World Health Assembly in May 2008.[49] The GSPA specified over one hundred actions to address medicines access and innovation in eight areas, including crucial recognitions regarding actions in relation to intellectual property rights. For example, it recognized that countries had general authority to use flexibilities recognized in the Doha Declaration and that appropriate pricing policies should include use of such flexibilities.[50] Further, the GSPA identifies flexibilities like research exceptions, export to countries with no manufacturing capacity, "regulatory exceptions," and abuse of intellectual property rights.[51]

However the GSPA also makes no mention of compulsory licensing, the flexibility at the heart of these debates and explicitly endorsed in the Doha Declaration. Nor does it mention parallel imports and restrictions of data-exclusivity to enable generic market entry—flexibilities in TRIPS that are generally restricted or removed in FTAs and whose usage generally prompts legal or economic pressures.[52] The GSPA also stepped back from explicitly addressing the kinds of "TRIPS-plus" rights promulgated in FTAs, with the final strategy deleting a section cautioning states not to adopt TRIPS-plus protection in bilateral trade agreements in favor of a suggestion that states take into account, where appropriate, the impact on public health when considering adopting more extensive intellectual property rights than in TRIPS.[53] While the strategy gives great clarity to action in many other places, the failure to identify key flexibilities and common practices limiting them suggests a weak commitment to supporting key strategies that can impact pricing, and to guarding against political and

48. *See* WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, *supra* note 25.

49. *See* WHO, GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY, at 1 (2011), http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf.

50. World Health Assembly Res. 61/21, ¶¶ 37–38 (May 24, 2008).

51. *Id.* ¶¶ 30(2.4)(e), 36(5.2)(d), 39(6.3)(a), 39(6.3)(f).

52. *See generally* Forman & MacNaughton, *supra* note 27.

53. *See* World Health Assembly Res. 61/21, *supra* note 50, ¶ 36(5.2)(b).

economic interference in this area. These gaps raise questions about whether the current strategy could respond to key domains of drug access.

Certainly global policy has progressed since then, with the medicine goal in the Sustainable Development Goals which replace the MDGs calling for states to:

> [s]upport the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.[54]

This goal is markedly broader and more ambitious than its corollary in the MDGs, encompassing both innovation of new medicines and access to existing medicines, incorporating both communicable and noncommunicable disease, and explicitly citing the Doha Declaration in affirming the right to use TRIPS flexibilities in full. A similar proposal is made in the 2016 report of the United Nations High Level Panel on Access to Medicines, which recommends that "WTO members should commit themselves, at the highest possible political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies,"and that this includes "adopt[ing] and implement[ing] legislation that facilitates the issuance of compulsory licenses."[55] These policy shifts suggest that the global perspective on access to medicines have changed considerably since the MDGs were formulated in 2001, albeit that specific references to mechanisms like

54. *Sustainable Development Goals*, U.N., https://sustainabledevelopment.un.org/?menu=1300 (last visited Apr. 11, 2016).

[55] United Nations. "Report of the United Nations Secretary-General's High-Level Panel on Access toMedicines: Promoting Innovation and Access to Health Technologies." 2016, p27-29. Available online: http://www.unsgaccessmeds.org/final-report/ (accessed on 14 November 2016)

compulsory licensing and parallel imports remain rare.

V. THE INADEQUATE OUTCOMES OF GLOBAL POLICY INITIATIVES

It is troubling then that this 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, with TRIPS flexibilities being limited, and even eradicated, and the global movement of generic medicines through international borders being continually obstructed under measures to eradicate counterfeit medicines.[56] TRIPS flexibilities are increasingly the only remaining aperture through which state policy for affordable medicines can operate and, as indicated above, India, the primary provider of these medicines, is being stringently targeted. Global access to affordable medicines is more, not less, threatened.

While the full use of TRIPS flexibilities may be the primary solution on the table to resolve the inaccessibility of affordable medicines, we should not be fooled into believing that it is anything but a poor solution. TRIPS flexibilities turn the fundamental human right to health and affordable medicines into a rigidly restricted exception to a property right,[57] and affordable medicines, the price developing countries must pay to enter wealthy markets and the global economy. Existing policy proposals do little to mitigate this impact and have failed to propose anything more than the most incremental of steps. As a case in point, the 2012 U.N. Commission on HIV and the Law recommended that WTO members urgently suspend TRIPS for essential drugs for low- and middle-income countries, and that the U.N. Secretary General convene a new body to recommend a new intellectual property regime for drugs.[58] The U.N. Secretary-General's High-Level Panel on Access to Medicines was set up in response, and offered an important testing ground for promoting an intellectual property system that didn't simply enhance protection of the public interest as an externality to its ethos of advancing trade interests, but that located this system within the broader system of international law

56. *See, e.g.*, Kaitlin Mara, *India May Be Nearing Dispute Settlement with EU over Generic Drug Seizures*, INTELL. PROP. WATCH (Aug. 28, 2009), http://www.ip-watch.org/2009/08/28/india-may-be-nearing-dispute-settlement-with-eu-over-generic-drug-seizures.

57. *See* Philippe Cullet, *Patents and Medicines*: *The Relationship Between TRIPS and the Human Right to Health*, 79 INT'L AFFAIRS 139 (2003).

58. *See* U.N. GLOBAL COMMISSION ON HIV AND THE LAW, RISK, RIGHTS & HEALTH (July 2012), http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf.

that recognizes that the "common good of humankind [is] not reducible to the good of any particular institution or 'regime.'"[59] Yet the Panel's report did little to move beyond prior policy proposals in this area, losing an important opportunity to progress beyond the status quo on access to medicines.[60]

Finally, it is worth noting that transformation in this area has always come from social actors who brought the full weight of human rights law and social pressures to bear on naming, shaming, and prodding appropriate action from international institutions, companies, and their supporting government in relation to AIDS treatment.[61] Their successes underscore that the global drug gap is created and reinforced by human decisions and action and can accordingly be undone by human decisions and action.

VI. CONCLUSION

Access to medicines in low- and middle-income countries globally has been negatively impacted by trade-related intellectual property rights in a range of fora. Global policy initiatives have failed to respond appropriately to the restrictive impact of these rights. If the global drug gap is to be remediated, bold and decisive action at the global level must replace the business as usual response that has characterized global policy initiatives to date. In the current political climate of a new U.S. administration, the boldness of action that we may see is highly unlikely to move in the direction of equity and fairness in access to medicines.

59. Int'l Law Comm'n, Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, ¶ 480, U.N. Doc. A/CN.4/L.682 (Apr. 13, 2006).

60 *See* Lisa Forman, Ifrah Abdillahi, and Jeannie Samuel, "Assessing the UN High-Level Report on Access to Medicines Report in Light of the Right to health," (2016) 5 LAWS 1-11, at 8.

61. *See* Mark Heywood & Dennis Altman, *Confronting AIDS: Human Rights, Law, and Social Transformation*, 5 HEALTH & HUM. RTS. 149 (2000).