UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	)	Civil Action No.: 1:05-CV-12237 WGY

AMGEN INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO COMPEL FROM ROCHE A COMPLETE RESPONSE TO AMGEN INTERROGATORIES 9, 10, AND 11

I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") improperly refuse to provide the specific claim-by-claim, limitation-by-limitation bases for their affirmative anticipation and obviousness invalidity defenses and counterclaims against the asserted claims. In refusing to answer Plaintiff Amgen Inc.'s ("Amgen") long-standing interrogatories, Roche has severely prejudiced Amgen's ability to prepare its rebuttals to Roche's affirmative defenses and counterclaims.

Amgen's December 2006 Interrogatories 9-11 request that Roche disclose on a claim-by-claim, limitation-by-limitation basis, each of Roche's anticipation or obviousness contentions, including where in each piece of asserted prior art claim limitation may be found. Rather than comply, Roche just identified *sixty-two* references, and "all underlying work" of the authors (inventors in the case of patents and patent applications) as "prior art." Roche's interrogatory responses are deficiencies at least because they:

- Fail to tie any reference to any specific asserted claim, much less to a limitation in that claim;
- Fail to identify where all limitations in an asserted claim are found in a single allegedly anticipating reference.
- Fail to disclose how references are to be specifically combined to render a claim obvious, much less where in each asserted combination, the limitation is found in the reference(s);
- Fail to disclose on a claim-by-claim and limitation-by-limitation basis, the grounds that allegedly support Roche's assertion that each of the asserted claims are invalid for double patenting; and
- Fail to identify and describe on a claim-by-claim, limitation-by-limitation basis, why 35 U.S.C. § 121 does not bar application of obviousness-type double patenting.

Amgen's interrogatories simply mirror the legal requirements for anticipation and obviousness. Roche, prior to asserting its defenses, necessarily must have gone through a claim-by-claim, limitation-by-limitation analysis for each piece of asserted prior art and/or patent claim

in order to satisfy its Rule 11 and 26(g) obligations. Moreover, such disclosure is routinely mandated by district courts around the country even in the absence of an interrogatory specifically calling for such information. *See, e.g.*, Patent Local Rule 3-3, N.D. Cal. (2001). No judicial interest is served by delaying such disclosure.

The prejudice to Amgen is manifest. With time running out on fact discovery that will close on April 2, 2007, and expert reports fast approaching, Roche's failure to comply with its fulsome discovery obligation is prejudicing Amgen.

Therefore, Amgen requests under Federal Rules of Civil Procedure 33 and 37 that an Order issue compelling Roche to:

- Provide, on a claim-by-claim and limitation-by-limitation basis, the grounds that allegedly support Roche's assertion that the patents-in-suit are invalid for double patenting and/or with respect to 35 U.S.C. §§ 102 (a-e) and 103 (Interrogatory 9);
- Identify where each and every claim limitation is disclosed in each reference that allegedly anticipates any of the asserted claims (Interrogatory 10);
- Identify where each claim limitation is disclosed in each reference, how the references are to be combined in order to render each asserted claim obvious, where the motivation to combine the references may be found, and why there would be a reasonable expectation of success in combining the references (Interrogatory 11);
- Identify and describe, on a claim-by-claim and limitation-by-limitation basis, why one of ordinary skill in the art would have found the claims of the patents-in-suit not to be patentably distinct from the claims in the patents that allegedly invalidate the patents-in-suit for double patenting (Interrogatory 11); and
- Identify and describe, on a claim-by-claim basis, why 35 U.S.C. § 121 does not bar the application of obviousness-type double patenting (Interrogatory 11).

II. SUMMARY OF FACTS

Roche pled affirmative defenses and sought declaratory judgment that the claims of the patents-in-suit are invalid for failing to satisfy the conditions for patentability under 35 U.S.C. §§

101, 102, 103, 112, 116, and/or 262 and for double patenting over claims of U.S. Patent No. 4,703,008. *See* Defendants' Answer and Counterclaims to Plaintiff's Complaint, Fifth and Sixth Affirmative Defenses, and Tenth Counterclaim (Docket 140).[1, 2] On March 2, 2007, Roche filed Defendants' Motion to Amend Their Sixth Affirmative Defense, which adds new grounds to Roche's contention of invalidity based on double patenting.[3] (Docket 304.)

A. AMGEN'S INTERROGATORIES 9-11 AND ROCHE'S RESPONSES

On December 11, 2006 Amgen served Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15). Interrogatory Nos. 9-11, the subjects of this motion, seek the legal and factual bases for Roche's invalidity defenses. Interrogatory 9 is directed to Roche's Fifth and Sixth Affirmative Defenses and Tenth Counterclaim, asserting that the patents-in-suit are invalid under 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 282. (*See* Declaration of William G. Gaede, III ("Gaede Decl."), Ex. 1.) Interrogatory 10 addresses Roche's claim that the patents-in-suit are anticipated, and Interrogatory 11 is drawn to Roche's defense that the patents-in-suit are obvious, either under 35 U.S.C. § 103 or for double patenting. (*See id.*) Significantly, each of the interrogatories request that Roche disclose for each piece of asserted art on a claim-by-claim, limitation-by-limitation basis, where and how the alleged anticipation and/or obviousness may be found.

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[1] Defendants' Fifth Affirmative Defense claims that the patents-at-issue are invalid "because they fail to satisfy the conditions for patentability, including as specified in 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 282." Defendants' Sixth Affirmative Defense claims that the patents-at-issue are invalid "for double patenting over claims of Amgen's earlier issued and now expired U.S. Patent No. 4,703,008." Count X of Defendants' counterclaims seeks a declaratory judgment the patents-at-issue are invalid for the reasons stated in its Fifth and Sixth Affirmative Defenses.

[2] Roche moved for leave to amend its Answer and Counterclaims on January 19, 2007. (Docket 252.) Roche's motion is still pending, however the affirmative defenses and counterclaim at issue in Amgen's motion to compel were not altered in Roche's [Proposed] First Amended Answer and Counterclaims to Plaintiff's Complaint.

[3] Roche's Sixth Affirmative Defense, as amended by its March 2 Motion, reads as follows: "The claims of the [patents-in-suit] are invalid for double patenting over claims of Amgen's earlier issued and now expired U.S. Patent No. 4,703,008 ("the '008 patent") *and U.S. Patent No. 4,667,016, and the claims of the '349, '933, '080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents.* [text added by amendment in italics]

Roche served its Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (No. 1-15) on January 11, 2007. (*See* Gaede Decl., Ex. 2.)[4] Disregarding Interrogatory 9-11's language, Roche merely listed sixty-two publications as alleged prior art—without identifying which reference purportedly invalidates which claim on a limitation-by-limitation basis and under which invalidity theory, as required. (*See id.*) The *only* discussion of 35 U.S.C. §§ 102 or 103 prior art in Roche's responses to Interrogatories 9-11 was one paragraph on a single publication, "the Goldwasser clinical study," discussed more fully below.

Roche supplemented its Interrogatory 9 response on February 9, 2007 with a table, a portion of which is reproduced below:

'080 Patent				
Claim	**§102**	**§103**	**§112**	**double patenting / §101**
3. A non-naturally occurring erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells. wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6.	✓	✓	✓	✓
4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3.	✓	✓	✓	✓
6. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.		✓	✓	✓

(*See* Gaede Decl., Ex. 2).

[4] As an exhibit to the Gaede Declaration, Amgen is providing the pages from Defendants' Second Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15), which contains Roche's Initial, Supplemental, and Second Supplemental Responses to Amgen's Interrogatories 9-11 in lieu of attaching each set of responses individually.

Roche did not supplement its Responses to Interrogatories 10-11, other than to repeat its direction to Amgen to "see Objections and Response to Interrogatory No. 9." Again, no claim-by-claim, limitation-by-limitation disclosure for each piece of asserted prior art was provided.

On February 26, 2007, Roche served Defendants' Second Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15). With respect to Interrogatories 9-11, this supplementation merely added a reference to two deposition transcripts of Eugene Goldwasser with no discussion; it still failed to provide the requested claim charts or any indication of how its voluminous "prior art" applied to any claim limitation. (*See id*.)

B. AMGEN EFFORTS TO OBTAIN FULL RESPONSES FROM ROCHE

Amgen tried on at least four occasions to elicit substantive responses to Interrogatories 9-11 from Roche. On January 17, 2007, Amgen sent Roche a letter highlighting the deficiencies in Roche's interrogatory responses and requesting confirmation that Roche will supplement its responses. (Gaede Decl., Ex. 3.) No response. Two days later, Amgen sent Roche a table identifying specific deficiencies in Roche's responses. (Gaede Decl., Ex. 4.) During a January 25 meet and confer, Roche agreed to supplement its responses. (Gaede Decl., Ex. 5.) More than two weeks later, the February 9, 2007 table Roche submitted was the only supplementation of Interrogatories 9-11. In a February 14, 2007 letter Amgen pointed out in detail the significant deficiencies still extant in Roche's supplemental responses and requested Roche's availability to discuss these deficiencies. (Gaede Decl., Ex. 5.) Finally, on February 23, 2007, Amgen tried once more, pointing out in a letter Roche's failure to respond to the request for a meet and confer. (Gaede Decl., Ex. 6.) To date, Roche has refused to supplement its responses and has informed Amgen's counsel that it has no obligation to do so. (Gaede Decl., ¶¶ 9-11 and Ex. 7.)

III. ARGUMENT

Under Federal Rule of Civil Procedure 37(a), if the answer provided in response to an interrogatory is incomplete or evasive, the other party is entitled to compel an answer, because it

shall be treated as "a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(3). Amgen's Interrogatories 9-11 ask the straightforward question on a claim-by-claim, limitation-by-limitation basis, of how and where the asserted prior art or alleged double-patenting renders any asserted claim invalid. These three interrogatories request no more information than that which Roche must know and has failed to disclose.

A. THE INTERROGATORIES MIRROR THE LEGAL REQUIREMENTS FOR ESTABLISHING ANTICIPATION AND/OR OBVIOUSNESS

The law that these interrogatories mirror is not unclear. To prove a claim is anticipated under 35 U.S.C. § 102, Roche must show that a single reference discloses ***each and every limitation of the claim***. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1372 (Fed. Cir. 2003) ("An anticipating reference must describe all of the elements and limitations of the claim in a single reference."). Amgen's Interrogatories 9 and 10 simply mirror this requirement, and ask Roche to disclose for each asserted piece of prior art where the limitations for each allegedly infringing claim may be found.

The same is true for obviousness. To invalidate a claim as obvious under 35 U.S.C. § 103, Roche must establish that a specific combination of prior art references includes: (1) all the limitations of the claim; (2) a motivation to combine the steps of the combination in the manner claimed; and (3) a reasonable expectation of success for the steps of the combination in the manner claimed. *See Micro Chem. Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1546 (Fed. Cir. 1997). Again, Amgen's Interrogatories 9 and 11 simply mirror this legal requirement.

Finally, to prove that an asserted claim is invalid for obviousness-type double patenting, Roche must compare the claims of the allegedly invalidating patent to the claims of the patents allegedly invalidated and demonstrate that the same invention is claimed in both patents. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279-80 (Fed. Cir. 1992). Amgen's Interrogatories 9-11 are simply directed to uncovering these underlying bases.

B. ROCHE'S FAILURE TO RESPOND TO THESE STANDARD INTERROGATORIES IS PREJUDICING AMGEN.

Any argument by Roche that it cannot or should not disclose for each asserted prior art reference and/or its combination Roche's claim-by-claim, limitation-by-limitation contentions, as required, lacks merit on several grounds.

First, when Roche asserted the claims were invalid for obviousness and anticipation, and subsequently identified sixty-two references as prior art, it was certifying that it had made a reasonable inquiry with respect to each reference and had formed a good faith belief that every limitation of each asserted claim could be found in each reference; Roche could not have identified the references without making such an analysis. *See* FED. R. CIV. P. 26(g)(2) (signing an interrogatory response constitutes certification that to the best of the signor's knowledge, information, and belief, formed after a reasonable inquiry, the responses are consistent with the rules and warranted by existing law, and not interposed for any improper purpose); s*ee* FED. R. CIV. P. 11(b); s*ee DOT Com Entm't Group, Inc. v. Cyberbingo Corp*., 237 F.R.D. 43, 45 (W.D.N.Y. 2006) (where defendants claim a patent was invalid as obvious, and requested declaratory relief to that effect, defendants were expected to have, even at an early stage, some good faith basis in fact and law for such claim and defense). Amgen is merely asking Roche to disclose analyses it necessarily must have performed prior to asserting the defense and each of the sixty-two prior art references related thereto.

Likewise, when Roche pled its Sixth Affirmative Defense stating that the patents-at-issue are invalid for double patenting over claims of U.S. Patent No. 4,703,008 (the "'008 patent") and now U.S. Patent No. 4,667,016 (the "'016 patent"), it was certifying that to the best of its knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, the defense was warranted by existing law, and it had evidentiary support for double patenting. *See* FED. R. CIV. P. 11(b). Roche therefore knows the specific limitation-by-limitation basis for its defenses; it is simply choosing not to disclose them to frustrate Amgen's legitimate rights to defend its patents.

Second, the information sought is typically disclosed in patent infringement suits. In fact, recognizing that patent defendants should disclose such information even without an interrogatory, a number of jurisdictions around the country require this very information to be disclosed.[5] For example, Patent Local Rule 3-3 in the United States District Court for the Northern District of California requires disclosure of:

> (a) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious …;
>
> (b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If a combination of items of prior art makes a claim obvious, each such combination, and the motivation to combine such items, must be identified;
>
> (c) A chart identifying where specifically in each alleged item of prior art each element of each asserted clam is found ….

(*See* N.D. Cal Patent L.R. 3-3 (2006)).

Amgen is asking Roche to do nothing more than what district courts routinely require patent defendants to disclose.

Third, the prejudice to Amgen is manifest. The patents are presumed valid. Amgen requires the specific claim-by-claim, limitation-by-limitation disclosure so that its experts may evaluate those assertions, and so that Amgen may also further conduct fact discovery on those issues. With fact discovery closing on April 2, 2007, Roche's refusal to provide this most basic discovery routinely mandated around the country is severely prejudicing Amgen's ability to defend itself.

For example, should Roche identify a specific reference as Section 102(a) prior art, Amgen has only a burden of production to provide evidence of an antedating conception or reduction to practice. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996); *Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1361 (Fed. Cir. 2001). Amgen cannot identify relevant conception and reduction to

[5] *See, e.g.*, N.D. Cal. Patent L.R. 3-3 (2006); S.D. Cal. Patent L.R. 3-3 (2006); E.D. Tx Patent L.R. 3-3; N.D. Tx. Patent L.R. 3-3 (2006); W.D. Pa. Patent Local Rule 3.4 (2005); N.D. Ga. Patent L.R. 4.3 (2004).

practice evidence to meet its burden of production until it knows what Section 102(a) date Roche is asserting. It is Roche's burden of proving by clear and convincing evidence that any art is asserts qualifies as "prior art."

In sum, the interrogatories mirror the law, reflect an analysis that Roche should have already performed, require information that is routinely discoverable, and is necessary in order for Amgen to defend itself.

C. ROCHE'S RESPONSES TO INTERROGATORIES 9-11 SHOULD BE SUPPLEMENTED TO COMPLY STRICTLY WITH INTERROGATORIES 9-11.

Against this general backdrop, Amgen turns to each of the three Interrogatories.

Amgen's Interrogatory 9 is intended to obtain discovery of the grounds for Roche's affirmative defenses and counterclaims asserting that the patents-in-suit are invalid. Roche's most recent supplemental response to Interrogatory 9 is merely an uninformative, conclusory table that indicates some claims are allegedly invalid under 35 U.S.C. §§ 101/double patenting, 102, 103, or 112. A claim chart matching the prior art to each of the limitations in the asserted claims, required by Interrogatory 9 (and the law), is notably absent from Roche's response. (*See* Gaede Decl., Ex. 2.) Roche's response to Interrogatory 9 is deficient at least because it does not provide, for each allegedly invalid patent claim, a chart that identifies, on a limitation-by-limitation basis, the legal and factual grounds underlying Roche's assertion that the claim is invalid as anticipated and/or obvious.

Roche relies on its deficient response to Interrogatory 9 to constitute its response to Interrogatories 10 and 11. However, the sum total of Roche's discussion of allegedly anticipating prior art is a few sentences related to one reference—the Goldwasser clinical study—which Roche claims "meets all of the relevant limitations of the claims of the '422 and '933 patents." Roche has not identified to Amgen the "relevant limitations" and how the Goldwasser clinical study meets them. Moreover, Amgen remains completely in the dark as to which, if any, other references listed by Roche anticipate which, if any, of the other asserted patent claims. Roche 's response to Interrogatory 10 is deficient at least because Roche does not

provide, for each claim allegedly anticipated, a chart that identifies and describes, on a limitation-by-limitation basis, where and how each claim limitation is disclosed in each piece of asserted prior art.

Roche makes even less effort to respond to the interrogatories with respect to its 35 U.S.C. § 103 defense. Specifically, Roche's response: (1) does not set forth the legal and factual basis for its 35 U.S.C. § 103 contentions for each claim on a limitation-by-limitation basis; (2) does not set forth factual bases for its contentions of obviousness, including where each claim limitation is disclosed in the sixty-two listed references; (3) does not identify the specific combinations of references Roche alleges would render particular claims obvious; (4) does not state where the motivation to combine the listed references may be found; and (5) does not explain why there would be a reasonable expectation of success in combining the listed references.

Interrogatories 9 and 11 both request information on Roche's double patenting affirmative defense, which it has sought to amend. Roche does not provide any factual basis for the contention that one of ordinary skill in the art would have found claims in the patents-in-suit obvious in light of earlier claims. Roche's responses to Interrogatory 11 is deficient at least because Roche has not provided a chart that compares the claims of each allegedly invalidating patent to the claims of each Asserted Patent that is allegedly invalidated for double patenting, and demonstrated that the same invention is claimed in both patents. In addition, Roche has not explained why 35 U.S.C. § 121 does not bar the application of the doctrine of obviousness-type double patenting to each Asserted Patent. If Roche had adequate facts to plead this defense and then amend it, Roche must have adequate facts to provide the information properly requested by Interrogatories 9 and 11. Roche has no legitimate reason to withhold this information from Amgen.

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court grant Amgen's motion to compel.

Dated: March 13, 2007

Respectfully Submitted,

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the plaintiff has met and conferred with counsel for the defendants, F. Hoffman-LaRoche Ltd., Hoffman LaRoche Inc. and Roche Diagnostics GmbH, in an effort to resolve or narrow the issues presented by this motion and that no agreement could be 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 March 13, 2007.

/s/ Michael R. Gottfried
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