



## **TPP Pharmaceuticals**

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The Trans-Pacific Partnership (TPP), is a trade agreement between the United States and eleven other Pacific Rim states, including Chile, Peru, and Mexico. Signed by all participating nations on February 4<sup>th</sup> of this year, it needs significant ratification before it can take effect, including a vote that will probably take place in Congress in September of this year. As has been characteristic of recent world trade negotiations in an era of such low tariff rates, new intellectual property rules and other regulations agreed to under the TPP are perhaps more significant than the parts of the deal regarding physical flow of goods.

Major areas of contention during TPP negotiations were intellectual property protection and patent rights regarding the pharmaceutical industry. That sector and its proponents throughout the negotiations made their typical argument that drug companies must have exclusive rights to sell their products abroad for several years to encourage innovation and to ensure they receive satisfactory compensation for their research and development investment. Meanwhile, detractors argued the powerful U.S. pharmaceutical industry would benefit disproportionately from these rules.

The final draft of the TPP includes a variety of concessions to the pharmaceutical industry that will ensure an extended monopoly for their drugs in member states, as well as several stipulations that could lead to unfair gaming of the system by drug companies. Though the drug industry evidently did not receive all the concessions it wanted in this deal, consumers, especially in developing Latin American countries will undoubtedly see a significant rise in the price of many essential medicines as generic brands are pushed out of the market or prevented from coming into the market.

### **Intellectual Property and Patent Measures of the TPP**

Perhaps the most unconscionable gift to the pharmaceutical industry that the deal contains is Article 18.37, which guarantees patents for inventions that are claimed as one of the following: “new uses of a known product, new methods of using a known product, or new processes of using a known product”.<sup>1</sup> Allowing companies to renew patents for new uses of existing products is known among consumer advocates as “evergreening”, and is a notorious industry practice used to collect monopoly profits for longer than deserved. If it is widely utilized, this is perhaps the most troubling threat to poor Latin Americans’ access to reasonably-priced generic medication in the deal. What the pharmaceutical industry refers to as “life-cycle management”, in which they pay legal fees to keep patents alive for new purposes that are often dubious or marginally used, have little or no benefit to health outcomes.

Some critics of the accords have exposed some other loopholes for pharmaceutical companies in the agreement. For example, the TPP protects Undisclosed Test Data, more commonly known as “data exclusivity”, for pharmaceutical companies. In doing so, the partner states are stipulating that drug regulators cannot rely on the original innovator’s data for their

vetting of competing manufacturers' products for a certain period after approving the innovator's drug.<sup>2</sup> Generic companies will thus have to conduct their own clinical tests of their drugs after patent protections expire even if they prove their drug to be bioequivalent to the original. Latin American consumers will be forced to pay monopoly prices for even longer and generic producers may be less inclined to enter the market with these arduous regulations in place.

Standardizing rules on working conditions, environmental protections, intellectual property, and the patent law were unsurprisingly of significant focus for TPP negotiators. The deliberating countries decided to include intellectual property as a covered asset in the TPP Investment Chapter, meaning that private investors will be able to use the Investor State Dispute Settlement (whose detrimental effects I explained in a previous article<sup>3</sup> about the TPP for the Council on Hemispheric Affairs) to interpret intellectual property chapter.<sup>4</sup> These private interests can also choose to use the TRIPS agreement that the World Trade Organization uses to set minimum intellectual property standards to adjudicate such questions.<sup>5</sup> Some observers, including DG Shah of Intellectual Property Watch, are concerned that having several mechanisms to solve these issues will lead drug companies to "forum shop" on aspects like compensation for non-voluntary use of intellectual property rights or standards of patentability, and thus find the most big-business friendly adjudicator in each case.

Yet another mechanism of the TPP that drug companies may be able to exploit is the patent extension provision that the agreement strengthens. These rules grant companies the ability to seek compensation in the form of patent extensions for administrative delays by drug regulation agencies or patent offices.<sup>6</sup>

Administrative delays in underfunded Latin American bureaucracies are inevitable, these extensions will be rife, and this will prove to be yet another blow to the prospects of generic drug manufacturers in Latin America.

Not all the intellectual property regulations agreed to under the TPP were so anti-consumer, however. Australia's negotiators should be lauded for holding up the talks at the last minute to make some protections sought by the U.S. pharmaceutical industry more reasonable. U.S. negotiators had sought a 12-year period for data exclusivity associated with pharmaceutical patents, which would be a marked extension of protection from lower-price competition.<sup>7</sup> Since the United States has without a doubt the world's most powerful and prolific pharmaceutical industry, the benefits of these protections would disproportionately go to its corporations. The Australians argued that each year beyond their current five-year period that the TPP extended data exclusivity privileges would cost their government more than \$100 million a year. Considering the average price difference between brand-name and generic drugs is over 70%,<sup>8</sup> the savings won by the Australian negotiators for consumers in all the TPP countries should be considerable. The data exclusivity period deal, which varies from five to eight years depending on the drug's classification, is a good compromise. However, too many loopholes remain for pharmaceutical companies to exploit as to make the TPP a good deal for poor Latin Americans' medicine purchasing power.

## **Lessons from NAFTA and CAFTA**

In 1994, the North American Free Trade Agreement (NAFTA) was ratified, and pharmaceutical trade underwent a similar tightening of regulations in member states that will take place under the TPP. Most observers agreed that U.S. pharmaceuticals won a major victory

under NAFTA since Canada had to eliminate special rules for compulsory licensing of prescription pharmaceuticals, which gave the U.S. industry much more access to markets there.<sup>9</sup>

Moreover, under NAFTA, pharmaceutical tariffs that had stood at an average of 15 percent were eliminated in Mexico, and Mexico was forced to open its pharmaceutical procurement contracts to competition from U.S. and Canadian firms.<sup>10</sup> As of 2002, U.S. pharmaceutical exports to Mexico were up 144 percent, while Mexican exports to the U.S. were up 78 percent, a fairly equilateral gain for both states. Of course, U.S. exports to Mexico in 2002 (\$748 million USD worth) were far larger than what Mexico sent to the U.S.<sup>11</sup>

However, benefits undoubtedly accrued to both states as a result of slashing pharmaceutical tariffs. Mexico experienced significant job growth in the industry and now produces over 80% of the pharmaceuticals its people consume domestically, with the largest penetration of generic drugs of any country in the world (84%).<sup>12</sup> After a period of paying monopoly prices after NAFTA, Mexico was able to create a solid generic industry that provides its people low-cost pharmaceuticals- American tourists famously buy cheaper Mexican drugs in bulk while traveling there. There is thus reason to believe other nascent pharmaceutical industries in Latin American states could experience a similar take-off under the terms of the TPP that Mexican pharmaceuticals experienced under NAFTA, and there is certainly reason to believe that the powerful U.S. pharmaceutical industry will be the main beneficiary again via the opening of new markets and a long period of receiving monopoly prices.

Another, more recent Latin American trade agreement with the U.S. provides more historical evidence for what to expect for pharmaceutical access under the TPP. The Central American Free Trade Agreement (CAFTA), ratified in 2005, essentially expanded NAFTA to Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua. Data protections for pharmaceuticals were extended to these new members.

One study by Ellen R. Shaffer and Joseph E. Brenner of the impact of CAFTA on Guatemalan pharmaceuticals found that CAFTA was responsible for the removal of several lower-cost generic drugs from the Guatemalan marketplace, and that 42 drugs will become open for generic competition in the United States before generics are legally available in Guatemala as a result of the agreement.<sup>13</sup> The study also found prohibitively high prices for data-protected drugs in Guatemala under CAFTA. For example, the insulin Lantus, which was protected by the intellectual property regime of CAFTA, cost 846 percent more than standard insulin. For many poor Guatemalans just scraping by in life, the significant climbs in prices for essential drugs were likely a painful burden.

## **Analysis of the Pharmaceutical Industry**

The intellectual property regime of the TPP and the impact of previous trade agreements on drug prices suggests that U.S. pharmaceutical companies will in all likelihood be getting a windfall under the new trade agreement. The negotiators of the TPP must have felt that these corporations were deserving and in need of favorable conditions to sell their products overseas. However, by almost any metric, the U.S. pharmaceutical industry is already remarkably well-off and reaping enormous profits.

In 2013, pharmaceutical giant Pfizer finished the year with a mind-boggling 42 percent profit margin, and the world's ten-largest drug companies, most of which are based in the U.S., made average profits of 19 percent.<sup>14</sup> There is simply no other industry that consistently makes

these kind of ridiculous profit margins. The justification given by these companies for these numbers is that they have outsized research and development (R&D) costs and that most of their trial drugs never turn a profit. However, these companies' balance sheets tell a different story, as nine of the ten largest pharmaceutical companies in 2013 spent more on marketing their drugs than R&D.<sup>15</sup> Notably, Johnson & Johnson spent \$8.2 billion USD on R&D, a noteworthy sum, but a whopping \$17.5 billion USD on advertising! Drug companies have also been widely derided by consumer advocacy groups like Public Citizen for inflating their stated R&D costs by neglecting to subtract government subsidies and by factoring in opportunity costs, or the money the company would have generated from alternative investments, to their totals.<sup>16</sup>

Even before they were extended new legal protections under the TPP, pharmaceutical companies were reaping monopoly profits that were not entirely justifiable by their R&D costs. The Nobel Prize-winning economist Joseph Stiglitz has argued that the intellectual property rights of the TPP could "help big pharmaceutical companies maintain or increase their monopoly profits on brand-name drugs".<sup>17</sup> Stiglitz, long considered a leading critic of inequality from a leftist perspective, cited the example of the U.S. opening its market to generic competition in 1984, which has led to generics being prescribed 86 percent of the time and savings for the government, consumers, and employers of over \$100 billion USD per annum.

The cost savings that the use of generics can provide are eminently clear from the United States' experience. However, these savings can have an even more positive humanitarian impact in the Global South, as in the case of the United States' own President's Emergency Plan for AIDS Relief (PEPFAR), which has used generic medication to treat over three million people afflicted with AIDS worldwide and saved \$380 million USD in 2010 alone by eschewing brand-name treatments.<sup>18</sup>

The greater risk of serious disease in the developing world makes the onus to provide cheaper generic medication all the more pressing. While allowing generic competition right away would destroy all incentive for pharmaceutical companies to innovate or bring their products to Latin America, they are clearly doing well enough to scale back some of their intellectual property demands for humanitarian reasons. Developing countries only make up about one percent of global demand for pharmaceuticals despite containing the vast majority of the world's citizens since they have limited financial flexibility for purchasing non-essential medication. The humanitarian obligation to provide affordable access to life-saving medicines (and the ensuing good publicity) vastly outweighs whatever small profits drug companies hope to reap in Latin America.

## **The State of Pharmaceuticals in Latin America**

The need for affordable medicine for impoverished Latin Americans has been laid bare in recent months by a new epidemic that threatens literally the entire region. There is no known vaccine or treatment for the Zika virus, which has been linked to brain damage in thousands of Brazilian newborns and has affected over two million Brazilians already.<sup>19</sup> Several Latin American countries have advised their women to try to avoid getting pregnant to sidestep the possibility of their infants being born with microcephaly, which has been linked to the Zika virus. This is an unprecedented step that reveals the seriousness of the crisis. Furthermore, the mosquito-borne virus is expected to be a serious threat as far north as Puerto Rico, and the litany of impacts it may have on a victim has yet to be fully explored.

Though no treatment is available yet, the drug industry is racing to develop some kind of response to the Zika virus,<sup>20</sup> and in March of this year, BioCryst Pharmaceuticals announced that an experimental antiviral drug they developed improved survival rates in infected mice.<sup>21</sup> If a U.S. company does happen upon a treatment for Zika, it will be at least eight years until affordable generics would be available, and possibly longer considering the loopholes discussed earlier. Unless significant exceptions are made, Latin America will be stuck paying monopolistic prices to combat a ubiquitous public health crisis.

The Zika crisis, notwithstanding, applying the normal logic of intellectual property rules for the pharmaceutical industry to Latin America makes little sense. Strict intellectual property rules and high prices for drugs certainly do not promote pharmaceutical innovation in developing countries where there is little or no capacity for drug development anyway.<sup>22</sup> Opening these markets for multinational companies to make some money while providing needed drugs should be enough incentive for them to enter Latin America, but allowing monopolistic prices for years on end for these companies that will reap the vast majority of their profits in the developed world regardless is overkill. Cheap drugs are not necessarily a fundamental right, but to pretend that “innovation” and “intellectual property protection” are at stake in selling patented drugs in developing countries is reprehensible.

A study in Peru in 2010 by the Director General of Medicines (DIGEMID) found the monthly cost of a patented medicine to treat head and neck cancer was 880 times the daily minimum wage there.<sup>23</sup> The intellectual property restrictions that make this abomination possible will only be strengthened by Peru’s ratification of the TPP. Allowing essential drugs like this to be basically unaffordable for several years under the TPP undermines the United States government’s mission to improve access to health care worldwide into which it pumps millions of dollars annually. It is no secret that in poor Latin American countries, most people pay for medications out of pocket as public health systems are lacking. Rendering patented drugs unaffordable to appease pharmaceutical companies is not the way to a healthier hemisphere.

In short, the skepticism that the TPP’s provisions for intellectual property and the pharmaceutical industry have generated is well-founded. While certainly providing some incentive for innovation and reward for creating a product that enhances public health is a laudable goal, there are several very dubious loopholes in Article 18 that have the potential to gratuitously extend monopoly rights for drug companies. Applying normal intellectual property rules and data exclusivity periods to a disease-stricken, poor region that has very little pharmaceutical innovation is unnecessary and even exploitative.

There is nevertheless some reason for optimism. Latin American drug producers, especially those who manufacture generics, have seen their business grow at a blistering 28 percent per year recently.<sup>24</sup> Latin America’s pharmaceutical industry will hopefully see increased growth with the slashing of tariff barriers they face and stronger intellectual property protections, but, as in the case of NAFTA and CAFTA, the United States’ mighty drug industry will probably secure the lion’s share of the gains. The main issue at stake is how these new regulations will impact poor consumers’ access to medicine in Latin America, and it is difficult to envision a scenario in which they do not suffer.

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