UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

AMGEN INC.'S POST HEARING MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Defendants assert that a recent initial determination by an Administrative Law Judge (ALJ) of the International Trade Commission (ITC) provides reason for this Court to grant Defendants' motion to dismiss for lack of subject matter jurisdiction. Although Amgen believes the ALJ's initial decision to be in error based on ITC jurisprudence and will petition the Commission for review, this decision should have no effect upon this Court's resolution of Defendants' pending motion for at least the following reasons:

(1) The ALJ's decision fails to consider evidence that is highly probative to this Court's jurisdiction under the Declaratory Judgment Act — evidence demonstrating that Defendants' non-exempt use and expected sale of infringing product in the United States are imminent.

(2) In submitting the initial determination, Defendants seek to rely on facts outside of Amgen's Amended Complaint, even though the ITC Protective Order prohibits Amgen from presenting facts discovered in the ITC action that compel denial of Defendants' motion in this Court.

(3) The ITC's jurisdiction is distinct from this Court's jurisdiction and, therefore, the ITC decision has no preclusive effect on any claim or issue before this Court.

As detailed in Amgen's Amended Complaint, even if Defendants have not already engaged in activities outside the scope of the clinical trial exemption under 35 U.S.C. § 271(e), they currently stand poised to engage in such non-exempt activities in the very near future.[1]

There is no doubt that Defendants will infringe Amgen's patent claims, and that they at least expect to do so imminently. In the context of this case, where the District Court has jurisdiction to declare the parties' respective rights and obligations,[2] Defendants' activities are now well beyond the point where the statutory policies underlying § 271(e)(1) inexorably give way to the statutory and constitutional policies underlying the Patent Act's protection of inventors' rights of exclusivity. Under these circumstances, the Federal Circuit has determined that would-be infringers should not be allowed to eviscerate a patentee's exclusionary rights or cause the patentee to suffer irreparable harm by further delaying a declaration of the parties' respective rights under the patent.[3]

As posited at the May 10 hearing on Defendants' motion, if not now, when is the time to hear Amgen's complaint? Is it fair to defer the declaration of the parties' respective rights to a time after Defendants have entered the market and Amgen has suffered irreparable harm? Is it sensible to defer that adjudication until it can only be made on an emergency basis? Amgen respectfully submits that the time for the Court to exercise its discretion to adjudicate Amgen's claim for declaratory relief is now.

The ALJ decision does not consider highly probative evidence regarding Defendants' imminent non-exempt uses of infringing product in the U.S.

Unlike the ITC, this Court has jurisdiction under the Declaratory Judgment Act. Where,

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[1] Amgen has reason to believe Defendants have engaged in actual infringement. Although it obtained only partial and limited discovery in the ITC, it has additional reason to believe so.

[2] *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997).

as here, Defendants are engaged in "meaningful preparation" for infringing activity, the Declaratory Judgment Act empowers this Court to exercise jurisdiction to determine whether such future activity will infringe Amgen's patent claims.[4] Indeed, as the Federal Circuit made plan in *Glaxo v. Novopharm*, this Court can exercise its discretion to hear Amgen's declaratory judgment action, "even though that action [is] premised in part on actions protected under § 271(e)(1)."[5] In *Glaxo*, declaratory relief was sought three months after filing of a drug marketing application and 15 months before the date the accused infringer projected it would enter the market. The complaint alleged, in part, that the application contained sufficient data to make approval imminent and that defendant intended to market its infringing product before the expiration of plaintiff's patent. The Federal Circuit concluded that the threat of defendants entering the market "was not years away," there was no doubt that defendant intended to sell some form of the patented pharmaceutical, and that the defendant "was systematically attempting to meet the applicable regulatory requirements while preparing to import its product."[6]

Here, the Amended Complaint alleges that Defendants submitted their marketing application to FDA on April 19, 2006. The Amended Complaint alleges that they could receive FDA approval and begin marketing their peg-EPO product in the U.S. nine months from now. As evidenced by activities such as hiring sales personnel, Defendants are in the final stages of preparations to commercialize their peg-EPO product within the U.S. As further explained below, the ITC proceeding reveals that the need for prompt adjudication is even more urgent and more real than this Court has previously been informed. Thus, a controversy of "sufficient

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[3] *Id.*

[4] *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

[5] *Glaxo*, 110 F.3d at 1564 and 1571.

[6] *Id.*

immediacy and reality"[7] to justify this Court's exercise of discretion to hear this declaratory judgment action exists. The initial determination does not review these facts or decide this issue.

In submitting the ID, Defendants seek to rely on facts outside of Amgen's Amended Complaint, even though the ITC Protective Order prohibits Amgen from presenting facts discovered in the ITC action that compel denial of Defendants' motion in this Court.

Although Defendants' motion seeks dismissal of Amgen's Amended Complaint solely on the basis of the allegations in the Complaint, Defendants now seek to make "part of the district court record" and rely on contested factual assertions in their ITC briefing papers and the ALJ's initial determination. Presumably, Defendants do so in recognition of the Supreme Court's holding in *Merck KGA v. Integra Lifesciences I, Ltd.*, which establishes that § 271(e)(1) provides an affirmative defense to infringement liability on which they bear the burden of proof.[8] Defendants' attempt to rely on contested assertions of fact in support of their motion is all the more reason to grant Amgen's pending request for discovery under Fed. R. Civ. P. 56(f) to fairly meet and rebut the assertions of fact upon which Defendants now seek to rely.

Worse yet, in seeking to supplement their motion with contested assertions of fact, Defendants omit facts currently protected under the ITC Protective Order that would compel the denial of their motion. For example, the limited discovery produced by Defendants in the ITC proceeding reveals that key representations previously made by Defendants to this Court cannot be sustained. Such representations concern the date on which they expect to achieve regulatory approval, the physical characteristics of the product they hope to sell, and their respective roles and involvement in its regulatory approval and sale. Despite Amgen's repeated efforts to secure Defendants' agreement to a reasonable protective order that would make the ITC record

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[7] *Lang*, 895 F.2d at 765.

[8] *Merck KGA v. Integra Lifesciences I, Ltd.*,545 U.S.193; 125 S. Ct. 2372, 2384 n.8 (2005) (specifically endorsing jury instructions assigning burden of proof to accused infringer).

available, Defendants have refused. The interests of fairness and efficiency compel that the entire ITC record and additional missing discovery be made available in this case.[9]

Defendants' selective submission of facts and documents available to them also prejudices Amgen. Defendants assert that because the initial determination was based on Amgen's requested discovery, there is more compelling reason to grant their motion. While Defendants provided limited discovery in the ITC, they effectively blocked Amgen's discovery of many issues relevant to this proceeding. For example, Defendants fail to inform this Court that: (1) Defendants' refused to provide discovery regarding their planned use or importation of infringing product beyond June 2006; (2) Defendants refused to produce their internal forecast and plan for regulatory approval and commercial launch of peg-EPO; and (3) Defendants' counsel repeatedly obstructed depositions by instructing Defendants' witnesses not to answer questions regarding their intended use of imported product. While the ALJ granted Amgen leave to move to compel Defendants to produce this and other requested discovery, and Amgen promptly did so, Amgen's motion remains under submission and undecided. Defendants also fail to inform this Court that the ALJ's interim decision rests on extensive factual assertions and interrogatory responses served by Defendants ***after*** the close of discovery, untested factual assertions for which Amgen was effectively denied discovery before the ALJ's decision. That too is the subject of Amgen's pending motion to compel before the ALJ and its expected petition to the Commission.

Finally, Defendants' post hearing submission entreats the Court to consider facts outside

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[9] The documents, deposition testimony and interrogatory responses of Defendants were all produced to Amgen's outside counsel of record in this case subject to the ITC Protective Order. Pursuant to Commission Rule 210.5(c), such "confidential business information may be transmitted to a district court, subject to a protective order as the district court determines necessary."

of the Amended Complaint and yet Defendants fail to convert their motion to dismiss to a motion for summary judgment. Thus, Amgen's request in its opposition papers that it be allowed an opportunity to conduct discovery is all the more appropriate. Amgen therefore will submit an affidavit pursuant to Fed. R. Civ. P. 56(f). At the very least, this Court should grant Amgen leave to submit to the Court the entire factual record developed through discovery in the ITC proceeding, not merely the selective snippets chosen by Defendants.

The ITC's jurisdiction is distinct from that of this Court, and therefore, the ITC decision has no preclusive effect on any claim or issue before this Court.

The initial determination has no preclusive effect as to the claims and issues before this Court. Notably, in their Post-Hearing Memorandum, Defendants assert only that the initial determination provides "more compelling reasons" to grant their motion, not that it has any preclusive effect. Although "[t]he district court can attribute whatever persuasive value to the prior ITC decision that it considers justified,"[10] the decisions of this administrative agency involving patent issues have no claim or issue preclusion effect in this Article III Court.[11] Moreover, as discussed above, because the initial determination fails to address issues and evidence relevant to this Court's jurisdiction under the Declaratory Judgment Act, it has no persuasive value on the issue presented in Defendants' motion.

Conclusion

Defendants have clearly set sail to leave the § 271(e)(1) safe harbor, and are now subject to this Court's declaratory judgment jurisdiction. Amgen respectfully submits that this Court

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[10] *Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996).

[11] *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996); *Texas Instruments*, 90 F.3d at 1568-69.

should exercise that jurisdiction now, deny Defendants' motion to dismiss, and declare the parties' respective rights in this controversy.

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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July 13, 2006

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on July 13, 2006.

/s/ Michael R. Gottfried
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