UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.: 05 Civ. 12237 WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM USING ALLEGED CLAIM FEATURES TO DISTINGUISH PRIOR ART WHEN THOSE CLAIM FEATURES WERE NOT PROVEN TO ESTABLISH INFRINGEMENT

Having obtained summary judgment that Roche infringes '422 claim 1 based on a broad interpretation of the claim, Amgen cannot now rely on a different, narrow interpretation to support the claim's validity. Accordingly, Amgen should be precluded from submitting evidence of—or arguments based on—structural and functional characteristics that allegedly distinguish the pharmaceutical composition of '422 claim 1 from the prior art, if, in moving summary judgment of infringement, Amgen did not show that CERA (the active ingredient in Roche's product, MIRCERA®) has those characteristics.

In support of its motion for summary judgment of infringement of '422 claim 1 (D.N. 509), Amgen relied on a perfunctory analysis of whether CERA satisfied the requirements of '422 claim 1. Amgen's supporting brief had but a single paragraph analyzing whether CERA satisfies all the requirements of '422 claim 1. (D.N. 510 at 7). Amgen emphasized in its brief that the key to infringement was whether CERA has the amino acid sequence of human

erythropoietin. (*Id.* at 2 and 7). However, for its attempt to distinguish the claimed subject matter over the prior art of naturally occurring EPO, Amgen apparently intends to read many more requirements into the claim. Simply put, Amgen should not be allowed to change the scope of the claim for purposes of the Court's validity analysis.

STATEMENT OF FACTS

A. Amgen's Motion for Summary Judgment of Infringement

Claim 1 of the '422 patent provides:

> A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

In successfully moving for summary judgment of infringement of this claim in the instant case, Amgen asserted that "the only difference between Lin's recombinant human EPO" and the EPO in CERA "is the attachment of a peg moiety to the EPO protein via a single bond." (*Id.* at 4). Amgen provided evidence that (1) the Epoetin beta that Roche uses in making CERA is purified from mammalian cells grown in culture; (2) that CERA has the amino acid sequence of Epoetin beta; and (3) CERA has the glycosylation of Epoetin beta. *Id.* at 4-5. That evidence apparently satisfied the Court that—even though CERA is not itself a product of mammalian cells—CERA is indistinguishable from "erythropoietin purified from mammalian cells grown in culture" as recited in '422 claim 1.

Amgen's summary judgment motion was argued on July 17, 2007, and Amgen's motion was granted with respect to '422 claim 1 on August 27, 2007.

B. Amgen's Expected Invalidity Argument

A preview of how Amgen will likely attempt to distinguish the subject matter of '422 claim 1 from the prior art may be seen in a recent submission filed by Amgen in *Amgen Inc. v.*

Hoechst Marion Roussel, Inc., Civil Action No. 97-10814-WG4. In the *HMR/TKT* case, Amgen filed a brief on August 24, 2007, asserting that the source limitation of '422 claim 1 ("purified from mammalian cells grown in culture") defines "structural and functional differences between recombinant urinary EPO and recombinant EPO." (Amgen's Brief on Remand Concerning Whether Goldwasser Anticipates '422 Claim 1, Document 863, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, Civil Action No. 97-10814-WG4).

Amgen argued that—even though Dr. Eugene Goldwasser's urinary EPO, which was in the prior art, has the same amino acid sequence as the EPO '422 claim 1, as construed by this Court—there are various "structural and functional differences" that distinguish Dr. Goldwasser's EPO preparation from the EPO of the claim. According to Amgen, these "structural and functional differences" prevent Dr. Goldwasser's EPO from invalidating '422 claim 1 under 35 U.S.C. § 102. By means of these "structural and functional differences"—which were not mentioned in Amgen's summary judgment briefing on infringement in the instant case—Amgen may well attempt to narrow the scope of '422 claim 1 in this case now that it is facing an invalidity challenge.

Amgen argued in its *HMR/TKT* brief that it was able to define the product of claim 1 of the '422 patent "by means of the source limitation 'purified from mammalian cells grown in culture' precisely because Lin's recombinant EPO is a novel product." *Id.* at 15. According to Amgen, "the source limitation 'purified from mammalian cells grown in culture' defines structural and functional differences between urinary EPO and recombinant EPO." *Id.* Amgen asserted that it could distinguish the prior art human EPO from the EPO of '422 claim 1 on eleven different grounds, namely:

1) glycosylation,

2) conformation (folding),

3) susceptibility to degradation by trypsin,

4) ease of iodination,

5) inactivation by iodination,

6) second derivative spectra,

7) circular dichroic spectra,

8) *in vivo* potency (specific activity),

9) clearance rate,

10) half-life, and

11) therapeutic effect.

Id. at 16-18.

Of these eleven characteristics—which Amgen alleges distinguish its claimed subject matter from the prior art—only glycosylation was discussed by Amgen in its brief for summary judgment of infringement. The other ten characteristics were not even mentioned by Amgen in its infringement argument, and thus these ten characteristics were presumably not considered by the Court in granting Amgen's summary judgment motion for infringement with respect to '422 claim 1.

In moving for summary judgment of infringement in the instant case, Amgen made no showing (and, indeed, could not have shown) that CERA is identical to the EPO of '422 claim 1 in terms of the "structural and functional" features that Amgen now argues in the *HMR/TKT* case—and will presumably attempt to argue in the instant case—are required by '422 claim 1.

ARGUMENT

Having prevailed on infringement by asserting a broad interpretation of '422 claim 1, Amgen should not be allowed to narrow '422 claim 1 in an effort to survive an invalidity challenge.

It is fundamental that a patent claim is to have a single meaning for both infringement and validity. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims"). As the Federal Circuit stated in *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001): "Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses. 'A patent may not, like a "nose of wax," be twisted one way to avoid anticipation and another to find infringement.'" (Citations omitted.)

In short, Amgen cannot have it both ways. Amgen cannot, for purposes of infringement, maintain that the amino acid sequence alone defines the erythropoietin of claim 1 of the '422 patent, but for purposes of validity assert -- as it does in the *HMR/TKT* case -- that the claim term "purified from mammalian cells grown in culture" defines the claimed EPO product in terms of an array of very specific structural and functional features which distinguish over the prior art.

CONCLUSION

For all of the reasons stated above, Roche respectfully requests that this Court preclude Amgen from distinguishing the subject matter of '422 claim 1 from the prior art with evidence relating to features that were not proven to show infringement.

Dated: September 10, 2007
Boston, Massachusetts

Respectfully submitted,

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