

DAY CASEBEER  
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September 6, 2007

VIA ELECTRONIC CASE FILING SYSTEM

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

**Re: *Amgen Inc. v. F. Hoffman-Roche, Ltd., et al.***  
Civil Action No: 05-12237-WGY

Dear Judge Young:

We write to address the letter from Roche's counsel to Your Honor yesterday (Document 996) regarding Roche's obviousness-type double patenting ("ODP") defenses. We appreciate Roche's desire to clarify the various permutations of ODP that Roche seeks to raise in this case, but we respectfully disagree with certain positions expressed in Roche's letter.

- Regarding Roche's "Theory No. 2," Amgen understands the Court's summary judgment Order to mean that the inventions claimed in Amgen's '933, '422 and '349 patents are exempt from ODP over the inventions claimed in Amgen's '008 patent under 35 U.S.C. § 121, the ODP safe harbor statute. As explained in Amgen's summary judgment briefing, two of the requirements for § 121 protection are: (1) that the '178 and '179 applications that gave rise to the '933, '422 and '349 patents were filed "as a result of" the PTO's 1986 restriction requirement; and (2) that the claims in the '933, '422 and '349 patents are "consonant" with the 1986 restriction requirement. These necessary findings to the Court's decision also impact Roche's Theory No. 4.
- Although Amgen did not move for summary judgment on Roche's ODP "Theory No. 3," that the '868 and '698 asserted claims are invalid for ODP over the '008 claims, Amgen will demonstrate at trial that these claims are patentably distinct. The PTO came to this same conclusion during the prosecution of Lin's process claims, in the face of similar arguments as presented here. Specifically, during prosecution of the '868 and '698 patents, Amgen overcame an explicit rejection for ODP over the '008 claims.
- Finally, Amgen agrees that Roche's ODP "Theory No. 4" is completely different from its "Theory No. 3." Unlike Roche's ODP Theory No. 3, which remains a triable defense as to the '868 and '698 claims, Amgen respectfully submits that Roche's Theory No. 4 is

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not appropriately in this case. Roche's ODP Theory No. 4 was not properly disclosed during discovery, was not developed in Roche's ODP expert reports, and is statutorily precluded by § 121 for the same reasons that § 121 precludes Roche's ODP Theory No. 2 (which involved the same claims from the '933, '422 and '349 patents). Amgen's position on this issue is more fully explained in Amgen's Emergency Motion for Order Precluding Roche From Arguing That the '933, '422 and '349 Patent Claims Are Invalid for Obviousness-Type Double Patenting Over the '868 and '698 Patent Claims (D.I. 965). Amgen will seek leave to file a short reply brief to respond to arguments raised in Roche's opposition to Amgen's emergency motion.

We welcome any opportunity to address questions or concerns that the Court may have regarding these issues.

Respectfully submitted,

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/s/Lloyd R. Day, Jr.  
Lloyd R. Day, Jr.

LRD:sv

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/s/ Patricia R. Rich  
Patricia R. Rich