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

ROCHE'S BENCH MEMORANDUM IN RESPONSE TO AMGEN'S BENCH MEMORANDUM REGARDING THE ADMISSIBILITY OF POST-FILING EVIDENCE OF STRUCTURAL AND FUNCTIONAL DIFFERENCES

In its "Bench Memorandum Regarding Admissibility of Post-filing Evidence of Functional and Structural Differences to Rebut Roche's Invalidity Allegations" (D.N. 1235), Amgen contends that the court should admit into evidence "Dr. Strickland's proffered laboratory notebooks, as well as Catlin's experiments," without any sponsoring witness. Today Amgen has rested its validity case and so has waived the right to move to admit any additional documents from Dr. Catlin or Dr. Strickland. In addition, today the Court ruled Dr. Catlin's image of a gel experiment, Exhibit FTF, inadmissible. It is unclear what, if anything else, from "Dr. Catlin's experiments" Amgen was seeking to admit in its bench memorandum. However, Roche submits this bench memorandum to briefly respond to Amgen's arguments regarding the admissibility and relevance of such documents. Roche points out the following:

- Amgen has failed to authenticate and lay a proper foundation for Dr. Strickland's lab notebooks and Dr. Catlin's alleged experiments.

- Well-established law makes clear that an inventor cannot rely on post-filing-date tests (like those purportedly detailed in Dr. Strickland's lab notebooks and Dr. Catlin's alleged experiments) to rebut invalidity; and

- Comparisons with a specific embodiment of commercial EPO--like those that Drs. Strickland and Catlin claim to have done--are completely irrelevant to the prior art analysis.

I. Amgen Has Failed to Authenticate or Lay a Foundation for Dr. Strickland's Notebooks and Dr. Catlin's Alleged Experiments

Amgen has failed to lay a proper foundation for the unidentified "Dr. Catlin's experiments" that it seeks to admit. In fact, the trial testimony thus far on these "experiments" shows that there is neither foundation for their admission, nor proper authentication of these "experiments." Indeed, the September 25, 2007 trial testimony of Dr. Catlin failed to establish that such experiments were even performed, let alone that they were reliable or relevant. In fact, Dr. Catlin testified that he did not personally conduct these experiments (Catlin 1386:9-13). Dr. Catlin also testified that there were other results of these experiments that were not disclosed. (Catlin 1404:13-22).

Likewise, Dr. Strickland testified that many of the contents of his notebooks were "pasted in" from other sources. (Strickland 2115:14 - 2116:6; 2117:8-17; 2134:9 - 2135:1). Because Amgen has failed to offer competent trial testimony authenticating these notebooks, they should not be admitted.

II. Post-Filing-Date Tests Cannot Rebut Invalidity

A product by process claim cannot be distinguished from the prior art based on properties that are not set forth in the claims or the specification. *See Smithkline Beecham Corp. v. Apotex, Corp.*, 2002 U.S. Dist. LEXIS 25275, *22 (E.D. Pa. Dec. 20, 2002). Consistent with this principle, evidence of invalidity cannot be rebutted by methods of analysis not available at the time the patents were filed. This principle is manifested throughout the validity provisions of

the Patent Statute. 35 U.S.C. § 103(a) provides "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious *at the time the invention was made* to a person having ordinary skill in the art . . ." (emphasis added). The relevant question for anticipation is "whether all the claim limitations in the patent at issue were, expressly or inherently, present in a single prior art reference, as understood by a person of ordinary skill in the art, *at the time the patent application was filed.*" *Scanner Tech. Corp. v. ICOS Vision Sys. Corp., N.V.,* 253 F. Supp. 2d 624, 639 (S.D.N.Y. 2003) (emphasis added). Thus, in analyzing prior art, courts must focus only on the state of knowledge at the time of the invention--not some later time. *See, e.g., In re Merck & Co., Inc.,* 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("[T]he test [for obviousness] is whether the references, taken as a whole, would have suggested appellant's invention to one of ordinary skill in the medicinal chemical arts at the time the invention was made."); *Elf Atochem N. Amer., Inc. v. LaRoche Indus., Inc.,* 85 F. Supp. 2d 336, 343 (D. Del. 2000) (Patent challenger "must show that the references, taken as a whole, would have suggested [patentee's] invention to one of ordinary skill in the chemical arts at the time the invention was made."). When addressing validity under 35 U.S.C. §112, court have been even more specific, stating that "to satisfy the statute, there must have been a test available at the time of the filing of the patent application which could have been employed by a person skilled in the art to which the patent applies." *Nat'l. Research Dev. Corp. v. Great Lakes Carbon Corp.* 410 F. Supp. 1108, 1124 (D. Del. 1975). In short, technology developed *after the time of invention* --like the tests allegedly detailed in the Strickland lab notebooks and the "Catlin experiments" are not relevant to the prior art analysis because they cannot possibly be imputed to one of ordinary skill *at the time of invention.*

III. Alleged Differences Between Specific Embodiments of Commercial EPO and Prior Art EPO Are Legally Irrelevant

Amgen's argument as to why the Strickland notebooks and "the Catlin experiments" are relevant is inherently flawed. Amgen's claims are directed to any EPO glycoproteins that can be produced in any mammalian host cells, under any conditions, in any populations, with any specific activity, and purified in any way. As Dr. Varki testified, Amgen's claims cover potentially thousands of different glycoforms. (*See, e.g.,* Varki 2247:1-23). Even if, *arguendo*, Amgen could prove that the specific commercial EPO preparations allegedly tested by Drs. Strickland and Dr. Catlin differed from the prior art EPO, this would be wholly irrelevant to the question at issue -- namely, whether the invention claimed in Amgen's patents (i.e., all EPO glycoforms under all circumstances) differs from the prior art EPO.

For all of the foregoing reasons, Dr. Strickland's notebooks and Dr. Catlin's alleged experiments should not be admitted into evidence.

DATED: Boston, Massachusetts
October 3, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Nicole A. Rizzo
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
Kimberly J. Seluga (BBO# 667655)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
nrizzo@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

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/s/ Nicole A. Rizzo
Nicole A. Rizzo

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