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HAND DELIVERY AND E-FILED

The Honorable William G. Young
District Court for the District of Massachusetts
John Joseph Moakley U.S. Courthouse
1 Courthouse Way
Boston, MA 02210

Re: Amgen Inc. v. F. Hoffmann-La Roche et. al., No. : 05-CV-12237 WGY

Your Honor:

We write to ask that the Court address the following issues relevant to the evidence that Roche will be presenting this week:

(i) Roche has requested that Amgen agree to the admissibility of certain documents, which Amgen has acknowledged appear to be Amgen business records. Nonetheless, Amgen has refused to agree to the admission of those documents. Roche requests the Court's assistance in this matter.

(ii) Amgen apparently plans to suggest that product or source limitations distinguish its claimed products from the prior art.[1] That position flies in the face of the position Amgen took in successfully moving in this case for summary judgment of infringement of the '422 patent: "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." (D.N. 510 at 4). In other words, Amgen is urging a broad interpretation of the claim for infringement purposes but a narrow interpretation of the claim for validity purposes. This is fundamentally improper. *Scripps Clinic & Res. Found. v. Genentech,*

[1] Amgen recently has argued in the HMR/TKT litigation 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 (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).

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"). Roche therefore respectfully requests that the Court provide the jury with the attached instruction (filed as D.I. 1030-2) explaining that when a patent claim describes a product by a process of making it or from a source, the process or source does not make the product patentable if the product is otherwise indistinguishable from the products that existed in the prior art.

(iii) Amgen continues to present evidence that contradicts admissions regarding the prior art made in the specifications of the patents in suit. As detailed in Roche's Motion in Limine to Preclude Amgen from Making Assertions that Contradict Statements Made in the Specifications of the Patents-in-Suit, filed August 13, 2007 (DI 808), recent decisions by the Federal Circuit establish that this is entirely improper. (*SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 n.7 (Fed. Cir. 2006) (finding invalid two product-by-process claims in a pharmaceutical composition patent, and holding that "a prior art disclosure of a product precludes a future claim to that same product, even if it is made by an allegedly novel process.")). Roche therefore respectfully requests that the Court grant Roche's motion (D.I. 808).

Respectfully submitted,

/s/Leora Ben-Ami
Leora Ben-Ami

cc: Lloyd R. Day, Jr., Esq.
Lee Carl Bromberg, Esq.

Exhibit A

SUPPLEMENTAL PROPOSED JURY INSTRUCTIONS

PRODUCT-BY-PROCESS CLAIMS

Sometimes a product may best be described by the process by which it is made, instead of by describing its structure or chemical characteristics. Such claims, which describe a product by describing the process by which it is made, are called "product-by-process" claims.[1] These claims are directed to specific products, any process steps you see in the claim are merely descriptive.[2] In other words, you could not patent a car just because you figured out a new process on how to put one together.

You may, however, consider the process steps in the claim if you believe that they make the product itself different.[3] This would happen, for example, if your new process in making a car gave the car the ability to fly. That process changed the underlying product.

The asserted claims of U.S. Patent No. 5,995,422 and 5,547,933 are product by process claims. As a result, the source or process limitations "purified from mammalian cells grown in culture" from the '422 patent and "non-naturally occurring," from the '933 patent only make the claimed products patentable if they serve to distinguish the structure of the claimed product from the products contained in the prior art.

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[1] *Smithkline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991).
[2] *Smithkline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006); *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938);
[3] *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973).