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 MOTION TO COMPEL A COMPLETE RESPONSE TO INTERROGATORIES 9, 10, AND 11

Introduction

Roche's responses more than satisfy Roche's obligations under Rule 33(b)(1). Roche has set out its bases for challenging the validity of each of the asserted patents, just as requested by Amgen, and has in fact supplemented its responses as it acquired additional information.

Amgen cannot claim to be left in the dark regarding Roche's invalidity defenses. The detail in Roche's responses to interrogatories 9-11 stands in stark contrast to the stonewalling on display in Amgen's responses to Roche's interrogatories.

Roche has amply responded to Amgen based on currently available information, but the interrogatories at issue seek certain information that Roche cannot yet provide, due to the prematurity of the discovery. Roche's invalidity contentions depend in large part on basic facts elicited in discovery. Fact discovery is not yet complete—in fact, the inventor of the patents in suit has not been provided by Amgen for deposition until later this week—and other depositions of significant Amgen fact witnesses remain to be taken. In addition, Amgen's requests that

Roche provide a claim-by-claim, limitation-by-limitation analysis, cannot be completed at this time, because the Court has not yet issued a claim construction ruling that would underlie such an analysis.

Lastly, an analysis by Roche's expert is required before Roche can add further support to its invalidity contentions. The expert reports will be finalized in less than two weeks and served on April 6. These reports, which will be incorporated into Roche's interrogatory answers, will substantiate Roche's invalidity contentions to the extent desired by Amgen. The expert reports are expected to incorporate the application of construed claim terms to the disclosure of the prior art disclosed by Roche, a highly technical exercise for which an expert is uniquely suited.

Thus, Amgen's request to compel fuller responses to interrogatories 9-11 is not justified, is an unnecessary burden on the Court's time, and seems calculated to obtain Roche's expert opinions and finalized contentions prematurely. Roche respectfully asks that the Court deny Amgen's motion or, in the alternative, allow both Roche and Amgen to supplement their responses to interrogatories after a claim construction has issued.

Statement of Facts

Amgen's interrogatories 9-11, which ask, *inter alia*, that Roche give a claim-by-claim, limitation-by-limitation analysis of all its invalidity contentions, were served on December 11, 2006. Although Roche's invalidity position is not finalized, Roche provided Amgen with its preliminary evidence of invalidity and its reasons why Amgen's asserted patent claims are invalid. Ex. A: Defendants' Responses and Objections to Amgen's First Set of Interrogatories, Jan. 11, 2007, at 47-61. Roche responded in detail, despite its objections that the interrogatories sought expert testimony and were premature due to the fact that no claim construction order had

been entered. *Id*. at 47, 60-61. Roche chose to answer interrogatories 9-11, which overlap each other in scope, in one response that addresses all three together.

Roche's response set out, in detail, its contentions of invalidity under 35 U.S.C. § 102, 103, 112, and on account of double patenting, sorted by the statute or doctrine under which Roche makes its contention. For example, Roche explained that all relevant limitations of the claims of the '422 and '933 patents are anticipated by the Goldwasser clinical study, which taught a "pharmaceutical composition" comprising a "therapeutically effective amount of human erythropoietin." *Id*. at 57-58. Roche's response showed that Goldwasser disclosed "the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells." *Id*. at 58. The response also outlined why the remaining limitations in those patent claims, directed to a source or process limitation, would not confer patentability on those claims, under Federal Circuit case law. *Id.*

Roche's response, in addition, outlined its double patenting argument with enough detail to apprise Amgen of its contentions. Roche explained that Amgen's asserted claims are obvious over the claims of the now-expired '008 patent. In doing so, Roche explicitly outlined the statements by Amgen that lead to the conclusion that all of Amgen's claimed limitations beyond the purification and isolation of the EPO gene are obvious. As such, Roche argues, the claims of the '008 patent, which teach this purification and isolation of the EPO gene, render the claims of Amgen's other EPO patents obvious. Ex. A at 48-50.

Further, Roche laid out the reasons that Amgen cannot rely on 35 U.S.C. § 121 in opposing Roche's defense of double patenting, and disclosed its evidence to that effect. *Id*. at 50.

Roche has twice updated its responses to interrogatories 9-11. Ex. B: Defendants' First Supplemental Responses and Objections, Feb. 9, 2007; Motion Brief Exhibits, (D.N. 318), Ex. 2: Roche's Second Supplemental Responses, Feb. 26, 2007. Each time, as discovery has progressed, Roche has further delineated its invalidity contentions. For example, by the time Roche prepared its February 9 supplement, it had learned what claims were being asserted by Amgen, and thus was able to disclose the statutory basis of its invalidity contentions for all of the patent claims asserted by Amgen. Ex. B at 64-69.

Roche's ongoing supplementation contrasts with Amgen's merely conclusory answer to Roche's specific interrogatories on Amgen's validity contentions. For example, Amgen has given no meaningful response to Roche's interrogatory No. 5, which seeks facts relevant to a specific issue (namely, whether or not having the EPO gene sequence rendered the production of a biologically active product obvious) relating to Roche's '008 double patenting claim. Ex. C, Plaintiff's Supplemental Response, at 21-22. Amgen's response remains unsupplemented, even though Amgen now has the benefit of Roche's position on the double patenting of claims over the '008 patent, as outlined in Roche's response to interrogatory No. 9.

Despite Roche's ongoing supplementation, Amgen has filed the present motion, demanding that Roche provide greater specificity in five areas, including Roche's claim-by-claim and limitation-by-limitation grounds for asserting invalidity under §§ 102(a-e), 103, and double patenting, and why 35 U.S.C. § 121 does not bar the application of obviousness-type double patenting.

Argument

A. Roche Has Fully Met Its Rule 33 Obligations

In assessing interrogatory responses, courts generally find them sufficient when the "answers as a whole disclose a conscientious endeavor to understand the questions and to answer fully those questions as are proper." *Parrott v. Morgan*, 707 F.2d 1262, 1273 n.26 (11th Cir. 1983) (Anderson, J.) (citing C. Wright & A. Miller, Federal Practice & Procedure § 2177) (party not penalized where it answered several interrogatories *en masse* rather than individually). Here, to the extent that such questions can be answered without requiring either a claim construction or expert testimony, Roche has sufficiently done so.

1. Roche Has Answered the Interrogatories in Detail

Roche has given Amgen considerable information with respect to its invalidity contentions, and has backed up its claims with relevant prior art references. For example, Roche has supported its contentions regarding double patenting of the asserted claims over the '008 patent. Ex. A at 48-50. As stated above, Roche has explained its double patenting position, through Amgen's statements to the Patent Office that the inventive content of Amgen's patent application is limited to the isolation of the EPO gene. *Id.*

Roche's position here is plain, that the isolation of the EPO gene disclosed in the '008 patent claims renders obvious Amgen's other patents arising from that application. Roche has thus given Amgen, on a limitation-by-limitation basis, exactly what it has asked for: Roche's grounds for asserting that the "patents-in-suit are invalid for double patenting," and why "one of ordinary skill in the art would have found the claims of the patent-in-suit not to be patentably distinct from" the '008 patent, as Amgen has requested in this motion. Motion Brief at 2. In

light of Roche's explication of its position, Amgen's insistence on a claim chart-type analysis of this contention elevates form over function. Motion Brief at 9.

Likewise, Amgen's charge that Roche's responses "[f]ail to tie any reference to any specific asserted claim" does not hold up. Motion Brief (D.N. 317) at 1. Roche has offered a detailed explanation of how the Goldwasser study anticipates all the relevant limitations of the '422 and '933 patents, including "pharmaceutical composition," "therapeutically effective amount of human erythropoietin," and "the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells." Ex. A at 57-58. Further, Roche explained why the claim limitation "wherein said erythropoietin is purified from mammalian cells grown in culture" is not sufficient to confer patentability over other human EPO. *Id.* at 57-58. Roche thereby supported, on a claim-by-claim and limitation-by-limitation basis, its assertion that the "patents-in-suit are invalid" for anticipation, as requested by Amgen. Motion Brief (D.N. 317) at 2. Again, Amgen argues over the form of Roche's response while ignoring its substance.

Roche's responses reflect its conscientious endeavor to answer Amgen's interrogatories to the extent Roche considered them proper. To the extent Roche has not answered, it has objected, specifically to Amgen's improperly seeking expert testimony and prematurely requesting a claim construction. Ex. A at 47, 60-61.

2. Roche Has Supplemented its Already Detailed Response, While Amgen Refuses to Supplement its Inadequate Response to Roche

Roche has shown its willingness to supplement its invalidity contentions as it gathers the facts necessary to support them. Amgen's demand that Roche give a full limitation-by-limitation analysis of every invalidity contention is unwarranted at this time. Amgen has

supplemented its responses to Interrogatories 9-11 on February 9 and February 26, each time adding substance to its contentions as discovery has progressed. Ex. B at 64-69; Motion Brief, Ex. 2.

In contrast, Amgen has shown an aversion to giving more than a conclusory response even to a narrowly-tailored interrogatory seeking to elicit information related to Amgen's contention that its claims are not invalid by double patenting over the '008 patent. Ex. C, at 21-22. Amgen's refusal to respond continued even after Roche disclosed its double patenting contentions.

Amgen has attempted to justify this unresponsive answer by claiming that, since Amgen's patents have a presumption of validity, it is not required to answer interrogatories directed to validity unless Roche disclose its invalidity contentions to the specificity desired by Amgen. Ex. C at 22. Beyond the fact that that it is improper for Amgen to hold Roche's discovery hostage in this manner, Amgen's continued refusal to supplement its response despite Roche's explanation of its double patenting contentions makes Amgen's justification less than credible.

3. Roche Has Disclosed its Contentions to the Extent Possible Without Claim Construction and Expert Discovery

Further, contrary to Amgen's assertion, Roche need not have performed the claim chart analysis demanded by Amgen before alleging the invalidity of Amgen's patents. Fed. R. Civ. P. 11(b) requires only that Roche's legal contentions be "warranted by existing law" and that its factual contentions "have evidentiary support," not that Roche have performed an exhaustive limitation-by-limitation analysis of each of Amgen's patent claims. Roche's responses to interrogatories 9-11 show that Roche has evidentiary and legal support for its contentions that

Amgen's claims are invalid due to anticipation and/or obviousness-type double patenting. Ex. A at 48-50, 57-58. In addition, Roche has shown that it has substantial evidence of prior art that may render Amgen's asserted claims obvious. Ex. A at 52-57. Nevertheless, it does not follow, as Amgen suggests, that Roche has at its fingertips the limitation-by-limitation analysis that Amgen demands, which in any event, as shown, requires both claim construction and expert testimony, both of which Roche has not yet obtained.

B. Roche Has Properly Objected To Amgen's Requests On The Basis That They Require Expert Testimony, Which Will Be Provided

Roche has objected that interrogatories 9-11 require expert opinions and for that reason are improper before the completion of expert discovery. Ex. A at 47, 60-61. Amgen's requests are premature, as expert testimony is necessary for the limitation-by-limitation analysis demanded by Amgen.

First, expert testimony is required for a definitive answer as to how and to what extent each prior art reference reads on each limitation. For example, with respect to Roche's contention of invalidity over the Goldwasser study, expert testimony is required to delineate how the results of the Goldwasser study anticipate a claim term such as "therapeutically effective." Second, the opinion of an expert concerning the level of skill in the art during this period is necessary, especially for Roche's obviousness and double patenting arguments. Expert testimony is required to determine not only that each prior art reference bears on a limitation of the claim, but that a combination or modification of references would be obvious to one skilled in the art, that a person skilled in the art would find a teaching or suggestion to combine or modify references, or whether such a combination or modification would have a reasonable likelihood of success.

Expert discovery has not yet commenced, much less concluded. It is therefore premature for Amgen to solicit responses that require expert interpretation and opinion. Amgen's interrogatories are thus improper to the extent that they require such expert testimony, and Roche is justified in objecting to them on this basis. Roche's expert reports, which will be presented on April 6, 2007, will set out, in yet further detail, Amgen's invalidity contentions.

C. Amgen's Requests are Premature, as They Require a Claim Construction, Which is Pending

Roche objected to Amgen's interrogatories, and opposes Amgen's motion, because it is premature to require the limitation-by-limitation analysis Amgen asks for before the *Markman* rulings and the completion of expert discovery. No *Markman* hearing has occurred and no order entered. Until the Court construes the claim terms in dispute following the *Markman* hearing and the parties complete expert discovery, Amgen's interrogatories seeking a limitation-by-limitation analysis of Roche's invalidity contentions are premature. For example, with respect to Roche's § 102 contentions regarding the Goldwasser study, a limitation-by-limitation analysis must be preceded by the Court's construction of the claim term "effective amount of a glycoprotein product effective for erythropoietin therapy." Defendants' Opening Memorandum in Support of their Proposed Claim Construction, (D.N. 311), at 2.

Likewise, a thorough analysis of Roche's double patenting contentions referring to the '008 patent will require the Court's construction of the claim term "process for the production of a glycosylated erythropoietin polypeptide," in order to determine whether such a limitation is nonobvious over the claims of the '008 patent. *Id.* at 1. Accordingly, Roche respectfully asks that the Court allow Roche to provide supplemental responses to these interrogatories after the Court's *Markman* rulings and the completion of expert discovery.

D. Amgen's Contention Interrogatories Should Not Be Compelled Until Late in Discovery

Amgen's interrogatories 9-11 constitute "contention interrogatories," that is, they ask Roche to "take a position, and then to explain or defend that position, with respect to *how the law applies to facts*." *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93, 95 (E.D. Pa. 1992) (quoting *In re Convergent Techs. Secs. Litig.*, 108 F.R.D. 328, 341 (N.D. Cal. 1985) (emphasis in original).

Fed. R. Civ. P. 33(c) provides that a "court may order that such an interrogatory need not be answered until after designated discovery has been completed or until a pre-trial conference or other later time." Such an order is appropriate in this case, especially as fact discovery, even at this date, is incomplete. For example, the deposition of Fu-Kuen Lin, scheduled for March 28, is expected to yield testimony relevant to whether the asserted patent claims are distinguishable over the claims of Mr. Lin's '008 patent. This testimony is necessary for Roche to adequately prepare its experts to outline the claim-by-claim, limitation-by-limitation analysis of Roche's double patenting contentions.

In addition, Amgen's interrogatories 9-11, relying as they do on the application of facts to law, are not ripe for response at this time. The law to be applied in these Interrogatories is not only the relevant sections of the Patent Code, but also the Court's anticipated claim construction order. Until that order issues, any responses to these Interrogatories will necessarily be incomplete, as is outlined in detail in Section C.

Amgen has not given any reason why a flawed claim chart of Roche's invalidity contentions, constructed without benefit of complete fact discovery, expert opinion, or claim construction, will materially aid in the disposition of this action, especially if Roche must essentially rewrite such a chart after expert discovery and claim construction.

Amgen will not be prejudiced if its Motion to Compel is denied. Roche has, contrary to Amgen's protestations, provided sufficient disclosure of its contentions of invalidity and its bases for those contentions, such that Amgen can prepare its experts and conduct further fact discovery. Amgen's argument that it will not be able to rebut Roche's prior art references if it does not know the priority date of each is likewise unavailing. Motion Brief, (D.N. 317), at 8-9. Amgen's evidence of its conception and reduction to practice of its patents is within its control, and to argue that it will not be able to defend itself without that information is far-fetched.

Since Amgen cannot show that it is sensible to compel Roche to compile a claim-by-claim, limitation-by-limitation chart of its invalidity contentions that would of necessity be incomplete, the motion should be denied, or alternatively, delayed until fact and expert discovery, as well as claim construction, are complete.

Conclusion

For all the foregoing reasons, Roche respectfully requests that Amgen's Motion to Compel a Complete Response to Interrogatories 9, 10, and 11 be denied. In the alternative, Roche respectfully requests that the court order that both Roche and Amgen provide supplemental responses to each other's interrogatories after the court's *Markman* rulings and the completion of expert discovery.

DATED: Boston, Massachusetts
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Respectfully submitted,

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