United States Court of Appeals for the Federal Circuit

2007-1014

AMGEN, INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

and

ROCHE HOLDING LTD., F. HOFFMANN-LA ROCHE LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMAN-LA ROCHE INC.,

Intervenors.

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Appealed from: United States International Trade Commission

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Intervenors.

Appeal from the United States International Trade Commission in Investigation No. 337-TA-568.

DECIDED: March 19, 2008

Before NEWMAN, LOURIE, and LINN, Circuit Judges.

Opinion for the court filed by Circuit Judge NEWMAN. Opinion concurring-in-part and dissenting-in-part filed by Circuit Judge LINN.

NEWMAN, Circuit Judge.

By complaint to the International Trade Commission under Section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. §1337, Amgen, Inc. charged that certain importations of recombinant human erythropoietin and derivatives thereof (collectively

"EPO") are in violation of Section 337. Amgen charged that the imported EPO and the process by which it is produced in Europe are covered by one or more claims of the following Amgen United States patents: Patent No. 5,411,868 (claims 1 and 2); Patent No. 5,547,933 (claims 3, 4, 5, and 11); Patent No. 5,618,698 (claims 4-9)[1]; Patent No. 5,621,080 (claims 4 and 6); Patent No. 5,756,349 (claim 7); and Patent No. 5,955,422 (claim 1). The Intervenors Roche Holding Ltd., F. Hoffmann-La Roche, Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") are producers and importers of the accused EPO.

Roche moved for summary determination of noninfringement as to all claims, on the ground that the imported EPO is exempt from infringement by operation of 35 U.S.C. §271(e)(1), the "safe harbor" statute, because the imported EPO is used only for the statutorily exempt purpose of the development and submission of information under a federal law regulating the manufacture, sale, and use of drugs. The Commission granted the motion for noninfringement, holding that all of Roche's activities are within the safe harbor, including the foreign production of the imported product. Amgen appeals this ruling, on the principal ground that the safe harbor statute does not apply to Tariff Act violations based on foreign practice of patented processes, and also on the ground that not all of the imported EPO was used for the statute's exempt purposes.

We affirm the Commission's ruling that the safe harbor provided by §271(e)(1) applies in proceedings under the Tariff Act relating to process patents as well as product patents, for imported product that is used for exempt purposes.

[1] Claims 4 and 5 of Patent No. 5,618,698 were removed from the case during the pendency of this appeal.

The Commission also ruled that it did not have jurisdiction to investigate and resolve the charges of infringement, reasoning that the product subject to the safe harbor had not been sold in the United States and was not the subject of an existing contract for sale, and ruling that sale as well as importation is required for Section 337 jurisdiction. Amgen appeals this ruling, arguing that Roche's announced imminent FDA approval of the imported EPO and the accompanying end of safe harbor protection, as well as Roche's extensive arrangements to sell in and to the United States market upon FDA approval, suffice to establish Commission jurisdiction. In this connection Amgen complains about the Commission's denial of discovery of Roche's marketing arrangements, thereby preventing Amgen from meeting the Commission's requirement of proving sale or contract for sale.

We reverse the Commission's ruling that it had no jurisdiction to determine violation of Section 337 in the posture of this case.

The Commission's statutory interpretations and rulings of law receive plenary review, applying the standards of the Administrative Procedure Act. See 19 U.S.C. §1337(c); 5 U.S.C. §706; e.g., Jazz Photo Corp. v. United States Int'l Trade Comm'n, 264 F.3d 1094, 1099 (Fed. Cir. 2001). Plenary review is given to the Commission's summary determinations, which are governed by the criteria of summary judgment and are reviewed accordingly. See 19 C.F.R. §210.18(b) (authorizing summary determination by the Commission if there is no genuine issue of material fact and the moving party is entitled to prevail as a matter of law); Hazani v. United States Int'l Trade Comm'n, 126 F.3d 1473, 1476 (Fed. Cir. 1997) (reviewing the Commission's summary determinations in accordance with the standards for summary judgment).

A

Section 337 assigns to the Commission the authority and obligation to investigate and prohibit importation based on unfair competition derived from patent, trademark, and copyright infringement, including:

> **19 U.S.C. §1337(a)(1)** Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> * * *
>
> **(B)** 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 under title 17, United States Code; 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. . . .
>
> * * *
>
> **(b)(1)** The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative. . . . The Commission shall conclude any such investigation and make its determination under this section at the earliest practicable time . . . .

The issues on this appeal center on the safe harbor statute for drug products, on application to the imported EPO of the following provisions of Title 35:

> **35 U.S.C. §271(e)(1)** It 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 or veterinary biological products.
>
> * * *
>
> **§271(e)(3)** In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

The Commission held that the safe harbor statute applies to products produced offshore by a process patented in the United States. Amgen argues that this statute does not bar the exclusion of such importation, reasoning that the §271(e)(1) reference to importing "a patented invention" is necessarily limited to importation of product, for a process cannot be imported. Amgen states that it is incorrect to assume that Congress, by silence, changed the long-standing Section 337 right and obligation of the Commission to reach importation based on offshore practice of a United States patented process. Amgen argues that the 1988 enactment of 35 U.S.C. §271(g), whereby the Patent Act provided remedy in the district courts for offshore practice of a patented process but explicitly applied the safe harbor to §271(g), shows congressional intent to limit the safe harbor to process patents that would be enforced under §271(g):

> **35 U.S.C. §271(g)** Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. . . . A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

Amgen states that the enactment of §271(g) makes clear that the Commission's authority under Section 337 was not changed by enactment of §271(g), because in adding §271(g) to Title 35 when Congress enacted the Process Patent Amendments of 1988, Congress stated that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under Section 337 of the Tariff Act of 1930, or under any other provision of law." Pub. L. 100-48, §9006(c) (1988). That is, Congress preserved

both the safe harbor, 35 U.S.C. §271(e)(1), and the Tariff Act's Section 337, in enacting §271(g). Amgen states that this means that process patent infringement would give way to the safe harbor when enforced in the district courts under §271(g), while remedy is retained for process patent infringement enforced under Section 337. Amgen stresses that Section 337 was enacted several decades before §271(g) was added to the Patent Act, and that the legislative record is clear that the Tariff Act remedy was intended to continue undiminished.

The Commission rejected these arguments, and held that the safe harbor statute fully applies to process patent liability under the Tariff Act. In support the Commission cited Glaxo Inc. v. Novopharm Ltd., 110 F.3d 1562 (Fed. Cir. 1997) and Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996). Novopharm related to determinations of infringement based on the filing of an ANDA for product produced offshore; and this court remarked that the "artificial" acts of infringement that are created by §271(e)(2) – concerning the conditions under which the patentee can sue for infringement during the pendency of the ANDA – relate only to "a drug claimed in a patent or the use of which is claimed in a patent" but not to the process for making the drug. However, the issues in that case did not relate to exclusion under the Tariff Act, but to the right to sue when the charged infringements arose under sections 271(e)(2) and 271(g). In Bio-Technology General this court held that the safe harbor statute applied in the district court as to product produced offshore after §271(g) was enacted; the district court did not rule on the safe harbor for process patents under the Tariff Act, although the court apparently assumed that the safe harbor would apply on the same terms. 80 F.3d at 1563-64 (explaining that although the ITC dismissed the patentee's

Section 337 complaint with prejudice for violation of discovery orders, this ruling cannot have claim preclusive effect on the case at bar involving the same transactional facts because "the ITC does not have the power to award damages for patent infringement" which was the form of relief sought by the patentee).

In Kinik v. United States International Trade Commission, 362 F.3d 1359 (Fed. Cir. 2004) this court explained that §271(g) provided a new right and remedy in the district court, but held that the Tariff Act remedy of exclusion based on practice of a patented process was unchanged, and that the exceptions set forth in §271(g)(1) and (2), shown supra, did not apply in Section 337 cases. Id. at 1362. Amgen argues that Kinik confirmed that no change whatsoever was made in the Commission's authority under the Tariff Act to exclude products made offshore by an infringing process, and that this was not changed by the enactment of either §271(g) or §271(e)(1). Amgen also argues that Congress intentionally included only product patents when enacting §271(e)(1), for the reference therein to "importation" and "patented invention" tracks the language of §271(a), which does not concern processes practiced abroad. Thus Amgen argues that an importation that is exempt under §271(e)(1) of the Patent Act may nonetheless be unlawful under Section 337 of the Tariff Act.

The Commission did not accept Amgen's distinction, and ruled that the safe harbor statute insulates the Roche EPO from Section 337 exclusion not only as to infringement of Amgen's product patents but also as to Amgen's process patents. We conclude that the Commission's ruling is in consonance with congressional policy as set forth in enactment of §271(g), and as elaborated by the Supreme Court in its applications of the safe harbor statute.

In enacting §271(g) the legislative history included the policy statement that:

> Specifically, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "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." See 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

S. Rep. No. 100-83, 48 (1987). Implementing in other contexts this broadly stated congressional policy, in Merck KgaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) the Court explained that Congress intended that the immunity of regulatory activity not be inhibited, stating that "§271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." Id. at 202 (emphasis in original). And in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) the Court held that §271(e)(1) includes medical devices, although the statute mentions only drugs and veterinary products; the Court stated that "[t]he phrase 'patented invention' in §271(e)(1) is defined to include all inventions, not drug-related inventions alone." Id. at 665. In both Merck and Eli Lilly the Court stressed the congressional purpose of removing patent-based barriers to proceeding with federal regulatory approval of medical products. This purpose and its application in precedent weigh heavily against selectively withholding the §271(e)(1) exemption depending on whether the infringement action is in the district court or the International Trade Commission. We thus affirm the Commission's ruling that the safe harbor statute applies to process patents in actions under Section 337, when the imported product is used for the exempt purposes of §271(e)(1).

B

Amgen argues that even on the Commission's interpretation of the safe harbor statute, at least some of the imported Roche EPO is not exempt because its actual use was not "reasonably related to the development and submission of information under [the FDCA]," §271(e)(1). Amgen points out that while §271(e)(1) is directed to the development of information for submission to the FDA, Amgen did not bring this action for exclusion of imports until after Roche had completed its submission to the FDA. Amgen states that Roche had entered the "post-BLA" (Biologics License Application) stage, which is the stage at which complete data have been obtained, analyzed, and presented to the FDA. See 21 C.F.R. §601.2(a) (requiring that the BLA contain "data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity and potency").

Amgen states that by the time this action was brought Roche had shifted its attention in the United States to infringement analysis experiments, market-seeding trials, and litigation-related activity. Amgen states that these activities are not shielded by the safe harbor, for they do not "contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant to the processes by which the FDA would decide whether to approve the product in question," a general definition of exempt activity endorsed by the Court in Merck as "consistent with, if less detailed than, the construction of §271(e)(1) that we adopt today." 545 U.S. at 208. Amgen argues that Roche's post-BLA activities are not exempt from infringement of either product or process patents.

The Commission appears to have assumed that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted. That assumption is incorrect, for the Court in Merck confirmed that "[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies." Id. at 200. The studies at issue in Merck were presented as scientific studies, and it is apparent that commercial and marketing studies are more clearly subject to separate evaluation for application of the exemption.

The ALJ denied most of Amgen's requests for discovery of Roche's post-BLA activities, with the exception of the experiments conducted by Dr. Veng-Pedersen, and perhaps some others - the briefs dispute what was disclosed in discovery. However, as to Dr. Veng-Pederson's work, Amgen asserts that these experiments were conducted for marketing purposes, with the objective of trying to distinguish Roche's EPO from that of Amgen. The evidence on this aspect was conflicting and required closer analysis than it received, in light of the distinctions drawn by the Court in Merck. For example, an email from Roche's Program Director for Oncology asked Dr. Veng-Pedersen to "explore the metabolism (uptake in the bone marrow vs. liver uptake) and to see if there are differences between CERA and EPO," a communication that Amgen states is directed to future marketing plans to distinguish the Roche and Amgen products, whereas the Roche position was that it contacted Dr. Veng-Pedersen because Roche was "currently studying CERA and EPO in terms of receptor interaction by using an in-vitro cellular model system only and would need to move into a more physiological situation." The Amgen position is that since this study was conducted after the BLA information had been submitted to the FDA, by definition this study was not directed to

obtaining information for submission for federal approval of the Roche product, as required for exemption under §271(e)(1).

The ALJ held that all of the imported EPO, including that used after the application for federal approval was completed, is exempt. However, the Court in Merck set careful boundaries to the exemption, requiring separate review of all studies for which the exemption was claimed. Roche does not appear to dispute that some imported product was used to conduct Roche's marketing department's recommended studies for purposes of brand recognition and not for FDA approval, and the record does not discuss whether any of the post-BLA work was supplemental to the BLA and intended for submission to the FDA, thereby subject to exemption. See 21 C.F.R. §601.12 (entitled "Changes to an approved application" and requiring an applicant to inform the FDA "about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s)").

To the extent that the Commission held all importation and all uses exempt while FDA approval was pending, the safe harbor statute does not so provide. The factual questions of the purposes of the post-BLA and other challenged activities were improperly summarily decided adversely to Amgen. On remand the Commission shall consider the exempt status of each study for which question has reasonably been raised.

II

The full Commission sustained the ALJ's holding that the Commission does not have jurisdiction to investigate and remedy infringement with respect to importation that

is subject to the safe harbor, unless there is also actual sale in the United States or contract for sale of the imported product. The Commission held that Roche's announced imminent FDA approval of the imported EPO, and imminent end of the safe harbor, do not suffice to establish Commission jurisdiction to determine the facts of infringement unless actual sale or contract for sale is also shown.

Amgen argues that actual sale and use are prohibited without FDA approval, and that when the importation and the potential injury to domestic industry are real, and sale in the United States is imminent, Section 337 authorizes and requires Commission action. This court's precedent, as well as the Commission's own prior rulings, support Amgen's position. In the Commission's words: "Clearly, the Commission's remedy is ineffectual after the accused imported product has entered the stream of domestic commerce." In the Matter of Certain Low-Nitrosamine Trifluralin Herbicides, Inv. No. 337-TA-245, 1986 ITC LEXIS 91 at *4 (Sept. 14, 1986) ("In view of the remedial purpose of Section 337, and the prospective nature of any remedy that may be afforded, the imminent importation by a party respondent in an ongoing investigation of a new product which is alleged to infringe complainant's patent and to have the tendency to injure the domestic industry, clearly falls within the Commission's jurisdiction."). In In re Certain Apparatus for the Continuous Production of Copper Rod, 214 USPQ 892, 895 (Int'l Tr. Comm'n 1980). the Commission stated:

> While the Commission often looks to domestic patent law for guidance in determining what constitutes an unfair method of competition or unfair act, it is clear that our jurisdiction is not limited to the strict application of analogous laws. The Commission, under the authority granted to it in section 337, may prevent unfair acts in their incipiency.

In In re Certain Variable Speed Wind Turbines and Components Thereof, Inv. No. 337-TA-376 (May 30, 1996), aff'd sub nom Enercom GmbH v. United States Int'l Trade Comm'n, 151 F.3d 1376 (Fed. Cir. 1998) there was no importation and although the Commission recognized that "[p]resumably, there could be an imminent importation without a sale," the action did not rely on this aspect because there was a contract for sale of the foreign goods.

Amgen stresses that the Roche application for FDA approval to sell the imported EPO in the United States of itself establishes the intent to sell. Amgen argues that the Commission erred in ignoring this undisputed fact and holding that it does not have jurisdiction to investigate complaints of violation of Section 337 unless the patentee has established not only importation but also actual sale or offer of sale. Amgen points to the contrary action in Trifluralin Herbicides, where the Commission explained that:

> It is well established that the Commission's jurisdiction under Section 337 is broad, and that Section 337 is a remedial statute which authorizes the Commission to "prevent unfair acts in their incipiency."

1986 ITC Lexis 91 at *4 (quoting Copper Rod, 214 USPQ at 895). This precedent has its foundation in In re Orion Co., 21 USPQ 563 (CCPA 1934), where our predecessor court explained:

> After the goods have been so released into the commerce of the country, the American manufacturer may assert his rights against anyone who has possession of, or sells, the goods. However, this method of control must be, and is, ineffective, because of the multiplicity of suits which must necessarily be instituted to enforce the rights of the domestic manufacturer. This phase of the matter obviously was in the minds of the Congress at the time of the preparation of said section 337.

Id. at 571. Additional precedent appears in connection with actions under §271(g), where this court has held that a declaration that a person will infringe a patent under

§271(g) in the future will satisfy declaratory judgment jurisdiction. For example, in Novopharm, supra, this court held that the requisite immediacy and reality of infringement was provided by Novopharm's systematic efforts to meet the regulatory requirements for the imported product upon expiration of the shelter provided by §271(e)(1), and explained that "[t]he only difference . . . is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Id. at 1569. Similarly in Glaxo Group, Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333 (Fed. Cir. 2001), the court recognized that although there cannot be sale and use until FDA approval is obtained and the safe harbor ends, the "standard infringement test" is appropriately conducted during the safe harbor period. Id. at 1338. As explained in Novopharm, "the protected status of Novopharm's activities leading to its submissions to the FDA does not by itself prevent the district court from considering Glaxo's request for declaratory relief because such relief is directed to the time after the ANDA is approved, when §271(e)(1) no longer provides a shelter against infringement liability." 110 F.3d at 1571.

Precedent also includes Allergan, Inc. v. Alcon Laboratories, Inc., 324 F.3d 1322 (Fed. Cir. 2003), in which this court, confirming jurisdiction, observed that the only difference is "the timeframe under which the elements of infringement are considered" for the accused product awaiting FDA approval. Id. at 1331. Again in Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003), the court applied §271(e)(1) and explained that the courts have jurisdiction to consider the issues of infringement during the safe harbor period of regulatory approval; this court recognized the propriety of a

declaratory action directed to future infringement, although "the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed." Id. at 1366. Thus the purposes of the safe harbor statute are met, while safeguarding the rights of the patentee that come into effect when the safe harbor has ended.

The Commission's assignment is to prevent and remedy unfair acts flowing from infringement. As explained in In re Orion, "the provision relating to unfair methods of competition in the importation of goods is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any anti-dumping statute the country has ever had," 21 USPQ at 571 (quoting legislative history discussing the purposes of the Tariff Act of 1922). Statute, precedent, and the policies they reflect, negate the Commission's rejection of its own authority to consider the issues of unfair competition based on infringement by product imported for purposes of obtaining federal approval, whether or not sale has already occurred. Although §271(e)(1) negates infringement by the imported EPO, the projected FDA approval established the Commission's jurisdiction to review and provide remedy to take effect as appropriate after the approval is granted and §271(e)(1) no longer shelters liability. When it has been shown that infringing acts are reasonably likely to occur, the Commission's obligation and authority are properly invoked.

The Commission erred in holding that it lacked jurisdiction under Section 337 absent actual sale or contract for sale of the imported EPO.

SUMMARY

Applying the safe harbor exemption of 35 U.S.C. §271(e)(1), the imported EPO is not subject to exclusion based on infringement of either product or process patents, to

the extent that the imported EPO is used to develop information that is reasonably related to the development and submission of information to the federal regulatory authority. The Commission's holding to this effect is affirmed. However, Roche's uses of imported EPO unrelated to obtaining FDA approval are not shielded by the exemption.

The issues of infringement and injury were properly before the Commission for resolution. We reverse the Commission's dismissal on jurisdictional grounds, and remand for further proceedings consistent with this opinion.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED

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Appeal from the United States International Trade Commission in Investigation No. 337-TA-568.

LINN, Circuit Judge, concurring-in-part and dissenting-in-part.

I am pleased to join Parts I.B and II of the majority opinion insofar as they relate to the asserted product claims, but I respectfully dissent from Part I.A, which holds that the safe harbor from infringement liability provided by 35 U.S.C. § 271(e) extends to the exclusion by the Commission of pharmaceutical products produced abroad by means of a patented process. Like the majority, I do not find persuasive Amgen's arguments that the term "patented invention" in § 271(e)(1) was intended to exclude process patents. See Majority Op. at 7. Nor do I disagree that § 271(e)(1) is to be construed broadly. See id. at 8. My conclusion, rather, follows from the fact that § 271(e)(1) declares that certain activities "shall not be an act of infringement," while the plain language of the

statute governing process claims before the Commission, 19 U.S.C. § 1337(a)(1)(B)(ii), does not require an act of infringement for the Commission to issue an exclusion order.

Specifically, § 1337(a)(1)(B)(ii) declares unlawful the importation, inter alia, of articles that "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." Assuming, arguendo, that Amgen prevails as to its infringement and validity contentions on the merits, the EPO at issue in this case would be "produced . . . by means of[] a process covered by the claims of a valid and enforceable United States patent"—regardless of whether the use to which the EPO is put is shielded from liability for infringement by § 271(e)(1). The thrust of the majority's position is that Congress probably intended § 271(e)(1) to apply in section 337 proceedings the same way it applies in patent infringement litigation under Title 35. While I agree that it would make sense for section 337 to apply that way, the problem remains that if that is what Congress intended, it is not what Congress unambiguously said.

The language of § 1337(a)(1)(B)(ii) contrasts with the language of § 1337(a)(1)(B)(i), the corresponding provision governing proceedings regarding patented products. Section 1337(a)(1)(B)(i) declares unlawful the importation of articles that "infringe a valid and enforceable United States patent." Thus, there is no dispute that the safe harbor of § 271(e) applies to product claims before the Commission; the unlawfulness under section 337 of the importation of a patented product hinges on whether the importation is itself an act of infringement.

It appears that this difference in language is not accidental. Although Title 35 and section 337 are ordinarily coextensive, their scope has differed with respect to

imported goods made by patented processes for almost seventy years. In 1940, Congress enacted § 1337a—the predecessor to today's § 1337(a)(1)(B)(ii) and the origin of its "covered by the claims" language—in response to a decision by our predecessor court that the importation of an article produced abroad by a process covered by a U.S. patent was not an unfair trade practice forbidden by section 337. See In re Amtorg, 75 F.2d 826 (CCPA 1935) (observing that it was not the "purpose of the Congress in enacting section 337 of the Tariff Act of 1930 to broaden the field of substantive patent rights"). Such importations were not acts of infringement until Congress enacted 35 U.S.C. § 271(g) in 1988. Even under the present statutory scheme, as the majority acknowledges, we have held that the defenses enumerated in § 271(g) do not apply in actions under § 1337(a)(1)(B)(ii). See Kinik v. Int'l Trade Comm'n, 362 F.3d 1359, 1362–63 (Fed. Cir. 2004). This is because the language of the two provisions differs and because the legislative history of § 271(g) indicates that Congress did not intend for it to narrow the scope of pre-existing remedies before the Commission.

It is important to recognize that the former § 1337a was recodified into § 1337(a)(1)(B)(ii) as part of the same statute that created 35 U.S.C. § 271(g). Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418. In enacting § 1337(a)(1)(B)(ii), Congress reaffirmed its choice of language that required only that a process be "covered by the claims of a valid and enforceable United States patent," even though § 271(e) had by this time been enacted. Congress easily could have referred to the newly-created § 271(g), which for the first time extended "liab[ility] as an infringer" to those who import products made abroad by processes patented in the

United States, or it could have used the same language in § 1337(a)(1)(B)(ii) as in § 1337(a)(1)(B)(i) if it intended those sections to correspond exactly to § 271(g) and § 271(a), respectively. Instead, it chose to recodify language that had deliberately broadened the scope of section 337 proceedings beyond the scope of infringement liability under § 271. Thus, with respect, I do not find persuasive the majority's conclusion that we should ignore the language of § 1337(a)(1)(B)(ii) based on "congressional policy as set forth in enactment of § 271(g)." Majority Op. at 7–8. Whether deliberately or through oversight, when Congress passed § 271(g), it enacted statutory text that is not consistent with the majority's interpretation of congressional policy.

In short, I see no basis for concluding that Congress did not intend what it said. I do not disagree with the majority's policy judgment that § 1337 and § 271 should be brought into synchrony. But that is not a decision for a court to make, particularly in light of the legislative history. "[I]t is not our function to eliminate clearly expressed inconsistency of policy and to treat alike subjects that different Congresses have chosen to treat differently." W. Va. Univ. Hosps., Inc. v. Casey, 499 U.S. 83, 101 (1991). Indeed, it is worth noting that there are also potential policy arguments in support of the textual reading of the statute. Congress may not have intended to extend the same benefits of § 271(e)(1) to foreign pharmaceutical companies as it extended to domestic ones, or it may have intended to discourage the importation of pharmaceuticals that have not yet been approved by the FDA. But "[i]t is not our job to speculate upon congressional motives." Riegel v. Medtronic, Inc., No. 06-179 (U.S. Feb. 20, 2008).

Accordingly, I would reverse and remand to the Commission for consideration of the merits of Amgen's complaint with respect to the process claims, without regard to the use to which the imported EPO is put. I join the majority's disposition as to the product claims.