

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

AMGEN INC.’S OPPOSITION TO ROCHE’S MOTION IN *LIMINE* TO PRECLUDE AMGEN FROM MAKING ASSERTIONS THAT CONTRADICT STATEMENTS MADE IN SPECIFICATIONS OF PATENTS-IN SUIT

Roche’s motion in *limine* to preclude Amgen from making assertions that contradict statements made in specifications of patents-in-suit is fundamentally flawed in that it inappropriately asks this Court to bind Amgen to reports of prior art references that are included within Amgen’s specifications of patents. Simply because Dr. Lin described in his patent specifications what the prior art references report does not mean that Amgen is bound to the accuracy of what these prior art references describe. Indeed, as part of its defense of Roche’s claim that Amgen’s patents lack novelty or are obvious, Amgen is entitled to show why the prior art reference was wrong in what it described or was not repeatable. The Court will recall that this was the exact situation with the Sugimoto reference in the TKT litigation – Dr. Lin described Sugimoto in the background section of his patent specification, but based upon compelling evidence both this Court and the Federal Circuit held that Amgen had proven Sugimoto was not repeatable. Roche’s motion wrongly seeks to preclude exactly this type of showing.

Moreover, Roche fails to provide any specificity as to the evidence that it seeks to preclude Amgen from offering at trial. It is axiomatic that a motion in *limine* is proper only when it is specific enough to allow the responding party to rebut the alleged claim and to allow the court to assess the admissibility — on any grounds — of the challenged evidence. Roche cites in Exhibit A to its motion various statements from an Amgen patent, but fails to cite to any evidence it anticipates Amgen will offer that contradicts the patent. Roche’s motion, based on broad generalizations about statements from Amgen’s interrogatory and expert reports, is improper.

I. Amgen Is Not Precluded From Explaining Prior Art References Made In The Common Specification Of The Patent-In-Suit.

As part of any defense to a claim that Amgen’s patents are obvious, Amgen is entitled to show why its inventions are novel and non-obvious in light of prior art. Roche, by this motion, is trying to bind Amgen to statements made in the background section of the patent and prevent Amgen from explaining why the prior art references show that Amgen’s inventions were novel and not obvious. In order to support this untenable proposition, Roche cites to a number of cases that stand for the unremarkable claim that once a party references a piece of work as prior art, the party cannot later claim that the work is not potentially relevant prior art for purposes of an inquiry into obviousness.¹ Amgen does not dispute that the references to prior art in the patent specifications are potentially relevant. But Roche cannot grossly expand this unremarkable proposition to bind Amgen to content of the descriptions where all Dr. Lin did was set forth what

¹ See *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 2007 U.S. App. LEXIS 16245 *49-54 (Fed. Cir. 2007) (admissions in the specification regarding prior art are binding on the patentee for a later inquiry into obviousness); *Sjolund v. Musland*, 847 F.2d 1573, 1577 (Fed Cir. 1988) (device described in preamble of patent claim is deemed to be prior art); *In re Fout*, 675 F.2d 297, 300 (CCPA 1982) (description of prior process in preamble of patent claim was acknowledgment of existence prior art); *In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975) (prior art referenced in patent should be considered for §103 analysis).

the references state. Dr. Lin did not verify the accuracy of the references or comment on the validity of their claims. Simply reciting what a reference says on its face does not bind a patent applicant to the accuracy of the statements nor foreclose Amgen from later showing that the reference was, among other things, inaccurate, incomplete, or not repeatable.

Significantly, for any challenge to Amgen's patents as obvious, Roche must show, *inter alia*, that a person of ordinary skill in the art could reasonably expect that combining or modifying prior art references would allow that person to achieve Amgen's inventions.² Thus, Roche must demonstrate that the prior art provided a reasonable expectation of successfully practicing the claimed invention.³ In response to this analysis, Amgen is entitled to rebut any contention that the prior art allowed someone to practice Amgen's inventions by showing that the prior art was incomplete.⁴

The TKT litigation provides a perfect example for why this Court should deny Roche's motion. In that case, HMR/TKT argued that the Sugimoto patent anticipated and rendered obvious many of Dr. Lin's patent claims. Dr. Lin's patent specification described Sugimoto as prior art and that Sugimoto reported high level production of EPO from fused cells. But this Court and the Federal Circuit held that Amgen had shown that Sugimoto's patent was not repeatable and thus was not prior art for novelty purposes. Indeed, this Court rejected the same argument Roche makes here. Like Roche argues today, HMR/TKT argued that because Dr.

² *Amgen v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 315-316 (D. Mass. 2004), *aff'd Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293 (Fed. Cir. 2006)

³ *Id.* at 318 and fn. 135 (noting that a particular reference need not be enabling to be considered in the obviousness inquiry, the asserted combination must provide a reasonable expectation of successfully practicing the claimed invention.)

⁴ *Id.* at 318-319, 323. *See also Pharmastem*, 2007 U.S. App. LEXIS 16245 *49-54 (recognizing that "[t]he more difficult question is whether the prior art would have given rise to a reasonable expectation of success in creating the process claimed" in the patent, thereby demonstrating that an obviousness inquiry involves more than just accepting the content of the prior art as an admission.)

Lin's patents describe Sugimoto in the background section, Amgen should be held to an admission of the enablement of Sugimoto. Neither this Court, nor the Federal Circuit, viewed Amgen as having admitted enablement or being foreclosed from challenging Sugimoto.⁵

Moreover, any obviousness inquiry also involves a review of "objective indicia of non-obviousness," or secondary considerations.⁶ Secondary considerations include: commercial success, long-felt but unresolved need, the failure of others, unexpected result created by claimed inventions, unexpected properties of the claimed invention, and the skepticism of skilled artisans before the invention.⁷ All of these factors require Amgen to probe and explain prior art. Indeed, as this Court stated in regards to secondary considerations when it rejected HMR/TKT's claims that Amgen's inventions were obvious, "if Sugimoto's invention truly rendered Amgen's invention obvious, one wonders why so many tried and failed."⁸

Roche's claim that Amgen must adopt any reference to prior art claims that are described in Amgen's patents is without merit. Amgen is entitled to explain why its inventions were not obvious, and why the PTO appropriately granted Amgen its patents.⁹

II. Roche Has Not Met Its Burden to Show That Amgen Has Made Statements That Contradict Its Patent Specification.

This Court should also deny Roche's motion because Roche fails to meet its burden that any Amgen evidence in fact contradicts claims in the patent specification. Determining whether there is a contradiction between evidence to be presented in court and Amgen's patent

⁵ *Id.* at 318-319, 323.

⁶ *Amgen v. Hoechst Marion Roussel*, 339 F. Supp. 2d at 319.

⁷ *Id.* at 314-315 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

⁸ *Id.* at 319.

⁹ If Roche believes Amgen is providing testimony that contradicts statements of prior art, then cross-examination is the appropriate mechanism to test that assertion. *See Davis v. Alaska*, 415 U.S. 308, 316 (U.S. 1974) ("Cross-examination is the principal means by which the believability of a witness and the truth of his testimony are tested.")

specification would require a highly fact specific analysis of the two allegedly contradictory statements.¹⁰

Here, Roche has failed to direct this Court to any Amgen argument or proposed evidence that would enable the court to conduct a detailed analysis between the evidence and Amgen's patent specifications. Roche's Motion consists of a number of excerpts from Amgen's patent specification and then summarily claims that "the positions taken [by Amgen] in interrogatory responses and advanced by [Amgen] experts in their expert reports" contradict these excerpts. Roche's general reference to interrogatory responses and expert reports is meaningless. Amgen responded to 41 interrogatories and prepared 30 expert reports, rebuttals and supplements. These documents consisted of well over a thousand pages. Roche is not entitled to a ruling in the abstract that Amgen's evidence will contradict statements made in the specification of the patents-in-suit.¹¹

CONCLUSION

For the foregoing reasons, this court should deny Roche's Motion in *Limine* to Preclude Amgen from Making Assertions that Contradict Statements Made in Specifications of Patents-in-Suit.

¹⁰ *PharmaStem*, 2007 U.S. App. LEXIS 16245 *49.

¹¹ *Glass v. Intel Corp.*, 2007 U.S. Dist. LEXIS 57666 *13 (D. Az. 2007) (denying motion in *limine* where defendant did not specifically state nor provide examples of the evidence that it sought to exclude); *United States v. Cline*, 188 F. Supp. 2d 1287, 1292 (D. Kan. 2002) (denying motion in *limine* as speculative, premature and vague); *Nat'l Union Fire Ins. Co.*, 937 F. Supp. 276, 287 (S.D.N.Y. 1996) (denying motion in *limine* where party sought to exclude alleged *parol evidence* but failed to identify with any specificity the purported evidence to be excluded).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

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