Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 99 Att. 2

rigorous, and requires the new drug's "sponsor" to (1) prepare and submit an Investigational New Drug Application ("IND"); (2) perform, with FDA approval, a series of clinical trials on human subjects; and (3) analyze the resulting clinical data and prepare and submit a Biologic License Application ("BLA"). All of these submissions are scrutinized by the FDA. See Kingma-Johnson Decl. ¶¶4-6. Roche is CERA's sponsor in the FDA approval process. Id. ¶4.

In compliance with the FDA's requirements, CERA is currently undergoing clinical trials to evaluate its use in two separate indications: (1) treatment of anemia associated with chronic kidney disease; and (2) treatment of anemia in an oncology setting. Id. ¶7. As part of routine drug development there are three phases of clinical trials designated Phase 1, Phase 2 and Phase 3. 21 C.F.R. §312.21; Kingma-Johnson Decl. ¶6. Clinical testing for the two separate indications for CERA is at different phases. The BLA for the use of CERA in chronic kidney disease was filed on April 19, 2006, but at least one trial will continue after filing. Kingma-Johnson Decl. ¶9. Even if all goes smoothly, the FDA might not approve this application until 22-25 months from now. See section II.B., below. The BLA for the use of CERA in cancer patients will not be filed until 2009. Kingma-Johnson Decl. ¶11. Accordingly, any ITC trial conducted as part of this investigation may be over before FDA approval of CERA is granted.

ARGUMENT

I. NONE OF ROCHE'S ACTIVITIES CONSTITUTES AN UNFAIR TRADE PRACTICE

A. The Summary Determination Standard

The Administrative Law Judge is well aware of the standard for granting summary determination:

> Motions for summary determination are governed by Commission Rule 210.18, which provides that any party may move with any necessary supporting affidavits for a summary determination of any or all of the issues to be determined in the investigation. "The

Dockets.Justia.com

accused product is not approved by the FDA and its use for the FDA approval process is protected as a matter of law.

C. Allowing This Investigation To Proceed Would Contravene The Purpose Of 35 U.S.C. § 271(e)(1)

Allowing this investigation to proceed completely undermines the policy endorsed by Congress in enacting 35 U.S.C. §271(e)(1). Congress intended that while a company was proceeding through the FDA approval process, the company would take steps to prepare for sale of a product if and when FDA approval were granted. Telectronics, 982 F.2d at 1525 ("Congress must have intended to allow competitors to be in a position to market their products as soon as it was legally permissible."). If a patentee can base a §337 action solely on the fact that the respondent has sought FDA approval for its product and undertaken actions to facilitate that approval, then §271(e)(1) is rendered useless in relieving the defendant of the type of "expensive, resource-draining, and personnel-distracting litigation" that §271(e)(1) was designed to avoid. Intermedics, 775 F. Supp. at 1290.

In the context of declaratory judgment actions under the same circumstances, the courts recognize that it would be "nonsensical" to permit a defendant to be protected from a direct suit for infringement and yet allow the same activities to be subject to a suit that sounds in declaratory relief. Intermedics, Inc. v. Ventritex Co., 1993 U.S. App. LEXIS 3620, *15 (Fed. Cir. 1993) (nonprecedential). They have also noted that such actions "may run afoul of the Congressional policy underlying the section 271(e)(1) exemption." Hoechst, 3 F. Supp. 2d at 112. In its decision declining to exercise declaratory judgment jurisdiction, but rather to "administratively stay" the case until "good cause" was shown for re-opening it, e.g., the grant of FDA approval, the Hoechst court noted that such a declaratory action "could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition":

> Declaratory judgment actions have the potential to discourage and hamper the very efforts that Congress sought to stimulate, by subjecting potential competitors to the same burdensome litigation that Congress sought to eliminate. Cf. Intermedics, 775 F. Supp. At 1289-90; Abbott Labs. v. Zenith Labs., Inc., 934 F. Supp. 925, 938-39 (N.D. Ill. 1995). Although it is true that Amgen seeks only a declaration of its rights, which would not preclude continuing exempt activities, the use of the declaratory action could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition. Because the Defendants in this case will violate the law only if they step outside the protective safe harbor that Congress has created, the Court is hesitant to invade the harbor under the auspices of declaratory relief.

Id. at 113. This appears to be what is happening here. When asked recently about Roche's plans to file for U.S. approval to market CERA for anemia for kidney disease, Amgen chief executive Kevin Sharer replied, "We have to stop them altogether." Amgen's 'Strategic Intention' is to Acquire – CEO, Reuters, Mar. 1, 2006, Wright Decl., Ex. 13.

CONCLUSION

The Notice of Investigation asks whether the accused acts fall within the safe harbor of 35 U.S.C. §271(e)(1). The answer is clear. There are no facts to support a determination that there is a violation of §337. The indisputable facts demonstrate that all of

A patentee cannot parrot the statute and escape dismissal of its amended complaint by merely asserting that defendant does what the statute prohibits. Ristvedt-Johnson, Inc. v. Peltz, No. 1991 U.S. Dist. LEXIS 17233 at *8-*13 (N.D. Ill. 1991) (amended complaint dismissed where plaintiff merely repeated the language of the statute with respect to defendant's induced infringement but failed to assert any facts to support allegation); see also Papasan v. Allain, 478 U.S. 265, 286 (1986) (a court is "not bound to accept as true a legal conclusion couched as a factual allegation"). This is precisely what Amgen has done here: it has recited the language of §337 and stated that Roche's importation and use of CERA violates that statute, but is unable to establish the existence of any facts that could constitute an unfair trade practice. Because Amgen's allegations constitute the very definition of non-infringement, and because Amgen has no factual support to the contrary, Amgen should not be permitted to launch the parties into full scale discovery into its unsupported allegations. Rather, this investigation should be concluded immediately on the basis of a summary determination.

II. ROCHE'S POTENTIAL COMMERCIALIZATION OF CERA IF FDA APPROVAL IS EVENTUALLY GRANTED PROVIDES NO BASIS FOR RELIEF UNDER §337

A. There Has Been No Sale For Importation Of The Accused Product

In addition to the present activities involving CERA, all of which were shown above to be noninfringing, Amgen also refers to activities that Roche may undertake after FDA approval is granted. See Amended complaint ¶7.1 (Roche importing for "imminent sale"); ¶7.2 (Roche is "imminently preparing to sell" CERA in the United States). In this respect, the amended complaint mirrors a complaint that Amgen recently filed against Roche in the U.S. District Court for the District of Massachusetts. That complaint asserts the same patents and makes the same allegations as the amended complaint in this investigation but identifies its only cause of action as a "Declaratory Judgment of Infringement." Wright Decl. Exh. 1. That

Amgen's argument that the safe harbor of §271(e)(1) is inapplicable because Roche intends to market CERA prior to the expiration of Amgen's patents is meritless. The ITC has expressly rejected this very argument:

> The administrative law judge rejects complainant's argument that section 271(e)(1) does not apply to BTG's importations because BTG intends to commercialize its BIO-TROPIN as soon as it obtains regulatory approval and prior to expiration of complainant's patents in issue. Congress expressly rejected an attempt to limit the applicability of section 271(e)(1) to the last year of the term of any relevant patents. H.R. Rep. No. 98-857, 98th Cong., 2d Sess., reprinted at 1984 U.S.C.C.A.N. 2647, 2692. Had Congress desired to so limit applicability of section 271(e)(1) it could have done so. Moreover, the fact that BTG's tests may have uses other than submission to the FDA does not revoke the exemption conferred by section 271(e)(1). [citing Telectronics Pacing Systems v. Ventritex, Inc., 982 F.2d 1520, 1525 (Fed. Cir. 1992), and Intermedics, 775 F. Supp. at 1274-75.]

In re Certain Recombinantly Produced Growth Hormones, 337-TA-358, 1994 ITC LEXIS 640, *59-*60 (1994), vacated on unrelated grounds, Genentech, Inc. v. U.S.I.T.C., 122 F.3d 1409 (Fed. Cir. 1997); see also Notice of Investigation at 2 (Commission is "mindful of the provision of §271(e")).

As shown above, aside from the incorrect statement that Roche is "offering [CERA] for sale" in the United States, Amgen makes no allegation of any specific act of Roche that would constitute infringement. At best, Amgen makes conclusory allegations that "Roche's importation and use of [CERA] in the United States infringes one or more claims of [the asserted patents]." Amended complaint ¶1.2. Indeed, the allegation of the act of importation was based on the fact that the product is undergoing clinical trials in connection with the FDA approval process together with the fact that information about those clinical trials is being submitted to the FDA – the very definition of non-infringement in §271(e).

suggestions. Roche has not in fact imported for sale and there has been no stockpiling. Kokino Decl. ¶¶3, 6; Van der Auwera Decl. ¶¶4, 7.

The amended complaint also alleges that Roche has made "meaningful preparations to market and sell [CERA] in the United States," including, among other things, hiring personnel, contacting potential customers, and building a new manufacturing facility in Germany. ¶7.20. Such activities are not acts of infringement as a matter of law under 35 U.S.C. §271(a)-(g) because they do not involve the manufacture, use, sale, offer for sale, or importation of a patented invention, and do not eviscerate the §271(e) safe harbor. Hoechst, 3 F. Supp. 2d at 107; Intermedics, 775 F. Supp. at 1277-78.

In summary, apart from the incorrect assertion that Roche is "offering [CERA] for sale" in the United States, each and every one of the ongoing activities cited by Amgen is not an act of infringement. To the contrary, all of Roche's importation and uses are protected by §271(e) as a matter of law.

C. Roche's Noninfringing Acts Cannot Constitute Unfair Trade Practices

Because 35 U.S.C. §271(e)(1) applies on its face to the importation of products for FDA related purposes, activities falling within the safe harbor of that statute do not constitute unfair trade practices within the meaning of §337. See In re Certain Excimer Laser Systems, Inv. No. 337-TA-419, 1999 ITC LEXIS 392, *9 (Dec. 15, 1999) ("Because the statute [§271(e)(1)] indicates that importation or use [for FDA-required testing] does not constitute infringement, such importation and use does not constitute unfair competition, and therefore falls outside the ambit of Section 337.") (emphasis added); In re Certain Minoxidil Powder, Inv. No. 337-TA-267, 1987 ITC LEXIS 19, *1 (Dec. 2, 1987) (terminating investigation as to one respondent where evidence showed that all of the allegedly infringing drug samples imported by that respondent were for experimental purposes exempted by §271(e)(1)).

only to activities that might constitute infringement . . . defendant need not show that all of its conduct falls under the section 271(e)(1) exemption, only the [allegedly infringing acts]." Amgen Inc. v. Hoescht Marion Roussel, Inc., 3 F. Supp. 2d 104, 107 (D. Mass. 1998). Non-infringing acts (acts that do not constitute infringement under §§ 271(a) or (g)) done for other uses are irrelevant, and have no bearing on whether the alleged infringing acts fall within the uses permitted by section 271(e)(1). Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1277-78 (N.D. Cal. 1991), aff'd, 991 F.2d 808 (Fed. Cir. 1993).

CERA has been and continues to be used in the United States in clinical trials to evaluate its safety and efficacy as a part of the FDA approval process. Buch Decl. ¶3; Kingma-Johnson Decl. ¶7; Marcopulos Decl. ¶¶3-6. CERA has also been used in the United States for non-clinical research directed to the development and submission of information to the FDA. Buch Decl. ¶3; Char Decl. ¶¶3-7. As such, Roche's uses of CERA in the United States for clinical and non-clinical study related to the requirements of the FDA approval process are encompassed within the "all uses" provision of the statutory safe harbor for uses that are reasonably related to the development and submission of "any information under the FDCA." Merck KGaA, 125 S. Ct. at 2380 (exemption under section 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.") (emphasis in original).

With respect to the assertions in the amended complaint that relate to alleged "offers for sale," it is undisputed that CERA is not approved for sale in the United States, and it cannot be disputed that Roche does not sell or offer the product for sale. Kokino Decl. ¶¶3-5; Van der Auwera Decl. ¶6. With respect to the sworn allegation of "importation for imminent sale" and the suggestion of "stockpiling," there is no basis in fact for these allegations or

> determination sought by the moving party shall be rendered if the pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to a summary determination as a matter of law." 19 C.F.R. §210.18(b).
>
> The evidence is to be viewed in the light most favorable to the nonmovant, and all reasonable inferences must be drawn in favor of the nonmovant. The moving party has the burden of demonstrating that there is no genuine issue of material fact in dispute and that it is entitled to judgment as a matter of law. If the movant meets its initial burden, the burden of coming forward shifts to the party opposing the motion.

In re Certain Laminated Floor Panels, Inv. No. 337-TA-595, 2006 ITC LEXIS 157, *2-*3 (Mar. 2, 2006) (internal citations omitted).

B. All Of Roche's Activities Are Noninfringing Under 35 U.S.C. § 271(e)(1)

Section 337(c) provides that "[a]ll legal and equitable defenses may be presented" in ITC investigations. 19 U.S.C. §1337(c). The Notice of Investigation here expressly directs the ALJ to consider the defense provided by 35 U.S.C. §271(e), which states:

> (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. . . .

The exemption under section 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA." Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372, 2380 (2005) (emphasis in original). The limitation to "uses reasonably related" to FDA approval broadly encompasses all activities germane to compliance with FDA regulations concerning drug approval, including, among other things, preclinical studies relating to the drug's safety, efficacy, mechanism of action, pharmacokinetics, and pharmacology. Id. at 2381. Since "section 271 applies generally

In contrast, CERA is an entirely new pharmaceutical product, not a generic copy of a previously-approved drug. Approval of Roche's BLA will therefore require the FDA to scrutinize the results of clinical trials to evaluate whether the new product is safe and effective. Amgen itself cautions its investors regarding the uncertainty inherent in clinical trials and the FDA's review of clinical trial data:

> Conducting clinical trials is a complex, time-consuming and expensive process. . . . Patients may. . . suffer adverse medical events or side effects in the course of our clinical trials that may delay or prohibit regulatory approval of our product candidates. Of course, even if we successfully manage our clinical trials, we may not obtain favorable clinical trial results and may not be able to obtain regulatory approval on this basis. (Amgen Form 10K for fiscal year ending 12/31/2005, Wright Decl. Exh. 10 at 30).
>
> The FDA and other U.S. and foreign regulatory agencies have substantial discretion to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval, require changes in labeling of our products, and mandate product withdrawals. (Amgen Form 10Q, Quarterly Period Ending 9/30/05. Wright Decl. Exh. 11 at 34).
>
> The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. (Amgen Form 8K, 4/18/06, Wright Decl. Exh. 12 at 3).

Thus, while Amgen would have the ITC believe that the FDA's review and approval of CERA amounts to nothing more than a rubber stamp formality, its disclosures to its investors tell a different story. This underscores the fact that neither the time nor the ultimate result of the FDA's review process is certain and that any potentially infringing importation, sale for importation, or sale after importation of CERA is far too remote to allow this investigation to proceed.

In summary, Amgen's theory about what might happen is based on pure speculation. What is not speculation, and what is not subject to dispute, is the fact that the