TPP Revisited

Recently, new reports have come out listing some of the unresolved IP issues remaining in the Trans Pacific Partnership negotiations. The issues leaked all have to do with the regulation of pharmaceuticals. My belief is that this reflects the desires of the leaker and does not comprehensively represent the outstanding issues.

Below is a brief summary of the issues that have been reported:

Patent Linkage and Patent Extensions: The problem here is relatively simple: regulatory approval for medical devices takes time that cuts into the effective marketing life of a newly patented invention. 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 is 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 Japan have been pushing for this in the TPP, there has been resistance.

Patents for New Uses: I am assuming this is a medical issue also. In many patent regimes, including the US, you can only patent a chemical compound once. Specifically, a previously known, or previously patented, chemical compound does not become patentable because of a newly discovered property. My understanding is that this is fairly common across patent regimes, however, even in the US law there is a fair amount of grey area. For example, assume that a medication has always been taken orally. If an application was filed that made this medication injectable, the patent office would reject the application as unpatentable. However, if the applicant could demonstrate an unknown and *unexpected* benefit from injecting the medicine into a patient, then a patent that was strictly for the method of injecting the medication might be approved. This type of issue is very situation specific and how the USPTO would proceed would depend heavily on the specific facts of the application.

Data Exclusivity: These are issues regarding how regulatory agencies protect and use the proprietary information of companies seeking regulatory approvals.

Standard for IP Protection: It has been reported that TPP negotiators have been working on allowing certain countries to maintain a lower standard for IP protections with a transition period that will allow those countries to migrate to a higher standard of IP protections. It has been known for some time that negotiating the details of this transition has been challenging.

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