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TPP Issue Analysis: Access to Medicines

The pharmaceutical provisions of the TPP text have raised three basic questions:

1. Does the current TPP text provide an appropriate balance between the need to incentivize innovation and to provide access to affordable medicines for patients in developing countries, like the balance struck under the May 10 Agreement of 2007?

2. Does the current TPP text either require changes to existing U.S. health or intellectual property laws, or prevent the United States from making reasonable changes to those laws?

3. What period of exclusivity is provided for biologic medicines, and is the period sufficient to incentivize the production of new biologic medicines in the future while also ensuring access to affordable medicines?

This paper discusses each of these issues.

Prepared by the Democratic Staff of the Committee on Ways and Means

I. Does the Current TPP Text Provide an Appropriate Balance between the Need to Incentivize Innovation and to Provide Access to Affordable Medicines for Patients in Developing Countries, like the Balance Struck under the May 10 of 2007?

Millions of people in developing countries lack access to life-saving medicines. According to an expert commissioned by the United Nations, 15 percent of the world's population consumes over 90 percent of the world's pharmaceuticals.[1]

Generic medicines can improve access in developing countries by dramatically lowering costs. At the same time, there would not be a generic version of a medicine if an innovative drug company did not first develop a patented version of the product. Pharmaceutical companies need incentives to invest in the research and development necessary to develop innovative products. Thus, the health of millions of patients in developing countries depends upon striking the right balance between "access" and "innovation." There have been efforts over many years to strike the right balance, including in the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPs Agreement) more than two decades ago, and during the WTO ministerial meeting in Doha in 2001.

More recently, in 2007, House Democratic leaders insisted on a number of changes to four pending trade agreements (with Peru, Panama, South Korea, and Colombia), particularly concerning labor standards, environmental protections, investment, and access to medicines. The pharmaceutical provisions were designed to strike a better balance between 'innovation' and 'access,' and established a different balance for developed and developing countries. Many development and public health advocates have expressed support for the May 10 Agreement. For example, according to Oxfam America:

> The agreement reached between Congressional leadership and the Bush administration on May 10, 2007, broke this trend of imposing increasingly stricter IP protections in trade agreements by scaling back so-called TRIPS-plus rules in the FTAs with Peru, Panama, and Colombia. This agreement was very significant[. … It] recognized that higher levels of IP protection can in fact run counter to public health interests and US trade and development goals. … If the TPP is to represent America's diplomatic, development, trade and commercial interests in a balanced manner, it is critical that USTR go back to the May 10 Agreement and build on its underlying principles and objectives for access to medicines, excluding any additional monopoly protections and enabling all the public health flexibilities in TRIPS.[2]

The pharmaceutical obligations in the current TPP text generally do not distinguish between developed and developing countries, unlike under the May 10 Agreement, and the uniform obligations generally are more restrictive than what is provided under the May 10 Agreement. However, the TPP text includes a number of country-specific "transition periods" and country-specific exceptions that must be analyzed for each TPP developing country to

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[1] "UN Rights Expert Unveils Draft Guidelines for Drug Companies on Vital Medicines," UN News Service, October 25, 2007 (referring to P. Hunt, "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines," prepared by the UN Special Rapporteur).

[2] http://policy-practice.oxfamamerica.org/work/trade/intellectual-property-and-access-to-medicine/

determine whether the current TPP text is consistent with the May 10 standard for each developing country.

A. The General Obligations in TPP

The following compares some of the key pharmaceutical provisions in U.S. FTAs *before* May 10, *under* May 10, and *in TPP*.

1. Market/Data Exclusivity for Small Molecule and Biologic Medicines

A manufacturer of a new drug must provide extensive clinical data on its safety and efficacy to a marketing approval agency, such as the FDA in the United States. The producer typically invests significant time and expense in conducting the clinical trials and deserves a period of exclusive use of the data in order to recoup the investment made in creating the data. In the absence of an exclusivity rule (i.e., a rule that prevents other companies from relying upon the data to market their product), a generic manufacturer would be able to immediately rely on the data produced by the innovative manufacturer to market its own product.[3] Under U.S. law, innovative drug manufacturers generally have five years of exclusivity for small molecule medicines and 12 years for biologics.

Before the May 10 Agreement of 2007, U.S. FTAs provided that a government was not permitted to authorize a generic manufacturer of a new pharmaceutical product to rely on the data submitted by the innovative manufacturer for a minimum of five years from the date the patented product is approved in that country.[4] Because the period begins when the innovative manufacturer first seeks and obtains approval in that country, the period can begin and end long after the period begins and ends in the United States, where medicines are often first marketed. Given that manufacturers of patented products often wait years before seeking regulatory approval in developing countries like Peru, the data exclusivity provision meant that a generic drug might not be available in a developing country until years after it is available in the United States.

The May 10 FTAs still generally[5] provide for five years of data exclusivity for pharmaceutical products.[6] However, if the foreign country is a developing country and relies on marketing approval granted by the United States FDA, the five-year period begins when the drug is first approved not in that country but in the United States (i.e., the five-year period runs "concurrently" in the two countries), if the country grants marketing approval within six months after receiving an application. Because the "clock is ticking" under the concurrent period, innovative drug companies have an incentive to market their medicines in developing countries at the same time or soon after they market them in the United States. For example, if they do not

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[3] Whether a generic manufacturer will be able to market its product will also depend on whether the patent has expired on the original product. But it is best to consider data/market exclusivity and patents separately.

[4] It is also important to note that the five-year term applied to all "new pharmaceutical products". There was no separate provision for biologics.

[5] Under May 10th, a developing country is required to provide a "reasonable period" of exclusivity, which "shall normally mean five years."

[6] Like FTAs before May 10, the May 10 five-year and five-year concurrent period language was intended to apply to both small molecule and biologic medicines, and that is how the language was interpreted in submissions to USTR by innovative pharmaceutical companies. Peru, however, argued it was not required to provide any exclusivity period with respect to biologic medicines.

seek approval until two years after the drug is approved in the United States, they will receive only three years of exclusivity in Peru.

The TPP text provides for five years of market exclusivity with no concurrent period with respect to all small molecule medicines (although some countries have established a concurrent period through country-specific exceptions).

Unlike past agreements, there is a separate breakout for biologics. The period of exclusivity for biologics is based on "effective market protection."[7] The period of "effective market protection" for biologics is ambiguous. There are two options.

- The first option requires the provision of effective market protection by providing a period of data exclusivity of eight years. Thus, this provision is similar to the provision for small molecule medicines, but requires eight years instead of five.

- The second option provides effective market protection that "delivers a comparable outcome in the market" to the first option through a combination of (1) a period of data exclusivity of five years; (2) "other measures;" and (3) "recognizing that market circumstances also contribute to effective market protection."

  There are arguments that this language sets a floor of five years, and other arguments that it sets a floor of eight years. The argument is that while a party may provide five years of data exclusivity, it can provide a longer period of market exclusivity if, for example, a generic version of the biologic is not permitted to be marketed until eight years after the marketing approval was first granted.

  The TPP text also provides an additional three years of exclusivity when a new use is found for an old medicine (although the applicability to biologics is unclear).[8]

2. Patent Extensions for Patent or Marketing Approval Delays

Under the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS), patent terms must be 20 years from the date of filing. Having the date of filing be the trigger for the patent term means that delays in actually granting the patent reduce the effective period of patent protection. Similarly, a delay in granting a marketing approval also effectively reduces the period of patent protection.

Before the May 10 Agreement, our trade agreements required countries to extend the life of a patent to compensate for "unreasonable delays" in the patent grants, or for "unreasonable curtailment of the patent term" due to delays in issuing marketing approvals.

Under the May 10 Agreement, rather than lengthening the term of the patent (which benefits the innovative pharmaceutical companies – but at the expense of patients), trade

[7] The biologics exclusivity provision does not provide for a concurrent period like the one under the May 10 Agreement.
[8] TPP, Article 18.50.2.

agreements required developing countries to make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. This provision was intended to improve access to medicines both by ensuring that government agencies process applications more quickly – and by avoiding delays that would result from inappropriate patent extensions.

The TPP general obligation reverts back to the pre-May 10 trade agreement text, requiring mandatory patent term extensions for patent or marketing approval delays.

3. "Linkage" between Patents and Marketing Approval

Before the May 10 Agreement, our trade agreements required a drug regulatory agency to withhold approval of a generic medicine until the agency could certify that no patent would be violated if the generic were marketed. This is known as "linkage," because marketing approval is linked to patent status. The problem with this provision is that it provided a one-sided fix to a two-sided problem: while it may help to ensure that pharmaceutical patents will not be infringed, it also "locks in" invalid patents. Every patent is assumed to be valid, and no mechanism is required under the FTA to allow for the prompt processing of challenges to the validity of a patent.

Under the May 10 Agreement, the linkage obligation was removed and replaced with a more flexible requirement that developing countries are to provide "procedures, such as judicial or administrative proceedings, and remedies, such as preliminary injunctions … for the expeditious adjudication of disputes concerning the validity or infringement" of a pharmaceutical patent. Note that this obligation applies not only to cases of alleged patent infringement, but also to cases of alleged patent *invalidity* – thereby providing a better balance between innovation and access.

The TPP text applies the May 10 Agreement language to all countries – both developing and developed.[9] The May 10 language was adopted in part because all other TPP parties, including developed countries like New Zealand, strongly supported it, but also because the United States does not "link" patent status with marketing approval for generic biologics (biosimilars).

4. The Right to Protect Public Health ("Doha Declaration")

During the WTO ministerial meeting in Doha in 2001, the WTO Members agreed to a declaration that recognized that the WTO Agreement on Trade-Related Aspects of Intellectual Property ("TRIPs Agreement") does not and should not prevent a party from taking measures to protect public health by promoting access to medicines for all.

[9] TPP, Article 18.51.

Some U.S. FTAs before the May 10 framework was established in 2007 included unenforceable side letters that included similar language. [10]

The May 10th Agreement changed that dynamic by moving the language into the body of the chapter and making it enforceable. That language states that the "obligations of [the Intellectual Property] Chapter do not and should not prevent a party from taking measures to protect public health by promoting access to medicines for all . . . . Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all."[11] The text also provided an exception to the data exclusivity obligation with respect to measures taken in accordance with the Doha Declaration.

The language from the May 10th Agreement is reflected in TPP.[12]

5. New Obligations Not Part of May 10 Agreements with Developing Countries

There are at least two important new obligations relating to pharmaceuticals that are included in the TPP text that were not in trade agreements with developing countries under the May 10 framework:

- ***Additional Three Years of Exclusivity for New Uses.*** As mentioned above, in addition to five years of exclusivity for small molecule medicines, a party is required to provide an additional three years of exclusivity when new clinical information is submitted in support of the marketing approval of a previously approved pharmaceutical for a new use.[13] This provision was included in the Australia and Korea FTAs, but specifically excluded from the Colombia, Peru, and Panama FTAs.

- ***Secondary Patents***. Secondary patents are obtained when a rightholder has a patent on a product and seeks a second patent (critics refer to this as "evergreening" patents), for example if a new use for the product is discovered. There is a new provision in TPP stating that "each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product."[14] In other words, parties are confirming that secondary patents are available.

  The language does not introduce new obligations on parties, because the parties are simply "confirming" that these types of patents are already available. It also does not appear to require parties to provide second patents unless the basic patentability criteria

[10] *See, e.g.*, U.S-Oman Free Trade Agreement, "Side Letter on Public Health," https://ustr.gov/sites/default/files/uploads/agreements/fta/oman/asset_upload_file44_8808.pdf
[11] *See, e.g.*, U.S.-Peru TPA, Article 16.13(a).
[12] TPP, Article 18.6 and Article 18.50.3.
[13] TPP, Article 18.50.2.
[14] TPP, Article 18.37.2.

are met; thus, a party remains free to reject a second patent if it is not new, does not involve an inventive step, or is not capable of industrial application.[15]

B. Treatment of TPP Developing Countries and Consistency with May 10

As mentioned above, the May 10 Framework clearly distinguishes between developed and developing countries with respect to intellectual property and access to medicines. The TPP Agreement does not. However, the TPP Agreement does include a number of transition periods and other special provisions unique to each developing country party. To assess whether those transition periods and other provisions provide flexibility for developing countries similar to the flexibilities in the May 10 Framework, one needs to determine which TPP countries are "developing" and when those countries could reasonably be expected to become "developed."

There are a variety of ways to draw the line between developed and developing countries. While GDP per capita is important, some have suggested income disparities, health burdens, and health care infrastructures in each country should also be considered. Things like the World Bank's "Human Development Index" help in considering these other factors. Nevertheless, many believe the line should be drawn according to the World Bank's definition of low- and medium-income countries versus high-income countries (currently about $12,700). That is the line Congress adopted under the GSP statute.

Four of the TPP parties appear to fall below the World Bank's high-income threshold: Malaysia, Mexico, Peru, and Vietnam. The TPP medicine obligations for each country are analyzed below, with reference to estimates as to when each country will become a high-income country. It cannot be emphasized enough that these estimates of development are preliminary; we will need much more input from experts on this point. And these estimates are likely a bit optimistic. They are based on the assumption that future economic growth rates will be similar to the relatively high rates in the recent past, and that the country will not suffer an economic collapse or crisis.

1. Malaysia

Under some estimates, Malaysia will become a high-income country in as few as two or three years. Under the TPP Agreement, Malaysia will not be required to implement the biologics exclusivity provision for five years (i.e., a five-year transition period), or to implement the linkage and patent term extension for marketing delay obligations for four and a half years after the agreement enters into force. Malaysia, however, will be required to implement the provision on patent term extensions for patent delays immediately upon entry into force of the Agreement.

Moreover, and very interestingly, Malaysia will also be allowed to keep an 18-month "window" in its exclusivity law and apply it to both small molecule and biologic medicines. Under this provision, if a brand-name medicine does not seek marketing approval within 18 months from the time it sought approval in another country, such as the United States, Malaysia will not provide any exclusivity period for that medicine. This provision is somewhat similar to the "concurrent period" provision in May 10. Under both provisions, the exclusivity clock starts running when the drug is first marketed in another country.

[15] TPP, Article 18.37.1.

Thus, if estimates are correct that Malaysia will become a high-income country in the next two or three years, it appears that the outcome for Malaysia as a developing country is similar under TPP to the outcome under May 10 in some respects (i.e., exclusivity for small molecule and biologic medicines; linkage; patent term extensions for marketing approval delays; and the Doha Declaration). On the other hand, the outcome under TPP is not similar to the outcome under May 10 with respect to patent term extensions for patent delays or the provision requiring three additional years of exclusivity for additional uses.

2. Mexico

According to some estimates, Mexico will become a high-income country in as soon as six years. Under the TPP Agreement, Mexico will not be required to implement the biologics exclusivity provision for five years; the small molecule exclusivity provision for five years; or the patent term extension for marketing delay provision for four and a half years after the agreement enters into force. Note that TPP is unlikely to enter into force before 2017. Mexico will, however, be required to implement the provision on patent term extension for patent delays upon entry into force of the agreement.

Thus, if estimates are correct that Mexico will become a high-income country in the next six years and if TPP does not enter into force before 2017, it appears that the outcome for Mexico as a developing country is similar under TPP to the outcome under May 10 in some respects (i.e., exclusivity for small molecule and biologic medicines, linkage, patent term extensions for marketing approval delays, and the Doha Declaration). On the other hand, the outcome under TPP is not similar to the outcome under May 10 with respect to patent term extensions for patent delays or the provision requiring three additional years of exclusivity for new uses.

3. Peru

According to some estimates, Peru will become a high-income country in about 12 years. Under the TPP Agreement, 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. Peru will be required to implement patent term extensions for both patent delays and for marketing approval delays immediately upon entry into force.

Very importantly, Peru will also be allowed to keep its five-year "concurrent period" provision from the Peru FTA under May 10 in perpetuity for small molecule medicines, and to apply a concurrent period in perpetuity for biologics as well. (It is unclear from the text whether Peru will be required to provide a five-year or a longer concurrent period for biologics.)

Thus, if estimates are correct that Peru will become a high-income country in 12 years, it appears that the outcome for Peru as a developing country under TPP may fall short of the outcome under May 10 with respect to: biologics exclusivity, the exclusivity provision for new uses, and patent term extensions for both patent and marketing approval delays. It is consistent with May 10 with respect to small molecule exclusivity, linkage, and the Doha Declaration.

4. Vietnam

According to some estimates, Vietnam will become a high-income country in approximately 18 years. Under the current TPP text, Vietnam has the following transition periods:

- Biologics Exclusivity: 10 years, possibly extended up to 12 years upon request unless the TPP Commission disapproves;
- Small Molecule Exclusivity: 10 years, extended up to 12 years upon request unless the TPP Commission disapproves;
- Patent Term Extensions for Patent Delays: 3 years possibly extended up to 4 years;
- Patent Term Extensions for Marketing Approval Delays: 5 years;
- Linkage: 3 years

Thus, if estimates are correct that Vietnam will become a high-income country in 18 years, it appears that the outcome for Vietnam as a developing country under TPP falls short of the outcome under May 10 with respect to: biologics and small molecule exclusivity (unless the parties agree to extensions in the future), the exclusivity provision for news uses, and patent term extensions for both patent and marketing approval delays. It is consistent with May 10 with respect to linkage and the Doha Declaration.

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II. Does the Current TPP Text Either Require Changes to Existing U.S. Health or Intellectual Property Laws, or Prevent the United States from Making Reasonable Changes to Those Laws?

There does not appear to be any obligation in the TPP text that would require changes to existing U.S. laws or practices relating to pharmaceuticals. However, some concerns have been raised that TPP could constrain future changes to U.S. law. Specifically, there have been two possible changes to U.S. law that have led to questions about whether TPP would somehow pose an impediment:

- Biologics Exclusivity. In his budget, the President has repeatedly proposed reducing the period in which a generic biologic medicine ("biosimilar") can be excluded from the market, from twelve years to seven.[16] As noted above, the biologics exclusivity period in TPP is ambiguous. Some believe the obligation is at least five years of exclusivity, while others believe it is at least eight. If the United States were to propose moving to seven years of exclusivity, arguments could be advanced that doing so would be inconsistent with TPP.

- Negotiating Drug Prices. TPP includes an annex designed to promote transparency in pricing and listing decisions by governments with respect to pharmaceuticals and medical devices. This type of annex was first included in the U.S.-Australia FTA.

[16] *See, e.g.*, HHS Budget in Brief, http://www.hhs.gov/about/budget/fy2015/budget-in-brief/cms/medicare/index.html.

The U.S.-Australia annex applies to procedures operated by a federal healthcare authority. It set out requirements such as ensuring that applications to be considered within a fixed timeframe (to be determined by the party), providing written information to applicants and the public regarding determinations about listing or reimbursement, and providing for the opportunity for review of the determination.

An annex was also included in the U.S.-Korea FTA (KORUS) and was expanded to include medical devices. The KORUS annex was criticized for going beyond mere transparency. It includes provisions that ventured into substantive reimbursement decisions in an article entitled "Annex to Innovation."

TPP reverts to a model closer to the U.S.-Australian FTA provisions (although it does apply both to pharmaceutical products and medical devices, like KORUS). The annex is limited to transparency; the "access to innovation" article from KORUS is not included. It also provides greater clarity about how U.S. programs are covered. For example, it defines "national healthcare authorities" as "Centers for Medicare & Medicaid Services (CMS), with respect to CMS' role in making Medicare national coverage determinations."[17] Thus, determinations regarding Medicaid are not included. Moreover, government procurement (for example, Veterans Administration decisions) is not included.[18] And, importantly, the obligations in the pricing annex are not subject to dispute settlement.

It is possible that the United States could change the way Medicare drug reimbursement is handled, and that it could become a program "operated by the national health care authorities." In that case, it would be subject to the provisions in the annex governing procedural fairness. Those procedures are similar to the procedures set out under the U.S.-Australia FTA but are elaborated. Despite the procedural nature of the obligations, concern has been expressed that requiring the government to disclose, for example, "methodologies, principles, and guidelines"[19] used to evaluate proposals for drug reimbursements, will impair the government's negotiating leverage by tipping off companies to the government's approach. On the other hand, the annex does not require parties to have methodologies, principles, and guidelines, nor does the annex prescribe the degree of detail that must be disclosed if such measures exist.

Concern has also been expressed that the annex could subject parties' determinations to investor state dispute settlement (ISDS). Any ISDS dispute must claim a violation of an obligation in the investment chapter, such as a claim of expropriation, denial of fair or equitable treatment, or discrimination based on nationality. And the merits of such a case will depend very much on the particular facts of that case. A claim that a party has breached an obligation in the pricing annex cannot serve as a direct cause of action in an ISDS case.

More specifically, concerns have been raised that, if a government insists on a negotiated price that does not fully reflect the value of the investment (the intellectual property) in

[17] TPP, Schedule to Annex 26-A.
[18] TPP, Annex 26-A, footnote 11.
[19] TPP, Annex 26-A, Paragraph 26-A.2(b).

the product, a pharmaceutical company could argue that its investment has been expropriated, which would constitute a breach of the investment chapter. It is difficult to analyze the merits of such a claim in the absence of specific facts. However, it is important to note that the pricing annex clearly demonstrates that the parties to the Agreement understand and agree that each party has the right to negotiate the prices of its medicines.

III. What Period of Exclusivity is Provided for Biologic Medicines, and Is the Period Sufficient to Incentivize the Production of New Biologic Medicines in the Future, while also Ensuring Access to Affordable Medicines?

As described above, TPP is the first trade agreement to include a separate exclusivity provision for biologic medicines. That provision has been the source of a great deal of controversy since the text was publicly released. Innovative pharmaceutical producers generally have expressed disappointment that the text does not provide 12 years of exclusivity, as provided under the Affordable Care Act in U.S. law. Others have noted that four of the 12 TPP parties currently provide no exclusivity for biologics, and five others provide just five years. Moreover, the U.S. Federal Trade Commission has concluded that it is not necessary to provide any exclusivity period for biologics, and the President has proposed in his annual budgets reducing the period from 12 to seven years.

It is also unclear to many whether the obligation is to provide eight years of exclusivity, or something less than that, such as five years. And some public health advocates have argued that countries, particularly developing countries, should not be required to provide any exclusivity period for biologic medicines.

On December 3, 2015, the congressionally established advisory committees issued their reports on the TPP. The Industry Trade Advisory Committee for Chemicals, Pharmaceuticals , Health/Science Products and Services (ITAC-3) and the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) each discussed the pharmaceutical provisions of the TPP text.

ITAC-3 was "unable to come up with a consensus" on the intellectual property provisions that relate to pharmaceutical products. The ITAC-3 members that represented generic interests "are in support of" the Agreement. The ITAC-3 members that represented innovative pharmaceutical companies are of the opinion that "portions" of the intellectual property text do advance the negotiating objectives in TPA. "However, there remain significant concerns about the provisions related to data protection for biologic medicines."[20]

The ITAC-15 Report includes a more detailed discussion of the biologics issue and the disagreement between the innovative and the generic pharmaceutical companies. The relevant pages of the ITAC-15 Report (pages 16-19) are attached.

[20] ITAC-3 Report, p. 13.

agreements that require provision of this minimum term of protection for pharmaceutical products. In addition, Article 18.50.3 extends the protection provided by the Doha Declaration on the TRIPS Agreement and Public health.

Article 18.51: Measures Relating to the Marketing of Certain Pharmaceutical Products

Article 18.51 provides measures that permit entry of competition to patented pharmaceutical products, while mandating that Parties have systems to provide timely notice and procedures to enforce patents rights. These measures have proven important to ensuring the effective protection of patents relating to pharmaceutical products.

Under Article 18.51.1(a)[2], each TPP Party must provide a system to allow notice to a patent holder prior to the marketing of products that rely on evidence or information concerning the safety and efficacy of a patented product. Article 18.51.1(b) mandates that Parties provide adequate time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, remedies provided in Article 18.51.1(c). Article 18.51.1(c) indicates that Parties must provide procedures, such as judicial and administrative proceedings, and expeditious remedies for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use. Examples of remedies to be provided include preliminary injunctions or equivalent effective provisional measures. In combination, these provisions require TPP Parties to provide a transparent system that gives notice to patent owners in advance of marketing of the product, so as to enable the rights holder to initiate the appropriate actions to effectively enforce the patent rights.

ITAC-15 encourages U.S. negotiators to press for implementation of transparent, efficient and balanced measures that will prove effective in providing patent holders the opportunity to timely initiate proceedings to enforce the patent and to expeditiously resolve disputes over patents, while avoiding unnecessary constraints on competition.

Article 18.52: Biologics

The TPP Agreement is the first U.S. trade agreement to include provisions expressly directed to new pharmaceutical products that are or contain a biologic. The inclusion of such provisions is consistent with U.S. law. *See* 42 U.S.C. §262(k)(7).

Pursuant to Article 18.52.1, a TPP Party must provide either (a) eight years of "effective market protection" in the manner by which five years of data protection is provided in Article 18.50.1 and 18.50.3 of the Agreement, or (b) a "comparable outcome" that includes at least five years of data protection in compliance with Article 18.50.1 and 18.50.2 in combination with "other measures." Article 18.52.2 requires TPP Parties to provide the protection period of Article 18.52.1 to at least those human biological products that are or which contain a protein produced by biotechnology processes. Finally, in recognition of the nascent stage of development of the biologic market and its regulatory framework, Article 18.52.3 provides for the TPP Parties to consult after 10 years from the date of this

[2] U.S. negotiators have informed ITAC-15 Members that Article 18.51.1 applies to all TPP Parties other than Japan and Mexico, to which Article 18.51.2 applies.

Agreement, or as otherwise decided by the Commission to review the period of exclusivity and scope of application.

Certain of the ITAC-15 Members had differing views on Article 18.52 and the perspective that U.S. negotiators might take toward its implementation in TPP Parties.

Certain ITAC-15 Members had the following views on Article 18.52:

A major negotiating objective for the U.S. was to establish in the TPP a uniform standard requiring TPP Parties to provide a period of regulatory data protection for pharmaceutical products that are biologicals of at least 12 years from the date of the approval of the product in each TPP Party. The existing U.S. standard is supported by a broad, bipartisan majority of Members of Congress, and is an articulated negotiating objective for the TPP.

The certainty of a 12-year regulatory data protection period for pharmaceutical products that are biologics has been recognized as being essential to encourage the continued clinical development of biological products. The 12-year period is supported by extensive economic analyses and policy considerations. Unfortunately, the standard established in the TPP falls short of this clear negotiating objective in several important respects.

First, the period of protection that must be provided by TPP Parties under Article 18.52.1 is defined to be only at least eight (rather than at least twelve years) in duration from the date of approval of the product in the Party. Specifically, pursuant to Article 18.52.1, a TPP Party must provide either (a) eight years of test data protection in the manner by which five years of test data protection are provided in Article 18.50.1 and 18.50.3 of the Agreement, or (b) eight years of effective market protection that includes at least five years of test data protection in compliance with Article 18.50.1 and 18.50.2 in combination with "other measures." The eight-year term of protection is a substantially shorter period of protection than has been recognized in the U.S. as being essential to encourage continued clinical development of biological products.

Second, while each TPP Party must provide measures that provide at least eight years of effective market protection for new biological products, the manner by which the TPP requires the Parties to provide this at least eight-year period of protection is not defined in objective or transparent terms in the Agreement. Instead, the TPP appears to provide discretion for a TPP Member to combine various types of measures that, in the aggregate, operate to provide the at least eight-year period of effective market protection. While Article 18.52.1 obliges TPP Parties to adopt government-applied measures, rather than point to the effect of patents or natural market forces, the lack of clarity in the nature of measures other than test data protection consistent with Article 18.50 may undesirably create uncertainty for developers of innovative biological products and other market participants. Article 18.52.1(b)(ii) and (iii), in particular, may be used by TPP Parties as a basis for adopting non-transparent or ineffective mechanisms for providing the required effective market protection for new biological products of at least 8 years.

Third, the Agreement provides extended periods for TPP Parties to implement the obligations specified in Article 18.52, ranging from four to ten years. Compounding this problem is that footnote 47 of the Agreement specifies that TPP Parties may apply the provisions of Article 18.52 to applications for marketing approval that are filed after the

date of entry into force of Article 18.52 in that Party. The effect of extended delays for implementation of Article 18.52, in combination with an application of its provisions only to applications for marketing approval filed after those provisions apply to the Party may function to discourage developers of new biological products from pursuing prompt approval of such products in those Parties.

The scope of biological products required to be subject to the obligation of Article 18.52.2 also falls short of U.S. objectives. In Article 18.52.2, TPP Parties are required to provide the at least 8-year protection period of Article 18.52.1 to at least those human biological products that are or which contain a protein produced by biotechnology processes. While the scope of the obligation for protein-based biological products is clear (i.e., it encompasses any protein-based product made in whole or in part by use of technologies recognized to be within the field of biotechnology), the Agreement does not require TPP Parties to make the period of protection specified in Article 18.52.1 available for other pharmaceutical products that are generally recognized to be human biological products. Consequently, TPP Parties may choose to extend to such non-protein based biological products the term of data protection required by Articles 18.50.1 and 18.50.3.

These ITAC-15 Members urge U.S. negotiators to address the lack of transparency and certainty in Article 18.52 during implementation of the Agreement, including, *inter alia*, by pressing for implementation of the protections specified in Article 18.52.1 entirely through test data protection consistent with the structure of Article 18.50. ITAC-15 also urges U.S. negotiators to press for early implementation of the protections specified in Article 18.52, and to extend the protections to all pharmaceutical products that are biologicals which are the subject of applications for marketing approval that, as of the date of application of the Agreement to the Party, have not been approved. Finally, ITAC-15 urges U.S. negotiators to advance the objectives specified in Article 18.52.3 to press for enhancement of the measures specified in Article 18.52 through cooperation and coordination with other TPP Parties.

Other ITAC-15 Members had the following views on Article 18.52:

These ITAC-15 Members would have preferred not to express an opinion or otherwise advocate within this report that the U.S. negotiators press for a specific data protection period, and simply commended the U.S. negotiators for reaching a balanced and equitable agreement in the context of a highly contentious and sensitive, but critically important, substantive area for which a widely divergent set of positions exist.

However, despite their misgivings about entering into a policy debate in this Report regarding what might have been agreed to in TPP – but was not – these Members feel compelled to briefly address some of the above statements by the other Members.

These Members agree that a major negotiating objective for the U.S. was to establish in the TPP at least 12 years of exclusivity for biologics. These Members also know that U.S. negotiators did their utmost to achieve that objective. However, the odds of achieving it were always slim. U.S. negotiators were candid with Members of the ITAC, as well as Members of Congress, in expressing their doubt that they could impose 12 years of biologic exclusivity on the eleven other TPP Parties, four of which have no exclusivity for

biologics in their domestic law, five of which have 5 years and two of which have 8 years. Given the diversity of policies on biologic exclusivity among the TPP Parties, the outcome reached by the negotiators is significant. These Members also note that this is the first time biologic exclusivity has been included in any U.S. trade agreement.

These Members disagree with the other Members' interpretation of the term of the exclusivity provided in Article 18.52.1(b): "*eight years* of effective market protection that includes at least five years of test data protection in compliance with Article 18.50.1 and 18.50.2 in combination with 'other measures'" (emphasis added). The number eight appears nowhere in Article 18.52.1(b). The provision, rather, uses the phrase "a comparable outcome in the market" to represent the sum of "at least five years" plus "other measures."

These Members also disagree with the following statements: "The certainty of a 12-year regulatory data protection period for pharmaceutical products that are biologics has been recognized as being essential to encourage the continued clinical development of biological products. The 12-year period is supported by extensive economic analyses and policy considerations. The eight-year term of protection is a substantially shorter period of protection than has been recognized in the U.S. as being essential to encourage continued clinical development of biological products." These Members note that the Federal Trade Commission (FTC) has concluded that it was not necessary for the U.S. to provide *any* exclusivity period for biologic products, while the President has, for each of the past five years, recommended in his budget proposals that the U.S. reduce the period of exclusivity from 12 years to 7 years. The excessiveness of 12 years of exclusivity (in addition to patent protection) for biologic products, which would have resulted in increased costs for and reduced access to medicines, was also recognized by the eleven other TPP Parties, resulting in a shorter period of protection.

Article 18.54: Alteration of Period of Protection

ITAC-15 notes that U.S. negotiators incorporated Article 18.54, which ensures that the expiration of a patent on a pharmaceutical product shall not alter the period of data protection for the product. This provision ensures the independent nature of the rights provided by patents and by regulatory data protection in a pharmaceutical product.

Copyright and Related Rights and the Protection of Certain Satellite Signals

As ITAC-15 noted in its report relating to the KORUS, it is the goal of ITAC to "ensur[e] that the model FTA intellectual property text, which has been carefully developed through the course of negotiation of eleven prior FTAs, continues to form the basis for" future FTAs. The KORUS standards in many important areas improved on the standards in TRIPS and NAFTA and, in others, clarified provisions in those agreements, in light of the industries' evolving business models and the U.S. copyright industries' wide experience with copyright enforcement globally. ITAC 15 notes that in a number of important areas TPP is less robust than the KORUS standard, and updates to KORUS standards to take into account developments since the negotiation of KORUS were not in every case achieved.