Much has been made in the news about the recently finalized Trans-Pacific Partnership (TPP) trade agreement. The TPP is an agreement signed by trade representatives from twelve Pacific Rim countries: United States, Canada, Mexico, Australia, Singapore, Malaysia, Japan, Chile, Peru, Vietnam, New Zealand, and Brunei. China and Korea are not parties to the agreement at this time. The TPP has the potential to impact many aspects of commerce, not the least of which is intellectual property. While the majority of the discussion in the patent world has been focused on the TPP’s provisions relating to data exclusivity and biologics, this was covered discussed in an article by Kristen Connarn that appeared in the December 2015 Biotech Buzz.

This article will take a look generally at the TPP’s general patent provisions in Chapter 18. First, Article 18.37 governs patent eligible subject matter, and indicates that patents shall be available “in all fields of technology.” However, exclusions are permitted in paragraphs 3 and 4:

1. Subject to paragraphs 3 and 4, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, 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. A Party may limit those new processes to those that do not claim the use of the product as such.
3. A Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law. A Party may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   (b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.

Note that although parties may “exclude from patentability plants other than microorganisms,” on its face, the TPP states that patents must be available at least for inventions that are “derived from plants.” Fortunately, the TPP does not explicitly incorporate the line of reasoning of the Supreme Court’s recent §101 jurisprudence. However, the broad language of paragraph 3 regarding “*ordre public* or morality” seems to leave patent eligibility open to different interpretations from Party to Party.

Next, Article 18.38 essentially passes on the AIA’s grace period to other Parties:

Each Party shall disregard at least information contained in public disclosures used to determine if an invention is novel or has an inventive step, if the public disclosure

   (a) was made by the patent applicant or by a person that obtained the information directly or indirectly from the patent applicant; and

   (b) occurred within 12 months prior to the date of the filing of the application in the territory of the Party.

Although this grace period may be compatible with similar grace periods in countries such as Canada and Australia, amendment of patent laws may be necessary in some countries with stricter novelty requirements.

In Article 18.46, the TPP provides for a patent term adjustment system similar to that in the U.S.P.T.O., and requires compensation for unreasonable delays. An
unreasonable delay is regarded as more than five years from filing in the territory or more than three years after a request for examination. Time periods not attributable to the local patent office or attributable to the applicant are excluded from the delay period. Article 18.46 also permits, but does not require, expedited examination procedures.

Similarly, Article 18.48 provides for patent term adjustment as compensation for unreasonable curtailment of patent term due to the marketing approval process for pharmaceutical products. This is similar to §156 patent term extension for FDA delays in the U.S. However, no specifics are provided as to what time period is considered unreasonable.

Of course, this is just the tip of the iceberg. As noted above, the biologics and data exclusivity aspects of the TPP will be discussed in a separate article. The full text of the intellectual property chapter of the TPP can be found here:


However, all of this may be irrelevant, at least in the short term. The TPP becomes effective only after it is (a) ratified by all member countries, or (b) ratified by at least six countries representing 85% of the GDP of the signatories, within 2 years of signature of the agreement (which has not yet occurred). Being that the U.S. represents about 60% of the GDP of the signatories, ratification will not happen without the U.S. Since 2016 is an election year in the U.S. and the TPP is politically controversial, it is quite unlikely that the TPP will be ratified in the near term.

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