UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S OPPOSITION TO 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 PATENTS

Preliminarily, Roche notes that the subject of this Opposition differs from the issue regarding invalidity of the '868 and '698 process patents addressed to the Court on September 4. This issue also differs from the subject of Amgen's motion that its '933, '349 and '422 patents are not invalid over Amgen's Lin '008 patent and Lai '016 patent due to obviousness-type double patenting, which the Court has previously decided.

The issue addressed herein concerns Roche's Sixth Affirmative Defense of invalidity of the '933, '422, and '349 patents for obviousness-type double-patenting ("ODP") over the '868 and '698 patents, which Roche included *with no opposition from Amgen* in its March 2, 2007 Motion to Amend. Amgen does not dispute that Roche disclosed its defense repeatedly throughout both fact and expert discovery, nor that Roche has admissible evidence to support its defense. Amgen has had ample opportunity

to respond to this affirmative defense, and Roche is entitled to argue, and to present evidence in support of, this affirmative defense.

ARGUMENT

I. Roche's Affirmative Defense of Invalidity of the '933, '422, and '349 Patents Has Been Repeatedly and Adequately Disclosed

Roche's defense of ODP of the '933, '349, and '422 over the '868 and '698 claims was disclosed at least as early as March 2, 2007, when Roche filed an unopposed motion to amend its answer and counterclaims to add to its sixth affirmative defense to include the language: "the claims of the '349, '933, '080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents." Thus, Amgen's purported surprise at seeing the same language in Roche's pre-trial brief and jury instructions is pure fabrication. Far from blind-siding Amgen with this ODP defense, Roche has disclosed it, and provided abundant evidence in its support, throughout this litigation.

Although Roche's positions were originally disclosed March 2, 2007, Amgen has waited until early September to cry foul concerning any delay or ambiguity in the disclosure of Roche's positions regarding ODP based on the '868 and '698 patents. Moreover, since March 2, Roche has repeatedly reminded Amgen of their position. In its First Amended Answer and Counterclaims filed March 30, 2007, under its sixth Defense of Double Patenting, Roche stated 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."[1] Subsequently, on May 1, 2007, in its response to Amgen's interrogatory asking for all the

[1] Defendants' First Amended Answer and Counterclaims to Plaintiff's Complaint, filed 3/30/07, D.I. 344, at 4-5.

bases for which Roche contends any of Amgen's asserted claims are invalid, Roche stated that "the 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 patents."[2] This position was reinforced the same day in the Supplemental Expert Report of Dr. Thomas Kadesch.[3] Finally, 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.[4] Nevertheless, Amgen, despite receiving at least five separate indications of Roche's position, claims unfair surprise.

Amgen admits in its memorandum that it received every one of these notifications. *See generally* Amgen's Memorandum. Amgen further admits that Roche disclosed this defense in its interrogatory responses more than four months prior to the commencement of trial (and more than two months prior to the July 3, 2007 deadline for expert discovery). *See* Amgen's Memorandum, p. 3, note 1. Contrary to Amgen's assertions regarding Roche's interrogatory response, however, answers to interrogatories do not limit the offers of proof a party may present during trial. *See* Fed. R. Civ. P. 33(c), Advisory Committee Notes to 1970 Amendment. Furthermore, contention interrogatories "need not be answered until after designated discovery has been completed or until a pre-trial conference or other later time." Fed. R. Civ. P. 33(c).

[2] Defendants' Fifth Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 9-11), served May 1, 2007, at p. 60.
[3] Supplemental Expert Report of Dr. Thomas Kadesch, 05/01/07, ¶ 8.
[4] Roche's Statement of Contested Issues of Fact, Ex. B to Joint Pretrial Memorandum, filed 8/10/07, D.I. 807, p.8 ¶ 72.

Discovery in this case closed on July 3, 2007, long after Roche disclosed its double patenting defense, and Amgen had ample opportunity to take discovery on it.

Despite ample time to seek discovery on Roche's claims to ODP on the basis of the '868 and '698 patents, Amgen never sought any discovery regarding Roche's positions. The clear reason for this is that Roche has no discovery that would be relevant to the validity of Amgen's patents.

As required by the federal rules, Roche disclosed its defense to Amgen as it obtained relevant information during discovery and developed its arguments. Amgen's contention that Roche's interrogatory responses contain "no specific mention of any claim and no information as to Roche's contentions" is simply false. (*See* Amgen's Motion at 3 n.1). Roche disclosed to Amgen, for example, the following details regarding its contention:

> **For all the reasons set forth in Roche's prior supplemental response to this interrogatory regarding obviousness-type double patenting based on the earlier issued '008 patent, the 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. The claims of the '868 and '698 patents are directed to the process of making recombinant erythropoietin by expressing DNA encoding the erythropoietin gene in vertebrate and mammalian host cells to make an in vivo biologically active glycoprotein. The various asserted claims of the '933, '080, '349, and '422 patents cover such glycoprotein products, pharmaceutical compositions containing such products, methods of treatment using these pharmaceutical compositions, and the process for using vertebrate cells to produce certain levels of erythropoietin. As a result, these latter claims would have been obvious over the earlier issued process claims of the '868 and '698 patents.
>
> (Emphasis added.)

Defendants' Fifth Supplemental Responses and Objections to Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 9-11), dated May 1, 2007, at 60-61. Amgen never sought a more detailed response to the interrogatory with respect to ODP based on the '868 and '698 patents. Furthermore, of the six claims Amgen asserts between the '868 and '698 patents, only two are independent; one per patent. It is unclear what additional notice or clarity Amgen would have gathered from actually listing the number of the claims. (Furthermore, it is clear from the emphasized portion of the interrogatory response quoted above that evidence for ODP based on the '008 patent would be directly relevant to ODP based on the '868 and '698 patents, and thus could be used as such.)

In light of these disclosures, Amgen's fanciful claim of unfair surprise merits no serious consideration.

II. Roche's ODP Defense Is Supported By Admissible Evidence

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. Roche's experts have laid out their expected testimony on this issue in great detail, which is described below. Since the claims of the '868 and '698 patents are directed to processes that use the EPO DNA sequence and host cells transfected therewith, this testimony and documentary evidence will establish that claims of the '349, '933 and '422 are obvious over the subject matter of the claims of the '868 and '698 patents.

Although the Court's recent summary judgment ruling precludes using the '008 patent as a reference for ODP, the presumed basis on which the Court found no ODP of

those claims over '008 (i.e., the application of 35 U.S.C. § 121[5]) does not, contrary to Amgen's assertions, shield the '422, '933, and '349 claims from ODP over the '868 and '698 claims. 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. Thus, 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.

III. Section 121 Provides No Safe Harbor for the '933, '422, and '349 Patents Over the '868 and '698 Patents, and the Court's Summary Judgment Decision Does Nothing to Disturb Roche's Theory

A. The '868 and '698 Patents Are Outside the Scope of §121

The '868 patent issued on August 15, 1995 from patent application no. 113,179 (the "179 application"), filed Oct. 23, 1987, claiming processes for producing a glycosylated erythropoietin polypeptide. The only independent claim of the '868 patent, Claim 1, states:

> 1. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of:
>
> (a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin; and

[5] While the Court has not yet handed down its opinion, protection under §121 was the basis on which Amgen urged the Court to find no ODP.

(b) isolating said glycosylated erythropoietin polypeptide therefrom.

The ‘698 patent issued on April 8, 1997 from patent application no. 468,381, filed June 6, 1995 as a continuation application from the ‘179 application that eventually issued as the ‘868 patent. All of the asserted claims of the ‘698 patent are process claims for making either an in vivo biologically active erythropoietin product or a glycosylated erythropoietin polypeptide. Asserted Claim 6 states:

6. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of:

(a) growing, under suitable nutrient conditions, vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of Fig. 6; and

(b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.

The order of issuance and dates of expiration of Amgen’s Lin patents are summarized in the chart below:

Patent Number	Issue Date	Expiration Date
4,703,008	Oct. 27, 1987	Oct. 27, 2004 - expired
5,441,868	Aug. 15, 1995	Aug. 15, 2012
5,547,933	Aug. 20, 1996	Aug. 20, 2013
5,618,698	Apr. 8, 1997	Aug. 15, 2012
5,621,080	Apr. 15, 1997	Aug. 20, 2013
5,756,349	May 26, 1998	May 26, 2015
5,955,422	Sep. 21, 1999	Aug. 20, 2013

The ‘868 patent issued prior to the ‘933, ‘349 and ‘422 patents, and thus is a reference patent making the claims of these later issued patents invalid for double

patenting because as summarized below, the claims of the '933, '349 and '422 patents are not patentably distinct from the claims of the '868 patent. The '698 patent issued prior to the '349 and '422 patents, and thus can serve as a reference for invalidity of the patentably indistinct claims of these two later issued patents. The prohibition preventing certain patents from serving as references for double patenting purposes contained in 35 U.S.C. § 121 does not apply to the '868 and '698 patents.

35 U.S.C. § 121 states in pertinent part:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. **A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement**, shall **not be used as a reference** either in the Patent and Trademark office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.
>
> (Emphasis added).

The '698 patent issued from a continuation application from the application that issued as the '868 patent, and both patents claim processes for making an erythropoietin product. Neither one meets the reference prohibition language in § 121, and therefore is not disqualified from being a reference for later issued patents. The process claims for making an erythropoietin product were not restricted out from the group of claims that eventually issued as the '008 patent, but instead were voluntarily removed from that group by Amgen and later separately filed the '179 application. Section 121 provides no protection from such voluntary abandonment or separation of claims and does not prevent

the '868 and '698 claims from acting as references to later issued patents such as the '933, '349 and '422 patents for the '868 patent and the '349 and '422 patents for the '698 patent. *Gerber Garment Tech., Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 687 (Fed. Cir. 1990) ("Plain common sense dictates that a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application.").

Amgen filed its '298 application on November 30, 1984. The patent office issued a restriction requirement on this application, separating the original claims into six groups as follows:

> "Restriction to one of the following inventions is required under 35 U.S.C. 121:
>
> I. Claims 1-13, 16, 39-41, 47-54 and 59, drawn to polypeptide, classified in Class 260, subclass 112.
>
> II. Claims 14, 15, 17-36, 58 and 61-72, drawn to DNA, classified in Class 536, subclass 27.
>
> III. Claims 37-38, drawn to plasmid, classified in Class 435, subclass 317.
>
> IV. Claims 42-46, drawn to cells, classified in Class 435, subclass 240.
>
> V. Claims 55-57, drawn to pharmaceutical composition, classified in Class 435, subclass 177.
>
> VI. Claim 60, drawn to assay, classified in Class 435, subclass 6."[6]

Although the Group II claims were described by the examiner as "drawn to DNA," in addition to including the claims directed to DNA, the actual claims in Group II included all of the pending process claims of the '298 application - claims 69-72 for processes for making the erythropoietin polypeptide products by growing the host cells

[6] Examiner's Action 198, 7/03/86, in U.S. patent application serial no. 675,298, R008891908-16 ("7/3/86 Restriction Requirement") at R008891909, attached as Ex. 1 to the Declaration of Peter Fratangelo submitted herewith ("Fratangelo Declaration")

with the exogenous DNA under suitable nutrient conditions. Group II also included claims directed toward the host cells that contain the exogenous DNA used for making the erythropoietin polypeptide products. Amgen chose to prosecute the Group II claims as part of the '298 application which matured into the '008 patent.[7] However, Amgen chose on its own to cancel original claims 69-72 for processes for making the erythropoietin polypeptide products by growing the host cells with the exogenous DNA under suitable nutrient conditions from the '298 application when it cancelled all of the claims in Group II and resubmitted them in that application as new claims (73-103) omitting the process claims.[8] This was not as a result of the restriction requirement issued by the PTO, as the examiner included these claims in Group II with the host cell and DNA claims that eventually matured into the '008 patent. These process claims eventually were re-filed by Amgen in the '179 application that matured into the '868 process claims, and from which the '381 application for similar process claims, which matured into the '698 process patent, was filed as a continuation.

Amgen could have prosecuted the process claims to issuance in the '298 application, but instead chose on its own to separate these claims and include them in a later filed application. For a patent to be unavailable as a reference to a later issued patent pursuant to section 121, the application from which the patent issued must be either: (1) an application with respect to which a requirement for restriction under this section has been made, or (2) an application filed as a result of such a requirement. Since Amgen chose to cancel the Group II process claims for making the erythropoietin

[7] Ex. 1 at R008891908.
[8] Applicant's Amendment and Reply Under 37 C.F.R. § 1.111 and § 1.115, 3/11/87, in U.S. patent application serial no. 675,298, R008892011-38, attached as Ex. 2 to Fratangelo Declaration.

polypeptide products by growing the host cells with the exogenous DNA under suitable nutrient conditions which eventually issued in the '868 and '698 patents from the '298 application, these patents did not issue from "an application with respect to which a requirement for restriction under this section has been made." If they had been maintained in the '298 application consistent with the PTO-issued restriction requirement, these claims would have issued in the '008 patent and have expired in 2004. These Group II process claims that eventually issued in the '868 and '698 patents also did not issue from "an application filed as a result of such a requirement" since they were removed from the '298 application not as a result of a restriction requirement, but by Amgen's choice.

The Federal Circuit in *Gerber,* 916 F.2d at 688, noted that "[t]o gain the benefits of Section 121 there outlined, however, [the patentee] must have brought its case within the purview of the statute, i.e., it must have limited the claims in its divisional application to the non-elected invention or inventions . . . Gerber failed to do so." Amgen not only chose to include in its later '179 application the process claims from the elected Group II of the restriction requirement issued to the '298 application, but these claims actually became the issued claims of the '868 and '698 patents. These patents contain the process claims from elected Group II and therefore did not issue from applications filed as the result of a restriction requirement, but were separated from the rest of the Group II claims by Amgen's choice. Since both the '868 and '698 process patents do not meet the requirements of section 121 prohibiting them from being references for later-issued patents, they render the asserted claims of the '933, '349 and '422 patents invalid for double patenting because as summarized below, the evidence at trial will establish that

inventions of the asserted claims of the ‘933, ‘349 and ‘422 patents are obvious from the claims of the ‘868 and ‘698 patents.

B. Amgen’s ‘933, ‘349 and ‘422 Patents are Invalid for Double Patenting Based Upon the ‘868 and ‘698 Patents.

The evidence at trial will establish that all of the asserted claims of the ‘933, ‘349 and ‘422 patents are obvious in light of the claims of the ‘868 patent and, for the ‘349 and ‘422 patents, the ‘698 patent. Amgen asserts that Roche infringes claims 3, 7-9, 11-12 and 14 of the ‘933 patent, which issued after the ‘868 patent. The asserted claims of the ‘933 patent are product-by-process claims directed to a product produced by carrying out the processes claimed in the ‘868 patent. A comparison of these claims reveals their similarity. Claim 1 of the ‘868 patent states:

> 1. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of:
>
> (c) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin; and
>
> (d) isolating said glycosylated erythropoietin polypeptide therefrom.

Claim 3 of the ‘933 patent states:

> 3. A non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin said product possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells.

Claims 3, 7 and 8 of the ‘933 patent are simply the inherent result of the ‘868 claimed processes. Claims 9 and 12 of the ‘933 patent claim pharmaceutical

compositions containing the products which result from carrying out the processes of the '868 claims, and claims 11 and 14 are directed to methods of treatment using these pharmaceutical compositions. The evidence at trial will show that it would have been obvious to formulate the products of the '868 process claims as a therapeutic according to claims 9 and 12 and to practice the methods of claims 11 and 14 of the '933 patent.

Amgen asserts that Roche infringes claim 7 of the '349 patent, which issued after both the '868 and '698 patents. Claim 7 of the '349 patent is directed to a process of producing erythropoietin by culturing vertebrate cells capable of a minimum production level. The '868 and '698 patents claim processes for producing a glycosylated erythropoietin polypeptide. The evidence at trial will show that the minimum production level specified in '349 claim 7 is the inherent result of practicing the processes of the '868 and '698 patents, and claim 7 of the '349 is an obvious variant of the '868 and '698 patent claims. For example, the evidence will show that the use of methotrexate to amplify and increase expression had already been reported before 1983, and it would have been obvious to increase production to the levels claimed in claim 7 of the '349 patent.[9] The use of transcription control elements recited in the '349 patent was already recited in the method claims of the '698 patent.

Amgen asserts that Roche infringes claim 1 of the '422 patent, which issued after both the '868 and '698 patents. Claim 1 of the '422 patent is directed to a pharmaceutical composition of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier. Carrying out the processes claimed in the '868 and '698 patents produces recombinant human erythropoietin. The evidence at trial will show that after expressing

[9] See, e.g., Second Supplemental Expert Report of Dr. Thomas Kadesch, 6/13/07, at 8 n.3.

and isolating a glycosylated erythropoietin polypeptide pursuant to the processes claimed in the '868 and '698 patents, it would have been obvious prior to November 30, 1984 to purify the product for use in a therapeutic composition with a pharmaceutically acceptable diluent, adjuvant or carrier to make the product of claim 1 of the '422 patent.

C. Amgen Has Not Cured Double Patenting Over the '868 and '698 Patents by Terminally Disclaiming the '933, '349 and '422 Patents.

Amgen could have cured the invalidity of the '933, '349 and '422 patents over the '868 and '698 patents by terminally disclaiming these patents to the expiration date of the '868 and '698 patents. 35 U.S.C. § 253; 37 C.F.R. § 1.321(c). However, Amgen has not filed such a terminal disclaimer, so the issue of invalidity for double patenting of the asserted claims of the '933, '349 and '422 patents over the '868 and '698 patents is ripe for adjudication by the jury at trial.

Additionally, although it appears that Amgen could have cured this invalidity for double patenting by filing a terminal disclaimer before litigation began, the Federal Circuit has made clear that whether a patentee can cure invalidity for double patenting by terminally disclaiming during litigation or certainly after a finding of invalidity is an open question that the court has never decided. *In re Metoprolol Succinate Patent Litigation*, 2007 WL 2080393, *8, n.4 (Fed. Cir. July 23, 2007) ("the parties dispute whether a patentee may reinstate the validity of a patent by filing a terminal disclaimer during litigation. This court has not decided the issue."). *See also Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) (stating that "while [a patentee] might still file a terminal disclaimer to overcome prospectively the double patenting basis for invalidity, this court makes no determination about the retrospective effect of such a terminal disclaimer.") In any case, Amgen has not terminally disclaimed

the '933, '349 and '422 patents over the '868 and '698 patents, so their invalidity for double patenting remains an issue for the jury to decide in this trial.

IV. ODP of '933, '422, and '349 over '868 and '698 Is Inextricably Linked to Roche's Invalidity Defense of Obviousness, So the Jury Must Hear the ODP Argument and Evidence

Amgen has consistently attempted to keep as many issues away from the jury as possible. As Roche argued in its Case Management Memorandum, its defenses and counterclaims must be tried to a jury, and the Court agreed. *See* Roche's Memorandum for July 17, 2007 Case Management Conference (D.I. 739). Roche's affirmative defense of ODP is closely intertwined with Roche's obviousness validity defense, and the Court has already construed the claims, so there is no reason that the jury cannot hear Roche's ODP evidence.

A. Where There Are Common Issues Of Fact Between A Question For The Judge And A Question For The Jury, The Jury Must Decide Both Issues.

Amgen does not cite any authority or make any argument to challenge this Court's discretion in submitting these issues to the jury -- nor is there any. Rather, because there are issues of fact common to both the ODP defense and the validity defense, and the Court has already decided that the jury will hear the validity defense, both defenses ought to be decided by the jury. *See Windsurfing Int'l, Inc. v. Fred Osterman, GmbH*, 534 F. Supp. 581, 585 (S.D.N.Y. 1982) ("any issues of fact common to the claims are for the jury") (citing *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500 (1959)). Furthermore, the analysis of ODP claims is analogous to the obviousness analysis under 35 U.S.C. § 103. *See The Manual of Patent Examining Procedure* § 804 (Eighth Ed. 2001, last revised Aug. 2006).

The jury will be required to consider these facts in the context of determining whether the patents-in-suit were obvious to one of ordinary skill in the art at the time the purported inventions were made. The jury will be required to make determinations regarding the factual matters underlying the question of obviousness, that is, the jury will have to determine the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) ("While the ultimate question of patent validity is one of law . . . the section 103 condition, which is but one of three conditions, each of which must be satisfied [in order to prove obviousness], lends itself to several basic factual inquiries").

These very same facts are at issue in the determination of ODP. In order to determine whether the '933, '422 and '349 patents are invalid for double patenting over the '868 and '698 patents, a fact finder will have to consider issues regarding obviousness. The very same factual determinations must be made for obviousness and double patenting purposes, *i.e.*, the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. Thus, the facts relating to the issue of inequitable conduct are obviously relevant to and overlap with other issues that the jury will hear and decide.

B. Submission Of Common Issues Of Fact Will Ensure Efficient Use Of Judicial Resources And Will Not Confuse The Jury Or Unfairly Prejudice Amgen.

Because the jury will already be required to consider these facts in connection with other issues to be decided in this case, the jury will not be confused, nor will the plaintiff

be unfairly prejudiced, by the jury's determination of these issues. Submission of these issues to the jury will result in efficient use of the Court's and the parties' resources.

Moreover, even if the Court were to make the ultimate determination regarding ODP, the jury would still be required to make the underlying factual determinations relevant to the factual issues at hand in connection with deciding the issues of obviousness, and these factual determinations would inform and constrain the Court's decision regarding ODP in any event. Thus, as the jury will already be making these factual determinations, the jury will be in an excellent position to apply these facts to ODP and to make the ultimate decision on this issue.

CONCLUSION

Based on the foregoing, Roche respectfully requests that Amgen's motion be denied.

Dated: September 4, 2007
Boston, Massachusetts

Respectfully submitted,

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