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

MEMORANDUM IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM OFFERING ARGUMENTS AND EXPERT TESTIMONY ON OBVIOUSNESS-TYPE DOUBLE PATENTING THAT IT FAILED TO DISCLOSE IN ITS INTERROGATORY RESPONSES AND EXPERT REPORTS

Pursuant to Federal Rule of Evidence 702 and Federal Rules of Civil Procedure 26 and 37, Amgen should be precluded from offering any opinion or additional evidence on obviousness-type double patenting that was not properly disclosed in Amgen's interrogatory responses or in Dr. Lodish's expert reports. In particular, Amgen should be precluded from:

- arguing that the '698 and '868 claims are patentably distinct merely on grounds that they recite other claim limitations not present in the '008 claims
- offering any additional evidence to rebut Roche's ODP theory 3[1] beyond its argument that the '698 and '868 claims are patentably distinct by requiring *in vivo* biological activity.

I. ARGUMENT

Amgen's contentions rebutting Roche's ODP theory No. 3 appear in only three places:

[1] *See* D.N. 966 ("Roche maintains that the '008 patent claims can render obvious the '868 and '698 process claims ("Theory No. 3")").

Amgen's Response to Roche's First Set of Interrogatories, Amgen's Supplemental Response to Roche's First Set of Interrogatories and in Dr. Lodish's expert reports. The only contention Dr. Lodish discusses at any length is his argument that the '698 and '868 patents are not invalid for ODP over the claims of the '008 patent, because the later issued '698 and '868 claims recite a "positive requirement" that the product of the claimed process has *in vivo* biological activity.[2] In support of Amgen's other contentions regarding ODP theory no. 3, Dr. Lodish provides nothing more than a conclusory statement, which he fails to support with any factual evidence. ("Exhibit G contentions").[3] For example, Dr. Lodish asserts that:

> '698 claim 5 recites the term "wherein said promoter DNA is viral promoter DNA." There is no equivalent limitation in any '008 claim.
>
> '698 claim 6 recites the term "comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6." There is no equivalent limitation in any '008 claim.
>
> '698 claim 7 recites the term "further comprise amplified marker gene DNA." There is no equivalent limitation in any '008 claim.[4]

If Dr. Lodish is called to testify on ODP, he can be expected to opine that the claims of the '698 and '868 patents are not invalid based on these additional Exhibit G contentions.

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[2] *See* Lodish May 11, 2007 Rebuttal Report ¶ 422, attached as Exhibit 1 to the accompanying Declaration of Patricia A. Carson in support of Roche's Motion in Limine to Preclude Amgen From Offering Arguments and Expert Testimony On Obviousness-Type Double Patenting That It Failed To Disclose In Its Interrogatory Responses And Expert Reports ("Carson Decl.").

[3] These contentions are listed in Exhibit G to Lodish's May 11, 2007 Rebuttal Report, attached as Ex. 2 to the Carson Decl., at ¶¶ 25-38.

[4] *See* Ex. 2 to the Carson Decl. (Lodish Rebuttal Report, Exhibit G) ¶¶ 35-37. Using similar conclusory language, Lodish states that '868 claims 1 and 2 and '698 claims 4-9 are patentably distinct from the '008 patent because they are to processes, not products; that '698 claims 4-9 are patentably distinct from the '008 patent because they do not require transfected isolated and purified EPO or EPO analog DNA; and that '698 claims 4-9 are patentably distinct because they recite additional claim limitations not present in the '008 claims such as promoter DNA (claim 4) and DHFR gene DNA (claim 8). See *Id*. ¶¶ 25-38.

However, the mere conclusion that certain claim limitations of the '698 and '868 patent have "no equivalent limitation" in the '008 patent is legally insufficient to find the claims patentably distinct:

> [The] analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination." *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). . . . [T]he factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103 are employed when making an obvious-type double patenting analysis.

MPEP § 804(II)(B)(1) (8th ed. rev. 4, Oct. 2005).[5]

A finding that the later issued '698 and '868 claims are patentably distinct from the '008 claims can only be made by demonstrating that any alleged differences between the later issued claims and the '008 claims (in particular any additional claim elements that Dr. Lodish alleges have no equivalent in the '008 claims) would not have been obvious to a person of ordinary skill at the time of Dr. Lin's alleged invention.[6] *See* MPEP § 804(II)(B)(1) (8th ed. rev. 4, Oct. 2005). This analysis must also take into account the prior art and any secondary considerations of nonobviousness. *Id*. Such evidence is entirely missing from Dr. Lodish's flawed analysis and from Amgen's interrogatory responses.

A. Dr. Lodish Should Be Precluded Under *Daubert* from Offering Unreliable Opinions Based on Speculation and Subjective Belief

Federal Rule of Evidence 702 permits the use of "scientific, technical or other specialized knowledge . . . [to] assist the trier of fact to understand the evidence or to determine a fact in issue." *Sutera v. Perrier Group of Am.*, 986 F. Supp. 655, 660 (D. Mass. 1997) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)). In evaluating expert testimony under Rule

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[5] Roche also respectfully directs the Court's attention to Defendants' objections to the Court's September 7, 2007 order, wherein Roche discusses in further detail the factual issues that underlie a determination of ODP. *See* D.N. 1022.

702, courts should assess the underlying reasoning or methodology. *Daubert*, 509 U.S. at 592-93. Should the court find that methodology flawed, it may preclude the testimony. *See, e.g.*, *Sutera*, 986 F. Supp. 655.

Dr. Lodish concludes that by incorporating certain additional claim elements (e.g., promoter DNA, viral promoter DNA, amplified marker DNA, or DHFR gene DNA) the '698 and '868 claims are patentably distinct over the '008 claims. However, Dr. Lodish fails to provide any explanation as to why incorporation of these further limitations would have rendered the claims as a whole non-obvious over the '008 claims. Strikingly missing from Dr. Lodish's purported analysis is any reference to or analysis of the relevant prior art.

Dr. Lodish's additional Exhibit G contentions are therefore unsupported by proper methodology and as a result should be excluded in their entirety. *See Sutera*, 986 F. Supp. at 661 ("the expert's opinion [must] be based on the methods and procedures of science rather than on subjective belief or unsupported speculation."). Moreover, an expert's conclusions must take account of the relevant law. *See Leverette v. Louisville Ladder Co.*, 183 F.3d 339, 341 (5th Cir. 1999) (because the expert's scientific analysis failed to account for the relevant legal standards, the testimony was inadmissible as it was not relevant). As Dr. Lodish failed to provide proper evidentiary bases for his additional ODP contentions, Amgen should be precluded under *Daubert* from presenting such testimony.

[6] Amgen has conceded that its '698 and '868 claims are not protected by § 121. *See* D.N. 1035.

B. Amgen Should Be Precluded from Improperly Supplementing its ODP Contentions Under Fed. R. Civ. P. Rules 26 and 37

Moreover, Amgen should be precluded from supplementing its ODP contentions with additional evidence and arguments that it failed to properly disclose through Dr. Lodish or through its interrogatory responses. Federal Rule of Civil Procedure 26(a)(2)(B) provides, in relevant part, that:

> The [expert] report shall contain a complete statement of all opinions to be expressed **and the basis and reasons therefor**; [and] the data or other information considered by the witness in forming the opinions . . . .

(emphasis added). As the Advisory Committee Notes explain, experts who fail to provide full disclosure are ordinarily precluded from offering testimony on the omitted evidence:

> Paragraph (2)(B) requires that persons retained [as experts] must prepare a detailed and complete written report, stating the testimony the witness is expected to present during direct examination, together with the reasons therefore . . . . Revised Rule 37(c)(1) provides an incentive for full disclosure; namely, that a party will not ordinarily be permitted to use on direct examination any expert testimony not so disclosed.

Advisory Committee Notes on the 1993 Amendments.

The general consequence of failure to comply with the disclosure requirements is exclusion of the offending testimony or evidence. *Gagnon v. Teledyne Princeton, Inc*., 437 F.3d 188, 191 (1st Cir. 2005) ("the required sanction in the ordinary case is mandatory preclusion"); *see also Omegaflex*, 425 F. Supp. 2d at 184 ("More often than not, mandatory preclusion is the required sanction."); *Alvez v. Mazda Motor of Am., Inc*., 448 F. Supp. 2d 285, 293 (D. Mass. 2006) (Wolf, J.).[7]

Dr. Lodish fails to provide the basis and reasons for his opinions, and therefore he should be precluded from offering such unsupported testimony. *See, e.g., Cell Genesys, Inc. v. Applied*

[7] Issues of civil procedure are not unique to patent law, and accordingly the law of the First Circuit applies. *See Omegaflex, Inc. v. Parker Hannifin Corp*., 425 F. Supp. 2d 171, 184 n.21 (D. Mass. 2006) (citing *Chimie v. PPG Indus., Inc*., 402 F.3d 1371, 1376-77 (Fed. Cir. 2005).

Research Sys. ARS Holding, N.V., 499 F. Supp. 2d 59, 2007 WL 2296771, (D. Mass. Aug. 13, 2007) (Wolf, J.) (precluding expert from offering opinion on obviousness of patents where opinion was not properly disclosed in her expert report, under Rules 26(a)(2)(B) and 37(c)(1)). Moreover, in its interrogatory responses, Amgen also failed to provide any further basis for these Exhibit G contentions. Amgen should therefore be precluded from doing so now.

C. Roche Will be Seriously Prejudiced if Amgen is Permitted to Introduce Additional Evidence

Roche will be seriously prejudiced if Amgen is permitted to ambush it with additional expert opinion testimony or evidence not disclosed in Dr. Lodish's expert reports. Amgen has had ample opportunity to develop its ODP contentions and to disclose them in any of Dr. Lodish's four validity reports, submitted on May 11th, June 4th, June 20th, and June 25th. Instead, Amgen has deprived Roche of the opportunity to cross-examine Dr. Lodish on his opinions, and of the ability to respond with testimony from Roche's own experts. This is exactly the type of litigation gamesmanship and prejudice that Rules 26(a) and 37(c)(1) were intended to prevent:

> The Civil Rules provide for extensive pretrial disclosure of expert testimony . . . consonant with the federal courts' desire to 'make a trial less a game of blindman's bluff and more a fair contest with the basic issues and facts disclosed to the fullest practical extent' . . . . For Rule 26 to play its proper part in this salutary scheme, discovery must not be allowed to degenerate into a game of cat and mouse.

Thibeault v. Square D. Co., 960 F.2d 239, 244 (1st Cir. 1992) (internal citations omitted).

II. CONCLUSION

For the foregoing reasons, Roche respectfully requests that Amgen be precluded from: (1) arguing that the '698 and '868 claims are patentably distinct by merely reciting other claim limitations not present in the '008 claims; and (2) offering any additional evidence to rebut Roche's ODP theory 3 beyond its argument that the '698 and '868 claims are patentably distinct by requiring *in vivo* biological activity.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement was reached.

DATED: Boston, Massachusetts
October 3, 2007

Respectfully submitted,

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

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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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