Northeastern Public Law and Theory Faculty Research Papers Series No. 369-2020

Access to Medicines Activism: Collaboration, Conflicts, and Complementarities

Intellectual Property Law and the Right to Health: A History of TRIPs and Access to Medicine (Srividhya Ragavan & Amaka Vanni eds., 2020)

Brook K. Baker
Northeastern University – School of Law

Access to Medicines Activism: Collaboration, Conflicts, and Complementarities

Brook K. Baker

Feb. 12, 2020

Introduction and context

Access-to-medicines (A2M) civil society activists and an informal network of affiliated legal scholars and other intellectual property ("IP") and global health experts have interacted with key global health institutions, leading Indian generic producers, and a loose and morphing vanguard of low- and middle-income countries ("LMICs") to achieve remarkable success in lowering the price of antiretroviral (ARV) medicines to respond to the global AIDS pandemic. The most important price blast heard around the world was the decision by Cipla, an Indian generic company, in 2001 to offer a triple-dose antiretroviral therapy (ART) for as little as $350 per year,[1] approximately 3% of the international price charged by Big Pharma companies six months earlier, $10,439.[2] Eighteen years later, best in class, triple-dose ART [tenofovir disoproxil fumerate (TDF)/lamivudine (3TC) plus dolutegravir (DTG)] whose equivalent (TDF/emtricibitine/DTG) can cost as much as $54,876 per person per year in the U.S.[3] is now available as single daily pill for as little for $75 per person per year[4] in approximately 130 countries covering 90+% of people in low- and middle-income countries (LMICs) living with HIV[5] – largely as a result of A2M campaigns and responsive actions by key partners. The advent of dramatically more affordable generic ARVs was a necessary precondition

[1] Donald G. McNeil, Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, NEW YORK TIMES (Feb. 7, 2001), https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html.

[2] Carmen Perez-Casas, Cécile Mace, Daniel Berman & Julia Double, *Accessing ARVs: untangling the web of price reductions for developing countries*, MEDICINS SAN FRONTIERES 3 (Sept. 20, 2001), https://msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW1_ENG_2001.pdf. Cipla actually initially set a price of $800 per person per year for a triple-dose ARV combination, which along with activism calling for Big Pharma ARV price reductions prompted innovators' first substantial ARV price discounts to select low- and middle-income countries.

[3] Dep't Health and Hum. Servs., *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*, NIH K-27 (Oct. 25, 2018), https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

[4] *New High-Quality Antiretroviral Therapy To Be Launched In South Africa, Kenya and Over 90 Low- and Middle-Income Countries At Reduced Price*, CLINTON HEALTH ACCESS INITIATIVE (Sept. 21, 2017), https://clintonhealthaccess.org/new-high-quality-antiretroviral-therapy-launched-south-africa-kenya-90-low-middle-income-countries-reduced-price/.

[5] Although the original announcement referenced coverage under the ViiV dolutegravir ("DTG") license with the Medicines Patent Pool ("MPP"), which at that point directly included 92 countries, another 38 or 39 countries/territories were included in the "indirect" coverage of the DTG license. *Cf.* Brook K. Baker, *Beyond the Obvious - Direct and Indirect Territorial Coverage of MPP/ViiV Voluntary License Dolutegravir*, IP Watch (May 24, 2017) (finding 38 named countries/territories with indirect coverage) https://www.ip-watch.org/2017/05/24/beyond-obvious-direct-indirect-territorial-coverage-mppviiv-voluntary-license-dolutegravir/; *When Will ViiV, Clinton Health and Partners Officially Repair the Mistake on Missing out 39 Countries From the DTG Pricing Agreement?*, MAKE MEDICINES AFFORDABLE (June 13, 2018) (reporting that the Clinton Health Access Initiative, the MPP, and ViiV will allow at least one licensee, Mylan, to honor the pricing agreement for public procurement in 39 additional, but unnamed, countries), http://makemedicinesaffordable.org/en/when-will-viiv-clinton-health-and-partners-officially-repair-the-mistake-on-missing-out-39-countries-from-the-dtg-pricing-agreement/.

to greatly increased donor and domestic funding[6] and to what has become the largest global response ever to a pandemic disease killing millions of people a year—a response that had 24.5 million people on treatment end June of 2019, a 65% of the 37.9 million people living with HIV globally.[7]

The need for a global access to medicines movement grew out of the ashes of a global IP protection bonfire ignited by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights, the so-called TRIPS Agreement (TRIPS Agreement).[8] This Agreement, pursued via a fifteen-year campaign by Big Pharma and 10 years of intensive US trade pressure,[9] instantiated new global minimum standards of intellectual property rights for pharmaceuticals. No longer could countries deny patents on pharmaceuticals as over fifty countries had done in the pre-TRIPS era. Instead WTO Member States were required to enact minimum patent terms of twenty-years,[10] provide for patents in all fields of technology including medicines, and eliminate discrimination against issuing patents based on the fact of foreign ownership or the likelihood of importation.[11] The resulting monopoly right to exclude generic competition guaranteed drug companies the power to charge whatever the market would bear and what would boost profits the most. In low- and middle-income countries with high degrees of income-inequality, this power to exclude meant that Big Pharma companies could maximize profits by selling at higher prices to economic elites, even if that meant that the vast majority of poor people went without.[12]

Despite the entrenchment of globalized patent monopolies on medicines under the TRIPS Agreement, it also contained important public health flexibilities that allow some policy space for countries to bypass or even override monopoly protections. These flexibilities were not routinely acknowledged, but they included longer transition periods of least developed countries, stringent standards of patentability and disclosure, allowance for opposition procedures challenging patents and patent applications, exclusions from and exceptions to patent rights, parallel importation, and compulsory and government use

---

[6] Between 2000 and 2016, total spending on HIV and AIDS in low- and middle-income countries increased from $4 billion to $19.9 billion. Annie Haakenstad et al., *Potential for Additional Government Spending On HIV/AIDS in 137 Low-Income and Middle-Income Countries: An Economic Modelling Study*, 6 LANCET HIV (2019).

[7] *Fact Sheet – World Aids Day 2019: Global HIV Statistics,* UNAIDS (Dec. 1, 2019), http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf.

[8] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 8(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 [hereinafter TRIPS Agreement].

[9] *See generally* PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY (Oxford Univ. Press 2003) (detailed history of the political and strategic genesis of the TRIPS agreement as engineered by U.S. knowledge industries); SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (Cambridge Univ. Press 2003) (arguing that the TRIPS Agreement resulted from the lobbying of powerful IP-based multinational firms who succeeded in bending intergovernmental decision-makers to their private corporate interests).

[10] TRIPS Agreement, *supra* note 8, at Art. 33.

[11] *Id*., Art. 27.

[12] Sean Flynn, Aidan Hollis, & Mike Palmedo, *An Economic Justification for Open Access to Medicines Patents in Developing Countries*, 37 J. L. MED. & ETHICS 184 (2009).

patents.

This chapter address three phases of A2M advocacy. The first phase started in the late 1990s and continuing into at least the mid 2000s when global cooperation and collaboration between A2M advocates grew as they confronted the terrible scourge of HIV compounded by the refusal of pharmaceutical companies and rich country governments to take measures to increase affordability of newly effective ART. After some significant victories in securing lower prices and gaining access to off-patent generic ARVs, the second phase, starting in the mid 2000s, focused on using a plethora of access strategies to overcome or bypass patent monopolies on medicines and to resist Big Pharma and rich government pressure to increase IP protections and to cease use of TRIPS flexibilities. Unfortunately, during this phase fractures developed in the A2M movement about the comparative advantages and potential complementarity of voluntary licensing with other access strategies—most especially patent oppositions. In the third phase, as activists turned to new diseases and new issues like delinkage and transparency and to international high-level forums and drug pricing campaign in rich countries, new tensions have arisen about the impact of these activities on the historical global health justice issue of ensuring affordable and equitable access to existing medicines in LMICs. Although truly monumental efforts have resulted in dramatic improvement in access to medicines, the path forward will be complicated and contested.

First phase – Contestation against shared enemies and international collaboration

The first phase of the emerging international A2M movement involved intense contestation with Big Pharma and growing collaboration and solidarity between activists in the Global North and Global South. Cipla's revolutionary $350 per year price point was achieved in the earliest days of the post-TRIPS era and during the first wave of global A2M activism, when most LMICs were newly required to abide with international norms for protecting pharmaceutical-related IP rights, especially patents. Although AIDS activists had previously attacked domestic high prices in the U.S.,[13] it wasn't until the late 90's and early 2000's that activists' attention was focused on the extortionate prices of newer and more effective ARVs that was limiting access to antiretroviral therapy in LMICs[14] to well under .1% of people infected. Global attention was also sharpened by multiple forms of aggressive pharmaceutical protectionism pursued by both Big Pharma companies and trade associations and by their rich government supporters particularly the U.S. This was the period of trade threats and WTO actions, Big Pharma lawsuits against progressive government action, and counteractions by developing countries and activists in courts, at the WTO, and in public arenas.

Despite the lack of media coverage of the global HIV/AIDS pandemic in the 1990s, pharmaceutical executives were well aware of the looming global crisis and the impact of high prices on ARVs. In 1991, chief executives of eighteen major pharmaceutical companies arrived at the World Health Organization's (WHO) Geneva headquarters where they discussed the magnitude of the AIDS crisis in the developing world and were

[13] *See* PATRICIA D. SIPLON, AIDS AND THE POLICY STRUGGLE IN THE UNITED STATES, 23-25 (Georgetown Univ. Press 2002).
[14] *Id*. at 111-134.

asked for flexibility in pricing new ARVs. Over the next two years, industry responded to repeated requests for discounted prices in poorer countries by championing its research and development (R&D) mission and questioning Africa's health infrastructure.[15]

Perversely, instead of offering discount prices, industry and its subservient government supporters, including President Clinton, went on the offensive. For example, in South Africa, thirty-nine U.S. and European drug companies and trade associations, and their South African subsidiaries, took Nelson Mandela and the South African government to court over their determination to purchase cheaper generic and brand name medicines for people living with HIV/AIDS pursuant to the Medicines and Related Substances Control Amendment Act No. 90 of 1997.[16] Originally filed in 1998, the industry's lawsuit was finally dismissed on April 18, 2001, after the Treatment Action Campaign (TAC) intervened in the lawsuit and after Global Days of Protest challenging the court case. During this protracted litigation, 400,000 South Africans died of AIDS. As a further example of misused corporate and state power, the Office of the U.S. Trade Representative routinely used its power under section 301 of the Trade Act to threaten trade sanctions[17] against developing countries that "abused" or threaten to abuse pharmaceutical patents. Significant pressure was brought to bear first on Thailand and later on South Africa to "respect intellectual property rights."[18] This pressure continued in South Africa until late 1999, when AIDS Coalition to Unleash Power (ACT-UP) and Health Global Access Coalition's African AIDS "zaps" against Vice President Al Gore[19] forced President Clinton to revise his pro-pharma policy in South Africa,[20] ultimately resulting in the issuance of an executive order in 2000 prohibiting trade pressure against any Sub-Saharan African country using TRIPS-compliant measures to access more affordable ARVs.[21] Shortly thereafter, there were civil society campaigns challenging the U.S.'s misguided WTO case against provisions in Brazil's compulsory licensing law allowing compulsory licenses when medicines were not produced locally in Brazil.[22]

Not only did the A2M movement fight defensively against negative pressures, activists and the WTO Africa Group turned the table on TRIPS-flexibility denialists to pursue clarification within the WTO system of the lawfulness of public health IP flexibilities and

---

[15] Barton Gellman, *An Unequal Calculus of Life and Death*, WASH. POST (Dec. 27, 2000), https://www.washingtonpost.com/archive/politics/2000/12/27/an-unequal-calculus-of-life-and-death/4f6d22c0-d918-441c-b6e9-e270554bc73b/?utm_term=.a6322191f597.

[16] David Barnard, *In the High Court of South Africa, Case No. 4138/98: The global Politics of Access to Low-Cost AIDS Drugs in Poor Countries*, 12 KENNEDY INST. ETHICS J. 159 (2002).

[17] Section 301 gives the Trade Office broad discretion to threaten and eventually impose trade sanctions against listed countries. 19 U.S.C. § 2242 (2012).

[18] Patrick Bond, *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. firms and Politicians,* 29 INT'L J. OF HEALTH SERVS. 765 (1999); Tido von Schoen-Angere & Jiraporn Limpananont, *Correspondence: US pressure on less-developed countries*, 358 LANCET 245 (2001).

[19] Mark Milano, *Personal Perspective: Zapping for Drugs*, THE BODY PRO (Sept. 1, 2016), https://www.thebodypro.com/article/personal-perspective-zapping-drugs.

[20] SIPLON, *supra* note 13, at 120-126 (detailing US pressure against South Africa and the activist response);

[21] Exec. Order No. 13155, 65 Fed. Reg. 30,521 (May 10, 2000), https://www.govinfo.gov/content/pkg/FR-2000-05-12/pdf/00-12177.pdf; Neil A. Lewis, *Clinton Issues Order to Ease Availability of AIDS Drugs in Africa*, N.Y. TIMES (May 11, 2000), https://www.nytimes.com/2000/05/11/world/clinton-issues-order-to-ease-availability-of-aids-drugs-in-africa.html.

[22] Haroon Ashraf, *USA and Brazil End Dispute Over Essential Drugs*, 357 LANCET 2112 (2001).

to assure access to medicines,[23] resulting ultimately in the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[24] As part of confirming WTO Member States right to advance public health and to promote "access to medicines for all," the Doha Declaration clarified national sovereignty to define grounds for compulsory licenses and to allow parallel importation. It further motivated for a new transition period for least development country (LDC) Member States with respect to recognition of and enforcement of pharmaceutical patents and data rights, while also mandating the adoption of a new compulsory licensing mechanism to allow manufacture, exportation, and importation of medicines to countries with insufficient domestic manufacturing capacity despite the limitations otherwise expressed in Article 31(f) of the TRIPS Agreement.[25]

As a result of ongoing and persistent A2M campaigns against Big Pharma companies for price reductions and expanded generic access, some innovator companies made early price concessions. The first highly touted corporate response to the African AIDS pandemic was launched by Bristol-Myers Squibb in the spring of 1999, its so-called Secure the Future program.[26] With this program, the company promised $100 million dollars over five years to fight AIDS in Africa, initially focused in Botswana but later expanded to fourteen countries. The second major drug company concession was announced on May 11, 2000, when, in conjunction with UNAIDS, a consortium of pharmaceutical giants, Bristol-Myers Squibb, Glaxo Welcome, Merck, Boehringer Ingelheim, and F. Hoffman-La Roche, announced that they had committed to substantial reductions in the price of HIV/AIDS medicines in poor countries through the Accelerated Access Initiative (AAI). Participating companies initially declined to specify reductions, choosing instead to negotiate drug-by-drug, company-by-company, country-by-country.[27] As of March 2002,

---

[23] *See* Brook K. Baker, *Arthritic Flexibilities for Access Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 623–628 (2004).

[24] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WTO Ministerial Conference, Fourth Session, Doha, WT/MIN(01)/DEC/2 (2001) [hereinafter Doha Declaration], https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm; *see* Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, J. INT'L ECON. L. 469 (2002).

[25] Baker, *supra* note 23, at 627–628. The adoption of a paragraph 6 waiver was long delayed by the U.S. and the resulting waiver unfortunately contains many unnecessary and labyrinth procedures. *Id*. 627–655.

[26] Bristol-Myers Squibb, *Secure the Future 10th Anniversary Brochure* (2009), http://securethefuture.com/Shared%20Documents/media/2008_STF_media.pdf.

[27] AAI participants did announce five broad conditions on their price reduction program: (1) "unequivocal and ongoing political commitment" by the recipient countries to a comprehensive HIV/AIDS program; (2) agreement by international agencies, particularly WHO, UNAIDS, and the World Bank, to assume responsibility for increasing public health infrastructures sufficient to monitor patient and their compliance with drug dosing regimens; (3) reduced cost drugs would be sent only into "an efficient, reliable and secure distribution system" to prevent interruption of supply and treatment and to prevent theft and diversion of supplies into a gray market that would subvert existing first world markets and profit margins; (4) acknowledgement that "affordability is an issue in developing countries" and that there would be unspecified price reductions (subsequently estimated at 80-90%); and (5) that developing countries and international bodies would support "adequate and enforced intellectual property rights" to "provide a satisfactory return on investment in the high-risk search for new medicines." Barton Gellman, *A Turning Point That Left Millions Behind*, WASH. POST (Dec. 28, 2000), https://www.washingtonpost.com/archive/politics/2000/12/28/a-turning-point-that-left-millions-behind/afe238d9-49a6-4b03-bfff-2ba83c0c4cd7/?utm_term=.68aba8ad39a9.

the number of people accessing ARVs through AAI efforts had only increased to 35,500 patients; however, prices had decreased 80-90% and there was significantly greater transparency on prices paid.[28]

On the heels of AAI and following the Durban AIDS conference, Dr. Hamied, on behalf of Cipla, made an initial offer to sell a triple-dose combination ART for $800 a day at a European Commission conference in Brussels in September of 2000.[29] The pharmaceutical executives at the conference sat in stunned silence and the politicians in attendance did nothing in response to Hamied's offer. After Jamie Love of the Consumer Project on Technology (now, Knowledge Ecology International (KEI)) asked Hamied for an even lower price, Cipla offered the dollar-a-day price on February 6, 2001.[30] This was a generative moment that both provoked a new round of price concessions from Big Pharma, and also renewed efforts to achieve generic access to all AIDS medicines. In response, on March 14, 2001, Bristol-Myers Squibb, under intense pressure from MSF in South Africa and Yale students protesting patent abuse of a medicine originally developed at Yale,[31] doubled down on Secure the Future by offering to make two of its AIDS medicines, didanosine (ddI) and stavudine (d4T) available "below cost" at $1 dollar per day to sub-Saharan African countries and agreeing further not to assert its patent rights to d4T in those same countries.[32] Ten days later on March 27, 2001, Abbott Laboratories announced that it too would sell two anti-retroviral medications, Norvir and Kaletra, in Africa at prices that would cover costs of manufacture, distribution, and import tax only, resulting in a price of less than $1000 per year for each medication.[33]

In addition to price concessions, some drug companies also started drug donation programs. Pfizer, which was not part of AAI, was put under heavy pressure by AIDS activists before, during, and after the 2000 International AIDS Conference in Durban concerning excessive pricing of fluconazole, which was important in the treatment of opportunistic fungal infections in people living with HIV. Shortly in advance of the Conference, Pfizer announced a planned partnership with the South African Ministry of Health to provide free fluconazole to patients living with HIV/AIDS. In response to

---

[28] WHO, ACCELERATING ACCESS INITIATIVE PROGRESS REPORT, Annex 3 & Annex 4 (2002), https://www.who.int/hiv/pub/prev_care/en/isbn9241210125.pdf?ua=1.

[29] Dr. Y.K. Hamied's speech at the European Commission (28 Sept., 2000), https://www.youtube.com/watch?v=NK7GDpYjGXM. For a description of the conference, *see Press Release, Commission, World Health Organization, and Joint United Nations Programe on HIV/AIDS Takes a United Stand Against Killer Diseases*, European Commission (September 28, 2000), http://europa.eu/rapid/press-release_IP-00-1072_en.htm.

[30] For a dramatic recounting of this story, *see* the film, *Fire in the Blood* (20), or its *Transcript*, 8-11, MEDIA EDUCATION FOUNDATION (2013), https://www.mediaed.org/transcripts/Fire-In-The-Blood-Transcript.pdf. For a newspaper account, *see* Donald G. McNeil, Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. TIMES (Feb. 7, 2001), https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html.

[31] Donald G. McNeil, Jr., *Yale Pressed to Help Cut Drug Costs in Africa*, N.Y. TIMES (March 12, 2001), https://www.nytimes.com/2001/03/12/world/yale-pressed-to-help-cut-drug-costs-in-africa.html.

[32] Melody Petersen & Donald G. McNeil Jr., *Maker Yielding Patent in Africa for AIDS Drug*, N.Y. TIMES (Mar. 15, 2001), https://www.nytimes.com/2001/03/15/world/maker-yielding-patent-in-africa-for-aids-drug.html.

[33] Melody Petersen, *Abbott to Sell Low-Cost AIDS Drugs in Africa*, N.Y. TIMES (March 18, 2001), http://www.nytimes.com/2001/03/28/business/28DRUG.html

inadequacies in Pfizer's donation program,[34] TAC launched its Defiance Campaign whereby it "illegally" imported generic fluconazole from Thailand and submitted samples to the South African Medicines Control Council for approval. On World AIDS Day, December 1, 2000, after months of tense negotiations, Pfizer and the South African Department of Health announced an expanded agreement concerning free distribution of fluconazole for two years in the public sector.[35] In response to continued, widespread demands, Pfizer announced on June 6, 2001, that it would expand its offer of free fluconazole to five other African countries and all least developed countries[36], later claiming that it had donated $1.2 billion worth of fluconazole to governments and NGOs in developing countries with an HIV prevalence rate greater than 1% over an 18 year period.[37] Around the same time that Pfizer announced its planned fluconazole donation program, Boehringer Ingelheim, the patent holder for nevirapine, announced that it would donate its medicine for five years throughout Africa to prevent mother-to-child-transmission. TAC and other treatment activists actively supported governmental acceptance and implementation of the nevirapine program despite reservations about donations as a general strategy.

Beginning in the early 2000s, as a result of pressure from AIDS activists and government threats to issue compulsory licenses (discussed and expanded further below in the discussion of Phase 2 of the A2M movement), several pharmaceutical companies, including BMS, Boehringer Ingelheim, GlaxoSmithKline, and Gilead offered territorially limited voluntary licenses or non-assertion/non-enforcement agreements for ARVs.[38] A unique, early case in this regard was the successful Hazel Tau Competition Commission case brought by TAC and the AIDS Law Project in South Africa against excessive pricing and refusal to license generic ARVs that resulted in the issuance of multiple voluntary

---

[34] What Pfizer did not announce was that it initially limited the donation in several important respects: (1) the drug would be provided only for treatment of cryptococcal meningitis not oral thrush or life threatening esophageal candidiasis; (2) the drug would be provided only for patients certified to be unable to afford the medicine, thus preserving profits in the private sector; (3) the donation was structured in many ways as a clinical trial with onerous reporting, training, and certification requirements; (4) the donation was time limited to 2½ years only (the remaining life of its patent in South Africa) and subject to reevaluation at that time, despite a life-time need for most patients; and (5) the donation was announced for South Africa only leaving the rest of the developing world to fend on its own.

[35] Pfizer estimated the value of the fluconazole donation program at $50 million, presumably based on the wholesale price of the donated medicine, not the $1-2 million dollar actual cost of production. In addition, it is quite likely that Pfizer will end up with significant tax advantages, exceeding the costs of the program, because of current charitable deduction rules.

[36] *Pfizer to Expand Fluconazole Donation Program to More than 50 Developing Nations*, KAISER HEALTH NEWS (June 7, 2001), https://khn.org/morning-breakout/dr00005040/.

[37] *Diflucan Partnership*, PFIZER https://www.pfizer.com/responsibility/global_health/diflucan_partnership_program (last visited June 5, 2019).

[38] Tahir Amin, *Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?,* OXFAM 7 (Feb. 28, 2007), https://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf; Peter Beyer, *Developing Socially Responsible Intellectual Property Licensing Policies: Non-Exclusive Licensing Initiatives in the Pharmaceutical Sector*, *in* RESEARCH HANDBOOK INTELL. PROP. LICENSING 227–256 (Jacques de Werra ed., 2013). On July 1, 2001, Bristol-Myers also offered "emergency patent relief" to Aspen Pharmacare in South Africa whereby it agreed not to sue the generic manufacturer for the next five years for its production and sale of ddI in South Africa and in 47 other African countries where it did not have a patent.

licenses.[39] One of the most influential early voluntary licenses (VL) was issued by Gilead. Because Gilead lacked an international presence and was facing protests from AIDS activists,[40] Gilead granted VLs to eight generic companies in India in 2006 with several over-restrictive terms.[41] Following a complaint to the Federal Trade Commission,[42] Gilead modified one of the questionable provisions, removing prohibitions against licensees challenging licensed patents.[43]

Second Phase – TRIPS-flexibilities law reform, compulsory licenses, oppositions, Medicines Patent Pool, TRIPS-plus trade agreements, and intra-coalition conflict

The second phase of the A2M movement overlaps chronologically with the first wave, but included more aggressive and offensive use of TRIPS-compliant measures to overcome IP monopolies on medicines. These measures included TRIPS-compliant law reform efforts such as adoption and extension of transition periods for LDC Member States, reliance on compulsory and government use licenses, use of patent opposition procedures, and increased resort to voluntary licenses negotiated by Medicines Patent Pool. This confluence of strategies unfortunately resulted in some contestation between proponents of different strategies and some fracturing in the access-to-medicines movement.

First, during this second phase, access-to-medicines activists initiated campaigns to amend patents laws to incorporate TRIPS public health flexibilities in India, the Philippines, South Africa, Indonesia, Uganda, and several other countries. Because India was famously called "the pharmacy of the developing world," the most important law reform effort occurred in 2004-2005 when the Indian Patent Act was being amended to meet minimum TRIPS requirements. Progressive forces in the Indian Congress, legal experts, and a mobilized civil society all called for measures that would restrict granting of unworthy primary and secondary patents and that further would create policy space for the use of TRIPS-compliant, public health flexibilities.[44] Although the resulting

---

[39] BELINDA BERESFORD, THE PRICE OF LIFE: HAZEL TAU AND OTHERS VS GLAXOSMITHKLINE AND BOEHRINGER INGELHEIM: A REPORT ON THE EXCESSIVE PRICING COMPLAINT TO SOUTH AFRICA'S COMPETITION COMMISSION 35–37 (Jonathan Berger et al. eds., 2003); Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 J. HUM. RTS. PRAC. 14, 14–36 (2009).

[40] Liz Highleyman, *Activists Protest Gilead*, THE BAY AREA REPORTER (May 17, 2006), https://www.ebar.com/news///236991.

[41] Press Release, *Gilead Announces Licensing Agreements with Eight India-Based Companies for Manufacturing and Distribution of Generic Versions of Viread in the Developing World*, GILEAD (Sept. 22, 2006), http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=908393. These generic licenses contained overly restrictive terms limiting sourcing of active pharmaceutical ingredients, seeking unwarranted royalties, and preventing sales in unapproved markets even where the licensed medicines were not patented. James Love, *Blog: Gilead Efforts to Control Global Market for Two AIDS Medicines*, HUFFINGTON POST (Feb. 15, 2007, updated May 25, 2011), https://www.huffingtonpost.com/james-love/gilead-efforts-to-control_b_41304.html.

[42] *KEI asks FTC to Investigate Gilead Effort to Control Market for AIDS Drugs Ingredients*, KEI BLOG (Feb. 15, 2007), http://keionline.org/content/view/23/1.

[43] *Amendment to the Gilead-Ranbaxy License Agreement*, KEI BLOG (June 9, 2008), https://www.keionline.org/?s=Amendment+to+the+Gilead-Ranbaxy+License+Agreement.

[44] Julie George, Ramya Sheshadri & Anand Grover, *Intellectual Property and Access to Medicines: Development and Civil Society Initiative in India, in* INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ARV MEDICINES: CIVIL SOCIETY RESISTANCE IN THE GLOBAL SOUTH, 110–25 (Renata Reis, Veriano Terto Jr. & Maria Cristina Pimenta eds., 2009).

amended Act was not perfect, especially with respect to actually preventing evergreening of patent monopolies,[45] it incorporated many safeguards by means of stringent standards of and exclusions from patentability, robust opposition procedures, and generous conditions for issuing compulsory and government use licenses.[46] The positive example set by India encouraged many countries and activist groups to pursue TRIPS flexibility law reform in other countries, with significant reforms accomplished in Zanzibar,[47] the Philippines,[48] Indonesia,[49] Uganda,[50] Zambia,[51] and elsewhere, with ongoing campaigns still underway in South Africa[52] and the ARIPO region.[53] The Fix the Patent Laws campaign in South Africa is particularly significant because at this point South Africa does not even examine patent applications and it has a very large number of patents on pharmaceuticals, many of which were rejected even by lenient patent offices in the U.S. and Europe. South Africa activists, led by the Treatment Action Campaign, MSF, and Section27, have waged an eight year campaign to amend South Africa's Patent Law, which is nearing success. The United Nations Development Program (UNDP) and the United

---

[45] *See* Sudip Chaudhuri, Chan Park & K. M. Gopakumar, *Five Years into the Product Patent Regime: India's Response* (2010); Bhaven N. Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice*, 38 J. POLITICS, POLICY & LAW 735–755 (2013); Feroz Ali et al., PHARMACEUTICAL PATENT GRANTS IN INDIA: HOW OUR SAFEGUARDS AGAINST EVERGREENING HAVE FAILED, AND WHY THE SYSTEM MUST BE REFORMED (2018), https://www.accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf; *cf.* Feroz Ali et al., REJECTED IN INDIA: WHAT THE INDIAN PATENT OFFICE GOT RIGHT ON PHARMACEUTICALS PATENT APPLICATIONS (2009-2016) (2018), https://www.accessibsa.org/media/2017/12/Rejected-in-India.pdf.

[46] Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, *97* COL. L.R. 1571 (2009); Janice M. Mueller, *The Tiger Awake: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L.R. 491 (2006).

[47] Zanzibar Industrial Property Act No. 4 of 2008 (Tanz.).

[48] An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293, or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 or the Pharmacy Law, and for other purposes, Rep. Act No. 9502, (2008).

[49] Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents, https://wipolex.wipo.int/en/text/421120 (English translation on file with the author).

[50] Uganda Industrial Property Act, 2014, https://www.wipo.int/edocs/lexdocs/laws/en/sc/sc014en.pdf.

[51] Patents Act, Cap, 40 (2016) (Zam.).

[52] *South African Cabinet Approves New Intellecutal Property Policy,* FIX THE PATENT LAWS (MAY 24, 2018), https://www.fixthepatentlaws.org (last visited June 9, 2019). For a partial history of the Fix the Patent Laws campaign, see Brook K. Baker, *International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Laws Campaign*, 60 N.Y.L. SCH. L. REV. 309, 312-314, 317-319, 320-321 (2015-2016) (and sources cited). For the recently adopted South African policy reform, see THE DEPARTMENT OF TRADE AND INDUSTRY, INTELLECTUAL PROPERTY POLICY FOR THE REPUBLIC OF SOUTH AFRICA – PHASE I (2018), https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf. For recommended legislative changes, see Brook K. Baker & Yousuf Vawda, *Submission by University of KwaZulu Natal Affiliated Academics on the Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017* (Oct. 23, 2017) http://law.ukzn.ac.za/Libraries/2017-doc/Submission_by_UKZN_Academics_on_SA_Draft_IP_Policy_2017_-_23_October_2017.sflb.ashx.

[53] For a description of civil society policy objectives of the ARIPO reform process, see Brook K. Baker, *A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and Critique Of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities* (March 5, 2019) (addressing national legislation), https://www.kelinkenya.org/wp-content/uploads/2019/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf; CIVIL SOCIETY PROPOSALS TO ADDRESS POLICY AND LEGAL INCOHERENCIES IN THE HARARE PROTOCOL THAT IMPACT ACCESS TO HEALTH TECHNOLOGIES IN ARIPO MEMBER STATES (June 4, 2019) (addressing Harare Protocol reforms), https://www.kelinkenya.org/wp-content/uploads/2019/06/CSO_TRIPSFlexibilitiesProposalsForARIPOFinal-with-sign-ons-4-6-19.pdf.

Nations Conference on Trade and Development (UNCTD) played an important advisory and convening role in many of these law reform efforts as have NGOs including Health Global Access Project (Health GAP), the Third World Network (TWN), and South Centre.

Moving from simply demanding price concessions or donations from recalcitrant Big Pharma companies to actively seeking to override, bypass, out-maneuver their patent barriers, A2M activists opened up an entirely new phase of campaigning for compulsory and government use licenses that focused directly on fostering robust generic competition to lower the price of medicines. In Brazil in the early 2000s, for example, activists worked with the government to threaten issuance of compulsory licenses, which at first simply resulted in discounted prices on two ARVs, nelfinavir and efavirenz.[54] Likewise, even though civil society in Thailand and the Governmental Pharmaceutical Organization unsuccessfully advocated for issuance of a compulsory license, they subsequently succeeded achieving revocation of a patent on ddI.[55]

The push for compulsory and government use licenses accelerated in the mid-2000s as funding expanded for treatment access and as global health initiatives like the Global Fund to Fight AIDS, Tuberculosis and Malaria and the President's Emergency Plan for AIDS Relief required non-violation of existing patent rights as a precondition to procuring quality assured generic medicines. Researcher Ellen t'Hoen reports as many as 100 formal and informal compulsory license efforts in sub-Saharan African countries and few a Southeast Asian and Latin American countries, eighty-one of which were actually implemented.[56]

One of the first government use licenses was issued in Malaysia in 2003.[57] Shortly thereafter, on October 5, 2004, Indonesia issued a government use license to allow manufacture of generic versions of lamivudine and nevirapine, which it later expanded in 2007 to cover efavirenz.[58] On September 3, 2012, Indonesia issued a new compulsory

---

[54] Jane Galvão, *Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health*, 95 AM. J. PUB. HEALTH 1110, 1112-13 (2005).

[55] *See* Gaëlle Pascale Krikorian, *From AIDS to Free Trade Agreements: Knowledge Activism in Thailand's Movement for Access to Medicines*, 3 ENGAGING SCIENCE, TECH. & SOCIETY 154 (2017); Nathan Ford et als, *Challenge and Co-Operation: Civil Society Activism for Access To HIV Treatment in Thailand*, 14 J. TROP. MED. & INT'L HEALTH 258 (2009).

[56] Ellen FM 't Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORG. 185-93 (2018) (reporting that 19 compulsory licensing undertakings were resolved by other means, including price reductions or voluntary licenses, or were otherwise abandoned or invalidated). For additional efforts to track and analyze experience with compulsory licenses on medicines, see Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MEDICINE e1001154 (2012), https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001154&type=printable; James Packard Love, *Recent examples of use of compulsory licenses*, KEI RES. NOTE NO. 2 (2007), https://www.keionline.org/misc-docs/recent_cls_8mar07.pdf.

[57] Chee Yoke Ling, *Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the "Government Use" Option*, THIRD WORLD NETWORK, IPR SERIES NO 9 (2006).

[58] Sinafah Tunsarawuth, *Indonesia Mulls Compulsory Licenses on Three More HIV/AIDS Drugs*, INTELL. PROP. WATCH (Nov. 26, 2007), https://www.ip-watch.org/2007/11/26/indonesia-mulls-compulsory-licences-on-three-more-hivaids-drugs/.

license on seven HIV and hepatitis B medicines.[59] One of the most famous and contested compulsory licensing cases occurred in Thailand. Between 2006 and 2007 and as a result of pro-health policies and long-standing civil society organizing, Thailand issued government-use licenses on three key ARVs and a cardiovascular medicine.[60] Although Thailand meticulously followed international and national law, Abbott Laboratories, the patent holder on ritonavir and lopinavir, retaliated against the government use license by withdrawing pending registration applications on multiple medicines. Supporting Abbott, the USTR lodged strident complaints with the Thai government and ultimately withdrew several trade preferences that Thailand had previously enjoyed. Not to be deterred, the Thai government announced additional government use licenses on several cancer medicines in 2008 before a change in government resulted in a regrettable pause in its compulsory licensing activities.[61]

During this same time period and inspired by Thailand's boldness, Brazil issued its only compulsory license on efavirenz.[62] Subsequently, in another influential case, on March 12, 2012, India's Controller General of Patents, Designs and Trade Marks, issued an order granting a compulsory license to patents on the cancer drug, sorafenib, in the matter of *Natco v. Bayer*,[63] which resulted in costs savings of 95%. Although this listing of compulsory licensing campaigns is incomplete, it is appropriate to acknowledge the successful campaign for multiple compulsory licenses in Ecuador,[64] for a hepatitis C

---

[59] *Indonesia issues compulsory licenses against seven HIV, hepatitis B drugs*, IHS MARKET (October 12, 2012), https://ihsmarkit.com/country-industry-forecasting.html?ID=1065972339.

[60] *The campaign for use of compulsory licensing in Thailand*, MAKE MEDICINES AFFORDABLE (Feb. 15, 2015), http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/.

[61] Suwit Wibulpolprasert, Vichai Chokevivat, Cecilia Oh & Inthira Yamabhai, *Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership*, 7 GLOBALIZATION & HEALTH (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3180369/pdf/1744-8603-7-32.pdf.

For a detailed history of compulsory licensing efforts and results in Thailand, see *Timeline for US-Thailand Compulsory Licensing Dispute*, PROGRAM ON INFORMATION JUSTICE AND INTELLECTUAL PROPERTY (2009) (and sources cited), http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf. For Thailand's defense of its government use licenses, see MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, FACTS AND EVIDENCES ON THE 10 BURNING ISSUE RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND (2007); MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFFICE, FACTS AND EVIDENCES ON THE 10 BURNING ISSUE RELATED TO THE GOVERNMENT USE OF PATENTS ON FOUR ANTI-CANCER DRUGS IN THAILAND (2008).

[62] Keith Alcorn, *Brazil issues compulsory license on efavirenz*, NAM AIDSMAP NEWS (May 7, 2007), http://www.aidsmap.com/Brazil-issues-compulsory-license-on-efavirenz/page/1427206/. For a broader description of Brazilian civil society campaigns to access medicines at the time, see Gabriela Costa Chaves, Marcela Fogaça Vieira and Renata Reis, *Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society*, 8 Sur Int't J. Hum. Rights 163 (2008).

[63] Natco v. Bayer, (2011) 1 C.L.A. (India).

[64] Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, AGENCIA LATINOAMERICANA DE INFOMACION (April 4, 2013), https://www.alainet.org/en/active/63292; Public Citizen, *Ecuador Takes One Step Forward for Health (Issues New Compulsory Licenses) and One Step Back (Signs Harmful Trade Agreement with the EU) (2014)*, https://www.citizen.org/wp-content/uploads/ecuador-compulsory-license-eu-fta-summary-english.pdf. The Colombian Foundation IFARMA has played a critical role in compulsory licensing campaigns in Ecuador. *Fundacion IFARMA is a Non-Profit Organization That Develops Research, Consulting and Activism Activities, Focused on Guarantee of the Right to Health and Access to Essential Medicines*, NAMATI Innovation In Legal Empowerment, https://namati.org/network/organization/fundacion-ifarma/ (last visited June 13, 2019).

compulsory license in Malaysia,[65] and for attempted compulsory licensing in Colombia,[66] Peru,[67] and Chile.[68] The U.S. has continually pressured countries against issuance of compulsory licenses, but its bark is much worse that its bite.[69]

Building on the transition periods for LDCs in Article 66.1 of the TRIPS Agreement, A2M activists fought for extensions of LDC's two TRIPS transition periods. Although many LDCs had already announced their intention not to protect patents on medicines broadly or in more selective circumstances,[70] TWN and other activists also sought to preserve WTO LDC Members flexibility to exclude patent and data protections on medicines by seeking extensions of the general TRIPS waiver from 2013-2021[71] and of the pharmaceutical

---

[65] Catherine Saez, *Malaysia Grants Compulsory License for Generic Sofosbuvir Despite Gilead License*, INTELL. PROP. WATCH (September 15, 2017), https://www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence/. Lekhya Kintada, *Compulsory Licensing for Hepatitis C Medicines in Malaysia*, CITIZENVOX (April 10, 2019), https://citizenvox.org/2019/04/10/compulsory-licensing-for-hepatitis-c-medication-in-malaysia/.

[66] *Background FAQ on Glivec (imatainib) Compulsory License in Colombia*, KNOWLEDGE ECOLOGY INT'l, https://www.keionline.org/book/background-faq-on-glivec-imatinib-compulsory-license-in-colombia (last visited June 13, 2019); *Press Release: Compulsory licensing in Colombia: Leaked documents show aggressive lobbying by Novartis*, PUBLIC EYE (April 12, 2017) (documenting threatened investment case), https://www.publiceye.ch/en/media-corner/press-releases/detail/compulsory-licensing-in-colombia-leaked-documents-show-aggressive-lobbying-by-novartis/; Ed Silverman, *U.S. Trade Rep is Urged to Revamp Trade Deal With Colombia Over Compulsory Licensing*, STAT PHARMALOT (June 26, 2018) https://www.statnews.com/pharmalot/2018/06/26/trade-rep-colombia-compulsory-licensing/.

[67] Ed Silverman, *Peruvian Lawmakers Seek a Compulsory Licenses for a Bristol HIV Drug*, STAT PHARMALOT (May 26, 2017), https://www.statnews.com/pharmalot/2017/05/26/peru-compulsory-license-bristol-drug/.

[68] *Inside Views: New Health Ministry of Chile Reaffirms Path to Compulsory Licence for Hepatitis C Drug*, INTELL. PROP. WATCH (Apirl 9, 2018), https://www.ip-watch.org/2018/09/04/new-health-ministry-chile-reaffirms-path-compulsory-licence-hepatitis-c-drugs/.

[69] Brook Baker, *Don't Be Afraid of Compulsory Licenses Despite US Threats: Special 301 Reports 1998-2017 – Listing Concerns But Taking Little Action*, INFOJUSTICE.ORG (February 20, 2018), http://infojustice.org/archives/39594; Brook Baker, *Lies, Distortions, and False Promise: The U.S. Position on Compulsory Licenses in the 2018 Special 301 Report*, INFOJUSTICE.ORG (May 1, 2018), http://infojustice.org/archives/39888; *see* Brook K. Baker, *Will the Modi Government Succumb to US and Industry Pressure to Modify its Pro-Access Pharmaceutical Patent Policy?*, 25:6 EXPERT OPIN. THER. PATENTS 1-4 (2015) (presenting a more detailed account of US pressure against India).

[70] Ellen FM 't Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORG. 185–93 (2018) (reporting 40 instances of 28 LDCs invoking the TRIPS pharmaceutical waiver).

[71] Article 66.1 of the 1994 TRIPS Agreement reads as follows:

> In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

TRIPS Agreement, *supra* note 8, at art. 66.1. The general requirement to become TRIPS compliant with respect to IPRs and their enforcement was extended from its original date of 2006 twice, first to 2013 (with some conditions) and later to 2021 (with fewer conditions). EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 FOR LEAST DEVELOPED COUNTRY MEMBERS, WORLD TRADE ORGANIZATION (Nov. 30 2005) http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf; EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 FOR LEAST DEVELOPED COUNTRY MEMBERS, WORLD TRADE ORGANIZATION ¶ 1 (June 12, 2013), https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf.

extension from 2016-2033.[72] In addition to building coalition support for unconditional extensions of existing waivers, civil society organizations made submissions in support of LCD transition demands,[73] provided technical assistance to LDC negotiators, publicized US and European pressure against extended transition periods,[74] and garnered letters of support from law professors and legal experts[75] and from several global health organizations and institutions including UNDP, and UNAIDS.[76]

Drawing on the additional TRIPS flexibilities they fought for or preserved, A2M activists also created platforms for coordinated attacks on unworthy patents through opposition procedures.[77] The Lawyers Collective in India was an early sponsor of such work and succeeded, along with generic companies, in challenging multiple patent applications

---

[72] Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health directly addressed LDC Members' need for an extended transition period with respect to pharmaceutical products:

> We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Actualizing Paragraph 7, the TRIPS Council first provided a pharmaceutical extension until January 1, 2016. EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST-DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS WITH RESPECT TO PHARMACEUTICAL PRODUCTS, WORLD TRADE ORGANIZATION (July 1, 2002), http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm. Thereafter, there was a further and broader extension until 2033. WTO Members Agree to Extend Drug Patent Exemption for Poorest Members, WTO (Nov. 6, 2015), https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm; COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT FOR LEAST DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS WITH RESPECT TO PHARMACEUTICAL PRODUCTS, WORLD TRADE ORGANIZATION (Nov. 6, 2015).

[73] Civil Society Letter to Members of the World Trade Organization: Request by Least Developed Country Members for an Extension of the Transitional Period with Respect to Pharmaceutical Products and for Waivers from the Obligation of Articles 70.8 and 70.9 of the TRIPS Agreement, http://infojustice.org/wp-content/uploads/2015/06/LDC-extension-letter.pdf.

[74] *US Position on LDC Pharmaceutical Extension of TRIPS Transition Period*, HEALTH GAP (September 15, 2015), https://healthgap.org/us-position-on-ldc-pharmaceutical-extension-of-trips-transition-period/.

[75] Global Academics' and Expert Letter on LDCs' TRIPS Extension Request to WTO TRIPS Council Members (April 27, 2013), https://d3n8a8pro7vhmx.cloudfront.net/healthgap/pages/102/attachments/original/1406058716/Global_Academics¹_Expert_Letter_on_LDC_Extension_(1).pdf?1406058716.

[76] UNAIDS & UNDP, ISSUE BRIEF: TRIPS TRANSITION PERIODS FOR LEAST DEVELOPED COUNTRIES (2013), https://www.unaids.org/sites/default/files/media_asset/JC2474_TRIPS-transition-period-extensions_en_0.pdf. TRIPS Article 70, available at: https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art70_jur.pdf

[77] The TRIPS Agreement directly references the legality of administrative opposition procedures in Art. 62.3, requiring only that they be governed by general principles set out in paragraphs 2 and 3 of Art. 41. *See* WIPO, *Opposition Systems*, WORLD INTELL. PROP. ORG. https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html (last visted Feb. 15, 2019). Countries with pre-grant opposition systems include: Argentina, Colombia, Costa Rica, Egypt, Honduras, India, Mongolia, Pakistan, Portugal, Spain, and Zambia. Countries and regional bodies with post- grant oppositions include: Brazil, Denmark, Finland, Germany, India, Japan, Norway, Pakistan, Moldova, Korea, Sweden, Turkey, U.S.A., EAPO and EPO.

released from India's backlog of applications held in its TRIPS Article 70 "mailbox."[78] Indian opposition procedures were used both to challenge unworthy or time-barred first patents but especially to challenge so-called secondary, "evergreening" patents on key medicines, including most famously Novartis's cancer medicine, imatinib (Glivec®).[79] More recently, supported with hard-fought grants from Unitaid[80] and with additional funding from MSF,[81] first the Lawyers Collective, and then Initiative for Medicines Access and Knowledge (I-MAK),[82] International Treatment Preparedness Coalition (ITPC), and their allies,[83] all launched new oppositions to key ARVs and hepatitis C medicines in India, Argentina, Brazil, Thailand, Ukraine, and other countries with viable patent opposition mechanisms.

Since 2006, after starting with opposition work in India where it won patent oppositions on four ARVs, I-MAK has emerged as a major player in the opposition space given the technical expertise of its founders. "Today, the organization's legal work and research has expanded to 49 countries and 33 therapies for 16 diseases, including hepatitis C, HIV, leukemia, tuberculosis, diabetes, cancer, and blood-related disorders."[84] I-MAK has helped catalyze a global coalition of five global partners to work on patent oppositions to key medicines in middle-income countries that were not typically benefitting from inclusion in voluntary licenses: Argentina, Brazil, Thailand, and Ukraine. The success of I-MAK and partners' opposition efforts has grown over time with significant estimated cost-savings from successful oppositions and related price negotiations and policy dialogues.[85]

As previously described, because of activist pressure, some pharmaceutical companies began to negotiate bilateral VLs with generic companies in the early 2000s. However, some activists, concerned about the slow pace of law reform and the country-by-country and drug-by-drug nature compulsory licenses and opposition procedures, worked to

---

[78] *India's Patent Office Rejects Boehringer's Application for Pediatric Antiretroviral*, KAISER HEALTH NEWS (June 23, 2008) (reporting 13 oppositions against AIDS medicines), https://khn.org/morning-breakout/dr00052881/.

[79] Chan Park & L. Menghaney, *TRIPS Flexibilities: The Scope of Patentability and Oppositions to Patents in India*, in ACCESS TO KNOWLEDGE IN THE AGE OF INTELL. PROP. (Gaelle Krikorian & Amy Kapczynski, eds. 2010), available at http://mitpress.mit.edu/books/chapters/189095196Xchap18.pdf.

[80] Unitaid supported Lawyers Collective's recent opposition work in India though the work was prematurely shut down because of actions taken by the government of India against the Lawyers Collective. *See* UNITAIDS' APPROACH TO INTELLECTUAL PROPERTY, 27 (2016), http://itpcglobal.org/wp-content/uploads/2018/05/ITPC-Annual-Review-2017.pdf. Unitaid has supported the ITPC-led coalition's past and ongoing opposition work in Argentina, Armenia, Belarus, Brazil, El Salvador, Georgia, Guatemala, Honduras, India, Kazakhstan, Kyrgyzstan, Moldova, Morocco, Russia, Thailand, Ukraine, Vietnam, *see Blog: Unitaid investment expands our work on access to medicines*, MAKE MEDICINES AFFORDABLE (Sept. 11, 2018), http://makemedicinesaffordable.org/en/unitaid-investment-expands-our-work-on-access-to-medicines/.

[81] In addition to providing financial support for oppositions, MSF also maintains a webpage reporting on and supporting use of oppositions. Patent Opposition Database, https://www.patentoppositions.org.

[82] See *Solving the Drug Patent Problem*, I-MAK, https://www.i-mak.org (last visited June 7, 2019) [hereinafter *Solving Drug Patent Problem*].

[83] *See* Make Medicines Affordable, http://makemedicinesaffordable.org/en/strategy/patent-challenges/.

[84] *See Our Impact*, I-MAK, https://www.i-mak.org/impact/ (last visited June 7, 2019) [hereinafter *Our Impact*].

[85] ITPC claims that its past opposition work (seven oppositions in four countries) under its first Unitaid grant produced $472 million in cost savings. ITPC, WHAT COMMUNITY ACTIVISM CAN ACHIEVE: ANNUAL REPORT 2017,15 (2018), http://itpcglobal.org/wp-content/uploads/2018/05/ITPC-Annual-Review-2017.pdf. I-MAK claims that its opposition work has resulted in $2 billion of cost savings. I-MAK, *supra* note 84..

create a more efficient for securing and coordinating VLs with more explicit pro-access terms – namely a patent pool for medicines. Jamie Love was the first and leading proponent of a patent pool for medicines, but he was joined by MSF, and others to push for the establishment of the Medicines Patent Pool (MPP) under the financial sponsorship of Unitaid.[86] Finally established in 2010, the early history of the MPP has been chronicled,[87] as have the provisions of its licenses,[88] and it has received multiple statements of high-level support in several international forums.[89]

The basic approach of the MPP is to seek VLs from originators and thereafter to negotiate multiple out-licenses to qualified generic producers who are thereby permitted to manufacture and sell single-dose and fixed-dose combination medicines in designated LMIC territories. In addition to granting permission to work the patent in the allowed field of use, the licenses frequently allow access to trade secret know-how and bypass of rules that would interfere with winning registration at national drug regulatory authorities. The licenses mandate that global quality standards be met – prequalification by the World Health Organization, registration by a stringent regulatory authority, or temporary approval by a WHO expert review committee. MPP licenses also must represent an improvement over existing agreements and must not interfere with countries' or generic producers' right to oppose or invalidate patents or to seek or grant compulsory licenses. Finally, transparency is assured as the agreements are published in full on the MPP webpage. Transparency is further expanded by the maintenance of MPP patents licenses database, MedsPaL, which seeks to keep accurate and up-to-date information on the

[86] UNITAID Executive Board, *Resolution No. 7: Memorandum of Understanding between UNITAID and Medicines Patent Pool Foundation*, UNITAID (June 8–9, 2010), https://unitaid.eu/assets/07_eb12-res7-mou-patent-pool.pdf; World Health Organization, *Memorandum of Understanding between the World Health Organization and the Medicines Patent Pool Foundation*, WHO (Sept. 14, 2010) (on file with the author).

[87] *See generally* Jorge Bermudez & Ellen 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 OPEN AIDS J. 37 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842943/pdf/TOAIDJ-4-37.pdf; Michelle Childs, *Towards a Patent Pool for HIV Medicines*, 4 OPEN AIDS J. 33 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2817875/pdf/TOAIDJ-4-33.pdf; Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L.J. 291 (2012).

[88] Brook K. Baker, *A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines*, 10 NORTHEASTERN U. L. REV. 226, 255-308 (2018).

[89] WHO, GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (2011) (referencing patent pools for medicines), http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf; endorsed in WHO, Consultative Expert Working Grp. on Research & Dev.: Fin. & Coordination, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, at 56-57 (April 2012), http://apps.who.int/iris/bitstream/10665/254706/1/9789241503457-eng.pdf?ua=1; and supported by the U.N. Secretary-General's High-Level Panel on Access to Med., *Promoting Innovation and Access to Health Technologies*, at 8, 10–11 (Sept. 2016), https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf. The Lancet Commission on Essential Medicines recommended that the coverage of the MPP be expanded to include access to all essential medicines. Veronika J. Wirtz et al., *Essential Medicines for Universal Health Coverage*, 389 LANCET 403, 454–455, 460 (2017), http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31599-9.pdf?code=lancet-site.

patent status of key AIDS, tuberculosis, hepatitis C and of essential medicines in as many LMICs as possible.[90]

The geographical scope of MPP licenses includes countries/territories directly included in licenses as well as those indirectly covered by pursuant to provisions permitting marketing to non-licensed countries where no patent would thereby be violated in the country of production or the country of import/use, or alternatively in some cases where there is no blocking patent in the country of use. A significant feature in a recent MPP license with ViiV allows for market segmentation by permitting generic sales in public and NGO sectors and to major global health initiatives but retaining the private sector for more profitable sales by innovators. These licenses are in most respects voluntary government-use licenses such as those directly provided for in Article 31 of the TRIPS Agreement. Coverage of MPP licenses in LMICs is highest for TB (100%) and HIV pediatric medicines (99%) but lower for HIV (78.9%-90%) and significantly lower for hepatitis C (47.5%-65.4%). Despite relatively broad coverage, millions of people living with HIV and tens of millions living with hepatitis C in certain MICs cannot source lower cost generic equivalents from MPP licensees.**[91]**

MPP licenses have had substantial public health impacts, most resulting thus far from the Gilead license. As of December 2018, the MPP signed licensing agreements with nine patent holders for thirteen HIV antiretrovirals, one HIV nanotechnology platform, one tuberculosis treatment, and four hepatitis C direct-acting antivirals. During that same time period, MPP executed sub-licensing agreements with twenty-three generic manufacturers and product developers.[92] The public health and market impacts of MPP Agreements include: (1) access to HIV and hepatitis C treatment access totaling 14.6 million treatment years in 125 countries, (2) reduced prices (average price drop of 89%) and cost savings of $631 million through June 2018[93] with projected cost savings of $2.3 billion on HIV medicines alone through 2028.[94]

In addition to achieving significant cost savings and expanded country coverage, the MPP has been instrumental in incentivizing new pediatric and adult formulations. The MPP has helped launch the Paediatric HIV Treatment Initiative,[95] and its licenses have helped Drug for Neglected Diseases *initiative* (DNDi) and generic innovators to develop at least one

---

[90] *MedsPaL Factsheet*, MEDS. PATENT POOL (Dec. 7, 2017), https://medicinespatentpool.org/uploads/2017/07/MedsPaL-Flyer_Dec17_FINAL.pdf.

[91] *License Overview*, MEDS. PATENT POOL, *https://medicinespatentpool.org/what-we-do/global-licence-overview/* (last accessed June 13, 2019). To access more details of licenses' direct territorial coverage, see *Products Licensed*, MEDS. PATENT POOL, https://medicinespatentpool.org/what-we-do/global-licence-overview/licences-in-the-mpp/ (last visited June 13, 2019).

[92] *Update On Progress of Sublicenses*, MEDS. PATENT POOL, https://medicinespatentpool.org/what-we-do/global-licence-overview/update-on-progress-of-mpp-sublicensees/ (last visited June 13, 2019). To find details of then current licenses, see *License Overview*, *supra* note 91.

[93] *Update on Progress of Sublicenses*, *supra* note 92.

[94] Sandeep Juneja et al., *Projected Savings Through Public Health Voluntary Licences of HIV Drugs Negotiated by the Medicines Patent Pool (MPP)*, 12 PLOS ONE e177770 (2017), http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0177770&type=printable.

[95] Press Release*: Paediatric HIV Treatment Initiative (PHTI) to Spur Innovation and Access to Improve the Lives of Children Living with HIV*, MEDS. PATENT POOL (May 19, 2014), https://medicinespatentpool.org/mpp-media-post/paediatric-hiv-treatment-initiative-phti-to-spur-innovation-and-access-to-improve-the-lives-of-children-living-with-hiv/.

new pediatric formulation.[96] For adults, MPP licenses have allowed novel co-formulation of TDF/lamiduvine (3tC)/efavirenz (EFV) and more recently TAF/3tC/EFV. MPP's most significant contribution to new adult formulations is the combination of dolutegravir (DTG), 3tC, and TDF, which is more efficacious, more durable, less toxic, and cheaper than previous first-line regimens and will be available for sale in at least 92 countries. In addition, the MPP has recently entered into a development license for new nanotechnologies that might eventually result in significantly improved formulations and is also exploring licensing of long-lasting formulations.[97] The MPP has recently explored whether to expand its mandate to other diseases, and GlaxoSmithKline has recently expressed an intention to license cancer medicines for some low- and middle-income countries via the MPP.[98]

There have been still other multilateral initiatives to expand access to needed medicines. A much earlier effort grew out of MSF and Drugs for Neglected Diseases Working Group's focus on so-called neglected diseases.[99] This campaign helped spawn a major push within the WHO to focus additional R&D on Type 3 neglected diseases that primarily affected the poorest of the poor in tropical regions.[100] This campaign also resulted in significantly more funding[101] and the establishment of multiple private-public and product-

---

[96] Press Release*: , Child-friendly Formulation of WHO-recommended Treatment Now Approved by the US FDA for Children Living with HIV*, DRUGS FOR NEGLECTED DISEASES INITIATIVE (June 3, 2015) https://www.dndi.org/2015/media-centre/press-releases/pr-phti-fda-approval-pellets/.

[97] E-mail from Esteban Burrone, Head of Policy, Medicines Patent Pool, to author (May 14, 2018, timestamp) (on file with author) (referencing adult TAF/FTC/DTG and pediatric ABC/3tC/EFV); Press Release:, The Medicines Patent Pool Signs a Collaborative Agreement with the University of Liverpool to Develop HIV Nanomedicines, MEDS. PATENT POOL (Dec. 1, 2015), https://medicinespatentpool.org/mpp-media-post/the-medicines-patent-pool-signs-a-collaborative-agreement-with-the-university-of-liverpool-to-develop-hiv-nanomedicines/; Meds. Patent Pool & Unitaid, INTELLECTUAL PROPERTY REPORT ON LONG-LASTING TECHNOLOGIES (2018), https://medicinespatentpool.org/uploads/2018/12/MPP-Unitaid_Intellectual-property-report-on-long-acting-technologies.pdf.

[98] *See* Press Release*: GSK Expands Graduated Approach to Patents and Intellectual Property to Widen Access to Medicines in the World's Poorest Countries,* GLAXOSMITHKLINE (Mar. 31, 2016), https://www.gsk.com/en-gb/media/press-releases/gsk-expands-graduated-approach-to-patents-and-intellectual-property-to-widen-access-to-medicines-in-the-world-s-poorest-countries/.

[99] MSF & DND, FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES (2001) (reporting that of the 1,393 total new drugs approved between 1975 and 1999, only 1% (13 drugs) were specifically indicated for a tropical disease), https://msfaccess.org/sites/default/files/MSF_assets/NegDis/Docs/NEGDIS_report_FatalImbalance_CrisisInR%26D_ENG_2001.pdf.

[100] The WHO Commission on Intellectual Property Rights, Innovation and Public Health was established in 2003 and issued its first report, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS in 2006. https://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1. Subsequently, as debates within the WHO continued, A GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY was published in 2011. https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1. There was as well a Consultative Expert Working Group on Research and Development, which issued its primary report in 2012. RESEARCH AND DEVELOPMENT TO MEET HEALTH NEEDS IN DEVELOPING COUNTRIES: STRENGTHENING GLOBAL FINANCING AND COORDINATION: REPORT OF THE CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION**,** https://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1.

[101] *See* Nick Chapman et al., NEGLECTED DISEASE RESEARCH: REACHING NEW HEIGHTS, G-FINDER POLICY CURES RESEARCH 22, 80 (2018) (reporting R&D investments that increased significantly from 2007 to 2009, followed by a dip in funding but then increases in 2016 and 2017, with 65% of funding in 2017 coming from public sources, 19% from charitable sources, and on 16% from private industry), https://www.policycuresresearch.org/wp-content/uploads/Y11_G-FINDER_Full_report_Reaching_new_heights.pdf.

development partnerships that focus on investigating new products for treating an expanding list of neglected diseases.[102] One of the most promising and progressive initiatives is Drugs for Neglected Diseases Initiative (DNDi), which has already brought several products to or near to market[103] with very significant cost savings in R&D expenses.[104]

At the same time as the neglected disease initiative, there was also a more fundamental interrogation of pluses and minuses of the IP system on development, including access to medicines. Following on the Commission on Macroeconomics and Health's monumental report,[105] the highly influential UK Commission on Intellectual Property Rights issued a major report, which contained trenchant critiques of several aspects of the new TRIPS regime on access to medicines.[106] Another multilateral effort to increase access to medicines was the pursuit of a development agenda at the World Intellectual Property Organization (WIPO). The first proposal to establish a development agenda was initiated by Argentina and Brazil in 2004, supported by twelve other developing countries, resulting in its adoption in 2007.[107] The 2007 Development Agenda included forty-five recommendations,[108] but unfortunately there have been significant criticisms of WIPO's implementation of technical assistance of the Development Agenda almost from the beginning.[109] A more successful initiative was the creation of Unitaid, a Geneva based organization supported largely with innovative levies on airline tickets, that is focused on overcoming market barriers to accelerate access to new medicines and diagnostics for HIV, tuberculosis, malaria, and more recently hepatitis C. Unitaid has had significant

---

[102] *See* Rachel Kiddell-Monroe et al., RE:ROUTE: A MAP OF THE ALTERNATIVE BIOMEDICAL R&D LANDSCAPE, UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES PINCITE? (2016), http://www.altreroute.com/assets/download/UAEM_Reroute_Report.pdf; *See also* Brook Baker, BACKGROUND PAPER: EXISTING AND PRIOR WORK, INITIATIVES AND PROPOSALS TO IMPROVE INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES, U.N. Secretary-General's High-Level Panel on Access to Medicines PINCITE? (March 2016), https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56da11782b8dde9c3d5865b4/1457132156145/DRAFT+Background+Paper+on+Existing+and+prior+work+initiatives+and+propo+++.pdf.

[103] DNDi, *R&D Portfolio Updates, February 2019*, https://mailchi.mp/dndi/dndi-rd-portfolio-update-pp0aldai09?e=17b66dfb62.

[104] DNDi, AN INNOVATIVE APPROACH TO R&D FOR NEGLECTED PATIENTS: TEN YEARS OF EXPERIENCE AND LESSONS LEARNED BY DNDI (Jan. 2014) (reporting DNDi's cost of development ranges from EUR 6-20 million for an improved treatment, to EUR 30-40 million for a new chemical entity, but taking risk of failure into account brings the cost range of an improved treatment to EUR 10-40 million, and to EUR 100-150 million for a new chemical entity), https://www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf.

[105] JEFFREY D. SACHS, WORLD HEALTH ORG. (WHO), COMM'N ON MACROECONOMICS & HEALTH, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT(2001), https://apps.who.int/iris/bitstream/handle/10665/42435/924154550X.pdf?sequence=1&isAllowed=y. http://www3.who.int/whosis/menu.cfm?path=whosis,cmh&language=english

[106] COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 29-55 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

[107] World Intellectual Prop. Org. (WIPO), *WIPO Development Agenda: Background 2004-2007*, https://www.wipo.int/ip-development/en/agenda/background.html (last visited June 10, 2019).

[108] WIPO, *The 45 Adopted Recommendations under the WIPO Development Agenda*, WIPO.int, https://www.wipo.int/ip-development/en/agenda/recommendations.html (last visited [DATE]);/ip-development/en/agenda/recommendations.html; *see generally* THE DEVELOPMENT AGENDA: GLOBAL INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES (Neil W. Netanel, ed., 2008).

[109] *See* Carolyn D. Birkbeck & Santiago Roca, AN EXTERNAL REVIEW OF WIPO TECHNICAL ASSISTANCE IN THE AREA OF COOPERATION FOR DEVELOPMENT (2011), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf.

public health impacts over its first thirteen years of existence.[110]

The discussion above focused primarily on the A2M movement's proactive and strategic offenses to accelerate access to medicines, but the second phase of activism also was forced to continue its long-lasting focus on protecting key LMICs from the IP-maximalist demands of the U.S. and Big Pharma. Defensive measures were required because the U.S. made repeated TRIPS-plus demands in bilateral and regional trade negotiations, including in failed negotiations in the Americas region,[111] with Thailand,[112] and with the Southern Africa Customs Union,[113] all of which failed in part because of protracted civil society opposition.[114] In these failed trade negotiations and in successfully completed ones, the U.S. consistently pursued substantive TRIPS-plus provisions that lengthen, strengthen, and broaden IP rights and their enforcement including: (1) eased standards of patentability and disclosure, (2) limitations on allowable exclusions from patentability and on limited exceptions to patent rights, (3) patent term extension for delays in patenting and market-approval decisions, (4) regulatory data exclusivity and patent-registration linkage, and (5) disallowance of opposition procedures.[115]

Simultaneously, the U.S. and Europe were seeking enhanced enforcement and anti-counterfeiting measures, e.g., market-price damages, new border measures, criminal enforcement, and investor-state dispute settlement of IP-related claims, in both bilateral and regional trade agreements. The most aggressive enforcement effort was the Anti-Counterfeiting Trade Agreement (ACTA).[116] Although A2M activists raised multiple

---

[110] Unitaid, *Our Impact: Defining and measuring impacts is at the core of Unitaid's strategic model*, https://unitaid.org/impact/#enhttps://unitaid.org/impact/#en (last visited June 10, 2019).

[111] Kimberly Amadeo, *FTAA Agreement, Its Members, With Its Pros and Cons: Why the World's Largest Trade Zone Failed*, https://www.thebalance.com/ftaa-agreement-member-countries-pros-and-cons-3305577 (last updated Dec. 21, 2018).

[112] Office of the U.S. Trade Representative, *Thailand*, https://ustr.gov/countries-regions/southeast-asia-pacific/thailand (last visited Apr. 24, 2019); *see also* Raymond J. Ahearn & Wayne M. Morrison, US-THAI FREE TRADE AGREEMENT NEGOTIATIONS, CRS Report for Congress (2006), https://nationalaglawcenter.org/wp-content/uploads/assets/crs/RL32314.pdf; *see generally* Jakkrit Kuanpoth et al., *Public Health at Risk: a US Free Trade Agreement could threaten access to medicines in Thailand*, OXFORD INT'L BRIEFING PAPER NO. 86 (2006),
https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1113&context=lawpapers (analyzing the negative impacts of the proposed US-Thai FTA on access to medicines).

[113] Jonathan Berger & Achal Prabhala, ADDRESSING THE IMPACT OF TRIPS-PLUS PATENT RULES IN THE PROPOSED US-SACU FREE TRADE AGREEMENT (draft 2005),
https://www.who.int/hiv/amds/capacity/tza2_oxfamreport_pricing_financing.pdf.

[114] *See* Biothai, *Fight FTAs: the experience in Thailand* (Oct. 2007),
https://www.bilaterals.org/IMG/pdf/fightingFTA-en-Hi-2-b-experience-in-thailand.pdf (documenting a long history of Thai opposition to FTAs, including a famous demonstration on January 11, 2006); Press Release, *Departing from USTR, Portman leaves dead US-Southern Africa negotiation behind*, AMERICAN FRIENDS SERVICE COMMITTEE (Apr. 18, 2006), https://www.bilaterals.org/?departing-from-ustr-portman-leaves (referencing an international campaign opposing US-SACU free trade negotiations); *Protest Photos*, CITIZENS TRADE CAMPAIGN (2003), https://www.citizenstrade.org/ctc/trade-policies/potential-trade-agreements/the-free-trade-area-of-the-americas-ftaa/protest-photos/ (displaying photos of protests against the FTAA in Miami).

[115] *See generally*, Sean Flynn et al., *U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement,* 28 AM. U. INT'L L. REV. 105-202 (2012).

[116] *See generally* MICHAEL BLAKENEY, INTELLECTUAL PROPERTY ENFORCEMENT: A COMMENTARY ON THE ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA) (2012).

concerns about ACTCA's impact on access to medicines,[117] especially given illegal seizures of lawful generic medicines-in-transit in Europe in 2008 and 2009,[118] it was European civil society challenging ACTA's restrictions on internet freedoms that ultimately led to its demise.[119] However, A2M activists had to fight anti-counterfeiting threats on other fronts including the IMPACT initiative at WHO[120] and anti-counterfeiting legislation in Uganda and Kenya.[121]

---

[117] *See* Brook K. Baker, *ACTA: Risks of Third-Party Enforcement to Access to Medicines*, 26 AM. U. INT'L L. REV. 579 (2011), http://www.auilr.org/pdf/26/26.3.3.pdf; Sean Flynn & Bifan Madhani, *ACTA and Access to Medicines*, PIJIP RES. PAPER SERIES, PAPER 22 (2011), http://digitalcommons.wcl.american.edu/research/22; Medecins Sans Frontieres, A BLANK CHECK: THE ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA) AND ITS IMPACT ON ACCESS TO MEDICINES (Feb. 2012), https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_ACTABlankCheque_ENG_2012.pdf.

[118] Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 W.I.P.O.J. 43 (2009), (detailing how civil society quickly mobilized to condemn the seizures sending protest letters to both the WTO and WHO and then later to the European Union); *see* William New, *International Health Groups Warn WHO and WTO On Medicines Seizures*, INTELL. PROP. WATCH (Feb. 21, 2009), https://www.ip-watch.org/2009/02/21/international-health-groups-warn-who-wto-on-medicines-seizures/; William New, *Alarm escalates Over Delayed Generic Shipments As Action Sought*, INTELL. PROP. WATCH (June 3, 2009), https://www.ip-watch.org/2009/03/06/alarm-escalates-over-delayed-generic-drug-shipments-as-action-sought/; *see generally* Bryan Mercurio, *'Seizing' Pharmaceuticals In Transit: Analysing the WTO Dispute that Wasn't*, 61 INT'L & COMPARATIVE L. QUARTERLY 389 (2012) (discussing the resulting WTO case and its settlement); Brook K. Baker, *Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough*, PIJIP RESEARCH PAPER SERIES (2012), http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1026&context=research.

[119] James Losey, *The Anti-Counterfeiting Trade Agreement and European Civil Society: A Case Study on Networked Advocacy*, 4 J. INFORMATION POL. 205 (2014), https://www.jstor.org/stable/pdf/10.5325/jinfopoli.4.2014.0205.pdf?refreqid=excelsior%3A064c10c698ba3f7a69bc8fe8ddd239fa; *see* Torie Bosch, *European Parliaments Rejection of ACTA Demonstrates the Power of Digital Activism,* SLATE (July 4, 2012), https://slate.com/technology/2012/07/acta-defeat-in-european-parliament-inspired-by-anti-sopa-activism.html.

[120] *See generally* World Health Org.,, *Growing threat from counterfeit medicines*, 88 BULL. WORLD HEALTH ORGAN. 245 (2010) https://www.who.int/bulletin/volumes/88/4/10-020410.pdf?ua=1. For a description of IMPACT and responses of its critics, *see* World Health Org. & Int'l Med. Products Anti-Counterfeiting Taskforce (IMPACT), IMPACT: FREQUENTLY ASKED QUESTIONS WITH ANSWERS (2010), https://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf; WHO & IMPACT, COUNTERFEIT DRUGS KILL!, https://www.gphf.org/images/downloads/impactbrochure.pdf; Sangeaeta Shashikant, *WHO: concerns voiced over IMPACT, Secretariat's role on "counterfeits"*, TWN INFO SERVICE ON WTO & TRADE ISSUES (Feb. 2, 2009) (expressing civil society opposition to IMPACT), https://www.twn.my/title2/wto.info/2009/twninfo20090201.htm; South Centre & Center for Int'l Envtl. Law, *Counterfeit Medical Products: Need for Caution against Co-Opting Public Health Concerns for IP Protection and Enforcement*, INTELL. PROP. QUARTERLY UPDATE (2009) (same), https://www.ciel.org/wp-content/uploads/2015/06/IP_Update_1Q09.pdf. For a response to the critique *see* Sushmi Dey & Khomba Singh, *WHO won't redefine fake drugs*, THE ECONOMIC TIMES (Jan. 27, 2009), https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/who-wont-redefine-fake-drugs/articleshow/4034234.cms?from=mdr.

[121] Allan Maleche & Emma Day, *Right to Health Encompasses Right to Access Essential Generic Medicines: Challenging the 2008 Anti-Counterfeit Act in Kenya*, 16 HEALTH & HUM. RIGHTS J. 96 (2014), https://cdn2.sph.harvard.edu/wp-content/uploads/sites/125/2014/12/Maleche-final1.pdf; Center for Health, Human Rights and Dev. (CEHURD), *Anti-counterfeiting laws and access to essential medicines in East and Southern Africa*, EQUINET POLICY BRIEF NUMBER 22 (2010), http://www.equinetafrica.org/sites/default/files/uploads/documents/POL_Brief22_counterfeits.pdf; Michael Wambi, *Uganda: New Version of Anti-Counterfeiting Bills Still Problematic*, INTER PRESS SERVICE NEWS AGENCY (May 6, 2010), http://www.ipsnews.net/2010/05/uganda-new-version-of-anti-counterfeiting-bill-still-problematic/.

To achieve IP maximalization, the U.S. and E.U. typically deployed an IP-ratchet that escalated IP demands in each successive agreement.[122] Although the ratchet ultimately faltered in the U.S. in 2007 as a result of the New Trade Policy,[123] the temporary retractions or limitations on the most damaging TRIPS-plus demands for developing country trade partners was ultimately reversed in Trans-Pacific Partnership Agreement negotiations[124] and more recently in NAFTA 2.0.[125] In addition to relentlessly pursuing TRIPS-plus trade and enforcement agreements, both the U.S. and Europe issued veiled trade threats against countries that failed to accede to their excessive demands or that used TRIPS-compliant public health flexibilities – in the U.S. via annual Special 301 Reports[126] and in Europe via recent reporting on the protection and enforcement of IP rights in third countries and through the reporting on counterfeiting and piracy.[127] In fact, U.S. Special 301 featured a new demand that countries cut back on their use of price controls, whether in the form of reference pricing or listing and pricing decisions in their

---

[122] Peter Drahos, *The Global Ratchet for Intellectual Property Rights: Why It Fails as Policy and What Should Be Done About It*, 1–2 (2003) (unpublished manuscript), available at: http://www.anu.edu.au/fellows/pdrahos/reports/pdfs/2003globalipratchet.pdf (summarizing that the intellectual property ratchet "means that each subsequent bilateral or multilateral agreement can and usually does e stablish a higher standard of IP protection."); *see* Bryan Mercurio, *TRIPS-Plus Provisions in FTAs: Recent Trends* in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM (Lorand Bartels & Federico Ortino eds., 2006); Susan Sell, *The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, PIJIP RESEARCH PAPER NO. 15 (2010) (applying the IP-ratchet metaphor to the TRIPS-plus enforcement agenda).

[123] I. M. (Mac) Destler, AMERICAN TRADE POLITICS IN 2007: BUILDING BIPARTISAN COMPROMISE, PETERSON INSTITUTE FOR INTERNATIONAL ECONOMICS NO. PB07-5, Appendix B (May 2007), https://piie.com/sites/default/files/publications/pb/pb07-5.pdf. Among other provisions addressing labor and environment, provisions on Patents/IPR and Access to Medicines provided for (1) concurrent period of data exclusivity if the trading partner granted marketing approval within six months of application; (2) permissive rather than mandatory patent term extensions to compensate for any unreasonable delays in the patenting or marketing approval process; (3) elimination of patent-registration linkage requires though parties would be required to provide expeditious procedures for adjudicating patent infringement or validity disputes; and (4) textual affirmation of the Doha Declaration including allowing a public health exception to data exclusivity. Id. at 25-26. These requirements were incorporated in the U.S.-Peru, U.S.-Panama, U.S.-Columbia, and U.S.-Korea free trade agreements, though there were certainly further improvements that could have been made. Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303, 335-341 (2008), https://journals.sagepub.com/doi/pdf/10.1177/009885880803400209.

[124] Sean Flynn et al., *supra* note 115; Brook K. Baker, *Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere*, 13 PLOS MEDICINE e1001970 (2016), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001970; Deborah Gleeson et al., *The Trans Pacific Partnership Agreement, intellectual property and medicines: Differential outcomes for developed and developing countries*, 18 GLOBAL SOCIAL POLICY 7-27 (2017).

[125] Burcu Kilic, NAFTA 2.0 CHAPTER 20 PHARMACEUTICAL-RELATED PATENT PROVISIONS, (2019), https://www.citizen.org/wp-content/uploads/nafta-2.0-pharmaceutical-related-patent-provisions.pdf.

[126] *Special 301*, Office of the United States Trade Representative, https://ustr.gov/issue-areas/intellectual-property/Special-301 (last visited Apr. 24, 2019); for a critique of the legality of US Special 301 practice, *see* Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicine*, 7 J. GENERIC MEDS. 309 (2010).

[127] *See* European Commission, COMMISSION STAFF WORKING DOCUMENT: REPORT ON THE PROTECTION AND ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS IN THIRD COUNTRIES, SWD (2018) 47 final, http://trade.ec.europa.eu/doclib/docs/2018/march/tradoc_156634.pdf; European Commission, Commission Staff Working Document: COUNTERFEIT AND PIRACY WATCH LIST, SWD (2018) 492 final, http://trade.ec.europa.eu/doclib/docs/2018/december/tradoc_157564.pdf.

therapeutic formularies.[128]

Similarly, during this second phase, Big Pharma pursued its TRIPS-plus and anti-TRIPS-flexibilities demands in lawsuits, most notably its infamous challenge to India's decision to deny a patent on a Novartis cancer medicine, Glivec®. Novartis pursued a two-part challenge against India's amended patent law and its decision to deny a secondary patent on the active pharmaceutical ingredient, imtabinib.[129] In the first lawsuit, Novartis tried to invalidate section 3(d) of the Amended India Patent Act of 2005, alleging that it was both unconstitutional and in violation of the TRIPS Agreement because it denied patents on mere variations of known substances unless there was significant new efficacy. This lawsuit was forcefully rejected by the Madras High Court.[130] Thereafter, Novartis appealed the underlying patent decision arguing that its patent application had been improvidently denied and that the exclusion from patentability in section 3(d) should be narrowly interpreted. In a momentous decision, the Supreme Court of India rejected this challenge, upholding a broad, anti-evergreening interpretation of section 3(d) and clarifying that any change in efficacy must have a significant impact on <u>therapeutic</u> efficacy.[131]

Halfway around the world, Big Pharma also filed a lawsuit against Argentina's stringent

---

[128]

> In order to promote affordable healthcare for American patients today and innovation to preserve access to the cutting-edge treatments and cures that they deserve tomorrow, USTR has been engaging with trading partners to ensure that U.S. owners of IP have a full and fair opportunity to use and profit from their IP, including by promoting transparent and fair pricing and reimbursement systems. USTR has sought to ensure robust IP systems; reduce market access barriers to pharmaceutical products and medical devices, including measures that discriminate against U.S. companies, are not adequately transparent, or do not offer sufficient opportunity for meaningful stakeholder engagement; and enable trading partners to appropriately recognize the value of innovative medicines and medical devices so that trading partners contribute their fair share to research and development of new treatments and cures.

2019 SPECIAL 301 REPORT, 12-13 (2019), https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf. "The IP-intensive U.S. pharmaceutical and medical device industries have expressed concerns regarding the policies of several trading partners, including Algeria, Australia, Canada, China, Japan, Korea, New Zealand, and Turkey, on issues related to pharmaceutical innovation and market access." *Id.* at 15. For a more detailed discussion of long-standing U.S. concerns about foreign price controls, see U.S. Dept. of Com. Internal Trade Admin., PHARMACEUTICAL PRICE CONTROL IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION (2004), https://2016.trade.gov/td/health/DrugPricingStudy.pdf.

[129] For an account of the Novartis lawsuits by the activist lawyer who tried them, *see* Anand Grover, *Analysing the Novartis Story*, XLVIII LAWYERS' COLLECTIVE NEWSL. No. 32 (Aug. 10, 2013), https://www.lawyerscollective.org/updates/analysing-the-novartis-story.

[130] *Novartis AG v. Union of India*, (2007) AIR 24759 (Madras H.C.); Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 299-302 (2008).

[131] For scholarly accounts with positive views of the case, *see* Ravinder Gabble & Jillian Calre Kohler, *"To patent or not to patent? the case of Novartis' cancer drug Glivec in India"*, 10 GLOBALIZATION & HEALTH (2014), https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/1744-8603-10-3; Saby Ghoshray, *3(d) View of India's Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others*, 13 J. MARSHALL REV. INTELL. PROP. L. 719 (2014); for a more negative view, *see* Dorothy Du, *Novartis AG v. Union of India: "Evergreening," TRIPS, and "Enhanced Efficacy" Under Section 3(d)*, 21 J. INTELL. PROP. L. 223 (2014).

pharmaceutical patent examination guidelines,[132] a suit that has a chilling effect on countries' willingness to closely examine and reject pharmaceutical patents.[133] More quietly, pharma companies have filed multiple other court challenges to patenting, regulatory, and pricing decisions by LMICs. Alarmingly, Pharma has recently resorted to pursuing IP-related claims through investor-state-dispute-settlement (ISDS) mechanisms whereby private arbitrators are appointed to consider whether government decisions and policies have unfairly or discriminatorily treated the investment-return interests of companies' intent on maximizing profits from their IP monopolies on medicines. The most notorious case is *Eli Lilly v. Canada*, where Eli Lilly unsuccessfully challenged court decisions invalidating patents on two of their medicines.[134] Unfortunately, ISDS claims were apparently more successful in chilling and reversing adverse decisions in Ukraine and Colombia, where governments backed down in their efforts to allow generic competition on overpriced medicines.[135]

It was in the aftermath of the MPP's first innovator license with Gilead that serious fractures began to develop in the A2M movement. "Initial reactions to MPP licenses with innovator companies, starting with Gilead, were mixed, some largely positive, but others quite negative, including a proposal that the Gilead license be revoked and that the MPP and its sponsor UNITAID impose a moratorium on new licenses until improvements in key licensing terms were guaranteed."[136] Activists in countries excluded from MPP licenses and strong proponents of opposition procedures thought that voluntary licensing gave too much power to Pharma companies to dictate covered territories and key licensing terms. They worried as well that reliance on voluntary licenses would coopt generic companies (with some cause[137]), weaken resolve in LMICs to use their full panoply of

---

[132] "Pautas para el examen de Patentabilidad de las solicitudes de Patentes sobre Invenciones Químico-Farmacéuticas", enacted by a joint regulation of the Ministries of Industry and Health and the Instituto Nacional de la Propiedad Industrial (the Argentine Patent Office), Nos. 118/2012, 546/2012 and 107/2012, issued on May 2, 2012. The official text (in Spanish) can be found at http://www.wipo.int/wipolex/en/details.jsp?id=13007. For an English translation, see *Argentina adopts guidelines to examine patent applications for pharmaceuticals*, DON'T TRADE AWAY OUR LIVES (May 31, 2012), https://donttradeourlivesaway.wordpress.com/2012/05/31/argentina-adopts-guidelines-to-examine-patent-applications-for-pharmaceuticals/.

[133] *Argentina civil society launch campaign "Big Pharma drop the case!"*, MAKE MEDICINES AFFORDABLE (July 11, 2016), http://makemedicinesaffordable.org/en/argentina-civil-society-launch-campaign-big-pharma-drop-the-case.

[134] Brook K. Baker & Katrina Geddes, *The Incredible Shrinking Victory:* Eli Lilly v. Canada, *Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS*, 49 LOY. CHI. L.J. 479 (2017).

[135] *Id.* at 508-512.

[136] Following these critiques and further negotiations, the Gilead-MPP license has been amended multiple times but that does not mean that controversy about the role of voluntary licenses has died down. Baker, *supra* note 88, at 248-51.

[137] The Indian generics industry has been quite frank that accepting VLs with commercial potential may in many instances be superior to pursuing what may be costly and time-delayed opposition strategies. *See* Patralekha Chatterjee, *Gilead Sovaldi Case Reveals Patent-Health Fissures in India*, INTELL. PROP. WATCH (Mar. 3, 2016), http://www.ip-watch.org/2016/03/09/gilead-solvaldi-case-reveals-patent-health-fissures-in-india, (reporting D.G. Shah of the Indian Pharmaceutical Alliance as saying: "We support provision for CL [compulsory license] to pre-empt abuse of monopoly. However, the CL route is full of thorns and uncertainties. VL [voluntary licensing] offered the same outcome without pain. We see in it a better solution than confrontation with Big Pharma;" . . . "We want the VL route to be adopted by more and more companies to provide access and create competition. It is the most effective way of reducing medicines prices. Hence, when the objective of access and affordability were addressed by VL, we had no reason to oppose.").

TRIPS flexibilities, and sooth pressure in LMICs to enact more transformative IP reform or to issue compulsory licenses more systematically. Critics were worried about the timing of MPP licenses, and disturbed as well that VL strategies were much better and more securely funded than oppositions and that there was almost no support for compulsory licensing activities. Proponents of MPP voluntary licenses, on the other hand, saw voluntary licenses as complementary to other access-to-medicines strategies and that such licenses had the added advantage of securing wholesale access for nearly 90% of people living with HIV in LMICs without the delays and uncertainties of patchwork, country-by-country oppositions and compulsory licenses.[138] Having access in a hundred-plus countries certainly decreased the burden of pursing opposition and compulsory licensing strategies in potentially hostile forums.

Nonetheless, the ultimate impact of voluntary licensing in terms of affordable access is country-specific and closely linked to whether a given country is included within the direct or indirect territory coverage of the relevant MPP license. Current MPP licenses routinely exclude commercially attractive middle-income countries, always China and Brazil and usually other so-called pharmerging markets.[139] In these circumstances, the suspicions of A2M activists in excluded countries were certainly understandable, but the antipathy for and even name-calling that occurred was regrettable. At a time when even greater unity was needed, as the lockjaw of TRIPS compliance tightened, a fractured A2M movement was the last thing needed.

Third Phase: Expansion – disease focus, delinkage, transparency, and global forums; and contraction - domestic campaigns in rich countries.

The third phase of CS access-to-medicines activism has been a strange mixture of expansion and contraction. On the expansion side, there has been a step-increase in A2M campaigns beyond HIV to other disease areas; a more intense focus on alternative incentives for better targeted pharmaceutical R&D; new demands for transparency on drug pricing, R&D expenditures, public financing and subsidies, and clinical trials; and a turn to new global forums including the broader UN system to agitate for IP reform. On the contraction side, the attention of many Northern activists has turned inward to challenge the impacts of crushing drug prices in high income countries. Although these new A2M campaigns have all been vigorous and headline grabbing, there are also concerns that attention has turned from bread-and-butter access concerns in LMICs.

---

[138] For a more detailed discussion of the pro and con arguments of A2M members about voluntary licenses and their potential complementarity or conflict with alternative strategies and priorities, *see* Baker, *supra* note 88 at 308-15.

[139] Twenty-two countries are considered "pharmerging" based on market size and prospects. Murray Aitken, Michael Kleinrock & Deanna Nass, *Outlook for Global Medicines through 2021: Balancing Cost and Value*, QUINTILESIMS INST., 44–49 (2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-outlook-for-medicines-through-2021.pdf?la=en&hash= 6EA26BACA0F1D81EA93A 74C50FF60214044C1DAB&_=1517325781735. China is alone is in Tier One class given its population size, growing wealth, and increased use of Western medicines. Brazil, Russia, and India are Tier Two countries, while Turkey, Mexico, Poland, Saudi Arabia, Argentina, Indonesia, Egypt, Pakistan, Vietnam, Columbia, Philippines, Algeria, South Africa, Bangladesh, Romania, Chile, Nigeria, and Kazakhstan are classified as Tier Three countries. Since 2011, global expansion in the volume of medicine usage has been driven by pharmerging markets. The pharmaceutical market growth rate in pharmerging countries is projected to be higher than in rich economies: 6-9% vs. 4-7%, respectively. *Id.* at 9.

The disease focus of A2M campaigns has expanded significantly beyond its roots in HIV. This was true to some degree even in Phase One and Two A2M campaigns, but more recently much greater attention has focused on hepatitis C (HCV) direct acting antivirals (DAAs), cancer medicines, insulin, and tuberculosis. The expanded disease focus getting the most attention has been HCV. When Gilead gained FDA marketing approval in 2014 for sofosbuvir, a backbone DAA that cured over 90% of all major genotypes, and as AbbVie, Merck, and other competitors were racing to the finishing line to bring their DAAs to market, there was a boom in A2M advocacy to get the combo treatment that could cure the 71 million people globally living with HCV. Although compared with older therapies, the new DAAs were more effective, easier to tolerate, and required a significantly shorter duration of treatment, the new therapies were priced in the stratosphere with sofosbuvir, for example, costing $1000 a pill for a twelve-week course of treatment ($84,000). Gilead partially addressed access concerns in LMICs with a voluntary license ultimately covering 105 countries, but a significant percentage of people in MICs were still excluded from coverage and the license had multiple other troubling provisions.[140] As a result of the A2M movement, governments have deployed a multitude of A2M strategies[141] such as ITPC and partners mobilizing to oppose Gilead patents in multiple countries[142] and activists successfully fighting for the issuance of a compulsory license on sofosbuvir in Malaysia.[143]

But global A2M advocacy moved far beyond HIV and HCV. The Fix the Patent Laws Campaign in South Africa really took off when it recruited patient organizations dealing with non-communicable diseases, diabetes, epilepsy, mental health, and especially cancer, that have emerged as a major force in the coalition. Global activism on affordable drug prices and equitable access has increased significantly for insulin[144] and even more so for cancer. Early efforts to access Novartis cancer medicine, imatinib, and other cancer medicines through opposition procedures and compulsory licenses have had modest

---

[140] Brook K. Baker, *Gilead's Hepatitis C Medicines License – Troubling Territorial Exclusions, Illusory Exceptions, and Tiered Pricing Policy Fracture Global Access*, INFOJUSTICE (Sept. 17, 2014), http://infojustice.org/wp-content/uploads/2014/09/brookbaker09172014.pdf; Tahir Amin, *The dirty motivation behind Gilead's hepatitis C agreement*, ALJAZEERA AMERICA (Nov. 21, 2014), http://america.aljazeera.com/opinions/2014/11/pharmaceuticals-gileadhepc.html.

[141] Caitlin H. Douglass et al., *Pathways to ensure universal and affordable access to hepatitis C treatment*, 16 BMC MED. 175 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6176525/pdf/12916_2018_Article_1162.pdf.

[142] Catherine Saez, *Collective Efforts by Civil Society Groups Bar the Way to Hepatitis C Patents*, INTELL. PROP. WATCH (Oct. 5, 2018), https://www.ip-watch.org/2018/05/10/collective-efforts-civil-society-groups-bar-way-hepatitis-c-patents/; *see Sofosbuvir*, PATENT OPPOSITION DATABASE, https://www.patentoppositions.org/en/drugs/sofosbuvir (last visited June 13, 2019); *Sofosbuvir/Velpatasvir*, PAT. OPPOSITION DATABASE, https://www.patentoppositions.org/en/drugs/sofosbuvir-slash-velpatasvir (last visited June 13, 2019).

[143] Fifa Rahman, *Inside Views: Malaysia Inclusion in Gilead Voluntary Licence – A Product of Compulsory Licence Pressure*, INTELL. PROP. WATCH (Aug. 24, 2017), https://www.ip-watch.org/2017/08/24/malaysia-inclusion-gilead-voluntary-licence-product-compulsory-licence-pressure/.

[144] Health Action International, *Access to Insulin*, https://haiweb.org/projects/acciss-study/ (last visited Feb. 7, 2019); *High insulin costs are killing Americans*, RIGHT CARE ALLIANCE, https://rightcarealliance.org/actions/insulin/ (last visited June 12, 2019).

success.[145] More recently, cancer price advocacy has expanded greatly making it center stage at the WHO.[146]

A2M advocacy has also expanded to address the medical innovation system not just access. Addressing existing medical R&D incentives systems and overreliance on patent and data exclusivities, a growing number of activists focused on the concept of delinkage[147] – a radical proposal to eliminate reliance on patents as the principal golden-goose incentive/reward system for pharmaceutical inventions. Instead they propose a delinked system with a first link for setting research priorities and sharing R&D costs,[148] supporting open and collaborative research,[149] and using a mix of push mechanisms, most commonly research grants,[150] subsidies,[151] and pull mechanism, most commonly prizes,[152] to incentivize innovation.[153] Thereafter the second link would be used to produce and market much more affordable generic medicines without monopoly prices.

> For more than a decade, the World Health Organization has been considering a new treaty or other agreement on the funding of biomedical R&D, based upon the principle of delinkage of R&D costs from product prices. More recently, there has been considerable mobilization for global cooperation on the development

---

[145] Cinthia Leite Frizzera, Borges Bognar, Brittany L. Bychkovsky & Gilberto de Lima Lopes Jr., *Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?*, 2 J. GLOBAL ONCOLOGY 292 (2016), https://ascopubs.org/doi/pdfdirect/10.1200/JGO.2016.005363.

[146] WHO, *Access To Medicines, Vaccines and Pharmaceuticals*, TECHNICAL REPORT: PRICING OF CANCER MEDICINES AND ITS IMPACTS (2018), https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1.

[147] *See Mechanics of Delinkage*, DELINKAGE.ORG, https://delinkage.org/mechanics/ (last visited June 10, 2019); James Love, AN ECONOMIC PERSPECTIVE ON DELINKING THE COST OF R&D FROM THE PRICE OF MEDICINES (2016), http://www.unitaid.org/assets/Delinkage_Economic_Perspective_Feb2016.pdf.

[148] The process for establishing R&D priorities and mechanisms for sharing costs of prioritized R&D are complicated indeed. With respect to prioritization, the WHO has already established a Global Observatory on Health Research and Development, which is trying to keep track of the global epidemiology of disease and gaps and opportunities in medical preventatives and therapies. WHO, Global Observatory on Health R&D, https://www.who.int/research-observatory/en/ (last visited June 10, 2019). *See* Marie Paule Kieny, Roderick F Viergever, Taghreed Adam, Ties Boerma & John-Arne Røttingen, *Global platform to inform investments for health R*&D, 387 LANCET 1157 (2016), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)00705-4.pdf. With respect to creating a mechanism for sharing R&D costs globally, one of the most promising mechanisms has been the call for an R&D treaty. For an early discussions of an R&D Treaty*, see* Nicoletta Dentico & Nathan Ford*, The Courage to Change the Rules: A Proposal for an Essential Health R&D Treaty,* 2 PLOS MED. 96 (2005), https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.0020014&type=printable*;* Suerie Moon, Jorge Bermudez & Ellen 't Hoen, *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?,* 9 PLOS MED. e1001218 (2012), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001218.2011).

[149] Delphine Gallaud, *Collaborative Innovation and Open Innovation*, ENCYCLOPEDIA OF CREATIVITY, INVENTION, INNOVATION AND ENTREPRENEURSHIP, 239-240 (Elias G. Carayannis ed., 2013).

[150] *Direct Funding of R&D by Government*, DELINKAGE.ORG, https://delinkage.org/mechanics/direct-funding/.

[151] *Subsidies*, DELINKAGE.ORG, https://delinkage.org/mechanics/subsidies/ (last visited June 10, 2019).

[152] James Love & Tim Hubbard, *Prizes for Innovations of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155 (2009), https://lawecommons.luc.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1111&context=annals; Kevin Outterson et al., *Delinking Investment in Antibiotic Research and Development from Sales Revenues: The Challenges of Transforming a Promising Idea into Reality*, 13 PLOS MED. e1002043 (2016), https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1002043&type=printable.

[153] *Incentives*, DELINKAGE.ORG, https://delinkage.org/mechanics/incentives/ (last visited June 10, 2019).

> of new antibiotic drugs, also embracing to some extent the principle of delinkage. Health groups, such as KEI, Médecins Sans Frontières (MSF), Oxfam, Health Action International (HAI) and the Treatment Access Campaign (TAC), to mention a few, have proposed addressing the need for additional public sector R&D funding in a variety of international agreements as an alternative to provisions in trade agreements that are designed to expand patent rights and raise drug prices, and also to address a variety of critical health innovation needs, including such public health challenges as Ebola, Zika, or Avian flu.[154]

The cost savings of a delinkage system are projected to be prodigious – at least $92 billion a year in the U.S. under Senator Sanders' 2017 Medical Innovation Prize Fund bill, much greater savings projected on a global scale.[155] The delinkage movement has a large number of individual, governmental, and institutional endorsers.[156]

A further expansion of A2M advocacy in the third phase of the movement is increased advocacy for transparency across the entire spectrum of pharmaceutical R&D, pricing, and related information. Transparency activists have advocated, successfully in part, for web-based access to clinical trial data so that researchers, clinicians, and patients can reexamine evidence on the safety and efficacy of medical products.[157] Although after protracted advocacy several such requirements and disclosure commitments are on the book,[158] implementation and enforcement have been relatively weak thus far.[159] More recently, transparency advocates have pressed for more granular information on the costs of drug development, especially clinical trials, and the various direct and indirect subsidies paid for with public and charitable resources, including tax subsidies. They have also argued for more transparency about drug pricing with special attention to manufacturers' drug pricing decisions, via-a-vis costs of manufacturing, marketing and net profits.[160] The high-water mark of this campaign thus far was the 2019 World Health Assembly, which passed a transparency resolution, first proposed by Italy that was strong on disclosure of drug prices but unfortunately watered down on disclosure of R&D

---

[154] *Direct Funding of R&D by Government*, *supra* 150 note 8.

[155] *Savings*, DELINKAGE.ORG, https://delinkage.org/savings/ (last visited June 10, 2019).

[156] *Endorsements*, DELINKAGE.ORG, https://delinkage.org/endorsements/ (last visited June 10, 2019).

[157] *The story of AllTrials*, ALLTRIALS, http://www.alltrials.net/news/the-story-of-the-campaign-thats-changing-the-world/ (last visited June 13, 2019).

[158] WHO, JOINT STATEMENT ON PUBLIC DISCLOSURE OF RESULTS FROM CLINICAL TRIALS, https://www.who.int/ictrp/results/ICTRP_JointStatement_2017.pdf?ua=1; Nicolas J. DeVito, Lisa French & Ben Goldacre, *Research Letter: Noncommercial Funders' Policies on Trial Registration, Access to Summary Results, and Individual Patient Data Availability*, 319 JAMA 1721 (2018).

[159] U.K. House of Commons Science and Technology Committee, *Research in integrity: Clinical Trials Transparency*, https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1480/1480.pdf; Lynn Eaton, *Clinical trials in Europe: less than a fifth report within 12 months*, 365 BRIT. MED. J. 1963 (2019); *see Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for Food and Drug Administration Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to the Food and Drug Administration; Availability*, 83 Fed. Reg. 47926 (September 21, 2018); *Who's sharing their clinical trial results?*, FDAAA TRIALS TRACKER (showing only 66.5% of trials are reported and that US government could have imposed fines over $3.4 million), https://fdaaa.trialstracker.net (last visited June 13, 2019).

[160] For a detailed listing and summary of key transparency efforts and publications, *see* KEI, *Background note on Transparency Norms* (February 11, 2019), https://www.keionline.org/wp-content/uploads/Background-Transparency-15Feb2019.pdf.

costs.[161] Civil society, led by KEI played a vigorous role in advocating for the strengthening and adoption of the resolution to the displeasure of several rich country delegations.[162]

The last expansion feature of this third phase of the A2M activism draws on the work of the earlier global institutional work of the Commission on Macroeconomics and Health, the UK Commission on Intellectual Property Rights, and the WHO Commission on Intellectual Property Rights, Innovation, and Public Health. Activists have increasingly turned to international platforms to advance A2M goals, including the Global Commission on HIV and the Law, the UN Secretary General's High Level Panel on Access to Health Technologies, and the Lancet Commission on Essential Medicines. The Global Commission on HIV and the Law produced a major report, a significant proportion of which focused on abuse of IP rights going so far as to call for a moratorium on the enforcement of pharmaceutical patent rights, a cessation of all TRIPS-plus demands, and accelerated adoption and use of TRIPS public health flexibilities.[163] The Report of the United Nations Secretary General's High-Level Panel on Access to Medicines (2016) took up the challenge to deeply interrogate defects in the current intellectual property regime and its negative impacts on both innovation and access, calling for new incentives for R&D, greater transparency, and increased use of TRIPS flexibilities.[164] Civil society produced the vast majority of submissions to the High-Level Panel. The Lancet Commission on Essential Medicines Policies relatedly highlighted five areas of work: paying for a basket of essential medicines, making them affordable, assuring their quality and safety, promoting quality use of medicines, and developing missing essential medicines.[165]

The contraction aspect of the third phase of the A2M movement has been an inward focus in high-income countries where escalation of prices on older on-patent medicines and truly exorbitant prices on newer medicines threatened to bankrupt even the richest payor systems and to leave many poorly insured or uninsured people bereft of access to life-saving and life-enhancing medicines. Although there had been growing concern about

---

[161] WHO, *Improving the transparency of markets for medicines, vaccines, and other health products*, A72/A/CONF./2 Rev.1 (May 28, 2019), http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf; *see* Priti Patnaik, *WHO transparency resolutions seeks to dispel opacity around drug prices and sheds light on international policy*, INT'L HEALTH POLICY NEWS (May 31, 2019), https://www.internationalhealthpolicies.org/who-transparency-resolution-seeks-to-dispel-opacity-around-drug-prices-and-sheds-light-on-international-policy-making/; Elaine Ruth Fletcher, *World Health Assembly Approves Milestone Resolution on Price Transparency*, HEALTH POLICY WATCH (May 29, 2019), https://www.healthpolicy-watch.org/world-health-assembly-approves-milestone-resolution-on-price-transparency/.

[162] Elaine Ruth Fletcher, *WHO's EB Considers New Ways to Work with NGOS – Some Countries Criticise Activists' Roles at WHA 72*, HEALTH POLICY WATCH (May 30, 2019), https://www.healthpolicy-watch.org/whos-eb-considers-new-ways-to-work-with-ngos-some-countries-criticise-activists-role-at-wha72/; *see* James Love, *KEI Statement on Adoption of the WHA72 Transparency Resolution*, KNOWLEDGE ECOLOGY INT'L (May 28, 2019), https://www.keionline.org/30887.

[163] UNDP, GLOBAL COMMISSION ON HIV AND THE LAW: RISKS, RIGHTS AND HEALTH, Ch. 6 (2012), https://hivlawcommission.org/wp-content/uploads/2017/06/FinalReport-RisksRightsHealth-EN.pdf.

[164] PROMOTING INNOVATION AND ACCESS TO MEDICINES (2016), https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

[165] Veronika J. Wirtz et als., *Essential medicines for universal health coverage*, 389 THE LANCET 403 (2017), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(16)31599-9.pdf.

escalating drug prices in upper-income countries for many years, near hysteria occurred when Gilead charged $1000 a pill for its new medicines sofosbuvir, which was the first-to-market direct acting antiviral that actually cured hepatitis C infections in over 90% of patients.[166] Not only was there widespread outrage among A2M activists, but even the U.S. Congress undertook investigations of Gilead's pricing practices.[167] Although Gilead's CEO ultimately expressed some remorse over sofosbuvir's pricing,[168] Gilead has laughed all the way to the bank, earning a projected $47 billion on sales of its HCV medicines by the end of 2018.[169]

Largely as an outgrowth of the Gilead pricing scandal, there are now major campaigns in the United States led by Public Citizen,[170] Families USA,[171] Coalition for Fair Drug Prices,[172] Social Security Works,[173] #BreakthePatent/PrEP$_4$All Collaboration,[174] #insulin4all and

[166] Richard Knox, *$1000 Pill for Hepatitis C Spurs Debate Over Drug Prices*, NAT'L PUBLIC RADIO (December 30, 2013), https://www.npr.org/sections/health-shots/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices.

[167] United States Senate Committee on Finance, *Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug* (December 1, 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.

[168] John LaMattina, *Gilead's CEO Admits To 'Failures' In Setting Price of $1000-A-Pill Breakthrough*, FORBES, (Dec. 8, 2016), https://www.forbes.com/sites/johnlamattina/2016/12/08/gileads-ceo-apologetic-about-sovaldis-1000-per-pill-price-tag/#707a4b791a97.

[169] Ned Pagliarulo, *Brief: Gilead forecasts steep slide in 2018 hepatitis C revenues*, BIOPHARMA DIVE (Feb. 6, 2018), https://www.biopharmadive.com/news/gilead-hepatitis-c-revenues-slide-fourth-quarter-earnings/516494/.

[170] *See* Public Citizens, *Access to Medicines Archives*, https://www.citizen.org/article/access-to-medicine-archives/ (last visited June 11, 2019) (listing multiple domestic drug pricing issues Public Citizens is engaged with).

[171] Families USA, *Prescription Drug Costs*, https://familiesusa.org/initiatives/prescription-drug-costs (last visited June 11, 2019).

[172] Families USA, *Coalition for Fair Drug Prices* (listing 12 coalition members), https://familiesusa.org/initiatives/coalition-fair-drug-prices (last visited June 11, 2019).

[173] Social Security Works, *NEW POLL: Swing District Voters Want Aggressive Action On Drug Pricing*, https://socialsecurityworks.org/2019/05/01/swing-district-big-pharma-poll/ (last visited June 11, 2019).

[174] Christopher Rowland, *An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But a Pharma Giant is Making Billions*, WASHI. POST, https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html?utm_term=.7dfb2ac8dd00.

Right Care Alliance,[175] Campaign for Sustainable Rx Pricing,[176] KEI ,[177] Treatment Action Group,[178] Fair Pricing Coalition,[179] AARP,[180] and many others seeking to lower drug prices and prevent abuses of patent monopolies for cancer drugs, insulin, HIV pre-exposure prophylaxis, gene therapies, and a host of other medical conditions. As a consequence, there are multiple bills in Congress and state legislatures purporting to address the U.S.'s drug pricing crisis with solutions ranging from stopping pay-for-delay deals, transparency about drug prices in advertisements and more broadly, parallel importation from Canada, Medicare price negotiation, reference pricing, compulsory and government-use licenses, government pharmaceutical manufacturing, and many more.[181]

Civil society activism and government initiatives against high drug prices are not limited to the U.S. – there are emerging campaigns and reform proposals in the U.K., the Netherlands, and Australia among others. In the U.K. a new organization, Just Treatment, is organizing campaigns to lower drug prices and to convince the U.K. government to issue government use licenses on over-priced medicines.[182] Its current campaigns include

---

[175] *The 3insulin4all campaign unites the diabetes community to fight together for access to diabetes supplies, care, and treatment for everyone*, T1INTERNATIONAl, https://www.t1international.com/insulin4all/ (last visited June 12, 2019); Allison Hagan, *Protesters at Sanofi in Cambridge decry high price of insulin*, BOSTON GLOBE (Nov. 16, 2018), https://www.bostonglobe.com/business/2018/11/16/protesters-sanofi-cambridge-decry-high-price-insulin/MeEajamQHARWqDTQKXqPVL/story.html; *see* Mike Hoskins, *Insulin Affordability Action: All Across the USA and Growing Stronge*r, HEALTHLINE (Apr. 4, 2018), https://www.healthline.com/diabetesmine/grassroots-insulin-affordability-advocacy-across-usa#1. Even more mainstream diabetes organizations are calling for decreased prices for insulin. Aaron J. Kowalski, *Congress, take action to make insulin affordable*, THE HILL, https://thehill.com/opinion/healthcare/437219-congress-take-action-now-to-make-insulin-affordable; Stand Up for Affordable Insulin, AMERICAN DIABETES ASSOCIATION, https://makeinsulinaffordable.org (last visited June 13, 2019).

[176] *The Campaign for Sustainable Rx Pricing*, https://www.csrxp.org (last visited June 11, 2019) (listing more mainstream and institutional partners).

[177] KEI, *Government Funded Inventions*, https://www.keionline.org/government-funded-inventions (last visited June 11, 2019) (showing a special interest in exercising U.S. government rights with respect to federally funded biomedical R&D).

[178] *See* Tim Horn, *Fair Pricing: Reclaiming Drugs for the Common Good,* 23 $TAGELINE (2016) (devoting solely to the issue of fair pricing), http://www.treatmentactiongroup.org/sites/default/files/201604/tagline%202016%20April%20web%20final.pdf; Treatment Action Group**,** *TAG Submitted Testimony to the House Committee on Oversight and Reform Hearing on "HIV Prevention Drug: Billions in Corporate Profits After Millions in Taxpayer Investments"* (May 16, 2019), http://www.treatmentactiongroup.org/content/submitted-testimony-congressional-hearing-hiv-prevention-drug-corp-billions-PrEP.

[179] Fair Pricing Coalition, *Mission*, https://fairpricingcoalition.org/mission/ (last visited June 11, 2019).

[180] Dena Bunis, *AARP Launches Campaign to Lower Prescription Prices*, AARP POLITICS & SOC. ADVOCACY (March 12, 2019), https://www.aarp.org/politics-society/advocacy/info-2019/prescription-drug-cost-survey.html.

[181] *See e.g.*, Thomas Sullivan, *Aggressive Drug Pricing Proposals Introduced in Congress*, POLICY & MEDICINE, (Jan. 28, 2019), https://www.policymed.com/2019/02/aggressive-drug-pricing-proposals-introduced-in-congress.html; Shefali Luthra, *Drug-Pricing Policies Find New Momentum As 'A 2020 Thing'*, KAISER HEALTH NEWS (January 25, 2019), https://khn.org/news/drug-pricing-policies-find-new-momentum-as-a-2020-thing/; Claire McAndrew, *Report: 2018 State Legislation on High and Rising Drug Prices*, FAMILIES USA (Aug. 2018), https://familiesusa.org/product/2018-state-legislation-high-and-rising-drug-prices; National Academy for State Health Policy, State Legislative Action to Lower Pharmaceutical Costs, https://nashp.org/rx-legislative-tracker-2019/ (last visited June 11, 2019).

[182] Just Treatment, *Just Treatment is a New Campaign Demanding That Fair Access to Medicines Comes Before Drug Company Profits*, *JUST* TREATMENT, https://justtreatment.org/about (last visited June 12, 2019).

advocacy against Vertex Pharmaceuticals concerning access to a cystic fibrosis drug,[183] against Roche to gain access to a breast cancer medicine, pertuzumab,[184] and against HCV medicines patent holders for affordable access.[185] In the Netherlands, a new organization, the Pharmaceutical Accountability Foundation, is also challenging unconscionable inflation of drug prices.[186] Under relentless pressure from high drug prices, the Dutch government has strengthened its control measures,[187] moved to allow pharmacy preparation of medicines,[188] and is even considering resort to compulsory licensing as a broader access strategy.[189] A Swiss NGO, Public Eye, has likewise asked the government of Switzerland to issue a compulsory license on Roche's cancer drug, pertuzumab.[190] Indeed, because of regionwide concerns about drug prices, the European Council has committed to undertaking a comprehensive review of incentive mechanisms in the pharmaceutic sector.[191] Similarly, although drug prices are nothing to brag about

---

[183] *Plan B on orkambi*, *JUST* TREATMENT, https://act.justtreatment.org/planb/ (last visited June 12, 2019); *see* Helping to Gain Access to Cystic Fibrosis Medicines for All, CYSTIC FIBROSIS BUYERS CLUB, https://www.cfbuyersclub.org/ (last visited June 12, 2019); Ellen 't Hoen, *Cystic Fibrosis Buyers Club Shows the UK Government The Way*, MEDICINES LAW & POLICY, https://medicineslawandpolicy.org/2019/06/cystic-fibrosis-buyers-club-shows-the-uk-government-the-way/.

[184] *Secure a Fair Price for the Life-Saving Pertuzumab Drug*, JUST TREATMENT, https://justtreatment.org/dunise (last visited June 12, 2019). There was also a successful campaign against Pfizer to drop the price on another breast cancer medicine, palbociclib; *Emma + Palcociclib*, *JUST* TREATMENT, https://justtreatment.org/emma-2 (last visited June 12, 2019).

[185] *Hepatitis C: Too Long to Wait*, *JUST* TREATMENT, https://justtreatment.org/hep-c (last visited June 12, 2019).

[186] Ellen 't Hoen, *New Dutch Foundation to Address High Medicines Pricing Announces Plan to File complaint with Competition Authority*, MEDICINES LAW & POLICY (Aug. 25, 2019), https://medicineslawandpolicy.org/2018/08/new-dutch-foundation-to-address-high-medicines-pricing-announces-plan-to-file-complaint-with-competition-authority/; Ed Silverman, *From $360 a year to $179,000: Drug price hike in Netherlands prompts call for investigation*, STAT+ PHARMALOT (Aug. 27, 2018), https://www.statnews.com/pharmalot/2018/08/27/drug-prices-netherlands-investigation/.

[187] Ellen 't Hoen, *Medicines Excitement in the Netherlands – New Health Minister announces firm action on "absurd" medicines pricing and gets the European Medicines Agency*, MEDICINES LAW & POLICY (Nov. 24, 2017), https://medicineslawandpolicy.org/2017/11/medicines-excitement-in-the-netherlands-new-health-minister-announces-firm-action-on-absurd-medicines-pricing-and-gets-the-european-medicines-agency/; Health Action International, *Report: New and Affordable Medicines in the Netherlands – Tracing the Dutch Government's Policy Commitments and Actions* (2018), http://haiweb.org/wp-content/uploads/2018/12/NL-Government-Commitments-on-New-Affordable-Medicines.pdf; Ed Silverman, *Pharma lashes out at the Netherlands over drug pricing policies*, STAT+ PHARMALOT, https://www.statnews.com/pharmalot/2019/02/06/netherlands-novartis-vertex-drug-prices/.

[188] Ellen 't Hoen, *Faced with unreasonable medicines prices, the Netherlands introduces pharmacy exemption in patent law*, MEDICINES LAW & POLICY (Feb. 22, 2019), https://medicineslawandpolicy.org/2019/02/faced-with-unreasonable-medicines-prices-the-netherlands-introduces-pharmacy-exemption-in-patent-law/.

[189] *Compulsory licencing proposed in Netherlands to enforce lower prices for medicines*, KLUWER PATENT BLOG (November 20, 2019), http://patentblog.kluweriplaw.com/2017/11/20/compulsory-licencing-proposed-netherlands-enforce-lower-prices-medicines/. For a detailed report on these proposals, *see* Council for Public Health & Society, DEVELOPMENT OF NEW MEDICINES: BETTER, FASTER, CHEAPER (2017), https://pink.pharmaintelligence.informa.com/PS122055/%22/-/media/supporting-documents/pink-sheet/2017/11/dutch-rvs-report.pdf%22.

[190] Public Eye Letter to Chancellor Alain Berset (January 30, 2019), https://www.publiceye.ch/fileadmin/doc/Medikamente/PublicEye_CL-Request-Perjeta_CH_2019.pdf.

[191] *Press Release: Council conclusions on strengthening the balance in the pharmaceutical systems in EU and its Member States*, EUROPEAN COUNCIL (June 17, 2016), https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/.

in Australia, it has recently used a Netflix model to procure affordable HCV medicines.[192] The government of Japan is instituting more vigorous cost containment measures[193] as is Canada.[194]

This third phase has created new conflicts and fissures in the global A2M movement, mainly because of a decrease in attention to affordable and equitable access to existing medicines in LMICs. Activists who have historically focused pragmatically on accelerating access to existing health technologies for people in desperate need in LMICs have hoped that a continuing focus on LMIC access would produce new inroads for the adoption, protection, and use of TRIPS-compliant health flexibilities that would expand access to medicines for all diseases in a broader range of countries. Delinkage advocates have counterargued that one can't win large scale battles for access without devising new incentive systems with ample resources for properly targeted R&D. Concurrently, domestic drug pricing advocates argue that reform to global IP structures and trade policies cannot occur unless people in rich countries, whose governments support IP maximalization, realize the harm that IP maximalization has on their own health. They argue that access to the newest breakthrough therapies is being rationed even in the US and Europe, where a crisis in affordability threatens government, institutional, and individual payers. If excessive pricing reform is achieved through IP flexibilities, price controls, competition policy, and other reforms in rich countries, their hope is that citizens in those countries might eventually express more solidarity for people living with inadequate access to affordable medicines in LMICs.

Nonetheless, at a time when new treatments for multidrug resistant tuberculosis, bedaquiline and delamanid, are still unavailable because of patent monopolies in key developing countries and a lack of generic alternatives,[195] when people in low-, middle-, and even high-income countries are dying from lack of access to new HCV direct acting antivirals and achievable elimination strategies are disastrously off-course,[196] and when people in poorer countries are routinely priced out of access to new cancer medicines and more broadly to newer medicines treating chronic non-infectious diseases, the inward

---

[192] Tina Rosenberg, *Treat Medicines Like Netflix Treats Shows*, NEW YORK TIMES (March 5, 2019), https://www.nytimes.com/2019/03/05/opinion/can-netflix-show-americans-how-to-cut-the-cost-of-drugs.html; Suerie Moon & Elise Erickson*, Universal Medicines Access through Lump Sum Remuneration – Australia's Approach to Hepatitis C*, 380 NEW ENGL. J. MED. 607 (2019), https://www.nejm.org/doi/pdf/10.1056/NEJMp1813728?articleTools=true.

[193] Takasi Umekawa, *As medical costs mount, Japan to weigh cost-effectiveness in setting drug prices*, REUTERS (Feb. 18, 2019), https://www.reuters.com/article/us-japan-drugs/as-medical-costs-mount-japan-to-weigh-cost-effectiveness-in-setting-drug-prices-idUSKCN1Q71ZG.

[194] Brittany Humphries & Feng Xie, *Canada's Amendment to Patented Drug Price Regulation: A Prescription for Global Drug Cost Control?*, 321 J. AM. MED. ASSOC. 1565 (2009), https://jamanetwork.com/journals/jama/fullarticle/2730014.

[195] MSF Access Campaign, DR-TB DRUGS UNDER THE MICROSCOPE (5th ed. 2018), https://msfaccess.org/sites/default/files/2018-11/TB_IssueBrief_UTM5thEdition_ENG_2018.pdf.

[196] Alastair Heffernan et al., *Scaling up prevention and treatment towards the elimination of hepatitis C: a global mathematical model*, 393 THE LANCET 1319 (2019), https://reader.elsevier.com/reader/sd/pii/S0140673618322773?token=94E35D913B700FFC5C1710B7AC173018C5314618CE9564D3659F6327983FA0DE55828B54DBE5B8448AF606BA05366802;Homie Razavi et al., *Global timing of hepatitis C virus elimination: estimating the year countries will achieve the World Health Organization elimination targets*, 70 J. HEPATOLOGY e748 (2019), https://www.journal-of-hepatology.eu/article/S0618-8278(19)31493-8/pdf.

turn of Northern activists to domestic campaigns and the "maybe David against mammoth Goliath" campaign for delinked innovation and access strategies seems to be leaving South allies behind. Paradoxically, the problem of access to affordable medicines of assured quality is becoming particularly acute in middle-income countries that are simultaneously transitioning out of eligibility for donors' health assistance.[197] And this at the same time that MICs face higher tier prices on medicines and are excluded from MPP licenses. Similarly, while Northern focus on LMICs fades, key populations, typically sidelined or even criminalized by government policies, are particularly at risk in post-transition settings[198] as are women and girls.[199] In this context, questions from Southern A2M activists are simmering.

Conclusion

This has been far from a complete history of the heroic civil society struggle for access to medicines, but even so it reveals the breadth of transformative actions undertaken and the shrewd and coordinated strategies deployed. Over a scant twenty-year history of concerted activism, the A2M movement, spawned in the depths of the AIDS crisis, has had tremendous impacts on the rights to health and access to medicines, most particularly with respect to HIV, but increasingly with respect to HCV and other health conditions as well. Fundamental structures in the international intellectual property regime have been challenged and countries have been pushed to adopt, use, and protect access to medicines flexibilities allowed under law. Intellectual property experts and human rights proponents have worked with and within a social movement led by grassroots activists, many of them people living with diseases for which medicines were both available and denied. Several global institutions have supported this work and recalcitrant and accommodating policy makers have enacted reforms that have reverberated throughout the global health system. Through concentrated domestic

---

[197] *See* EQUITABLE ACCESS INITIATIVE REPORT (2016) (criticizing inappropriate reliance on World Bank county income categories as the sole measure to establish cut-offs for health aid eligibility), https://www.theglobalfund.org/media/1322/eai_equitableaccessinitiative_report_en.pdf; Rachel Silverman, *Project Health Financing Transitions: Timeline and Magnitude*, CENTER FOR GLOBAL DEVELOPMENT WORKING PAPER 48 (2018), https://www.cgdev.org/sites/default/files/projected-health-financing-transitions-timeline-and-magnitude.pdf; *Beyond Gross National Income: Innovative methods for global health aid allocation*, 33 HEALTH POLICY AND PLANNING SUPPL_1 (2018); Gavin Yamey et al., *Transitioning from foreign aid: is the next cohort of graduating countries ready?*, THE CTR. FOR POLICY IMPACT IN GLOB. HEALTH WORKING PAPER (2018), http://centerforpolicyimpact.org/wp-content/uploads/sites/18/2018/03/Transition-from-foreign-aid_DukeCPIGH-Working-Paper-final.pdf; Open Society Foundations Public Health Program, LOST IN TRANSITION: THREE CASE STUDIES OF GLOBAL FUND WITHDRAWAL IN SOUTH EASTERN EUROPE (2017), https://www.opensocietyfoundations.org/publications/lost-transition; Mercedes Taty & Els Torreele, *Ensuring access to life-saving medicines as countries shift from Global Fund support*, 97 BULL. WORLD HEALTH ORG. 311 (2019) (decrying the risks of rapid transition from Global Fund support with respect to procurement of affordable and quality assured medicines), https://www.who.int/bulletin/volumes/97/5/19-234468.pdf?ua=1.

[198] Sara L. M. Davis, *Donors Risk Human Rights Violations When Leaving Middle-Income Countries*, HEALTH & HUMAN RIGHTS J.,. (April 29, 2019), https://www.hhrjournal.org/2019/04/donors-risk-human-rights-violations-when-leaving-middle-income-countries/.

[199] UK All-Party Parliamentary Group on HIV& AIDS, NO ONE LEFT BEHIND: TOWARDS A SUSTAINABLE HIV RESPONSE FOR KEY POPULATIONS AND WOMEN AND GIRLS (2018), https://stopaids.org.uk/wp/wp-content/uploads/2018/07/No-One-Left-Behind-HIVAIDS-report-ONLINE-VERSION.pdf; Stop AIDS, *STOPAIDS submission to the APPG on HIV & AIDS inquiry into key populations and women and girls in middle income and transitioning countries* (2018) (on file with the author).

advocacy and collaborative coalition work on regional and global scales, the issue of access to affordable medicines is now at the head of policy debates within the UN, at the WHO, in legislative chambers, and in the court of public opinion.

During the three phases of the A2M movement, old and new conflicts and disconnections have emerged and persisted between key actors about "optimal" access strategies. However, these tension and fractures must be redressed. Clearly, there is no single strategy sufficient to the pressing task of assuring the universal human rights for all people to access the affordable health technologies they need no matter where they live, no matter how much money they have, no matter what their health need. The biopharmaceutical industry has enormous economic clout and political leverage and it has the support of the rich countries that host it. Industry pays huge amounts to lobby receptive government officials and to detail medical prescribers to steer their prescribing practices towards more profitable medicines. Enshrined IP and regulatory systems bind the hands of potential generic producers and in some instances the hands of governments themselves. Clearly timelines to impact and the impacts themselves are different between different access strategies, as are prospects for more transformative and disruptive changes. And clearly, more thought is needed on how strategies can be deployed to maximize complementarities rather than conflicts. It is hoped that this chapter contributes to better collaboration, cohesion, and trust in the A2M movement as it continues its virtuous struggle against a trillion dollar Big Pharma industry and its rich government supporters.