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International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Laws Campaign

BROOK J. BAKER
Professor of Law at Northeastern University School of Law

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ABOUT THE AUTHOR: Brook Baker is a Professor of Law at Northeastern University School of Law and an Honorary Research Fellow at the University of KwaZulu-Natal, in Durban, South Africa.

I. INTRODUCTION

In 2000, my colleague Yousuf Vawda[1] and I became active in the global campaign to address intellectual property rights (IPRs), human rights, and barriers to access to affordable medicines for treating HIV and AIDS in South Africa. Anonymous HIV testing at the University of Durban-Westville (UDW) had revealed a staggering rate of untreated infection. In response, from 2001 to 2002, we sketched outlines of reforms to South Africa's patent regime in order to take advantage of the public health flexibilities allowed under governing international norms.

From 2001 to 2007, Yousuf and I engaged in intellectual property (IP) and access-to-medicines work, publishing academically and advocating in support of treatment campaigns being waged in South Africa and elsewhere.[2] In 2008, we received support for an intensive course on IP and access to medicines offered to grassroots activists, academics, health practitioners, and interested government officials. Although we introduced participants to rigorous analysis of IPRs, the right to health, pharmaceutical economics, procurement and supply systems, and more, the course, funded by the Open Society Institute (OSI),[3] was also designed to expose

1. Yousuf Vawda is an Associate Professor at the University of KwaZulu-Natal School of Law. *Professor Yousuf Vawda*, U. KwaZulu-Natal, http://law.ukzn.ac.za/School-Staff/Academicstaff/law-staff.aspx (last visited Apr. 9, 2016).

2. *See, e.g.*, Brook K. Baker, Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilise TRIPS Flexibilities in Non-Producing Countries 7 (DFID Health Systems Resource Centre, 2004) [hereinafter Baker, Processes and Issues for Improving Access to Medicines]; Brook K. Baker, *ACTA—Risks of Third-Party Enforcement for Access to Medicines*, 26 Am. U. Int'l L. Rev. 579 (2011); Brook K. Baker, *Arthritic Flexibilities for Accessing 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 (2004) [hereinafter Baker, *Arthritic Flexibilities for Accessing Medicines*]; Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space, Not IP Shackles*, *in* International Economic Law and African Development 82 (Laurence Boulle et al. eds., 2014) [hereinafter Baker, *Debunking IP-for-Development*]; Brook K. Baker, *Ending Drug Registration Apartheid—Taming Data Exclusivity and Patent/Registration Linkage*, 34 Am. J.L. & Med. 303 (2008); Sean Flynn, Brook K. Baker, Margot Kaminski & Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 Am. U. Int'l L. Rev. 105 (2012) [hereinafter Flynn et al.]; Y.A. Vawda, *Free Trade Agreements with the US—Are They Good for Your Health?*, 32 J. Juridical Sci. 116 (2007); Yousuf Vawda, *From Doha to Cancun: The Quest to Increase Access to Medicines Under WTO Rules*, 19 SAJHR 679 (2003); Yousuf A. Vawda, *Tripped-up on TRIPS: The Story of Shrinking Access to Drugs in Developing Countries*, 13 Stellenbosch L. Rev. 352 (2002); Yousuf A. Vawda & Brook K. Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 Afr. Hum. Rts. L.J. 55 (2013) [hereinafter Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*]; Tenu Avafia & Brook K. Baker, *Laws and Practices that Facilitate or Impede HIV-Related Treatment Access* (Global Comm'n on HIV and the Law, Working Paper No. GCHL/MTG1/WP/13, 2010); Brook K. Baker & Tenu Avafia, The Evolution of IPRs from Humble Beginnings to the Modern Day TRIPS-Plus Era: Implications for Treatment Access (July 7–9, 2011) [hereinafter Baker & Avafia, The Evolution of IPRs] (unpublished working paper), www.hivlawcommission.org/index.php/working-papers/the-evolution-of-IPRs-from-Humble-Beginnings-to-the-Modern-Day-TRIPS-plus-Era-Implications-for-Treatment-Access.pdf.

3. This organization is now known as the "Open Society Foundations" (OSF). *See About Us: History,* Open Soc'y Found., https://www.opensocietyfoundations.org/about/history (last visited Apr. 9, 2016).

participants to global access-to-medicines campaigns fought in South Africa and elsewhere and to help participants plan campaigns that might be waged in their own countries or regions.[4] We taught the two-week intensive course for five years and in the fourth year recruited strong participants from the Treatment Action Campaign (TAC)[5] and Médecins Sans Frontières (MSF).[6] Yousuf had been conducting Ph.D. research on flaws in the South African patent regime, especially the failure to examine patent applications, which revealed excessive patenting for medicines that delayed access to more affordable generic equivalents. In the last week of the 2011 course, TAC, MSF, and other sub-Saharan African participants drafted a comprehensive campaign strategy to launch the Fix the Patent Laws Campaign (the "Campaign") in South Africa.

With the support of OSI/OSF and other funders, the Campaign was launched as planned in late 2011. In addition to creating popular education materials, organizing demonstrations, and orchestrating a press strategy, the Campaign also engaged in a heady insider strategy within the Department of Trade and Industry (DTI), which houses the South African Patent Office, and the Department of Health. Through a series of public events and private consultations, key officials were made aware of the heavy toll South Africa was paying because of its retrograde patent regime. The Campaign also drew contrasts between the pro-IP flexibilities that South Africa was espousing on the international stage and its weak legislation at home. While the Campaign has not yet fully won the reforms it seeks, the South African government released a draft National Policy on Intellectual Property (the "Draft IP Policy") in September 2013 outlining intended reforms along the lines of what the Campaign had proposed.

This paper details our academic collaboration, our activist-oriented "clinical" offering, and the vibrant campaign that it helped to spawn. It also situates the Campaign within the global framework of pro-Pharma legal rules and diplomatic pressures, showing the connections between the global political economy and local reform efforts grounded in the right to health enshrined in the South African

4. *Intellectual Property and Access to Medicines*, U. KwaZulu-Natal, http://ipatm.ukzn.ac.za/Homepage.aspx (last visited Apr. 9, 2016).

5. TAC was started in 1998 to advocate for South Africa to begin a more vigorous response to the HIV and AIDS pandemic, particularly by providing access to anti-retroviral therapy. For a history of its early years, see Treatment Action Campaign, Fighting for our Lives: The History of the Treatment Action Campaign 1998-2010, at 3 (2010), http://www.tac.org.za/files/10yearbook/index.html.

6. MSF is a well-known medical relief organization that received the Nobel Peace Prize in 1999. That same year it started its Access Campaign "to push for access to, and the development of life-saving and life prolonging medicines, diagnostic tests and vaccines for patients in MSF programmes and beyond." *About Us*, Médecins Sans Frontières Access Campaign, http://www.msfaccess.org/the-access-campaign (last visited Apr. 9, 2016). MSF and TAC participants who attended in 2011 and strategized the Fix the Patent Laws Campaign included Catherine Tomlinson, Mara Kardis-Nelson, Marcus Low, and Lynette Mabote.

Constitution. In Part II, I discuss the beginning of my involvement in IP and access-to-medicines work. Part III describes law reform efforts that address upstream barriers to the right to health and the collaboration between academics, practitioners, funders, and social movements that help energize needed reforms. Part IV explains the creation of IP systems that block access to generic medicines. Part V outlines the IP flexibilities permitted by the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Part VI discusses the deficiencies of the South African Patents Act of 1978. Part VII focuses on my involvement in developing a two-week IP course at the University of KwaZulu-Natal (UKZN). Part VIII details the creation of the Fix the Patent Laws Campaign. Part IX concludes the paper.

II. BIRTH OF MY CAMPAIGN TO FIX PATENT LAW LEGISLATION

At the Thirteenth International AIDS Conference, held on July 9 through July 13, 2000 in Durban, South Africa,[7] I cheered with excitement at the satellite conference organized by MSF and TAC at Durban City Hall. Yousuf, who directed the law clinic at UDW, was there along with his wife Cati Vawda, who was on TAC's National Executive Council leading the children's sector response to HIV. I had heard reports about the staggering prevalence of HIV in South Africa during my previous visits to Durban. By the time of the conference, I had heard about anonymous testing at UDW, which showed that nearly twenty-five per cent of students tested positive for HIV,[8] with much higher rates among black Africans than Indian or white students. Prior to the conference, I had worked for three years developing an HIV-related curriculum and worked with Yousuf in UDW's clinic, where we routinely confronted cases of clients affected by HIV,[9] but that response felt and was inadequate.

The satellite conference was electrifying, as speakers spoke about the high cost of medicines, an MSF anti-retroviral (ARV) treatment program being piloted in Kyayelitsha, and a campaign against Pfizer, a major U.S. pharmaceutical company, to lower the costs of fluconazole, an antifungal medication used to treat cryptococcal meningitis and systemic thrush. For the first time in my life, I heard the words

7. For a brief, activist account of the Durban conference, see Nathan Geffen, *What Happened in Durban? A South African Perspective*, Body, http://www.thebody.com/content/art13213.html (last visited Apr. 9, 2016).

8. *See* Linda Vergnani, *AIDS Virus is Widespread on South African Campus*, Chron. Higher Educ. (June 11, 1999), http://chronicle.com/article/AIDS-Virus-Is-Widespread-on/18092/ (noting that the majority of students testing positive for HIV were women).

9. For a description of some of those cases, see Brook K. Baker, *Teaching Legal Skills in South Africa: A Transformation from Cross-Cultural Collaboration to International HIV/AIDS Solidarity*, 9 J. Legal Writing 145 (2003).

"parallel importation"[10] and "compulsory licenses."[11] They were uttered not by law professors, but by activists on the stage describing the campaigns needed to supply affordable medicines to millions of people living with HIV in South Africa. In particular, I heard that TAC had launched a campaign against President Thabo Mbeki's AIDS denialist policies, demanding that ARVs be used to prevent mother-to-child transmission of HIV.[12] Speakers denounced the high cost of fluconazole,[13] which was selling for ZAR50[14] per pill in the private sector and ZAR29 per pill in the public sector but was available generically in Thailand for less than ZAR2 (approximately $0.28).[15] I heard that thirty-nine pharmaceutical companies and trade associations had filed suit against the South African Amended Medicines and Related Substances Control Act that was designed to lower drug prices by allowing parallel importation of branded medicines sold more cheaply elsewhere, generic substitution by pharmacists, and price transparency and control.[16]

Perhaps most movingly, we heard Constitutional Court Justice Edwin Cameron's famous and brave speech:

> I can tell you that you taste death in your mouth when you have AIDS. . . .
>
> . . . .
>
> I fell ill 33 months ago. So I should be dead by now. Instead of which, I'm here, "ngikhona", "ngiyaphila", I'm still living.

10. Parallel importation is the legal importation of a medicine that is otherwise patent protected in the importing country from another country where the patent owner has previously marketed the medicine or allowed it to be marketed. An alternative understanding of parallel importation argues that it is permissible whenever the product has been lawfully marketed elsewhere, with or without the patent holder's assent. Where an importing country has adopted the international exhaustion rule, the first sale of the product anywhere in the world "exhausts" the patent holder's rights, meaning the patent holder cannot block the export or import of the medicines. Countries pursue parallel importation when patented medicines are available more cheaply abroad. *See generally* Chang-Fa Lo, *Potential Conflict Between TRIPS and GATT Concerning Parallel Importation of Drugs and Possible Solution to Prevent Undesirable Market Segmentation*, 66 Food Drug L.J. 73, 73–74 (2011) (discussing parallel importation).

11. Compulsory licenses are rights granted by governments that allow non-patent holders to work a patent, thereby creating some degree of competition with the patent holder. A compulsory license may be granted on any public interest grounds, but international trade law requires that certain formalities be followed and that adequate remuneration, usually in the form of royalties, be paid. *See generally* Laura Bloodgood, U.S. Int'l Trade Comm'n, ICT Pub. No. 3931, Competitive Conditions for Foreign Direct Investment in India, at 5–6 n.42 (2007) ("A compulsory license is one issued by the government that allows the use of a patented invention without consent of the owner, upon payment of a royalty.").

12. Treatment Action Campaign, *supra* note 5, at 19–25.

13. Fluconazole is used to treat cryptococcal meningitis and systemic thrush. *Christopher Moraka Defiance Campaign Against Patent Abuse and AIDS Profiteering by Drug Companies*, Treatment Action Campaign, http://www.tac.org.za/Documents/DefianceCampaign/defiancecampaign.htm (last visited Apr. 9, 2016) [hereinafter *Christopher Moraka Defiance Campaign*].

14. ZAR refers to Rand, South Africa's currency.

15. *Christopher Moraka Defiance Campaign*, *supra* note 13.

16. *See Pharm. Mfrs.' Ass'n of S. Afr.* 2000 (2) SA 674 (CC) at paras. 1, 60–61.

. . . .

> There are people throughout Africa, 24 or 25 million people in Africa and nearly 34 million people in our whole world who are this moment dying. And they [are] dying because they don't have the privilege that I have, of purchasing my health and life.[17]

We also heard from Dr. Peter Mugyenyi, an AIDS clinician from Uganda who, pointing out the disparities in global access to highly active anti-retroviral therapy (HAART), said: "Drugs are where the disease is not . . . . The disease is where the drugs are not."[18]

After the satellite conference, thousands of people gathered on the steps of Durban City Hall. Thousands strong, in the first international march for global AIDS treatment, protestors danced, sang, and chanted to the site of the opening ceremonies of the International AIDS Conference to deliver demands to the organizers.[19] Once inside, we listened to President Mbeki question whether a single virus could cause South Africa's health woes and defend his convening of an HIV/AIDS panel in which credible AIDS scientists and discredited AIDS dissidents were equally represented.[20] Shortly thereafter, he walked off the stage, shunning the presence of Nkosi Johnson, an eleven-year-old South African with AIDS who urged the government to take action to prevent mother-to-child transmission of HIV and implored everyone "Care for us and accept us- we are all human beings."[21]

That day and evening, July 9, 2000, changed my life. Our son, Chad, who had been diagnosed with pediatric cancer in June 1986, had avoided the risk of HIV transmission from blood transfusions by a matter of months. Elsewhere, parents just like me were watching their children die untreated. Like thousands in Durban, I knew that ARVs were not available in South Africa because patent-holding drug companies located in Europe and the United States were charging the same prices for ARVs in Africa that they were charging in the United States: approximately $10,439 per year.[22] Some drug companies had announced a discount price initiative

17. Edwin Cameron, Judge, Constitutional Court of S. Afr., Closing Remarks at the Thirteenth International AIDS Conference (July 14, 2000), http://www.tac.org.za/Documents/Speeches/ec9july.txt.

18. *See* Sabin Russell, *Mbeki's HIV Stand Angers Delegates/Hundreds Walk Out on his Speech*, S.F. Chron. (July 10, 2000) (quoting Peter Mugyenyi), http://www.sfgate.com/health/article/Mbeki-s-HIV-Stand-Angers-Delegates-Hundreds-2749508.php.

19. *See* Richard Pithouse, *Report on Global March for Treatment Access*, Treatment Action Campaign, http://www.tac.org.za/Documents/Other/march.htm (last visited Apr. 9, 2016).

20. *See* Russell, *supra* note 18; *see also* Thabo Mbeki, President of S. Afr., Speech at the Opening Ceremony of the Thirteenth International AIDS Conference (July 9, 2000), http://www.actupny.org/reports/durban-mbeki.html.

21. *See* Nkosi Johnson, Speech at the Opening Ceremony of the Thirteenth International AIDS Conference (July 9, 2000), http://www.ieterna.org/archive-pdf/people/autobiography/Nkosi%20speech.pdf.

22. *See* Médecins Sans Frontières, Untangling the Web of Antiretroviral Price Reductions 10 (15th ed. 2012), http://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW15_ENG_2012.pdf.

in May of that year, but negotiations were being conducted on a secretive drug-by-drug, country-by-country basis.[23]

I returned to the United States energized and motivated. I dedicated myself to learning more about the international IP regime and how to make national laws more conducive to manufacturing and importing cheaper generic equivalents of grossly overpriced medicines. While exploring global AIDS activism in the United States, I started working with Health Global Access Project ("Health GAP"), which had helped organize protests in Durban and had also been fighting U.S. trade pressure against South Africa[24] and the lawsuit by thirty-nine pharmaceutical companies and trade associations against President Nelson Mandela.[25]

III. SOUTH AFRICAN ACTIVISTS AND ALLIES FIGHT PHARMACEUTICAL APARTHEID IN SOUTH AFRICA

The HIV/AIDS pandemic peaked globally in 1997 with approximately 3.6 million recorded infections, and in South Africa from 1998 to 1999 with an estimated 650,000 new infections.[26] AIDS policy in South Africa was constipated at best long before Thabo Mbeki's presidency. The apartheid government was indifferent to a disease thought to target gay men and poor black Africans. The apartheid health system was appallingly unequal; over 80% of the population were not members of a medical scheme and only 23% of the population used private sector services regularly, yet nearly 60% of total health financing went to the privileged, primarily white

23. *See* World Health Org. [WHO] & Joint United Nations Programme on HIV/AIDS [UNAIDS], Accelerating Access Initiative: Widening Access to Care and Support for People Living with HIV/AIDS—Progress Report (2002), http://www.who.int/hiv/pub/prev_care/isbn9241210125.pdf.

24. With respect to U.S. trade pressure, see Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681 (1999) (denying assistance to South Africa until the repeal, suspension, or termination of section 15C). According to U.S. State Department documents and statements, "[multiple federal agencies] have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15(C) . . . ." Patricia D. Siplon, AIDS and the Policy Struggle in the United States 120–21 (2002) (quoting U.S. Dep't of State, U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965 (1999)); *see also* Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 Int'l J. Health Serv. 765 (1999). For a description of some of Health GAP's activism against U.S. trade pressure, see *Candidate GORE Zaps*, ACT UP, http://actupny.org/actions/gorezaps.html (last visited Apr. 9, 2016).

25. *See Pharm. Mfrs.' Ass'n of S. Afr.* 2000 (2) SA 674 (CC); *see also* Pat Sidley, *Drug Companies Sue South African Government over Generics*, 322 Brit. Med. J. 447, 447 (2001).

26. For global statistics, see Joint United Nations Programme on HIV/AIDS [UNAIDS], How AIDS Changed Everything: HIV Estimates with Uncertainty Bounds 1990-2014 (2015), http://www.unaids.org/sites/default/files/media_asset/MDG6Report_en.pdf. *But see* Christopher Murray et al., *Global, Regional, and National Incidence and Mortality for HIV, Tuberculosis, and Malaria During 1990–2013: A Systematic Analysis for the Global Burden of Disease Study 2013*, 384 Lancet 1005, 1030–31 (2014) (questioning UNAIDS's global HIV prevalence statistics).

private health sector.[27] Although the new African National Congress (ANC) government developed preliminary AIDS strategies,[28] its major preoccupations were inward: its new governance role, its economic policy, and the persisting legacies of apartheid. President Mandela was initially tongue-tied about HIV, not mentioning it until late in his presidency.[29] His successor, President Mbeki, fell under the sway of AIDS dissidents. Suspicious of the agenda of multinational drug companies and the governments that supported them, inattentive to the vast weight of scientific evidence, and angry over the prevailing portrayals of dangerous, hyper-sexualized African men, Mbeki retreated further from positive engagement of the HIV crisis, dragging his Minster of Health, Manto Tshabalala-Msimang, with him into the vortex of HIV denialism.[30]

The legacies of apartheid, including a tattered and inequitable public health system; the squeamishness, frugality, and denialism of ANC policy; and the myriad domestic drivers of HIV—a migrant labor force, sexual patriarchy, and disrupted families—combined with global determinants including intellectual property hegemony, export-oriented trade, and structural adjustment.[31] These confluences produced the perfect storm for South Africa's viral holocaust.

Through its most public anti-HIV effort, the farcical HIV prevention debacle *Sarafina II*,[32] and the false AIDS cure Virodene P058,[33] the ANC revealed itself to be bungling at best. In the midst of this policy miasma, TAC was founded in 1998 to fight for prevention of mother-to-child transmission (PMTCT) and a more robust

27. These figures come from an early post-apartheid study, Health Sys. Tr. & World Bank, Health Expenditure and Finance in South Africa 1, 14 (1995), http://www.hst.org.za/sites/default/files/hstefsa.pdf.

28. *See A National Health Plan for South Africa*, Afr. Nat'l Congress (May 30, 1994), http://www.anc.org.za/show.php?id=257; *see also* Anthony Butler, *South Africa's HIV/AIDS Policy, 1994–2004: How Can It Be Explained?*, 104 Afr. Aff. 591, 592–93 (2005); Mark Heywood & Morna Cornell, *Human Rights and AIDS in South Africa: From Right Margin to Left Margin*, 2 Health & Hum. Rts. 60, 66–68 (1998).

29. Although Mandela eventually became an influential spokesperson on HIV, he first publicly addressed HIV and AIDS in 1997, three years into his presidency. *See* Interview by Renata Simone, PBS Frontline Producer, with Constitutional Court Justice Edwin Cameron (2009), http://www.pbs.org/wgbh/pages/frontline/biographies/nelson-mandelas-mixed-legacy-on-hivaids/.

30. For histories of AIDS neglect and AIDS denialism in South Africa, see Pieter Fourie & Melissa Meyer, The Politics of AIDS Denialism: South Africa's Failure to Respond (2010); Nathan Geffen & Edwin Cameron, *The Deadly Hand of Denial: Governance and Politically-Instigated AIDS Denialism in South Africa* (Ctr. for Soc. Sci. Research, Working Paper No. 257, 2009).

31. *See generally* Brook K. Baker, *The Impact of the International Monetary Fund's Macroeconomic Policies on the AIDS Pandemic*, 40 Int'l J. Health Servs. 347 (2010).

32. *See* Suzanne Daley, *South Africa Scandal Over 'Sarafina' Spotlights Corruption in the A.N.C.*, N.Y. Times (Oct. 8, 1996), http://www.nytimes.com/1996/10/08/world/south-africa-scandal-over-sarafina-spotlights-corruption-in-the-anc.html. *Sarafina II* was a controversial and very expensive South African musical promoted as presenting an HIV prevention message.

33. *See* Pat Sidley, *Miracle AIDS Cure Hits the South African Press*, 314 Brit. Med. J. 450 (1997) (detailing the false claim of an HIV/AIDS cure that was in fact an industrial solvent).

state response to the pandemic.[34] However, from the earliest stages, TAC recognized that the prices of ARVs in South Africa would provide a ready excuse for governmental neglect, procrastination, and prevarication.

After the Durban conference, TAC and its network of affiliated AIDS activists[35] gained momentum by focusing on the global and national determinants of access to medicines.[36] Marshaling the language of human rights while mobilizing communities,[37] TAC waged a "defiance campaign" to force Pfizer to make fluconazole more widely available to treat opportunistic infections.[38] Zackie Achmat, TAC's chair, flew to Thailand, purchased generic equivalents, and flew back to South Africa, defying South African authorities to prosecute him.[39] As pressure mounted, Pfizer partially relented and on December 1, 2000, announced that it would make Diflucan, Pfizer's brand-name fluconazole, available free of cost in South Africa to the government and non-governmental organizations for the treatment of cryptococcal meningitis and esophageal candidiasis, opportunistic infections commonly affecting those with AIDS.[40] Pfizer was widely criticized for limiting the donation program to South Africa and later announced the expansion to

34. Treatment Action Campaign, *supra* note 5, at 3, 19–25.

35. During its entire history, TAC collaborated closely with the AIDS Law Project, now Section27. *See AIDS Law Project of South Africa Honored*, Hum. Rts. Watch (Sept. 11, 2003), https://www.hrw.org/news/2003/09/11/aids-law-project-south-africa-honored. For a short history, see Mark Heywood, *South Africa's Treatment Action Campaign (TAC): An Example of a Successful Human Rights Campaign for Health*, Treatment Action Campaign (Mar. 26, 2008, 4:19 PM), http://www.tac.org.za/community/node/2064.

36. *See* Treatment Action Campaign, *supra* note 5; *see also* Mandisa Mbali, South African AIDS Activism and Global Health Politics 1–2 (2013); Eduard Grebe, *The Treatment Action Campaign's Struggle for AIDS Treatment in South Africa: Coalition-building Through Networks*, 37 J. Southern Afr. Stud. 849 (2011) (discussing the TAC coalition-building strategy designed to create networks of influence); 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 (2009). *See generally* Jonathan Michael Berger, *Litigation Strategies to Gain Access to Treatment for HIV/AIDS: The Case of South Africa's Treatment Action Campaign*, 20 Wis. Int'l L.J. 596 (2003) (describing TAC's early litigation strategies); William Forbath, *Cultural Transformation, Deep Institutional Reform, and ESR Practice: South Africa's Treatment Action Campaign*, *in* Stones of Hope: How African Activists Reclaim Human Rights to Challenge Global Poverty (Lucie E. White & Jeremy Perelman eds., 2011) (describing TAC's early growth).

37. *See* Leslie London, *What is a Human Rights-based Approach to Health and Does it Matter?*, 10 Health & Hum. Rts. J. 65, 67–68 (2013); *see also* Krista Johnson, *Framing AIDS Mobilization and Human Rights in Post-apartheid South Africa*, 4 Persp. on Pol. 663 (2006).

38. After the joint TAC/MSF campaign for access to affordable fluconazole was launched, Pfizer had offered to supply Diflucan for cryptococcal menigititis, but that promise had not been formalized. *See* Pat Sidley, *AIDS Patients in South Africa to Get Free Drug*, 320 Brit. Med. J. 1095 (2000).

39. Tony Karon, *South African AIDS Activist Zackie Achmat*, Time (Apr. 19, 2001), http://content.time.com/time/nation/article/0,8599,106995,00.html.

40. Konji Sebati, *Pfizer Diflucan Partnership Program*, 361 Lancet 72 (2003).

include all of the Southern African Development Community[41] and fifty least developed countries (LDCs).[42]

TAC also sought to intervene in a major drug-company lawsuit against the South African government over proposed amendments to allow wider access to cheaper generic medicines.[43] The drug company plaintiffs complained that section 10 of the 1997 Medicines and Related Substances Control Amendment Act, which added section 15C, was unconstitutional and violated the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) by authorizing parallel importation.[44] TAC's involvement significantly raised the global profile of the ill-advised lawsuit, and the AIDS Law Project, which represented TAC in its amicus intervention, strongly challenged the drug companies' assertions.[45] TAC called for a Global Day of Action on March 5, 2001, leading to demonstrations worldwide.[46] On April 19, 2001, the drug companies dropped their lawsuit.[47]

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41. *Id*. The Southern African Development Community includes Angola, Botswana, the Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, the United Republic of Tanzania, Zambia, and Zimbabwe. *Member States*, S. Afr. Dev. Community, http://www.sadc.int/member-states/ (last visited Apr. 9, 2016).

42. Press Release, Pfizer Inc., Pfizer to Offer Diflucan Antifungal Medicine at No Charge to HIV/AIDS Patients in 50 Least Developed Countries Around the World (June 6, 2001), http://www.prnewswire.com/news-releases/pfizer-to-offer-diflucan-antifungal-medicine-at-no-charge-to-hivaids-patients-in-50-least-developed-countries-around-the-world-72062052.html.

43. *See* Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 Seattle J. Soc. Just. 257, 257, 276–77 (2002); Mark Heywood, *Debunking 'Conglomo-Talk': A Case Study of the* Amicus Curiae *as an Instrument for Advocacy, Investigation, and Mobilisation*, 5 Law Democracy & Dev. 133 (2001) (describing the TAC's intervention strategy at length).

44. *See Pharm. Mfrs.' Ass'n of S. Afr. v. President of the Republic of S. Afr.*, case no. 4183/98, Notice of Motion in the High Court of South Africa (Feb. 18, 1998). With respect to section 15C, the plaintiffs argued that it (1) allowed a constitutionally impermissible delegation of powers to the executive branch, in that the Minister of Health was authorized to decide patent rights without regard to the South African Patents Act and in that the Minister could allow compulsory licenses and parallel importation without any limiting guidelines, thereby depriving IP owners of their property without full compensation in violation of section 25 of the South African Constitution; and (2) violated Article 27 of TRIPS and did so in further violation of sections 44(4) and 231(2)–(3) of the South African Constitution. *Id.* The South African government defended on two grounds: (1) "it claimed that Section 15C was constitutional, because it did not grant the Minister of Health broad powers to abrogate patent rights," and (2) it maintained that section 15C complied with TRIPS because parallel importation was lawful under TRIPS and because section 15C did not address compulsory licensing. William W. Fisher III & Cyrill P. Rigamonti, The South Africa AIDS Controversy: A Case Study in Patent Law and Policy 6 (2005). For an early discussion of the South African pharmaceutical case even before it was decided, see Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 Berkeley Tech. L.J. 485 (2000). For analysis post withdrawal of the lawsuit, see Fisher & Rigamonti, *supra*.

45. *See* Heywood, *supra* note 43, at 142–43, 148–51.

46. *See, e.g.*, John S. James, *March 5: "Global Day of Action Against Drug Company Profiteering," as Pharmaceutical Companies Sue South Africa to Block Low-Cost Medicines*, Body (Jan. 26, 2001), http://www.thebody.com/content/art32009.html; Anso Thom, *Overwhelming Support From Around the Globe*, Health-E News (Mar. 2, 2001), http://www.health-e.org.za/2001/03/02/overwhelming-support-from-around-the-globe.

47. Ann M. Simmons, *Suit Against Cheap AIDS Drugs Ends in S. Africa*, L.A. Times (Apr. 20, 2001), http://articles.latimes.com/2001/apr/20/news/mm-53295; Rachel L. Swarns, *Drug Makers Drop South Africa Suit*

These initial TAC campaigns were directed at the symptom, high prices, rather than the source, namely international and South African IP regimes. Even so, TAC turned its attention toward national health policy and pressed the government to implement a PMTCT program that provided a single dose of nevirapine to the mother and the newborn to reduce the risk of HIV transmission by nearly fifty per cent.[48] Despite all available scientific evidence and an offer of free nevirapine from pharmaceutical manufacturers, the government refused to make nevirapine broadly available, provoking TAC, the Children's Rights Centre, and others to lodge a Constitutional Court challenge.[49] This now-famous case established a constitutional right-to-health rule requiring the government to engage in rational planning to address the interests of mothers and children in preventing vertical transmission of HIV.[50] The Constitutional Court ordered the government to abandon its cautious pilot-study approach and instead to allow doctors working in the public sector to routinely administer voluntary ARV prophylaxis to reduce the risk of vertical transmission.[51] In sum, the Constitutional Court ruled that the government had an obligation to plan and to act, thereby setting the stage for a more robust response to the HIV/AIDS pandemic and its intergenerational transmission.

Not satisfied with a long-delayed victory on PMTCT, TAC turned its attention to the government's failure to commit to an ARV treatment plan.[52] In early 2003, TAC launched its "Dying for Treatment" civil disobedience campaign.[53] In addition to organizing a demonstration of about 20,000 people on February 14, 2003,[54] TAC formed a research committee of health economists and medical professionals that produced a draft National Treatment Plan demonstrating that initial costs of treatment scale-up would be offset in the future because of cost savings from averted orphanhood,

Over AIDS Medicine, N.Y. Times (Apr. 20, 2001), http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html. Unfortunately, it has taken years for the South African government to adopt implementing regulations on parallel importation and the regulations adopted are overly complex, bureaucratic, and burdensome. *See* General Regulations Made in Terms of the Medicines and Related Substances Act 101 of 1965, As Amended, GN R510 of GG 24727 (10 Apr. 2003).

48. *See* Treatment Action Campaign, *supra* note 5, at 19.

49. *See Minister of Health v. Treatment Action Campaign* 2002 (5) SA 721 (CC). *See generally* Mark Heywood, *Preventing Mother-to-Child Transmission in South Africa: Background, Strategies and Outcomes of the Treatment Action Campaign Case Against the Minister of Health*, 19 SAJHR 278 (2003); Amy Kapczynski & Jonathan Berger, *The Story of the* TAC *Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa*, *in* Human Rights Advocacy Stories 43 (Deena R. Hurwitz et al. eds., 2009).

50. *See Treatment Action Campaign*, 2002 (5) SA 721 at para. 135.

51. *Id.*

52. *See* Neil Overy, Int'l Budget P'Ship, In the Face of Crisis: The Treatment Action Campaign Fights Government Inertia with Budget Advocacy and Litigation 5 (2011), http://www.internationalbudget.org/wp-content/uploads/LP-case-study-TAC.pdf.

53. *Dying for Treatment: TAC Briefing Document on the Civil Disobedience Campaign*, Treatment Action Campaign (Mar. 10, 2003), http://www.tac.org.za/Documents/CivilDisobedience/briefingdocument.htm.

54. Ralph Berold, *Review of 14 February March*, Treatment Action Campaign (March 10, 2003), http://www.tac.org.za/newsletter/2003/ns10_03_2003.html.

sick leave, and premature mortality.[55] TAC enlisted the support of the Congress of South African Trade Unions (COSATU) and HIV/AIDS clinicians and published a leaked report from the government's Joint Treasury and Health Task Team that also demonstrated affordability and reduced mortality.[56] Achmat, the TAC Chair and activist, famously promised not to begin AIDS treatment for his own worsening infection until other South Africans had access to medicine.[57] In the face of public pressure, political risk from opposition parties, and global incredulity at its totally incoherent denialist stance, the South African Cabinet finally approved an ARV treatment plan on November 19, 2003.[58] The impact of the government's procrastination was measured in at least 333,000 lives lost and 35,000 babies born with HIV because of a failure to implement a reasonably feasible anti-retroviral treatment program and prevention of mother-to-child-transmission program between 2000 and 2005.[59]

At the same time that TAC was advocating for a National Treatment Plan, it turned to competition authorities to force drug companies to lower the price of patent-protected medicines. In 2002, Hazel Tau, a woman diagnosed with HIV, and others lodged a complaint before the Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) for excessive private-sector pricing of their ARVs AZT, lamivudine, and nevirapine.[60] This was a complicated case, requiring proof that the companies had dominant economic positions and that the ARVs in question were overpriced.[61] TAC requested that the Competition Tribunal order compulsory licenses that would authorize generic manufacture and sale and a four to five per cent royalty.[62] Experts retained by the Competition Commission broadened

55. *See* Overy, *supra* note 52, at 5–6.

56. *Id.*

57. *Id.* at 7.

58. *See* Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (2003), http://www.gov.za/sites/www.gov.za/files/aidsoperationalplan1_0.pdf; *see also* Sarah Jane Marshall, *South Africa Unveils National HIV/AIDS Treatment Programme*, 82 Bulletin of the World Health Organization [WHO] 73 (2004). Despite this commitment, the treatment campaign did not meaningfully begin until 2006.

59. Pride Chigwedere et al., *Estimating the Lost Benefits of Antiretroviral Drug Use in South Africa*, 49 J. Acquired Immune Deficiency Syndromes 410, 412 (2008).

60. *See* Treatment Action Campaign, The Competition Commission Complaint: Questions and Answers 1, 4 (2002); *see also* 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); *CPTech's 2003 Reports for the RSA Competition Commission, in Hazel Tau et al.v GSK, Boehringer, et al*, Knowledge Ecology Int'l (Aug. 13, 2014), http://keionline.org/node/2074.

61. Beresford, *supra* note 60, at 39.

62. The enforcement of competition law in South Africa is overseen by the Competition Commission, which investigates whether there is probable cause to believe that anti-competitive behavior has occurred, after which a referral might be made to the Competition Tribunal for administrative hearings and enforcement orders. *See Who are We?*, Competition Comm'n S. Afr., http://www.compcom.co.za/who-are-we/ (last visited Apr. 9, 2016); *see also* Competition Tribunal S. Afr., http://www.comptrib.co.za (last visited Apr. 9, 2016).

the competition theories to include the essential facilities doctrine, arguing that each medicine was independently necessary to formulate triple-dose ARVs.[63]

On October 16, 2003, the Competition Commission found that GSK and BI had contravened the Competition Act by abusing their dominant positions.[64] The companies were found to have denied competitors access to essential facilities and to have engaged in excessive pricing and other exclusionary acts.[65] The Commission referred the matter to the Competition Tribunal for determination.[66] Before the case reached the Tribunal, GSK and BI settled by agreeing to license their ARVs to generic companies for sales throughout sub-Saharan Africa.[67] A competition strategy was used again in 2007 to seek broader access to efavirenz.[68] TAC again lodged a complaint against a Merck subsidiary, Merck Sharp Dohme Ltd. (MSD), for its refusal to license efavirenz on reasonable terms.[69] In response, MSD licensed four generic companies, two local and two foreign, to produce single- and fixed-dose efavirenz in South Africa and ten other southern African countries.[70]

These cases have virtually ensured that drug companies will include South Africa and the whole of sub-Saharan Africa in their voluntary licenses or offer significant price discounts. As a consequence of this judicial and social activism, South Africa and the entire region have been included in the territorial limits of almost every license on anti-retroviral medicines granted to the Medicines Patent Pool.[71] This inclusion is especially important for South Africa because almost all ARVs are patented there.[72] Bigger markets also encourage more generic companies to enter and to engage in robust competition at efficient economies of scale, resulting in even more affordable prices.

However, the relative ease of access with respect to first- and second-generation ARVs has not been extended to newer ARVs or to other classes of medicines,

63. *See* Consumer Project on Tech., Report to the Competition Commission of the Republic of South Africa, Evaluation of the Essential Facilities and Exclusionary Acts 7, 108 (submitted Sept. 9, 2003), http://keionline.org/sites/default/files/Evaluation_Essential_Facilitites_Exclusionary_Acts%20Final%20Report_Redacted_20030909.pdf.

64. Press Release, Competition Comm'n, Media Release from the Competition Commission (Oct. 16, 2003), http://www.sahistory.org.za/article/media-release-competition-commission.

65. *Id.*

66. *Id.*

67. *See Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines*, Treatment Action Campaign (Dec. 10, 2003), http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm.

68. *See Access to Generic Efavirenz in South Africa: MSD Agrees to Grant Licenses on Reasonable Terms*, I-Base (Aug. 30, 2008), http://i-base.info/htb/560.

69. *Id.*

70. *Id.*

71. *See Licenses in the MPP*, Medicines Pat. Pool, http://www.medicinespatentpool.org/licensing/current-licences/ (last visited Apr. 9, 2016).

72. *See Patent Status Database*, Medicines Pat. Pool, http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/ (last visited Apr. 9, 2016).

including expensive cancer, diabetes, and cardiovascular medicines that are also desperately needed.[73] The legal and structural fault that had not yet been addressed was a patent regime that made it extraordinarily easy in South Africa to obtain initial patents and secondary patents that perpetuate patent monopolies, thereby continuing to block generic access. It is to that regime that we now turn our attention.

IV. THE ORIGINS OF IP MONOPOLIES AND HIGH PRICES[74]

Colonialism imposed IP systems on subject countries that mimicked the home-country system while prioritizing the interests of the colonial masters' domestic industries.[75] More recent neo-liberal economic theory has promoted longer, stronger, and broader IPRs, including those of pharmaceutical producers, as the engine to innovation, direct foreign investment, and economic and technological development in low- and middle-income countries.[76] Under the siren song of this false ideology, heightened global and domestic IP protections allegedly promote research and development of medicines for indigenous diseases and further promote the development and registration of medicines for disease prominent in both the global south and the global north.[77]

Even though this theory of IP's catalytic effect has little or no evidence to support it, the U.S. and European governments have consistently pursued the commercial interests of their hugely profitable pharmaceutical industries at the expense of access to more affordable medicines in developing countries. One of the prime examples of this warped sense of priorities is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[78] forced on developing country negotiators during the Uruguay round of General Agreement on Tariffs and Trade (GATT) negotiations from 1986 to 1994. Despite TRIPS's imposing globalized standards for patents, data protection, and enforcement, upper-income countries have continued to pursue ever-higher IP standards through trade agreements and other bilateral pressure.[79] Fortunately, TRIPS is not entirely one-

73. *See* Hans V. Hogerzeil et al., *Promotion of Access to Essential Medicines for Non-communicable Diseases: Practical Implications of the UN Political Declaration*, 381 Lancet 680, 684–85 (2013).

74. For a longer and more detailed discussion of the origins of intellectual property rights, see Baker & Avafia, The Evolution of IPRs, *supra* note 2, at 2–5.

75. In Africa, Asia, and the Pacific, the formal introduction of intellectual property laws began in the late nineteenth century, initiated by European colonial powers after the 1884 Congress of Berlin. *See* Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries 35 (2009).

76. For a description and critique of this perspective, see Baker, *Debunking IP-for-Development*, *supra* note 2, at 82–110.

77. *Id*. at 90–91.

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

79. *See* United Nations Dev. Programme & Joint United Nations Programme on HIV/AIDS, The Potential Impact of Free Trade Agreements on Public Health 3–4 (2012); Peter Drahos,

sided. As detailed below, a number of flexibilities were built into TRIPS that provide policy space for accessing more affordable medicines, and many of those flexibilities were subsequently confirmed by the Doha Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration").[80]

As stated, TRIPS introduced minimum global standards for protecting and enforcing nearly all forms of IPR, including patents, copyrights, and trademarks.[81] Under key provisions, member states must provide patent protection for a minimum of twenty years[82] for any invention, including a pharmaceutical product or process that fulfills the criteria of novelty,[83] inventive step,[84] and industrial applicability.[85] Although preceding patent-rule pluralism in both the developed and undeveloped world had allowed discrimination between fields of invention, for example by excluding medicines,[86] TRIPS expressly outlawed such discrimination.[87] Similarly, it was no longer permissible to discriminate against imports in favor of locally produced products, thus allowing major pharmaceutical companies to control the place of production.[88] Via TRIPS, pharmaceutical multinationals succeeded in consolidating their monopoly power internationally and now have the right to exclude others from making, using, offering for sale, selling, or importing patented medicines or

Expanding Intellectual Property's Empire: The Role of FTAs, GRAIN (Nov. 30, 2003), https://www.grain.org/article/entries/3614-expanding-intellectual-property-s-empire-the-role-of-ftas.

80. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

81. The pharmaceutical industry played a highly active role in a coalition of IP industries that persuaded United States and European trade negotiators to champion an enforceable international intellectual property regime. *See* Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy? 61 (2003).

82. TRIPS Agreement, *supra* note 78, art. 33.

83. *Id.* art. 27(1). Definitions and standards of novelty, inventive step, and industrial applicability vary significantly between nations. Novelty generally requires that the alleged invention be new in the sense that it has not been anticipated in the prior art, all forms of written publication, oral disclosure, or public display anywhere in the world. *See* World Intellectual Prop. Org., WIPO Intellectual Property Handbook: Policy, Law and Use 19 (2004), http://www.wipo.int/about-ip/en/iprm/ [hereinafter WIPO Handbook].

84. TRIPS Agreement, *supra* note 78, art. 27(1). Inventive step requires that the alleged invention not be obvious to persons skilled or highly skilled in the relevant art or arts and that it entails essential progress or advancement over the prior art. *See* WIPO Handbook, *supra* note 83, at 20.

85. TRIPS Agreement, *supra* note 78, art. 27(1). Industrial applicability generally requires that the alleged invention have some non-theoretical practical use resulting in a tangible product or a process to produce a product. *See* WIPO Handbook, *supra* note 83, at 18.

86. When the Uruguay round of trade negotiations began in 1986, more than forty of the ninety GATT members did not grant patents for pharmaceutical products, while others granted process patents only. *See* World Health Org. [WHO], *Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines*, Meeting Report, at 15 (Feb. 19–21, 2001), http://apps.who.int/medicinedocs/pdf/s2284e/s2284e.pdf.

87. TRIPS Agreement, *supra* note 78, art. 27(1).

88. *Id.*

medicines made with a patented process. In addition, TRIPS protected undisclosed information, including clinical test data that under some interpretations impede registration of generic drugs.[89] For example, the United States interprets Article 39(3) of TRIPS to require a period of data exclusivity, which prevents drug regulatory authorities from referencing or relying on originator's confidential clinical data when assessing the therapeutic equivalence of a follow-on generic.[90] Repeating such clinical trials would be costly and time-consuming and would also ordinarily violate human subject guidelines, meaning that data exclusivity acts as a de facto barrier to generic registration.[91] Given rich countries' comparative advantage in research and development, the developed world secured near-absolute competitive advantage over the developing world's IPR-related industries via TRIPS.[92]

Even after the passage of TRIPS, the United States continued a heavy-handed trade policy, threatening countries such as Thailand, South Africa, and Brazil with trade sanctions because they refused to grant TRIPS-plus rights to patent holders or because they proposed using TRIPS-compliant means to access more affordable medicines.[93] As the HIV/AIDS pandemic intensified, and as treatment activists demanded a relaxation of the stranglehold patent holders had over life-saving medicines, developing countries collaborated to demand that public health be given a more meaningful role in the interpretation and implementation of the TRIPS Agreement.[94] Thus, the Africa Group, in early 2001, requested that the WTO TRIPS Council meet to clarify TRIPS's public health flexibilities.[95] On November 14, 2001, WTO members unanimously approved the Doha Declaration, which

89. *See id.* art. 39(3). For an extended discussion of options concerning appropriate use of undisclosed data, see Carlos María Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement (2002), http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf.

90. *See* Karin Timmermans, *Monopolizing Clinical Trial Data: Implications and Trends*, 4 PLoS Med. 206, 207 (2007).

91. *See* Baker, *Arthritic Flexibilities for Accessing Medicines*, *supra* note 2, at 709–10.

92. *See Table 5.13, World Development Indicators: Science and Technology*, World Bank, http://wdi.worldbank.org/table/5.13 (last visited Apr. 9, 2016).

93. *See* Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chi. J. Int'l L. 27, 30–33 (2002) (detailing U.S.T.R. and pharmaceutical industry actions against South Africa and Brazil); Brook K. Baker, *Myths and Realities: The Impact of the U.S.-Thai FTA on Access to Medicines*, CPTech (Jan. 25, 2006), http://www.cptech.org/ip/health/c/thailand/hgap01252006.html.

94. For a detailed account of this collaboration, see Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469, 480–90 (2002). Developing countries rejected the theory that differential pricing would meet their needs.

95. The Africa Group is the collection of all African countries that are in the relevant timeframe members of the World Trade Organization. With respect to the request of the Africa Group, see Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard from 2 to 5 April 2001*, WTO Doc. IP/C/M/30, ¶¶ 229–33 (June 1, 2001); Submission to TRIPS Council Discussion on Access to Medicines, *Developing Country Group's Paper*, WTO Doc. IP/C/W/296 (June 19, 2001), https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm.

emphasized the primacy of public health and the right of member nations to take measures to increase access to medicines for all.[96]

Although the Doha Declaration confirmed member states' freedom to issue compulsory licenses and rely on parallel imports as an alternative source for lower-cost medicines,[97] it left open sourcing issues for poor countries that could not produce medicines via domestic production because of insufficient or inefficient pharmaceutical capacity.[98] Even if these "non-producing" countries issued TRIPS-compliant compulsory licenses to importers and the exporting country also issued a compulsory license bypassing its domestic patent, the exporting company could only export non-predominant quantities pursuant to TRIPS Article 31(f).[99] Since sub-Saharan Africa has ten times as many HIV infections as India,[100] this export restriction meant that India's vibrant generic industry could never supply needed quantities in Africa. After twenty-one months of intense wrangling, WTO members finally resolved this problem with the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Paragraph 6 Decision").[101] The solution adopted is a procedural labyrinth,[102] and its effectiveness is increasingly in doubt as it has been used only once in twelve years, to allow export from Canada to Rwanda.[103]

While most upper-income WTO members had to comply with TRIPS by January 1, 1996, developing countries were able to make use of transition periods until 2000,[104]

96. Doha Declaration, *supra* note 80, ¶ 4.

97. *See id.* ¶ 5.

98. *See id.* ¶ 6.

99. Accordingly, if a medicine were patented in the exporting country and thus that country would need to issue a compulsory license, South Africa, with the highest number of people living with HIV and AIDS in the world, might not be able to import sufficient quantities to treat its population. This restriction could apply even to countries like India that did not previously patent medicines but would have to eventually do so with respect to medicines invented after 1994. *See* Baker, Processes and Issues for Improving Access to Medicines, *supra* note 2, at 15.

100. *See* UNAIDS, The Gap Report A18, A20 (2014), http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2014/UNAIDS_Gap_report_en.pdf.

101. General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Sept. 2, 2003).

102. *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317 (2005); Baker, *Arthritic Flexibilities for Accessing Medicines*, *supra* note 2.

103. Canada and Rwanda are the only two countries that have cooperated thus far to use the complex 30 August 2003 Decision, and accounts of that effort suggest that further use of "Canada's Access to Medicines Regime" is unlikely absent some key reforms. *See* Richard Elliot, *Delivery Past Due: Global Precedent Set Under Canada's Access to Medicines Regime*, 13 HIV/AIDS Pol'y & L. Rev. 1, 6 (2008). The practicability and effectiveness of the mechanism is the subject of a continuing debate at the WTO Council for TRIPS. *See generally* Kaitlin Mara, *Efficacy of TRIPS Public Health Amendment in Question at WTO*, Intell. Prop. Watch (Jan. 3, 2010), http://www.ip-watch.org/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/.

104. *See* TRIPS Agreement, *supra* note 78, art. 65(2).

and countries that did not previously provide product patent protection for pharmaceuticals or other fields of technology had until January 1, 2005 to introduce such protection.[105] In addition, least developed country (LDC) members were given a transition period until 2006.[106] Via two agreed-upon extensions of that initial transition period, LDCs now have until July 2021 to become fully compliant,[107] with the possibility of further extensions. Paragraph 7 of the Doha Declaration also extended the transition period for LDCs with respect to pharmaceutical products, data protections, and exclusive marketing rights until 2016.[108] That period has since been extended until January 1, 2033.[109]

Despite TRIPS's public health flexibilities having become more firmly enshrined post-Doha, the United States and European Union continued their offensive to expand their own industries' IP empires by shifting forums to bilateral and regional initiatives and using a ratchet strategy to always increase protections in subsequent agreements.[110] Such efforts focused on easing patent standards, lengthening patent terms, restricting adoption and use of flexibilities, adding new drug registration-related barriers to generic access, and greatly expanding enforcement measures.[111] In the African context, the U.S. Trade Representative sought such enhanced, TRIPS-plus IP rights and protections in trade negotiations with the Southern Africa Customs Union.[112] At the

105. *See id.* art. 65(4).

106. *See id.* art. 66(1).

107. *Responding to Least Developed Countries' Special Needs in Intellectual Property*, World Trade Org., https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm (last updated Oct. 16, 2013).

108. Doha Declaration, *supra* note 80, ¶ 7; *see also* Council for TRIPS, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/25 (July 1, 2002); General Council, *Least-Developed Country Members—Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products*, WTO Doc. WT/L/478 (July 12, 2002).

109. Council for TRIPS, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO Doc. IP/C/73 (Nov. 6, 2015).

110. The intellectual property ratchet "means that each subsequent bilateral or multilateral agreement can and usually does establish a higher standard of IP protection." 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), http://www.anu.edu.au/fellows/pdrahos/reports/pdfs/2003globalipratchet.pdf.

111. *See, e.g.*, Flynn et al., *supra* note 2, at 152, 177–78, 181 n.245; Dalindyebo Shabalala, Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries: What Way Forward After the Cariforum EPA and the Interim EPAs? 10 (2008) (unpublished manuscript), http://www.ciel.org/Publications/Oxfam_TechnicalBrief_5May08.pdf; *see also* Carlos M. Correa, Negotiation of a Free Trade Agreement European Union-India: Will India Accept TRIPS-Plus Protection? 10–12 (2009); Jean-Frédéric Morin, *Tripping up TRIPS Debates IP and Health in Bilateral Agreements*, 1 Int'l J. Intell. Prop. Mgmt. 37 (2006).

112. On November 5, 2002, U.S. Trade Representative Robert B. Zoellick formally notified congressional leaders of the administration's intent to initiate negotiations for a free trade agreement with the nations of the Southern Africa Customs Union (SACU): Botswana, Lesotho, Namibia, South Africa, and Swaziland. To meet "standard[s] of protection similar to that found in U.S. law and that build on the foundations established" in TRIPS, SACU nations would have been required to limit compulsory

time, there was a strong argument that these efforts violated U.S. law[113] and an even stronger argument that that they violated international human rights law.[114]

V. TRIPS MINIMUMS, TRIPS-PLUS, AND TRIPS PUBLIC HEALTH FLEXIBILITIES

Before detailing the Fix the Patent Laws Campaign, it will be useful to briefly summarize global initiatives for fundamental redrawing of IP norms and the more modest public health flexibilities that South Africa is free to adopt within the TRIPS regime. Naturally, it is possible to argue that the one-size-fits-all TRIPS regime is ill-adapted to meet the developmental needs and human rights obligations of low- and middle-income countries. The Global Commission on HIV and the Law has gone so far as to demand a moratorium on enforcement of TRIPS with respect to pharmaceuticals, a cessation of trade pressure for low- and middle-income countries to adopt TRIPS-plus measures, and a United Nations review of the current monolithic, IP-centric legal regime with respect to medicines.[115] Consultations have also been underway at the World Health Organization via its Global Strategy and

licenses to national emergencies or to governmental, non-commercial use only, to bar parallel trade, to extend patent monopolies for administrative delays, and to link drug registration rights to patent status. *Zoellick Letter to House and Senate Reveals USA Trade Designs on Africa*, Afr. Faith & Justice Network (Nov. 4, 2002), http://www.mindfully.org/WTO/Africa-Zoellick-Trade4nov02.htm. Finally, these nations would have been required to enhance protections for clinical trial testing data and to adopt criminal enforcement for patent violations, including improvidently granted compulsory licenses. In sum, the proposed negotiation objectives would completely eviscerate the Doha flexibilities, dramatically increase IP protection, and shamefully reduce access to more affordable generic products. *See id*.; Tenu Avafia, *The Potential Impact of US-SACU FTA Negotiations on Public Health in Southern Africa* (Trade Law Centre for Southern Africa, Working Paper No. 6/2004, 2004), www.cptech.org/ip/health/trade/sacu/avafia112004.doc. Fortunately, the negotiations were suspended in 2006.

113. These intellectual property negotiation objectives also directly violate the principal negotiating objectives in the Trade Act of 2002, which requires the United States "to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001." 19 U.S.C. § 3802(b)(4)(C) (2002). Similarly, by seeking TRIPS-plus provisions found in U.S. law, the U.S. Trade Representative also directly violated Executive Order 13155, which in relevant part reads:

> (a) In administering sections 301–310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:
>
> (1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and
>
> (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

Exec. Order No. 13155, 65 Fed. Reg. 30,521 (May 10, 2000).

114. *See* Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2.

115. *See* Glob. Comm'n on HIV and the Law, Risks, Rights & Health 86 (2012), http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf.

Plan of Action on Public Health, Innovation, and Intellectual Property, which recommends even more radical solutions for rectifying imbalances in the innovation and access ecology.[116] Despite the potential merits of these more ambitious critiques of the IP system, pragmatic campaigners have focused on TRIPS flexibilities to ensure that they are adopted and used.[117]

Figure 1: Key TRIPS Public Health Flexibilities[118]

Art. 27 Standards of patentability	• Strict standards of patentability, especially concerning combinations of prior art, novelty, inventive step, and industrial applicability • A requirement that variations of existing medicines demonstrate significantly enhanced therapeutic efficacy • No patents on new uses of existing medicines • No patents on combinations or admixtures of known medicines • No presumption of patentability
Art. 27.3 Exclusions from patentability	• No patents on surgical, diagnostic, and therapeutic methods—can justify no new uses and methods of use patents • No patents on plants or animals, except sui generis system for plant varieties • No patents on genes or extractions from naturally occurring matter • No patents on abstract ideas, discoveries, theories of nature, computer software, or business methods
Art. 29 Disclosure	• Applicant must disclose all known practical methods of carrying out the invention, and the best known mode • Patent holder must disclose status of corresponding applications and patents in other jurisdictions and the international non-proprietary names for medicines

116. *See* World Health Org. [WHO], Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2011), http://apps.who.int/medicinedocs/documents/s19648en/s19648en.pdf. For follow-up reports of the Consultative Expert Working Group on Research and Development: Financing and Coordination, see World Health Org. [WHO], Report by the Secretariat, WHO Doc. A/CEWG/3 (Nov. 2, 2012), http://www.who.int/phi/cewg/en/; World Health Org. [WHO], Report of the Open-ended Meeting of Member States on the Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, Geneva, 26–28 November 2012, WHO Doc. A/CEWG/4 (Dec. 5, 2012), http://www.who.int/phi/cewg/en/; World Health Org. [WHO], Report of the Regional Committee Discussions by the Director-General, WHO Doc. A/CEWG/2 (Nov. 7, 2012), http://www.who.int/phi/cewg/en/.

117. *See* Brook K. Baker, *Placing Access to Essential Medicines on the Human Rights Agenda*, *in* The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing, and Pricing 239, 244–45 (Jillian Clare Cohen et al. eds., 2006).

118. *See* TRIPS Agreement, *supra* note 78.

Arts. 62.4 and 32 Opposition procedures and grounds for revocation	• Pre- and post-grant opposition procedures allowed with broad standing rights and easy-to-use administrative procedures • Broad grounds for revoking patents, including inequitable conduct, fraud, non-payment of patent maintenance fees, failure to make required disclosures, and failure to satisfy requirements or standards of patentability
Patent term	• No provision requiring extensions for regulatory delays
Art. 30 Limited exceptions	• Early working of pharmaceutical patents allowed both domestically and for export for the purpose of obtaining regulatory approval • Commercial and non-commercial research rights and educational use rights • Prior use and private, non-commercial use • Formulation at pharmacies for individual use • And other limited exceptions as needed, including exception from Article 31(f) with respect to production for export
Art. 6 Parallel importation	• Adoption of international exhaustion rule and easy parallel import procedures • Outlaw contractual limitations on export in support of parallel importation
Arts. 31 and 44.2 Compulsory licenses and government use	• Broad grounds for issuing compulsory licenses, including but not limited to excessive pricing, refusal to license or to permit use of an essential facility, failure to supply in sufficient quantities, failure to work, including local working, ensuring source of supply, and allowing combination products ◦ Reasonable time limits on required prior negotiations ◦ Easy-to-use administrative procedures ◦ Continued validity of license pending appeal • Licenses based on emergencies or matters of extreme urgency, public, non-commercial-use, and competition violations without prior negotiation • Competition-based licenses without restrictions on quantities exported • Production for export licenses either pursuant to the Paragraph 6 Decision or an Article 30 limited exception • Judicial licenses allowed pursuant to Article 44.2 • Clear, easy-to-use remuneration guidelines established

Arts. 8.2 and 40 Competition policies	• Prevent abuse of IP rights by right holders, licensing practices, or the resort to other practices that unreasonably restrain trade or adversely affect transfer of technology

VI. SOUTH AFRICA'S POROUS PATENTS ACT

Having catalogued TRIPS flexibilities, it is now time to examine the South African Patents Act 57 of 1978 as amended (the "Patents Act")[119] to discern whether it fulfills the government's TRIPS obligation to take all available legislative measures to ensure access to medicines. Although the Patents Act has many defects in terms of maximizing TRIPS's public health flexibilities, the most obvious is its failure to require examination of patent applications, instead allowing a "depository" regime.[120] Under this regime, the Companies and Intellectual Property Registry Office (CIPRO) collects patent applications but does not examine novelty, inventive step, or industrial applicability.[121] Instead, CIPRO only ascertains if the correct forms are filled out and payment has been made; thereafter, the application is approved without any substantive review whatsoever.[122] Compounding this problem, patent application fees in South Africa are among the lowest in the world, twenty to thirty times cheaper than other patent regimes.[123]

To say that South Africa has a problem in terms of its excessive granting of patents on medicines is an understatement.[124] South Africa granted 2,442 patents on medicines in 2008 alone.[125] South Africa grants about forty per cent more patents on medicines than even the European Union or the United States.[126] In contrast, Brazil granted only 278 patents from 2003 to 2008, Columbia granted 439 from 2004 to

119. Patents Act 57 of 1978.

120. *See id.* § 34 ("The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it."). Substantive examination is not prescribed by implementing regulations.

121. Anthipi Pouris & Anastassios Pouris, *Patents and Economic Development in South Africa: Managing Intellectual Property Rights*, 107 S. Afr. J. Sci., Nov./Dec. 2011, Art. # 355, at 5.

122. *Id.* at 111–12.

123. *Id.* at 6.

124. *Id.* (estimating that eighty per cent of South African patents would not have been granted were they actually examined); *see also* Catherine Tomlinson & Lotti Rutter, *The Economic & Social Case for Patent Law Reform in South Africa* (Treatment Action Campaign Research Paper, 2014), http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf.

125. Carlos Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* 7 (South Centre Research Paper No. 41, 2011), http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf.

126. Amy Kapczynski, Chan Park & Bhaven N. Sampat, *South African Pharmaceutical Patenting: An Empirical Analysis*, Treatment Action Campaign (Oct. 23, 2012), http://www.tac.org.za/sites/default/files/resources/Create%20Resources/files/Sampat%20presentation.pdf.

2008, and Argentina granted 951 from 2000 to 2007.[127] Likewise, India granted only 3,488 patents between 2005 and 2010.[128]

Given its despository system, it is no surprise that South Africa has no patent opposition procedures. Making opposition procedures open to competitors and other interested parties could result in information and argumentation about prior art and standards of patentability leading to higher quality patents. Many countries, most notably India, have successfully adopted both pre- and post-grant opposition procedures.[129] In contrast, competitors in South Africa are left to costly, time-consuming, and economically impractical court invalidation procedures. Compounding the problem, South Africa has an untransparent patent registry that provides only limited information on patent applications, grants, and a filing's current status.[130]

Although South Africa has relatively high standards of novelty,[131] except that new therapeutic or diagnostic methods shall be considered novel, its inventive step requirement is weak both on the books and as applied.[132] As a result, patent holders can file recursive patent applications and thus evergreen their patent monopolies for minor changes in the form of the active pharmaceutical ingredient and in formulations and dosages.[133] Extensive academic commentary suggests that such evergreening is a major problem.[134] Also, the requirement that the invention be capable "of being used

127. Correa, *supra* note 125, at 7.

128. Sushmi Dey, *Drug Patents on the Rise: 3,488 in 5 Years*, Bus. Standard (Sept. 24, 2012), http://www.business-standard.com/article/companies/drug-patents-on-the-rise-3-488-in-5-years-112092400024_1.html.

129. *See* World Intellectual Prop. Org. [WIPO], Standing Committee on the Law of Patents, Eighteenth Session, *Opposition Systems and Other Administrative Revocation and Invalidation Mechanisms*, WIPO Doc. SCP/18/4 (April 3, 2012), http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf.

130. *See* Pouris & Pouris, *supra* note 121, at 6.

131. *See* Patents Act 57 of 1978 § 25(5)–(9).

132. *See id.* § 25(10) ("Subject to the provisions of section 39(6), an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8)).."). For a recent example of a weak application of the inventive step requirement, see *Pharma Dynamics (Proprietary) Ltd. v. Bayer Pharma AG* [2014] (4) All SA 302 (SCA) (holding that formulation with an enteric was sufficiently inventive to allow a secondary patent on rapidly soluble oral contraceptive).

133. *See* Tomlinson & Rutter, *supra* note 124, at 8–9.

134. The UK Commission on Intellectual Property Rights recommended that developing countries exclude medical methods from patentability, "[a]void patenting of new uses of known products," and "[a]pply strict standards of novelty, inventive step and industrial application or utility (consider higher standards than currently applied in developed countries)." Comm'n on Intellectual Prop. Rights, Integrating Intellectual Property Rights and Development Policy 122 (2002); *see also* Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 Health Aff. 2286 (2012); C. Scott Hemphill & Bhaven Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2012); Carlos Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain* (South Centre Research Paper No. 52, 2014), http://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_

or applied in trade or industry or agriculture"[135] is barely defined, except with respect to an exclusion for surgical, therapeutic, or diagnostic methods.[136]

With respect to limited exceptions allowed by Article 30 of TRIPS, the Patent Act is also deficient. South Africa does not have a robust research and education exception that allows research with and on patented technologies for commercial, non-commercial, or educational purposes.[137] This weakens university research and incremental research in general, particularly in the generic pharmaceutical industry that South Africa is trying to strengthen. Article 6 of TRIPS[138] also expressly allows countries flexibility to adopt an international exhaustion rule, permitting parallel importation of medicines lawfully placed on the market in other countries. Unfortunately, regulations implementing section 15C's allowance of parallel importation[139] are overly complex, rendering it essentially unusable.

Similarly, compulsory and government use licenses, allowed under Article 31 of TRIPS, are incompletely operationalized in South African law. On the plus side, South Africa permits compulsory licenses for dependent patents that represent important technical advances of considerable economic significance.[140] The Patents Act also allows compulsory licenses on the grounds of: (1) failure to work within a specified period of time,[141] (2) failure to meet demand for the patented article to an adequate extent and on reasonable terms,[142] (3) detrimental refusal to grant a license on reasonable terms,[143] and (4) excessive prices for imported goods in relation to prices charged in countries where those goods are manufactured.[144] However, these grounds are still incomplete in that the Patents Act does not have a general public health or public interest exception, a clear unreasonable price exception, a local-

EN.pdf; Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLoS ONE (Dec. 5, 2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470#s1.

135. Patents Act 57 of 1978 § 25(1).

136. *Id.* § 25(11)–(12).

137. Evans Misati & Kiyoshi Adachi, U.N. Conference on Trade and Dev. [UNCTD] & Int'l Ctr. for Trade and Sustainable Dev. [ICTSD], The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda, Policy Brief No. 7, at 7 (2010), http://www.ictsd.org/sites/default/files/research/2011/12/the-research-and-experimentation-exceptions-in-patent-law-jurisdictional-variations-and-the-wipo-development-agenda.pdf.

138. TRIPS Agreement, *supra* note 78, art. 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.").

139. *See* Medicines and Related Substances Act 101 of 1965 § 7.

140. *See* Patents Act 57 of 1978 § 55; TRIPS Agreement, *supra* note 78, art. 31(l)(i).

141. Patents Act 57 of 1978 § 56(2)(a).

142. *Id.* § 56(2)(c).

143. *Id.* § 56(2)(d).

144. *Id.* § 56(2)(e).

working exception, a competition-based exception,[145] or an exception grounded in the need to produce fixed-dose medicines combining products from multiple patent holders. In addition, the procedural requirements for issuing compulsory licenses are unduly burdensome and time-consuming and the Patents Act lacks remuneration guidelines. The result of these omissions is that no compulsory licenses on medicines have ever been issued in South Africa. Finally, despite provisions for acquisition of patents by the state and for "public purpose" use by a Minister of State,[146] there are no specific provisions for public, non-commercial use licenses or for licenses in response to national emergencies or other matters of extreme urgency, though both might be covered by the public purpose language. Section 4 also unnecessarily requires negotiated agreement with the patent holder prior to issuing a compulsory license or a protracted formal court hearing with court appeal rights,[147] neither of which is required by TRIPS Article 31.

This is by no means an exhaustive list of defects in the Patents Act,[148] but these deficits have been well known to Section27[149] and to TAC and MSF activists. However, with the emergence of multi-drug resistent tuberculosis, hepatitis C, and other HIV co-infections, and with the exhorbitant prices often charged for medicines to treat these and other conditions, AIDS activists were becoming increasingly concerned post-2007 about the overarching structural defects in South Africa's IP regime. They recognized that the high cost of medicines needed to treat other conditions, including the exploding burden of non-communicable diseases,[150] meant that South Africa had fewer resources to expand its health workforce and strengthen its public sector health services. Activists knew that the DTI had begun deliberations on a new IP policy for South Africa in 2008. Accordingly, beginning in 2011, TAC once again turned its attention to the IP-determinants of unaffordable prices for

145. There is an argument that the abuse of rights section at least partially covers violations of competition policy. *See* Jonathan Berger, *Advancing Public Health by Other Means: Using Competition Policy*, *in* Negotiating Health: Intellectual Property and Access to Medicines 181, 188 (Pedro Roffe et al. eds., 2005).

146. Patents Act 57 of 1978 § 4.

147. *Id.*

148. For example, the TRIPS Agreement allows for the use of competition policy to prevent abuse of IP rights under the Patents Act and to permit close regulations of the terms of IP licensing agreements. *See* TRIPS Agreement, *supra* note 78, arts. 8(2), 40. In addition, the South Africa IP regime has some excessive provisions in its IP enforcement rules that might also be revised. *See* Frederick Abbott et al., United Nations Dev. Programme [UNDP], Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries (2014), http://www.undp-globalfund-capacitydevelopment.org/media/468621/undp-using_competition_law_to_promote_access_to_medicine-05-14-2014.pdf.

149. Section27, the successor to the AIDS Law Project, has expanded its focus beyond HIV and AIDS and even health and is now focused more broadly on socioeconomic rights. *See* Section27, http://section27.org.za (last visited Apr. 9, 2016).

150. *See* Bongani M. Mayosi et al., *The Burden of Non-Communicable Diseases in South Africa*, 374 Lancet 934 (2009).

medicines and announced its interest in receiving intensive training on IP and access to medicines.[151]

VII. ADVOCACY-ORIENTED TEACHING AND LEARNING AT THE INTERSECTIONS OF HUMAN RIGHTS, INTELLECTUAL PROPERTY, AND ACCESS TO MEDICINES[152]

Historically, specialist training in IP "was offered by institutions operating within the UN system, such as the World Intellectual Property Organisation (WIPO), or patents offices in developed countries."[153] Such training has been criticized because developing country policymakers and patent examiners tended to adopt the biases and priorities of their pro-IP advisors and trainers.[154] Similarly, in South Africa, IP has typically been taught from a pro-IP, pro-corporate perspective.[155] A developmental, human rights-based approach, by contrast, would situate IP analysis in the developing country context, with specific attention to human rights, public health, and other public interest concerns. Some South African university courses in the late 2000s were beginning to adopt this perspective, most notably at the Masters level.[156] However, these courses were "generally aimed at post-graduate students or public sector employees."[157] Additionally, "[n]o course previously catered for the training, participation or perspectives of activists and advocacy specialists . . . ."[158]

In an effort to increase activist participants' knowledge about IP within a human rights framework, capacitate participants to engage in country and regional campaigns to overcome IP barriers, and promote access to medicines, Yousuf and I

151. These observations emerged from series of conversations with MSF and TAC activists during the UKZN IP and Access to Medicines short course in 2011. For a discussion of the material covered in the course, see *infra* notes 154–65.

152. This section is largely drawn from Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2.

153. Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2, at 77–78; *see also* John Braithwaite & Peter Drahos, Global Business Regulation 83 (2000); Peter Drahos, "*Trust Me": Patent Offices in Developing Countries*, 34 Am. J.L. & Med. 151 (2008); World Intell. Prop. Org., http://www.wipo.int/portal/en/ (last visited Apr. 9, 2016).

154. *See* Carolyn Deere Birkbeck & Santiago Roca, An External Review of WIPO Technical Assistance in the Area of Cooperation for Development (2011), http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf; Drahos, *supra* note 153, at 153. Recently, a more balanced approach to the training has been offered by the United Nations Development Programme in collaboration with international NGOs such as South Centre. United Nations Dev. Programme & South Centre, *Intellectual Property Enforcement and Access to Essential Medicines* (Regional Consultation, 2011) (on file with author).

155. *See* Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2, at 78.

156. The University of Pretoria's Centre for Human Rights, for example, offers a one-week short course on "Human rights and Access to Medicines." *See Access to Medicines*, U. Pretoria, http://www.chr.up.ac.za/index.php/about-access-to-medicines.html (last visited Apr. 9, 2016).

157. Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2, at 78.

158. *Id.*

developed an intensive two-week shortcourse[159] that was supported by the Open Society Institute and delivered at UKZN.[160] In addition to focusing on economic, legal, and regulatory issues affecting access to medicines, the course also devoted a full third of its curriculum to the development of strategic access-to-medicines campaigns by its participants. The objectives of the course were multifaceted and the subject matter diverse, but the fundamental pedagogy was one of collaboration and mutual learning oriented towards action. A variety of instructional methodologies was used, based primarily on exploring successful access-to-medicines campaigns and using a problem-solving pedagogy. There were formal presentations of complex material by the two co-instructors and other experts,[161] in addition to small- and large-group discussions, breakaway sessions, and snap one-on-one discussions on critical or confusing points. Participants were also required to write reaction papers on assigned topics. In addition, instructors used media, roleplay, and debates to enhance understanding of key concepts.

The main innovation of the course was to set aside three days for participants to work in country-based affinity groups to develop detailed strategic plans for actionable access-to-medicines campaigns. Participants conducted research and identified campaign goals, targets, strategies, and tactics. Midway through their strategy development, there were "grand rounds" where each planning team presented its emerging campaign for feedback and comment from other course participants. Finished campaigns were presented again on the last day of the course and received feedback and comment from the course instructors and other course participants.[162] As hoped, "[o]ne significant outcome generated by this course [was] the emergence of a pan-African solidarity among the participants."[163] In addition, "[t]he intensive

159. *Id.* The course attempted, relatively unsuccessfully, to engage public officials. We did have two successes in this regard with the participation of an officer from the patent office in Zambia and a counsel to the Legislative Drafting Committee of the Ugandan Parliament. We also succeeded in attracting several academics from the Universities of KwaZulu-Natal and Zululand (South Africa), Makerere (Uganda), University of Malawi, and the National University of Lesotho.

160. Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2, at 78 n.118 ("[T]he UKZN School of Law . . . offered a short course on Intellectual Property and Access to Medicines, training . . . academics."); *see also Intellectual Property and Access to Medicines*, U. KwaZulu-Natal, http://ipatm.ukzn.ac.za/Homepage.aspx (last visited Apr. 9, 2016).

161. We are especially grateful for the participation of experts such as Jonathan Berger, then from Section27; Andy Gray, Senior Lecturer and pharmaceutical expert from the Nelson R. Mandela School of Medicine, University of KwaZulu-Natal; Sean Flynn from the Washington College of Law, American University; Jerome Singh, lecturer from UKZN and ethical officer for Centre for the AIDS Programme of Research in South Africa; Anand Pillay from the South African Department of Health; Malebakeng Forere, Tabello Thabane, Ann Strode, and Devina Perumal from the UKZN faculty of law; Enga Kameni from the University of Pretoria; and various civil society experts including Catherine Tomlinson, TAC South Africa, and Paul Kasonkomona, Treatment Advocacy and Literacy Campaign Zambia.

162. Graduates of the UKZN course have also been involved in grassroots campaigns relating to stock-outs of medicines, demands for faster rollout of HIV treatment programs, the adoption of safer medicines, and earlier initiation of treatment.

163. Vawda & Baker, *Achieving Social Justice in the Human Rights/Intellectual Property Debate*, *supra* note 2, at 80.

interaction over two weeks yield[ed] a strong camaraderie, and participants develop[ed] a deeper understanding of their respective realities, challenges and prospects for change."[164] They continue to offer one another guidance and support in their work, usually on an informal basis.[165] It was within this framework that the 2011 participants in the course planned the Fix the Patent Laws Campaign.[166]

VIII. TAC, MSF, AND SECTION27 LAUNCH THE FIX THE PATENT LAWS CAMPAIGN

On November 16, 2011, almost exactly ten years after the Doha Declaration on the TRIPS Agreement and Public Health, TAC and MSF formally launched the Fix the Patent Laws Campaign (the "Campaign").[167] In its first press release, TAC directly referenced the constitutional guarantee of the right to health.[168] TAC's November issue of its *Equal Treatment* magazine was devoted entirely to an explanation—in lay terms—of why the South African Patents Act had to be reformed for treatment access to occur.[169] In January 2012, the Campaign issued a briefing document outlining needed reforms: (1) improved substantive standards and streamlined procedures for issuing compulsory licenses; (2) stricter standards for patentablity, excluding patents on new forms, uses, or formulations of existing medicines; and (3) adoption of a rigorous patent examination system with pre- and post-grant opposition.[170] In February, TAC contacted the DTI about its delayed IP policy, delivering a letter requesting a meeting with Rob Davies, the Minister of Trade and Industry, to discuss the IP policy and Patents Act amendments that were needed.[171]

Trying to persuade the media to take a more active role in reporting the urgency of patent law reform, TAC and MSF organized two media workshops on IP and access to medicines in late March 2012.[172] To mobilize health activists, TAC and MSF organized a workshop at the July 2012 People's Health Assembly[173] and

164. *Id.*

165. *See id.*

166. In 2012, course participants refined a similar plan concerning reform of the Industrial Property Act that was underway in Uganda.

167. *See* Press Release, Treatment Action Campaign, TAC Calls on Government to Amend South Africa's Patents Act and Protect Our Right to Health (Nov. 16, 2011), http://www.fixthepatentlaws.org/?p=17.

168. *Id.*

169. *Fix the Laws—Save Our Lives!*, Equal Treatment, Nov. 2011, at 1.

170. *Fix the Patent Laws: Campaigning for Pro-Public Health Reform of South Africa's Patents Act*, Fix The Pat. Laws (Jan. 26, 2012), http://www.fixthepatentlaws.org/?p=79.

171. Although the DTI had been promising release of its heretofore hidden IP policy for some time and had promised public consultations as well, the effort was marked by lethargy rather than alacrity. *See South Africa's Intellectual Property Policy: Process for Public Consultation?*, Fix The Pat. Laws (Feb. 14, 2012), http://www.fixthepatentlaws.org/?p=116.

172. *TAC/MSF Media Workshop on Intellectual Property and Access to Medicine*, Fix The Pat. Laws (Mar. 2, 2012), http://www.fixthepatentlaws.org/?p=136.

173. *Invitation to Attend TAC and MSF Workshop During the Peoples Health Assembly*, Fix The Pat. Laws (June 27, 2012), http://www.fixthepatentlaws.org/?p=338. Professor Vawda spoke at this workshop.

organized a public lecture on patent law reform.[174] TAC's public messaging strategy included a brochure[175] and a myth-buster paper.[176] Responding to this pressure, the DTI's Chief Director of Policy and Legislation announced that the Draft IP Policy would be submitted to the Cabinet on December 5, 2012.[177] When the December date passed, TAC called on the DTI to submit its IP policy at the Cabinet's January 2013 sitting,[178] and when that date was missed, another call for action was issued.[179]

Their patience at an end, TAC activists picketed the African Intellectual Property Forum and delivered a memorandum to Minister Davies before his keynote address.[180] Although the Minister predicted that the policy would be released shortly, once again it was delayed.[181] Unsatisfied, TAC and MSF delivered yet another demand to the DTI in August.[182] The DTI finally released its Draft IP Policy and invitation for public comment on September 4, 2013.[183]

In response to the freshly released Draft IP Policy, TAC, MSF, and Section27 expressed appreciation and promptly organized consultations in Johannesburg and Cape Town to discuss the policy with other members of civil society.[184] Meanwhile, TAC members, MSF, and Section27 experts worked on a formal response. With the fruit of that labor in hand, protestors marched to the DTI in October 2013 and handed in a joint submission commenting on the Draft IP Policy.[185] Shortly

174. *Invitation to a Public Lecture at UCT: Fix the Law, Save our Lives*, Fix The Pat. Laws (June 6, 2012), http://www.fixthepatentlaws.org/?p=302.

175. Treatment Action Campaign & Médecins Sans Frontières, Fix the Patent Laws!, Campaign Brochure, http://fixthepatentlaws.org/brochure/Fix%20the%20patents%20web.pdf.

176. *Myth-Buster*, Fix the Pat. Laws, http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/TAC_MythBuster_Patent_Reform.pdf (last visited Apr. 9, 2016).

177. *TAC and MSF Welcome Government's Announcement that the Draft IP Policy Will Be Presented to Cabinet on 5 December 2012*, Fix the Pat. Laws (Oct. 29, 2012), http://www.fixthepatentlaws.org/?p=459. Professor Vawda presented at this consultation as well.

178. *TAC Calls on the Department of Trade and Industry to Submit the IP Policy to Cabinet at its Next Sitting in January 2013*, Fix the Pat. Laws (Dec. 13, 2012), http://www.fixthepatentlaws.org/?p=523.

179. *TAC Calls on the DTI to Set a New Date for Submission of the IP Policy to Cabinet*, Fix the Pat. Laws (Jan. 18, 2013), http://www.fixthepatentlaws.org/?p=526.

180. *Activists Make Concerns Heard at African IP Forum—Minister Davies Responds*, Fix the Pat. Laws (Feb. 27, 2013), http://www.fixthepatentlaws.org/?p=540.

181. *DTI Reneges on IP Policy Commitments*, Fix the Pat. Laws (April 30, 2013), http://www.fixthepatentlaws.org/?p=583.

182. *TAC & MSF Memorandum to DTI to Urgently Fix the Patent Laws*, Fix the Pat. Laws (Aug. 7, 2013), http://www.fixthepatentlaws.org/?p=630.

183. Draft National Policy on Intellectual Property 2013 and Invitation for the Public to Comment, GN 918 of GG 36816 (4 Sept. 2013).

184. *Public Consultation on Draft National Policy on Intellectual Property—27th Sept*, Fix the Pat. Laws (Sept. 20, 2013), http://www.fixthepatentlaws.org/?p=673.

185. *See South Africa: Stop Blindly Handing Out Patents!*, Fix the Pat. Laws (Oct. 17, 2013), http://www.fixthepatentlaws.org/?p=777. *See generally* Médecins Sans Frontières, Treatment Action Campaign & SECTION27, Joint Submission on the Draft National Intellectual Property Policy, 2013 (Oct. 17,

thereafter, TAC and MSF prepared a more technical analysis of why South Africa could and should adopt a patent examination system.[186] Although the central demands of the joint submission were similar to those articulated twenty-three months earlier, TAC and MSF had to balance continuing advocacy for needed reform with some positive acknowledgement of the commitments to a more pro-access approach articulated in the somewhat confusing and poorly written Draft IP Policy. Knowing that the Draft IP Policy would face stiff opposition from IP industries, especially pharmaceuticals, the joint submission recognized South Africa's commitment to consider adoption of a patent examination system.[187] Nonetheless, the joint submission made a very concrete set of key recommendations.[188]

2013) [hereinafter MSF, TAC & Section27 Joint Submission], http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf.

186. *See* Treatment Action Campaign, Médecins Sans Frontières & Research and Info. Sys. For Developing Countries, Briefing by TAC, MSF and RIS: Why South Africa Should Examine Pharmaceutical Patents (2012), http://www.tac.org.za/community/files/file/WhySAneedsanexaminationsystem.pdf.

187. MSF, TAC & Section27 Joint Submission, *supra* note 185, ¶ 54.

188. Specifically, the recommendations include:

> 6.1. On patentability criteria:
>
> 6.1.1. The Patents Act should be amended to include stricter patentability criteria; and
>
> 6.1.2. In the context of medicines and other health-related products, new uses and methods of treatment should expressly be precluded from being granted patent protection; new forms of known substances should not be patentable to the extent that they fail to demonstrate the required degree of inventive step, strictly construed;
>
> 6.2. On patent searches:
>
> 6.2.1. CIPC online patent search database should be improved to facilitate access to accurate information on patents for ordinary users of the system. This would in turn help stakeholders, such as civil society take action to limit the granting of abusive medicines patents.
>
> 6.3. On substantive patent examination and opposition proceedings:
>
> 6.3.1. Recognising that the Patents Act already requires substantive patent examination, we call for the making of regulations dealing with the establishment and phased implementation of a substantive patent examination system; and
>
> 6.3.2. The Patents Act should provide for meaningful pre- and post-grant opposition mechanisms that recognise broad standing requirements inclusive of civil society and adequate access to information to facilitate such interventions;
>
> 6.4. On the relationship between medicines registration and patent protection:
>
> 6.4.1. Other than what is already contained in section 69A of the Patents Act, no linkage between medicine registration and patent protection should be recognised; and
>
> 6.4.2. Remedies for addressing delays in medicine registration processes should exclude patent extensions;

Yousuf and I continued to support the Campaign by reviewing campaign documents and writing blogs.[189] Recognizing that it would be important to garner

6.5. On compulsory licensing and parallel importation:

6.5.1. The current process in terms of section 56 of the Patents Act should be replaced by a simple, expeditious administrative procedure that is subject only to review proceedings in the High Court or the Court of the Commissioner of Patents. Government use licenses should not require any review proceedings in the High Court;

6.5.2. Pending any review of the grant of a compulsory license, interim relief should only be available—upon application—in exceptional circumstances and should not be available for the exercise of government use licenses;

6.5.3. Default positions regarding license conditions (including but not limited to royalty rates) and negotiation timelines should expressly be included in sections 4 and 56 of the Patents Act;

6.5.4. Licensing practices should expressly be regulated, as contemplated by Article 40 of TRIPS; and

6.5.5. Regulation 7 of the General Regulations made under the Medicines and Related Substances Act 101 of 1965 ("the Medicines Act") should be amended to give full effect to section 15C(b) dealing with parallel importation;

6.6. On research and development ("R&D"), public funding, innovation and access:

6.6.1. The Department of Trade and Industry ("the dti") should collaborate with relevant departments and statutory councils to ensure that publicly-financed R&D in South Africa is aimed at delivering affordable inventions; and

6.6.2. In particular, the dti should engage with the Department of Science and Technology ("DST") regarding the need to consider possible amendments to the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008 ("the IPRs from Publicly Financed R&D Act");

6.7. On exceptions to patent infringement:

6.7.1. The Patents Act should exempt those aspects of scientific research that are not covered by section 69A; and

6.7.2. The Patents Act should also include an educational use exception;

6.8. On data protection and exclusivity:

6.8.1. Calls for data exclusivity should be rejected on the basis that they are not required by Article 39.3 of TRIPS and they unreasonably and unjustifiably limit access to medicines; and

6.8.2. The status quo in this regard should be retained, with the Patents Act only making provision for data protection.

Id. ¶ 6.

189. *See, e.g.*, *Open Letter: Promoting Access to Affordable Medicines in South Africa Through Patent Law Reform*, Fix the Pat. Laws (June 15, 2015), http://www.fixthepatentlaws.org/?p=959; *Over 130 International Organisations & Experts Demand Patent Law Reform in South Africa!*, Fix the Pat. Laws (Oct. 17, 2013), http://www.fixthepatentlaws.org/?p=773; Yousuf Vawda, *The IP Debate—Let's Not Be Fooled…*, Fix the Pat. Laws (Sept. 19, 2013), http://www.fixthepatentlaws.org/?p=662. Yousuf also co-authored a book chapter assessing a pre-draft of the IP Policy. Andy Gray, Yousuf Vawda & Caron Jack, *Health Policy and Legislation*, *in* South African Health Review 2012/2013, at 3 (2013).

expert analysis supporting the basic pro-public health thrust of the Draft IP Policy, we collaborated to obtain the signatures of over 140 organizations and global experts on an open letter to the DTI supporting the proposed patent law reform.[190] In addition, along with other pro-access South African academics, we authored a submission to the DTI assessing the strengths and weaknesses of the Draft IP Policy,[191] while authors of an influential United Nations Development Programme (UNDP)[192] report again detailed the need for broad reform.[193]

Although TAC and MSF had anticipated industry opposition to the Campaign and had discussed strategies for neutralizing that opposition as part of the UKZN course, even seasoned activists were surprised by leaks about the U.S.-based pharmaceutical industry's well-funded but covert disinformation campaign against the proposed reform.[194] Hundreds of thousands of dollars were spent setting up a campaign funded by U.S. companies but presented as if locally inspired and led.[195] Circulation of a leaked e-mail initiated a scandal, now called Pharmagate, and the activist and government response was prompt and harsh.[196] Health Minister Aaron Motsoaledi described the plan as "genocide" and the conspiracy one of "satanic magnitude."[197] The issue received international attention at an Executive Board meeting of the World Health Organization.[198] Besides immediately condemning the

190. *Over 130 International Organisations & Experts Demand Patent Law Reform in South Africa!*, *supra* note 189.

191. Tobias Schonwetter & Yousuf A. Vawda et al., Comments on Draft National Policy on Intellectual Property (IP) of South Africa, 2013 (Oct. 17, 2013), http://ip-unit.org/wp-content/uploads/2013/10/IP-Policy-Academics-Submission_final171013.pdf.

192. *See generally Intellectual Property*, United Nations Dev. Programme, http://www.undp.org/content/undp/en/home/ourwork/povertyreduction/focus_areas/focus_trade_and_investment/intellectual_property/ (last visited Apr. 9, 2016) ("UNDP helps strengthen developing countries' capacity to sustainably procure affordable HIV and AIDS drugs within the rules and clauses of multilateral and other trade agreements.").

193. *See* Chan Park, Achal Prabhala & Jonathan Berger, United Nations Dev. Programme, Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law (2013), http://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf.

194. On January 10, 2014, Michael Azrak, Merck's Managing Director for South and East Africa, wrote an e-mail implicating two dozen companies and trade associations in a secret campaign to undermine patent law reform in South Africa. E-mail from Michael Azrak, Managing Dir., Merck & Co. (Jan. 10, 2014, 12:18 PM), http://keionline.org/sites/default/files/merck-email.pdf; *see also* Sarah Boseley, *South African Pharma Firms Accused of Planning to Delay Patents Law Reform*, The Guardian (Jan. 14, 2014), http://www.theguardian.com/world/2014/jan/17/south-african-pharma-accused-delay-patents-law-reform.

195. *See* James Love, *New Leaked Merck Missive Reveals Deep Drug, Medical Device Company Opposition to South African Patent Reforms*, Knowledge Ecology Int'l (Jan. 20, 2014), http://keionline.org/node/1908.

196. *See, e.g.*, Brook Baker, *US PhRMA Bares Its Fangs—South Africa Patent Law Reform and Access to Medicine at Risk Yet Again*, infojustice (Jan. 18, 2014), infojustice.org/archives/31986.

197. Phillip De Wet, *Motsoaledi: Big Pharma's 'Satanic' Plot is Genocide*, Mail & Guardian (Jan. 17, 2014), http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide.

198. *See Statement of South Africa on Access to Essential Medicines (in the Wake of Pharmagate)*, Fix the Pat. Laws (Jan. 24, 2014), http://www.fixthepatentlaws.org/?p=847.

pharma conspiracy in broad terms,[199] TAC and MSF also released a paper debunking the pharmaceutical industry's claims.[200]

Sensing that the time was ripe post-Pharmagate and marching to the Department of Trade and Industry in Pretoria in March 2014, 1,000 health activists, led by TAC, MSF, and Section27, demanded finalization of the National Intellectual Property Policy before the general elections.[201] Unfortunately, that finalization of the policy is still delayed. However, at a consultation in Pretoria on October 20, 2014, the DTI announced that it expected to finalize the IP Policy and to submit it to the Cabinet by the end of the year.[202] The Department's Deputy Director General of Consumer and Corporate Regulation expressed the DTI's determination to adopt an examination system, to make patent-related data more transparent, to allow pre- and post-grant oppositions, to prevent evergreening, and to liberalize compulsory licensing.[203] Regrettably, the long-awaited release of a final IP Policy will only be one step in an arduous reform process. The matter will eventually have to be taken up for Parliament to consider and pass implementing legislation. During this entire process, decisionmakers will face continuing pressure and lobbying from industry, and perhaps once again from the United States.[204]

IX. CONCLUSION

The rebuff of pharmaceutical hegemony, and the promotion of generic competition within the framework of the right to health, is a case study of the impact that a coordinated social movement can have in challenging the basic legal architecture of monopoly power. Step by step, South African AIDS activists and their allies have focused far upstream at the underpinnings of exclusive rights, attacking structural and legal barriers to access to medicines, admittedly in a context still far too constrained by industry's previous gains. Activists have used the rhetoric of human rights and South Africa's constitutional guarantees to convince the government that it must effectuate its obligation to protect the right to health by reforming patent legislation that burdens the realization of that right. TAC, MSF, and other activists have also attempted to extend human rights practice by arguing that foreign powers, like the United States, must refrain from outside influence that thwarts access to medicines and have chastened the multinational pharmaceutical

199. *See TAC, SECTION27 and MSF React to PharmaGate*, Fix the Pat. Laws (Jan. 18, 2014), http://www.fixthepatentlaws.org/?p=823.

200. *See* Tomlinson & Rutter, *supra* note 124.

201. *See MINISTER ROB DAVIES—OUR LIVES ARE IN YOUR HANDS!*, Fix the Pat. Laws (March 12, 2014), http://www.fixthepatentlaws.org/?p=873.

202. E-mail from Julia Hill, MSF, to the author (October 20, 2015) (on file with author).

203. *Id.*

204. *See* Phillip De Wet & Sarah Wild, *New Drug Policy is Patently High Risk*, Mail & Guardian (October 31, 2014), http://mg.co.za/article/2014-10-30-new-drug-policy-is-patently-high-risk; Peter Fabricius, *SA Offers Chickens for AGOA Renewal*, BusinessReport (Aug. 5, 2014), http://www.iol.co.za/business/news/sa-offers-chickens-for-agoa-renewal-1.1730442#.VEgu-yhy9UN.

industry for its continuing, pernicious, and backdoor efforts to prioritize monopoly profits over people's affordable access to essential public health goods. Over the course of a fifteen-year campaign, these activists have helped to increase the number of South Africans receiving anti-retroviral therapy to over three million today.[205]

The Campaign has deployed diverse discourses—competition, public health, IP-moderation, and human rights—in pursuit of reform that will keep South Africa's population healthy enough to overcome the legacies of apartheid. AIDS activists' amalgamated right-to-access discourse, unlike some mainstream human rights discourses, is neither individualistic nor negative; it is instead a discourse of communal needs and equity whereby the rigid structures of pharmaceutical hegemony are at least partially dismantled.

Advocacy efforts such as the Campaign, spawned and supported by the UKZN course, speak directly to issues of social justice. By further capacitating individuals and organizations to effectively analyze, understand, and engage with complex issues affecting the daily lives of people in South Africa, the course played a small but catalytic role in what might become a great achievement. The course sought to do so by leveraging the expertise and commitments of academics with the tenacious and hard-hitting activism of people living with HIV and AIDS and their allies. It sought to distribute knowledge and make it actionable in the service of global health justice. The most significant force for change, however, comes not from academics or even from the capacitated experts in TAC and MSF but rather from the broad social movement that TAC and others have helped to build and its network with AIDS activists worldwide. But an informed social movement is a stronger social movement. It has not only grounded experience of its human rights needs but also greater insight into the legal structures of oppressive corporate power, both national and international. Such a movement learns that even the most technical subjects can be translated into effective, humane calls for justice.

205. *See South Africa Reflects on Battle to Curb HIV and AIDS*, SouthAfrica.Info (June 10, 2015), http://www.southafrica.info/about/health/aids-conference-100615.htm#.VZ_jBe1Viko.