

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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|----------------------------|---|----------------------------------|
| _____                      | ) |                                  |
| AMGEN INC.,                | ) |                                  |
|                            | ) |                                  |
| Plaintiff,                 | ) |                                  |
|                            | ) |                                  |
| v.                         | ) |                                  |
|                            | ) | CIVIL ACTION No.: 05-CV-12237WGY |
| F. HOFFMANN-LA ROCHE, LTD  | ) |                                  |
| ROCHE DIAGNOSTICS GmbH     | ) |                                  |
| and HOFFMANN-LA ROCHE INC. | ) |                                  |
|                            | ) |                                  |
| Defendants.                | ) |                                  |
| _____                      | ) |                                  |

**DEFENDANTS’ OBJECTIONS TO THE COURT’S SEPTEMBER 7, 2007 ORDER  
THAT THE ISSUE OF OBVIOUSNESS-TYPE DOUBLE PATENTING IS A MATTER  
OF LAW THAT IT IS NOT TO BE PRESENTED TO THE JURY**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively “Roche”) respectfully submit these objections to the Court’s September 7, 2007 Order (“the Order”) that the issue of obviousness-type double patenting (“ODP”) is a matter of law that is not to be presented to the jury.

First, the Court’s Order has unfairly prejudiced Roche’s presentation of evidence to the jury. During the direct examination of Roche’s invalidity expert witness, Dr. John Lowe, Roche’s Counsel specifically requested permission from the Court during a sidebar conference on whether Roche could present evidence on ODP Theory No. 3 through this witness to the jury.

The Court unequivocally gave consent without any conditions:

Ms. Ben-Ami: I wanted to let you know that, your Honor, that the next topic with this witness is this obviousness type double --

The Court: You told Ms. Smith and you did just right. Here’s the thing. I’m working from Amgen’s most recent letter, doesn’t mean

I agree with it, but it fixes things in my mind and identifies these theories by number. The truth is that you people are on Theory Number 4, ahead of me, that I don't think I can make a principle ruling right now. **So what I propose is that -- you can do your Theory Number 3, but that just is the one that we all agree was not given summary judgment and the like.**

Ms. Ben-Ami: That's the only ones he's doing. He's not doing Theory 4.

Mr. Day: He has no opinions on Theory 4, he never disclosed any his report.

Ms. Ben-Ami: That's why he's not doing them. He's only doing Theory 3.

The Court: That's probably as far as we're going to get on this issue today. On Theory Number 4, you've given me stuff to wrestle with and I will.

Ms. Ben-Ami: You have time for that. That's not coming up tomorrow. I just wanted to give you this heads-up.

The Court: Fine.

(Tr. 9/6/07 at 306-307) (emphasis added); *see also* (Tr. 9/5/07 at 138) (“The Court: The short of it is you may use this. I think you're very thin on this claim and you deftly just brushed over it. You may use it. You go ahead, you try your case.”).

As a result, Roche did present ODP evidence to the jury which compared the claims of the '008 patent with those of the '868 and '698 patent. This was consistent with the Court's instruction, and as discussed below, also consistent with Supreme Court and Federal Circuit precedent, which recognizes that issues of ODP necessarily involve underlying factual issues.

However, the Court's subsequent Order has now taken this issue away from the jury after the jury has already heard *prima facie* evidence. By not allowing the jury to hear additional evidence on this matter, Roche is unduly prejudiced because the jury will be given the distinct

impression that portions of Roche's case have been disposed of, even though the Court gave Roche clear permission that it could present this evidence to the jury.

As Roche presented in its Opposition to Amgen's Emergency Motion on Double Patenting (D.I. 994) and at Oral Arguments, the issue of ODP includes issues of fact that are suitable for a jury. The U.S.P.T.O. Manual of Patent Examining Procedure ("M.P.E.P.") states:

Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985).

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claims relative to claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

M.P.E.P. Section 804 (II)(B)(1) (8<sup>th</sup> Edition) (Rev. 4) (October 2005). For purposes of comparing the claims of the '008 patent against the claims of the '868 and '698 patents ("ODP Theory No. 3") and comparing the claims of the '868 and '698 patents against the claims of the '422, '933, and 349 patents ("ODP Theory No. 4"), the Court should allow the jury to hear and decide these factual issues before ruling on obviousness-type double patenting, since these comparisons should be conducted *in light of the existing prior art*. See *In re Longi*, 759 F.2d

887, 893 (Fed. Cir. 1985) (“Under that facet of the doctrine of double-patenting, we must direct our inquiry to whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, *in light of the prior art.*”) (emphasis added); *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 356 (Fed. Cir. 1985) (holding obviousness-type double patenting did not apply where defendant “offered no evidence of the scope and content of the pertinent art, other than the '115 patent, the level of skill in the art, or what would have been obvious to a person skilled in the art.”)

Comparison of the claims to determine invalidity based on ODP cannot be performed based solely on the file histories, and is distinct from the legal issues surrounding the safe harbor provision of 35 U.S.C. §121. Since the fact finder must consider all the prior art and other relevant evidence, such as expert testimony, comparison of the claims is tantamount to the determination of obviousness. *See Longi*, 759 F.2d at 892 n.4 (a double patenting of the obviousness type rejection is analogous to a failure to meet the non-obviousness requirement of 35 U.S.C. § 103, except that the patent principally underlying the double-patenting rejection is not considered prior art); *In re Jezl*, 396 F.2d 1009, 1013, 55 C.C.P.A. 1234, 1238, 158 U.S.P.Q. (BNA) 98 (1968) (“That rejection - one of ‘double patenting of the obvious type’ - presents the same basic question as the § 103 rejection, but in narrower aspect.”); *In re Braithwaite*, 379 F.2d 594, 600 n.4, 54 C.C.P.A. 1589, 1597 n.4, 154 U.S.P.Q. (BNA) 29 (1967).

As the court in *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F.Supp. 2d 820, 911 (S.D. Ind. 2005), stated,

Where the reference patent is prior art, as in this case, the analysis for obviousness-type double patenting and obviousness under § 103 certainly begin in the same way . . . In this regard, the PTO itself has long recognized that the obvious-type double-patenting analysis parallels the obviousness analysis under *Graham*. "The factual inquiries set forth in *Graham v. John Deere Co.*, that are

applied for establishing background for determining obviousness under 35 U.S.C. § 103 are employed when making an obvious-type double patenting analysis,' including 'objective indicia of nonobviousness'.

*Id.*; see also *Smith & Nephew, Inc. v. Arthrex, Inc.*, 2007 WL 1467228 at \*14 (D. Or. 2007).

In addition to comparing the claims of the later-issued patent to the earlier patent and examining the claims in light of all the prior art, secondary considerations of non-obviousness are relevant in determinations of invalidity based on ODP. *In re Emert*, 124 F.3d 1458, 1462 (Fed. Cir. 1997) (finding obviousness “[a]bsent some indication of unexpected properties.”); *In re Glaxo ‘845 Patent Litigation*, 450 F.Supp. 2d 435, 437 (S.D.N.Y. 2006) (“It is also clear to this Court that the Federal Circuit and its predecessors have recognized the relevance of such secondary considerations in connection with the refutation of prima facie demonstrations of obviousness in the double-patenting context.”)

The jury is the fact finder in this case, and should make these factual determinations. Importantly, it appears that there is no disagreement between the parties that this issue - comparison of the claims to determine if they are patentably distinct - is a question for the jury. At the September 7<sup>th</sup> hearing, Counsel for Amgen stated “The issue would be that, okay, even if these, even if these claims claimed different inventions and there is no entitlement under 121 to safe harbor protection against this earlier issued claim, would this different invention then have been obvious in light of the earlier issued claim. That would be perhaps a question of fact for which the jury might have decide.”<sup>1</sup> (emphasis added)

Therefore, (1) the Court previously ruled that the ODP issues could be presented to the jury; (2) as a result, ODP issues of fact were presented to the jury; (3) this was consistent with

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<sup>1</sup> 9/7/07 Transcript of Afternoon Proceedings at 10:17-23.

Federal Circuit and Supreme Court precedent establishing that ODP determinations require underlying factual inquiries; and (4) Amgen counsel has even conceded that comparison of the claims for purposes of ODP includes questions of fact which the jury should decide. Based on at least the foregoing, Roche objects to the Court's September 7<sup>th</sup> Order.

DATED: September 10, 2007  
Boston, MA

Respectfully submitted,

F. HOFFMANN-LA ROCHE, LTD,  
ROCHE DIAGNOSTICS GMBH, and  
HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ Thomas F. Fleming  
Leora Ben-Ami (*pro hac vice*)  
Patricia A. Carson (*pro hac vice*)  
Thomas F. Fleming (*pro hac vice*)  
Howard S. Suh (*pro hac vice*)  
Christopher Jagoe (*pro hac vice*)  
Peter Fratangelo (BBO# 639775)  
KAYE SCHOLER LLP  
425 Park Avenue  
New York, New York 10022  
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)  
Julia Huston (BBO# 562160)  
Nicole A. Rizzo (BBO# 663853)  
BROMBERG & SUNSTEIN LLP  
125 Summer Street  
Boston, MA 02110  
Tel. (617) 443-9292

**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 (NEF) on the above date.

/s/Thomas Fleming  
Thomas F. Fleming