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360 DEGREE GLOBAL TRADE AND THE URGENT NEED FOR THE TRANS-PACIFIC PARTNERSHIP



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360° Trade

When it comes to global trade, there is no value to living in the past. We no longer trade in barter or beads. The Trans-Pacific Partnership (TPP) acknowledges that we live in a global village – and innovation is an essential commodity. Why are some people finding this so surprising?

The evolution of the TPP has been long and arduous – but the basic premise has never changed. In order for global trade to flourish in an equitable manner, there have to be rules. Minus the rule of law, chaos ensues and we find ourselves in a survival of the fittest situation without fairness, predictability, or incentives for innovation. In a world without rules, ambiguity trumps investment and risk outweighs rewards.

One of the more important aspects of the TPP is intellectual property (IP) protection for biopharmaceutical innovation. This is of particular importance to the United States, where the U.S. biopharmaceutical research sector leads the world in the development of new medicines with about 4,000 in development or FDA review in the U.S. and more than 7,000 in development worldwide. This sector generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as the foundation upon which one of the U.S.' most dynamic innovation and business ecosystems is built.

According to the Information Technology and Innovation Foundation (ITIF):

America's biopharmaceutical companies are among its most innovative and commercially important. In 2014, the sector generated \$97 billion in economic value-added, produced \$54 billion in exports, and supported more than 3.4 million jobs. As measured by Battelle, the overall economic impact of the biopharmaceutical sector on the U.S. economy totals \$789 billion on an annual basis when direct, indirect, and induced effects are considered. Moreover, the sector is extremely research-intensive, investing over 21 percent of its sales in research and development (R&D), while accounting for 23 percent of domestic R&D funded by U.S. businesses—more than any

other sector. And measured by R&D expenditure per employee, the U.S. biopharmaceutical sector leads all other U.S. manufacturing sectors, investing more than 10 times the amount of R&D per employee than the average U.S. manufacturing sector. Strong private and public sector investment has made the United States the world's largest global funder of biomedical R&D investment over the past two decades, a share that some analyses suggested reached as high as 70 to 80 percent.

Let's not forget the wise words of our sixteenth President, Abraham Lincoln, who commented that patents "add the fuel of interest to the passion of genius."

The TPP's life sciences IP provisions make progress in several important areas toward creating a robust regional innovation ecosystem. While some nations already had data protection, also referred to as data exclusivity, obligations in place, the TPP commits countries to provide patent term adjustments for unreasonable curtailments of effective patent terms. It includes measures improving transparency in the listing and drug reimbursement programs run by national healthcare authorities. And it commits countries -- such as Vietnam -- which had previously lacked explicit data protection periods for the clinical trial data of biologic drugs to introduce them.

While patents incentivize innovation and disclosure of that innovation to the public, data exclusivity protects the investment necessary to generate the extensive clinical and other data that are needed for, but that do not guarantee, FDA approval. It also encourages further research and development (R&D) following initial product approval— R&D that has led to medical advances in treatments and patient care. Data exclusivity does not prevent competitors from entering the market, if those competitors generate their own safety and efficacy data.

It is essential to provide innovative manufacturers with a period of exclusivity for the data they generate in order to help recoup the significant investment necessary to develop that data and to encourage future R&D.

If American innovation isn't protected, not only will our economy, but, more importantly, patients around the world will suffer from the unfortunate unintended consequence of forgone innovation. And that is not acceptable.

There are several tough, but important basic principles when it comes to innovation in health care technologies that must inform public policies.

Innovation is slow. As any medical scientist will tell you, there are few “Eureka!” moments in health research. Progress comes step by step, one incremental advance at a time. Better treatments often come by biopharmaceutical companies improving existing molecules and making processes more efficient than by revolutionizing the whole field with new miracle products. Discontinuous innovation is the wonderful exception to the rule.

Innovation is hard. Today only about 12% of molecules that enter clinical testing ever receive FDA approval. This observation itself is disconcerting, but, further, only 2 out of 10 new medicines earn back average R&D costs. Moreover, unlike other R&D- intensive industries, biopharmaceutical investments generally must be sustained for over two decades before the few that make it can generate any profit.

Innovation is expensive. The costs of development also continue to escalate. In 2003, researchers at Tufts Center for the Study of Drug Development (CSDD) estimated the costs to bring a new medicine to market to be \$802 million. The most recent estimate (as of December 2014) has risen to almost \$2.6 billion, including the cost of the many failures that never reach patients.

Innovation is under attack. From accusations of the “me-too” variety, to questionable schemes to replace biopharmaceutical patents with a prize system, biopharmaceutical innovation is constantly being criticized. It is most certainly under attack from those who believe the TPP offers protections that are too generous.

Nonetheless, innovation is important. In the United States, increases in life expectancy resulting from better treatment of cardiovascular disease from 1970 to

1990 have been conservatively estimated as bringing benefits worth more than \$500 billion a year. In 1974, cardiovascular disease was the cause of 39% of all deaths. Today it is about 25%. Cerebrovascular diseases were responsible for 11% of deaths back then. In 2004 they caused 6.3% of deaths. Kidney diseases were linked to 10.4% of deaths and now are associated with 1.8%.

The United States, with a largely market-based system, rewards the major risks that must be taken to bring new drugs to market. New drug development cannot occur unless innovators have the opportunity to be compensated for their financial risks. Put simply, the new medicines of today allow our industry to continue research into the cures of tomorrow. Our IP system, that covers patents and data protection, is among the strongest in the world, which is why the U.S. has the most medicines in development.

However, our system also encourages competition from generics and biosimilar manufacturers. This is of great benefit to U.S. patients: new medicines improve patient lives and can help reduce healthcare spending by mitigating the need for costly surgery or hospital visits, while allowing follow-on manufacturers to compete once those IP protections expire. Generics and biosimilars would not exist without the IP of the innovators who assumed all the risks and costs associated with bringing a new drug to market. In fact, a healthy innovative biopharmaceutical sector is a prerequisite for the generic and biosimilar industries to thrive. In short, for the generics and biosimilar industries to continue their growth, IP rights must continue to help spawn the medicines of tomorrow.

As Harvard University health economist (and health care advisor to President Obama) David Cutler has noted: “The average person aged 45 will live three years longer than he used to solely because medical care for cardiovascular disease has improved. Virtually every study of medical innovation suggests that changes in the nature of medical care over time are clearly worth the cost.” That biopharmaceutical innovation is a key point in the debate over the Trans-Pacific Partnership is not an accident.

Per the ITIF report:

Congressional Trade Promotion Authority directed the Obama administration's trade negotiators to seek IP protections similar to those enshrined in U.S. law. Thus—while certainly achieving progress with regard to nations that previously lacked biologics data protection altogether -- it is disappointing that the TPP commits partners to provide at most eight years of data exclusivity protection.

But even if all TPP partners were to clearly enact eight years of data exclusivity protection for biologics (and outside of Canada and Japan, which already provide eight years of regulatory data protection for biologics, this is far from a certainty), the TPP will still have fallen short of promoting globally a 12-year data exclusivity standard that has proven instrumental in contributing to world-leading levels of biomedical innovation being produced in the United States.

This represents a step back compared to the only other regional group of nations to have established a biologics data exclusivity standard—the European Union, with at least 10 years of data protection—thus setting a lower global standard for data exclusivity protections for biologics. This matters significantly, not only with regard to the countries currently participating in the TPP, but also to countries that may join the TPP in the future—such as China, Indonesia, or Korea. With as much as half of U.S. biopharmaceutical companies' revenues now stemming from foreign sales, the TPP's eight-year data exclusivity standard will constrain some share of those revenues, relative to a 12-year standard.

Per ITIF:

If the United States were to reduce its period of biologics data protection (as the Obama administration called for in its 2016 budget proposal), this would have a chilling impact on biotechnology investment. For example, Deloitte Consulting notes

that insufficient data protection periods may cause R&D investment to shift to other sectors or to shift overseas, with a potentially devastating impact on the life sciences sector in the United States. Likewise, Duke economist Henry Grabowski has argued that if the incentives for continued R&D investment are inadequate, companies large and small may choose not to invest in biologics because of concerns that there would be insufficient time to recoup their investment and/or would shift their R&D operations to other countries with a more favorable environment for innovation.

By failing to secure a commitment of 12 years of data protection from U.S. trade partners in the Trans-Pacific Partnership agreement, negotiators have settled on a low bar that will be detrimental to biotechnology innovation, and ultimately patient health outcomes, for years to come. As Representative Anna Eshoo (D, CA) recently wrote to President Obama:

The TPP includes a convoluted proposal providing for only five or eight years of data exclusivity for brand name biologics. This proposal is so unclear that there isn't any guarantee companies will ever receive eight years of protection. Failure to secure adequate data protection will jeopardize future innovation in lifesaving biologic medicines, and the reduction of protection for innovators from twelve years to five in the TPP will leave American businesses in the dust.

Appropriately robust IP protection doesn't only benefit the United States, but encourages faster entry of innovative medicines into overseas markets. In addition, growth in generics and maintaining the new drug pipeline are not mutually exclusive, as demonstrated in the United States where there is not only a strong IP system that supports innovation, but where generic penetration is at 88 percent. Further, there is no evidence that watering down IP protections has in any way helped to tackle the real access challenges developing economies face; however, it is clear that a lack of commitment to protect IP in trade agreements will ultimately impair future R&D necessary to help patients, grow innovative ecosystems, and

develop the next generation of therapies.

Failure to take full advantage of the opportunity provided by the TPP to establish a 12-year standard of regulatory data protection can only limit the promise and potential of biologics.

To borrow an over-used adjective from the world of global climate change – we must protect “sustainable” innovation.

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