Prescription for the People

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Unfortunately for sick people in low-income countries, the 1994 signing of the TRIPS Agreement did not signal an end to the efforts of the United States and pharmaceutical companies to put up a monopoly pay wall around essential medicines. TRIPS was a watershed moment for corporate patent rights, but from the pharmaceutical-company perspective, it was not quite perfect. TRIPS includes some concessions to the needs of low-income countries facing public health crises, including provisions that allow those countries to import generic medicines or permit the domestic manufacturing of generics when the public interest calls for access to less expensive medicines. These terms are widely known as “TRIPS flexibilities.” While the ink was still drying on the TRIPS Agreement, the United States and pharmaceutical corporations moved to block the use of those flexibilities.

In the late 1990s, when Brazil began to respond to its HIV/AIDS crisis and the unaffordability of patent-protected antiretroviral medicines by licensing the generic manufacturing of the drugs, the United States filed a
complaint with the WTO.\textsuperscript{2} When the South African Parliament responded to its own emergency by passing 1997 legislation to allow the importation of generic antiretroviral medicines, thirty-nine pharmaceutical corporations and a trade association sued the Nelson Mandela government to block the law.\textsuperscript{3}

The U.S. Bill Clinton administration, whose relationship with the Pharmaceutical Research and Manufacturers of American (PhRMA) was so close that the brother of the president’s chief-of-staff, John Podesta, served as a lobbyist for the industry, aggressively supported the lawsuit brought by the pharmaceutical companies against South Africa.\textsuperscript{4} An official from the Office of the U.S. Trade Representative called the South African effort to obtain cheaper AIDS medicine “offensive,” the administration placed South Africa on the trade watch list, and favorable tariff treatment for South African imports was denied.\textsuperscript{5} Similar pressure from the United States forced Thailand to drop its own plans to allow the generic manufacturing of antiretrovirals.\textsuperscript{6} Fortunately, as we see in the conclusion to this book, medicine activists in Brazil and South Africa, joined by a global coalition of allies, forced the U.S. government and the corporations to back down.

But the U.S. government and Big Pharma learned a lesson from those experiences: the fence TRIPS built around essential medicines had too many gates for their liking. So they embarked on a multidecade process of locking up those gates via what came to be known as TRIPS-Plus agreements. Article One of the TRIPS Agreement allows countries to “implement in their law more extensive (patent) protection than is required by this Agreement.”\textsuperscript{7} The United States has seized that part of TRIPS as an opportunity to push for stricter levels of medicine patent protections in its post-TRIPS trade agreements. The platforms for more stringent medicine patent protections were deals negotiated with just one other country, known as bilateral agreements, or regional trade agreements that included a limited number of countries.\textsuperscript{8}

TRIPS-Plus deals used the same tried and true carrot-and-stick approach that had created TRIPS. Serving as the carrots were concessions in trade terms for agricultural products or textiles, which opened up the lucrative U.S. market to less wealthy nations. In bilateral agreements, the sticks can be particularly imposing: the withdrawal of trade relations altogether, or a cut-off in foreign assistance.\textsuperscript{9} For example, Thailand did
eventually decide to defy U.S. wishes and took steps to allow the domestic generic manufacturing of antiretroviral drugs, along with a much-needed heart medication. In response, the U.S. trade representative cited “indications of a weakening respect for patents” and placed Thailand on the same dreaded special 301 priority watch list that had brought so many other countries to heel during the TRIPS negotiations.\textsuperscript{10}

Sometimes, the U.S. pro-Pharma pressure goes beyond mere trade sanctions. In 2016, the U.S. trade representative and a U.S. Senate staffer were accused of threatening Colombia with the loss of $450 million in promised U.S. funds for a national peace process if Colombia followed through with a proposal to use its TRIPS flexibilities to allow the generic manufacturing of a leukemia drug. The drug was patented by Novartis and priced at nearly twice the national income of Colombia, and the Colombian minister of health called efforts to sharply reduce that cost “a question of survival.” The U.S. trade representative later denied directly threatening the loss of the peace funds, but advocates say that the message was clear enough. “We always assume that this kind of intervention is happening behind the scenes but rarely do you get the chance to see it up close,” Andrew Goldman, an attorney for the medicine access group Knowledge Ecology International, told the Associated Press.\textsuperscript{11}

The result of the TRIPS-Plus pressure has been a number of trade agreements that cement the monopoly rights of medicine patent-holders even more firmly than TRIPS does. TRIPS-Plus agreements include broader availability for the evergreening of patents, extending patents beyond the twenty-year TRIPS minimum; blocking importation of generics; and limiting the ability of countries to license domestic generic manufacturing.\textsuperscript{12}

The impact of these concessions may even extend beyond those countries that have bowed to U.S. pressure. A clause in TRIPS, usually referred to as the most-favored-nation provision, requires that an advantage granted to one country be granted to all. That promise sets the stage for the U.S.-forced TRIPS-Plus terms to become the de facto global standards.\textsuperscript{13}

The bullying by United States and Big Pharma on patent rights is enormously harmful to people in developing countries. Consider the problem in South Africa, where HIV-positive patients are at risk because patented medicines are often out of stock. This presents a particularly dangerous situation with HIV/AIDS medications because when a patient who misses the scheduled doses, the virus can develop a resistance to the effects of
the medicine. “The problem is very big, because it’s life and death,” says Thandi Shabangu, a South African HIV patient who has faced stock-outs of her medicine. “If you don’t drink your Alluvia (lopinavir/ritonavir), you are going to resist.”

These are indeed life and death problems, and there is a clear solution to them. There should be no restrictions on essential medicines being manufactured in the countries where they are needed. Countries such as India, Brazil, Mexico, and China have proven manufacturing capacities and the ability to make and sell medicines cheaply, which would also boost their local economies with much-needed jobs and incomes. The Indian pharmaceutical sector employs 4.5 million people and reliably produces high-quality medicines at a fraction of the cost of the patented versions. Other low- to middle-income countries stand ready and eager to follow the lead of India.

But that is not happening. Instead, most of the world’s drug production takes place in wealthy countries. And aggressive TRIPS-Plus enforcement of patent monopolies by the U.S. government and the pharmaceutical industry will keep it that way. Health activists such as Médecins Sans Frontières/Doctors Without Borders (MSF) have documented that the patent monopolies are blocking new manufacturers from entering the vaccines markets. These monopolies are stopping the in-country production of much-needed generic HIV/AIDS and cancer medicines, too. Now, the United States and the pharmaceutical industry are using trade pressure to try to also squeeze India out of the low-cost medicine business. People in low-income countries need medicines, and they need jobs, too. Too often, they get neither, thanks to wealthy corporations that insist that the only medicines that are allowed to be manufactured are their monopoly-protected products, which are then priced out of the range of affordability. Those corporations have ascended to dizzying financial heights, only to use patent enforcement to kick away the ladder before poor countries can do any climbing of their own.

The promotion by the U.S. government of medicine patent protection overseas is not always matched by its respect for patent rights in our own country, at least when a public health crisis appears. That hypocrisy became apparent one week after the devastating attacks of September 11, 2001, when the United States was confronted with a new threat:
the purposeful spread of the deadly infectious disease anthrax. Envelopes containing anthrax spores, postmarked September 18, 2001, were mailed to major U.S.-based media outlets. Two more infected envelopes, these post-marked October 9, 2011, were mailed to two U.S. senators. Twenty-two people were infected with anthrax due to the mailings, and five died.22

The only approved oral treatment for anthrax was the antibiotic ciprofloxacin, patented and marketed in the United States by Bayer Corporation under the name Cipro. This presented a problem: there was a limited supply of Cipro in the United States, and the price was thirty times higher than in nations where generic versions were available.23 The response by the U.S. government was swift. Tommy Thompson, the secretary of the U.S. Department of Health and Human Services, demanded that Bayer significantly discount the price of Cipro. If Bayer failed to do so, Thompson vowed to seek congressional approval to obtain a generic version of the medicine. “The price is the question, not the supply,” Thompson told a congressional committee in October 2001.24 After Thompson’s testimony, the chair of that committee publicly stated that any request to bypass the Bayer patent would probably be approved by Congress.25 But that proved to be unnecessary. Bayer got the message and responded by cutting its Cipro price in half and pledging to provide 100 million tablets.26

This U.S. response was revealing. When it faced its own perceived public health crisis, the level of U.S. respect for the sanctity of medicine patents proved to be quite different from the stance it assumed in trade negotiations with lower-income countries. The contrast did not go unnoticed. “Even where there is clear evidence of a public health emergency, such as the HIV crisis in Africa and many parts of Asia, the U.S. government has used its might to limit these countries’ options to provide affordable drugs,” wrote the editors of the respected British medical journal The Lancet in November 2001. As The Lancet editors pointed out, the United States had recently lodged complaints to the WTO against Brazil and had supported the lawsuit by the pharmaceutical industry to block access to generic HIV/AIDS medicine in South Africa. “[P]ublic health needs may have to override trade profits,” the editors wrote. “The U.S. government should apply the same standards abroad as at home.”27 Advocates for access to generic HIV medicines quickly seized the opportunity to point out U.S. hypocrisy on the issue.28
It turns out that the U.S. threat to break the Cipro patent was not a new approach. Instead, it was just the latest in a long line of examples of the United States overriding intellectual property rights when it suits its domestic interests, all while insisting on the strict enforcement of those rights by other nations. In the late eighteenth and early nineteenth centuries, the United States did not allow foreigners to file for patents at all, and the United States dragged its feet for over a century before finally signing the 1886 Berne Copyright Convention. The U.S. Capitol building is literally built on a foundation of patent infringement: the concrete on the Capitol grounds was laid, without permission, in a manner that had been previously patented by one John J. Schillinger. The U.S. Court of Claims threw out Schillinger’s patent infringement suit, ruling that the U.S. government had immunity from such claims.

The most famous case of the United States conveniently bypassing patent rights involved a couple of stubborn American icons, a future president, and the demands of war. After their breakthrough discoveries in the invention of the airplane, Orville and Wilbur Wright proved to be as tenacious in defending their patent rights as they had been in pursuing motorized flight. In 1906, they obtained a patent for their method of flight control. For years afterward, the Wrights fiercely defended it, both in courts of law and in the court of public opinion. Wilbur Wright said in 1910, “It is our view that morally the world owes its almost universal use of our system of lateral control to us. It is also our opinion that legally it owes it to us.”

Together, the Wright Company and its rival, the Curtiss Company, held the major U.S. patents on airplane technology. They guarded their monopolies so jealously that the United States had fallen far behind Europe in the manufacture of planes. By 1917, as the United States was on the eve of entering into World War I, this was considered to be a national security problem. In response, an ambitious young assistant secretary of the navy, Franklin D. Roosevelt, convened a committee that strong-armed the Wright and Curtiss companies into joining a “patent pool” called the Manufacturers Aircraft Association. Members of that pool were obligated to license their patent rights to other manufacturers in return for royalties.

By 1949, the U.S. Congress had granted official permission to bypass patents on a grand scale. For example, 29 U.S. Code section 1498 allows the U.S. government, or anyone it authorizes, to manufacture a patented
good or use a copyright without permission. This provides a broad platform for issuing compulsory licenses, under which patent-holders are entitled to compensation for use of their products but cannot halt the manufacture of the items they have patented.

In this way, U.S. law opens wide the door to ignoring patent rights, and the government has quite often strolled right through. Following in the Wright-Roosevelt tradition, the United States has issued multiple compulsory licenses for patents to military technologies such as satellites, camouflage screens, and protective eyewear; it has also issued compulsory licenses for advances in energy technology and methods to reduce air pollution.

Often, compulsory licenses have been the remedy of choice in resolving U.S. antitrust lawsuits, including the blunting of patents for the manufacture of truck parts, plastics, personal computers, corn seeds, microprocessors, animal vaccines, and gasoline. The same U.S. trade representative who so vigorously pushed the extension of medicine patents in the proposed Trans-Pacific Partnership Agreement had also advocated that Apple be allowed to infringe on the smartphone patent rights of Samsung Electronics. The trade representative supported the breaking of the Samsung patent, he said, because the enforcement of the patent could be against the interests of U.S. consumers.

The 2001 U.S. threat to override the Bayer Cipro patent was not the first time that the U.S. government determined that access to medicine and other health care technologies was more important than patent rights. In the late 1950s and early 1960s, the U.S. military repeatedly ignored the Pfizer U.S. patent for the antibiotic tetracycline; the military simply ordered a generic version for less than half the price from a manufacturer in Italy, where medicine patents were not enforced. In 2004, the U.S. government threatened Abbott Laboratories with an override of its patent for the HIV/AIDS drug ritonavir. Like Bayer did when faced with the Cipro threat, Abbott got the message, and dropped its price 80 percent for patients in federally funded programs. Antitrust litigation and threats of a government patent override have led to compulsory licenses being issued for stem cells, laser eye surgery, gene therapy, ultrasound imaging catheters, and the irritable bowel syndrome drug dicyclomine. In a single five-year period, from 2006 to 2011, U.S. courts issued six different compulsory licenses for medical technologies.
The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) is reported to be the world’s leading consumer of generic medicines manufactured under compulsory licenses. In 2010, the U.S. Affordable Care Act included a mechanism for compulsory licenses to ensure U.S. access to patented biologic drugs. The double standard is quite clear: for the U.S. government, the strict enforcement of health and medicine patents is a policy that poor nations must adhere to or face the consequences, but when enforcing those rules is not convenient in the United States itself, the need for enforcement seems to fade away.

We have discussed how the United States and pharmaceutical corporations achieved the piece-by-piece TRIPS-Plus erosion of the TRIPS flexibilities, the protections for affordable medicines included in TRIPS. But those setbacks paled in comparison to the potential sweeping impact of what was designed to be the most ambitious proposed TRIPS-Plus agreement of them all: the Trans-Pacific Partnership Agreement (TPP). At the time of this writing, the TPP has been put on indefinite hold, with U.S. President Donald Trump formally withdrawing the United States from the agreement. (I discuss in the conclusion to this book the role that spirited activism in support of access to medicines played in the demise of the TPP.) But Trump’s action was immediately followed by discussion of a partial revival of the TPP, or creation of a similar “son of TPP” pact. So it is important to understand the dangerous TPP terms that are likely to find their way into future proposals, including a possible NAFTA renegotiation.

The intellectual property section of the TPP included the same “TRIPS-Plus” medicine patent–extending terms we have discussed earlier: evergreening of patents by allowing patent extensions for minor changes in existing medicines, investor-state dispute systems that allow corporations to force a government into arbitration over decisions that harm their interests (including refusals to grant or extend patents), and patent-linkage terms that provide a platform for litigation by corporate patent-holders. All have the effect of delaying generic medicines from being available for patients in a country’s market.

We know from previous TRIPS-Plus agreements the deadly impact of those medicine barriers. The intellectual property rules of the Central American Free Trade Agreement (CAFTA) when applied in Guatemala increased some medicine prices by 846 percent and blocked some generic drugs
from entering the market. The U.S.-Jordan free trade agreement caused a 20 percent increase in medicine prices and forced the Ministry of Health to spend a quarter of its budget on medicine. After that agreement went into effect, the prices of medicines in Jordan rose up to 800 percent higher than in neighboring Egypt. After Morocco signed a patent-protecting 2006 trade agreement with the United States, spending on drugs there quickly doubled. So it was not surprising when a study of the likely effect of TPP in Vietnam projected that the agreement would cause tens of thousands of HIV-positive Vietnamese patients to go without lifesaving treatment.

But the TPP draft even went beyond the previous TRIPS-Plus agreements by including a new insistence on limiting access to affordable versions of biologic medicines. Biologics are treatments that are derived from a genetically-engineered, nonplant biological source—a human, an animal, or a microorganism. These medicines are usually much larger and more structurally complex than traditional small-molecule drugs. Examples of biologics include vaccines, gene therapies, and many cancer drugs.

Biologics play an important and growing role in medical treatment, but the patented versions of biologics drugs are often enormously expensive. For example, the breast cancer biologic drug trastuzumab, marketed by Roche as Herceptin, can cost as high as $70,000 for a course of treatment. The biologic rheumatoid arthritis drug Remicade can cost $2,500 per injection.

Because the costs of biologics is often so high, access to “biosimilars,” more affordable generic-type alternatives, is critically important. But the TPP aimed to delay access to biosimilars by adding to patent protection the additional monopoly-protecting mechanism known as data exclusivity. As I have previously discussed (chapter 12), data exclusivity means that the companies producing the nonpatented alternatives, in this case biosimilars, are blocked from accessing the testing data they need to get approval to sell their drug.

For biologics, TPP called for between five and eight years of data exclusivity. Because testing is complicated and expensive, and there are ethical issues involved in conducting unnecessary testing, it is unlikely that biosimilar-producing companies will replicate the data for the biologics through their own testing. Instead, they will probably just wait out the data-exclusivity period before offering patients their less expensive alternative.
The impact of this TPP barrier to biosimilars would have been enormous. Many important new medicines are biologics, especially cancer medicines, and patent-protected prices will place them out of the reach of patients in many low-to-middle-income nations. Peru, Vietnam, Malaysia, and Mexico, which were all set to join as parties to the TPP, currently have no monopoly protection on data for biologics. “Now they’ll have to wait at least five years before allowing cheaper biosimilars onto the market,” said Judit Rius Sanjuan from MSF, when the deal looked to be moving forward. “It’s a loss for people in developing countries. They’ll face higher prices for longer periods of time, and there are many products we need that are biologics.”

In assessing the overall TPP damage to access to medicines, MSF said the deal promised to be the worst trade agreement in history. As Zahara Heckscher, a breast cancer survivor, activist, and founder of CancerFAM, said, “Try telling a woman with breast cancer in Vietnam, where annual per capita income is under $2,000, that she has to pay $100,000 a year for the medicine that would save her life.”

The TPP was explicitly designed to be a template for future trade agreements. So it’s medicine-barring provisions are likely to be pursued again, putting millions at risk. All who are concerned about access to medicines must be on watch to prevent future trade agreements from wreaking the same kind of damage the TPP was slated to cause.