

Data Exclusivity for Biologic Drugs:
the TPP's Potential Poison Pill?
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INTRODUCTION

On October 5, 2015, after many years of secretive negotiations, the US government with 11 other countries across the Asia-Pacific and Latin America reached an agreement on the largest free-trade deal in history, the Trans-Pacific Partnership (TPP). [1] Addressing everything from wildlife conservation and tax reductions for agriculture, to the free flow of information on the Internet and intellectual-property rights for movies and pharmaceutical drugs, this far-reaching agreement has the potential to impact up to one-third of world trade. [2] One of the most contentious parts of the agreement involves intellectual property rights of pharma companies to data exclusivity for biologics, a hot and promising type of pharmaceutical derived from living organisms. [3]

Biologics

Vaccines, gene and cellular therapies, and allergy shots are all synthesized from living organisms, as are medicines for treating cancer, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease. [4] The drugs fighting these diseases are produced using DNA recombinant technology¹, these "biologic" drugs are made of molecules typically much larger and more structurally complex than traditional "small molecule" drugs, and are also more difficult and much more costly to develop and manufacture. Biologics are among the most expensive drugs on the market, costing an average of 22 times more than non-biologic drugs synthesized by combining chemical ingredients. [5]

¹ DNA recombinant technology is a scientific process used to cut and paste together different DNA sequences. It is widely used in biotechnology, medicine and basic research. The first licensed drug produced using DNA recombinant technology was human insulin for the treatment of diabetes. In that application, human insulin gene is inserted into *E. coli* or yeast genome to exploit their ability to quickly reproduce mass quantities of the insulin protein deficient in people with diabetes.

Because biologics are synthesized using living cells, different cell lines will produce slightly different drugs non-identical to the original. [6] These slight differences may allow a competing company to claim that they are not in violation of the patent. For this reason, biologics may be more vulnerable to imitation than chemically synthesized drugs and pharmaceutical companies are pushing for greater IP protection. [7]

Biosimilars: Saving Lives for Less

Because of the high cost of biologic drugs; patients, healthcare practitioners, and public health watchdogs are advocating for the development of biosimilars, essentially “follow-on” versions of biologics that are cheaper and analogous to generics. [8] To qualify as a biosimilar in the US, the drug must share the same mechanism of action for the FDA-approved condition of use, and there must be no clinically significant differences between the two drugs in terms of purity, safety, or potency. [9]

According to a recent Brookings Institute report, the competition from biosimilars could cut US consumer spending on biologics by \$44 to \$66 billion over the next ten years. [10] In the European Union, a 2013 analysis found that the average price discount was about 25 percent for 14 biosimilars that have been on the market since 2006. [11]

These savings significantly impact access to essential and life-saving drugs for patients and non-profit medical humanitarian organizations like Médecins Sans Frontières (MSF, Doctors Without Borders). MSF treats almost 300,000 people with HIV/AIDS across 21 countries with generic drugs. With the introduction of generics in such treatments, the MSF’s treatment costs have fallen from \$10,000 per patient per year to only \$140. [12]

Data Exclusivity

Escalating the tensions between pharmaceutical companies and patient advocates is the issue of data exclusivity within the TPP. Data exclusivity is an IP protection granted to pharmaceutical companies to keep critical information about their drugs from the makers of generics. [13] Whereas patents recognize a drug's non-obvious novelty and utility, data exclusivity, for a period of time following market approval, bars the use of a brand name company's clinical test data required to establish safety and efficacy. [14][15]

Pharmaceutical companies claim this additional layer of protection is needed for biologics because of the nuances of their manufacturing process, and argue that patents alone are insufficient in safeguarding the IP. [16] Pharma companies also point to the lengthy drug-development and patent-approval processes, and the expiration of a patent shortly after a drug makes it to market. This problem was addressed in 1984 with the passage of the Hatch-Waxman Act that provided innovative drug companies with a period of patent extension as well as data exclusivity. [17][18] However, as technology advanced and demand increased, pharma companies wanted to extend the IP protection conferred by Hatch-Waxman from products regulated under the Federal Food, Drug and Cosmetic Act to those regulated under the Public Health Service Act as well. [19][20]

Terms of Data Exclusivity

To recoup investments in laborious data collection and expensive clinical trials, US pharmaceutical companies lobbied for and were granted the world's longest term of data exclusivity for biologics. In the Biologics Price Competition and Innovation Act (BPCIA), a provision of the Affordable Care Act (ACA) passed in March of 2010, biologics were granted 12 years of data exclusivity in addition to the regular 20-year patent term. [21]

Cons of Data Exclusivity

Opponents argue that these exclusivity terms are contradictory to the spirit of free trade and create a monopoly on biologic drugs. As a result, makers of biosimilars may be forced out altogether, leaving patients with even fewer and costlier options. Also concerned about the skyrocketing cost of drugs and its impact on health insurance, the Obama administration has proposed reducing the 12-year extension to 7 in his fiscal year 2016 budget, arguing it would save Medicare \$4.4 billion over the next decade. [22]

Furthermore, data exclusivity is a weak legal tool for IP protection because it generates social and economic waste. The ban on access to a biologic drug's clinical test data forces makers of biosimilars to repeat time-consuming and expensive clinical trials in order to obtain the regulatory authority's approval. Furthermore, requiring the use of more human subjects and animals when the outcome of the tests is already known would be a breach of medical ethics under the standards of Institutional Review Boards. [23]

Rather than protect the IP generated by research and development (R&D), opponents allege that data exclusivity is instead being used to inflate already disproportionate profit margins. Expenditures in advertising by the world's largest pharmaceutical companies far surpass their expenditures in R&D. [24] In 2013, Johnson & Johnson spent \$17.5 billion on sales and marketing, compared with \$8.2 billion on R&D. [25] stuff

Data Exclusivity: Encouraging Disparity within the TPP

Other countries party to the TPP have varying periods of data protection for biologics that range from zero (Peru, Mexico, Vietnam, Brunei) to eight years (Japan). During the closed-door negotiations on the agreement, American pharmaceutical companies were pushing for the same 12-year term that they enjoy back at home. With its five-year exclusivity, Australia stood as the firmest opponent to the US in the TPP

negotiations. [26] They wanted to maintain and shield its beloved government-subsidized medicines program, the Pharmaceutical Benefits Scheme, from the influence of “big pharma.” [27] The disparity in IP protection among member states of the TPP highlights the distinction between developing countries trying to increase their access to medicines and developed countries that could afford the costs of medical innovation. Higher IP protections for drugs make it more difficult for developing countries to grow their own industry, forcing them to continue relying on and abiding by the terms of “pharma superpowers” like the US and Japan. [28]

The Compromise

According to the leaked TPP text, a compromise among the twelve nations reached on October 5th sets forth two exclusivity options: either eight years of full exclusivity, or five years of data exclusivity plus an additional three years of semi-exclusivity. [29] ‘Full exclusivity’ refers to market exclusivity – a bar on approval for competing products like biosimilars to enter the market for a period of time.

There is dissatisfaction on all sides of the deal. The terms fell short of the 12-year demand by pharmaceutical companies; but by setting a minimum, the agreement requires countries that previously had zero years of exclusivity to have five. [30] Shortly after the signing of agreement, MSF released a statement condemning the negative impact it would have on public health, “The TPP will go down in history as the worst trade agreement for access to medicines in develop[ing] countries... a dangerous blueprint for future agreements.” [31]

CONCLUSION

As of now, 12 years of data exclusivity still stand for big-pharma in the US. Given the widespread criticism of the TPP, Congress's history of support for IP protections, and the dominating influence of pharmaceutical companies, this hard-fought compromise may too be a waste.

These tensions between innovation and access call for the legal community to invent also, to find a tool that better equips us to regulate rapidly developing technology and to recognize the unique nature of essential medicines. These tensions, rooted in our Constitution with protection of individual rights conflicting with its declaration to promote general welfare, are chronic and unlikely to be resolved. However, with income inequality at its highest in US history and still rising [32] - now more than ever, we need to reevaluate whether what is legal in our society is also just.

ENDNOTES

[1] Dennis Normille and Kelly Servick, *Trade Agreement Praised and Panned*, (October 6, 2015), SCIENCE, <http://news.sciencemag.org/health/2015/10/trade-agreement-praised-and-panned>.

[2] Elizabeth Richardson, *Health Policy 101: How the Trans-Pacific Partnership will Impact Prescription Drugs*, (May 9, 2015), <http://www.brookings.edu/blogs/health360/posts/2015/05/19-trans-pacific-partnership-prescription-drugs>.

[3] *Id.*

[4] *The Trans-Pacific Partnership (TPP) threatens access to affordable cancer treatments and other biologics*, (last visited November 6, 2015), <http://www.citizen.org/documents/biologics%20final%20draft1.pdf>.

[5] *See* Richardson, *Health Policy 101: How the Trans-Pacific Partnership will Impact Prescription Drugs*.

[6] *Id.*

[7] Jim Zarroli, *TPP Negotiations Reached Agreement with Sticky Compromise on Biologic Drugs*, (October 8 2015), NATIONAL PUBLIC RADIO, <http://www.npr.org/2015/10/08/446980186/tpp-negotiators-reached-agreement-with-sticky-compromise-on-biologics-drugs>.

[8] *See The Trans-Pacific Partnership (TPP) threatens access to affordable cancer treatments and other biologics*, Citizen.org.

[9] 42 U.S.C. § 262(a)(2)(C) (2010)

[10] *See* Richardson, *Health Policy 101: How the Trans-Pacific Partnership will Impact Prescription Drugs*.

[11] *Id.*

[12] Tharanga Yakupityage, *Doctors Without Borders Oppose TPPAs Worst 'Trade Agreement'*, (October 9 2015) <http://www.thecitizen.in/NewsDetail.aspx?Id=5426&DOCTORS/WITHOUT/BORDERS/OPPOSE/TPP/AS/WORST/%E2%80%98TRADE/AGREEMENT%E2%80%99>; Amy Kapczynski, *The Trans-Pacific Partnership - Is it Bad for Your Health?*, THE NEW ENGLAND JOURNAL OF MEDICINE, 373, 201-203 (last visited November 6, 2015).

[13] See *The Trans-Pacific Partnership (TPP) threatens access to affordable cancer treatments and other biologics*, Citizen.org.

[14] *Id.*

[15] Kristina Lybecker, *When Patents Aren't Enough: The Case for Data Exclusivity for Biologic Medicines*, (July 9, 2015), IPWATCHDOG, [HTTP://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/](http://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/).

[16] *Id.*

[17] *Id.*

[18] See Zarroli, *TPP Negotiations Reached Agreement with Sticky Compromise on Biologic Drugs*, NATIONAL PUBLIC RADIO.

[19] 21 U.S.C. §301(1938).

[20] 42 U.S.C. § 201(1944).

[21] 42 U.S.C. §262 (2010).

[22] Amy Kapczynski, *The Trans-Pacific Partnership - Is it Bad for Your Health?*, THE NEW ENGLAND JOURNAL OF MEDICINE, 373, 201-203 (last visited November 6, 2015).

[23] 45 C.F.R. 46.

[24] Ana Swanson, *Big pharmaceutical companies are spending far more on marketing than research*, (February 2011, 2015), *The Washington Post*, <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>.

[25] Liyan Chen, *2015 Global 2000: The World's Largest Drug and Biotech Companies*, (June 4, 2015), FORBES, <http://www.forbes.com/sites/liyanchen/2015/06/04/2015-global-2000-the-worlds-largest-drug-and-biotech-companies/>.

[26] Michael Mezher, *Trade Talks Stumble Over Biologics Data Exclusivity*, (February 11, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/02/11/21309/Trade-Talks-Stumble-over-Biologics-Data-Exclusivity/>.

[27] *The Pharmaceutical Benefits Scheme: About the PBS*, (August 27, 2015), <http://www.pbs.gov.au/pbs/home>.

[28] *Id.*

[29] Emily R. Gabranski and Sanya Sukduang, *IP Update: The Trans-Pacific Partnership and Its Potential Impact on Exclusivity Periods for Biological Products*, (October 15 2015), <http://www.finnegan.com/IPUpdateTransPacificPartnershipandImpactforBiologicalProducts/>.

[30] *Id.*

[31] Judit Rius Sanjuan, *Statement by MSF on the Conclusion of TPP Negotiations in Atlanta*, (October 5, 2015), <http://www.doctorswithoutborders.org/article/statement-msf-conclusion-tpp-negotiations-atlanta>.

[32] Richard Fry and Rakesh Kochi, *America's wealth gap between middle-income and upper-income families widest on record*, (December 17, 2014), PEW RESEARCH CENTER, <http://www.pewresearch.org/fact-tank/2014/12/17/wealth-gap-upper-middle-income/>.