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TPP Proposes Intriguing Changes in US IP Law

The 12-nation trade treaty would impose some U.S.-style protections in foreign markets while reducing the U.S.'s biologic product exclusivity period

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LAW WEEK COLORADO

After years of clandestine negotiations and a contentious preliminary battle in Congress, the Trans-Pacific Partnership treaty's text has officially been revealed. In setting baseline industry standards among 12 participating nations, the TPP's proposed regulatory changes span numerous legal areas from labor to the environment.

The treaty's chapters regarding intellectual property law have received particular scrutiny. In short, the TPP will extend many U.S. standards of IP protection to the other member nations, but not without some significant adjustments to the U.S.'s domestic policy.

The TPP agreement's primary purpose is to reduce or eliminate trade barriers such as tariffs among its participating nations: the United States, Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam. Each of the nations must approve the TPP agreement before it becomes effective.

Earlier this year, Congress approved the Trade Promotion Authority measure that would "fast-track" passage of the trade agreement, but not without resistance from Democrats over the treaty's secrecy and potential implications for domestic labor laws.

Once the TPP legislation reaches Congress next year, it will be subject to an up-or-down vote, and lawmakers will be unable to negotiate amendments to the agreement.

The draft text of the TPP was released Nov. 5 on the government of New Zealand's website, and numerous interest groups in the member nations have been combing through its 30 chapters of proposed regulations.

While it's difficult to predict with certainty what practical changes pending legislation will bring about — there's a chance Congress won't ratify the TPP — IP practitioners can look at the proposed regulatory changes and speculate on their legal implications.

MEMBER COUNTRIES ADOPTING U.S. IP STANDARDS

"There is a lot of language in the draft treaty that I would say brings a lot of the countries that would be signatories ... up to the U.S. level of protection," said **Gene Bernard, intellectual property attorney and managing partner of Kilpatrick Townsend & Stockton's Denver office**.

Bernard said that the provisions on trade secrets would be especially impactful, as many of the other countries lack a robust framework for those protections. The treaty would require each nation to "provide for criminal procedures and penalties" for unauthorized and willful access to, misappropriation of and fraudulent disclosure of a trade secret in a computer system. There's been no criminal element to prosecuting trade secret misappropriation in some of these countries, whereas the U.S. has had this for some time.

This could prove a boon to the U.S. computer and software industry in markets overseas, as their properties rely heavily upon trade secret protection as opposed to patents. The TPP treaty encourages other countries to develop a regulatory system for trade secret protection and enforcement, though it doesn't go into specifics, according to Bernard.

"There's not a lot in it that mandates that they (member countries) do certain things in order to get there," he said. It will be interesting to see what the other member countries ultimately do to comply with the TPP's trade secret protection provisions, Bernard said, adding that some might try to maintain their status quo if given the room to do so.

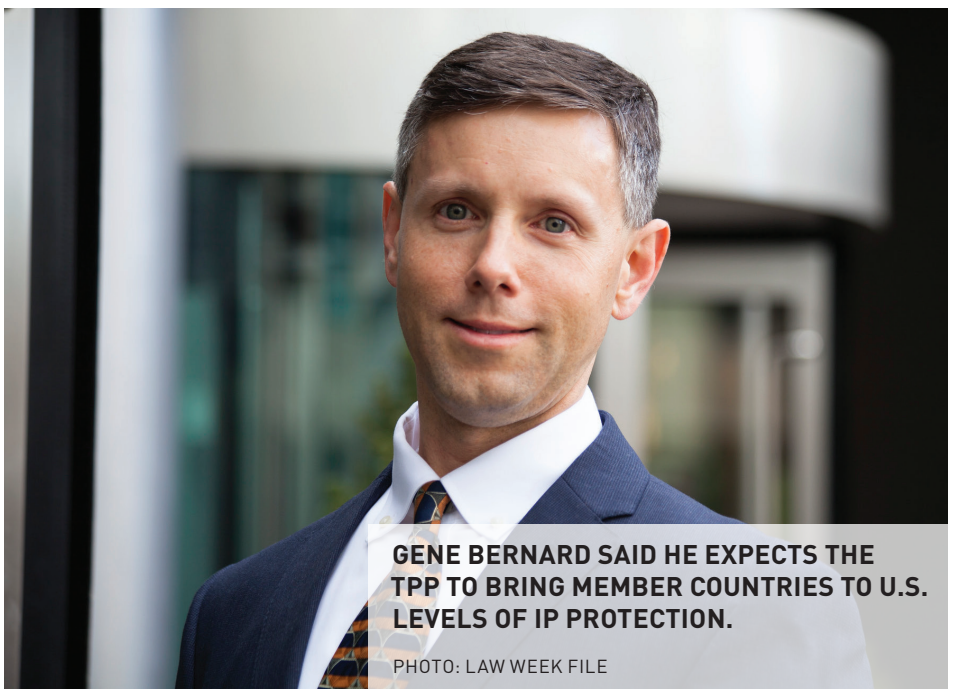
Also notably, the treaty proposes that participating countries adopt the U.S.'s copyright term of protection of 70 years after the author's death — a point of consternation with nations such as Canada, which currently follows a 50-year posthumous term on copyright protection.

The treaty also calls for patent term adjustment, which allows for a life extension on patents that experienced an unreasonable delay in the patent application process. The treaty defines these as either a five-year-plus issuance delay after the patent filing date or a three-year delay after an examination request for the application is made, whichever is later.

Most of the TPP nations lack patent term adjustment currently, and Bernard considers this item "a win" for patent holders.

REDUCED EXCLUSIVITY PERIOD ON BIOLOGICAL DRUGS

Biological drugs are pharmaceutical products derived from living organisms, and they can include vaccines and antibodies.



GENE BERNARD SAID HE EXPECTS THE TPP TO BRING MEMBER COUNTRIES TO U.S. LEVELS OF IP PROTECTION.

PHOTO: LAW WEEK FILE

Currently, the U.S. pharmaceutical industry enjoys a 12-year market exclusivity term on biologics under the Patient Protection and Affordable Care Act's Price Competition and Innovation Act. Pharmaceutical patent holders generally support longer exclusivity periods so they are more likely to recoup their products' research and development costs.

But under the TPP treaty, member countries could limit that term to eight years or a five-year exclusivity term plus a three-year "regulatory period." Australia currently employs this 5+3 model, which its government used as a compromise instead of eight years of exclusivity. What protection the regulatory period offers is very vague, Bernard said.

A four-year reduction in biologic exclusivity would likely have a huge impact on U.S. pharmaceutical companies' profits. Bernard noted that while some U.S. legislators have been vocal in their opposition to this reduction, the pharmaceutical industry itself hasn't, and they might have known this was coming and even had some buy-in.

While pharmaceutical companies give up some protection domestically, the new protections imposed on other countries might strengthen their markets abroad as a tradeoff.

A QUESTION OF PATENTABLE SUBJECT MATTER

The TPP agreement could expand subject matter eligibility on patents in the U.S. based on its broad language. The agreement makes patentable "any invention, whether a product or process … provided that the invention is new, involves an inventive step and is capable of industrial application." Optional exclusions include medical treatment methods and biological processes for the production of plants and animals.

"Under the treaty, it looks like naturally occurring DNA is patent subject matter eligible again," Bernard said. In 2012, the U.S. Supreme Court decision in Mayo Collaborative Servs. v. Prometheus Labs Inc. declared large swaths of naturally occurring DNA not to be patent eligible, and subsequent rulings have followed suit. "If the U.S. becomes a signator to this treaty, what happens to those supreme court decisions?" Bernard asked.

There's potential for a unique case of Congress stepping in and dictating what is patent eligible just by way of ratifying the TPP agreement, perhaps overturning landmark patent decisions by statute — one with 29 other chapters of sweeping multi-industry provisions. •

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