UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S MOTION *IN LIMINE* TO EXCLUDE THE FACT TESTIMONY AND EXPERT TESTIMONY OF DR. CATLIN ON THE BASIS THAT ATHLETE DOPING IS IRRELEVANT TO ANY ISSUE IN THIS CASE

The testimony of Dr. Catlin, who is ostensibly offered by Amgen as a "fact" witness should be excluded for at least the following reasons:

(i) Any facts that Dr. Catlin arguably has personal knowledge about, i.e., tests developed sixteen years after the filing date of Amgen's patent to detect illicit doping by athletes, are completely irrelevant to any issue in this case.

(ii) To the extent that Amgen attempts to improperly introduce expert testimony through Dr. Catlin, the only area that Dr. Catlin would properly qualify as an expert in--detecting illicit doping by athletes- is irrelevant to this case.

(iii) By his own admission, Dr. Catlin has no background, experience or training in carbohydrate chemistry and as such, he is not qualified to testify as an expert regarding any purported differences in glycosylation between uEPO and rEPO.

I. Dr. Catlin's Factual Testimony Is Irrelevant To Any Issue In This Case

Dr. Catlin's testimony pertains solely to "anti-doping" tests developed "to catch athletes who used an EPO." (Transcript of Deposition of Dr. Don Catlin at 95:12-17, dated June 14,

2007). According to Dr. Catlin's expert report, using methodology that was developed in the year 2000, he compared certain urinary EPO samples with a panel of commercial EPO products.[1] The issue in this litigation is whether the pharmaceutical formulation and use of Dr. Goldwasser's prior art urinary EPO to treat patients anticipates or renders obvious certain of the asserted claims. A test addressing this issue must compare the prior art with the proper scope of the claims. Critically, Dr. Catlin never tested Dr. Goldwasser's prior art uEPO, and the panel of commercial EPO products tested are not commensurate with the scope of the claims in this litigation. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) ("Under s 103 . . . differences between the prior art and the *claims* at issue are to be ascertained . . . .") (emphasis added); *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001) ("To anticipate, every element and limitation of the *claimed* invention must be found in a single prior art reference, arranged as in the claim.") (emphasis added); *Jackson Jordan, Inc. v. Plasser American Corp.*, 747 F.2d 1567, 1578 (Fed. Cir. 1984) ("The *claims*, not particular embodiments, must be the focus of the obviousness inquiry.") (emphasis in original). Here, the claims at issue are not limited to commercial preparations of EPO, such as those tested by Dr. Catlin. They are much, much broader, covering any EPO molecule that can be produced by any mammalian cell, grown under any culture conditions and purified by any technique. Consequently, Dr. Catlin's tests are fatally flawed.

Even if Dr. Catlin had tested relevant samples and used technology available in 1984, his tests would still have no relevance. Dr. Catlin testified repeatedly at his deposition that his tests do not provide any information regarding the molecular structure of uEPO and rEPO

[1] Roche has not submitted the transcript of Dr. Catlin's deposition or a copy of Dr. Catlin's Expert Report to the Court for review because they have been designated by Amgen as confidential. Roche does not wish to burden the Court with a potential motion to file under seal. If the Court wishes to review these documents in order to rule on this motion, Roche will make them available pursuant to the Court's procedures for *in camera* review.

samples tested. (Transcript of Deposition of Dr. Don Catlin at 35, 36, 67, 70-71, 95, 96, dated June 14, 2007). As such, his tests (even if reliable, which, as discussed below, they were not) are *incapable* of generating any data relevant to a proper comparison between the asserted claims and the relevant prior art. Therefore, since Dr. Catlin's tests show nothing about molecular structure, his tests and testimony are irrelevant on this basis as well. In short, Dr. Catlin's tests do not and can not provide any information relevant to the issues in this case.

Dr. Catlin's testimony is not only based on irrelevant tests, but the evidence demonstrates that those tests are unreliable. Dr. Catlin supervised merely one hour of the 2 ½ day test that he purports to have personal knowledge of. (Transcript of Deposition of Dr. Don Catlin at 108, dated June 14, 2007). He did not know the content of all of the EPO samples tested. (Catlin Expert Report ¶¶ 51-56, dated May 11, 2007.) Nor had he ever run this type of test before. (Transcript of Deposition of Dr. Don Catlin at 29, 20, 44-45, dated June 14, 2007). Dr. Catlin admitted to running the test two or three times, and discarding those results, omitting them from his report. (Transcript of Deposition of Dr. Don Catlin at 108-111, dated June 14, 2007). Thus, Dr. Catlin's reports and testimony are not the product of reliable principles and methods and should be excluded on this basis as well. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) ("…under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable."). *See Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 69 (D. Mass. 2000) (Stearns, J.) (expert opinion based on speculation rather than investigation properly excluded).

II. Dr. Catlin's Expertise is Irrelevant to this Case

Although Amgen attempts to circumvent the ten expert limit in this case by listing Dr. Catlin as a fact witness in its pretrial papers, Amgen now betrays its true purpose stating that he "is uniquely qualified to testify as an expert regarding the structural differences between

recombinant and urinary EPO." (*See* D.I. 1083 at 2). Yet Dr. Catlin testified repeatedly in his deposition that his tests do not provide *any* information regarding the molecular structure of the uEPO and rEPO samples tested and that he is in no way an expert on this subject. (Transcript of Deposition of Dr. Catlin at 35-36, 67, 70-71, 74-75, 95, 96, dated June 14, 2007). In fact, Dr. Catlin candidly describes his *only* area of expertise stating in his expert report--"for more than 25 years, I have devoted my practice and research to detecting illicit doping by athletes." (Catlin Expert Report ¶ 3, dated May 11, 2007). Expert testimony must assist the trier of fact, and before admitting such testimony, the court must determine that it is relevant. *Daubert*, 509 U.S. at 589. Dr. Catlin's expertise lies in developing and performing tests to detect whether athletes are doping, which is irrelevant to this case. (Transcript of the Deposition of Dr. Catlin at 70, 95, dated June 14, 2007).

Moreover, Dr. Catlin's expert report submitted "in support of the validity" of the patents-in-suit is not based on any proper legal framework. He has not read any of the patents-in-suit and does not understand the relevance of his tests to the validity of the patents-in-suit. (Catlin Expert Report ¶ 19, dated May 11, 2007; Transcript of the Deposition of Dr. Catlin at 95-96, dated June 14, 2007.) Thus, Dr. Catlin was engaged by Amgen to perform a task for which he had no qualifications and offer opinions for which he has no basis.

Accordingly, for the reasons stated above, Roche respectfully requests that the Court grant its motion to exclude the fact and expert testimony of Dr. Don Catlin.

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 could be reached.

Dated: September 21, 2007
Boston, Massachusetts

Respectfully submitted,

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