

INSIGHT: Biologics Success Could Mean More Work for International Trade Commission

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Biologics—large-molecule, protein based drugs that are made in living organisms—have revolutionized medicine. The success of biologics in the clinic has been met with a growing volume of patent litigation in district courts and the Patent Office.

To date, very few biologics cases have been filed in the U.S. International Trade Commission (ITC), an independent government agency that has the power to bar the importation of products that infringe intellectual property rights. But as broader IP protections, such as trade secrets, become increasingly important in litigation involving this class of drugs, there are signs this may all change.

Biologics are among the top-selling drugs in the U.S. With the enactment of the Biologics Price Competition and Innovation Act in 2010 and further encouragement from the Food and Drug Administration (FDA), competitors today increasingly seek to enter the market with new innovator products and “generic” products called biosimilars.

Biologic drug development, however, presents unique challenges. Unlike small-molecule drugs, which are relatively easy to identify and make, biologics are typically complex substances with structural features that are very sensitive to manufacturing conditions. Minor process variations can lead to subtle changes that are not only difficult to detect, they can also raise significant safety and efficacy concerns.

Complexities such as these have led to what former FDA Commissioner Scott Gottlieb recently called an “inverted” regulatory paradigm that places much more focus on the manufacturing, chemistry, and control (CMC) portions of a new application.

This heightened emphasis on CMC also makes follow-on work more difficult. Potential competitors are not privy to the extensive knowledge (for example, to ensure drug substance identity, potency, and purity) that the manufacturer has obtained through years of experience developing and marketing the product.

Trade Secrets Vitaly Important

As more and more of this information is kept confidential, trade secrets have become vitally important in this field. A recent high profile case illustrates not only the growing significance of trade secrets in biologic litigation, but also the risks posed by the global nature of the biotech industry, and increasingly mobile workforce, particularly with smaller companies.

In October 2018, a federal grand jury indicted two former Genentech employees for allegedly stealing trade secrets relating to the development and manufacture of several biologics, including, Rituxan and Herceptin, from the South San Francisco company to help a Taiwanese firm, JHL Biotech. The secrets identified in the criminal indictment include manufacturing information, drug product specifications, in-process quality controls, and test procedures.

Earlier this year, a federal judge issued a preliminary injunction in a related civil case brought under California trade secret law and the Defend Trade Secrets Act enjoining JHL from marketing any biologic developed “in whole or in part” with the benefit of Genentech’s information.

One question raised by the rapid emergence of biotech firms outside the U.S. is the international reach of trade secret protections and whether meaningful remedies can be obtained for misappropriation that has occurred abroad. The answer may lie in part with the ITC, a forum that has so far not been widely utilized in cases involving biologics.

Section 337 of the Tariff Act of 1930 was originally enacted to protect U.S. domestic industries from unfair competition in the importation into the U.S. of goods made by companies located abroad. Over the years, Section 337 has evolved into one of the primary means for companies to protect U.S. IP rights in cases involving infringing imports.

One feature of the ITC is that its reach has been interpreted to extend to conduct occurring outside the U.S. In *TianRui Group Co. v. ITC*, 661 F.3d 1322 (Fed. Cir. 2011), the Federal Circuit held that the ITC has authority over a business’s overseas conduct that violates U.S. trade secret laws.

The case involved an American company, Amsted, and a Chinese company, TianRui, that competed in the U.S. market for cast steel railway wheels. Amsted licensed manufacturing trade secrets to several Chinese foundaries, whose employees disclosed the trade secrets to TianRui.

In the ITC, TianRui moved to terminate the proceedings on the ground that the alleged misappropriation “occurred in China and that Congress did not intend 337 proceedings to be applied extraterritorially.” The Federal Circuit disagreed finding that a trade secret theft cannot be “immune from scrutiny if the act of misappropriation occurred overseas.”

ITC Rises in Trade Secret Popularity

The ITC is primarily known for investigating patent infringement, but it has also become a popular forum for investigating trade secrets. Additionally, the ITC has seen a steady increase in the number of pharmaceutical and medical device cases. In 2010, only two cases involving medical devices or pharmaceuticals were filed with the ITC. In both 2011 and 2012, five were filed each year. In 2018, the number of these kinds of cases rose to 15. As more companies around the world seek to market biologic drugs, this trend may continue.

A recent dispute involving another biologic provides clues on why more litigants may choose the ITC. In *In re Certain Botulinum Toxin Products*, Inv. No. 337-TA-1145, a case filed in late-January 2019, a Korean company named Medytox alleges that trade secrets used to manufacture the biologic drug Botox were stolen by a former employee. This information was allegedly provided to another Korean drug company, and used to prepare an application submitted with the FDA.

The proceeding remains in its early stages, but the complainants are presumably relying on the *TianRui* decision to remedy extraterritorial acts of misappropriation.

The Botox case highlights another unique feature of the ITC's jurisdiction. In related state court actions brought in California and Indiana, numerous motions to dismiss were filed by the defendants based on lack of personal jurisdiction and forum inconvenience. Personal jurisdiction over JHL was also contested in the Genentech civil suit. Because the ITC exercises jurisdiction over the accused imported products, challenges like these are difficult to raise.

The ITC is no stranger to biologics. *E.g.*, *In re Recombinant Factor VII Products*, Inv. No. 337-TA-956; *In re Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568. As the market for biologics expands and trade secret protections become more important, it will be interesting to see if more litigants choose the ITC to resolve disputes involving these important drugs.

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