

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**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**

On the last business day before trial, Roche filed a pre-trial brief and jury instructions that set forth theories of obviousness-type double patenting (“ODP”) which Roche never developed and had long since abandoned. Worse yet, Roche apparently seeks to circumvent the Court’s recent summary judgment determination that 35 U.S.C. § 121 shields Dr. Lin’s ‘933, ‘422 and ‘349 patent claims from ODP over Lin’s ‘008 patent claims, by arguing that the ‘933, ‘422 and ‘349 claims must expire on the same date as Lin’s ‘868 and ‘698 claims, which in turn, Roche argues, are obvious over the ‘008 claims which expired in 2004. Thus, Roche is improperly trying to use the ‘868 and ‘698 patents as an intermediate stepping stone to achieve a result that this Court has already precluded. That is, despite being statutorily precluded from arguing that the ‘933, ‘422 and ‘349 claims are invalid for ODP over the ‘008 claims, Roche nonetheless seeks to have those claims limited to the same 17-year term as the ‘008 patent.

Roche's attempt to ambush Amgen on the eve of trial with several additional ODP defenses that were neither sufficiently disclosed nor developed during discovery is unfairly burdensome and prejudicial to Amgen. Even Roche's last-minute description of these additional ODP defenses does not specify the actual claims of the '868 and '698 patents that Roche seeks to use as ODP references. The Court should put an end to Roche's procedural gamesmanship.

The additional ODP defenses that Roche seeks to add to the case should also be precluded under 35 U.S.C. § 121, for the same reasons that the Court granted summary judgment of § 121 protection against Roche's '008-based ODP defenses. Roche can't have it both ways. If the '868 and '698 claims fall within Group II of the PTO's restriction requirement, then those claims are patentably distinct from the '933, '422 and '349 claims, which the Court previously determined do *not* fall within Group II. On the other hand, if the '868 and '698 claims fall outside of Group II, then Roche's argument that those claims are invalid for ODP over the Group II claims of the '008 patent necessarily fails because they are protected under § 121. In either event, all ODP defenses that Roche is permitted to pursue at trial should be decided by the Court, not the jury, for the same reasons that courts alone decide issues of claim construction.

**A. Roche Should Be Precluded From Arguing That the '933, '422 and '349 Claims Are Invalid for Obviousness-Type Double Patenting Over the '868 and '698 Claims**

**1. Roche's additional ODP defenses were not properly disclosed during discovery**

Roche's attempt to reshape the validity case on the eve of trial by adding new alleged grounds of obviousness-type double patenting makes a mockery of the Federal Rules of Civil Procedure and the Court's disclosure requirements and must be rejected. Obviousness-type double patenting is determined on a claim-by-claim basis by assessing whether a later-issued claim is patentably distinct from an earlier-issued claim in a commonly-owned patent. *In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. LEXIS 17463, at \*10-11 (Fed. Cir. July 23,

2007). Because each of the 14 claims in the earlier-issued '868 and '698 patents defines a separate invention, each of those claims constitutes a separate ODP "reference" for purposes of determining the appropriate term of the '933, '422 and '349 patent claims, and each necessitates a separate "patentably distinct" analysis.

Despite Amgen's interrogatories requesting the specific details of Roche's ODP arguments, Roche failed to disclose any ODP position based on the claims of the '868 or '698 patents before the close of fact discovery. Although this Court had allowed Defendants' Motion to Amend Their Sixth Affirmative Defense on March 20, 2007 to allow Roche to plead that "the claims of the '349, '933, '080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents," the Court's Order stated that the "time for Discovery and other Pre-trial Scheduled dates are not extended." In Roche's original response to Amgen's Interrogatory Nos. 9 and 11 which requested the details of Roche's invalidity and ODP contentions, Roche only identified its contentions that the claims-in-suit were obvious over the '008 claims. In their First, Second and Third Supplemental Responses to Amgen's interrogatories, Roche only identified its contentions of ODP over the '008 claims and failed to mention anything concerning its contentions based on claims of the '868 and '698 patents. Roche's Third Supplemental Response was served on April 2, 2007, the last day of fact discovery and nearly two weeks after the Court allowed Roche to amend its ODP pleadings.<sup>1</sup>

Moreover, during expert discovery, Roche abandoned its ODP theories based on the '868

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<sup>1</sup> Not until its Fifth Supplemental Responses to Amgen's interrogatories, which Roche served on May 1, 2007, a month after the close of fact discovery and in the middle of expert discovery, did Roche say anything about its ODP allegations based on the '868 and '698 patents: "[T]he asserted claims of the '933 patent, '080 patent, '349 patent, and '422 patent are either invalid for obviousness type double patenting based on the earlier issued claims of the '868 and '698 patent or should be deemed to expire on 8/15/12, the expiration date of the '868 and '698 patents." Roche's 5/1/07 Supp. Response to Interrog. No. 9, at 60. This general allegation fails to state any of the required specifics to establish a defense of ODP. There is no specific mention of any claim and no information as to Roche's contentions is provided.

and '698 claims and chose instead to focus on its allegations of ODP based on the '008 and Lai/Strickland '016 patent claims. Roche filed at least half a dozen different expert reports concerning ODP. Those expert reports focused on Roche's ODP defenses based on the '008 and '016 patent claims, and did not address ODP based on the '868 and '698 patent claims. Relying on Roche's failure to describe its ODP defense based on the '868 and '698 patents either in its interrogatory responses or its expert reports, Amgen's experts did not address ODP based on the '868 and '698 claims in their rebuttal expert reports. Roche further signaled its intent not to pursue ODP defenses based on claims in the '868 and '698 patents in its summary judgment briefing, where Roche expressly referenced its '008- and '016-based ODP defenses but made no mention whatsoever of any ODP defenses based on the '868 or '698 claims.<sup>2</sup>

Recently, the Court granted Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting, which disposed of most of Roche's ODP defenses based on the '008 and '016 patent claims.<sup>3</sup> In light of this ruling, Roche now seeks to revive the ODP theories that it abandoned during discovery. Roche hopes to establish invalidity of the '933, '422 and '349 claims for ODP over the '008 claims (expired in 2004) through the '868 and '698 claims (which Roche argues *should* have expired in 2004) because the direct route via the '008 claims is blocked by the Court's summary judgment ruling that § 121 applies. Yet, even now, at the start of trial, it remains unclear which claims of the '868 and '698 patents Roche seeks to assert as a basis for ODP. Roche's pre-trial brief merely contends that the '933, '422 and '349

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<sup>2</sup> See, e.g., Mem. In Supp. of Defendants' Mot. for Sum. Judgment That the Claims of Patents-In-Suit Are Invalid for Double Patenting Over Amgen '016 Patent (D.I. 491), at 1 n.1 (noting that, in addition to Roche's ODP defense based on the '016 claims, Roche also had an additional ODP defense based on the '008 patent claims).

<sup>3</sup> See Electronic Order, dated Aug. 27, 2007, granting Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 498).

claims are invalid for ODP over “the claims of the ‘868 or ‘698 patents.”<sup>4</sup> Thus, even with these additional untimely disclosures, Amgen still has no adequate notice regarding the specific ODP defenses Roche seeks to assert at trial. Furthermore, Roche’s pre-trial brief greatly expands on the ODP contentions provided by Roche a few weeks earlier in the parties’ Joint Pretrial Memorandum.<sup>5</sup>

Roche’s decision to unfairly surprise Amgen with additional ODP theories at the beginning of trial is unduly burdensome and distracting for Amgen. Furthermore, if Roche is allowed to proceed with these additional ODP defenses, the prejudice to Amgen will be significant because its experts did not have the opportunity to address these defenses in their reports. For the foregoing reasons alone, the Court should preclude Roche from arguing that the ‘933, ‘422 and ‘349 claims are invalid for ODP over claims in the ‘868 and ‘698 patents.

## **2. Roche’s additional ODP defenses are precluded by 35 U.S.C. § 121**

Consistent with the Court’s Order granting Amgen’s Motion for Summary Judgment of No Obviousness-Type Double Patenting, Roche’s new ODP defenses also should be precluded under 35 U.S.C. § 121, the ODP safe harbor statute. Roche repeatedly has argued that the ‘868 and ‘698 patent claims fall within the scope of Group II of the PTO’s 1986 restriction requirement.<sup>6</sup> Indeed, this contention is essential to Roche’s other, properly disclosed, ODP defenses that the ‘868 and ‘698 patent claims are invalid for ODP over the ‘008 patent claims

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<sup>4</sup> See Roche’s 8/31/07 Pre-Trial Brief (D.I. 919), at 34, 41, 50.

<sup>5</sup> If the Court allows Roche to present defenses of ODP based on the ‘868 and ‘698 claims notwithstanding Amgen’s positions that these defenses were not adequately disclosed and are barred by statute, at the very least the Court should limit Roche to the specific grounds of ODP that Roche disclosed in the Joint Pretrial Memorandum. Specifically, in its list of contested issues for trial, Roche alleged only one claim from the ‘868 and ‘698 patents as a basis for ODP: “Whether subject matter covered by the Asserted Claims is obvious in view of *claim 1 of the ‘868 patent.*” Joint Pretrial Memorandum (D.I. 807), Ex. B at 8.

<sup>6</sup> See, e.g., Roche’s Opp. to Amgen’s Mot. For Summary Judgment of No Obviousness-Type Double Patenting (D.I. 568), at 2, 5.

(the '008 claims belong to Group II). If the '868 and '698 claims belong to Group II, as Roche contends, then these claims are patentably distinct from the claims in the '933, '422 and '349 patents, which the Court, in granting Amgen's summary judgment motion, necessarily determined do not belong to Group II.<sup>7</sup>

In its pre-trial brief, Roche contends that § 121 does not shield the '933, '422 and '349 claims from ODP over the '868 and '698 claims because, according to Roche, the '179 application was not filed "as a result of" the PTO's 1986 restriction requirement.<sup>8</sup> But once again, the Court, in granting Amgen's motion for summary judgment of no ODP, necessarily determined that the '179 application *was* filed "as a result of" the 1986 restriction requirement — that was one of the elements of Amgen's claim of § 121 protection for the '422 and '349 claims.<sup>9</sup>

Roche cannot have it both ways. If the '868 and '698 claims belong to Group II, as Roche repeatedly has argued, then § 121 precludes Roche's new defenses that the '933, '422 and '349 claims are invalid for ODP over claims in the '868 and '698 patents, for the very same reasons that the Court held that § 121 shields the '933, '422 and '349 claims from ODP over the Group II claims of the '008 patent.<sup>10</sup> Alternatively, if Roche intends to change its tune at trial and argue that the '868 and '698 claims do *not* fall within the scope of Group II, then Roche's other, properly disclosed, ODP defenses that the '868 and '698 claims are invalid for ODP over

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<sup>7</sup> See Mem. In Supp. of Amgen's Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 499), at 12-13; Amgen's Reply Br. In Support of Its Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 676), at 6-12.

<sup>8</sup> 8/31/07 Pre-Trial Brief (D.I. 919), at 34, 41, 50.

<sup>9</sup> See Mem. In Supp. of Amgen's Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 499), at 10-12; Amgen's Reply Br. In Support of Its Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 676), at 3-6.

<sup>10</sup> See Mem. In Supp. of Amgen's Mot. for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 499), at 10-12 (explaining that § 121 immunizes the '933, '422 and '349 claims from ODP over the Group II claims because (1) the '178 and '179 applications giving rise to these patent were filed as a result of the PTO's 1986 restriction requirement and (2) the claims in these patent maintained consonance by not crossing the line of demarcation drawn around Group

the Group II claims of the '008 patent necessarily fail and should be dismissed.

**B. Roche's Obviousness-Type Double Patenting Defenses Should Be Decided By the Court, Not the Jury**

“Determining what is patented by correct claim interpretation is essential to determination of obviousness-type double patenting issues.” *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279 (Fed. Cir. 1992) (capitalization altered). Accordingly, the Federal Circuit has repeatedly held that, as with claim construction, obviousness-type double patenting is a question of law that is reviewed *de novo*, without deference. *See id.* at 1277 (“Double patenting is altogether a matter of what is claimed. Claim interpretation is a question of law which we review *de novo*.”); *In re Metoprolol Succinate Patent Litig.*, 2007 U.S. App. LEXIS 17463, at \*10 (Fed. Cir. July 23, 2007) (“*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.”) (internal quotation omitted). Because of this crucial relationship between ODP and claim construction, all ODP defenses that Roche is permitted to pursue at trial should be decided by the Court, not the jury.

It is especially important that the Court, and not the jury, decide any Roche defenses of obviousness-type double patenting over claims in the '868 and '698 patents, should the Court allow Roche to present those defenses at trial notwithstanding Amgen's above-stated positions. Roche has no evidence to support its allegations of ODP based on the '868 and '698 claims. None of Roche's expert witnesses provided an analysis of obviousness-type double patenting over claims in the '868 or '698 patents.<sup>11</sup> Presumably, Roche will seek to establish the elements

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II).

<sup>11</sup> One of Roche's experts did provide a conclusory, two-sentence opinion in his § 112 invalidity report: “there is no significant difference between claim 7 of the '349 patent and claim 4 of the '698 patent. Therefore, claim 7 of the '349 patent is invalid for double patenting.” 5/1/07 Supp. Expert Rpt. of Dr. Thomas Kadesch. But this unsupported opinion is not the type of clear and

of these affirmative defenses based entirely on prior statements by Amgen.<sup>12</sup> As the motion *in limine* briefing addressing these statements make plain, however, the purported “admissions” relied on by Roche are entirely inadequate to justify a holding that the ‘933, ‘422 and ‘349 patent claims are invalid for obviousness-type double patenting over claims in the ‘868 and ‘698 patents.<sup>13</sup>

For example, the “different manifestations of the same invention” statement that Roche features prominently in its briefing was the position of one of Amgen’s competitors regarding the priority relationship between the *DNA* and process inventions at issue in the ‘096 and ‘097 Interference proceedings.<sup>14</sup> This statement does not relate at all to whether Dr. Lin’s ‘933 and ‘422 *product* or ‘349 *cell* claims are patentably distinct from the process claims in the ‘868 and ‘698 patents, which is what Roche must prove by clear and convincing evidence to prevail on its recently-revived ODP defenses.<sup>15</sup> The other purported “admissions” that Roche has identified to date are similarly inadequate to justify a holding of ODP over claims in the ‘868 and ‘698 patents. On this record, and given that Roche cannot offer any expert witness evidence addressing the details of these particular ODP defenses, Amgen respectfully submits that it would be improper even to allow a jury to consider Roche’s additional ODP defenses.

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convincing evidence required to justify a holding of obviousness-type double patenting. Moreover, it addresses only one of the numerous ODP theories that Roche seeks to add on the eve of trial.

<sup>12</sup> See Roche Proposed Jury Instruction for Double Patenting (D.I. 917, at 42) (instructing the jury that it “may consider Amgen’s assertions in prior proceedings” when assessing ODP over the ‘868, ‘698 and ‘008 patent claims).

<sup>13</sup> See generally Amgen’s Opposition to Roche’s Motion *In Limine* To Preclude Amgen From Contradicting Arguments Made In Prior Administrative and Judicial Proceedings (D.I. 867).

<sup>14</sup> See *id.* at 3-4.

<sup>15</sup> In fact, the Patent Office had itself already determined Lin’s product inventions to be patentably distinct from Lin’s process inventions, not only through the PTO’s 1986 restriction requirement, but also in declaring separate counts for the interference proceedings, and in a letter signed by the Acting Commissioner of Patents regarding those separate interference proceedings.

### **CONCLUSION**

For the foregoing reasons, the Court should preclude Roche from arguing that the '933, '422 and '349 patent claims are invalid for obviousness-type double patenting over claims in the '868 and '698 patents. Furthermore, all ODP defenses that Roche is permitted to raise at trial should be decided by the Court, not the jury.

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Respectfully Submitted,

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**CERTIFICATE PURSUANT TO LOCAL RULE 7.1**

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried  
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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 3, 2007.

/s/ Michael R. Gottfried  
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