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CLIENT ALERT

Pending Regulatory Approval Does Not Confer Automatic Safe Harbor Exemption

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In *Amgen, Inc., v Int'l Trade Commission* (No. 2007-1014, March 19, 2008), a Federal Circuit panel affirms the International Trade Commission's ruling that the Section 271(e)(1) "safe harbor" exemption applies to process patents in actions under Section 337 of the Tariff Act, but remands to the Commission for further consideration.

Amgen, by complaint to the International Trade Commission ("the Commission"), charged that certain importations of erythropoietin ("EPO") by Roche were in violation of Section 337. The Commission granted Roche's motion for summary determination for non-infringement based on the safe harbor statute. On appeal, Amgen argued that the safe harbor exemption does not apply to Tariff Act violations based on non-US practice of patented processes. Amgen further argued that even on the Commission's interpretation of section 271(e)(1), at least some of the imported Roche EPO was not exempt because its actual use was not "reasonably related to the development and submission of information under [the Federal Food, Drug and Cosmetics Act]." Amgen asserted that Roche conducted infringement analysis experiments, market-seeding trials and litigation-related activities, activities which were not shielded by the safe harbor exemption.

The Federal Circuit panel affirms the Commission’s interpretation of the safe harbor exemption as applying to proceedings under the Tariff Act when the imported product is used for the exempt purposes of §271(e)(1), but disagrees with the Commission’s holdings that the exemption applies to all importation and all uses while regulatory approval is pending. The Federal Circuit panel therefore remands to the Commission for consideration of the exempt status of each study for which safe harbor is claimed.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.