**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| AMGEN INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation,<br><br>Defendants. | Civil Action No.: 05-12237 WGY |

**AMGEN'S OPPOSITION TO ROCHE'S MOTION FOR RECONSIDERATION OF THE COURT'S GRANT OF SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1**

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Roche's motion for reconsideration of the Court's order granting summary judgment of infringement of '422 claim 1 should be denied because Roche has not established (a) that a genuine issue of material fact exists precluding summary judgment or (b) that the Court erred as a matter of law in construing '422 claim 1.

Instead, Roche's motion for reconsideration rests solely on supposed "new evidence" consisting of a statement that Amgen made in a brief recently submitted in the *Amgen v. HMR/TKT* case. Not only is that statement not a "new fact," but it is entirely consistent with the position that Amgen has taken in this case. In short, it provides no basis for reversing the Court's grant of summary judgment of infringement of '422 claim 1.

Roche's motion rests on a fallacious legal argument. Because Amgen disputes that Goldwasser's uEPO preparation anticipates '422 claim 1, Roche argues summary judgment of infringement of '422 claim 1 should be denied.[1] To support its *non sequitur* reasoning, Roche quotes a portion of a section heading in Amgen's *HMR/TKT* brief, which states that "the source limitation 'purified from mammalian cells grown in culture' defines structural and functional differences between urinary EPO and recombinant EPO."[2] Roche now argues that summary judgment of infringement should not have been granted because Amgen did not show that Roche's peg-EPO product "is indistinguishable from Dr. Lin's EPO in terms of the structural and functional criteria that Amgen now claims define an EPO that is 'purified from mammalian cells grown in culture."[3]

The fundamental flaw in Roche's argument is its confusion of the law of anticipation with the law of infringement. To prove ***anticipation*** of '422 claim 1, Roche (and HMR/TKT)

[1] At the close of Roche's invalidity case, the Court granted Amgen's motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(a)(1) that Roche failed to establish a legally sufficient evidentiary basis to find anticipation of '422 claim 1.

[2] Docket # 863, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, No. 97-10814-WGY at 15.

must prove by clear and convincing evidence that some prior art EPO product satisfies every limitation of Lin's claimed invention. Lin's '422 claim 1 recites "a pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin … ***purified from mammalian cells grown in culture***." Because no prior art EPO product was "purified from mammalian cells grown in culture," Roche has asked the Court to ignore that claim limitation on the pretext that "purified from mammalian cells grown in culture" fails to differentiate Lin's claimed product from Goldwasser's prior art EPO preparation purified from human urine.

But that is not the law. Because Amgen established to the satisfaction of the Patent Office that various structural and functional differences distinguished Lin's claimed invention over Goldwasser's urinary EPO, it was permitted to claim Lin's invention by reference to the sources from which it can be produced. The structural and functional differences that justify the use of a source limitation are not limitations of the claims. As this Court recently explained:

> "[T]the factual dispute here is whether it's a new product. . . . The jury is going to have to resolve whether the prior art, which I have let in, all right, the so-called prior art, is in fact the same product. If it is, the source limitation won't save them. If it's not, the source limitation is part of the limitation . . . ."[4]

In order to prove anticipation of '422 claim 1, Roche must prove by clear and convincing evidence that Lin's source limitation does not distinguish his claimed product over the prior art. That, in turn, requires Roche to prove that Goldwasser's urinary EPO preparation was identical in structure and function to the claimed human EPO purified from mammalian cells grown in culture. As the Court has now determined, Roche has failed to present evidence that can meet this burden. In light of that failure, the source limitation properly defines the scope of Lin's claimed invention, both for purposes of anticipation and for purposes of infringement.

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[3] Docket # 1062, at 6 (Roche's Motion for Reconsideration).

[4] 9/12/07 Trial Tr. 870:18-19, 871:11-16.

To prove ***infringement***, Amgen must show by a fair preponderance of the evidence that Roche's accused peg-EPO product satisfies every limitation of '422 claim 1 as construed by the Court, including the source limitation, "purified from mammalian cells grown in culture."[5] Amgen need not prove that the accused product is identical to any other product. Rather, Amgen need only prove that the accused product satisfies every limitation of '422 claim 1.

The Court has construed "purified from mammalian cells grown in culture" as a source limitation meaning "obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture."[6] The Court rejected Roche's argument that the construction should be modified, noting that the Federal Circuit has long recognized that "source or process limitations can and do serve to define the structure of a claimed product where such limitations are the best means to distinguish a claimed product over prior art."[7]

Given that construction, Amgen's motion for summary judgment of infringement established that there was no genuine issue of material fact that the human EPO in Roche's Mircera product was "purified from mammalian cells grown in culture." Notably, Roche's motion does not cite the Court's claim construction, nor does it attempt to show that its product does not satisfy the limitation – as construed by the Court. Rather, Roche tries to argue that infringement should be assessed based upon the "structural and functional criteria that ***Amgen now claims define*** an EPO that is 'purified from mammalian cells grown in culture.'"[8] But

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[5] *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1339 (Fed. Cir. 2003); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

[6] *Amgen, Inc. v. F. Hoffman La Roche, Inc.*, 494 F. Supp. 2d 54, 65 (D. Mass. 2007).

[7] *Id.*

[8] Docket #1062 at 6 (emphasis added).

Amgen claims no such thing. Lin's inventions are defined by his claims, not the structural or functional differences that justify the source limitation contained in his claims. It is the Court's claim construction that controls the infringement inquiry, and that construction makes no reference to any structural or functional difference. The fact that the claimed pharmaceutical compositions have certain unrecited structural or functional differences from the prior art uEPO compositions by virtue of the source from which they are purified is irrelevant to the infringement inquiry.

For purposes of infringement, the only relevant issue is whether the human EPO in Roche's accused pharmaceutical composition was "purified from mammalian cells grown in culture" as that limitation has been construed by the Court. Since Roche has not identified any new evidence to show that the human erythropoietin contained in its accused pharmaceutical composition is not purified from mammalian cells grown in culture, Roche's motion for reconsideration should be denied.

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Respectfully Submitted,

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By its attorneys,

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