

**Testimony of
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***Trans-Pacific Partnership Agreement: Likely Impact on the U.S.
Economy and on Specific Industry Sectors***

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The Information Technology and Innovation Foundation appreciates the ITC's invitation to testify regarding the intellectual property provisions impacting life sciences innovation in the TPP. My testimony will articulate why America's biotech sector is a key driver of the U.S. economy—and of global life sciences innovation—and why robust IP standards in the TPP are critical to the health of both.

America's biopharmaceutical enterprises and industries are among its most innovative and commercially important. The sector generated \$97 billion in economic value in 2014, produced \$54 billion in exports, and supported more than 3.4 million jobs. Battelle estimates the sector's total impact on the U.S. economy reaches \$790 billion annually. Moreover, the sector is extremely research-intensive, investing over 18 percent of its sales in R&D, while accounting for 23 percent of R&D funded by U.S. businesses—more than any other sector. Strong public and private sector investment has made the United States the world's largest funder of biomedical R&D—accounting for as much as 70 to 80 percent of total global investment—over the past two decades. Today, U.S. biopharmaceutical companies have more than 3,400 drugs—many first of their kind—under clinical development.

Strong IP protections are vital to creating an ecosystem where robust levels of innovation can occur—something which holds for all knowledge-intensive sectors, from digital content to the life sciences. The TPP's IP provisions matter greatly because they will set the terms of trade, competition, and innovation in the life sciences—and other IP-intensive sectors—among countries in the 12-nation pact...as well as any additional countries that may join the TPP in the future.

The TPP's life sciences IP provisions make progress in several important areas. 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 explicitly lacked data protection periods for the clinical trial data proving the safety and efficacy of biologic drugs to introduce them.

Biologic drugs—those derived from and produced within living organisms—represent the future of biomedical innovation. More than 900 are under development today, and by 2020 they are projected to account for over 50 percent of sales within the top 100 prescription products. But biologics are enormously risky, time-consuming, and expensive to develop—a process that on average takes 12 to 14 years, at a cost approaching \$3 billion—meaning that biologics makers have a limited amount of time in which to recoup their investment before the drug's IP rights expire. Accordingly, most countries afford biologics two forms of IP protection: a patent for the original compound and data protection to incentivize the lengthy development work necessary to establish its clinical safety and efficacy.

Recognizing the need to strike an appropriate balance between promoting competition and providing adequate incentives to support continued innovation of new treatments and cures, the U.S. Congress—on a bipartisan basis and after extensive deliberation—enshrined 12 years of data exclusivity protection into U.S. law in 2009. Similar deliberations in the European Union led it to provide 10 years of data exclusivity.

The success of this balanced system is reflected in the fact that the United States has become the world's leading biotech innovator—from 1997 to 2012, more than half of the IP related to the world's new medicines was invented in America, while in the 2000s, U.S. biopharmaceutical companies introduced more new chemical entities than did companies in the next five nations combined. At the same time, U.S. policies support a thriving generics market that fills over 85 percent of U.S. prescriptions.

In short, America's IP environment allows innovators to capture profits from one generation of biomedical innovation to finance investment in the next while also enabling today's breakthrough drug to engender tomorrow's generics competitor, explaining how many generic breast cancer drugs are commonly prescribed today.

Congressional Trade Promotion Authority directed the administration 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—it's disappointing the TPP concluded commits TPP partners to provide a minimum of five, and a maximum of eight, years of data protection. A 12-year standard would have helped promote globally a standard that has been instrumental in contributing to world-leading levels of biomedical innovation from the United States.

Yet some believe even five to eight years is too much, claiming that it and other patent-related provisions will diminish access to medicines—and/or raise their price—for citizens in developing countries. But there are at least four problems with this contention.

First, and most fundamentally, while *access to medicines* is vitally important, it presumes in the first place *the existence of medicines*. And that requires a system which permits the profits earned from one generation of biomedical innovation to sow the seeds for investment in the next. As the OECD writes, “**There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.**” In other words, more revenues means more R&D, more medical discovery, more innovative biologics drugs, and ultimately more generics competitors.

Second, to the extent the TPP induces partner countries to introduce stronger life sciences IP protections, this enhances U.S. market access and increases market scale, which benefits the U.S. biopharmaceutical sector by allowing it to support more jobs and exports, to invest more in R&D, and to develop more drugs.

Third, the TPP will have virtually no impact on access to the vast majority of the world's Essential Medicines—including ones treating the largest causes of mortality in developing countries—more than 90 percent of which are already off-patent. Moreover, the notion that lengthier periods of regulatory data protection are automatically associated with a nation's increased expenditures on medicines is not a certainty. That has not been borne out in the experiences of countries such as Canada, Japan, and Peru.

Finally, policymakers must not only consider access for citizens in developing vs. developed countries, but also the interests of present vs. future generations. We must continue investing in solutions to diseases and conditions which remain unsolved by medical science. Diseases like Parkinson's or Alzheimer's, for example,