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Amgen Ruling Will Increase Section 337 Investigations

Portfolio Media, New York (March 27, 2008)--The Federal Circuit's March 19, 2008, decision in **Amgen** Inc. v. International Trade Commission, No: 2007-1014 (Fed. Cir. 2008), significantly expanded both the ITC's jurisdiction to conduct investigations and the defenses available to some accused infringers.

This decision, by a split panel, will have important effects on the frequency and scope of Section 337 investigations of alleged patent infringement involving FDA-regulated products.

The Court's opinion in this case is significant for two reasons.

First, the Court determined that the safe harbor provided by 35 U.S.C. § 271(e)(1) precludes use of Section 337 of the Tariff Act to prohibit the importation of goods produced abroad by a process patented in the United States when the imported goods are used for purposes falling within the safe harbor.

Second, the Court held that the ITC has jurisdiction to investigate whether to exclude imported goods whose use might fall within the safe harbor even if there is no actual sale or contract for sale of the imported product in the United States.

This ruling reversed the ITC's own determination of its jurisdiction and expanded the availability of Section 337 investigations to patent owners.

The Interaction Of The Safe Harbor And Section 337

The first significant effect of the Court's decision is to expand the protection provided by the safe harbor provision to products produced abroad by a process patented in the U.S. so long as those products are used to develop and submit data to the FDA.

In this case, Roche Holdings imported recombinant human erythropoietin ("EPO") and EPO derivatives. Amgen claimed that the imported EPO and methods used to make it infringed the claims of six of its patents.

In its defense, Roche asserted that it was using the imported EPO to develop and submit data to the FDA. The availability of this defense depends upon the interaction of the Patent and Tariff Acts.

Section 271(e)(1) of the Patent Act states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

The Tariff Act allows the ITC to issue orders prohibiting:

The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B).

The Court held that § 271(e)(1), which provides that certain uses of products covered by U.S. patents do not constitute infringement, precluded the issuance of an exclusion order pursuant to § 1337(a)(1)(B)(i), which applies to goods that infringe a patent.

The Court, however, split on the application of § 271(e)(1) to orders under § 1337(a)(1)(B)(ii), which does not, on its face, require infringement of a patent as the basis for exclusion.

Judge Newman, writing for the court, agreed with the Commission in holding that the safe harbor statute fully applies to process patent liability under § 1337(a)(1)(B)(ii) of the Tariff Act, citing congressional policy in enacting § 271(g) and the Supreme Court's applications of the safe harbor statute.

For example, the legislative history of § 271(g) includes statements that it shall not be an act of infringement to import a product made by a patented process solely for the exempt purposes set forth in § 271(e)(1).

Further, in Merck KgaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005), and **Eli Lilly** & Co. v. **Medtronic**, Inc., 496 U.S. 661 (1990), the Supreme Court expanded the scope of the safe harbor exemption to all uses of patented inventions reasonably related to the development and submission of any information to the FDA and that it covers medical devices, as well as drugs and veterinary products.

The Supreme Court in these cases stressed the congressional purpose of removing patent-based barriers to proceeding with federal regulatory approval for FDA-regulated products.

In dissent, Judge Linn, looked to the "plain language of the statute governing process claims before the Commission", specifically, § 1337(a)(1)(B)(ii) which clearly declares unlawful the importation of articles "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent" (emphasis added).

Unlike § 1337(a)(1)(B)(i), relating to patented products, § 1337(a)(1)(B)(ii) does not make violation of Section 337 tied to "infringement" under Title 35.

Thus, while it would make sense for the safe harbor to apply equally to patented products or products made from a patented process in Section 337 actions, the dissent argues, "the problem remains that if that is what Congress intended, it is not what Congress unambiguously said."

ITC Jurisdiction Expanded

The second significant effect of the Court's decision is to expand the ITC's jurisdiction to investigate uses of products that are potentially covered by the § 271(e)(1) safe harbor.

The ITC had held that it lacked jurisdiction to investigate and remedy the alleged infringement by Roche because the imported EPO had not been sold in the U.S. and was not the subject of an existing contract for sale.

The Federal Circuit reversed this determination.

The Court held that the ITC has the authority and jurisdiction to prevent unfair acts in their incipiency and when infringing acts are reasonably likely to occur.

The Court held that even though § 271(e)(1) exempts the imported EPO from infringement, the projected FDA approval of Roche's product established ITC jurisdiction to review and provide a remedy to take effect as appropriate after the approval is granted and § 271(e)(1) no longer shelters liability.

Summary

The net effect of the Court's ruling in this case is to expand the ITC's ability to investigate whether an imported good is being used in a manner that falls within the safe harbor provided by § 271(e)(1) while increasing the availability of this defense to importers.

--By George C. Best and Veronica S. Ascarrunz, **Foley & Lardner** LLP

George C. Best is a partner at Foley and a member of the firm's IP litigation and appellate practices. Veronica S. Ascarrunz is an associate at the firm and a member of its IP litigation practice.