Book

The battle for access to medicines for all

In 2000, I returned to Durban, South Africa for the fourth time. For my first visit, in 1997, I took a 6-month sabbatical at the faculty of law of the University of Durban-Westville (UDW). Although 1997 was the height of new HIV infections globally and in South Africa, public awareness of HIV was fairly muted—the *Sarafina 2* musical scandal was rocking the country amid half-hearted HIV-prevention efforts, but the science and reality of HIV treatment was far, far away. When I returned for a shorter visit in 1998, the science of HIV reached an even lower point, with the then Minister of Health promoting Virodene, which contained an industrial solvent, as an HIV treatment.

A year later, I learned that 26% of the female students and 12% of the male students tested anonymously at the UDW health clinic were HIV positive. The rate was much higher for the black African, mainly Zulu, population than for students from Indian backgrounds. I knew that none of my students could afford the recently discovered triple antiretroviral therapy that was already producing a two-thirds reduction in deaths back home in the USA. I realised that more people would become infected, that those with HIV infection would die, and that the energy they might bring to the transformation of South Africa would be lost.

In 2000, at the International AIDS Society's International AIDS Conference in Durban, the convergence of the personal and the political turned me to AIDS activism. On a personal level, I couldn't bear the idea of parents having children with treatable diseases being unable to afford medicines for their loved ones. My younger son is a cancer survivor, whose life had been saved 9 years earlier with expensive oncology drugs and HIV-free blood transfusions. It was a close call. Another father in the parents' support group I attended had seen his son survive cancer, only to die of AIDS because of untestable blood transfusions. On a political level, at the outset of the 2000 Durban Conference, thousands of marchers, myself included, demanded that medicines costing US$10 439 per person per year be made affordable to the millions of sub-Saharan Africans living with and dying of HIV/AIDS. Marchers also denounced the bizarre AIDS denialism of the then President Thabo Mbeki.

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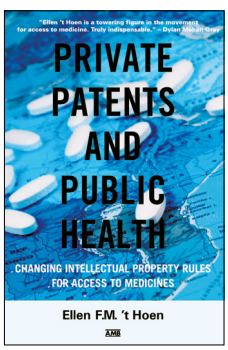
Ellen 't Hoen was then, and is now, a giant in the access to medicines movement and her insider book, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, cogently describes the legal and political conundrums, the victories and defeats, and the new horizons and threats facing those who think that the right to health should trump corporate hegemony over the elixirs of life. Starting with her brief history of the move from intellectual property pluralism to harmonised global minimums under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 't Hoen spends most of her book focusing on protracted battles to promote and protect the use of TRIPS flexibilities that ameliorate the harshest impacts of pharmaceutical monopolies.

Although the pharmaceutical industry's out-sized role in the negotiation of the TRIPS Agreement has been described more fully by Peter Drahos and John Braithewaite in *Information Feudalism: Who Owns the Knowledge Economy* (2002) and by Susan Sell in *Private Power, Public Law: The Globalization of Intellectual Property Rights* (2003), 't Hoen captures the post-TRIPS campaigns that AIDS activists and their allies waged to win access to generic medicines of assured quality.



Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines
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Photo ©International AIDS Society/Rogan Ward

Treatment Action Campaign (TAC) march in Durban, South Africa, July 18, 2016, during the 21st International AIDS Conference (AIDS 2016)

She describes Big Pharma's 1998–2001 lawsuit against the Government of South Africa over its amendments to its Medicines and Related Substances Control Act and the USA's trade threats and sanctions over the same, both defeated by campaigns waged by the Treatment Action Campaign in South Africa and by Act Up, Health GAP (Global Access Project), and others in the USA. She describes how generics fired a shot heard around the world when Yusuf Hamied, at the Indian pharmaceutical company Cipla, offered a triple-dose combination antiretroviral to Médecins Sans Frontières (MSF) for under $1 a day. 't Hoen also examines the negotiation of the historical WTO Doha Declaration on the TRIPS Agreement and Public Health in 2001 that clarified and reaffirmed key TRIPS flexibilities, including compulsory licensing, parallel importation, and a waiver for least-developed countries in enforcing pharmaceutical patents and data protections.

In *Private Patents and Public Health*, 't Hoen corrects the widely held misperception that the Doha Declaration has been underused and that it has only been used for HIV medicines. On the basis of exhaustive research, she summarises 34 instances of developing country use of compulsory licenses in 2001–2014, 51 examples of government use, and 32 instances of 24 least-developed countries using their TRIPS waiver. Although the use of these flexibilities waned after the establishment of the Medicines Patent Pool by UNITAID in 2010, in other ways, the reach of the access to medicines movement has broadened considerably. 't Hoen meticulously describes activists' increasing concentration on other TRIPS flexibilities, including the adoption of stringent patentability criteria and opposition procedures to reduce the incidence of low quality, secondary patents on new forms, uses, and formulations of known medicines. 't Hoen also documents the expanding scope of the access to medicines movement beyond HIV/AIDS to include medicines to treat and cure hepatitis C, cancer, and other diseases.

However, this battle over access to medicines is not one-sided. At the same time that countries were adopting and using TRIPS flexibilities those flexibilities were under attack via TRIPS-plus provisions in trade agreements and through other high-income country and pharmaceutical industry pressures on low-income countries. In this book 't Hoen's documents how Big Pharma has pursued additional, highly effective monopoly controls over the use of clinical trial data and other data submitted to drug regulatory authorities so as to block the marketing of generic equivalents. Drug company lobbyists have sought and won mandatory extensions of patent terms to compensate for delays in patenting decisions and regulatory processes. They have sought and won enhanced Intellectual Property (IP) enforcement powers, including custom agents' duty to seize generic medicines lawfully being transported to and from countries where they were lawfully produced and consumed. Finally, they have sought and won provisions that allow foreign pharmaceutical company "investors" to bring IP-related arbitration claims directly against governments when investors' expectations of monopoly profits are thwarted by government policies and decisions. India is at the centre of this counterattack because of its comprehensive adoption and use of TRIPS flexibilities, its international advocacy for their preservation, and the strength of its generic pharmaceutical industry.

The most exciting part of 't Hoen's analysis, however, is her argument that the IP system is not only bad for access but is also fundamentally inefficient and ineffective in catalysing and prioritising medical research and development focused on pressing unmet needs, including antimicrobial resistance. Demonstrating that a disproportionate amount of IP-related medical research and development (R&D) is designed to perpetuate existing monopolies and to market me-too alternatives instead of addressing neglected diseases and the needs of marginalised populations, 't Hoen castigates a system that guarantees high prices without delivering needed innovations. Declaring that "high prices are everyone's problem now", she champions a new generation of advocates and activists who are challenging the fundamentals of an IP-based medical R&D regime. These activists argue that push (grants) and pull (prize) mechanisms designed to incentivise collaborative R&D of new medical technologies should be "delinked" from the system of manufacturing, and that the resultant technologies should be sold at or near the marginal cost of production.

Last year I returned to Durban for the 21st International AIDS Conference. Instead of virtually no one having access to life-saving antiretrovirals, nearly 3·5 million South Africans were on treatment largely because the cost of an improved antiretroviral regimen had been reduced to under $100 per person per year. Despite that progress, thousands marched again to ensure access for the nearly 20 million people with HIV/AIDS worldwide still untreated, and for reform of the IP-based intellectual property regime that delivers neither innovation nor access to medicines for many diseases.

This monumental progress has been achieved because of the passion, shrewd campaigning, and activism of advocates like Ellen 't Hoen. One can only hope that the next time she revises her book, there is comparable success in the campaign to come up with a more rational and effective system for incentivising medical research and development targeted towards priority health needs and not monopoly profits.

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