UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFF FROM ARGUING THAT THE GOLDWASSER CLINICAL STUDY IS NOT PRIOR ART

Defendants' F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") respectfully move that the Court preclude Amgen from arguing that the Goldwasser clinical study is not prior art. Amgen is likely to raise the same argument in this case — that the Goldwasser clinical study is not prior art because it was allegedly unavailable to the public — as it has in its current litigation against Hoechst Marion Roussel.[1] Issue preclusion prevents Amgen from re-litigating these issues, and doing so would violate the both *stare decisis* and the Court's rulings in this case.

Under the doctrine of issue preclusion (collateral estoppel), Amgen is prohibited from re-litigating issues that have already been decided where the following factors are met: "(1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the

[1] Civil Action No. 97-10814-WGY D.I. 863 p. 36-37 (Arguing that the Goldwasser clinical study was unavailable to the public because Illinois patient confidentiality law required the results of the study to remain confidential.).

party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action. *Amgen, Inc. v. F. Hoffmann La-Roche Ltd.*, 454 F. Supp. 2d 54, 59 (D. Mass. 2007).

Each factor is clearly met here. This Court correctly held that "Amgen was a party in a previous case before this Court which construed many of the patent claims at issue here, and it had a full and fair chance to assert its arguments at that time. Thus, Amgen is barred from re-litigating the claims that were subject of that previous patent suit." *Amgen, Inc. v. F. Hoffmann La-Roche Ltd*, 454 F. Supp. 2d at 60. The identical issue present in both cases, the prior art status of the Goldwasser clinical study, has already been fully litigated and decided. In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 111 (D. Mass. 2001), Amgen argued that Goldwasser's clinical study was not prior art, and this Court held "[f]or the same reasons that the Court rejected Amgen's attack on [other prior art], the Court rebuffs this attack as well. Because the documents submitted as exhibits in this case reveal that Dr. Goldwasser began this clinical study in 1979-1980 at the University of Chicago in Illinois . . . it predates Amgen's patent application." *Id.* The Federal Circuit concurred, saying "[i]f the claim term 'therapeutically effective' encompasses the patient responses described in the specification, as it appears to us it does, then the Goldwasser study may constitute invalidating prior art under §102(a) or §103 even if he did not achieve his intended result." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003). The prior art status of the Goldwasser study was essential to the judgment, and Amgen was a party to the Hoechst case. Thus, all four factors for issue preclusion are met, and Amgen should be precluded from re-litigating the prior art status of the Goldwasser clinical study.

If Amgen does try to re-litigate this issue it will be contradicting this Court's ruling and violating stare decisis. "*Stare decisis* is the preferred course because it promotes evenhanded,

predictable, and consistent development of legal principals, fosters reliance on judicial decisions, and contributes to the actual and perceived integrity of the judicial process." *Payne v. Tenn.*, 501 U.S. 808, 827 (1991). Amgen litigated this issue in a lawsuit regarding infringement of the same patents at issue in the present litigation and in the same Court. Whatever arguments Amgen failed to raise previously before this Court and the Federal Circuit are waived. Moreover, should Amgen be allowed to press their arguments, they would be in conflict with the purpose of an analogous doctrine, the law of the case, which, similar to collateral estoppel, limits the ability to re-litigate an issue once it has been decided. The doctrine of law of the case "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Christianson et al. v. Colt Inds. Operating Corp.*, 486 U.S. 800, 815-16 (1988). The law of the case doctrine "promotes the finality and efficiency of the judicial process by 'protecting against the agitation of settled issues'." *Id.* at 816 (1988) (quoting Moore's Federal Practice P0.404[1], p. 118 (1984)). As the Supreme Court said in *Christianson*, while a court has the power to revisit prior decisions of its own "as a rule courts should be loathe to do so in absence of extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice'." *Id.* at 817 (quoting *Arizona v. California*, 460 U.S. 605, 618 n.8, 75 L.Ed. 2d 318, 103 S. Ct. 1382 (1983)). The current litigation is analogous; Amgen seeks to revisit an issue already decided by the Court. Roche respectfully requests that the Court not allow Amgen to re-litigate these prior rulings.

For the foregoing reasons, Defendants request that this Court preclude Amgen from arguing that the Goldwasser clinical study is not prior art.

Dated: September 10, 2007

Respectfully submitted,

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

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