

## **Amgen v. International Trade Commission: FDA-Related Safe Harbor for Importation Applies to Process Patents, Not Just Product Patents**

Amgen Inc. commenced an action before the International Trade Commission (“ITC”) under section 337 of the Tariff Act of 1930 seeking to prevent the importation of recombinant human erythropoietin (“EPO”) from Europe into the United States. Amgen claimed that the EPO produced in Europe was made using processes that are covered by various Amgen patents. Hoffman La-Roche and affiliated companies (“Roche”) intervened and asserted that the importation of the EPO was exempt from infringement, and therefore from the ITC’s exclusionary powers under section 337, because the purpose of the importation was to develop and submit information to the FDA, an activity for which a statutory safe-harbor exists. Amgen disputed these facts, saying that some of the EPO was being used to conduct studies related to marketing and to preparing a defense to a patent infringement lawsuit.

The ITC sided with Roche on the question of the safe harbor. It held for the first time that the safe harbor applies not only to patented products, but to products made by a patented process. The ITC also said it was unable to investigate the question of why the EPO was being imported as long as the FDA safe-harbor was in effect and there was no sale or offer of sale of EPO to third parties.

The Federal Circuit upheld the ITC’s ruling that the safe harbor applied to products made with patented processes, but disagreed with the holding that the ITC lacked the jurisdiction to investigate the purpose of the importation under the circumstances presented. The Federal Circuit said that the purpose of the exclusionary powers of Section 337 were to prevent infringement before it occurred, and that therefore the ITC does not have to wait for such infringement before investigating the purposes to which the imported EPO were being put. The Court pointed out that it is possible that protected, safe-harbor activities might be occurring at the same time as activities not covered by the safe harbor, and that the ITC could investigate and provide appropriate remedies under those circumstances.

*Amgen v. International Trade Commission* (Federal Circuit March 19, 2008), available at <http://www.caafc.uscourts.gov/opinions/07-1014.pdf>

*Bromberg & Sunstein LLP appeared on behalf of Roche in the ITC proceeding and in a related patent infringement litigation in the Federal District of Massachusetts.*