

## Trans-Pacific Partnership Lost Important IP Provisions

By **Jeremiah Frueauf** and **Matthew Smith** (April 6, 2018, 12:16 PM EDT)

With one of his first executive orders, President Donald Trump withdrew the United States from the previous administration's years-long effort to negotiate and ratify the Trans-Pacific Partnership agreement.[1] Many thought the withdrawal of the United States would key the beginning of the end of the TPP, which sought to harmonize intellectual property rights among various multilateral trade-focused provisions. However, the remaining 11 member nations of the TPP revived and revised the agreement, renaming it the Comprehensive and Progressive Agreement for Trans-Pacific Partnership.



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On March 8, 2018, the CPTPP member nations executed the CPTPP.[2] While the CPTPP suspended only 22 of the over 600 provisions in the TPP, the majority of the suspended provisions relate to the negotiated intellectual property rights.[3] In the void left by the United States withdrawal, the remaining member states suspended several important provisions originally in the TPP: market exclusivity for pharmaceuticals and biologics, patent term extension for regulatory delay, patent term adjustment for patent office delay, and a broadening of patentable subject matter to include new uses of known products. Many of these suspended provisions would have benefited pharmaceutical and biotechnology companies developing pharmaceuticals and biologics. What negotiated intellectual property rights remain, e.g., some the inventor-derived public disclosure grace periods and agricultural chemical product marketing exclusivity, while important, pale in comparison to those set forth in the original TPP agreement. We discuss below the patent-related provisions retained by the CPTPP, those suspended, and explain the potential implications these changes could have on global patent practice.



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### Grace Period and Agricultural Chemical Exclusivity Provisions Retained in CPTPP

An important patent law harmonization provision retained by the CPTPP is the inventor-derived grace period.[4] The grace period provision prevents inventor-derived public disclosures from being used in a novelty or inventive step determination against a later filed patent application as long as the disclosure occurred one year or less before the application's filing date. Currently, all CPTPP member nations have some form of grace period protection for inventor-derived public disclosures. However, the laws are not uniform and are in many instances quite complex, which can potentially cause issues for patent applicants.[5] For example, Brunei Darussalam, Malaysia, Mexico, Singapore and Vietnam only provide a

grace period for novelty determinations, while the other member nations provide a grace period for novelty and inventive step determinations.[6] Moreover, Japan, Vietnam, and in some circumstances New Zealand, only provide a grace period of six months, while the other member nations provide a grace period of one year.[7]

Of note, the grace period implemented by the CPTPP mirrors the grace period enacted by the America Invents Act in 2011.[8] Thus, even with the withdrawal of the United States from the TPP, implementation of the CPTPP will harmonize and simplify this important area of patent law in the member nations. As a result, applicants that need to rely on a grace period in the U.S. and CPTPP implemented nations should encounter reduced uncertainty and costs associated with patent application filing strategies.

Another important provision retained by the CPTPP relates to agriculture chemical marketing exclusivity. It requires member nations to provide at least 10 years of marketing exclusivity for a new agriculture chemical product that has not been previously approved in a member nation, if data is required for submission to a governmental agency for safety and efficacy purposes.[9] Because many of the member nations in the CPTPP have large agricultural industries, it is not surprising the final agreement retained this provision. Its retention will benefit agricultural chemical companies and support research in this area.

### **New Product Uses Not Expanded Under CPTPP**

The TPP required all member nations to include "new uses of a known product, new methods of using a known product, or new processes of using a known product" within the scope of patentable subject matter.[10] This provision would have provided patent applicants with an opportunity to receive patent protection for the discovery of new uses of, for example, an old drug to treat diseases. Such a change could spur research and development in pharmaceutical and biotechnology industries, among others, in the member nations. While the CPTPP suspended this new use provision, several CPTPP member nations provide at least some form of patent protection for second medical use of known compounds except Peru and Vietnam.[11]

### **Patent Term Adjustment for Unreasonable Granting Authority Delays and Fast Track Examination Removed Under CPTPP**

While largely unique to United States patent practice, the TPP required member nations to allow patent applicants to request adjustment of patent term due to unreasonable or unnecessary delays by the member nation's patent office.[12] Indeed, the TPP would have allowed patent applicants to request adjustment of patent term if (1) a patent takes more than five years to issue from the filing date or (2) patent examination continues beyond three years from the date of filing the request for examination, whichever is longer.[13] Following the withdrawal of the United States from the TPP, the CPTPP suspended this provision despite the clear benefit of holding member nations' patent offices accountable for long delays that frequently occur during examination.[14]

The United States has its own unique system for determining patent term adjustment, rife with many pitfalls for applicants to lose term adjustment in the course of typical prosecution. Of the CPTPP member nations, only Chile and Peru have patent term adjustment provisions, which are similar to the TPP's provision. Availing of these provisions requires a detailed understanding of the local requirements. For example, in Chile, a patent applicant has up to six months after the patent grants to request patent term adjustment. In Peru, a patent applicant only has 30 days after the patent grants to request patent

term adjustment, and Peru does not allow patent term adjustment for pharmaceutical products or any processes related to pharmaceuticals.

Additionally, the TPP suggested member nations implement a system for requesting expedited examination, similar to a Track One application in the United States.[15] Fast track examination processes provide applicants with several benefits, including rapid portfolio growth and a quick path to enforcement. Although the CPTPP suspended the expedited examination efforts under the TPP, Australia, Canada, Japan and Malaysia each have some form of expedited examination. Additionally, all CPTPP member nations, except Brunei Darussalam and Vietnam, participate in the global patent prosecution highway, which can increase the speed of examination.

### **Patent Term Extension Due to Regulatory Delay Removed Under CPTPP**

In 1984, the Drug Price Competition and Patent Restoration Act (Hatch-Waxman Act) introduced patent term extension in the United States, which gave drug developers an opportunity to restore patent term lost due to delays in regulatory approval.[16] Several CPTPP member nations have adopted at least some form of term extension resulting from regulatory review delay. In its final form the TPP required all member nations to establish a system to allow patent applicants to extend patent term for delays based on regulatory approval for pharmaceutical products.[17] The TPP did not set a minimum or maximum amount of time to tack onto a patent's term for regulatory delay. Moreover, the TPP suggested, but did not mandate, member nations establish an expedited regulatory review process for pharmaceutical products.[18] However, with the United States withdrawal from the TPP, the remaining member nations suspended this provision.[19] Despite its suspension, patent applicants have the opportunity to gain patent term extension in Canada, Singapore, Brunei Darussalam, Australia, New Zealand and Japan.

### **Expanded Pharmaceutical Marketing Exclusivity Removed Under CPTPP**

A robust exclusivity strategy includes both patent and marketing exclusivities. The United States, for example, provides varying periods of marketing exclusivity for, among others, new chemical entities (up to 7.5 years), orphan indications (7 years), new antibiotics or antifungals (5 years), new clinical information (three years), and pediatric populations (six months). As a member of the TPP, the United States negotiated for similar marketing exclusivities in the TPP. For example, the TPP required member nations to provide at least five years of marketing exclusivity from the date of marketing approval for any new pharmaceutical product in that member nation.[20] Additionally, the TPP required member nations to provide at least three years marketing exclusivity for a previously approved pharmaceutical product covering a new indication, new formulation, or new method of administration.[21] Alternatively, the TPP required member nations to provide at least five years marketing exclusivity for new pharmaceutical products that contain a chemical entity that has not been previously approved by the member nation.[22] While the CPTPP suspended these provisions,[23] all member nations except Brunei Darussalam have some form of marketing exclusivity for pharmaceutical compounds, typically lasting at least five years.

### **Extended Biologic Marketing Exclusivity Removed Under CPTPP**

Unlike other CPTPP member states, the United States provides 12 years of marketing exclusivity from the approval date for new biological products, which prevents competitors from gaining approval for a biosimilar product for the same indication. Despite the U.S. delegation's efforts to achieve similar protection in the TPP, the final agreement settled on a shorter exclusivity period: either eight years or five years of exclusivity and "other measures" to deliver a comparable outcome in the market.[24] The

withdrawal of the United States from the TPP allowed the remaining member nations to scrap the biologic marketing exclusivity provision.[25] While the added biologic marketing exclusivities would have greatly benefited biologics innovators, all member nations have at least five years of biologic marketing exclusivity, except for Brunei Darussalam, which provides no marketing exclusivity for biologics.

## Conclusion

The U.S. and other TPP member nations took seven years to negotiate the final TPP trade agreement. Despite this extended effort, the U.S. quickly withdrew after the TPP became ensnared in the political theater of the last election cycle. The final agreement had several U.S.-centric and noncontroversial intellectual property provisions that — but for the link to several non-IP related multilateral trade initiatives — would have harmonized and strengthened patent and regulatory exclusivities to the benefit of all patent applicants, including innovator pharmaceutical and biotechnology companies. For example, many member nations do not have any form of patent term adjustment for unreasonable delays based on that member nation's patent office, yet the TPP would have required day-for-day term compensation for patent applicants resulting from patent examination delays. This provision would have benefited all patent applicants, especially in member nations where examination lasts into the second half of the 20-year utility patent term.

As expected, the TPP has now moved forward without the United States as a member nation but with several important patent-related provisions suspended. Although the CPTPP has been ratified, it will not enter force until "60 days after the date on which at least six or at least 50 per cent of the number of signatories to this Agreement ... have notified the Depository in writing of the completion of their applicable legal procedures." [26] Thus, the provisions in the CPTPP likely will take effect within the next several years, and patent applicants should begin strategizing to maximize the CPTPP benefits, particularly those in the agriculture chemical field. And despite the U.S. withdrawal from the TPP, CPTPP member nations appear open to welcoming the United States and other countries that are interested to join. In fact, the chief negotiator for Japan stated that if the United States were to rejoin, the suspended intellectual property provisions could be reinstated.[27] Thus, it is worth monitoring how President Trump and future United States leaders view the CPTPP going forward, as it is possible the suspended provisions could be reinstated and effect a move toward increased global intellectual property harmonization.

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[1] Trump Executive Order Pulls Out of TPP Trade Deal, British Broadcasting Corporation News (Jan. 24, 2017), <http://www.bbc.com/news/world-us-canada-38721056>.

[2] Ernesto Londoño and Motoko Rich, U.S. Allies Sign Sweeping Trade Deal in Challenge to Trump, The New York Times (Mar. 8, 2018), <https://www.nytimes.com/2018/03/08/world/asia/us-trump-tpp-signed.html>.

[3] Id.

[4] Trans-Pacific Partnership, Article 18.38, <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[5] Jeremiah B. Frueauf and Matthew A. Smith, Public Disclosure Grace Periods and the Trans-Pacific Partnership: Member States Seek Harmonization With the America Invents Act, *Bloomberg BNA: Patent, Trademark & Copyright Journal*, Feb. 2016.

[6] Id.

[7] Id.

[8] 35 U.S.C. § 102(b)(1) (2012).

[9] Trans-Pacific Partnership, Article 18.47, <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[10] Id. at Article 18.37(2).

[11] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex Article 7(b)(i), <https://www.mfat.govt.nz/assets/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf> (last visited April 4, 2018).

[12] Trans-Pacific Partnership, Article 18.46, <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[13] Id. at Article 18.46(4).

[14] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex Article 7(c), <https://www.mfat.govt.nz/assets/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf> (last visited April 4, 2018).

[15] Trans-Pacific Partnership, Article 18.46(2), <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[16] 21 U.S.C. § 355 (2012); 35 U.S.C. §§ 156, 271, 282 (2012).

[17] Trans-Pacific Partnership, Article 18.48, <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[18] Id. at Article 18.48(4).

[19] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex Article 7(d), <https://www.mfat.govt.nz/assets/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf> (last visited April 4, 2018).

[20] Trans-Pacific Partnership, Article 18.50(1), <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[21] Id. at Article 18.50(2)(a).

[22] Id. at Article 18.50(2)(b).

[23] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex Article 7(e), <https://www.mfat.govt.nz/assets/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf> (last visited April 4, 2018).

[24] Trans-Pacific Partnership, Article 18.51, <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf> (last visited April 4, 2018).

[25] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Annex Article 7(f), <https://www.mfat.govt.nz/assets/CPTPP/Comprehensive-and-Progressive-Agreement-for-Trans-Pacific-Partnership-CPTPP-English.pdf> (last visited April 4, 2018).

[26] Id. at Article 3(1).

[27] Ernesto Londoño and Motoko Rich, U.S. Allies Sign Sweeping Trade Deal in Challenge to Trump, The New York Times (Mar. 8, 2018), <https://www.nytimes.com/2018/03/08/world/asia/us-trump-tpp-signed.html>.