Prescription for the People

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As I discussed in chapter 16, medicines are clearly a public good. All of us understand in our hearts that it is profoundly wrong for a person to suffer because they cannot afford the price of a medicine that would comfort or even heal them. As we shall see later in this book, centuries of faith and moral traditions, more recently buttressed by human rights law, clearly support that view.

So why are essential medicines still unavailable to so many? To answer that question, we need to understand how corporations have recently written and promoted laws and trade agreements that elevate profits over people. The next few chapters may not be much fun to read, because they explain the many ways that these corporations have erected layers of complicated legal barriers blocking sick people from the medicine they need. But it is important to understand the path that led us to this shameful state in which people suffer needlessly. I promise that I will conclude this book by describing a very different path, one that leads us back to a place where medicine is treated as a public good. And I will share some stories of inspiring activists who are already blazing that trail for the rest of us.
When those activists, along with caregivers and researchers, argue today that lifesaving medicines and monopoly patents do not go together, they are actually following in the long-established traditions of intellectual property laws over many generations. Modern intellectual property law started when the governments of ancient Persia and Greece occasionally awarded exclusive rights to artists. Monarchs in the Middle Ages granted some monopolies for purposes of political patronage or to block other territories from learning craft secrets. “Letters patent,” meaning open letters, were issued in fourteenth-century England to induce foreign craftsmen to relocate there.

The first intellectual property law that systematically granted patents to inventors was adopted in Venice in 1474. Under that law, Venice carefully preserved the right of the government to issue what are still known as “compulsory licenses.” Under compulsory licenses, governments bypass patents when necessary and license non-patent-holders to manufacture the otherwise protected goods, with an accompanying responsibility to pay a royalty to the patent-holder. Centuries later, compulsory licenses remain an important part of intellectual property law and are at the core of efforts to return medicines to their status as a public good.

Until well into the twentieth century, intellectual property rules did not exist in every nation, and they differed from one country to the next. Attempts to coordinate these varying global intellectual property rules led to the 1883 Paris Convention and the 1886 Berne Convention, and eventually to the creation of the UN World Intellectual Property Organization in 1967. But when nations signed on to those agreements, they retained the ability to determine the length of the patents and what products would be covered. For many nations, that flexibility meant excluding medicines from patent protection. For example, the German patent law of 1877 labeled medicines “essential goods,” along with food and chemicals, and prohibited any attempts to patent them.

In the middle of the twentieth century, several post-colonial nations adopted laws that were similar to the German law. The Indian patent law extended only to the processes for creating medicines, not the chemical formulas of the drugs themselves. (The United States, by contrast, allows patents for both.) So, the law in India opened the door for Indian pharmaceutical manufacturers to reverse-engineer patented drugs and then devise different, cheaper production methods.
to medicine patent rights allowed India to become the site of a thriving generic drug industry, and the country became known as “the pharmacy of the developing world.”

The approach taken by India is not a new one. During the twentieth century, Brazil, Mexico, and other Central and South American countries also adopted limits on the patentability of medicines. European countries such as Sweden and France did not grant pharmaceutical patents until the 1970s. Spain refused to do so until 1992. For decades, Switzerland had a constitutional prohibition on pharmaceutical patents. In the mid-twentieth century, Italy was one of the world’s leading producers of pharmaceuticals while prohibiting all drug patents until a Supreme Court ruling in 1978.

Even when medicine patents were given, most laws included lots of exceptions. Many nations granted liberal access to compulsory licenses for patented drugs, meaning that generic manufacturers were free to make the drugs, as long as they paid a royalty to the patent-holders. For example, during the period between 1962 and 1992, Canada granted 613 licenses to import or manufacture pharmaceutical products.

Over the course of human history, patent interests have been consistently limited in favor of ensuring access to medicines for those who needed them. As the UN special rapporteur in the field of cultural rights, Farida Shaheed, recently reminded the global community, there is no human right to patent protection. “The human rights perspective demands that patents do not extend so far as to interfere with individuals’ dignity and well-being,” Shaheed said in a 2015 report that explicitly cited concerns over patents limiting the accessibility of essential medicines. “Where patent rights and human rights are in conflict, human rights must prevail.”

By the late twentieth century, the scarcity of medicine patent protection, and the limitations and lack of uniform enforcement of medicine patents when they did exist, had become a real problem for pharmaceutical corporations. Over time, an industry that had once competed on the basis of manufacturing innovation and price had come to rely on the profits of products sold in the countries that enforced medicine patents. Pfizer, for example, in the mid-twentieth century had a full 33 percent of its global sales attributable to just two patented drugs. So, as extensively chronicled in Peter Drahos and John Braithwaite’s 2002 book, Information
Feudalism: Who Owns the Knowledge Economy?, Pfizer executives decided to do something about it. They took the lead in an ambitious campaign to create a global system of intellectual property protection, a for-profit barrier between patients and the medicines they need.22

The first step in that effort was to counter the global norm that medicines were a public good. The pharmaceutical industry needed to establish a narrative that medicine compounds were property that could be owned by private companies and individuals, and that this private property should be protected by international law. An example of their efforts came in a high-profile July 1982 op-ed column in the New York Times by the chair of Pfizer International. That column, entitled “Stealing from the Mind,” charged that U.S. inventions were being stolen by governments that did not protect patent rights. When governments outside the United States did not block the generic manufacturing of medicines, the pharmaceutical industry argued, they were indulging acts of piracy.23

The piracy allegation provided a vivid public relations image, but the industry executives realized that there was little in the way of binding international law to back up that position. So they pushed the U.S. government to make intellectual property protection a priority in all trade negotiations.24

It is worth pointing out that inserting monopoly patent rights into so-called free trade agreements creates an oxymoron. Patent exclusivity runs counter to the stated purpose of those agreements, the dismantling of barriers to global competition.25 As Michele Boldrin and David Levine, economists, wrote in 2012, “Patents are very much akin to trade restrictions as they prevent the free entry of competitors in national markets, thereby reducing the growth of productive capacity and slowing down economic growth.”26 Another economist compared drug patents to a 10,000 percent tariff.27

But that contradiction did not stop the lobbying efforts by the pharmaceutical industry. And those efforts were quite successful, in large part because, then as now, the industry was reliably at the top of the U.S. lists in both lobbying expenditures and political campaign contributions. As U.S. Senator Richard J. Durbin (D-IL) said in 2002, “PhRMA, this lobby, has a death grip on Congress.”28 (Recall from chapter 15 that pharma lobbying had already achieved a coup when the Bayh-Dole Act of 1980 allowed private entities to claim monopoly patent rights on inventions
discovered from government-funded research.) So it did not take long for the industry to find willing partners on Capitol Hill and in the White House. Soon, the United States had adopted intellectual property protection as a litmus test for its trade partners.

The role played by the U.S. government in this process was an essential one. As late as the 1980s, Drahos and Braithwaite write, a global treaty protecting patent rights was a business “pipe dream”: “Why (would) more than one hundred nations that were large net importers of intellectual property rights sign an agreement that is so transparently against their interest, as well as being an economic and health disaster for them?” As it turned out, the answer to that question was trade pressure exerted by the United States.

That pressure was applied by way of carrots offered to patent-resistant countries—enhanced access to U.S. markets and some reductions in the subsidies of U.S. agricultural exports—while simultaneously brandishing some imposing sticks. In 1984, aggressive pharmaceutical-sector lobbying led to an amendment to the U.S. Trade Act that gave the president the authority to impose duties on, or withdraw trade benefits from, any nation that did not provide “adequate and effective” protection for U.S. intellectual property.

The law was soon amended again to give the U.S. trade representative the power to put offending countries on what became known as a special 301 watch list, a designation dreaded by countries whose economies relied on trade with the United States. Soon, the two countries who resisted pharmaceutical patents most vigorously, India and Brazil, were placed in the more serious “priority” watch list and faced significant trade sanctions.

Against this ominous backdrop, in 1986 the World Trade Organization (WTO) convened talks to create a global intellectual property agreement. At the time these talks began, more than forty of the ninety counties involved did not grant patents for pharmaceutical products, and others had adopted strict limits on them. But the United States continued to wield big sticks: between 1985 and 1994, the U.S. trade representative brought special 301 actions dealing with intellectual property against Brazil, India, Argentina, Korea, Thailand, China, and Taiwan. That pressure wore down even the once-firm resistance of countries such as Brazil and India, the latter of which was the final holdout.
By April 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed by 123 government ministers representing virtually the entire world community. The deal finalized one of the foundational documents of the WTO, and it immediately became the most significant intellectual property agreement in history. As Edmund Pratt, the Pfizer CEO, later boasted, “Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what become TRIPS.”

TRIPS transformed an uneven worldwide patchwork of intellectual property law into a blanket of standards mandating protection for the holders of patents, copyrights, and trademarks. For patent-holders, that protection features at least twenty years of government-granted monopolies on their products, including medicines. TRIPS also requires each nation to award intellectual property rights regardless of national origin, a boon for multinational pharmaceutical corporations and a death blow to their local manufacturing rivals.

As medicine activists would later lament, these corporations had essentially written the very regulations that were meant to govern them. Big Pharma and the United States had succeeded in erecting a for-profit fence barring access to essential medicines.