Case 1:05-cv-12237-WGY

Filed 07/06/2007

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

| AMGEN INC., |)) |
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| Plaintiff, |) |
| V. |)) CIVIL ACTION No.: 05-CI-12237WGY |
| F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. |))) |
| Defendant. |)) |

ROCHE'S MOTION PURSUANT TO FED. R. CIV. P. 56(f) FOR RELIEF FROM AMGEN'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

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Dated: New York, New York July 6, 2007

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Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") hereby moves under Fed. R. Civ. P. 56(f) for relief from Amgen Inc.'s Motion For Summary Judgment Of No Inequitable Conduct. Roche has already filed an opposition to Amgen's summary judgment motion (Docket 633). In the alternative, Roche also moves under Rule 56(f) as an independent basis for denying Amgen's summary judgment motion. At the April 17, 2007 Markman Hearing, the Court granted in part Roche's motion to compel the further testimony of Amgen's prosecuting attorney, Michael Borun. Since then, Amgen resisted producing Mr. Borun, and as a result, Roche was once again forced to move the Court on this issue (Docket 496). Just yesterday, on July 5, 2007, the Court ordered Amgen to produce Mr. Borun within 14 days for a 7 hour deposition on topics 49 and 50 from Roche's Appendix materials of its original motion.

As detailed in Roche's Opposition to Amgen's motion for summary judgment, one of Roche's allegations of inequitable conduct is that Amgen's prosecuting attorneys affirmatively misstated to the Patent Examiner the differences in the structure and molecular weight between urinary erythropoietin (which was in the prior art) and recombinant erythropoietin (which was being claimed). *See* Roche's Opposition to Amgen's Motion of Summary Judgment of No Inequitable Conduct, at 9-14 (Docket No. 633).

By its April 17, 2007 and July 5, 2007 Orders, the Court has allowed Roche the opportunity to take the deposition of Mr. Borun, one of Amgen's prosecuting attorneys of the patents-in-suit, on this very subject. Topics 49 and 50, which the Court granted leave for discovery, relate to data within the patents which purported to show glycosylation differences between urinary erythropoietin ("uEPO") and recombinant erythropoietin ("rEPO"). *See* Roche's Memorandum In Support of its Motion To Compel, Appendix A (Docket 338). The Court stated

that Roche should be given an opportunity to find out where Mr. Borun received that data and when. Discovery into these matters are germane both to materiality and intent, because Roche should be allowed to discover whether Mr. Borun knew he was providing incorrect data on differences between uEPO and rEPO to the Patent Office as a basis for overcoming prior art. Such discovery is sufficient to defeat Amgen's summary judgment motion, because at minimum, it would create an issue of fact regarding Amgen's representations to the Patent Office.

Before granting summary judgment, the Court must first ensure that there is no reasonable version of the material disputed facts under which the non-movant could prevail and that judgment is correct as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250; 106 S.Ct. 2505; 91 L.Ed.2d 202 (1986). Because of the dispositive nature of such motions, the Supreme Court has cautioned against the "railroading" of parties by the filing of premature summary judgment motions before the non-moving party has had an adequate opportunity to make full discovery on the disputed issues. Celetex Corp. v. Catrett, 477 U.S. 317, 322; 106 S.Ct. 2548; 91 L.Ed.2d 265 (1986). The First Circuit has noted the critical importance of the need for discovery in the context of summary judgment motions. See e.g. Carmona v. Toledo, 215 F.3d 124, 132-133 (1st Cir. 2000). Accordingly, summary judgment before discovery has begun should only be granted in the clearest of cases. De La Fuenta v. DCI Telecommunications, Inc., 206 F.R.D. 369, 387 (S.D.N.Y. 2002). In order to protect parties against "judges swinging the summary judgment axe too hastily," Rule 56(f) provides parties with a safety valve where they are genuinely in need of further time to marshal the facts essential to their opposition to a summary judgment motion. Resolution Trust Corp. v. North Bridge Assoc's, Inc., 22 F.3d 1198, 1204 (1st Cir. 1994).

According to First Circuit precedent, there are four criteria for the granting of relief under Rule 56(f): authoritativeness and timeliness, good cause, utility and materiality. *Morrissey v. The*

Boston Five Cents Savings Bank, 54 F.3d 27, 35 (1st Cir. 1995); Resolution Trust, 22 F.3d at 1203. Although it may not be necessary to demonstrate all four requirements, the satisfaction of all four give rise to a strong presumption in favor of relief. Reid v. State of New Hampshire, 56 F.3d 332, 341 (1st Cir. 1995); Resolution Trust, 22 F.3d at 1203. Courts should further construe motions under Rule 56(f) generously, and unless the court reasonably concludes that the motion is a stalling tactic or an exercise in futility it should be treated liberally. Resolution Trust, 22 F.3d at 1203; United States v. One Lot of U.S. Currency (\$68,0000), 927 F.2d 30, 33-34 (1st Cir. 1991). It is respectfully submitted that Roche's motion meets the requisite standard for the granting of the relief requested.

A Rule 56(f) motion is authoritative when it is support by an affidavit signed by a person who possesses firsthand knowledge and who is competent to address the specifics of the matters discussed. *Resolution Trust*, 22 F.3d at 1204. Such affidavit may acceptably take the form of written representations of counsel. *Paterson-Leitch Co. v. Massachusetts Mun. Wholesale Elec. Co.*, 840 F.2d 985, 988 (1st Cir. 1988). Roche respectfully refers to the Court to the attached Declaration of Thomas F. Fleming as support for this motion.

There is no fixed time limit for filing a motion under Rule 56(f). Accordingly, the First Circuit has held that such motions must be filed within a reasonable time following receipt of a motion for summary judgment. *Resolution Trust*, 22 F.3d at 1204. Roche has not been dilatory in filing this motion, but have acted promptly and within the spirit of the Rule. Indeed, the Court only yesterday ordered Mr. Borun's continued deposition because of Amgen's dilatory tactics. Accordingly, Roche's motion has been filed at the earliest convenient moment and should be considered timely.

The good cause requirement is readily satisfied here. Because of Amgen's delay and obstructionist tactics at deposition, the Court has allowed the continued deposition of Mr. Borun, who was one of Amgen's prosecuting attorneys. Therefore, discovery on certain inequitable conduct issues are still ongoing and provide the basis for Roche's Rule 56(f) motion. This is precisely the type of circumstance that Rule 56(f) was designed to prevent. See e.g. Anderson, 477 U.S. at 250 note 5 ("Rule 56(f)'s provision [requires] that summary judgment be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition").

The utility requirement tests whether the moving party has presented a plausible basis for a belief that discoverable materials exist that would likely suffice to raise a genuine issue of material fact, and thus defeat summary judgment. Resolution Trust, 22 F.3d at 1206. As the Declaration of Thomas F. Fleming clearly sets out, Mr. Borun's deposition is likely to uncover the source and circumstances surrounding the inclusion of false data within the patent application. This data, which allegedly shows structural differences in glycosylation between uEPO and rEPO, was put forth before the examiner as one of the bases for overcoming prior art. If this data was submitted with the knowledge that it was false, this would demonstrate a genuine issue of fact regarding both materiality and intent, which weighs heavily in favor of relief under Rule 56(f). Vivid Tech., 200 F.3d at 809; *Reid*, 56 F.3d at 342

Materiality for the purposes of Rule 56(f) means material to the issues raised on summary judgment. Resolution Trust, 22 F.3d at 1207. The facts that the movant seeks to discover must be foreseeably capable of breathing life into their claim or defense. Resolution Trust, 22 F.3d at 1207. Here, Roche seeks discovery directly relevant to the issues of inequitable conduct as set out in the Declaration of Thomas F. Fleming. Because such discovery is likely to show that Amgen or

its representatives knowingly submitted false data to the Patent Office, such discovery will "breath life" into Roche's inequitable conduct defense.

Based on the foregoing, Roche requests that its Rule 56(f) Motion For Relief be granted and Amgen's motion for summary judgment of no inequitable conduct be denied.

Dated: July 6, 2007

New York, New York

Respectfully submitted,

F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc.

By their Attorneys,

/s/ Thomas F. Fleming

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ *Thomas F. Fleming* Thomas F. Fleming