UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| 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' MEMORANDUM IN OPPOSITION TO AMGEN INC.'S MOTION TO STRIKE UNTIMELY EXPERT TESTIMONY REGARDING AMGEN'S MOTION FOR SUMMARY JUDGMENT OF NO OBVIOUSNESS-TYPE DOUBLE PATENTING**

Amgen's motion must be denied because: (1) Roche had "substantial justification" to rely upon paragraph 5 of the declaration of Dr. Harlow in opposition to Amgen's motion for summary judgment because this portion of Dr. Harlow's declaration rebuts Amgen's improperly submitted new opinion in Dr. Bradshaw's declaration in support of Amgen's motion; and (2) Dr. Lowe's declaration in opposition to Amgen's Motion for Summary Judgment contains no new evidence not previously disclosed.

**A. Dr. Harlow's Declaration Rebuts New Evidence in Dr. Bradshaw's Declaration**

In support of its Motion for Summary Judgment of No Obviousness-Type Double Patenting (hereinafter "Motion for Summary Judgment"), Amgen submitted a new opinion of Dr. Ralph A. Bradshaw, one not found in his expert report. Declaration of

Ralph A. Bradshaw, Ph.D. in Support of Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting ("Bradshaw Decl."), Docket Item ("D.I.") 504. Roche responded to the motion with a well-supported rebuttal opinion from Dr. Edward Harlow. Second Declaration of Dr. Edward Everett Harlow, Jr., in Support of Defendants' Opposition to Amgen Inc.'s Motion for Summary Judgment of No Obviousness-Type Double Patenting ("Harlow Decl."), D.I. 569. Amgen seeks to strike one paragraph of Dr. Harlow's opinion (paragraph 5) because it was not in his expert report. Harlow's expert report, however, was served on Amgen months before receipt of Dr. Bradshaw's new opinion. *See* Ex. A,[1] Expert Report of Dr. Edward Everett Harlow, Jr. ("Harlow Report"), served on April 6, 2007. In ruling on summary judgment, the Court should consider all of the evidence and testimony of the experts. But if the Court determines that it should strike the new expression of an opinion from one side, then the new opinion of the other side's expert should be struck as well.

Obviousness-type double patenting involves a determination of whether *later-issued* claims are obvious in light of *earlier-issued* claims. *See, e.g., In re Longi*, 759 F.2d 887 (Fed. Cir. 1985); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Experts for both parties addressed this dispositive issue in their expert reports.

Not until filing its Motion for Summary Judgment did Amgen seek to have Dr. Bradshaw give expert testimony on the rarely applicable opposite issue--whether *earlier-*

[1] Ex.__" refers to exhibits submitted with the Declaration of Timothy M. Murphy in Support of Defendants' Memorandum in Opposition to Amgen Inc.'s Motion to Strike Untimely Expert Testimony and Defendants' Motion, in the Alternative, to Strike Untimely Testimony of Ralph A. Bradshaw Regarding Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting, filed contemporaneously herewith.

*issued* claims were obvious in light of *later-issued* claims. *See* Bradshaw Decl., D.I. 504 at ¶¶ 33-34. Neither of Dr. Bradshaw's previous expert reports had expressed the opinions given in Dr. Bradshaw's Declaration. *See* e.g., Ex. B, 5/11/07 Rebuttal Report of Ralph A. Bradshaw, Ph.D. ¶¶ 12-14, 81; Ex. C, 6/1/07 Rebuttal Report of Ralph A. Bradshaw, Ph.D. to New Non-Infringement Arguments Raised in the Rebuttal Reports of Defendants' Experts ¶¶ 4-5. This reverse test of obviousness is only properly applied as part of the "two-way test" of obviousness. But the Federal Circuit has repeatedly held that the two-way test is a rare exception to the general rule. *See,* e.g. *Eli Lilly & Co. v. Barr Labs, Inc.,* 251 F. 3d 955 at n.7; *In re Berg,* 140 F. 3d 1428, 1432 (Fed. Cir. 1998).

In support of its Motion for Summary Judgment of No Obviousness-Type Double Patenting, Amgen submitted a Declaration of Ralph A. Bradshaw, Ph.D. *See* D.I. 504. Dr. Bradshaw earlier submitted an expert report regarding the difficulty of purifying EPO from natural sources and the adequacy of Dr. Lin's disclosure as to how to purify recombinant human EPO to apparent homogeneity. *See* Ex. B, Rebuttal Report of Ralph A. Bradshaw, Ph.D., dated May 11, 2007 at ¶¶ 12-14, 81. But Bradshaw's Declaration, filed June 14, 2007, expresses for the first time his "opinion that one of ordinary skill in the art in 1983-1984 would have found the erythropoietin purification process claimed in the Lai '016 patent claims, including claim 10, to be non-obvious over any of the claims in Dr. Lin's '933, '422, '349, '868 and '698 patents." Bradshaw Decl. (D.I. 504) at p. 12-13.

Amgen's bold effort to sneak a new opinion in along with its Motion for Summary Judgment necessitated a response from Roche's expert, Dr. Edward Harlow.

Harlow's rebuttal in ¶ 5 of his declaration was "substantially justified" by the new opinion expressed by Bradshaw.

Dr. Harlow properly supported his rebuttal opinion with facts based on a study of the prior art. Amgen seeks to suppress the facts regarding prior art. Amgen improperly seeks summary judgment simply based on Dr. Bradshaw's knowledge. He declared, "To my knowledge, the resulting combination was and is an improvement…" Bradshaw Decl. at ¶ 33. Dr. Harlow, on the other hand, produced references supporting his opinion. Harlow Decl. (D.I. 569) at ¶ 5 and Exs. 34-43 thereto (*See* D.I. 574). Dr. Bradshaw, in deposition, further testified to the lack of support for his new opinion. *See* Ex. D, Deposition of Ralph Bradshaw, taken June 19, 2007. Specifically, Dr. Bradshaw testified as follows:

> MR. JAGOE: Q. So you formed the opinion that the Lai patent was a novel, nonobvious method, and you didn't review what prior art existed about purification of proteins?
>
> MS. CARTER: Objection; mischaracterizes his testimony.
>
> THE WITNESS**: I did not review all the prior art for the Lai patent**. But in my experience, the urea, acid urea treatment was unique. I did not do a literature search, but I had never encountered that before.
>
> Whereas, I certainly had encountered use of C4 columns. We use C4 columns in my laboratory to purify proteins. Even though we may never have published it, we certainly did. So I was well familiar with C4 columns.
>
> I was not familiar with a urea DEA column, so in my opinion this was a novel step. I wasn't a patent examiner and **I didn't look at the prior art**.

Bradshaw deposition, p. 173, l. 23-p. 174, l. 16 (emphasis added).

> MR. JAGOE: Q. Do you know what the state of the art was in terms of efforts to purify human erythropoietin from recombinant cells as of 1985?

> A. My knowledge of this is based on the Lin patents, and **I have really no other information as of 1985** for purifying recombinant erythropoietin from anybody else.

Bradshaw deposition, p. 177, l. 11-17 (emphasis added).

The casual inclusion, in his declaration in support of summary judgment, by Dr. Bradshaw of an opinion based on his incomplete knowledge compelled Roche to have Dr. Harlow present a rebuttal opinion in his Declaration based on a more complete understanding of the prior art.

The Court should not strike Dr. Harlow's testimony in ¶5, as it would deprive the Court of a full understanding of the relevant prior art. All that would remain is Dr. Bradshaw's expression of an opinion merely based on his personal knowledge. That opinion, having been raised for the first time in the declaration accompanying Amgen's motion, made Dr. Harlow's testimony justified and indeed necessary to a just resolution of the matter at issue.

When summary judgment is the first occasion on which an opinion is asserted, "substantial justification" exists for not earlier disclosing a rebutting expert's opinion. *Friends of Santa Fe County v. LAC Minerals, Inc.*, 892 F. Supp. 1333, 1351 (D.N.M. 1995) (Nonmoving party had "substantial justification" for failing to disclose expert's opinion until summary judgment, thus precluding sanction of exclusion of opinion, because plaintiffs' summary judgment motion represented first occasion on which plaintiffs asserted the expert opinion rebutted by the nonmoving party). Where "substantial justification" exists, Rule 37(c)(1) by its own terms cannot be applied to preclude use of expert testimony. Thus, in the instant case, Roche has "substantial justification" for submitting the rebuttal testimony of Dr. Harlow in his declaration in

opposition to summary judgment because Amgen relied on new evidence by Dr. Bradshaw in his declaration in support of summary judgment that was not disclosed in his expert report.[2]

Should the Court determine that Amgen requires additional discovery into Dr. Harlow's opinion, the Court should not resort to the drastic remedy of striking ¶5 of his declaration, but instead schedule a deposition limited to this topic. In the alternative, Roche respectfully suggests that if the Court strikes Dr. Harlow's ¶5 for untimeliness, then the Court must likewise strike the new opinions of Dr. Bradshaw set forth in ¶ 33 and 34 of his declaration.

**B. Dr. Lowe's Declaration Contains No New Evidence**

Amgen's contention that Dr. John Lowe's June 29, 2007, declaration contains information never previously disclosed is also unwarranted. Dr. Lowe's opinions in his declaration regarding the lack of consonance regarding claim 7 of the '349 patent and Group 2 of the restriction requirement are merely an extension of his extensive obviousness-type double patenting positions stated in his April 6, 2007 expert report. *See* Declaration of John Lowe, M.D., in Support of Defendants' Opposition to Amgen Inc.'s

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[2] In addition, Rule 37(c)(1) does not require the sanction of excluding evidence but instead provides for the court to exercise discretion and impose lesser sanctions in lieu of of exclusion. The rule provides in pertinent part "In addition to **or in lieu of** this [exclusion of evidence] sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions. Rule 37(c)(1) (emphasis added). *See also Albert v. Warner-Lambert*, 2002 WL 745822 (D.Mass.) (In a case where the party could not demonstrate that its failure to comply with an expert disclosure deadline was justified or harmless, the court allowed, in lieu of exclusion, a supplemental report contingent upon submitting to additional deposition and additional supplementation by the adverse party).

Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 571) ("Lowe Decl.").

As stated in Roche's opposition to Amgen's motion for summary judgment, Amgen's lack of consonance is based on the proposition that claim 7 of the '349 patent is not patentably distinct from the Group 2 claims within the application of Amgen's earlier and now expired '008 patent. Roche's Opposition to Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 568) at p. 5-6. In his April 6, 2007 expert report, Dr. Lowe devotes numerous paragraphs regarding the lack of patentable distinctions between claim 7 of the '349 patent, and the claims of the '008 patent. Exhibit E, Expert Report of Dr. John Lowe, ¶¶ 185-189. For example, under the subheading "Claim 7 of the '349 Patent is not Patentably Distinct from Claims 2, 4, 6, 7 and 25 of the '008 Patent," Dr. Lowe stated that "it would have therefore have been obvious to one of skill to use a mammalian host cell as recited by '008 claim 25, or specifically the CHO host cell recited by '008 patent claim 27, transformed with an appropriate expression vector to allow one to generate a host cell capable of expressing human EPO at levels recited by '349 claim 7." Exh. E at ¶188.

Dr. Lowe also concluded in his expert report that "there is no patentable distinction between claim 2 of the '008 patent to a DNA sequence 'consisting essentially of a DNA sequence encoding human erythropoietin,' and the process recited by '349 patent claim 7 for producing a human erythropoietin" and "there is no patentable distinction between claims 4 or 6 of the '008 patent to the recombinant host cells, in particular host cells transformed with the DNA sequence encoding human erythropoietin of '008 claim 2 and the claimed process as recited by '349 claim 7." *Id.* at ¶189.

Thus, Dr. Lowe's statements within his declaration concerning lack of consonance are based entirely on his understanding that claim 7 of the '349 patent is not patentably distinct from the Group 2 claims which became in part the '008 patent. As demonstrated above, this understanding was fully presented in Dr. Lowe's April 6, 2007 Expert Report.

Moreover, as Amgen readily admits, Roche's positions regarding lack of consonance between claim 7 of the '349 patent and the Group 2 claims are not new, and were fully disclosed in Roche expert reports, including Mr. Sofocleous' April 6, 2007 report. *See* Ex. F, April 6, 2007 Expert Report of Michael Sofocleus, ¶¶ 452-458. Another Roche Expert, Dr. Kadesch, also explained in one of his reports that claim 7 of the '349 patent and the Group 2 claims are not patentably distinct. *See* Ex. G, Second Supplemental Report of Dr. Thomas Kadesch, dated June 13, 2007 at ¶ 19, n. 3. Roche's position was also set forth as early as February 26, 2007 in discovery responses. *See* Exhibit H, Roche's Second Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15), at 56. Therefore, Amgen was fully apprised of Roche's position and cannot claim unfair prejudice. In fact, Amgen fully had the opportunity to respond to Dr. Lowe's opinions in a reply declaration by one of its experts, but failed to do so. Should the Court determine that Amgen requires additional discovery into Dr. Lowe's opinion, the Court should not resort to the drastic remedy of striking his declaration, but instead schedule a deposition limited to these topics.

## CONCLUSION

For all of the foregoing reasons, Amgen's motion to strike portions of the declarations of Dr. Harlow and Dr. Lowe should be denied.

Dated: July 16, 2007
Boston, Massachusetts

Respectfully submitted,

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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.

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