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Obama Administration Releases Much Anticipated Text of the Trans-Pacific Partnership Agreement

Jeremiah B. Frueauf & John M. Covert

This client alert examines intellectual property proposals in the Trans-Pacific Partnership from the perspective of biotechnology, pharmaceutical, and chemical industries.

On November 5, 2015, the U.S. trade representative's office published the final text of the Trans-Pacific Partnership agreement (TPP), including Chapter 18 containing the negotiated Intellectual Property provisions. Each party must still ratify the agreement, but in doing so, it has to abide by the framework described in the agreement save for several country-specific exceptions outlined in Article 18.83.4 and Annexes 18-A to 18-D. Below is list of important take-aways from the TPP, followed by a summary of its provisions as they apply to the patent rights of each party to the agreement.

TPP Quick Takeaways:

- Possible conflict of U.S. case law with patentable subject matter provisions
- One year grace period for Applicant's own disclosures available
- Patent term adjustment available for prosecution delay
- Patent term extension available for regulatory delay
- At least 5 years exclusivity for new pharmaceutical chemical entities
- At least 8 years exclusivity for biologics or at least 5 years but with market outcome comparable to 8 years
- At least 10 years exclusivity for new agricultural chemical entities

General – The TPP aims to provide each party "no less favourable" treatment for intellectual property rights protection than it accords its own nationals. Art. 18.8.1. However, there are exceptions allowed for judicial and administrative procedures (e.g., requiring use of a designated local address for service of process) and for procedures provided in multilateral agreements for acquisition or maintenance of intellectual property rights, where those agreements were "concluded under the auspices of WIPO." Art. 18.8.2 and 18.8.4. In addition, the obligations provided by Chapter 18 extend generally to all subject matter existing at the date of entry into force. Art. 18.10.1.

Patentable Subject Matter – The TPP reflects a general consensus that patents should be available in all fields of technology for any invention (a product, a method of use, or a process of using a known product) that is "new, involves an inventive step[, which is defined as synonymous with non-obvious] and is capable of industrial application[, which is defined as synonymous with useful]. Art. 18.37.1-2. The TPP permits exclusions, including when necessary to protect human, animal, or plant life or health, as well as general exclusions of "diagnostic, therapeutic and surgical methods" of treatment, animals and plants other than microorganisms, and "essentially biological processes for the production of plants or animals." Art. 18.37.3-4. Notably, the provisions on patentable subject matter do not specify that a party may exclude

naturally-occurring microorganisms, or naturally-occurring molecules, from patentability. While this may be in tension with the U.S. Supreme Court's decisions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (2012) and *Ass'n for Molecular Pathology v. Myriad Genetics* (2013), the general exclusion to protect human life or health may admit these decisions.

Applicant Grace Period for Prior Art – The TPP provides that public disclosures 1) "made by the patent applicant or by a person that obtained the information directly or indirectly from the patent applicant," and 2) that occurred within 12 months before the date of application filing in the party's territory, may not be used as prior art to determine novelty or non-obviousness. Art. 18.38. This provision aligns with the America Invents Act exception under 35 U.S.C. § 102(b)(1).

Patent Term Adjustment – The TPP provides that the parties shall provide means to adjust patent term for "unreasonable delay in a Party's issuance of patents." Art. 18.46.3. An unreasonable delay is defined as including "a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later." Art. 18.46.4. Exclusions from the adjustment include administrative processing that does not occur during examination, such as upon receipt of an application or at the time of grant, delay outside the direction or control of the granting authority, and delay attributable to the applicant. Art 18.46.4 and n.37-38. By footnote, Article 18.46 provides that its provisions on patent term adjustment are effective for applications filed after the date of entry into force of the TPP for the party or two years after the party signs the agreement, whichever is later. Art 18.46.4, n.39. While largely consistent with the USPTO rules for patent term adjustment, the provision appears to allow for an exclusion of positive adjustment for administrative processing at the time of grant. This may conflict with 37 C.F.R. § 1.703(b)(1), which allows for positive adjustment accruing beyond the three year examination period, where applicant files a Request for Continued Examination and subsequently receives a notice of allowance, to adjust for the delay between the notice of allowance and patent issuance.

Patent Term Extension – The TPP requires each party's "best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner," and provides a patent term adjustment to a patentee for "unreasonable curtailment of the effective patent term as a result of the marketing approval process." Art. 18.48.1 and 18.48.2. The negotiated language fails to define what that period of adjustment (or "extension" as referred to under 35 U.S.C. § 156) will be, by how many days it will extend, and what limits will be acceptable under the TPP. By footnote, Article 18.48 provides that its provisions on patent term adjustment will apply to all applications for marketing approval filed after the date of entry into force of the TPP for the party. Art 18.48.2, n.47.

Agricultural Chemical Products Marketing Exclusivity – The TPP provides at least ten years of marketing exclusivity from the date of marketing approval of a new agricultural chemical product where, as a condition for granting marketing approval for a new agricultural chemical product, the party requires submission of undisclosed test or other safety and/or efficacy data of the product in the party's territory or evidence of prior marketing approval of the product in another territory. Art. 18.47.1 and 18.47.2. By footnote, each party can limit the period of marketing exclusivity to ten years and no more. Art. 18.47.1, n.43.

Pharmaceutical Product Marketing Exclusivity – Consistent with the Hatch-Waxman regime, the TPP provides at least five years of marketing exclusivity from the date of marketing approval of a new pharmaceutical product where, as a condition for granting marketing approval for a new pharmaceutical product, the party requires submission of undisclosed test or other safety and/or efficacy data of the product in the party's territory or evidence of prior marketing approval of the product in another territory. Art. 18.50.1. By footnote, each party can limit the period of marketing exclusivity to five years and no more. Art. 18.50.1, n.53.

Article 18.50 also provides for marketing exclusivity of 1) at least three years for new clinical information required for marketing approval for new indications, formulations, or methods of administration of an approved pharmaceutical product, or alternatively, 2) at least five years for new chemical entities not previously approved in the party's territory. Art. 18.50.2. However, if a party provides at least eight years of protection under Art. 18.50.1, then that party is not required to apply these additional exclusivity periods. Art. 18.50.2, n.55.

The TPP provides each party with the right to "take measures to protect public health" consistent with the Declaration on TRIPS and Public Health, any waiver of any provision of the TRIPS Agreement granted by WTO Members, or any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health. Art. 18.50.3. In addition, the TPP outlines a Hatch-Waxman-like framework for follow-on pharmaceutical products that rely on the safety and efficacy data of an approved product. This includes providing notice to the patent holder or marketing approval holder and judicial or administrative proceedings to resolve validity or infringement of applicable patent rights "claiming an approved pharmaceutical product or its approved method of use." Art. 18.51. In lieu of the latter, the TPP authorizes a party to adopt or maintain a system other than judicial proceedings that preclude issuance of marketing approval absent consent or acquiescence of the patent holder. Art. 18.52.

Biologics Marketing Exclusivity – The TPP largely applies the Pharmaceutical Product Marketing Exclusivity provisions under Article 18.50 for protecting new biologics, which permits fewer years of exclusivity than the 12 years of data exclusivity provided under the Biologic Price Competition and Innovation Act. Thus, a holder of the first marketing approval in a party's territory for a new pharmaceutical product that is or contains a biologic can get at least eight years of marketing exclusivity from the date of first marketing approval through implementation of Article 18.50.1 (protecting undisclosed test or other safety and/or efficacy data) and Article 18.50.3. Art. 18.52.1(a). However, as an alternative, the party may provide for a lesser protection of at least five years, through implementation of Article 18.50.1 (protecting undisclosed test or other safety and/or efficacy data) and Article 18.50.3, "through other measures, and recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market." Art. 18.52.1(b). The TPP does not explain what other measures or market circumstances are relevant to delivering "a comparable outcome in the market."

The TPP requires that each party define a biologic, at a minimum as "a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition." Art. 18.52.2. And because regulation of biologics is largely in a formative stage in the territories of many parties, the TPP provides for the parties to consult either after 10 years from the date of entry into force or as otherwise decided by the Commission to review the biosimilars provisions under Article 18.52.

By footnote, the TPP permits each party to limit biosimilar marketing approval requests within the first five years following the date of entry into force in the territory of the party, to those products in the same class of products approved under the same procedures as in Article 18.50.1 (protecting undisclosed test or other safety and/or efficacy data), before the date of entry into force for that party. Article 18.52.1(a), n.61.

Marketing Exclusivity Does Not Diminish Patent Term – For agricultural chemical products, pharmaceutical products, and biologics, the TPP requires that a party providing marketing exclusivity under its marketing exclusivity provisions (Art. 18.47, 18.50, and 18.52) shall not alter the marketing exclusivity period where patent protection on the product terminates earlier than the marketing exclusivity period. Art. 18.54.

For more information, please contact:

Jeremiah B. Frueauf, Director
JFrueauf@skgf.com

John M. Covert, Director
JCovert@skgf.com