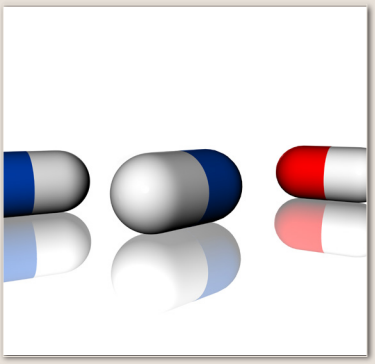
NATIONAL CENTER FOR POLICY ANALYSIS

Fast Track to Nowhere? Biologic Intellectual Property in the Trans-Pacific Partnership

Brief Analysis No. 822 by John R. Graham February 24, 2016

The Trans-Pacific Partnership (TPP) trade agreement is in deep trouble. It has taken nine years to finalize this extremely important multilateral deal among the United States and 11 other countries. These countries — Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam — include developed nations with deep and rich trading ties to the United States, as well as emerging economies relatively new to global markets.



Dallas Headquarters:
14180 Dallas Parkway, Suite 350
Dallas, TX 75254
972.386.6272

www.ncpa.org

Washington Office:
202.830.0177
governmentrelations@ncpa.org

What they all shared was a commitment to try their best to overcome domestic political obstacles to expand the benefits of free trade. The final text was released publicly November 5, 2015, starting a legally required 90-day countdown before the president could sign it. This waiting period ended with the U.S. delegation joining representatives of the other countries in New Zealand on February 4 to ink the deal.

Sinking Fast. In January 2016, the Office of the U.S. Trade Representative released endorsements of the TPP from a "diverse coalition of American businesses, farmers, and manufacturers." And yet the TPP appears to be sinking fast. The deal requires congressional approval, but the day after the final text was released U.S. Senator Orrin Hatch (R-Utah), Chairman of the Senate Finance Committee, repudiated it in a speech to the U.S. Chamber of Commerce. More recently, House Speaker Paul Ryan has expressed skepticism that the deal will pass Congress; and Senate Majority Leader Mitch McConnell doubts it will even come to a vote before November.

The biggest obstacle to congressional approval appears to be the pact's inadequate protection of intellectual property in biologic medicines. The administration's failure to secure this has led to a complete turnaround among politicians — especially Senator Hatch — who had previously been enthusiastic about giving the president so-called "fast track" authority.

Until Now, "Fast Track" Was a Winner for Free Trade. The best way to increase free trade has been for governments to negotiate deals, either bilaterally or multilaterally, through which they mutually reduce trade barriers.

Because U.S. executive and legislative political power is divided, it was very difficult for the federal government to commit to trade deals before 1974. The domestic breakthrough was Trade Promotion Authority, or "fast track" legislation, whereby Congress committed to give presidentially negotiated trade agreements a straight up or down vote, with limited time for debate and no amendments. This gave foreign countries the confidence that trade deals would not become mired in interminable grandstanding in Congress.

According to the Congressional Research Service, 14 bilateral and two multilateral trade liberalization agreements have been successfully finalized under fast track. Only one bilateral trade deal negotiated during the period,

with Jordan, was approved without fast track.

The previous fast track authority expired in 2007. After much debate, Congress finally gave President Obama fast track authority in 2015. Importantly, leading Republican legislators, led by Senator Hatch, insisted President Obama receive this authority. The TPP, which had been bogged down since 2009, was the first negotiation completed under the new authority.

The TPP Fails to Protect Biologic Innovation. Free trade requires a common recognition of property rights, including intellectual property rights critical to innovation. With respect to biologic medicines, the TPP fails to achieve this.

Biologic medicines differ from most prescription drugs in that they are made from living matter (such as human cells, bacteria or yeast) instead of synthetic chemicals. The Food and Drug Administration approved the first biologic medicine, Eli Lilly & Co.'s human insulin, in 1982.

Biologic medicines' relative novelty introduced another challenge: protection of intellectual property. New prescription drugs are protected by U.S. patents, which limit competitors' ability to copy the innovative drug for a fixed period. However, by themselves, patents do not give the same protection to pharmaceutical and biologic innovators as they do to most entrepreneurs, because a new medicine cannot be sold without permission from the FDA. FDA approval takes years, during which an innovator earns no return on capital and the clock ticks on its patents.

To win regulatory approval, innovators submit reams of research data. U.S. law prevents the FDA from disclosing this data to competitors for a period, so they cannot take unfair advantage of inventors' having to wait for FDA approval. This so-called data exclusivity, as well as marketing exclusivity on top of the patents, partially compensates the innovative company for the cost of waiting.

Because of the novelty of biologic medicines, the question of data and marketing exclusivity for these therapies was not settled in U.S. law until 2010. The Affordable Care Act, which gave us Obamacare, grants 12 years of exclusivity, combining four years of data exclusivity and eight years of market exclusivity. The TPP, however, gives only eight years of data exclusivity, or five years of data exclusivity plus delays due to regulatory or administrative procedures to achieve a comparable length of protection.

Although the U.S. Trade Representative attempted to win 12 years of exclusivity, he did not have meaningful support from President Obama. For years, President Obama has called for the period of exclusivity to be reduced to seven years. He re-iterated this position in his budget for fiscal year 2017, released February 9, 2016. So, it is not surprising other countries realized they could stick to a weaker, eight-year period of exclusivity.

The extra four years of protection in U.S. law is one factor that has made America the world leader in biologic innovation. In 2014, says Ernst & Young:

- Of the global biotech industry's revenues of $123 billion, over three-fourths ($93 billion) was earned by U.S. companies.
- However, U.S. firms invest more in research and development than foreign biotech companies, accounting for 81 percent ($29 billion) of the global industry's $35 billion R&D budget.
- U.S. companies accounted for 403 (56 percent) of the world's 714 biotech firms, and employed 110,090 (60 percent) of the global industry's 183,610 employees.

It is not surprising that politicians like Senator Hatch who are interested in maintaining and improving on this success are disappointed with the president's failure to negotiate adequate protection for this investment in the TPP.

Conclusion: President Obama's TPP Failure Will Harm Free Trade Overall. As demonstrated by the endorsement of a number of leading business groups, overall, TPP would be beneficial to free trade. Other industries dependent on intellectual property rights, such as the film industry, achieved satisfactory outcomes and support the TPP. By failing to secure adequate intellectual property rights in biologic medicines, thereby making the TPP unacceptable to many in Congress, the president has jeopardized future innovation in those industries, too.

In hindsight, giving President Obama fast track authority led to countless wasted hours negotiating a deal that is failing. If the next president manages to resuscitate the TPP and other trade deals, he or she will have to ensure all types of intellectual property are protected to the highest standard. Not doing so will perpetuate the harm done to free trade by President Obama's misuse of fast track.

John R. Graham is a senior fellow with the National Center for Policy Analysis.