Book Review

Are We Getting Closer to Using Intellectual Property Safeguards to Improve Public Health?

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***Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines*, AMB, Diemen, The Netherlands, 2016, 181 pp., €45.00, paper, ISBN: 97890 79700 851**

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This book is a gift for all who may have tried — and come away unsatisfied or simply avoided the daunting chore — of learning the intellectual property aspects of why the world is stuck with more than a few painful public health incongruities: (1) prices so high that huge populations in need never get the benefit of vaccines and drugs readily available to many in more affluent countries; (2) products that align poorly with long anticipated needs of sizeable populations worldwide (a recent example is the need for more antibiotics to replace those where pathogens have acquired resistance); and (3) delays in assuring that new science and technology are put to work creating affordable products practical for use in environments less privileged than North America or Europe, and in neglected populations. (For therapeutics 'neglected' includes all of the world's children, as most medicines have been studied only in adults.)

't Hoen structures her book around questions to which she has devoted her career. *Are public health approaches to medicines patents developed in response to the HIV/AIDS crisis exclusive to HIV — or can they be applied more broadly?* This question was central. In several organizations (as, for example, policy and advocacy director at the Médecins sans Frontières' campaign for the access to essential

medicines and as the first executive director of the Medicines Patent Pool, co-founded by UNITAID) she created the institutional role in which she worked to expand access to HIV/AIDS therapeutics. Now she is looking to do the same for other products, especially those that the World Health Organization (WHO) has already categorized as "essential medicines"[I] — or may in the future.

't Hoen's analysis unfolds like a fugue — with reinforcement of the main messages through purposeful repetition of essential points. She helps readers follow the many strands of her argument and the complex dynamics of trade, intellectual property, and public health. She reaches back to the 1950s to introduce forces that shaped relations among governments, the pharmaceutical industry, trade agreements (and their enforcement), international organizations (World Trade Organization (WTO), World Intellectual Property Association (WIPO), and the WHO, and now the Office of the United Nations Secretary General, and the world's people. She shows how a once more promising set of international trade rules emerged as pressure grew to impose international patent regimes into lower income countries. More recently, after formation of the (1995) World Trade Organization Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), this progress has been eclipsed by regional trade agreements; they encroach on the space ostensibly left open to guard health from trade overreach. A timeline of all key events, in the introduction, eases readers into the history and themes in the chapters ahead.

Notable gains for improving health from the 1990s created a certain buoyancy among advocates — for assuring new and new combinations of HIV/AIDS drugs that would reach populations in lower income settings. Progress came through battles over affordability of brand name, patented HIV drugs, over generic alternatives, and over combining drugs for practicality of use where medical care is rudimentary or stressed beyond capacity. But for other diseases, including therapeutics for cancer, hepatitis C, and tuberculosis, expectations for public health success is muted. A seemingly impenetrable wall of high prices and aggressive self-protection by the pharmaceutical industry takes many forms, including lawsuits against generic approaches in India and elsewhere.

Despite her long history of confronting the industry in words (publications and many other forms) and deeds, 't Hoen's book is not a rant. Her prose glides along above the name-calling fray with confident elegance while she builds credibility and momentum. She has assembled

extensive documentation of the mismatch between the international intellectual property system we have and a different sort she believes the world needs. She lays out evidence to support many points that advocates and media coverage often just assert. For example, she describes the evolution of prices for first-line HIV drugs combined in different therapeutic regimes; tracks instances of governments' use of compulsory licenses as the trade rules evolved. (This enabled them to make use of industry know-how while getting around industry's practice of setting prices beyond the means of public health purchasing), and tracks governments' use of medicines' patents. She also produces estimates of the minimum costs of production and prices of Hepatitis C medicines (listing all of her sources), compares prices of the cancer drug glivec from branded sources versus the Indian generic, and catalogs patent disputes in India involving cancer drugs. She accumulated many other tools that readers will find in text boxes, figures, tables, and the like, including case studies of elements of 'the problem' as manifest in different parts of the world (for example, Ecuador, South Korea, Zimbabwe).

Having laid out several decades of her learning about how the current means of incentivizing R&D leave public health problems without resolution, problems that disproportionately affect those in developing countries, those suffering from rare diseases, and from bacterial infections that no longer respond to antibiotics — she moves on: What do we do now?

She argues for 'delinking' investment in R&D from the price of the product and for finding new ways to share the burden of development costs internationally. What is the status of this approach? So far WTO, WIPO, and WHO are studying 'delinking,' and 't Hoen and colleagues are debating all aspects vociferously — among themselves and with all the players.

't Hoen's topic is one that has fascinated me for decades. In the early 1980s, General Philip K. Russell (now retired, then Major General in the U.S. Army Medical Corps at Fort Detrick) introduced me to these issues around the edges of meetings on vaccine development at WHO headquarters in Geneva.

More soldiers die in every war from disease than from war making — so preparations to protect and treat diseases is a very big business for the military. General Russell brought the US military's public health approach to a council of civilian vaccine researchers at

WHO where they strategized how to strengthen and continue to expand… the Expanded Program on Immunization (EPI). At that time I had just shifted from working for the United States (US) Congress on an investigation subcommittee concerned with basic science and the future of biotechnology to an academic sabbatical at the US Institute of Medicine to pursue strategies for how to use new science and biotechnology to accelerate development of vaccines for the developing world. The General decided it was worth trying to educate me about how the science and business of vaccines worked — and did not work — for improving the health of populations. He was interested in how far the US Congress might take the military's experience into the realm of civilian public health, domestically and especially internationally.

Back in Washington, he and his military scientist colleagues laid out the playbook for how the US military had made huge gains getting new vaccines and drugs developed, manufactured, and into use during World War II. The War Department (renamed Department of Defense in 1949) had engaged expertise from industry, academia, and government to cooperate, putting aside many barriers created by conventional secrecies — and to work at unprecedented speed. The General elaborated how the military continued to hold powers to commandeer cooperation from industry under special circumstances. The military perspective on new vaccine development for civilians exposed us (Anthony Robbins, then professional staff member for health at the Committee on Energy and Commerce of the US Congress, and me) to policy considerations for every step from basic research and product development through pilot manufacturing and scale up, regulation, distribution, and monitoring and surveillance of health outcomes to feed into the next generation of research. Intellectual property already played an important role in this saga, international trade agreements did not — yet. This experience instilled in me a certain optimism about finding ways to open the pharmaceutical lock on vaccine R&D and its proceeds.

We carried these lessons — largely from the era predating the HIV/AIDS breakthroughs — into a variety of arenas for public debate, policy, and lawmaking — with only modest success. In the 1980s Robbins and I packaged and tossed our military public health-inspired insights back and forth between our two institutions — the Institute of Medicine/National Academy of Sciences and the Committee on Energy and

Commerce in the US House of Representatives like a football — in hopes of advancing public policy for the country and for the developing world. With Roy Widdus (a colleague at the US Institute of Medicine), Sam Their (then President of the Institute of Medicine at the National Academies) and Chairman John Dingell of the Energy and Commerce Committee, we organized a meeting to comprehensively review the state of vaccine development and health — that might form the basis for new policy and legislation.[2,3] This venture went only a small way toward fulfilling our hopes for cooperation among researchers, public health entities, industry, other health sector institutions and professionals, and all other critical players in the US and abroad (especially those involved with United Nations efforts to immunize all of the world's children against more diseases). If nothing else we learned how very daunting is the challenge that 't Hoen and colleagues have assumed.

I can appreciate the complexity of challenges that 't Hoen's has taken on as her own, and the importance of laying out the issues that, more than any other, may deter potential activists from — activism. The intellectual property and trade issues are foreign to most public health activists. Their complexity discourages potential allies. That may have been unavoidable before this book, but need not continue to be so.

Readers will come away with a new sense of the terrain and of obstacles to overcome if we are to enter a new era where intellectual property can contribute to the greatest gains in health for the greatest number of the world's inhabitants, current and future.

By way of disclosure, it came as no surprise that I would find 't Hoen's analysis to be masterful and especially reader friendly. We at the *Journal of Public Health Policy* have previously published several slices of her analyses in this domain[4–6] — and wooed her onto the *JPHP* Editorial Board.

- The book is available for purchase in paper from: http://www.amb-press.nl/Webwinkel-Product-173747881/85-'t-Hoen-Private-Patents-and-Public-Health.html.
- It is also available to download without charge at: http://accesstomedicines.org/wp-content/uploads/private-patents-and-public-health.pdf.
- A summary version of the book including many graphics is available at: www.accesstomedicines.org.

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