

Workshop on “Constitutional Rights, Judicial Independence and the Transition to Democracy: Twenty Years of South African Constitutionalism”

International Collaboration in Training on Intellectual Property and Access to Medicines: The Birth of the S. Africa Fix the Patent Laws Campaign

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Introduction:

In 2000, I became politically and legally active in the global campaign to address intellectual property, human rights, and other barriers to access to affordable medicines for treating HIV and AIDS in South Africa and throughout sub-Saharan Africa. Anonymous HIV testing at the South African university I was regularly visiting revealed a 26% infection rate among female students, with much higher rates of infection among black African females. My closest collaborator in South Africa was Yousuf Vawda, a senior lecturer at what is now the University of KwaZulu Natal in Durban. Together, in 2001-2002, we sketched the outlines of reforms that might be enacted in South Africa's patent regime to take advantage of public health flexibilities for accessing generic medicines allowed under the WTO TRIPS Agreement.

From 2001 to 2007, Yousuf and I both engaged in IP and access to medicines work, publishing both academically and advocating in support of myriad access-to-medicines and treatment campaigns being waged in South Africa and elsewhere.¹ Yousuf took the

¹ See, e.g., Yousuf Vawda, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing – Country Case Study: South Africa* (2011) (unpublished, on file with the author); YA Vawda, *Free Trade Agreements with the US – Are they good for your health*, 32 J. JURIDICAL SCI. 116-131 (2007); Yousuf Vawda, *From Doha to Cancun: The Quest to Increase Access to Medicines under WTO Rules*, 19 SA J. Human Rights (2003); Yousuf Vawda, *Tripped-up on TRIPS: The Story of Shrinking Access to Drugs in Developing Countries*, 3 STELLENBOSCH L. REV. (2002); Yousuf Vawda & Brook Baker, *Achieving Social Justice in the Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 AFRICA HUMAN RIGHTS L. J. 57-84 (2013); Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles* in INTERNATIONAL ECONOMIC LAW AND AFRICAN DEVELOPMENT (Laurence Boule, Emmanuel Laryea & Franziska Sucker eds. 2014) available at: http://www.ahrj.up.ac.za/images/ahrj/2013/ahrj_vol13_no1_2013_vawda_baker.pdf; Sean Flynn, Brook Baker, Margot Kaminski, Jimmy Koo, *Public Interest Analysis of US TPP Proposal for an IP Chapter*, 28 AM. U. INT'L L. REV. 105-202 (2012) (principal author Part III); Brook K. Baker, *ACTA: Risks of Third-Party Enforcement to Access to Medicines*, 26 AM. U. INT'L L. REV. 579-599 (2011) available at: <http://www.auilr.org/pdf/26/26.3.3.pdf>; Brook K. Baker & Tenu Avafia, *THE EVOLUTION OF IPRS FROM HUMBLE BEGINNINGS TO THE MODERN DAY TRIPS-PLUS ERA: IMPLICATIONS FOR TREATMENT ACCESS*, UNDP/UNAIDS Global Commission on HIV and the Law (commissioned June 2011) <http://www.hivlawcommission.org/index.php/working-papers?start=10>; Tenu Avafia & Brook K. Baker, *BACKGROUND PAPER: LAWS AND PRACTICES THAT FACILITATE OR IMPEDE HIV-RELATED TREATMENT ACCESS*, UNDP/UNAIDS Global Commission on HIV and the Law (commissioned Sept. 2010) <http://www.hivlawcommission.org/index.php/background-papers>; Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008); Brook K. Baker, *Placing Access to Medicines on the Human Rights Agenda* in THE POWER OF PILLS: SOCIAL, ETHICAL & LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING & PRICING, 239-248 (Jillian Clare Cohen, Patricia Illingsworth & Edo Schüklenk eds., 2006); Brook K. Baker, *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilize TRIPS Flexibilities in Non-Producing Countries*, U.K. Dept. for Int'l Development, Health Systems Resource Centre (Commissioned Sept. 2004) available at: http://www.iprsonline.org/resources/docs/Baker_TRIPS_Flex.pdf; Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the*

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extra step of enrolling in a PhD program at UKZN to write a dissertation on needed access-to-medicines reforms in South Africa. Beginning in 2008 we received support for an intensive course on intellectual property and access to medicines that would be offered to grassroots activists, academics, health practitioners, and interested government officials. Although the course would introduce participants to rigorous analysis of intellectual property rules and norms, human rights, especially the right to health, pharmaceutical economics, procurement and supply systems and more, the course, funded by the Open Society Institute, was also designed to expose participants to global access-to-medicines campaigns fought in South Africa and elsewhere and also to help participants plan campaigns that might be waged in their own countries or regional groupings.²

We taught the two-week intensive course for five years and had the good fortune in the fourth year to recruit strong participants from the Treatment Action Campaign (TAC) and Medicines Sans Frontiers (MSF). We had jointly been advocating for stronger campaigns within countries to adopt TRIPS-compliant flexibilities especially around the time of the 2011 ten-year anniversary of the Doha Declaration on the TRIPS Agreement and Public Health. Yousuf had been conducting research on fatal flaws in the South Africa patent regime, especially the absence of examination on the merits of patent applications, which revealed excessive patenting for medicines and greatly delayed access to more affordable generic equivalents. In the last week of the 2011 course, TAC, MSF, and other Southern African participants drafted a comprehensive campaign strategy to launch a Fix the Patent Laws campaign in South Africa on or near the November anniversary of the Doha Declaration.³

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 Fix the Patent Laws campaign also engaged in a heady insider strategy within the Department on Trade and Industries (DTI), which houses the S.A. patent office, and within the Department of Health, which is led by a dynamic minister of health who understand the health costs of high medicines prices. Through a series of public events and private consultations with government, key officials were made aware of the heavy toll South Africa was paying because of its retrograde patent regime. Contrasts were also drawn with respect to the pro-developing country, pro-IP flexibilities that South Africa was espousing on the international stage and its TRIPS-plus legislation at home. Although the Fix the Patent Laws campaign has not yet fully won the reforms it seeks, in September of 2013, the South Africa government released a draft National Policy on Intellectual Property, 2013, (Draft IP Policy) outlining intended reforms much along the lines of what has been proposed in the Fix the Patent Laws Campaign.

Doha Declaration on the TRIPS Agreement and Public Health, 14 IND. INT'L & COMP. L. REV. 613-715 (2004); Brook K. Baker, *Working Paper: Analysis and Response to Recent WTO Action Regarding TRIPS Agreement and Public Health*, United Nations Millennium Development Goals Project, Task Force 5: Infectious Diseases and Access to Essential Medicines (Commissioned Dec. 2003); Brook K. Baker, *Teaching Legal Skills in South Africa: A Transition from Cross-Cultural Collaboration to International HIV/AIDS Solidarity*, 9 J. LEGAL WRITING INST. 145-183 (2003).

² University of KwaZulu Natal, Intellectual Property and Access to Medicines, available at: <http://ipatm.ukzn.ac.za/Homepage.aspx>.

³ MSF and TAC participants who attended the course and strategized the Fix the Patents Act Campaign include Catherine Tomlinson, Mara Kardis-Nelson, Marcus Low. Lynette Mabote also worked on planning the campaign.

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This paper will detail examples of international collaboration, the development of an activist-oriented “clinical” offering, and the Fix the Patent Laws campaign that it helped to spawn. It will describe systemic 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. It also situates this 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 substantial part on the promise of the right to health enshrined in the South African constitution.

Birth of My Own Fix the Patent Laws Fixation:

At the XIII Int'l AIDS Conference, held on July 9-13, 2000, in Durban, South Africa,⁴ I sat and cheered with excitement at the free satellite conference organized by *Medicins Sans Frontieres* and the Treatment Action Campaign at Durban City Hall. With me was my best friend and colleague from the University of Durban-Westville, Yousuf Vawda, who directed the law clinic there. His wife Cati Vawda, who was on the national executive of the Treatment Action Campaign and who was helping to lead the children's sector response to HIV, was working the hall engaged in rapid-fire consultations.

I had heard reports about the staggering prevalence of HIV in South Africa during my previous visits to Durban following my 1997 six-month sabbatical. By the time of the conference, I had heard about anonymous testing at the UDW, which showed a 26% infection rate among female students and 12% among male students, with higher rates among black Africans than Indian or white students. I had worked for three years developing law curricular materials that would include HIV content and I had worked with Yousuf in UDW's clinic where we routinely confronted cases of clients affected by HIV,⁵ but that pedagogy-only response felt and was inadequate.

At Cati's request, I had solicited funds from my colleagues at Northeastern University School of Law to buy TAC “HIV-Positive”⁶ t-shirts for a treatment access demonstration planned in advance of the Conference's opening ceremonies. I was wearing one of the t-shirts at the satellite conference and the air was electric as speakers spoke about the high cost of medicines, an MSF antiretroviral treatment program being piloted in Kyayelitsha, and a campaign against Pfizer to lower the costs of fluconazole. For the first time in my life, I heard the words parallel importation and compulsory licenses. They were uttered not by law professors, but by activists on the stage describing needed campaigns to supply affordable medicines to the millions of people living with HIV in South Africa.

⁴ For a brief, South African activist account of the Durban conference, see Nathan Geffen, *What Happened in Durban? A South African Perspective*, GMHC TREATMENT ISSUES (Sept.-Oct. 2000), available at: <http://www.thebody.com/content/art13213.html>.

⁵ For an account of some of those cases and my close collaboration with Yousuf, see *Teaching Legal Skills in South Africa: A Transition from Cross-Cultural Collaboration to HIV/AIDS Solidarity*, 9 J. LEG. WRITING INST. 146-183 (2003).

⁶ TAC's HIV Positive t-shirts became famous in S. Africa and throughout the world, perhaps reaching a high point when worn by Nelson Mandela when meeting with TAC leadership in December 2002. See “Nelson Mandela activism remembered at AIDS and STIs conference,” IRIN NEWS (Dec/ 13, 2013), available at <http://www.irinnews.org/report/99288/nelson-mandela-s-activism-remembered-at-aids-and-stis-conference>. The t-shirt symbolizes the fight against stigma, solidarity, and living positively with HIV.

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In particular, I heard that the Treatment Action Campaign was launching a campaign against President Tabo Mbeki's AIDS denialist policies demanding that ARVs be used to prevent mother-to-child transmission of HIV. Speakers denounced the high cost of Pfizer's anti-fungal medicine, fluconazole or Diflucan®, used to treat fatal cryptococcal meningitis and systemic thrush, which was selling for 127 rand per pill in the private sector (80 rand wholesale, approximately \$11) and 29 rand per pill (approximately \$4) in the public sector, but which was available generically in Thailand for less than 2 rand (approximately \$.28).⁷ I heard that 39 pharmaceutical companies and trade associations had filed suit against the South African Amended Medicines and Related Substances Control Act that was attempting to lower drug prices by allowing parallel importation of branded medicines sold more cheaply in other countries, generic substitution by pharmacists, and some measure of price transparency and control.

Perhaps most movingly, I, and hundreds of other participants, heard Constitution Court judge Edwin Cameron's famous and brave speech during which he said:

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. ... 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 dying because they don't have the privilege that I have, of purchasing my health and life. ... [O]n the salary of a judge I have the privilege to purchase my life. ... Now why should I have the privilege of purchasing my life and health when 34 million people in the resource poor world are falling ill, feeling sick to death, and are dying?⁸

We also heard from Dr. Peter Mugenyi, an AIDS clinician from Uganda, who, pointing out the disparities in global access to highly active antiretroviral therapy, said: "Drugs are where the disease is not," he said. "The disease is where the drugs are not."

After the satellite conference, thousands of people gathered on the steps of Durban City Hall to hear rallying calls, Zulu songs, and speeches from Winnie Mandela, Zackie Achmat, and others. Sixty-five hundred strong, in what was called the first international march for AIDS treatment in the global South, protestors danced and sang and chanted to the site of the opening ceremonies of the International AIDS Conference at Kings Mead, a cricket stadium near the beachfront, to deliver a petition of demands to the organizers of the conference. Once inside, we had the distressing experience of listening to South African President question whether a single virus could cause the health woes that South Africa was experiencing and defending his convening of an HIV/AIDS panel composed with equal representation of credible AIDS scientists and discredited AIDS dissidents.⁹ Shortly thereafter, he walked off the stage shunning the presence of Nkosi Johnson, an 11-year old South African with full blown AIDS, who urged the government to take action to prevent mother-to-child transmission of HIV and who implored everyone

⁷ TAC, *Christopher Moraka Defiance Campaign Against Patent Abuse and AIDS Profiteering by Drug Companies*, available at:

<http://www.tac.org.za/Documents/DefianceCampaign/defiancecampaign.htm>.

⁸ Available at: <http://www.tac.org.za/Documents/Speeches/ec9july.txt>.

⁹ Sabin Russell, "Mbeki's HIV Stand Angers Delegates / Hundreds walk out on his speech," S.F. CHRONICLE (July 10, 2000), available at: <http://www.sfgate.com/health/article/Mbeki-s-HIV-Stand-Angers-Delegates-Hundreds-2749508.php>. For the text of the speech, which is tellingly not available on the official website of President Mbeki's speeches (<http://www.dfa.gov.za/docs/speeches/mbeki.htm#2000>), see Richard Horton, *Mbeki defiant about South African HIV/AIDS strategy*, 355 LANCET 225-232 (2000).

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“Care for us and accept us - we are all human beings.”¹⁰ (Nkosi never had access to ART and died the next year.)

That day and evening, July 9, 2000, changed my life. Our son, Chad, who had been diagnosed with pediatric cancer in June of 1986, had avoided the risk of HIV transmission from blood transfusions by a matter of month. He received tremendous care with life-saving medicines for chemotherapy, anesthesia, and antibacterial prophylaxis. Elsewhere, parents just like me, were watching their children die untreated, without any medicines whatsoever. I, like thousands in Durban, knew that antiretroviral medicines were not available in South Africa because patent-holding drug companies, located in Europe and the U.S., were charging virtually the same prices for ARVs in Africa that they were in the U.S., approximately \$10,439 per year for three separate medicines.¹¹ Although some of the drug companies had announced an Accelerating Access Initiative in May of that year, negotiations for lower drug prices were being conducted drug-by-drug, country-by-country basis.¹²

I returned from South Africa energized and motivated. With others I formed an offshoot of the Boston Anti-Globalization Network, the BGAN Africa AIDS Project. In addition to protesting at Pfizer’s Cambridge R&D facility in September and December,¹³ I dedicated myself to trying to learn more about the international intellectual property regime and how to make national laws more conducive to manufacturing and/or importing cheaper generic equivalents of grossly overpriced medicines. While exploring global AIDS activism in the U.S., I became aware of the Health GAP (Global Access Project) Coalition, which had helped organize the protests in Durban and which had also been fighting against U.S. trade pressure against South Africa¹⁴ and the lawsuit filed by drug

¹⁰ Nkosi Johnson, *The Face of AIDS*, Beholders.org, available at: <http://www.beholders.org/spirit/inspirationalpeople/110-nkosijohson.html> (accessed October 4, 2014).

¹¹ See, MSF, *UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS*, 10 (15th ed., 2012), available at: http://www.msfastcess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW15_ENG_2012.pdf.

¹² WHO & UNAIDS, *ACCELERATING ACCESS INITIATIVE: WIDENING ACCESS TO CARE AND SUPPORT FOR PEOPLE LIVING WITH HIV/AIDS – PROGRESS REPORT (2002)*, available at: http://www.who.int/hiv/pub/prev_care/isbn9241210125.pdf.

¹³ For a report on the December World AIDS Day demonstration, see Naveen Sunkavally, *Protestors Attack Pfizer’s Drug Policies*, THE TECH (December 5, 2000), available at: <http://tech.mit.edu/V120/PDF/V120-N62.pdf>.

¹⁴ See, e.g., Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681 (1999):

[N]one of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United State Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa’s Medicines and Related Substances Control Amendment Act No. 90 of 1997.

According to U.S. State Department documents and statements at the time, “[multiple federal agencies] have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa to modify the provisions of Article 15(C)” that the United States believed violated the TRIPS Agreement. Patricia D. Siplon, *AIDS AND THE POLICY STRUGGLE IN THE UNITED STATES 120-21* (2002); see *Time-line of Disputes over Compulsory Licensing and Parallel Importation in South Africa*, available at: <http://www.cptech.org/ip/health/sa/sa-timeline.txt> (accessed October 4, 2014); Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 INT’L J. HEALTH SERV. 765-792 (1999), available at <http://hivpolicy.info/wp->

companies against the Mandela government.¹⁵ I started working with Health GAP in the spring of 2000 and became a core member volunteer in December of 2001 and a senior policy analyst shortly thereafter.

South African Activists and Allies Fight Pharmaceutical Apartheid in South Africa

The HIV/AIDS pandemic peaked globally in 1997 and in South Africa in 1998-99 when the highest numbers of new infections were recorded, 3.7 million and 650,000 respectively.¹⁶ AIDS policy in South Africa was constipated at best and was so long before Thabo Mbeki. The apartheid government was pathologically indifferent to a disease first thought to target gay men and later poor black Africans. The apartheid health system was appallingly unequal with 80% of the population receiving less than 20% of the health resources, while the privileged, primarily white private health sector absorbed nearly 80% of the health workforce and health financing. Although the new ANC government had developed some preliminary AIDS strategies,¹⁷ it is fair to say that its major preoccupations were inwardly focused on its new governance role, neo-liberal economic policy, and the calcified inequalities of apartheid in terms of housing, electrification, and water and sanitation. South Africa's first democratically elected president, Nelson Mandela, was initially tongue-tied about HIV and didn't even mention the pandemic until late in his presidency. More ominously, the new President, Thabo Mbeki, came under the sway of AIDS dissidents. Suspicions about the agenda of multinational drug companies and the governments that supported them, inattention 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, dragging his all too compliant Minister of Health, Manto Tshabalala-Msimang, with him into the vortex of denialism.¹⁸

content/uploads/2013/02/Bon-on-AIDS-medicines-struggle-in-International-Journal-of-Health-Services-IJHS.pdf.

For a description of some of Health GAP's activism against US trade pressure, see, *Candidate GORE zaps*, available at: <http://actupny.org/actions/gorezaps.html> (accessed October 4, 2014).

¹⁵ Pat Sidley, *Drug companies sue South African government over generics*, 522 *BMJ* 447 (Feb. 24, 2001), available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119675/pdf/447.pdf>.

¹⁶ For global statistics, see UNAIDS, *HIV with Uncertainty Bounds 1990-2012*, available at: <http://www.unaids.org/en/resources/campaigns/globalreport2013/globalreport/>; 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* 1005-1070 (2014) (finding 17% lower rates of HIV incidence than those reported by UNAIDS), available at: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60844-8/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60844-8/abstract).

¹⁷ See, African National Congress, *A National Health Plan for South Africa* (May 1994), available at: <http://www.anc.org.za/show.php?id=257>; see generally, Mark Heywood & Morna Cornell, *Human Rights and AIDS in South Africa: From Right Margin to Left Margin*, 2 *HEALTH & HUMAN RIGHTS* 61-82 (1998); Anthony Butler, *South Africa's HIV/AIDS Policy, 1994-2004: How Can It Be Explained?*, 104 *AFRICAN AFFAIRS* 591-614 (2005), available at: <http://afraf.oxfordjournals.org/content/104/417/591.full.pdf#page=1&view=FitH>.

¹⁸ 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*, CSSR Working Paper No. 257 (2009), available at: <http://www.cssr.uct.ac.za/sites/cssr.uct.ac.za/files/pubs/WP257.pdf>. For a detailed look at the origins of AIDS denialism, see Seth C. Kalichman, *DENYING AIDS: CONSPIRACY THEORIES, PSEUDOSCIENCE, AND THE HUMAN TRAGEDY* (2009);

The legacies of apartheid; the squeamishness, fiscal frugality, and denialism of post-apartheid ANC policy; the broad foothold of the disease; the tattered and inequitable public health system; the domestic drivers of HIV founded in the migrant labor force, the sexual imperatives of patriarchy, and disrupted family relations; and the global determinants of intellectual property hegemony, export-oriented trade, and IMF and World Bank mediated structural adjustment produced¹⁹ the perfect storm for the viral holocaust that confronted South Africa at the turn of the millennium. Despite new science showing that mother-to-child transmission of HIV could be significantly reduced by administration of Zidovudine or Nevirapine during delivery, the government refused to act. Through its most public anti-HIV efforts, the farcical HIV prevention debacle of Sarafina 2²⁰ and the false AIDS cure Virodene P058,²¹ the ANC revealed itself to be bungling at best. In the wake of this policy miasma, the Treatment Action Campaign was founded in 1998, specifically to fight for prevention of mother-to-child prevention and the development of a more robust government response to the pandemic. However, from the earliest stages, it also recognized that the prices of AIDS-related medicines 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 treatment activists and activist lawyers²² gained strength and momentum by focusing on the global and national determinants of access to affordable medicines.²³ Effectively marshaling the language of human rights and the right to health while organizing inclusive community

¹⁹ Brook K. Baker, *The Impact of the International Monetary Fund's Macroeconomic Policies on the AIDS Pandemic*, 40 INT'L J. HEALTH SERVICES 347-363 (2010) http://people.pwf.cam.ac.uk/ds450/details/40_3p.pdf.

²⁰ Suzanne Daley, South Africa Scandal Over 'Sarafina' Spotlights Corruption in the ANC, NYT (October 8, 1996), available at: <http://www.nytimes.com/1996/10/08/world/south-africa-scandal-over-sarafina-spotlights-corruption-in-the-anc.html>.

²¹ Pat Sidley, *Miracle AIDS cure hits the South African press*, 314 BMJ 450 (1997).

²² During its entire history the TAC collaborated closely with the AIDS Law Project, now Section27. For a short history of some of that collaboration, see Mark Heywood, South Africa's Treatment Action Campaign (TAC): An Example of a Successful Human Rights Campaign for Health. Chapter 3 in Introduction: Politics, Human Rights and Poor Global Health (Treatment Action Campaign 2008), available at: <http://www.tac.org.za/community/node/2064>.

²³ TAC's many AIDS campaigns and victories are detailed in Treatment Action Campaign, 1998-2010 FIGHTING FOR OUR LIVES: THE HISTORY OF THE TREATMENT ACTION CAMPAIGN (2010), available at: <http://www.tac.org.za/community/files/10yearbook/index.html>; see also Mandisa Mbali, SOUTH AFRICAN AIDS ACTIVISM AND GLOBAL HEALTH POLITICS (2013); Mandisa Mbali, *Tac in the History of Rights-Based, Patient Driven HIV/AIDS Activism in South Africa* (2005), available at: <http://quod.lib.umich.edu/p/passages/4761530.0010.011/--tac-in-the-history-of-rights-based-patient-driven-hiv-aids?rgn=main;view=fulltext>; Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 J. HUMAN RIGHTS PRACTICE 14-36 (2009), available at: <http://jhrp.oxfordjournals.org/content/1/1/14.full.pdf+html>. For a discussion of TAC coalition-building strategy designed to create networks of influence, see Eduard Grebe, *The Treatment Action Campaign's Struggle for AIDS Treatment in South Africa: Coalition Building Through Networks*, 37 J. SOUTHERN AFRICAN STUDIES 849-868 (2011), available at: <http://www.tandfonline.com/doi/pdf/10.1080/03057070.2011.608271>. For a description of TAC's early litigation strategies, see Jonathan Micheal Berger, *Litigation Strategies to Gain Access to Treatment for HIV/AIDS: The Case of South Africa's Treatment Action Campaign*, 20 WISC. INT'L L.J. 596 (2003); William Forbath, *Cultural Transformation, Deep institutional Reform, and ESR Practice*, in STONES OF HOPE: HOW AFRICAN ACTIVISTS RECLAIM HUMAN RIGHTS TO CHALLENGE GLOBAL POVERTY (Lucie White, Jeremy Perelman eds. 2011).

mobilization,²⁴ TAC continued its defiance campaign trying to force Pfizer to follow through on promises to make its fluconazole medicine, Diflucan®, more widely available to fight opportunistic fungal infections.²⁵ Zachie Achmat, the TAC chairperson, flew to Thailand, purchased generic equivalents, and flew back to South Africa defying South African authorities to prosecute him.²⁶ As the pressure on Pfizer mounted, Pfizer partially relented and on December 1, 2000, announced that it would make Diflucan® available free of cost in South Africa to the government and non-governmental organizations for the treatment of cryptococcal meningitis and oesophageal candidiasis. Limiting the donation program to South Africa only was widely critiqued, and shortly before the UN General Assembly on HIV/AIDS in June of 2001,²⁷ Pfizer announced the expansion of its country coverage to include all Southern African Development Community countries and 50 least developed countries.²⁸

TAC also intervened in the lawsuit that 39 drug companies had filed against the South African government over proposed amendments to its national law to allow access to cheaper generic medicines.²⁹ In particular, the pharmaceutical plaintiffs complained that the section 10 of the 1997 Medicines and Related Substances Control Amendment Act, adding a section 15C to the 1965 Act, was unconstitutional under South African law and violated the WTO TRIPS Agreement by authorizing parallel importation – comparison shopping for cheaper medicines overseas.³⁰ The challenged provision, though initially

²⁴ See Leslie London, What is a human-rights based approach to health and does it matter, 10 Health and Human Rights 65, 67-68 (2013), available at: <http://www.hhrjournal.org/wp-content/uploads/sites/13/2013/07/6-London.pdf>; Krista Johnson, Framing AIDS Mobilization and Human Rights in Post-apartheid South Africa, 4 Perspectives on Politics 663-70 (2006), available at: <http://users.polisci.wisc.edu/schatzberg/ps362/Johnson2006.pdf>.

²⁵ After the joint TAC/MSF campaign for access to affordable fluconazole was launched, Pfizer offered to supply Diflucan® for cryptococcal meningitis only in the early 2000, but that promise had not been translated into a formal agreement with the government of South Africa. See Pat Sidley, *AIDS patients in South Africa to get free drug*, 320 BMJ 1095 (2000).

²⁶ Tony Karon, "South African AIDS Activist Zachie Achmat," TIME MAGAZINE (April 19, 2001), available at: <http://content.time.com/time/nation/article/0,8599,106995,00.html>.

²⁷ *United Nations Special Session on HIV/AIDS, 25-27 June 2001 – Background Information*, available at: <http://www.un.org/ga/aids/background.htm>.

²⁸ Konji Sebati, *Pfizer Diflucan Partnership Program*, 361 LANCET 72 (2003); Pfizer, Press Release: Pfizer to offer Diflucan antifungal medicine at no charge to HIV/AIDS patients in 50 least developed countries around the world (June 6, 2001), available at: <http://www.prnewswire.co.uk/news-releases/pfizer-to-offer-diflucan-antifungal-medicine-at-no-charge-to-hiv-aids-patients-in-50-least-developed-countries-around-the-world-154460935.html>. The list of eligible countries was subsequently expanded to 63 countries in Africa, Asia, the Caribbean and Latin America with an emphasis on countries with an HIV prevalence rather than 1%. See, Eligible Countries, available at: <http://www.directrelief.org/focus/disease-prevention/hiv-aids/diflucan-partnership-program/eligible-countries/>. As of 2010, Pfizer claims to have distributed \$1.2 billion worth of Diflucan®, presumably based on the US wholesale price. See, Pfizer, *Diflucan Partnership*, available at: http://www.pfizer.com/responsibility/global_health/diflucan_partnership_program.

²⁹ Debora Halbert, *Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOCIAL JUSTICE 257 (2002). TAC's intervention strategy is described at length in Mark Heywood, *Debunking 'Conglomo-talk': A case student of the amicus curiae as an instrument for advocacy, investigation, and mobilisation*, 6 LAW DEMOCRACY & DEVELOPMENT 135-162 (2002), available at: <http://www.saflii.org/za/journals/LDD/2001/3.pdf>.

³⁰ See Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98. With respect to Section 15C, the plaintiffs argued that it: (1) allowed a constitutionally impermissible delegation of powers from the legislative to the executive branch of government, 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 expand the supply of

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thought to implicate standardless compulsory licenses, was in truth geared solely towards parallel importation:

15C - Measures to ensure supply of more affordable medicines

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

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, adopted strategies that challenged all of the drug companies' assertions. TAC called for a Global Day of Action on March 5, 2001, and AIDS activists demonstrated all over the world,³¹ including in Boston. On April 19, 2001, the drug companies, who had faced horrendous global publicity, opted to drop their lawsuit.³²

more affordable medicines via compulsory licenses and parallel importation without any limiting guidelines thereby depriving intellectual property owners of their property without full compensation in violation of Article 25 of the South African Constitution, and (2) violated Art. 27 TRIPS and did so in further violation of Articles 44(4) and 231(2)-(3) of the South African Constitution. 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, both because parallel importation was lawful under Article 6 of the TRIPS Agreement and because Section 15C did not address compulsory licensing. 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. 485-502 (2000). For analysis post withdrawal of the lawsuit, see William W. Fisher III & Cyrril P. Rigamonti, *The South African AIDS Controversy: A Case Study in Patent Law and Policy* (2005), available at: <http://cyber.law.harvard.edu/people/ffisher/South%20Africa.pdf>.

³¹ 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*, The Body (January 26, 2005), available at: <http://www.thebody.com/content/art32009.html>; Ravi Nessman & Andrea Babbington, "Protest in Britain as drug companies sue South African government," THE INDEPENDENT (UK) (March 5, 2001), available at: <http://www.independent.co.uk/news/business/news/protest-in-britain-as-drug-companies-sue-south-african-government-694706.html>.

³² Rachel L. Swarns, "Drug Makers Drop South Africa Suit Over AIDS Medicine," NYT (April 20, 2001), available at: <http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html>; Ann M. Simmons, "Suit Against Cheap AIDS Drugs Ends in S. Africa," LA TIMES (April 20, 2001), available at: <http://articles.latimes.com/2001/apr/20/news/mm-53295>. 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 Medicines and Related Substances Act 101 of 1965 - Regulations and Notices - Government Notice R510, section 7, available at: http://www.saflii.org/za/legis/consol_reg/marsa101o1965rangnr510723/.

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These initial TAC drug company campaigns were directed at the symptoms of high prices rather than their foundations, namely the international and South African intellectual property regimes. Nonetheless, following its partial success against Pfizer and the dismissal of the industry-wide lawsuit, TAC turned its attention toward national health policy and pressed the government to implement a comprehensive mother-to-child-prevention campaign using the then-best and simplest strategy, administration of single-dose nevirapine to the mother during labor and to the newborn immediately post-delivery to reduce the risk of vertical transmission by nearly 50%. Despite all science to the contrary and an offer by Boeringer-Ingelheim to supply nevirapine free of charge to prevent vertical transmission, the government steadfastly refused to make nevirapine broadly available provoking TAC, the Children's Rights Centre and others to lodge a constitutional court challenge.³³ This now famous case established a constitutional basis in the right to health for the government to engage in rational planning to address the interests of mothers and children in the preventable vertical transmission of HIV. On July 5, 2002, the Constitutional Court ordered the government to abandon its cautious, pilot-study approach to prevention-of-mother-to-child-transmission and instead to allow doctors working in the public sector to routinely administer voluntary antiretroviral prophylaxis to reduce the risk of vertical transmission. The Constitutional Court ruled that the government had an obligation to act and to plan, thereby setting the stage for a more robust response to the HIV/AIDS pandemic and its intergenerational transmission.

Not satisfied with a belated victory on PMTCT, TAC turned its attention of the failure of the government to commit to an antiretroviral treatment program in the public sector.³⁴ In February and March of 2003, TAC launched its "Dying for Treatment" civil disobedience campaign promising to disrupt the government after having proven that the government's claims that treatment was unaffordable was wrong.³⁵ In addition to organizing a demonstration of 20,000 people on February 10, 2003, demanding government action, TAC formed a Research Committee of health economists and medical professionals that produced a draft National Treatment Plan that demonstrated that initial costs in treatment scale-up would be offset in the mid-term because of cost savings from averted orphanhood, sick leave, and premature mortality. TAC enlisted the support of COSATU and HIV/AIDS clinicians, and published a leaked report from the government's Joint Treasury and Health Task Team, which also demonstrated both affordability and greatly reduced mortality. Zackie Achmat, famously promised not to begin AIDS treatment for his own worsening infection until other South Africans would have equitable access to publicly supported treatment.³⁶ In the face of public pressure, political risk from opposition parties, and global incredulity at its totally incoherent stance, the South African cabinet

³³ *Minister of Health and Others v. Treatment Action Campaign and Others* 2002 (10) BCLR 1075 (CC); see 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 S.A. J. HUMAN RIGHTS 278-315 (2003), available at: http://www.escri-net.org/sites/default/files/Mark_Heywood_-_Preventing_Mother-to-Child_HIV_Transmission_in_South_Africa.pdf; Amy Kapczynski & Jonathan Berger, *The Story of the TAC Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa*, HUMAN RIGHTS ADVOCACY STORIES (Deena R. Hufowitz, Margaret L. Satterthwaite & Douglas B. Ford eds., 2009)

³⁴ See Neil Overy, *In the Face of Crisis: The Treatment Action Campaign Fights Government Inertia with Budget Advocacy and Litigation*, International Budget Partnership Study No. 7 (2011), available at: <http://internationalbudget.org/wp-content/uploads/LP-case-study-TAC.pdf>.

³⁵ TAC, *Dying for Treatment: Briefing Document on the Civil Disobedience campaign* (March 2003), available at: <http://www.tac.org.za/Documents/CivilDisobedience/briefingdocument.htm>.

³⁶ In doing so, he stood up to Nelson Mandela who met with him to request that he begin treatment and also a vote of the TAC National Congress held in Durban in August of 2003.

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finally approved an ARV treatment plan on November 19, 2003.³⁷ Unfortunately, the impact of the Government's protracted procrastination could be measured in hundreds of thousands of lives lost unnecessary according to conservative estimates of Harvard researchers.³⁸

At the same time that TAC was successfully advocating for the adoption of a national treatment plan, it had returned to South African tribunals to force drug companies to lower their price of patent-protected medicines. In 2002, Hazel Tau and 10 others lodged a complaint before the Competition Commission against GlaxoSmithKline and Boehringer Ingelheim for excessive pricing of their antiretroviral medicines, AZT, lamivudine, and nevirapine, in the private sector.³⁹ This was a complicated case entailing proof offered by TAC and its AIDS Law Project lawyers that the companies had dominant economic positions in the AIDS medicines market and that the ARVs in question were significantly overpriced compared to their fair economic value. TAC sought non-exclusive licenses from the right-holders to generic producers who could thereafter sell in both public and private sectors in exchange for a 4-5% royalty on sales. Given the absence of voluntary licenses, TAC requested that the Competition Tribunal order a compulsory license, which would also authorize generic manufacture and sale by qualified producers in exchange of a royalty. Experts retained by the Competition Commission broadened the theories of anticompetitive behavior in the case to include the essential facilities doctrine, arguing that each medicine was independently necessary to formulate triple-dose, highly active antiretroviral therapy.

On October 16, 2003, the Competition Commission found that GSK and BI had acted in contravention of the Competition Act by abusing their dominant positions in their respective anti-retroviral markets. They were found to have denied competitors access to essential facilities and to have engaged in excessive pricing and other exclusionary acts. The Commission referred the matter to the Competition Tribunal for determination.⁴⁰ Before the case reached the Tribunal, GSK and BI settled the complaint by agreeing to license their ARVs to generic companies for sales in public and private sectors through

³⁷ OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA (19 November 2003), available at: <http://www.hsph.harvard.edu/population/aids/southafrica.aids.03.pdf>; see, Sarah Jane Marshall, *South Africa unveils national HIV/AIDS treatment programme*, 82 WHO BULLETIN 73-74 (2004). Despite this commitment, the treatment campaign did not meaningfully begin until 2006.

³⁸ Price Chigwedere et al., *Estimating the Lost Benefits of Antiretroviral Drug Use in South Africa*, 49 J. ACQUIR. IMMUNE DEFIC. SYNDR. 410-415 (2008) (estimating at least 3330,000 live and 2.2 million person-years lost because of delayed introduction of PMTCT and antiretroviral therapy in the public sector in South Africa), available at: http://aids.harvard.edu/Lost_Benefits.pdf. This report received wide attention. See e.g. Cecelia Dugger, *Study Cites Toll of AIDS Policy in South Africa*, NYT (November 25, 2008), available at: http://www.nytimes.com/2008/11/26/world/africa/26aids.html?_r=0

³⁹ See, TAC, *The Competition Commission Complaint: Questions and Answers* (October 30, 2002). For a much more extensive presentation of the case, see Belinda Beresford, *THE PRICE OF LIFE – HAZEL TAU AND OTHERS V GLAXOSMITHKLINE AND BOEHRINGER INGELHEIM: A REPORT ON THE EXCESSIVE PRICING COMPLAINT TO SOUTH AFRICA'S COMPETITION COMMISSION* (2003), available at: <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=222>. For a detailed report on the key documents and expert submissions in the case, see Knowledge Ecology International, *CPTech's 2003 reports for the RSA Competition Commission, in Hazel Tau et al. v GSK, Boehringer, et al* (August 13, 2014), available at: <http://keionline.org/node/2074>.

⁴⁰ Competition Commission Press Release, 16 October 2003.

sub-Saharan Africa.⁴¹ The Hazel Tau strategy was used again in 2007 to seek broader access to efavirenz. TAC lodged a complaint with the Competition Commission against a Merck subsidiary for its refusal to license efavirenz on reasonable terms. In response, MSD Ltd licensed four generic companies, two local and two foreign, to produce stand alone, co-packaged, and eventually fixed-dose combinations to the market in South Africa and 10 other southern African countries.⁴²

These cases have proved invaluable to people living with HIV in South Africa and throughout sub-Saharan Africa (SSA) as they have virtually ensured that drug companies will include South Africa and SSA in their voluntary licenses and/or that they offer South Africa 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 every patent on antiretroviral medicines granted to the Medicines Patent Pool. South Africa and SSA also been included other access licenses, including Johnson & Johnson's ARV licenses and Gilead's recent hepatitis C license. This inclusion is vitally important for South Africa because almost all ARVs are patented there, which, as described further below, has one of the world's highest rates of granting pharmaceutical patents because of failings in its patent examination process. Having a regional generics market is also advantageous because a larger market encourages more generic companies to enter the aggregated market to engage in robust competition at efficient economies-of-scale that result 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 nor to other classes of medicines. AIDS exceptionalism and heady campaigning has won generic access to older triple-dose combinations that now are known to both treat and prevent HIV, but not to expensive cancer, diabetes, and cardio-vascular medicines that are so desperately needed. The legal/structural fault that had not yet been addressed was a patent act that made it extraordinarily easy to obtain patents not only on new medicines but also on recursive secondary patents that perpetuate patent monopolies and thereby continue to block generic access. However, before turning to TAC's latest campaign attacking the root causes of high drug prices, it is first necessary to briefly describe the national patent regime that the new South Africa inherited and the globalized system of intellectual property monopoly rights that still constrain South Africa's options, but that also still allows meaningful patent law reform.

The origins of IP monopolies and high prices⁴³

Colonialism imposed intellectual property systems on subject countries that patterned the home-country system while prioritizing the interests of the colonial masters' domestic industries.⁴⁴ More recent neo-liberal economic theory promotes longer, stronger, and

⁴¹ See, "Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines," TAC NEWSLETTER (December 10, 2003), available at: http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm.

⁴² See "Access to generic efavirenz in South Africa: MSD agrees to grant licenses on reasonable terms," I-BASE HIV TREATMENT BULLETIN (August 30, 2008), available at: <http://i-base.info/htb/560>.

⁴³ For a longer and more detailed discussion of the origins of intellectual property rights, see Brook K. Baker and Tenu Avafia, THE EVOLUTION OF IPRS FROM HUMBLE BEGINNINGS TO THE MODERN DAY TRIPS-PLUS ERA: IMPLICATIONS FOR TREATMENT ACCESS (2011), available at: <http://www.hivlawcommission.org/index.php/working-papers?task=document.viewdoc&id=101>.

⁴⁴ 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

broader intellectual property rights, including those of pharmaceutical producers, as the engine to innovation, direct foreign investment, and economic and technological development in low- and middle-income countries. 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.⁴⁵

Even though this theory of IP's catalytic effect has little or no evidence in its support, the U.S., E.U., and European governments have consistently pursued the commercial interests of their hugely profitable patent 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 instantiated in the WTO TRIPS Agreement,⁴⁶ forced on aspiring developing country negotiators during the Uruguay round of GATT negotiations, 1986-1994, that resulted in the formation of the World Trade Organization. Although the TRIPS Agreement imposes minimum standards for patents, data protection, and IP enforcement, these same upper-income countries have continued to pursue even higher standards of intellectual property protections and enforcement through trade agreements and bilateral pressure. However, even though the TRIPS Agreement surely consolidates monopoly power for northern-based IP-based industries, it is not entirely one-sided. As detailed further below, a number of flexibilities were built into the Agreement that provide policy space for accessing more affordable medicines and some of those flexibilities were confirmed by the Doha Declaration on the TRIPS Agreement and Public Health.⁴⁷

As stated, the TRIPS Agreement introduced minimum global standards for protecting and enforcing nearly all forms of intellectual property rights, patents, copyrights, and trade secrets, including those applying to pharmaceuticals.⁴⁸ The Agreement covers basic principles, standards and use of patents, enforcement, dispute settlement and multiple other subjects, many of which are tilted in favor of intellectual property owners and against the interests of consumers. Under key provisions in TRIPS relating to

Berlin. See Carolyn Deere, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES*, 35 (2009).

⁴⁵ See Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles* in *INTERNATIONAL ECONOMIC LAW AND AFRICAN DEVELOPMENT* (Laurence Boule, Emmanuel Laryea & Franziska Sucker eds. 2014).

⁴⁶ Art. 8(1), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

⁴⁷ Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Nov. 9-14 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm.

⁴⁸ The pharmaceutical industry played a highly active role in forming a coalition of IP industries that persuaded US and European trade negotiators to champion a uniform and enforceable international intellectual property regime via the GATT negotiations. See Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (2003) for a detailed history of the political and strategic genesis of the TRIPS Agreement as engineered by US knowledge industries. Pfizer played a leading role ideologically throughout the 1970s and 1980s, especially in forging the Intellectual Property Committee, an international business coalition whose paper became the blueprint for IP demands by high-income countries in the Uruguay GATT negotiations. See, *Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese and United States Business Communities*. The pharmaceutical industry was interested in eliminating rules preventing the patenting of medicines, but it was also motivated to try to gain monopoly control over its regulatory data to forestal registration of generic equivalents.

pharmaceuticals, member countries must provide patent protection for a minimum of 20 years from the filing date of a patent application,⁴⁹ for any invention, including a pharmaceutical product or process, that fulfills the criteria of novelty, inventive step and industrial applicability.⁵⁰ Although preceding patent-rule pluralism in both the developed and undeveloped world had allowed discrimination between fields of invention, for example by excluding medicines,⁵¹ TRIPS expressly outlawed such discrimination.⁵² Similarly, it was no longer permissible to discriminate routinely against imports in favor of locally produced products, thus allowing major pharmaceutical companies to control the *place* of production.⁵³ Via TRIPS, pharmaceutical multinationals succeeded in consolidating their monopoly power internationally, and they now have exclusive rights under Article 28 to exclude others from “making, using, offering for sale, selling, or importing” patented pharmaceutical products or products made with a patented process. In addition, the Agreement has provisions protecting undisclosed information (including clinical test data) that under some interpretations impede registration of generic drugs.⁵⁴ Given U.S., E.U., and Japanese comparative advantage in conducting research and development, the developed world secured near absolute competitive advantage over the developing world in intellectual property rights via the TRIPS Agreement.⁵⁵

Even after the passage of TRIPS, the U.S. continued a heavy-handed trade policy threatening countries such as Thailand, South Africa, and Brazil with trade sanctions because they refused to grant even greater, TRIPS-plus rights to patent holders and/or because they proposed using TRIPS compliant means to access more affordable medicines.⁵⁶ 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.⁵⁷ Given Big Pharma's lawsuit the U.S.'s trade threats against South Africa and given comparable attacks against Brazil and Thailand with respect to their attempted adoption and use of TRIPS flexibilities, the Africa Group, led by Zimbabwe, insisted in April of 2001 that the WTO TRIPS Council meet in order to clarify public health flexibilities that Member States had, especially with respect to compulsory licenses and parallel importation. Although the US was initially reluctant to concede that patents were an impediment rather than a boon to treatment access, the anthrax scare post-9/11 changed the direction of the negotiations.

⁴⁹ Article 33.

⁵⁰ Article 27.1.

⁵¹ When the Uruguay Round of trade negotiations began in 1986, more than 40 of the then 90 GATT Members did not grant patents for pharmaceutical products⁵¹ while others granted process patents only. WHO, Network for monitoring the impact of globalisation and TRIPS on access to medicines, Health Economics and Drugs, 1, EDM Series no 11, WHO/EDM/PAR/2002 (2002).

⁵² *Id.*

⁵³ Article 27.1.

⁵⁴ See Article 39.3. For an extended discussion of options concerning appropriate use of undisclosed data, see Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (South Centre, 2002).

⁵⁵ World Bank, *World Development Indicators 2000*, Table 5-12.

⁵⁶ See Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chi. J. Int'l Law 27, 30-33 (2002) (detailing U.S.T.R. and pharmaceutical industry actions against South Africa and Brazil).

⁵⁷ 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.

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On November 14, 2001, WTO members unanimously approved the Doha Declaration. Designed by developing countries to counteract continuing trade threats and a crisis in medical care, the Doha Declaration emphasized the primacy of public health and the right of Member Nations to take measures designed to increase access to affordable medicines. In relevant part, the Doha Declaration states:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement *does not and should not prevent Members from taking measures to protect public health*. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that *the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all*.
In this connection, *we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose*. (Emphases added.)
5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Although the Doha Declaration confirmed member states' freedom to issue compulsory licenses and to rely on parallel imports as an alternative source for lower-cost medicines, it left open sourcing issues for poor countries that could not produce medicines via domestic production because of insufficient or inefficient pharmaceutical capacity. Even if

these non-producing countries issued TRIPS-compliant compulsory licenses to importers and even if 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). Since sub-Saharan Africa had ten times as many HIV infections as India, this export restriction meant that India's vibrant generic industry could never supply needed quantities in Africa. Despite an end-of-2002 deadline on this issue, U.S. intransigence resulted in impasse, necessitating an additional nine months of negotiation. Finally after months of intense wrangling, WTO members unanimously approved the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Implementation Agreement).⁵⁸ The solution adopted was procedurally labyrinth⁵⁹ and described as being "bound in red tape" at the time it was issued. The effectiveness of the solution is increasingly in doubt as the Decision has only been used only once in nine years to allow export from Canada to Rwanda.⁶⁰ Although there have been efforts to codify the Paragraph 6 Implementation Agreement via an amendment to the TRIPS Agreement, enough countries have remained skeptical that Article 31bis has not yet been adopted.

While most upper-income WTO Member States had to comply with TRIPS by 1 January 1996, developing countries were able to make use of transition periods until 2000,⁶¹ and those countries that did not previously provide product patent protection for pharmaceuticals or other fields of technology when the TRIPS Agreement came into force had until 1 January 2005 to introduce protection.⁶² In addition, least developed country Members were given an initial extended transition period until 2006.⁶³ Via two agreed-upon extensions of that initial transition period, least-developed countries now have until July 2021 to become fully compliant,⁶⁴ with the possibility of further extensions, including an extension of the 2016 pharmaceutical transition period.

Despite TRIPS public health flexibilities having become more firmly enshrined at the multilateral level, pharmaceutical super powers continued their offensive to their industries' IP empires, but did so by shifting forums to bilateral and regional initiatives and by building on any newly gained advantage to leverage even higher protections in the

58. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Sept. 1, 2004) WT/L/540, available at http://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm (last visited Apr. 4, 2004) [hereinafter Paragraph 6 Implementation Agreement].

59 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. 613-715 (2004); Fred Abbott, (2005), *The WTO Medicines Decision: World Pharmaceutical Trade and Public Health*, 99 AM. J. INT'L L. 317-358 (2005).

60 Canada and Rwanda are the only two countries that have cooperated thus far to use the complex 30 August 2003 Decision, via Canada's legislation implementing that decision, and all accounts of that effort suggest that further use of "Canada's Access to Medicines Regime" is unlikely absent some key reforms. Richard Elliott, *Delivery past due: global precedent set under Canada's Access to Medicines Regime*, 13 HIV/AIDS POLICY & LAW REV. 1-9 (2008), available at <http://www.aidslaw.ca/publications/publicationsdocEN.php?ref=864>. The practicability and effectiveness of the mechanism is the subject of a continuing debate at the WTO Council for TRIPS. K Mara, *Efficacy of TRIPS Public Health Amendment in Question at WTO*, IP WATCH (March 1, 2010), available at <http://www.ip-watch.org/weblog/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/>.

61 TRIPS Article 65.2.

62 *Id.* at Article 65.4.

63 *Id.* at Article 66.1.

64 WTO, Responding to least developed countries' special needs in intellectual property, available at: http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

next round, using an upward ratchet strategy. Such efforts, as detailed further below, 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. 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.⁶⁵ At the time, there was a strong argument that these efforts violated U.S. law⁶⁶ and an even stronger argument that that they violated international human rights law.⁶⁷

TRIPS minimums, TRIPS-plus, and TRIPS public health flexibilities

Before detailing the Fix the Patent Laws campaign, it will be useful to briefly summarize the key requirements of the TRIPS Agreement, the threat of TRIPS-plus provisions, and the public health flexibilities that South Africa could adopt into its IP regime. This summary will provide an international law context for assessing the policy space available to South Africa and the technical as well as human rights merits of the Campaign. Naturally, it is possible, as many have done, to argue instead 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

⁶⁵ Pursuing this end-run strategy, on November 5, 2002, United States 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 South African Customs Union: Botswana, Lesotho, Namibia, South Africa and Swaziland. To meet "standards of protection similar to that found in U.S. law and that build on the foundation established" in TRIPS, SACU nations would have been required to limit compulsory 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. 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 have completely eviscerate the Doha flexibilities, dramatically increase IP protection, and shamefully reduce access to more affordable generic products. See, Tenu Avafia, *The potential impact of US-SACU FTA negotiations on public health in southern Africa* (2004), available at: <http://www.tralac.org/scripts/content.php?id=3114>. Fortunately, the negotiations were suspended in 2006. See, US-SACU, available at: <http://www.bilaterals.org/?-US-SACU->.

⁶⁶ These intellectual property negotiation objectives also directly violate the principal negotiating objectives in the Trade Act of 2002, which requires the U.S. "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 is also directly violating Executive Order 13155, 3 C.F.R. 268 (2000), 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)).

⁶⁷ Yousuf Vawda & Brook Baker, *Achieving Social Justice in the Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 AFRICA HUMAN RIGHTS L. J. 57-84 (2013), available at: http://www.ahrli.up.ac.za/images/ahrli/2013/ahrli_vol13_no1_2013_vawda_baker.pdf.

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Law has gone so far as to demand a moratorium on enforcement of TRIPS with respect to pharmaceuticals, a cessation of pressure for low- and middle-income countries to adopt TRIPS-plus measures, and a United Nations review of the appropriateness of the current monolithic, IP-centric legal regime with respect to medicines.⁶⁸ Consultations have also been underway at the World Health Organization via its Global Strategy and Plan of Action on Public Health, innovation, and Intellectual Property, which recommends consideration of even more radical solutions for rectifying imbalances in the innovation and access ecology.⁶⁹ Despite the potential merits of these more ambitious critiques of the IP system, pragmatic campaigners like TAC also need to identify unused flexibilities and then make sure that they are adopted and subsequently used.

Minimum patent requirements in TRIPS

Standards of patentability	Art. 27.1 <ul style="list-style-type: none"> Patents shall be available for both products and processes Patents shall be available for any inventions ... provided they are new, involve an inventive step and are industrially applicable
Exclusive rights	Art. 28 <ul style="list-style-type: none"> Patents grant exclusive right to prevent third parties not having consent from “making, using, offering for sale, selling, or importing” the product or using the process
Disclosure	Art. 29 <ul style="list-style-type: none"> Applicant shall disclose the invention in a sufficiently clear and complete manner
Patent term	Art. 33 <ul style="list-style-type: none"> “Twenty years from filing date”
Non-discrimination	Art. 27.1 <ul style="list-style-type: none"> Patents shall be available for all fields of technology without discrimination Patents shall be available and patent right enjoyable without discrimination based on place of invention and whether products are imported or locally produced
Enforcement	Arts. 41–47 <ul style="list-style-type: none"> There must be fair, equitable and appealable judicial enforcement procedures allowing effective action against infringement Judicial authorities shall have the authority to order a party to desist from infringement and to prevent entry of infringing imported goods into channels of commerce immediately after customs clearance Judicial authorities shall have the authority to order an infringer to pay adequate compensation for the injury suffered when the infringer has knowingly, or with reasonable grounds to know, engaged in infringing activity

⁶⁸ Global Commission on HIV and the Law, RISKS, RIGHTS & HEALTH, Recommendations 6.1, 6.2, and 6.3 at 86 (2012), available at: <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.

⁶⁹ Available at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf. See also follow-up reports of the Consultative Expert Working Group on Research and Development: Financing and Coordination, available at: <http://www.who.int/phi/cewg/en/>.

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	<ul style="list-style-type: none"> • Judicial authorities shall have the authority to order that infringing goods be disposed of outside the channels of commerce or destroyed • Judicial authorities shall have the authority to order the infringer to identify third persons involved in the production and distribution of infringing goods and their channels of distribution • Judicial authorities shall have the authority to order prompt and effective provisional measures to prevent an IP infringement and to preserve evidence thereof
State-to-state dispute settlement	Art. 64 <ul style="list-style-type: none"> • General Agreement on Tariffs and Trade (GATT) state-to-state dispute resolution applies to alleged Member violations of the TRIPS Agreement

Minimum data protection requirements

Data protection — unfair commercial use	Art. 39.3 <ul style="list-style-type: none"> • Applies when submission of data is required for marketing approval of pharmaceuticals • Applies to undisclosed information only, and only where its origination involved considerable effort • Applies to unfair commercial use, not all uses (e.g. by drug regulatory authority)
Data protection — disclosure	<ul style="list-style-type: none"> • Non-disclosure except where necessary to protect the public or • Non-disclosure unless data are protected against unfair commercial use

Although Member States may not provide lower levels of protection than those set out by TRIPS, they may go higher,⁷⁰ to the extent that consistency with the provisions of the Agreement is ensured.⁷¹ As previously discussed these higher standards are routinely pursued in U.S. and E.U. free trade agreement negotiations.⁷²

⁷⁰ Article 1.1.

⁷¹ See, e.g., Ruse-Khan, Henning Grosse and Kur, Annette, ENOUGH IS ENOUGH - THE NOTION OF BINDING CEILINGS IN INTERNATIONAL INTELLECTUAL PROPERTY PROTECTION Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 09-01 (December 8, 2008), available at SSRN: <http://ssrn.com/abstract=1326429> or <http://dx.doi.org/10.2139/ssrn.1326429>

⁷² See, e.g., Sean Flynn, Brook Baker, Margot Kaminski, Jimmy Koo, *Public Interest Analysis of US TPP Proposal for an IP Chapter*, 28 AM. U. INT'L L. REV. 105-202 (2012); CIEL, INTELLECTUAL PROPERTY IN EUROPEAN UNION ECONOMIC PARTNERSHIP AGREEMENTS WITH THE AFRICAN, CARIBBEAN AND PACIFIC COUNTRIES: WHAT WAY FORWARD AFTER THE CARIFORUM EPA AND INTERIM EPAs (April 2008) available at: http://www.ciel.org/Publications/Oxfam_TechnicalBrief_5May08.pdf; Carlos M. Correa, *Negotiation of a Free Trade Agreement European Union-India: Will India Accept TRIPS-plus Protection?* (2009), available at: http://www.oxfam.de/download/correa_eu_india_fta.pdf; Jean-Frederick Morin, *Tripping up TRIPS Debates: IP and Health in Bilateral Agreements*, 1 INT'L J. INTELLECTUAL PROP. MNGT. 37 (2006) available at: <http://www.inderscience.com/storage/f112412510769138.pdf>; E. Biadgleng & J-C Maur, THE INFLUENCE OF PREFERENTIAL TRADE AGREEMENTS ON THE IMPLEMENTATION OF INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES (2011) <http://ictsd.org/downloads/2011/11/the-influence-of-preferential-trade-agreements-on-the-implementation-of-intellectual-property-rights-in-developing-countries.pdf>; Pedro Roffe, INTELLECTUAL PROPERTY, BILATERAL AGREEMENTS AND SUSTAINABLE DEVELOPMENT: THE CHALLENGES OF IMPLEMENTATION (Jan. 2007) http://www.ciel.org/Publications/IP_StrategyNote_Apr07.pdf; Francisco Rossi, *Free trade agreements and TRIPS-plus measures*, 1 INT'L J. INTELLECTUAL PROP. MNGT. 150 (2006)

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The major TRIPS-plus provisions involving patents, data protection, and enforcement are as follows:

Key TRIPS-plus provisions negatively affecting access to medicines

Eased standards of patentability	<ul style="list-style-type: none"> • Required patents on new uses or methods of use of known medicines • Required patents on new forms of known substances (e.g. active pharmaceutical ingredient regardless of improved therapeutic efficacy) • Lowering standards on novelty, on inventive step down to obviousness, and on industrial applicability to useful, allowing original and secondary patents on a broader range of ‘inventions’ and, in particular, allowing evergreening patents on new formulations, dosages and standard optimization efforts • Adopting utility patent models that have absent or lower standards for inventive step and allow evergreening for the utility patent term, typically 10 years
Elimination of patent exemptions	<ul style="list-style-type: none"> • Required patents on diagnostic, therapeutic and surgical methods for treatment of humans
Disclosure	<ul style="list-style-type: none"> • Lower disclosure requirements
Patent term extensions	<ul style="list-style-type: none"> • Extensions for delays in processing patent applications • Extensions for delays in medicines registration process
Patent oppositions and revocation	<ul style="list-style-type: none"> • No allowance of pre- and/or post-grant opposition procedures • Restrictions on grounds of patent opposition/revocation
Weakened limited exceptions	<ul style="list-style-type: none"> • Restrictions on use of early working/Bolar provision with respect to exporting patented subject matter for the purpose of obtaining foreign registration • No exception or weak exception for non-commercial and commercial research and educational use • No allowance of an exception for prior use
No parallel importation	<ul style="list-style-type: none"> • Disallowance of international exhaustion regime
Data exclusivity	<ul style="list-style-type: none"> • Exclusive rights with respect to regulatory data prohibiting regulator’s reliance on or reference to innovator’s Art. 39.3 data or the fact of prior registration for a minimum period of years — prevents registration of follow-on generic products without new clinical trial data even in the absence of a patent • Possibility of extending data exclusivity upon submission of additional clinical data (evergreening data exclusivity)
Patent–registration linkage	<ul style="list-style-type: none"> • Restricting the drug regulatory authority’s ability to register a generic medicine whenever an originator claims that a patent would be infringed

<http://www.inderscience.com/storage/f713411102912685.pdf>; UNDP/UNAIDS ISSUE BRIEF, THE POTENTIAL IMPACTS OF FREE TRADE AGREEMENTS ON PUBLIC HEALTH (2012)
http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC23_49_Issue_Brief_Free-Trade-Agreements_en.pdf.

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Mandatory injunctions	<ul style="list-style-type: none"> • Outlawing of judicially mandated royalties remedy under Art. 44.2
Enhanced civil remedies	<ul style="list-style-type: none"> • Deterrent remedies, such as damages based on average retail price
Broadened criminal remedies	<ul style="list-style-type: none"> • Criminal sanctions for patent violations (beyond TRIPS requirement for criminal trademark counterfeiting and copyright piracy only)
Enhanced border measures	<ul style="list-style-type: none"> • Seizures of goods in transit • Mandatory destruction of goods • Third-party enforcement • Enhanced provisional measures
Investment clause enforcement	<ul style="list-style-type: none"> • Inclusion of IP as covered investments • Allowance of investment claims based on patent decisions (denial, revocation, invalidation, opposition, compulsory licences, registration of generics) • Investor–state dispute settlement allowing private arbitration of investment claims

At the opposite end of the IP spectrum from TRIPS-plus are TRIPS-compliant public health flexibilities, which allow governments to limit or bypass the otherwise exclusive rights held by right holders. These flexibilities can be lawfully used, when appropriate and when enacted into national law, to protect the right to health and other public interests, including to redress anti-competitive practices. Many of the TRIPS Agreement's public health flexibilities were affirmed with the 2001 Doha Declaration and have been successfully used to achieve access to more affordable essential medicines by both developed and developing countries. The chart below lists many key TRIPS public health flexibilities that could serve as a guide for constructive IP reform in South Africa.

Key TRIPS public health flexibilities

Standards of patentability	<p>Art. 27</p> <ul style="list-style-type: none"> • High/strict standards of patentability, especially concerning combinations of prior art, novelty, inventive step and industrial applicability • If appropriate, requirement that variations of existing medicines demonstrate significantly enhanced therapeutic efficacy • No patents on new uses of existing medicines • No patents on combinations/admixtures of known medicines • No presumption of patentability
Exclusions from patentability	<p>Art. 27.3</p> <ul style="list-style-type: none"> • Surgical, diagnostic and therapeutic methods — can justify no patent for new uses and methods of use • 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
Disclosure	<p>Art. 29</p> <ul style="list-style-type: none"> • 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

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Opposition procedures and grounds for revocation	<p>Arts. 62.4 and 32</p> <ul style="list-style-type: none"> • 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/standards of patentability
Patent term	<ul style="list-style-type: none"> • No extensions for regulatory delays
Limited exceptions	<p>Art. 30</p> <ul style="list-style-type: none"> • Early working/Bolar 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 Art. 31(f) with respect to production for export
Parallel importation	<p>Art. 6</p> <ul style="list-style-type: none"> • Adoption of international exhaustion rule and easy procedures for parallel importation • Possible restrictions on contractual limitations on export in support of parallel importation
Compulsory licenses and government use	<p>Art. 31 and Art. 44.2</p> <ul style="list-style-type: none"> • Broad grounds for issuing a compulsory license, including but not limited to excessive pricing, refusal to license/essential facility, failure to supply in sufficient quantities, failure to work, including local working, to have redundant sources of supply and to allow combination products <ul style="list-style-type: none"> ○ 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 without prior negotiation • Public, non-commercial-use or government-use licenses without prior negotiation • Competition-based licenses without prior negotiations and without restrictions on quantities exported • Production for export licenses either pursuant to the Paragraph 6 Decision (proposed Art. 31bis) System or Art. 30 limited exception • Judicial licenses allowed pursuant to Art. 44.2 • Clear, easy-to-use remuneration guidelines established
Competition policies	<p>Art. 8.2 and Art. 40</p> <ul style="list-style-type: none"> • Prevent abuse of IP rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect international transfer of technology • Prevent licensing practices or IP rights conditions that restrain competition or adversely affect trade and may impede transfer of technology

Having catalogued both requirements and flexibilities under the TRIPS Agreement, and measures that are TRIPS-plus, it is now time to examine the South African Patent Act 57

of 1978 as amended⁷³ to discern how it is defective in human rights terms with respect to the government's obligation to take all available legislative measures to ensure that South African IP legislation does not unnecessarily impede access to medicines.

South Africa's Porous Patent Act

Although South Africa's Patent Act has many defects in terms of maximizing TRIPS public health flexibilities, the most obvious defect is its failure to require examination of patent applications and to instead allow a "depository" regime.⁷⁴ Under this regime, the Companies and Intellectual Property Registry Office simply collects patent applications, but it does not examine the novelty, inventive step, or industrial applicability of the product or process. Instead, the office only ascertains if the correct forms are filled out and that payment has been made; thereafter, the application is approved without any substantive review whatsoever. Compounding this problem, patent application fees in South Africa are among the lowest in the world, 20-30 times cheaper than other patent regimes.⁷⁵

To say that South Africa has a problem in terms of its excessive granting of patents is an understatement.⁷⁶ South Africa granted 2442 patents on medicines in one year alone, 2008.⁷⁷ South Africa grants 40% more patents on medicines than even the E.U. or the U.S.⁷⁸ In contrast, Brazil, a comparable middle-income country, granted only 278 patents between 2003 and 2008, followed by 439 by Columbia 2004-2008, and 951 in Argentina 2000-2007.⁷⁹ Likewise, India, which had a ten-year backlog of pharmaceutical patent

⁷³ Available at: <http://www.wipo.int/edocs/lexdocs/laws/en/za/za051en.pdf>.

⁷⁴ Section 34 of the Act says, "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." If substantive examination were in fact prescribed in implementing regulations then South Africa could examine substantively, but no such regulation exists.

⁷⁵ Anthipi Pouris & Anastassios Pouris, *Patents and economic development in South Africa: Managing intellectual property rights*, 107 S.A. J. Science 1-10, 5 (2011).

⁷⁶ *Id.* (estimating that 80% of South African patents would not have been granted were they actually examined), available at: http://repository.up.ac.za/bitstream/handle/2263/17574/Pouris_Patents%282011%29.pdf?sequence=1; Catherine Tomlinson & Lotti Rutter, *The Economic & Social Case for Patent Law Reform in South Africa* (TAC 2014), available at: <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf>;

⁷⁷ Yousuf A. Vawda, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Country Case Study: South Africa* (2011) (finding that 2442 pharmaceutical patents were granted in South Africa in 2008, 1988 of which were granted to US and EU countries and only 16 to South African inventors; also finding that only seven patents had been judicially challenged in South Africa 2003-2008).

⁷⁸ Amy Kapczynski, Chan Park & Bhaven N. Sampat, *South African Pharmaceutical Patenting: An Empirical Analysis*, Presentation at TAC/MSF 23 October 2012 meeting (2012), available at: <http://www.tac.org.za/sites/default/files/resources/Create%20Resources/files/Sampat%20presentation.pdf>.

⁷⁹ Carlos Correa (2011) *PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING*, Research Paper No. 41 (2011), available at: <http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>.

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applications after collecting “mailbox” applications in anticipation of becoming fully TRIPS compliant in 2005, granted only 3488 patents between 2005 and 2010.⁸⁰

Given its depository system, it is no surprise that South Africa has no patent opposition procedures. Ordinarily, making opposition procedures open to competitors and other interested parties can result in information and argumentation concerning existing prior art and standards of patentability that will lead to more informed decisions and higher quality patents. Many countries have successfully adopted both pre- and post-grant opposition procedures, most notably India.⁸¹ In contrast, in South Africa, competitors are left to costly court challenges seeking to invalidate granted patents. Such litigation is costly, time consuming, and in many cases impracticable. In the pharmaceutical context, given South Africa’s relatively small population, unless the medicine has an unusually large market and unless expected profits are sufficiently enticing, the potential generic entrant will simply sit on the sidelines and wait until patent term expiration. Compounding the problem of not examining patents, South Africa has a totally untransparent patent registry that provides extremely limited information about patent applications, grants, and current status.

Relatedly, although South Africa has relatively high standards of novelty,⁸² except with respect to its requirement that new therapeutic or diagnostic methods shall be considered novel, its inventive step requirement is quite weak both on the books and as applied.⁸³ As a result, patent holders can file successive and 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. Extensive academic commentary suggests that such evergreening is a major problem.⁸⁴ In this respect, even

⁸⁰ Drug patents on the rise: 3,488 in five years, Rediff Business (Sept. 24, 2012), available at: <http://www.rediff.com/money/report/drug-patents-on-the-rise-3488-in-five-years/20120924.htm>.

⁸¹ See, WIPO Standing Comm. on the Law of Patents, OPPOSITION SYSTEMS AND OTHER ADMINISTRATIVE REVOCATION AND INVALIDATION MECHANISMS (2012) available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf; MSF, PATENT OPPOSITION DATABASE, available at: <http://patentoppositions.org/>.

⁸² See, section 25(5)-(9) of the Act.

⁸³ See, section 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) Limited v. Bayer Pharma AG and Another* (468/2013) ZASCA 123 (2014) (holding that formulation with an enteric was sufficient was sufficiently inventive to allow a secondary patent on rapidly soluble oral contraceptive).

⁸⁴ The UK Commission on Intellectual Property Rights recommended that developing countries exclude medical methods from patentability, avoid patenting new uses of known products, and “apply strict standards of novelty, inventive step and industrial applicability or utility (consider higher standards than currently applied in developed countries).” Integrating Intellectual Property Rights and Development Policy, 122 (CIPR, 2001). See, also, Carlos Correa, TACKLING THE PROLIFERATION OF PATENTS: HOW TO AVOID UNDUE LIMITATIONS TO COMPETITION AND THE PUBLIC DOMAIN (South Centre 2014), available at: http://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf; Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ‘Secondary’ Pharmaceutical Patents*, 7 PLoS ONE e49470 (2012), available at: <http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0049470&representation=PDF>; C. Scott Hemphill & Bhaven Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECONOMICS 327–39 (2012); Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals*:

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India, which has adopted relatively stringent standards of patentability, appears to have been lax in its application of those standards.⁸⁵ Also in South Africa's Patents Act, the requirement that the invention be capable "of being used or applied in trade or industry or agriculture,"⁸⁶ is barely defined except with respect to an exclusion for surgical, therapeutic or diagnostic methods.⁸⁷

In the area of limited exceptions to exclusive patent rights allowed by Article 30 of the TRIPS Agreement, the South African Patents Act is also deficient. In particular, South Africa does not have a robust research and education exception that allows research with and on patented technologies for commercial, non-commercial, and educational purposes.⁸⁸ 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 the TRIPS Agreement⁸⁹ also expressly allows countries flexibility to adopt an international exhaustion rule allowing parallel importation of medicines lawfully placed on the market in other countries. Section 15C(b) of the Medicines and Related Substances Control Act, as amended, authorizes the Minister of Health to take advantage of Article 6 and to allow and regulate parallel importation. Unfortunately, the implementing regulations with respect to parallel importation⁹⁰ are overly complex and protracted, meaning that medicines are not easily parallel imported into the country.

Similarly, compulsory and government use (public, non-commercial use) licenses are allowed under Article 31 of the TRIPS Agreement, but South Africa has incomplete standards and overly bureaucratic procedures with respect to these key public health flexibilities. On the plus side, South Africa expressly permits compulsory licenses for dependent patents that represent a important technical advance of considerable economic significance.⁹¹ Moreover, Article 56 of the Patent Act allows compulsory licenses on the grounds of: non-working within a specified period of time,⁹² demand for the patented article is not being met in South Africa to an adequate extent and on reasonable terms,⁹³ refusal to grant a license on reasonable terms to the detriment of trade, industry, or agriculture in South Africa,⁹⁴ or the price of the patented article, if imported, is excessive in relation to prices charged in countries where it is manufactured⁹⁵. However, the grounds for issuing compulsory licenses are incomplete in

A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades, 31 HEALTH AFFAIRS 2286-94 (2012).

⁸⁵ See, Sudip Chaudhuri, Chan Park & K. M. Gopakumar, FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA'S RESPONSE (2010), available at: <http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf>; Bhaven N. Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?*, 38 J. HEALTH POLICY 735-755 (2013), available at: <http://jhppl.dukejournals.org/content/38/4/735.long>.

⁸⁶ Section 25(1).

⁸⁷ Section 25(11)-(12).

⁸⁸ Evans Misati & Kyoshi Adachi, THE RESEARCH AND EXPERIMENTATION EXCEPTIONS IN PATENT LAW: JURISDICTIONAL VARIATIONS AND THE WIPO DEVELOPMENT AGENDA (2010), available at: http://ictsd.org/downloads/2010/04/evans_paper-v2.pdf.

⁸⁹ "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."

⁹⁰ Regulation 7 of the General Regulations, 2007.

⁹¹ S.A. Patent Act, Article 55; see TRIPS, Article 31(l).

⁹² Section 56(2)(a).

⁹³ Section 56(2)(c).

⁹⁴ Section 56(2)(d).

⁹⁵ Section 56(2)(e).

that the Act does not have a general public health or public interest exception, a clearer unreasonable price exception, a local-working exception, a competition-based exception,⁹⁶ 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 overly burdensome and time-consuming and the Act lacks remuneration guidelines, the result of which is that no compulsory licenses on medicines have ever been issued in South Africa. Finally, although there are provisions for acquisition of patents by the State and for “public purpose” use by a Minister of State,⁹⁷ there are no specific provisions for public, non-commercial use licenses nor for licenses in response to national emergencies or other matters of extreme urgency, though both might easily fit in the public purpose language. Section 4 of the Act would appear to require negotiated agreement with the patent holder or a protracted formal court hearing with court appeal rights, none of which is required by TRIPS Article 31.

This is by no means a complete or exhaustive list of defects in the South African Patent Act, but these deficits were well known to Section27 and to TAC and MSF activists.⁹⁸ However, with the emergence of multi-drug resistant tuberculosis, hepatitis C, and other HIV co-infections, and with the exorbitant prices often charged for medicines to treat these conditions, AIDS activists became increasingly concerned about the 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,⁹⁹ meant that South Africa had fewer resources to expand its health workforce and to strengthen its public sector health services as needed. Likewise, although the process was relatively opaque, activists knew that DTI had begun deliberations on a new IP policy for South Africa in 2008. Accordingly, beginning in 2011, the TAC once again turned its attention to the ip-related, structural determinants of unaffordable prices for medicines. It was on the basis of recognizing this activist interest and need that stronger TAC and MSF participation in intensive training on intellectual property and access to medicines was pursued.

Advocacy-oriented teaching and learning at the intersections of human rights, intellectual property, and access to medicines¹⁰⁰

⁹⁶ 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*, 188 (P. Roffe, G. Tansey & D Vivas-Eugui eds., 2005).

⁹⁷ Article 4.

⁹⁸ For example, the TRIPS Agreement specifically allows the use of competition policy to prevent abuse of IP rights and to permit close regulations of the terms of IP licensing agreements. See, Articles 8.2 and 40; see, generally, Frederick Abbott, Sean Flynn, Carlos Correa, Jonathan Berger, Natasha Nyak, *USING COMPETITION LAW TO Promote Access to Health Technologies: A guidebook for low- and middle-income countries* (UNDP 2014), available at: <http://www.undp-globalfund-capacitydevelopment.org/media/468621/undp-using-competition-law-to-promote-access-to-medicine-05-14-2014.pdf>.

In addition, the South Africa IP regime has some excessive provisions in its IP enforcement rules that might also be revised.

⁹⁹ Bongani M. Mayosi, Alan Flisher, Umesh Laloo et al., *The burden of non-communicable diseases in South Africa*, 374 LANCET 934-947 (2009).

¹⁰⁰ This section is largely drawn from Yousuf Vawda & Brook Baker, *Achieving Social Justice in the Intellectual Property Debate: Realising the Goal of Access to Medicines*, 13 AFRICA HUMAN RIGHTS L. J. 57-84 (2013).

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Historically, specialist training in intellectual property was offered by institutions operating within the UN system, such as the World Intellectual Property Organization (WIPO), or patents offices in developed countries. Such training was decidedly pro-IP, and has been criticized because developing country policy makers and patent examiners tended to adopt the biases and priorities of their pro-IP advisors and trainers.¹⁰¹ 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.¹⁰²

Also in the African context, intellectual property has typically been taught in law schools from a pro-IP, pro-corporate perspective.¹⁰³ A developmental, human rights approach, in contrast, might seek to situate IP analysis in the developing country context, with specific attention to human rights, public health, and public interest concerns. Some university courses are beginning to address this perspective, most notably at the Masters level.¹⁰⁴ However, these courses are generally aimed at postgraduate students or public sector employees. No course previously catered for the training, participation or perspectives of activists and advocacy specialists in the area of IPRs, and their impact on accessibility of medicines.

In an effort to increase activists' and other participants'¹⁰⁵ knowledge about intellectual property within a human rights framework and to capacitate participants to engage in country and regional campaigns to overcome IP barriers and to promote access to medicines, Yousuf and I developed an intensive two-week shortcourse that was supported by the Open Society Institute and delivered at the University of KwaZulu Natal in Durban, South Africa.¹⁰⁶ 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 UKZN IP & Access to Medicines Short Course, in its five years of existence 2008-2012, trained over 65 participants drawn from throughout Africa, with a more intense focus on Eastern and Southern Africa.¹⁰⁷ Although the home countries of participants were diverse legally, economically, and culturally, they all had significant commonalities –

¹⁰¹ See PD Bierbeck & S Roca, AN EXTERNAL REVIEW OF WIPO TECHNICAL ASSISTANCE IN THE THE AREA OF COOPERATION FOR DEVELOPMENT (2011), available at:

http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf; Peter Drahos, "Trust me": Patent offices in developing countries, *Am. J. Law & Med.* 151-174 (2008).

¹⁰² UNDP/South Centre 'Intellectual property enforcement and access to essential medicines', Regional Consultation, 22-23 June 2011, Pretoria, South Africa FINAL REPORT (on file with authors).

¹⁰³ See YA Vawda, *Intellectual property: Putting the 'public' back into 'private' law*, *DE REBUS* 75-76 (Jan-Feb 2008).

¹⁰⁴ The University of Pretoria's Centre for Human Rights, for example, offers a one-week short course on 'Human rights and access to medicines' www.chr.up.ac.za/index.../human-rights-a-access-to-medicines.html.

¹⁰⁵ The course attempted, relatively unsuccessfully to engage public officials in the course. We did have two successes in this regard with an officer from the patents office in Zambia and a counsel to the legislative drafting committee of the Uganda parliament as course participants. We also succeeded in attracting several academics the Universities of KwaZulu-Natal and Zululand (South Africa), Makerere (Uganda), University of Malawi and the National University of Lesotho.

¹⁰⁶ Since 2008, the UKZN School of Law has offered a short course on Intellectual Property and Access to Medicines, training a cross-section of groups: academics, community activists, government decision-makers, and advocates for social justice. Details may be sourced at <http://ipatm.ukzn.ac.za/Homepage.aspx>.

¹⁰⁷ The last year of the course, we had two participants from Eastern Europe.

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widespread poverty and inequality, under-development, poor health and weak health systems, and unaffordable high prices for newer life-saving medicines. In addition, all of these countries had legal and regulatory regimes that provided unnecessarily strong intellectual property protection for medicines and other medical products. The impact of overly high IPRs and their related monopoly prices on access to medicines was palpable, and would grow worse in the future if countries acceded to efforts by the pharmaceutical industry and their rich country surrogates, to seek broader, stronger, and longer IP protections and enhanced IP enforcement measures. Thus the potential and need for collaborative regional and national-level advocacy in the IP arena was enormous.

The objectives of the course were multi-faceted¹⁰⁸ and the subject matter diverse,¹⁰⁹ but the fundamental pedagogy was one of collaboration and mutual learning oriented

¹⁰⁸ The course description included the following course objectives:

- The UKZN IP & Access to medicines Short Course attempts to achieve a number of objectives: To make legal and policy issues and debates accessible to participants drawn for a wide variety of sectors of society.
- To combine in one programme, the specific skills sets, knowledge and experience of diverse groups including university academics, civil servants, community activists and NGOs, and have the respective enhance their understanding and involvement in the issues of others, for example, academics will not only engage with the issues covered in their teaching, but also become involved in whatever capacity in the campaigns devised and led by activists.
- To critically reflect on the roles of government, civil society, industry as they impact on the research, innovation, development, production, distribution, availability, affordability and accessibility of medicines.
- To examine specific access to medicines campaigns and strategies in order to explore effective means of advancing better access for all.
- To conceptualise, plan, devise and, ultimately, implement campaigns around problems created by IP-related monopolistic practices in this area.
- To establish a network of resources and resource personnel comprising alumni and instructors of the course, capable of providing on-going ideas, support and solidarity for access to medicines campaigns.

¹⁰⁹ A wide range of topics were covered in the programme:

- An overview of medicines, from inception/inspiration to end use.
- An examination of medicines pricing, funding and health systems through which they are delivered; and the 'grand arc' of the access to medicines campaign.
- Discussion of selected South African access to medicines campaigns, their successes and failures.
- An overview of intellectual property regime.
- The notion of the right to health in international and domestic law.
- Global health ethics; the ethics of clinical trials involving humans, and associated issues.
- Gender and access issues – rights of women and persons of diverse sexual orientations.
- Unpacking the TRIPS Agreement, in particular understanding the 'flexibilities' available to improve access to medicines:
 - Patent standards, opposition procedures and revocation of patents.
 - The principle of non-discrimination in the granting of patents, exemptions from and exceptions to patents, and parallel importation of medicines.
 - The use and effect of compulsory licences.
- The economics of the innovator and generic pharmaceutical industries.
- The role of industrial policy and self-sufficiency in the developing country context.
- The use of competition law and policy in enhancing access; and a review of South African Competition Commission cases.
- Regional and international co-operation, at both governmental and non-governmental levels, in enhancing access to medicines.
- Rational drug use, the registration and market approval of medicines; the impact of permitting data exclusivity, and patent and registration linkage on access.

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towards an action agenda. A variety of teaching and instructional methodologies are utilized, based primarily on exploring past exemplars of successful access-to-medicines campaigns and using a problem-solving pedagogy. The students had a course packet that included a curriculum outline detailing daily schedules, a glossary of key terms, and compilation of required and supplementary readings, many of which involved case study of past treatment access campaigns. There were formal presentations of complex material by experts,¹¹⁰ including Yousuf and me. However, there were also small and large-group discussions, breakaway sessions, snap one-on-one discussions on a critical or confusing point of debate or analysis. Participants were required to write reaction papers on certain topics both to ascertain their grasp of prescribed material, and to enable them to express opinions on a topic. In addition, instructors used media, role-plays and debates in enhancing understanding of key concepts.¹¹¹

In addition to these more traditional pedagogies, the main innovation of the course was to set aside 2-3 days for participants to work in country-based affinity groups to develop a detailed strategic plan for an actionable access-to-medicines campaign that they might carry out in the future. Participants conducted guided 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. Yousuf and I acted as expert resources to each group and provided detailed comments and suggestion on the draft campaigns. Finished campaigns were presented again on the last day of the course and against received feedback and comment from Yousuf, me, and other course participants.¹¹² As hoped, one significant outcome generated by the course, was the emergence of durable, pan-African solidarity among the participants, which survives after the course. The intensive interaction over two weeks yields a strong camaraderie, and participants develop a deeper understanding of their respective realities, challenges and prospects for change. They continue to offer one another guidance and support in their

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- TRIPS-plus free trade and economic partnership agreements; the new IP enforcement agenda, and the impact of anti-counterfeiting measures on access to generic medicines.
 - Pooled procurement of medicines, and problems of medicines stockouts.
 - The future of innovation in medicines, and the development of an African research agenda.
 - Planning and strategising country campaigns on IP and access to medicines.

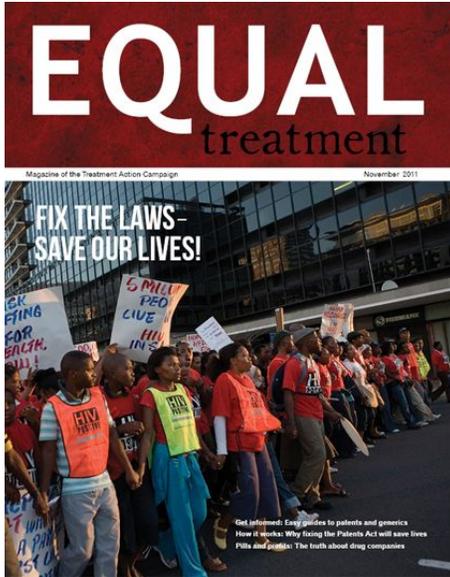
¹¹⁰ We are especially grateful to the participation of experts such as Jonathan Berger, then from Section27; Andy Gray, Senior Lecturer and pharmaceutical expert from the Nelson R. Mandela School of Medicine, University of KwaZulu Natal; Sean Flynn from the Washington College of Law, American University; Jerome Singh, lecturer from UKZN and ethical officer for CAPRISA, 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, TALC, Zambia,

¹¹¹ For example, a topic which participants in previous years found difficult to understand is the concept of ‘data exclusivity’ – the drive by innovator pharmaceutical companies to deny generic competitors reference to, and use of, their clinical trial data, for the purpose of obtaining marketing approval for their follow-on products. In the 2011 course, the instructors presented this theme as a role-play in which they acted out the roles of the innovator company, the generic company, and the drug regulator, using props to illustrate the data for which exclusivity was being claimed. Participants responded spontaneously that they were able to understand the issues more clearly.

¹¹² 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 program, the adoption of safer medicines, and earlier initiation of treatment.

work, usually on an informal basis. It was within this framework that the 2011 participants in the course planned the 2011 Fix the Patent Laws campaign.¹¹³

TAC, MSF and Section 27 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.¹¹⁴ Included in its first press release, TAC directly referenced the constitutional guarantee of the right to health: “Under the Constitution, the South African government is obligated to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right to have access to health care services, which includes access to medicines.”¹¹⁵ 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.¹¹⁶

In January of 2012, the Campaign issued a Briefing Document outlining the patent reforms that were needed: (1) improved substantive standards and streamlined procedures for issuing compulsory licenses, (2) stricter standards for patentability 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 procedures.¹¹⁷ In February, TAC contacted DTI about its delayed IP policy,¹¹⁸ delivering a letter requesting a meeting with Rob Davies to discuss the IP policy and Patents Act amendment that were need. The letter also expressed concern about an upcoming Africa IP summit that was dominated by U.S. and pharmaceutical industry participants.¹¹⁹

¹¹³ In 2012, course participants refined a similar plan concerning reform of the Industrial Property Act that was underway in Uganda.

¹¹⁴ *TAC calls on government to amend South Africa’s Patents Act and protect our right to health* (Nov. 16, 2012), available at: <http://www.fixthepatentlaws.org/?p=17>.

¹¹⁵ *Id.*

¹¹⁶ *Fix the Laws – Save Our Lives*, EQUAL TREATMENT – MAGAZINE OF THE TREATMENT ACTION CAMPAIGN (Nov. 2011) (reviewed and commented upon by course instructors), available at: <http://www.tac.org.za/community/files/file/etmag/ET41/ET41English.pdf>.

¹¹⁷ *Briefing Document – Fix the Patent Laws: Campaigning for pro-public health reform of South Africa’s Patents Act* (Jan. 26, 2013), available at: <http://www.fixthepatentlaws.org/?p=79>.

¹¹⁸ Although 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. *South Africa’s Intellectual Property Policy: process for public consultation?* (Feb. 14, 2012), available at: <http://www.fixthepatentlaws.org/?p=116>.

¹¹⁹ *Open letter to the Department of Trade and Industry* (Feb. 20, 2012), available at: <http://www.fixthepatentlaws.org/?p=118>. The planned Summit was subsequently cancelled and rescheduled as a result of civil society objections. See, *Africa IP Forum Postponed* (Feb. 28, 2012), available at: <http://www.fixthepatentlaws.org/?p=133>; *IP summit for Africa?* (Feb. 12,

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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 of 2012.¹²⁰ Continuing their effort to educate health activists about the need for patent law reform, TAC and MSF organized a workshop at the July 2012 Peoples Health Assembly held at the University of the Western Cape¹²¹ and also organized a public lecture on the topic of patent law reform.¹²² TAC's public messaging strategy included a brochure¹²³ and a Myth-Buster paper¹²⁴. Later in 2012, TAC and MSF hosted a meeting examining intellectual property law in South Africa from a public health and human rights perspective. At that meeting MacDonal Netshitenzhe, Chief Director of Policy and Legislation at the DTI stated that the Draft IP Policy would be submitted to the Cabinet on December 5, 2012, after which there would be three months of public consultation.¹²⁵ When the December date came and passed, TAC once again called on the DTI to submit its IP policy at the Cabinet's next sitting in January of 2013;¹²⁶ when that date was missed, yet another call for action was issued.¹²⁷ Obviously, the long series of broken promises and delayed response continued to frustrate activists.

2012), available at: <http://www.fixthepatentlaws.org/?p=110>. My statement on the planned summit was:

It is deeply problematic that the Obama administration continues to pursue efforts to strengthen, widen, and lengthen patent, data, and copyright monopolies in African countries that desperately need expanded access to medicines, educational materials, and climate control technologies and that it simultaneously seeks even stronger enforcement of IP protections than what is currently required under international law. Carrying the policy portfolio of Big Pharma and other IP-based multinationals under the guise of addressing Africa's needs, the proposed African IP Summit is a chilling example of US duplicity and conflict of interest at its worst. ...

William New, *US, WIPO Training Programme on IP Rights in Africa Comes Under Fire*, IP-WATCH (Feb. 12, 2012), available at: http://www.ip-watch.org/2012/02/12/us-wipo-training-programme-on-ip-rights-in-africa-comes-under-fire/?utm_source=post&utm_medium=email&utm_campaign=alerts.

¹²⁰ *TAC/MSF media workshop on intellectual property and access to medicines* (March 2, 2012), available at: <http://www.fixthepatentlaws.org/?p=136>.

¹²¹ *Invitation to attend TAC and MSF workshop during the Peoples Health Assembly* (June 27, 2012), available at: <http://www.fixthepatentlaws.org/?p=338>. Professor Vawda spoke at this workshop.

¹²² *See, Invitation to a public lecture at UCT: FIX THE LAW, SAVE OUR LIVES* (June 6, 2012) available at: <http://www.fixthepatentlaws.org/?p=302>.

¹²³ TAC, *FIX THE PATENT LAWS! CAMPAIGN BROCHURE*, available at: <http://fixthepatentlaws.org/brochure/Fix%20the%20patents%20web.pdf>.

¹²⁴ Available at: http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/TAC_MythBuster_Patent_Reform.pdf.

¹²⁵ *TAC and MSF welcome government's announcement that the draft IP policy will be presented to Cabinet on 5 December 2012* (Oct. 29 2012), available at: <http://www.fixthepatentlaws.org/?p=459>. Professor Vawda presented at this consultation as well. See,

<http://www.tac.org.za/sites/default/files/resources/Create%20Resources/files/Vawda%20presentation.pdf>.

¹²⁶ *TAC calls on the Department of Trade and Industry to submit the IP policy to Cabinet at its next sitting in January 2013* (Dec. 13, 2012), available at: <http://www.fixthepatentlaws.org/?p=523>.

¹²⁷ *TAC calls on the DTI to set a new date for submission of the IP policy to Cabinet* (Jan. 18, 2013), available at: <http://www.fixthepatentlaws.org/?p=526>.



Finally, their patience coming to an end, TAC activists picket the February rescheduled African Intellectual Property Forum and delivered a memorandum to Minister Davies before his keynote address.¹²⁸ Once again the Minister predicted that the policy would be released shortly. Reversing position, on April 24, 2013, the Minister of Trade and Industry announced that South Africa's long-pending IP policy would not be released for public comment any time soon.¹²⁹ Not satisfied, TAC and MSF delivered yet another memorandum of demand¹³⁰ to the DTI at the National Workshop on Intellectual Property and Public Health held in Pretoria on August 7, 2013.¹³¹ After years of delay and several broken promises, DTI finally released its Draft IP Policy and an invitation for public comment on August 4, 2013.¹³²

In response to the freshly released 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.¹³³ Meanwhile TAC Members, MSF, and Section27 experts worked furiously to prepare a formal response. With the fruit of that labor in hand, protestors again marched to DTI in October of 2013, and handed in a Joint Submission commenting on the Draft IP Policy.¹³⁴ (Shortly thereafter, TAC and MSF prepared an additional technical analysis of why South Africa could and should adopt a patent examination system.¹³⁵) Although the central demands of the Joint Submission were similar to those articulated 23 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

¹²⁸ *Activists Make Concerns Heard at African IP Forum – Minister Davies Responds* – (Feb. 27, 2013), available at: <http://www.fixthepatentlaws.org/?p=540>.

¹²⁹ *DTI reneges on IP policy Commitments* (April 30, 2013), available at: <http://www.fixthepatentlaws.org/?p=583>.

¹³⁰ *TAC & MSF Memorandum to DTI to urgently Fix the Patent Laws* (Aug. 7, 2013), available at: <http://www.fixthepatentlaws.org/?p=630>.

¹³¹ *SA's Dept of Trade & Industry delay patent law reform, while local drug prices remain excessive* (Aug. 7, 2013), available at: <http://www.fixthepatentlaws.org/?p=638>.

¹³² Notice 918 of 2013, Department of Trade and Industry, Draft National Policy on Intellectual Property, 2013, (Sept. 4, 2013), available at: http://www.ip-watch.org/weblog/wp-content/uploads/2013/09/SA-IP-Policy-Sept-2013-36816_gen918.pdf. (Note: the consultation period was shortened to 30 working days only.)

¹³³ *Public Consultation on Draft National Policy on Intellectual Property – 27th Sept* Sept. 20, 2013), available at: <http://www.fixthepatentlaws.org/?p=673>.

¹³⁴ *See, South Africa: Stop Blindly Handing Out Patents!* (Oct. 17, 2013), available at: <http://www.fixthepatentlaws.org/?p=777>; *Joint Submission on the Draft National Intellectual Property Policy, 2013*, available at: http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf.

¹³⁵ Leena Menghaney, *Why South Africa Should Examine Pharmaceutical Patents* (Dec. 2012), available at: <http://www.tac.org.za/community/files/file/WhySAnedasanexaminationsystem.pdf>.

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opposition from IP industries, especially pharmaceuticals, the Joint Submission praised the commitment to tighten patenting standards and to consider adoption of a patent examination system. Nonetheless, the Joint Submission made a very concrete set of key recommendations:¹³⁶

1. On patentability criteria:
 - 1.1. The Patents Act should be amended to include stricter patentability criteria; and
 - 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;
2. On patent searches:
 - 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.
3. On substantive patent examination and opposition proceedings:
 - 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
 - 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;
4. On the relationship between medicines registration and patent protection:
 - 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
 - 4.2. Remedies for addressing delays in medicine registration processes should exclude patent extensions;
5. On compulsory licensing and parallel importation:
 - 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;
 - 5.2. Pending any review of the grant of a compulsory licence, interim relief should only be available – upon application – in exceptional circumstances and should not be available for the exercise of government use licenses;
 - 5.3. Default positions regarding licence conditions (including but not limited to royalty rates) and negotiation timelines should expressly be included in sections 4 and 56 of the Patents Act;
 - 5.4. Licensing practices should expressly be regulated, as contemplated by Article 40 of TRIPS; and
 - 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. On research and development (“R&D”), public funding, innovation and access:
 - 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
 - 6.2. 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”);
7. On exceptions to patent infringement:
 - 7.1. The Patents Act should exempt those aspects of scientific research that are not covered by section 69A; and
 - 7.2. The Patents Act should also include an educational use exception;
8. On data protection and exclusivity:

¹³⁶ Available at: <http://www.fixthepatentlaws.org/?p=764>.

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

Throughout the Fix the Patents Law campaign, Yousuf and I continued to support the campaign by reviewing campaign documents and writing blogs in support of the campaign.¹³⁷ Yousuf was also deeply engaged presenting at Campaign consultations, writing blogs and being quoted in the press. Recognizing that it would be important to garner expert analysis supporting the basic pro-public health thrust of the Draft IP Policy, we collaborated to get over 140 organizations and global experts to sign an open letter to DTI supporting the proposed patent law reform in South Africa.¹³⁸ 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.¹³⁹ Our so-called “expert” efforts were supported and supplemented by the inputs of many other activist experts including the authors of an influential UNDP report calling for patent law reform in South Africa.¹⁴⁰ At the close of submissions, which totalled thousands of pages, DTI commissioned Genesis Analytics to undertake an external, independent regulatory assessment and to benchmark South Africa’s Draft IP Policy against IP policies from other countries.

Although TAC and MSF had anticipated industry opposition to a progressive, pro-access IP policy and to their Fix the Patent Laws Campaign and had discussed strategies for neutralizing that opposition as part of their course-related strategizing, even seasoned activists were somewhat surprised when the U.S.-based pharmaceutical industry planned a well-funded, covert disinformation campaign against the proposed reform. On January 10, 2014, Michael AZrak, Merck’s Managing Director for South and East Africa, wrote a email implicating two dozen companies and trade associations in a secret campaign to undermine patent law reform in South Africa.¹⁴¹ Hundreds of thousands of dollars were going to be spent setting up a campaign funded by U.S. companies but presented as if locally inspired and led.¹⁴² Circulation of the leaked email initiated a scandal, now called Pharmagate, and the activist and government response was prompt and harsh. I wrote a blog, “US PhRMA Bares its Fangs – South Africa Patent Law Reform and Access to Medicine at Risk Yet Again.”¹⁴³ Health Minister Motsoaledi described the plan as

¹³⁷ See sources cited at: <http://www.fixthepatentlaws.org/?s=Yousuf+Vawda> and <http://www.fixthepatentlaws.org/?s=Brook+Baker>. Yousuf also co-authored a book chapter for the 2012/2013 South African Health Review assessing a pre-draft of the IP Policy, Andy Gray, Yousuf Vawda & Caron Jack, Intellectual Property – An Unfinished Agenda in 2012/2013 South African Health Review, available at: <http://www.fixthepatentlaws.org/?p=559>.

¹³⁸ Available at: <http://www.fixthepatentlaws.org/?p=773>.

¹³⁹ Tobias Schonwetter, Yousuf A. Vawda et al., *Comments: Draft National Policy on Intellectual Property (IP) of South Africa, 2013* (17 Oct. 2013), available at: http://ip-unit.org/wp-content/uploads/2013/10/IP-Policy-Academics-Submission_final171013.pdf.

¹⁴⁰ See, Chan Park, Achal Prabhala and Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition, and Medicines Law* (2013), available at: http://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf.

¹⁴¹ Available at: <http://keionline.org/sites/default/files/merck-email.pdf>.

¹⁴² See, James Love, *New leaked Merck missive reveals deep drug, medical device company opposition to South African patent reforms*, KEI blogs (Jan. 20, 2014), available at: <http://keionline.org/node/1908>.

¹⁴³ Available at: <http://keionline.org/sites/default/files/merck-email.pdf>

“genocide” and the conspiracy one of “satanic magnitude.”¹⁴⁴ The issue received international attention when Malebona Precious Matsoso, Director General of the Department of Health spoke about it at the 134th Executive Board meeting of the World Health Organization.¹⁴⁵ Besides immediately condemning the pharma conspiracy in broad terms,¹⁴⁶ TAC and MSF also released a research paper debunking industry’s claims.¹⁴⁷ Although pharmaceuticals and their trade associations quickly retreated from the covert campaign, they nonetheless stated their intent to engage in direct lobbying on the proposed IP reforms. That they certainly did since the vast bulk of submission to DTI were from industry, imploring that South Africa maintain its IP friendly patent regime but that it strengthen IP protection by adopting data exclusivity and patent-registration linkage.

Sensing that the time was ripe post-Pharmagate and marching to the Department of Trade and Industry in Pretoria in March of 2014, 1000 health activists, led by TAC, MSF, and Section27, demanded finalization of the National Intellectual Property Policy before the general elections.¹⁴⁸ Unfortunately, the finalization of the policy has been delayed, in part because the Department did not receive Genesis Analytics 200-page benchmarking assessment until August. However, at a consultation in Pretoria on October 20, 2014, DTI announced that it expected to finalize the IP Policy and to submit it to the Cabinet by the end of the year. In a statement at the consultation, Zodwa Ntuli, Deputy Director General of Consumer and Corporate Regulation, expressed the department’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. Of course, the release of a finalized IP Policy by DTI will only be one additional step in an arduous patent reform process. The matter will have to eventually be taken up in Parliament to consider and pass implementing legislation. During this entire process, decision makers will face continuing pressure and lobbying from industry, and perhaps once again from the U.S. For example, it has been reported in the press that the U.S. Chamber of Commerce is lobbying the U.S. Congress that South Africa must protect US IP rights as a condition of Africa Growth and Opportunity Act reauthorization.¹⁴⁹

Conclusion

The rebuff of patent fundamentalism and the promotion generic competition within the framework of a collective right to health is a case study of the impact that a coordinated social movement can have on the reconstruction of public imagination and legal arrangements. Step by step, South African AIDS activists and their allies have focused far upstream at the ultimate pinnacles of economic power, attacking structural and legal

¹⁴⁴ Phillip De Wet, Motsoaledi: *Big Pharma’s ‘satanic’ plot is genocide*, MAIL&GUARDIAN (Jan. 17, 2014), available at: <http://mg.co.za/article/2014-01-16-motsoaledi-big-pharmas-satanic-plot-is-genocide>.

¹⁴⁵ Statement of South Africa on Access to Essential Medicines (in the wake of Pharmagate), (Jan. 24, 2014), available at: <http://www.fixthepatentlaws.org/?p=847>.

¹⁴⁶ TAC, Section27 and MSF react to PharmaGate (Jan. 18, 2014), available at: <http://www.fixthepatentlaws.org/?p=823>.

¹⁴⁷ Catherine Tomlinson & Lotti Rutter, *The Economic and Social Case for Patent Law Reform In South Africa* (Feb. 2014), available at: <http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf>.

¹⁴⁸ Available at: <http://www.fixthepatentlaws.org/?p=873>.

¹⁴⁹ Peter Fabricius, SA offers chickens for Agoa renewal, Business Report (Aug. 5, 2014), available at: <http://www.iol.co.za/business/news/sa-offers-chickens-for-agoa-renewal-1.1730442#.VEgu-yhy9UN>.

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barriers to access to medicines. They have used the rhetoric of human rights and the shadow of the South African constitutional guarantees to convince the government that it must effectuate its obligation to protect the right to health by reforming 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 U.S., must refrain from outside influence that thwarts access to medicines and have chastened the multinational pharmaceutical industry for its continuing, pernicious, and backdoor efforts to prioritize monopoly profits over peoples' affordable access to essential public health goods. Over the course of a 15 year campaign, these stalwart activists have helped to increase the number of South Africans receiving antiretroviral therapy from perhaps 20,000 in 1999 to nearly 3 million today.

The Fix the Patent Laws Campaign is a campaign that has deployed diverse discourses – competition, public health, IP-moderation, and human rights – in pursuit of law reform that will keep South Africa's population healthy enough to overcome the legacies of apartheid. In this regard, 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 Fix the Patent Laws campaign, spawned and supported by the UKZN IP & Access to Medicines course, speak directly to issues of social justice. By capacitating individuals and organizations to effectively analyze, understand and engage with complex issues affecting the daily lives of people in South Africa, the course has played a small, but catalytic role in what might be a great achievement. The course sought to do so by leveraging the hard-earned expertise and commitments of activist academics with the tenacious and hard-hitting activism of people living with HIV and AIDS and their social movement allies. It sought to distribute knowledge and to make it actionable in the service of global health justice. In doing so, the course has helped to develop capacity and expertise in South African activists. The most significant force for change, however, comes not from academics nor from the capacitated experts in TAC and MSF – it comes 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 not only has grounded experience of its human rights needs but it has greater insight into the legal structures of oppressive corporate power, both national and international. It learns that even the most technical subjects can be translated into effective, humane calls for justice.

Postscript: TAC Faces Closure

As successful and important it has been to AIDS activism and treatment access, TAC faces closure because of a severe shortage of funding. Twice in the past few years, TAC has downsized in response to reduced donations. Now at a critical juncture of its Fix the Patent Law campaign and its other ongoing campaigns to support regular HIV and viral load testing, to provide treatment literacy, and to address health services weaknesses, TAC has only one-third of its 2015 budget. On the cusp of crucial decisions about reforms to South Africa's porous and permissive patent regime, the world's leading AIDS activist organization is teetering on the edge of closure.¹⁵⁰ Governments cannot be held accountable to their human rights obligations if social movements are euthanized.

¹⁵⁰ Laura Lopez Gonzalez, *Treatment Action Campaign Faces Closure*, HEALTH-E (Sept. 30, 2014), available at <http://www.health-e.org.za/2014/09/30/treatment-action-campaign-faces-closure/>.