Case 1:05-cv-12237-WGY

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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

OPPOSITION TO ROCHE'S MOTION IN LIMINE TO PRECLUDE AMGEN FROM INTRODUCING INTO EVIDENCE OR REFERENCING TO THE JURY: 1) THE SEPTEMBER 30, 1985 AMGEN/ORTHO PRODUCT LICENSE AGREEMENT, AND 2) EVIDENCE CONCERNING LICENSING OF THE PATENTS-IN-SUIT

Roche's Motion in Limine to Preclude Amgen from Introducing Into Evidence or Referencing to the Jury the Amgen/Ortho Product License Agreement or Evidence concerning licensing is nothing more than a desperate attempt to preclude the introduction of highly relevant and powerful evidence that shows Roche's claim that the patents-in-suit were obvious is totally unfounded. It cannot be seriously contested that secondary considerations are critical to the analysis of obviousness. As numerous courts have held, licensing agreements like Amgen's agreement with Ortho, are indicia that the invention was not obvious because the industry respects and acquiesces to the patentee's invention.

Roche's request to preclude this extremely relevant evidence is baseless. Indeed, every justification that Roche purports to offer fails upon inspection. There is no judicial estoppel because Amgen never claimed that the Ortho license did not grant rights to the patents-in-suit. Furthermore, Roche's complaint that Amgen would not acquiesce to Roche's improper request Case 1:05-cv-12237-WGY

T. Amgen's License Agreement With Ortho Is Further Evidence That Secondary Considerations Do Not Support Roche's Claim that Amgen's Patents-In-Suit Are Obvious.

The law is clear that this Court must look at the public and commercial response to Amgen's patents when assessing Roche's claim that the patents are obvious. 1 Indeed, as the Federal Circuit has held, "evidence of secondary considerations may often be the most probative and cogent evidence in the record.²" Secondary considerations are even more important in a highly technical case.³ This is because although Courts may not always fully understand the technical considerations, economic and motivational factors are more susceptible to judicial treatment.4

Here, the fact that Ortho Pharmaceutical Corporation — a large company affiliated with Johnson and Johnson — was willing to pay Amgen to use the products of Amgen's inventions, directly rebuts Roche's claim that Amgen's patents are obvious. As this Court and numerous others have recognized, one of the key factors in the Court's analysis of secondary

¹ See Graham v. John Deere Co., 383 U.S. 1, 35-36 (1966) (stating that secondary considerations of nonobviousness serve to "guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue"); Amgen v. Hoechst Marion Roussel, 339 F. Supp. 2d 202, 319 (D. Mass. 2004) (setting forth factors to consider to assess objective indicia of non-obviousness).

² Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957 (Fed. Cir. 1997) (finding that patentee's licenses showed objective indicia that patent was not obvious).

³ Ortho Pharmaceutical Corp v. Smith, 1990 U.S.Dist.LEXIS 1951 at *22 (E.D.Pa 1990) (stating that courts "had best appraise the originality involved by the circumstances which preceded, attended and succeeded the appearance of the invention").

⁴ Graham v. John Deere Co., 383 U.S. at 35-36.

considerations is whether other persons have licensed the invention.⁵ A license shows that the relevant industry respects the invention and has acquiesced to the patent.⁶ In light of the uncontroverted importance of this evidence to the analysis of obviousness, Amgen's license of its invention to Ortho is incredibly relevant.

Roche's claims that Amgen's license with Ortho is somehow not relevant are baseless. First, Roche makes the disingenuous claim that the license agreement is not relevant because Amgen and Ortho entered into it before the patents-in-suit had been filed. As Roche is well aware, when Amgen and Ortho entered into the license agreement the patents-in-suit were pending before the PTO. Thus, the applications that led to the issuance of each of the patents-in-suit were included as attachments to the license agreement. Significantly, when this Court dealt with Ortho's request to intervene it recognized that the Amgen/Ortho license agreement "encompasses the art claimed in the product patents at issue."

Roche's second claim that the Amgen/Ortho license agreement fails to establish that Amgen's EPO product was the driving force behind Ortho's decision to enter into the agreement is similarly disingenuous. Amgen does not need to show that Ortho's decision to enter into the license agreement was driven by obtaining rights to Amgen's EPO product. What is critical for purposes of evaluating secondary considerations is that members of the industry licensed Amgen's EPO patents and thus, recognized and respected Amgen's inventions.⁸

⁵ See Arkie Lures, Inc., 119 F.3d at 957; Amgen v. Hoechst Marion Roussel, 339 F. Supp. 2d at 319; Ortho Pharmaceutical Corp v. Smith, 1990 U.S.Dist.LEXIS 1951 at *22;

⁶ *In re Denis Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (stating one of the secondary considerations is "licenses showing industry respect for the invention"); *Ortho Pharmaceutical Corp v. Smith*, 1990 U.S.Dist.LEXIS 1951 at *22 (stating licenses show "the acquiescence of the industry").

⁷ See October 20, 2006 Memorandum and Order, p. 22. Docket # 121.

⁸ In re Denis Rouffet, 149 F.3d at 1355; Ortho Pharmaceutical Corp v. Smith, 1990 U.S.Dist.LEXIS 1951 at *22.

II. Amgen Is Not Judicially Estopped From Asserting The Relevance of the License Agreement

Roche's claim that Amgen is judicially estopped from asserting the relevance of the license agreement is based on Roche's mischaracterization of Amgen's prior position regarding Ortho's motion to intervene. Amgen did not state in its Opposition to Ortho's request that the license agreement did not provide Ortho a right to Amgen's patents. The Amgen/Ortho agreement clearly has a grant clause in it conferring Ortho rights to Amgen's patents, including the then-pending Lin applications. This is, in part, the reason why the applications are attached to the Agreement. Amgen has not denied the existence of this grant. Instead, Amgen argued that Ortho could not intervene because the license agreement gave Ortho a bare license, rather than an exclusive license and because the license agreement gave Amgen the right to sue third parties for patent infringement. These arguments in no way support Roche's contention about Amgen's prior representations.

III. Roche Has Relevant Discovery Related to Amgen's License Agreement with Ortho.

Roche's claim that it was denied meaningful discovery regarding Amgen's license agreement with Ortho is similarly unfounded. Amgen produced documents regarding its license with Ortho, including, among other documents, the product license agreement and the stipulation between Amgen and Ortho that settled a prior arbitration. In addition, Amgen provided a 30(b)(6) witness who testified to "the terms and operation of the agreement between Amgen and Ortho Pharmaceutical Corporation, dated September 30, 1985.¹⁰" Finally, Ortho produced — pursuant to a subpoena from Roche — documents relevant to the license agreement.

⁹ Moreover, judicial estoppel does not apply because Roche cannot show that the Court relied on Amgen's position. *See InterGen N.V. v. Grina 344 F.3d 134, 144 (1st Cir. 2003).*

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¹⁰ Defendants' First Notice of Deposition to Amgen Pursuant to Rule 30(b)(6), Topic 15.

Accordingly, Roche has been provided a full and fair disclosure of the Amgen/Ortho license

Roche's claim that Amgen objected to documents related to the Amgen/Ortho license agreement is simply incorrect. As this Court twice held, Roche's requests to produce all <u>documents</u> from a prior arbitration and litigation with Ortho were inappropriate.¹¹ Amgen objected to these requests as overbroad and because they lacked relevance as the documents responsive to the requests would have related primarily to sales of rEPO into the oncology clinic channel, a market segment that is not at issue. Amgen did not refuse to produce documents related to the Amgen/Ortho license agreement, and as set forth above, did in fact produce these documents.

For the foregoing reasons, this Court should deny Roche's Motion in Limine to Preclude Amgen from Introducing Into Evidence Or Referencing to the Jury: 1) the September 30, 1985 Amgen/Ortho Product License Agreement, and 2) Evidence Concerning Licensing of the Patents-In-Suit.

agreement.

¹¹ See Electronic Orders of Jan. 3, 2007 and Jan. 29, 2007.

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Respectfully Submitted,

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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.

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