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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:

In that it is likely that Roche will turn its validity case before the jury this week, we respectfully request that the Court provide guidance on the following issues at its earliest convenience:

(i) In light of the Court's decision that no further evidence regarding double patenting is to be presented to the jury, Roche asks for guidance as to how the Court will take testimonial evidence on this matter outside the presence of the jury.[1] If the Court's schedule permits, Roche suggests that the parties present evidence through witnesses after 1:00 pm on certain days this week.

Moreover, the Court has indicated that it will not entertain further evidence regarding Amgen's '008 patent before the jury. However, as detailed in Roche's Opposition to Amgen MIL No. 7 (D.I. 923), Amgen has raised a number of secondary indicia of non-obviousness issues in this case, including the alleged commercial success of the claimed products. Roche has maintained that Amgen's commercial success has no nexus to the claimed invention, but are instead derived from other things, including Amgen earlier filed '008 patent. Thus, Roche seeks guidance on this and other issues where presentation of the '008 patent is contemplated.

(ii) During the 2:00 pm hearing on September 7th, Amgen's counsel admitted that the '868 and '698 patents are not entitled to the statutory protection of 35 U.S.C. § 121 because these patents both belong within Group II of the 1986 restriction requirement. (9/7/06 Tr. at 496) In light of this admission, Roche respectfully requests that the Court rule that Amgen is not entitled to invoke § 121 as a defense to Roche's obviousness double patenting attack on these patents. Alternatively, Roche requests that the Court grant Roche's Motion in Limine to Preclude Amgen from Asserting that there was a Restriction Requirement Separating the '008 Patent Claims from the Claims of the '868 and '698 Patents, filed on September 6, 2007 (DI 1005).

[1] Roche is filing a formal objection to the Court's ruling in a separate submission today.

(iii) Based on the cross-examination of Dr. Lowe, it is clear that Amgen is presenting 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.")). Amgen should not be permitted to continue to present contradictory evidence. Roche therefore respectfully requests that the Court grant Roche's motion (D.I. 808).

(iv) Amgen has signaled its intent to argue that the Baron/Goldwasser clinical trial does not constitute 102(g) prior art. Since Dr. Goldwasser is currently providing testimony, this issue will likely come up during testimony on Monday, September 10th. As detailed in Roche's Motion in Limine to Preclude Plaintiff from Arguing that the Goldwasser Clinical Study Is Not Prior Art, which will be filed today, this Court and the Federal Circuit have already determined that the Goldwasser clinical trial is prior art under 35 U.S.C. § 102(a) and (g). (*Amgen, Inc. v. Hoechst Marion Roussel*, Inc.,126 F. Supp. 2d 69, 111 (D. Mass. 2001)[2]; *Amgen, Inc. v. Hoechst Marion Roussel*, Inc.,314 F.3d 1313, 1354 (Fed. Cir. 2003)[3]). Amgen is properly precluded from arguing otherwise and Roche respectfully requests that the Court grant Roche's motion.

(v) Amgen has also signaled its intent to argue that the process steps recited in the asserted claims of the '933 patent or source limitation recited in claim 1 of the '422 patent can distinguish the claimed products. As detailed in Roche's Bench Memorandum in Support of Roche's Request that the Court Instruct the Jury that Process or Source Limitations Do Not Distinguish Product Claims Over the Prior Art, those claims cannot be distinguished over the prior art simply because they contain process steps or source limitations. Roche respectfully requests that the Court grant Roche's motion in limine and preclude Amgen's improper arguments.

(vi) In explaining Roche's defenses to the jury, the Court has, on more than one occasion, omitted a number of Roche's defenses. Roche requests a brief conference at the Court's earliest convenience to review Roche's defenses that properly remain in this case.

We will be happy to address any questions and/or concerns that the Court may have on these matters, and appreciate the Court's consideration of these requests.

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[2] Stating, "For the same reasons that the Court rejected Amgen's attack on the 1985 Saito et al. and 1986 Sherwood and Shouval experiments, the Court rebuffs this attack as well. Because the documents submitted as exhibits in this case reveal that Dr. Goldwasser began this clinical study in 1979-1980 at the University of Chicago in Illinois, see Trial Ex. 2055, it could fairly be said that it predates Amgen's patent application. See 35 U.S.C. § 102(a), (g)."

[3] Stating, "If the claim term 'therapeutically effective' encompasses the patient responses described in the specification, as it appears to us it does, then the Goldwasser study may constitute invalidating prior art under §102(a) or §103 even if he did not achieve his intended result."

Respectfully submitted,

/s/

Leora Ben-Ami

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