UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	CIVIL ACTION No.: 05-CV-12237WGY

MEMORANDUM IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM ASSERTING THAT THERE WAS A RESTRICTION REQUIREMENT SEPARATING THE '008 PATENT CLAIMS FROM THE CLAIMS OF THE '868 AND '698 PATENTS

I. INTRODUCTION

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this memorandum in support of their motion *in limine* to preclude Amgen Inc. ("Amgen") from asserting at trial that there is a restriction requirement separating the '008 patent claims from the asserted claims of the '868 and '698 patents.

First, with respect to the '868 patent, Amgen has conceded in discovery responses that 35 U.S.C. § 121 ("Section 121") does not apply to this patent as a defense to obviousness-type double patenting ("ODP") over the '008 patent. As a result, Amgen cannot as a matter of law argue that there was a restriction requirement between the claims of the '008 and '868 patent.

Second, as to the '698 patent, Amgen waived its right to present evidence or argue at trial that there was a restriction requirement between these claims and the '008 patent claims. A Section 121 defense from ODP based on a restriction requirement is Amgen's burden of proof. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003). Roche specifically requested interrogatory responses for Amgen's contentions. Amgen provided none. Moreover, Amgen's expert reports failed to even argue that such a restriction exists between these claims. Amgen's own briefing concedes that during the '698 prosecution, there was an Office Action rejection based on ODP. Thus, even Amgen recognized that there is no restriction between the claims of the '698 and '008 patents. Finally, it is undisputed that the '698 patent is terminally disclaimed over the '868 patent. This is compelling evidence that the '698 patent claims arise from the same application as the '868 patent, and therefore cannot be protected from ODP based on the Section 121 safe harbor.

II. FACTS

On December 12, 2006, Roche served its First Set of Interrogatories (1-13) upon Amgen. Among these, Roche requested that Amgen identify all patents and claims that may be subject to Section 121, and that Amgen explain its contentions. Interrogatory No 10 requested:

> As to each asserted claim of the patents-in-suit identified in response to Interrogatory No. 1, describe the reasons why each claim is not rendered invalid under the claims of U.S. Patent No. 4,703,008 pursuant to obviousness-type double patenting, the reasons for this contention, including whether 35 U.S.C. § 121 applies as a defense to obviousness-type double patenting, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.

(Ex. A). Amgen first responded by failing to identify any claims or patents with respect to Section 121. Amgen merely stated that "many of the patents-in-suit are exempt." (Ex. B). Amgen supplemented this response on February 9, 2007 and indicated that the '868 patent was not subject to the Section 121 safe harbor. *Id.* While Amgen did indicate that the '698 patent was exempt under Section 121, Amgen still failed to explain any basis for its contention regarding why the '698 patent claims were separated from the '008 patent claims by a restriction requirement. *Id.*

Critically, Amgen never supplemented this discovery response in this case, and to this day, Amgen has failed to disclose any explanation as to why the '698 patent claims should be immunized from an ODP defense over the '008 patent claims based on Section 121 and the restriction requirement.

With respect to expert reports, only Dr. Lodish and Mr. Kunin opined on Amgen's Section 121 position regarding the restriction requirement. Both Amgen experts limited their

analysis to the '933, '422, '349, and '080[1] patents, and specifically excluded the '868 and '698. (Exs. C, D). Thus, even Amgen's experts conceded that Section 121 does not apply to separate the claims of the '008 patent from the asserted claims of the '868 and '698 patents.

Amgen moved for summary judgment of no ODP of the '933, '422, and '349 patent claims over the '008 patent based on Section 121 and the restriction requirement. In its moving papers, Amgen acknowledged that there was no Section 121 defense available to the 868 and '698 patents since, during their prosecution, the Patent Office issued a double patenting rejection over the '008 patent. (D.I. 499 at n. 3).[2]

III. ARGUMENT

A. Amgen Should Be Precluded From Arguing That A Restriction Requirement Exists Between The Claims Of The '008 And '868 Patent

Amgen has conceded in discovery responses that it is not relying upon Section 121 as a defense against ODP of the '868 patent claims over the '008 patent claims. As a result, Amgen should be bound by its position taken in discovery and prevented from contradicting itself at trial. *See Licciardi v. TIG Ins. Group*, 140 F.3d 357, 363-64 (1st Cir. 1998) (Testimony of defendants medical expert that was directly contradictory to and beyond experts prior report should have been excluded on grounds of unfair surprise); *McIsaac v. Didriksen Fishing Corp.*, 809 F.2d 129, 132 n.2 (1st Cir. 1987) ("we hesitate to permit Wise to benefit from a sworn statement made at trial by a company employee which contradicts an earlier sworn statement, properly relied upon by an expert witness, made by the company's president in response to an interrogatory").

[1] Amgen has since dropped the '080 patent claims from the case.

[2] Amgen stated "during prosecution of the '868 and '698 patents, Amgen overcame an explicit rejection for ODP over the '008 claims...Amgen is not moving for summary judgment on this issue at this time." *Id.*

B. Amgen Should Be Precluded From Arguing That A Restriction Requirement Exists Between The Claims Of The '008 And '698 Patent

A party that fails to make the required disclosures should not be permitted to use undisclosed evidence at trial. *See Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998) ("Introducing a new theory at this stage of litigation-where factual and expert discovery has closed-with no explanation for the delay is unacceptable") *Cytyc Corp. v. TriPath Imaging, Inc.*, 2007 WL 2429423, *6 (D. Mass. Aug. 22, 2007); *Hipsaver Co. v. J.T. Posey Co.*, 2007 WL 2050861, *5 (D. Mass. July 19, 2007) ("A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed").

The Court instructed the parties at the start of trial that "the time has already started running" and that exclusionary rulings based on a waiver and a failure to disclose discovery would be seriously considered. (Daily Tr., 9/4/07 at 29). Here, Amgen has failed to provide any explanation as to why Section 121 applies to protect the '698 patent claims from ODP over the '008 patent. A Section 121 defense is Amgen's burden of proof. *See Geneva Pharms.*, 349 F.3d at 1382. Yet Amgen has provided no information regarding the applicability of this defense to the '698 patent. Amgen withheld this information during both fact and expert discovery even though it was specifically requested by Roche. Consequently, Amgen should be precluded from springing new theories during trial that were never disclosed in the case.

It is not surprising that Amgen has failed to disclose anything, since no credible theory exists. After all, Amgen conceded that there was no Section 121 defense for the '698 patent when it moved for summary judgment on the other patents (D.I. 499 at n. 3). Moreover, the '698 patent is terminally disclaimed over the '868 patent (Ex. E). During prosecution of a patent, a

terminal disclaimer will cure ODP rejections by the Patent Office since this alleviates any concerns of am unfair time-wise extensions of the patent term. *See In re Vogel,* 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970). That Amgen filed a terminal disclaimer of the '698 patent claims over the '868 patent claims is further compelling evidence that the '868 and '698 patents arose out of the same application, and thus were not separated from the '008 patent claims by virtue of the restriction requirement.

IV. CONCLUSION

Based on the foregoing, Roche respectfully requests that the Court grant Roche's motion *in limine* to preclude Amgen from asserting at trial that there is a restriction requirement separating the '008 patent claims from the asserted claims of the '868 and '698 patents.

Dated: September 6, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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