Post-hearing Statement of
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Trans-Pacific Partnership Agreement: Likely Impact on the U.S.
Economy and on Specific Industry Sector

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The Information Technology and Innovation Foundation appreciates the ITC’s invitation to provide a post-hearing statement regarding the intellectual property (IP) provisions impacting life sciences innovation in the Trans-Pacific Partnership (TPP) agreement.

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.1 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.2 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.3 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.4 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.5

Today, U.S. biopharmaceutical companies have more than 3,400 drugs—many first-of-their kind—under clinical development.6 And while some assert that biotechnology companies focus too often on “me-too” drugs, the reality is that the sector is producing innovative breakthroughs. Indeed, since 2000, the U.S. Food and Drug Administration (FDA) has approved more than more than 500 new medicines. In 2014, the FDA approved 51 new medicines across a wide variety of disease areas. Forty-one of those approvals were made by the Center for Drug Evaluation and Research (CDER) at the FDA, the highest number since 1996.7 Among the CDER approvals in 2014, 41 percent were identified as first-in-class medicines, meaning they used a unique mechanism of action to treat a medical condition that is different from any other approved medicine. Moreover, 41 percent of these medicines were approved to treat rare diseases.8

Strong intellectual property protections are vital to sustaining an ecosystem where robust levels of innovation can occur—something which holds for all knowledge-intensive sectors, from digital content to the life sciences.9 The TPP’s IP provisions matter immensely because they will set the terms of trade, competition, and innovation for the life sciences (and other IP-intensive sectors) among countries already participating in the agreement as well as any countries that may join in the future.

The TPP’s life sciences IP provisions make progress in several important areas toward creating a robust regional innovation ecosystem. 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.
Biologic drugs—those derived from and produced within living organisms—represent the future of biomedical innovation. More than 900 novel biologic drugs targeting more than 100 different diseases are under development today, addressing a range of conditions from cancers such as leukemia and melanoma to diabetes and infectious diseases.10 By 2020, biological products are projected to account for more than 50 percent of sales within the top 100 prescription products.11 According to the latest Global Pharmaceutical R&D Pipeline report by Fitch Ratings, FDA approvals for biologics accounted for 28 percent of all new drug approvals in the last 21 months (as of December 4, 2015), up from 17 percent over the 2010 to 2013 period.12

Unlike traditional pharmaceutical drugs, which involve smaller molecules that operate largely on the basis of chemical reactions and that work by treating the consequences of a disease, biologics work by blocking diseases earlier in their development, in the immune system. And since they can be tailored to individuals taking the medicine, biologics constitute an important step toward realizing the vision of personalized medicine.13 But as biologics are large, complex molecules that must be manufactured within living tissues, the resulting protein is unique to the cell lines and the specific process used to produce it, and even slight differences in the manufacturing of a biologic can alter its nature.14 Indeed, the sensitivity of these complex proteins make them more difficult to characterize and to produce such that even minor differences in manufacturing processes or cell lines may result in variations in the resulting protein.15 Accordingly, the intellectual property components of a biologic include both the structure of the molecule itself and the process for how to reliably, safely, and consistently manufacture the molecule at scale in living tissues. That is why most countries afford biologics two forms of IP protections: a patent for the original compound and data protection to incentivize the lengthy development work necessary to establish its clinical safety and efficacy.

Unfortunately, the process of developing a biologic drug is extremely risky, time-consuming, and expensive. In fact, the vast majority of biologic medicines never make it to the approval stage, with less than 15 percent moving from initial pre-clinical studies to clinical trials.16 Yet the cost to develop a new prescription medicine that gained marketing approval in 2013 was $2.6 billion (a 145 percent increase over 2003 costs), while estimated post-approval R&D costs of $312 million “boosts the full product life cycle cost per approved drug” to close to $3 billion.17 Moreover, for biologic drugs that are approved, development of manufacturing facilities represent an additional cost beyond R&D that can range from $90 million to $450 million or more. Given the time, risk, and expense involved in developing biologics, studies find that the break-even time to recover development, manufacturing, promotion, and capital costs averages 14.6 years.18 Specifically, Grabowski et al. find that a representative portfolio of pioneer biologics would be expected to break-even (that is, to recover the average costs of development, manufacturing and promotion, and the cost of capital) in 12.9–16.2 years.19 This long break-even timeframe means that biologics makers have a limited amount of time in which to recoup their investment before a biologic drug’s intellectual property rights expire. Affording
innovators, for a finite period of time, data exclusivity protection on the clinical trial data that validates the safety and efficacy of novel biologic drugs extends the period of time during which they can recoup their risky and expensive investments in novel drug development.

Importantly, while patents constitute one important form of IP protection for biologics, they are not sufficient to support the environment needed to promote large-scale investment in biologic R&D, for two principal reasons. First, because biologics are structurally complex molecules which are closely tied to a specific manufacturing process, many biologic patents are process patents or relatively narrowly constructed product patents. This means that biologics patents are susceptible to being circumvented by small changes to the molecule or to the process of making it.\textsuperscript{20} Because patents fail to provide the same certainty for biologics as they do for traditional pharmaceutical drugs, they do not necessarily assure that biologics will enjoy the same length of time on the market before facing competition from generics. Second, patents do not safeguard the IP involved in developing the extensive clinical trial data and results required to prove the safety and efficacy of a biopharmaceutical product (e.g., the regulatory data).

This creates a situation in which, as Kathleen Kelleher explains in the \textit{Michigan Telecommunications and Technology Law Review}, “The complexity of most biologics may allow a biogeneric manufacturer to design around an innovator’s patents, but still secure regulatory approval through its “biosimilarity” to the pioneer (original) biologic.”\textsuperscript{21} In other words, because regulatory approval for biosimilar drugs does not require identity with the pioneer biologic drug it references, without an extended period of data exclusivity—which protects the actual investment needed to prove the safety and efficacy of a biopharmaceutical product—a competing biosimilar product could elude the innovator’s patent while still relying on the innovator’s clinical data for regulatory approval, thus creating a “patent protection gap.”\textsuperscript{22} (This gap does not exist for small molecule drugs, which receive five years of data exclusivity protection, because generic drugs are required to have the \textit{identical} active ingredient.)\textsuperscript{23} As the Biotechnology Industry Organization (BIO) writes, the likelihood of generics competitors exploiting this patent protection gap is exacerbated by two key facts:

First, because of the nature of biologic products—large molecules produced by living cells and organisms through highly specific processes—patent protection is often narrower than that of small molecule drugs. Second, the creation of an abbreviated pathway for approval of similar biological products creates new and strong incentives for competitors to exploit this patent protection gap.\textsuperscript{24}

As Professor Kristina Lybecker concludes, “Although patent protection and data exclusivity may be considered complementary forms of protection, they serve distinct purposes. Patents are granted for innovations that are novel, non-obvious and useful…while data protection incentivizes the lengthy development work which is necessary to establish safety and efficacy regulatory approval of a new product.”\textsuperscript{25}
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 for biologic drugs into U.S. law in 2009 as part of the Biologics Price Competition and Innovation Act (BICIPA). This protection means that biosimilar manufacturers must independently conduct the comprehensive pre-clinical and clinical trials for their own product, or wait the 12 years required by the BICIPA before requesting a regulatory shortcut to approval based on the innovator’s prior approval and data.\textsuperscript{26} Congress’s decision relied in part on findings from the National Academies of Science and Engineering report \textit{Rising Above the Gathering Storm} which wrote that, “It is critical that a balance be struck in finding an appropriate period of exclusivity such that innovation is stimulated and sustained but patients have access to generic-drug-pricing structures” and recommended that this data exclusivity period should be “at least 10 to 11 years.”\textsuperscript{27} Similar deliberations in the European Union led it to provide 10 years of data exclusivity for novel biologic drugs (with an eleventh year of data exclusivity available for significant new indications that are approved within the first 8 years after approval).\textsuperscript{28}

The success of this balanced system is reflected by the fact that the United States has become the world’s leading biotech innovator—in fact, from 1997 to 2012, more than half 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 companies from the next five nations combined.\textsuperscript{29} At the same time, U.S. policies support a thriving generics market that fills 86 of U.S. prescriptions.\textsuperscript{30}

In short, a healthy innovative pharmaceutical industry promotes a thriving generics sector. America’s system allows innovators to capture profits from one generation of biomedical innovation to finance investment in the next while enabling today’s breakthrough drug to engender tomorrow’s generic competitor, explaining how generics can account for many commonly prescribed breast cancer drugs today. As Jack Scannell, a Senior Fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation (CASMI), explains, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”\textsuperscript{31} As Scannell observes, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.”\textsuperscript{32} Put simply, the U.S. system encourages vigorous innovation in the private sector by providing strong intellectual property protections and a drug reimbursement system that together allow companies to earn sufficient revenues to reinvest in highly risky research and development.\textsuperscript{33} And the innovative medicines this sector produces ultimately gives rise to thriving generics competition. In fact, as Deloitte notes, a concern for the global generics industry is that there may not be enough innovative drugs coming off patent to fill their pipeline in the future. As Deloitte writes, “Generics manufacturers are also beginning to see the downstream effects of slowing patent expiries, which means they can no longer count on
rapid growth for new products.\textsuperscript{94} Put simply, a healthy generics industry depends upon a healthy innovative biopharmaceutical industry.

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. And the period could possibly be as little as only five years of data exclusivity protection, depending on how TPP partners interpret and implement Article 18.52(b), which gives parties the ability to provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, \textit{mutatis mutandis}, for a period of at least five years from the date of first marketing approval of that product in that Party;

(ii) through other measures; and

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.\textsuperscript{95}

But even if all TPP partners were to clearly enact eight years of data exclusivity protection for biologic drugs (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 from the United States. Moreover, it 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. pharmaceutical 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.

Moreover, 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.

In short, in failing to secure a commitment of 12 years of data exclusivity 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. Yet some believe that even five or eight years of data exclusivity protection is too much, claiming that it and other patent-related provisions in the TPP will diminish access to medicines—and/or raise their price—especially for citizens in developing countries. But there are at least five 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, for there exists a direct link between the pharmaceutical industry’s ability to earn profits and its ability to invest in innovation. As the Organization for Economic Cooperation and Development (OECD) writes, “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.” Indeed, as Figure 1 illustrates, recent data from the United Kingdom Department of Innovation, Universities, and Skills’ R&D Scoreboard show a very strong relationship between R&D expenditures and sales for the largest 151 pharmaceutical firms worldwide.

Figure 1: R&D Expenditures and Sales in the Pharmaceutical Industry, 2006

![Graph showing correlation between R&D expenditures and sales](image-url)

Note: The data were prepared on the basis of annual reports and consolidated accounts received up to and including 31 July 2006. Annual reports with a year-end older than 30 months from the cut-off date or a publication date older than 24 months from cut-off date are excluded.

Likewise, the health care economists Henderson and Cockburn have identified scale effects for R&D in the pharmaceutical industry, finding that R&D expenditures are directly proportional to the amount of sales revenues available to undertake R&D investment. And this explains why academic research shows a statistically significant relationship between a biopharmaceutical enterprise’s profits from the previous year and its R&D expenditures in the current year. Indeed, Simanjuntak and Tjandrawinata estimate that a 1 percent increase in a firm’s one-year lagged profitability is accompanied by a 0.2 percent increase in the firm’s R&D expenditure. Moreover, the pharmaceutical firms with the greatest sales are also the ones with the largest R&D investments, which may in part explain why most global R&D investments are undertaken by the largest multinational biopharmaceutical firms. Symeonidis notes that this is in part because large firms are better able to spread the risks of R&D uncertainty, since they can undertake several projects simultaneously.

As the erstwhile U.S. Office of Technology Assessment (OTA) wrote in its report, Pharmaceutical R&D Costs, Risks, and Rewards, “The rapid increase in revenues for new drugs throughout the 1980s sent signals that more investment would be rewarded handsomely. The pharmaceutical industry responded as expected, by increasing its investment in R&D.” The OTA report goes on to contend, lower drug prices would mean that, “Research on pioneer drugs could also decline as firms realize that the returns to the winner are likely to be reduced by early price competition from me-too drugs.” Likewise, the U.S. Government Accountability Office (GAO) asserts that pharmaceutical spending control policies “would decrease R&D spending.” And lower drug prices (whether a result of drug price controls or hastened biosimilars competition engendered by shorter periods of data exclusivity protection) would lead to fewer innovative drugs. In fact, Maloney and Civan estimate that a 50 percent drop in drug prices in the United States could see the number of drugs in the development pipeline reduced by between 14 percent and 24 percent.

Indeed, one reason why Europe has produced fewer biopharmaceutical innovations than the United States is because its biopharmaceutical firms have not generated as much profits (which can be reinvested in R&D) as American ones. That explains why, in the 2000s, more new chemical entities were developed in the United States than in the next five nations—Switzerland, Japan, the United Kingdom, Germany, and France—combined. European drug price controls factor into this reality. Golec and Vernon contend that, because of drug price regulations, “European Union [EU] pharmaceutical firms are less profitable, spend less on R&D, and earn smaller stock returns than U.S. firms.” By using data from 1986 through 2004, they go on to show that the economic tradeoff for the European Union, by maintaining real pharmaceutical prices constant over 19 years, was forgoing about 46 new medicine compounds and 1,680 research jobs. They took this one step further by presenting a counterfactual scenario of the United States adopting EU-type price controls over the same time period and estimate that similar price controls would have resulted in 117 fewer new medicine compounds and 4,368 fewer research jobs. Put simply, more revenues mean more R&D, more medical
discovery, more innovative biologics drugs, and ultimately more generic competitors—and the TPP’s terms upset this dynamic by establishing a relatively weak data exclusivity protection period for biologics.

The second problem with the assertion that the Trans-Pacific Partnership will limit access to medicines is that 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.53 Despite this, at least one-third of the world’s citizens living in developing countries lack access to those medicines.54 This owes largely to weak healthcare systems, infrastructure, and investment in too many developing countries (and in some cases to high taxes and tariffs on medicines imposed by developing-country governments).

Third, 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 either developed nations, such as Canada and Japan, or developing nations, such as Peru. For instance, in 2006, Canada changed its laws to increase the duration of IP rights for clinical data from zero to eight years, but pharmaceutical expenditures as a percentage of Canada’s health care expenditures actually decreased over that period.55 Likewise, Japan increased its data protection window from six to eight years in 2007, yet pharmaceutical expenditures as a share of Japan’s health care expenditures have actually decreased since 2005.56 These experiences show that bolstering IP rights does not necessarily result in meaningful increases in expenditures on medicines relative to overall health care budgets.

Likewise, as Luis Miguel Castilla Rubio, Peru’s Ambassador to the United States, testified at the first day of hearings regarding Investigation No. TPA-105-001 before the International Trade Commission on January 13, 2016, Peru did not experience an increase in the price of medicines after it signed the U.S.-Peru Free Trade agreement, which committed it to provide five years of test data protection for pharmaceutical drugs.57 As Peru’s Ambassador noted, opponents at the time argued that the price of medicines would rise and that access would be diminished, but those predications did not materialize.58 As he noted, after entry into force of the U.S.-Peru FTA, the price of medicines increased less than that of the rate of inflation, with prices for medicines in 2009 increased by 2 percent over 2007 but inflation increased by 3.3 percent.59 And as the Ambassador further noted, the price of medicines is not affected solely by regulatory data protection periods, especially as Peru’s government introduced a range of other policies, such as ones to increase competition, and other health care reform policies. The Ambassador also noted that stronger IP rules have lead to more technology transfer and increased investment in Peru. Finally, here, when considering how the TPP’s biologics data exclusivity terms will impact the price of (and access to medicines) in Peru, it bears mention that Peru will not be required to implement the biologics exclusivity provision for 10 years (or to implement the exclusivity provision for new uses for five years) from date of entry into force of the TPP agreement. That is particularly notable because Peru is expected to become a high-income country by the year 2027.60 For its
part, Vietnam will enjoy up to ten years to implement data exclusivity periods for both biologics and small molecule drugs, meaning it will be some time before the TPP’s data protection terms have any impact on access to or the price of medicines in Vietnam.

When it comes to the impact of increased intellectual property protections on the price of medicines, Peru’s experience has been similar to that of India. As Duggan, Garthwaite, and Goyal write in *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India*, which assessed more than 6,000 products consisting of approximately 1,000 molecules, “a molecule receiving a patent experienced an average price increase of just 3-6 percent” with “little impact on quantities sold.”61 This reality stands in stark contrast to the assertions of those who claimed that India’s introduction of patent protections for pharmaceutical drugs as part of its World Trade Organization Trade-Related Aspects of Intellectual Property Rights (TRIPS) commitments would lead to substantial increases in prices for those drugs. For example, Abbot, Kapczynski, and Srinivasan proclaimed that, for India, “[i]t is likely that prices of essential drugs will go up significantly once patents are granted.”62 Likewise, Chaudhuri, Goldberg, and Jia wrongly estimated that implementing a strong Indian product patent system (i.e., one that removed domestic firms currently manufacturing the product) would raise prices by 100 to 400 percent in a sub-segment of the antibiotic sector and thereby reduce welfare.63 But as Duggan, Garthwaite, and Goyal write, “Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment.”64 They also found that anticipated price increases for molecules with single-firm producers would be still be relatively small compared to the estimates of the patent premium in developed economies such as the United States of America.65 These findings substantially contradict the contentions of those, such as Patralekha Chatterjee, who asserted that TRIPS, “will make it far more difficult for poor people across the developing world to access vital drugs, especially new ones, at affordable prices.”66

Analogous to Duggan, Garthwaite, and Goyal’s analysis, Margaret Kyle and Yi Qian, in their National Bureau of Economic Research paper *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS*, also find TRIPS to introduce only relatively modest price increases across developing countries.67 In their study, Kyle and Qian examine the effect of pharmaceutical patent protection on the speed of drug launch, price, and quantity in 60 countries from 2000 to 2013. The authors also find that IPRs have a very large bearing on product launch. Indeed, on-patent products are most likely to be launched and to sell in higher quantities (and also to command the highest prices). Products with expired patents sell in lower quantities and at lower prices than those that are on patent, but at higher prices and quantities relative to those that were never protected. In fact, drugs that are never patented are unlikely to be marketed, regardless of a country’s income level. Thus, it appears that IPRs may increase the availability of new treatments to populations in developing countries.68
The authors further explore whether TRIPS changed the value of patents. Overall, drugs are more likely to be launched if they have post-TRIPS patents, as well as to sell in higher quantities. The most surprising result is that the price of such drugs is lower than pre-TRIPS patented products, on average, in the poorest category of countries. However, the authors interpret these results with caution, because it was driven by a small number of drugs (the TRIPS compliance deadline was 2005, and very few drugs have completed a development cycle by 2013). In general though, post-TRIPS, prices have not significantly increased and quantities have not significantly decreased in poor countries. These types of findings show that the TRIPS Agreement and intellectual property rights (IPRs) in general, have not damaged global public health in the way that many in the public health community had suggested.

Moreover, these studies join a growing body of evidence pointing to a deep connection between stronger IPRs and the development of both innovative medicines—and even innovative pharmaceutical sectors—in developing nations. For instance, Georgetown University Professor Michael Ryan has found in a study of biomedical innovations and patent reform in Brazil that patents provided incentives for biomedical technology entrepreneurs to make risky investments into innovation, facilitated technology markets among public-private technology innovation networks, and encouraged entrepreneurs to tap into the rich biodiversity of Brazil to develop innovative medicines that help citizens not just in Brazil but throughout the world. Likewise, the report Policies that Encourage Innovation in Middle-Income Countries by Charles River Associates finds that for countries whose “objective is to develop an innovative biopharmaceutical industry, intellectual property is a necessary building block.” The report finds that middle-income countries such as Colombia and Malaysia which perform less strongly relative to peers in innovation indicators—such as biopharmaceutical R&D spending, number of biopharmaceutical patents filed, journal articles published, and clinical trials carried out—have fallen behind because they “lack a consistent system for securing intellectual property rights.” Yet, unfortunately, one PriceWaterhouseCoopers survey finds that 60 percent of multinational corporations and 56 percent of domestic drug companies in the Asia-Pacific region find that a lack of IP protection is a major deterrent to investment.

In contrast, the OECD report Trade & Innovation: Pharmaceuticals attributes part of the success of the pharmaceutical sectors of Brazil, China, and India to the introduction of patent protection. It shows that emerging economies are increasingly important markets for pharmaceutical companies and more active participants in the R&D process. In addition, it demonstrates that stronger patent protection—alongside less stringent price controls—tends to encourage more or faster launches of drugs, while IPRs lead to much greater introduction of foreign pharmaceutical products into developing markets and helps contribute to the globalization of clinical trials.

One signal that stronger intellectual property rights for pharmaceutical drugs in developing countries—such as the stronger patent protections many developing countries implemented because of TRIPS—are not
deleterious to access to medicines is the fact that life expectancy at birth has risen from 66 in 1994 to 71 as of 2013, or essentially by five years since the period in which the TRIPS Agreement went into force. And for low-income countries, life expectancy increased more than double that length, 10.5 years, from 1994 to 2013. Likewise, from 1990 to 2013, extreme poverty rates (now defined at $1.90 per day, in 2011 dollars) have dropped from 37 percent of the world’s population in 1990 to a projected 9.6 percent of population in 2015, with the number of the world’s citizens living in extreme poverty dropping from 2 billion to 700 million people.

The simple reality is that stronger intellectual property protections are associated with greater levels of biomedical innovations that save lives. For instance, a Canadian study on the impact of pharmaceutical innovation on premature cancer mortality finds pharmaceutical innovation has saved more than 100,000 years of aggregate life. And anti-cancer biologic drugs (such as Avastin and Herceptin) account for the overwhelming majority of the most effective anti-cancer drugs, with more than 300 anti-cancer biologics currently under development. In other words, stronger intellectual property protections actually increase access to the medicines that save lives—that is, by underpinning an innovation system that enables their invention in the first place.

One last point regarding the impact on prices of longer data exclusivity periods (e.g., by their slightly delaying biosimilars competition) is that biosimilars may not reduce the cost of biologic drugs exceptionally significantly. In the case of conventional “small molecule” drugs, over three to five years the cost of developing a generic is approximately $1 to $5 million, thus providing patients a lower-cost alternative. But as Lybecker explains, “In contrast, many of the shortcuts available to generic manufacturers will not be available to biosimilar producers who are expected to need to invest in clinical trials as well as manufacturing and post-approval safety monitoring programs similar to those of the innovative biologic company. Consequently, biosimilar products are estimated to take eight to ten years to develop at a cost of $75-250 million.” Lybecker notes that, “Current studies estimate cost savings from biosimilars will be between 10 and 20 percent less than the cost of the pioneer biologic.” In fact, European data suggests that biosimilars may offer just a 10 percent discount from a branded pioneer biologic. As Lybecker concludes, “It is not worth undermining the future of this technology [biologics] with weakened intellectual property protection for the limited cost savings anticipated through biosimilar competition.”

The fourth problem with the TPP and access to medicines dissent is that policymakers must not only consider access for citizens in developing versus developed countries, but also the interests of present versus 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, which if left unchecked have the potential to cripple our healthcare system in years to come. But the payoffs for finding treatments or cures for these diseases could be tremendous. For instance, a 1 percent reduction in mortality from cancer would
deliver roughly $500 billion in net present benefits, while a cure would deliver $50 trillion in present and future benefits. Likewise, the financial impact of Alzheimer’s disease is expected to soar to $1 trillion per year by 2050, with much of the cost borne by the federal government, according to the Alzheimer’s Association’s report, Changing the Trajectory of Alzheimer’s Disease. However, the United States could save $220 billion within the first five years if a cure or effective treatment to Alzheimer’s disease were found. But this requires preserving sufficient incentives to invest in biomedical research. Otherwise, society will be left with the stock of medicines it has today, and our children will end up taking the same kinds of drugs we’re taking and continue suffering from the same medical conditions.

Finally, to the extent the TPP induces partner countries to introduce somewhat 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 ultimately develop more breakthrough medical innovations for patients around the world. The U.S. Census Bureau’s list of Advanced Technology Products (ATPs) defines “Biotechnology” as products “Focus[ing] on medical and industrial applications of advanced scientific discoveries in genetics to the creation of new drugs, hormones and other therapeutic items for both agricultural and human use.” In 2015, the United States ran an almost $1.6 billion trade surplus with TPP partner countries, with exports of $2.64 billion and imports of $1.04 billion. TPP member countries represent important and growing markets for U.S. biotechnology exports.

The purpose of trade policy for the United States should be fundamentally about enabling the United States to maximize its comparative advantage in global markets. Unfortunately, the United States has lost competitive advantage in many industries. Fortunately that has not been the case in the biopharmaceutical sector, which employs 3.4 million Americans, 800,000 directly at an average wage that is roughly twice the U.S. average. What the TPP should be accomplishing for this sector is protecting those jobs and potentially creating more by supporting the creation of innovative drugs that can be exported to foreign markets.

In conclusion, this debate is not about drug companies versus patients in developing TPP countries. It’s about whether, in the new global trading regime, the United States will be allowed to enjoy its true comparative advantage in industries such as life sciences, or whether low-cost developing countries will seek to limit that, while taking advantage of U.S. markets to run trade surpluses in lower-cost commodity goods (yet not allow America to sell to them our innovation-based goods and services, including in life sciences).

Moreover, this debate is not about drug companies versus patients in developing countries; it’s about future innovation vs. low prices. Most fundamentally, it should be about preserving the economics of a virtuous innovation system that allows biopharmaceutical innovation to flourish to the maximum extent possible (in the United States and elsewhere), thus affording the best possibility to develop treatments and cures to
conditions currently unsolved by medical science. In fact, it was that understanding that led a diverse group of more than 100 organizations in February 2015 to sign onto *The Declaration Supporting Incentives for Medical Innovation in Trade Agreements.* The organizations represented include a wide variety of patient health advocacy organizations, health care associations and providers, chambers of commerce, university health organizations, and other non-profits from across the United States, all recognizing that the trade agreements the United States enters into need to preserve the incentives for investment in biomedical innovation that are vital to finding cures or treatments to a wide range of diseases that currently have no solution. These groups recognize that stronger intellectual property protections are not the barrier, but rather the path, to greater levels of medical discovery and more cures.
Endnotes

8. Ibid.
19. Ibid.
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