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The Trans-Pacific Partnership Patent Provisions' Impact on the U.S. Pharmaceutical Industry

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On Oct. 5, 2015, Ministers of the 12 Trans-Pacific Partnership (TPP) countries—Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the U.S. and Vietnam—reached a trade deal that will regulate 40 percent of the world economy. What does it mean for American pharmaceutical companies? The TPP will make it easier for American pharmaceutical and biologic companies to sell pharmaceutical and biologic products abroad by eliminating taxes and other trade barriers on American products across the 11 other countries in the TPP.

Patent laws in the U.S. and elsewhere grant patents and other legal protections to the first company to invent a new drug. The framers of the U.S. Constitution recognized the importance of rewarding inventors to encourage research and development. Article 1, Section 8, Clause 8 of the U.S. Constitution recites:

> The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

After these legal protections expire, which in the U.S. and most other countries is 20 years from the date of filing the invention with the Patent Office, other companies can make less expensive generic versions of the drugs.

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TPP Provisions

The TPP provides for patent protection and recites that 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 application. The TPP has the following exclusions: commercial exploitation necessary to protect human, animal or plant life; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than the nonbiological and microbiological processes; and plants other than microorganisms.

The TPP includes a provision for a 12-month grace period whereby the inventors' own publication of data or information will not negatively impact the patentability of the invention.

The TPP provides for a patent revocation proceeding on grounds that would have justified refusal to grant the patent, such as prior art, fraud, misrepresentation or inequitable conduct.

The TPP has provisions for delaying the introduction of generic drugs into the market, by expanding the types of inventions that are eligible for patent protection to include modifications of existing drugs. Pharmaceutical companies believe that this is necessary to provide improvements in drugs for treating diseases. Critics say this would make it easier for drug companies to engage in "evergreening," a process by which pharmaceutical companies make minor modifications to their

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products in order to extend the effective length of patent protection.

The TPP requires governments to extend the term of patent protection if the Patent Office processes a patent application too slowly, or if regulators delay approval of a pharmaceutical patent. In the U.S., the right to patent term extension based on regulatory review is part of the Hatch-Waxman Act. The principle behind the patent term extension is two-fold. The first is because the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second part occurred after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive Food and Drug Administration approval before patent expiration. Under the Hatch-Waxman Act, the branded pharmaceutical company can receive up to five years of additional patent term based upon the time spent in obtaining FDA approval for the drug to which the patent is directed. In exchange for extension of the term of the patent, Congress provided that it shall not be an act of infringement, for example, for the generic pharmaceutical company to make and test a patented drug solely for the purpose of developing and submitting information for an abbreviated new drug application (ANDA).

The TPP also contains provisions for complex drugs called biologics, which is any substance derived from animal products or other biological sources used to treat or prevent disease. The TPP set the regulatory exclusivity period for novel biologics to at least five and up to eight years.

Regulatory Exclusivity

In the U.S., the regulatory exclusivity period for novel biologics was set at 12 years in the Biologics Price Competition and Innovation Act of 2009 (BPCIA), a relatively small but significant part of the much greater Patient Protection and Affordable Care Act (ACA). The BPCIA was enacted into law on March 23, 2010. The 12-year regulatory exclusivity period was selected after careful consideration of the time and expenses involved in researching, formulating and gaining regulatory approval for a novel biologic compound.

For example, the time required to develop a novel biologic compound is estimated at between 10 to 15 years.[1] With the U.S. having joined the rest of the world in the adoption of a ''first-inventor-to-file'' patent regime in 2013, as part of the America Invents Act (AIA), a premium has been placed on applicants to ''rush'' to the U.S. Patent and Trademark Office (PTO) to secure a filing date for patent applications. Furthermore, under the current patent regime (June 1996-present), patent terms consist of a term of 20 years from the earliest (non-provisional) filing in the patent family. This combination puts significant new pressures on applicants. Previously, an applicant could conceive of the invention, begin reducing it to practice and then proceed to wait for a reasonable time period before filing with the PTO in order to ensure both an adequately broad and enabling disclosure as well as to maximize patent term. If an applicant was faced with a rejection over prior art, the applicant was able to ''swear behind'' certain references with prior inventions. Not so any longer.

With such a long time required to develop novel biologic compounds, and with a premium being placed on being the absolute ''first to file,'' pharmaceutical and biotechnology developers find themselves in a position where they are by necessity filing patent applications on relatively nascent technology—often within the first few years of the typical 10-to-15-year development period—and then refining it through subsequent applications, drawing priority to previous filed applications, all while watching the proverbial sand fall through the 20-year hourglass. This places a significant premium on the 12-year regulatory exclusivity period granted by the FDA, as the issued patents, all too often, have only a few precious years of term left for the name-brand entity to recoup their significant investment, which is up to a cost of about $1.2 billion per new biologic.[2]

Indeed, many experts have already cast their opinion that, for biologics, the regulatory exclusivity period will prove to be more valuable and critical to the success of this rapidly growing and emergent field than will patent protection, as patent protection is subject to collateral attack by generic (and other) competitors, and is limited to the claim scope of the patents, which are carefully narrowed during patent prosecution to secure patentability. Regulatory exclusivity is much broader and represents the government's recognition of the investment and contribution the developer has made to society in bringing a safe and effective novel biologic to market approval.

Before these drugs can be introduced to the market, the FDA requires companies to prove they are safe and effective. Often, data from one drug's clinical trials are useful to other companies wanting to introduce competing, biologically similar drugs. U.S. law requires competing drug manufacturers to wait 12 years before they can use these data in their own applications. Critics have argued that this exclusivity period makes it harder for generic pharmaceutical companies to get into the market, raising prices. The TPP provides for a period of exclusivity from at least five and up to eight years.

Implications

The TPP can be expected to reduce competition and therefore raise the prices of drugs in some TPP countries. The deal probably won't have much effect in the U.S., where biologics already receive 12 years of protection and the law is relatively friendly to evergreen patents, but it will have a bigger impact in other TPP countries. Concerns have been raised that the 12 years of protection for biologics will be reduced to eight years.

Clearly, the TPP provides protection for technological innovation. In order to compete internationally, the U.S. must maintain a strong patent and regulatory system that attracts talent and the investments that follow. Nowhere is this exclusivity more important to recovering significant research and development costs than in the pharmaceutical/biotechnology landscape.

[1] http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

[2] PhRMA Ref. (see above).

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