What are the Issues?

With the meeting of Trans Pacific Partnership negotiators in Hanoi this week, I thought it might be appropriate to discuss what is known about the IP issues in the TPP.

The truth is that we don't know a lot about the IP negotiations in the TPP because the participants simply are not talking. Most of our information has come from a leak of the US IP proposals in 2011 and a leak of the draft negotiating text from Wikileaks in November 2013. This blog is a summary, with some updates, of the Wikileaks documents.

General Patent Issues: The issues here involve disagreements over the patentability of plants, animals, medical methods and biological processes. In addition, there are disagreements over what constitutes adequate disclosure in a patent application.

Issues Involving Pharmaceuticals, Biologic Products and Agricultural Chemicals: The issues here are much more involved but come down to three issues: patent term adjustment for regulatory delay, protection of proprietary information, and genetics.

Regulatory Delay: With the major patent regimes following a first to file or first inventor to file protocol, owners of biological IP are really forced to file for patent protection as soon as possible. The problem with this is that regulatory approvals take time. In the US, it can take a company 10 years to get a phase III approval and up to an additional 12 months after that for final FDA approve a drug for prescription use. Other countries can take longer. From the perspective of the patent owner, this means that half of the 20 year life of a patent can be lost due to the regulatory processes. Under US law, the USPTO can extend the term of a patent to compensate the patent holder for this lost time. While the US (and I believe Japan) have been pushing for this in the TPP, there has been resistance.

Protection of Proprietary Information: These are the issues regarding how regulatory agencies protect and use the proprietary information of companies seeking regulatory approvals. While the US is good at protecting a company's proprietary information, other countries follow different practices. These practices include publishing the results of company's clinical trials and later using this published information to expedite regulatory approvals for competitive products. There even appear to be examples of agencies accepting this published data in lieu of the competitive products performing their own testing.

Genetics: The questions here are about the use and application of IP protections to genetic information. While I am the first to agree that there are many ethical issues regarding IP protection and genetics, my guess is that these are not the issues slowing down the TPP.

Recent reporting is suggesting that the Pharmaceuticals, Biologic Products and Agricultural Chemicals issues will be resolved by allowing the LDCs to meet a lower standard of IP protection for some period of time as they transition to the higher standard. Of course, this simply moves the fight from what the standard should be to how long it will take to harmonize the two standards.

Copyrights: The copyright issues include the term of the copyright, whether performances can be copyrighted, and the legal tools and enforcement to prevent circumvention of anti-copying technology.

Trademarks: I suspect the big issue here is trademark exhaustion (also referred to as parallel imports). The idea of exhaustion in IP is that IP protection often ends after the first point of sale. The reason this can be a problem is best explained by example. Say I buy 1000 pieces of a high end trademarked watch in country A. If I bought those watches legally, then the seller's trademark rights are exhausted at that point. If I were then to import those watches into country B, I could sell those trademarked watches however I wanted even if it were against the seller's wishes and desires. While the seller can prevent importation of counterfeit goods under their trademark protection, it is much harder to prevent importation of non-counterfeit goods. Well written contracts can deal with some of these issues but, in general, exhaustion creates a lot of problems in IP protection and the problem is compounded because the laws and enforcement regarding exhaustion are not consistent across countries.

Enforcement: There are a lot of disagreements regarding the appropriate civil and criminal penalties for counterfeiting, improperly decoding encrypted information, and circumvention of anti-copying technology.

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