Questions for the Record
Submitted by Senator Arlen Specter, Ranking Member
Senate Judiciary Committee
"Process Patents"
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Responses of Wayne Herrington
Assistant General Counsel
U.S. International Trade Commission

Question

1. If a district court applies a legal standard that ultimately absolves a defendant from infringement liability, then why shouldn't this same standard apply in an ITC proceeding where a finding of infringement is a predicate before an exclusionary order is entered?

Response

The Commission acts as a quasi-judicial tribunal in its section 337 investigations according to statutory authority. The Commission applies the patent law (Title 35 of the United States Code) and patent jurisprudence in its patent-based section 337 investigations except in those instances where Congress has stated otherwise. In the *Abrasives* case, the Commission construed the relevant legal provisions and legislative history to indicate the intent of Congress that the defenses of 35 U.S.C. § 271(g)(1) and (2) were not to be applied to proceedings under the Commission's process patent provision, section 337(a)(1)(B)(ii). The Commission reached this conclusion by applying principles of statutory construction, and the U.S. Court of Appeals for the Federal Circuit agreed with the Commission on this point.

Question

2. In exclusion proceedings, what does the ITC consider when determining whether to bar a product from being imported into the U.S.?

Response

In arriving at its determination on whether a product should be excluded from entry into the United States, the Commission first considers whether the complainant has shown that a violation of section 337 exists. In a patent-based case, this means that the complainant must show that the imported articles infringe the asserted patent claims. Where the Commission's process patent provision is involved, the complainant must show that the product is "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent," as set out in section 337(a)(1)(B)(ii). These showings are subject to applicable defenses, *e.g.*, patent invalidity and unenforceability. The complainant must also show that a domestic industry exists or is in the process of being established, as

required by section 337(a)(2)-(3).

If the foregoing requirements are met, and a violation of section 337 thus established, the Commission ordinarily will issue an exclusion order directing Customs to exclude the infringing articles from entry. There are two types of exclusion orders: a limited exclusion order and a general exclusion order. A limited exclusion order excludes from entry infringing articles from named sources who were respondents in the Commission's investigation. A general exclusion order excludes from entry infringing articles regardless of source, and thus not only applies to persons who were respondents in the Commission's investigation, but also to persons who were not. However, additional criteria (set out in section 337(d)(2)) must be met for issuance of a general exclusion order. In addition to, or in lieu of, an exclusion order, the Commission may issue cease and desist orders against persons who were respondents in the Commission's investigation. Cease and desist orders are usually sought against respondents who have commercially significant domestic inventories.

Notwithstanding a finding of a violation of section 337, the Commission may decline to issue relief after considering the effect of such relief "upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers," as provided, for example, in section 337(d)(1). However, it is rare for the Commission to deny relief on this basis.

The final component of a Commission final determination is the amount of bond importers would have to post to permit importation during the 60-day Presidential review period which follows affirmative Commission determinations, *i.e*, determinations that a violation of section 337 exists and the issuance of remedial orders. During the Presidential review period, the United States Trade Representative, acting under delegated authority from the President, may disapprove the Commission's determination for "policy reasons," as provided in section 337(j). Such disapproval is rare.

Question

3. I understand that during exclusion proceedings, there is an attorney serving the public interest. What public interest does the ITC seek to serve and how is this different from the district courts?

Response

A Commission investigative attorney from the Commission's Office of Unfair Import Investigations is assigned to each of the Commission's section 337 investigations. This office is distinct from the Commission's Office of the General Counsel and does not provide advice to the Commission in individual proceedings. The Commission investigative attorney acts as an independent party in the investigation, representing the public interest by developing relevant information and advocating on behalf of the public an independent position on the issues to

assist the Commission and its Administrative Law Judges in the discharge of their decision-making responsibilities during the course of the investigation. The private parties (the complainant and the respondent) are represented by their own counsel. There is no counterpart to the Commission investigative attorney in district court proceedings.

Question

4. I understand that last year the ITC dismissed without prejudice an exclusion proceeding brought by Amgen against Roche and that an appeal of the dismissal is currently pending before the Federal Circuit. If Congress were to amend 271(g) in the manner discussed today, what impact would that have on future proceedings between these parties before the ITC?

Response

On May 12, 2006, the Commission instituted an investigation under section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) ("section 337") entitled *Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568. The investigation was based on a complaint filed by Amgen Inc. ("Amgen") which asserted infringement of six United States patents. The asserted claims included process claims, product claims, and method of use claims. Amgen named four firms as respondents: Roche Holding Ltd., F. Hoffmann-La Roche, Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, "Roche"). Since process claims were involved, the investigation was based in part on the Commission's process patent provision, section 337(a)(1)(B)(ii).

On July 7, 2006, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") granting Roche's motion for summary determination (the Commission's equivalent to summary judgment) of no violation of section 337. On August 31, 2006, the Commission determined not to review the ALJ's ID, making it the final determination of the Commission.

Amgen has appealed the Commission's final determination to the U.S. Court of Appeals for the Federal Circuit. The appeal is titled *Amgen Inc. v. International Trade Commission et al.*, Appeal No. 2007-1014. Roche has intervened in the appeal on the side of the Commission. The appeal is fully briefed and awaiting scheduling of oral argument. The issues on appeal are: (1) whether the Commission has jurisdiction over so-called "imminent infringement" in the absence of at least a sale for importation; (2) whether 35 U.S.C. § 271(e)(1) can be raised as a defense in cases involving importations of products made abroad by a patented process, including cases brought under the Commission's process patent provision; and (3) whether the ALJ correctly found that there were no genuine issues of material fact regarding whether the accused importations by Roche fell within the defense of 35 U.S.C. § 271(e)(1).

In the appeal, Amgen has argued that the Federal Circuit's decision in *Kinik Co. v. International Trade Commission* requires that 35 U.S.C. § 271(e)(1) not be available in cases brought under the Commission's process patent provision. In *Kinik*, the Federal Circuit agreed with the

Commission that the defenses of 35 U.S.C. § 271(g)(1) and (2) do not apply to Commission section 337 investigations brought under the Commission's process patent provision. The Commission has argued that *Kinik* is not germane to the question of whether 35 U.S.C. § 271(e)(1) is a defense in section 337 investigations brought under the Commission's process patent provision. The Commission's argument would not be affected by an amendment which would eliminate the language "for purposes of this title" from 35 U.S.C. § 271(g).

The question of how such an amendment might affect the availability of the defenses of 35 U.S.C. § 271(g)(1) and (2) in cases brought under the Commission's process patent provision is another matter. Since the Commission acts as a quasi-judicial tribunal in its section 337 cases, it is not in a position to state what the effect of such an amendment might be in a future case. However, the Commission notes that the language referred to was one of two bases on which the Commission relied in the *Abrasives* case to conclude that the defenses of 35 U.S.C. § 271(g)(1) and (2) were not applicable to section 337 cases brought under the Commission's process patent provision. The other basis for the Commission's decision was section 9006(c) of the Process Patent Amendments Act. The Commission also notes that in considering defenses in cases brought under the Commission's process patent provision, it may be argued that the construction of that provision, section 337(a)(1)(B)(ii), should also be taken into account.