

**EXHIBIT A**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**[PROPOSED] AMGEN’S REPLY IN SUPPORT OF ITS 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**

Roche’s opposition to Amgen’s emergency motion removes any doubt as to Roche’s aim in seeking to add several new ODP defenses on the eve of trial. Roche bluntly asserts that it will support these additional ODP defenses with “testimony and documentary evidence that the purified and isolated EPO DNA sequence, and host cells transfected with this sequence [*i.e., the ‘008 claimed inventions*], render the claims of the ‘422, ‘933, and ‘349 patents obvious to one of ordinary skill in the art.”<sup>1</sup> This is precisely the argument that the Court precluded on summary judgment when it held that the product and cell inventions claimed in Amgen’s ‘422, ‘933 and ‘349 patents are exempt from obviousness-type double patenting over the DNA and host cell inventions claimed in Amgen’s expired ‘008 patent under 35 U.S.C. § 121, the ODP safe harbor

<sup>1</sup> Roche Opp. (D.I. 994), at 5.

statute. Unless Amgen's emergency motion is granted, Roche's procedural gamesmanship will trump the Court's summary judgment Order.

**I. ROCHE CONFIRMS ITS PLAN TO USE THESE NEW ODP DEFENSES AS A VEHICLE TO ARGUE TO THE JURY THAT THE DNA AND HOST CELL INVENTIONS CLAIMED IN AMGEN'S '008 PATENT RENDER OBVIOUS THE PRODUCT AND CELL INVENTIONS CLAIMED IN AMGEN'S '933, '422 AND '349 PATENTS**

In its opposition brief, Roche expressly and unambiguously confirms that it seeks to prove its new ODP defenses by arguing that the DNA and host cell inventions claimed in Lin's '008 patent render obvious the product and cell inventions claimed in Lin's '422, '933 and '349 patents:

Roche will offer admissible testimony and documentary evidence that the purified and isolated EPO DNA sequence, and host cells transfected with this sequence, render the claims of the '422, '933, and '349 patents obvious to one of ordinary skill in the art.<sup>2</sup>

This is not an isolated statement taken out of context. In the following paragraph, Roche reiterates its position that the issue "is still very much alive" whether the '422, '933 and '349 claimed inventions are obvious over the '008 claimed inventions:

Accordingly, the question of obviousness of the '422, '933, and '349 claims over the purified and isolated EPO DNA sequence and host cells transfected with the sequence is still very much alive, and it is directly relevant to the issue of ODP over the '868 and '698 patents.<sup>3</sup>

Although Roche carefully avoids any mention of the '008 patent claims, it is beyond dispute that Roche's reference to "the purified and isolated EPO DNA sequence, and host cells transfected with this sequence" is a reference to the inventions claimed in the '008 patent:

- '008 claim 2: "A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 6.

- '008 claim 4: "A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA sequence according to claim 1, 2, or 3 in a manner allowing the host cell to express erythropoietin."

Thus, Roche's position is absolutely clear: unless Amgen's emergency motion is granted, Roche intends to argue to the jury that the inventions claimed in the '933, '422 and '349 patents are obvious over the inventions claimed in the '008 patent.

But this is precisely the line of argument that is precluded by the Court's August 27, 2007 summary judgment Order. Amgen explained in great detail in its summary judgment briefing how the inventions claimed in the '933, '422 and '349 patents are exempt from obviousness-type double patenting over the DNA and host cell inventions claimed in the '008 patent under 35 U.S.C. § 121, the ODP safe harbor statute.<sup>4</sup> The Court granted Amgen's motion.

Roche tries to distract the Court by arguing that § 121 does not apply to the '868 and '698 patents because, according to Roche, the issued claims in those patents belong to Group II of the PTO's 1986 restriction requirement and therefore were not forced apart from the other Group II claims that issued in the '008 patent.<sup>5</sup> This is nothing more than a red herring. Roche's new ODP defenses challenge the validity of the '933, '422 and '349 claims — the same claims that were the subject of Amgen's successful motion for summary judgment. Roche's new ODP defenses do not challenge the validity of the '868 or '698 claims. The relevant inquiry is whether § 121 exempts the inventions claimed in the '933, '422 and '349 patents from ODP. The answer is yes, for the same reasons argued in Amgen's summary judgment briefing. Roche's new ODP defenses are nothing more than a complex scheme to have the jury nullify the Court's summary judgment order of no obviousness-type double patenting.

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<sup>4</sup> See D.I. 499, at 8-13; D.I. 676, at 2-12.

<sup>5</sup> See Roche Opp. (D.I. 994), at 6-12.

## II. ROCHE MISREPRESENTS ITS PRIOR DISCLOSURE OF THESE ADDITIONAL ODP DEFENSES

It would be especially inequitable to allow Roche to circumvent the Court's summary judgment ruling using defenses that were not properly disclosed during discovery. Amgen addressed this issue in its opening brief (D.I. 965) and will not repeat those points here, except to reiterate that these ODP defenses were not mentioned in interrogatories served at the close of fact discovery on April 2, 2007. Roche's mention of these defenses in later supplemental responses lacked any detail or any claim-to-claim comparisons and was legally insufficient to mount these defenses. Roche's opposition contains two other misstatements.

First, Roche's representation that it disclosed these additional ODP defenses "repeatedly throughout . . . expert discovery"<sup>6</sup> is false. The only Roche expert to even mention these defenses was Dr. Kadesch. As Amgen noted in its opening brief, Dr. Kadesch provided nothing more than a conclusory, two-sentence opinion addressing only one of the numerous additional ODP defenses the Roche seeks to put on at trial.<sup>7</sup> Aside from this, none of Roche's experts opined in their reports that the any of the '933, '422 or '349 asserted claims are invalid for ODP over the '868 or '698 claims. For example, Roche's expert, Dr. Lowe, did not opine that the inventions claimed in the '933, '422 and '349 patents are invalid for ODP over the inventions claimed in the '868 and '698 patents. Yet, Roche's opposition states that "Roche will present evidence, including, *inter alia*, the testimony of Dr. John Lowe and Dr. Lin's own statements, that the DNA sequence and transfected host cells render the '422, '933, and '349 claims obvious in light of the claims of the '868 and '698 patents."<sup>8</sup> The Court should preclude Roche from

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<sup>6</sup> Roche Opp. (D.I. 994), at 1.

<sup>7</sup> D.I. 965, at 7 n.11.

<sup>8</sup> Roche Opp. (D.I. 994), at 6.

using expert opinions concerning ODP over the '008 claims to support Roche's new defenses alleging ODP over the '868 and '698 claims.

Second, Roche's representation that "Roche reiterated its contention that the claims of the '933, '349 and '422 patents are invalid for double patenting over the claims of the '868 and '698 in the Joint Pretrial Memorandum filed August 10, 2007"<sup>9</sup> is also false. As Amgen noted in its opening brief, Roche asserted only one of these additional ODP defenses in the Joint Pretrial Memo: "Whether subject matter covered by the Asserted Claims is obvious in view of claim 1 of the '868 patent."<sup>10</sup> Now, Roche seeks to put on at trial an undisclosed number of additional ODP defenses based on other claims in the '868 patent, as well as claims in the '698 patent. This should not be allowed.

### **III. THE COURT HAS A NECESSARY ROLE IN DECIDING ALL ODP DEFENSES THAT ROCHE IS PERMITTED TO PURSUE AT TRIAL**

Roche contends that it is within the Court's discretion to allow the jury to decide all aspects of Roche's ODP defenses.<sup>11</sup> The Federal Circuit has indicated otherwise:

- "Determining what is patented by correct claim interpretation is essential to determination of obviousness-type double patenting issues."<sup>12</sup>
- "Double patenting is altogether a matter of what is claimed. Claim interpretation is a question of law which we review de novo."<sup>13</sup>
- "De novo review is appropriate because double patenting is a matter of what is claimed, and therefore is treated like claim construction upon appellate review."<sup>14</sup>

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<sup>9</sup> *Id.* at 3.

<sup>10</sup> D.I. 965, at 5 n.5 (quoting D.I. 807, Ex. B at 8, ¶ 72).

<sup>11</sup> Roche Opp. (D.I. 994), at 15.

<sup>12</sup> *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F. 2d. 1272, 1279 (Fed. Cir. 1992) (capitalization altered).

<sup>13</sup> *Id.* at 1277.

<sup>14</sup> *In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. 17463, at \*10 (Fed. Cir. July 23, 2007) (quoting *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir.

- “Accordingly, analysis of the claims at issue is the first step in determining if the second invention is merely an obvious variation of the first.”<sup>15</sup>
- “Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct.”<sup>16</sup>

Whether or not the Court allows the jury to hear evidence relevant to Roche’s ODP defenses, Amgen urges the Court to make the final, *legal* determination on Roche’s ODP defenses. At the very least, the Court must be the one to construe each claim implicated by Roche’s ODP defenses. It is the Court’s role, not the jury’s, to determine the metes and bounds of Amgen’s claimed inventions. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

#### IV. CONCLUSION

For the reasons provided above and in Amgen’s opening brief and summary judgment briefs, Amgen respectfully requests that the Court grant an order precluding Roche from arguing that the inventions claimed in the ‘933, ‘422 and ‘349 patents are invalid for ODP over the inventions claimed in the ‘868 and ‘698 patents.

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1999)).

<sup>15</sup> *Georgia-Pacific*, 195 F.3d at 1326.

<sup>16</sup> *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

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Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on September 6, 2007.

/s/ Patricia R. Rich  
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