UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S OPPOSITION TO ROCHE'S MOTIONS IN LIMINE TO PRECLUDE AMGEN INC. FROM:
USING ALLEGED CLAIM FEATURES TO DISTINGUISH PRIOR ART WHEN THOSE CLAIM FEATURES WERE NOT PROVEN TO ESTABLISH INFRINGEMENT (D.N. 1026),
ARGUING THAT SOURCE LIMITATIONS DISTINGUISH THE PRIOR ART FROM ITS '422 PATENT CLAIM 1 (D.N. 1046), AND
ARGUING THAT PROCESS LIMITATIONS DISTINGUISH THE PRIOR ART FROM ITS '933 PRODUCT-BY-PROCESS CLAIMS (D.N. 1047)

Amgen respectfully submits that the Court should deny Roche's motions in *limine*[1] seeking to prevent Amgen from presenting evidence or argument concerning the source and process limitations of '422 claim 1 and '933 claims 3, 7-9, 11, 12 and 14, and whether the claimed inventions are distinguished from the prior art. These motions improperly confuse the law of anticipation with the law of infringement.

To prove anticipation of '422 claim 1, Roche must prove—by clear and convincing evidence—that some prior art EPO product was identical in both structure and function to the claimed human EPO purified from mammalian cells grown in culture. The trial evidence establishes that the structure and function of Dr. Goldwasser's urinary EPO product differed in several important respects from Dr. Lin's human EPO purified from mammalian cells grown in culture, including differences in the proportions of certain N-linked carbohydrates,[2] differences in the distribution of EPO glycoforms comprising each product,[3] differences in the conformational structures of those products,[4] and differences in the relative potency (or specific activity) of each product.[5] Indeed, the evidence shows that the Board of Patent Appeals and Interferences not only addressed whether Goldwasser's urinary EPO anticipated Lin's claimed products, but also considered most, if not all, of the same evidence presented by Roche. Based on that evidence, the Board found that Goldwasser's urinary EPO was not identical to Lin's claimed products,[6] and that Lin's claimed product-by-process was novel over Goldwasser's

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[1] Docket Nos. 1026, 1046 and 1047.

[2] TX 0005 ('422 Patent, col. 28:49-67); TX 2057 at 799 (AM-ITC 00092890).

[3] Trial Tr. at 1116:7-19; 1127:3-11; 1128:14-22.

[4] Trial Tr. at 1115:7-1116:6 (Bertozzi addressing "folding").

[5] TX 2059 at 699; TX 2062 at 247.

[6] TX 2011.309-312 (*Fritsch v. Lin*, 21 U.S.P.Q.2d 1739, 1741-42 (U.S.B.P.A.I. 1992)).

urinary EPO product.[7] The existence of these structural and functional differences not only establish the novelty of Lin's claimed products, but they also establish Lin's right to claim his invention by reference to the source or process that imbues his claimed product with its novel properties.

Against this backdrop, the burden falls to Roche to prove by clear and convincing evidence that Lin's source and product-by-process limitations fail to imbue his claimed product with novel properties. To carry that burden, Roche must prove by clear and convincing evidence that Goldwasser's prior art urinary EPO product was identical in both structure and function to a product purified from mammalian cells grown in culture. The evidence of record fails to provide such proof. Indeed, evidence presented by Roche fails to show that the composition and potency of Goldwasser's urinary EPO is identical to any human EPO product purified from mammalian cells grown in culture.

For purposes of infringement, Amgen must prove—by a fair preponderance of the evidence—that Roche's accused peg-EPO product satisfies every limitation of Dr. Lin's claimed invention including the source limitations. Once the claim is upheld over the prior art based on differences conferred by the source limitation, Amgen does not need to prove those differences again for purposes of infringement, but rather, simply has to show that an accused product meets the source limitation—i.e., is produced by mammalian cells grown in culture.

Roche's 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 (Docket No. 1026) falsely presumes that the structural and functional differences which establish the propriety of Lin's source and product-by-process limitations must be read into Lin's claimed

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[7] *Id.*

inventions, and that they limit the scope of Lin's claims for purposes of infringement. That is not the law. Where, as here, the precise structural or functional differences that distinguish a new product, (such as Lin's recombinant EPO), over the products of the prior art are not susceptible to precise definition, a patentee may properly claim his invention by reference to the source or process that imbues its claimed product with its novel characteristics.[8] In such circumstances, the claimed invention is defined by the source or process by which it is obtained, not by reference to particular structural or functional differences, precisely because such differences are not susceptible to precise definition.

Since Roche has failed to prove by clear and convincing evidence that Goldwasser's prior art urinary EPO product is identical to a product claimed in '422 claim 1, the source limitation "purified from mammalian cells grown in culture" properly distinguishes the prior art, and serves to define Lin's claimed invention for purposes of infringement. Thus, to prove infringement, Amgen must show that Roche's peg-EPO product satisfies the source limitation as construed by the Court—a burden Amgen fully met. Thus, Roche's motion (Docket No. 1026) to preclude Amgen from distinguishing the prior art based structural and functional differences that justify its source and product-by-process limitations should be denied.

With regard to Roche's Motions in *Limine* to Preclude Amgen Inc. From Arguing That Source Limitations Distinguish the Prior Art From Its '422 Patent Claim 1 (Docket No. 1046) and From Arguing That Process Limitations Distinguish the Prior Art From Its '933 Product-By-Process Claims (Docket No. 1047), Roche's motions should be seen as little more than an attempt to re-argue claim construction. In its *Markman* opinion, the Court applied Federal

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[8] *In re Luck*, 476 F.2d 650, 659 (C.C.P.A. 1973); *Ex Parte Painter*, 1891 C.D. 200, 57 O.G. 999.

Circuit precedent to hold that source and process limitations can serve as the sole basis to distinguish a novel product from the prior art:

> [A]s has long been recognized by the Federal Circuit, 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. . . . In this context, Roche/Hoffmann's citation to *SmithKline Beecham Corp*. is misplaced since it omits the next passage, which recognizes that process limitations may impart novel structure to a product claim . . . .[9]

Thus, both of these motions should similarly be denied.

As the Court noted on September 12, in the context of '422 claim 1 and '933 claims 3, 7-9, 11, 12 and 14, the factual issue for the jury to resolve is whether the claimed product is novel as compared with the prior art:

> 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 . . . .[10]

The Court thus rejected Roche's position that Amgen should not be permitted to present evidence or argument concerning structural and functional differences between prior art products and the products claimed in the '933 claims and '422 claim 1.[11] Because the Court has rejected Roche's position and agreed to hear Amgen's evidence and arguments, Roche's motions concerning source and process limitations (Docket Nos. 1046, 1047) of the '422 and '933 patents should be denied.

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[9] *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp. 2d 54, 65 (D. Mass. 2007) (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006)).

[10] 9/12/07 Trial Tr. at 871:11-16.

[11] 9/12/07 Trial Tr. at 871:11-24.

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Respectfully Submitted,

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