

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 Civ. 12237 WGY

ROCHE'S MEMORANDUM OF LAW IN SUPPORT OF ITS 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

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Dated: Boston, Massachusetts
August 31, 2007

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I. INTRODUCTION

In the Pre-Trial Memorandum, Amgen Inc. (“Amgen”) asserts its intent to offer “objective evidence demonstrating the non-obviousness of Lin’s inventions.” Among the indicia Amgen proffers is “[t]he taking of licenses under the patents by others.” Specifically, in Amgen’s Statement of Contested Facts, Amgen makes statements about the September 30, 1985 Amgen/Ortho Product License Agreement (“the PLA”) by which Ortho Biotech Products, L.P. (“Ortho”) was granted the right to sell recombinant human erythropoietin under the trademark PROCRI[®]. The mention of the Agreement in Amgen’s Statement of Facts leads Roche to believe that Amgen will attempt to present the PLA as evidence at trial. The Court should preclude Amgen from doing so.

First, Amgen has consistently claimed in this case that Ortho’s license was not a “patent license” at all but a “product license” that did not confer any direct or substantial rights in the ‘008 patent or any of the patents-in-suit. Amgen argued this very point in its April 11, 2006 Opposition to Ortho’s Motion to Intervene in this litigation, stating that because Ortho had no legally protectable interest in the patent claims-in-suit, Ortho had no standing to intervene. Amgen’s current characterization completely contradicts its prior statement. Amgen should be precluded from adopting one position in one proceeding (and securing a favorable decision) and then taking a contradictory position now solely for the purposes of obtaining a legal advantage. Moreover, it is indisputable that none of the patents-in-suit existed at the time the parties entered into the PLA; therefore, the PLA has little to no relevance or bearing on the obviousness or non-obviousness of the patents-in-suit.

Additionally, Amgen refused in discovery to produce documents related to the Ortho/Amgen arbitration which, according to Amgen, centered squarely on the PLA at issue.

Roche moved to compel production; Amgen opposed; and the Court denied Roche's request. As Roche was denied meaningful discovery on subject matter directly relevant to the PLA, it would be unfair and against the spirit of the Court's January 22, 2007 order to allow the PLA into evidence now. Accordingly, Defendants respectfully request that the Court preclude Amgen from offering into evidence and/or referencing to the jury the September 30, 1985 Amgen/Ortho Product License Agreement.

In addition, Amgen apparently intends to introduce evidence that third parties, including Ortho have "sought and received a license under" the patents in suit as part of its validity defense. Amgen should be precluded from presenting any such evidence because, as explained, Amgen has characterized the Ortho license a product license and not a patent license. In addition, during discovery Amgen produced no documents or other evidence of any inquiries or discussions with third parties about licensing the patents in suit despite various discovery requests seeking such evidence. As this Court has previously ruled "No Witness May Rely on Evidence Withheld From Discovery." (5/16/07 Electronic Order). As Amgen failed to produce any evidence concerning licensing discussions of the patents at issue, it must be precluded from relying on such evidence at trial. .

II. ARGUMENT

A. The Ortho PLA Is Irrelevant To This Action and Amgen Should Be Judicially Estopped from Asserting Otherwise

On September 30, 1985, Amgen and Ortho entered into a Product License Agreement in which, to borrow Amgen's own phrasing: "Ortho was granted the 'exclusive' right to make and sell a single product . . . to a specified class of patients and the non-exclusive right to make the LICENSED PRODUCT using the LICENSED PATENTS under certain circumstances."

(Amgen Inc.'s Opposition and Memorandum to Ortho Biotech Product L.P.'s Motion to

Intervene, Docket No. 34, at 6). In response to Ortho's motion to intervene in this litigation, Amgen dismissed Ortho as "nothing more than a 'bare licensee' without standing to bring suit under a Lin Patent." (*Id.* at 7.) Amgen stated that the Product License Agreement clearly showed that Ortho lacked a "'direct, substantial and legally protectable' interest in the patent claims-in-suit" and that this interest, by the terms of the PLA, "remaine[d] exclusively in Amgen's hands." (*Id.* at 9.)

On October 20, 2006, the Court, while chiding the reasoning of Amgen's opposition (calling Amgen's argument a "fundamental misunderstanding of patent law or a deliberate attempt at obfuscation"), nevertheless noted that the dispute over Ortho's right to intervene was at root a contract dispute - the type of dispute which must be arbitrated. (10/20/06 Young Memorandum and Order, Docket No. 121 at 26, 32). Accordingly, the Court denied Ortho's Motion to Intervene without prejudice, subject to a determination of the issue of contract interpretation by an arbitral panel. (*Id.* at 34).

The First Circuit has made clear that "in a prototypical case, judicial estoppel applies when a party has adopted one position, secured a favorable decision, and then taken a contradictory position in search of legal advantage[,]" *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004), quoting *InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir. 2003); *see also, Patriot Cinemas, Inc. v. General Cinemas, Corp.*, 834 F.2d 208 (1st Cir. 1987) (holding that "where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position"). "Judicial estoppel should be employed when a litigant is 'playing fast and loose with the courts,' and when 'intentional self-contradiction is being used as

a means of obtaining unfair advantage in a forum provided for suitors seeking justice.” *Id.* at 212, quoting *Scarano v. Central R. Co.*, 203 F.2d 510 (3d Cir. 1953).

In the instant matter, judicial estoppel clearly applies. First, Amgen argued in its Opposition to Ortho’s Motion to Intervene that Ortho should be precluded from intervention because the PLA was a mere product license offering no direct, substantial, or legally protectable interest in the patent claims-in-suit. Despite the Court’s reservations, Amgen ultimately succeeded in getting a favorable judgment and Ortho’s motion to intervene was denied pending arbitration. Amgen seeks to reverse its position on the character and effect of the PLA - asserting now that it is a “patent license” by which Ortho recognized patent validity and also a secondary indicia of non-obviousness. This naked about-face is precisely the type of intentional self-contradiction the doctrine of judicial estoppel was meant to stomp out. Amgen in one motion cannot claim the PLA is a mere *product* license with no substantial patent rights attached only to be permitted to say in a later motion that it is a *patent* license which the jury should consider as evidence of non-obviousness.

In fact, the evidence is clear that at the time the parties entered into the PLA the patents-in-suit had not even been filed with the Patent Office, let alone issued with the broad scope that Amgen now claims. Thus, Ortho could not have then licensed rights to the specific claims that Amgen seeks to enforce with any meaningful evaluation of their validity. However, in an attempt to unfairly gain benefit from the mere existence of the Ortho product license, Amgen attempts to lump the expired ‘008 patent with the patents-in-suit as if they were an

indistinguishable bundle.¹ This is clearly improper. *See Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996) (“By statutory and common law, each patent establishes an independent and distinct property right.”). As Ortho could not have had any idea of the validity or non-obviousness of patent claims that did not yet exist, the PLA cannot be used as evidence of those patents’ validity now.

Furthermore, the existence of the PLA fails to establish that Amgen’s EPO product -- let alone the patents-in-suit -- was the driving force behind Ortho’s decision to enter into the agreement with Amgen. Indeed, the PLA makes clear that the product and know-how licensed from Amgen is also covered by patent applications filed by inventor Egrie (Ser. No. 463,724 which issued as U.S. 4,558,066) and inventors Lai and Strickland (Ser. No. 747,119 which issued as U.S. 4,667,016) relating to EPO -- patents which Amgen must necessarily concede are separate from the Lin ‘008 patent and the patents-in-suit. Moreover, the license also covers at least two other products which are wholly independent from Lin’s purported EPO inventions, namely (1) recombinant yeast-derived hepatitis B surface antigen vaccine and (2) recombinant-methionyl human interleukin-2[alanine 125] (“IL-2”). Additionally, the license also covers much more than product sales in the United States and, in fact, confers worldwide rights to Ortho with respect to the hepatitis B vaccine (except China) and IL-2. Thus, the license agreement has little to no probative value vis-a-vis evaluating secondary considerations of obviousness with respect to the patents-in-suit because, at a minimum, Amgen plainly cannot prove the requisite nexus. *See In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995); *Automotive Tech. v. TRW Vehicle*

¹ Interestingly this situation serves as another example of Amgen’s unwavering tactic of relying on contradictory positions at different times based on whichever is most beneficial to its then-current needs. On one hand, Amgen wants to lump the claims the patents-in-suit together with the claims of the ‘008 patent with the hopes that it can use the PLA to its advantage for proving validity. However, on the other hand, Amgen argues that the claims of the patents-in-suit are separate and distinct from the ‘008 patent and cannot be lumped together for the purposes of obviousness-type double patenting over the ‘008 patent. Amgen cannot have it both ways.

Safety Sys., Inc., 2006 WL 2794338, *33 (holding that “because none of the licenses identified by [the patentee] concern the [patent-in-suit], . . . they are not pertinent to the obviousness determination”). Instead, introduction of the PLA at trial will only unfairly serve to confuse the issues to be decided by the jury and prejudice Roche’s obviousness defense. Fed. R. Evid. 403.

In January of this year, Roche moved to compel Amgen to produce documents related to the Ortho/Amgen arbitration (Defendants’ Memorandum in Support of Their Motion to Compel the Production of Documents, Docket #255, at 17-19). Amgen opposed production, stating that the “arbitrations with Ortho pertained to the scope of Amgen’s product license to Ortho” and that the documents related to this arbitration were “not pertinent.” (Amgen Inc.’s Opposition to Defendant’s Motion to Compel the Production of Documents, Docket #265, at 18). The referenced product license is the same PLA at issue here. The Court, in a January 29, 2007 order, denied Roche’s request for documents regarding the Ortho arbitration. Accordingly, Roche was denied discovery relevant to the PLA. It is entirely possible that the Ortho arbitration proceedings materially changed the terms of the PLA. It is possible that Ortho even challenged the validity of the patents. *See, e.g., MedImmune, Inc. v. Genentech*, 127 S.Ct. 764, 776 (holding that “[p]romising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity.”) Without proper discovery, Roche is left a document with no context. All that is known is that Amgen was ordered to pay Ortho \$164,000,000 on Ortho’s claims regarding erythropoietin, and Johnson & Johnson was ordered to pay \$89,700,000 to Amgen regarding the hepatitis B vaccine and interleukin-2 licensed from Amgen through the PLA. *See Amgen Inc.’s Public Annual Report 1994 (10-K)*. In its January 22, 2007 order, this Court made clear that no party could introduce into evidence anything which was called for in discovery and not produced. As Roche was denied any meaningful discovery

on the circumstances and context of the PLA, Amgen should not be allowed to introduce the PLA now.

B. Evidence Regarding Licensing Should Be Excluded

In its contested issues of fact, Amgen indicates that it will seek to introduce evidence that other entities, including Ortho, “sought and received a license under” the patents in suit purportedly as a secondary consideration of non-obviousness. Joint Pretrial Memorandum, Docket No. 807, Exh. A, Amgen Contested Fact Issue No. 61. Because Amgen produced no evidence in discovery that it has licensed the patents-in-suit, nor that it has engaged in any discussions about doing so, it must not be permitted to refer to such evidence to the jury. This Court clearly put the parties on notice that evidence not produced during discovery could not be mentioned at trial. *See* May 16, 2007 Electronic Order in regard to Motion to Strike Infringement Allegations in Amgen’s Expert Reports (“No Witness May Rely on Evidence Withheld from Discovery”).

Here, for the reasons explained above, Amgen has contended that the Ortho PLA is a product license, not a license of any of the patents in suit. Moreover, Amgen has deliberately withheld discovery from Roche on the Ortho license contending that the scope of that license was not pertinent to the issues in this suit.

Moreover, although claiming that other unspecified entities have “sought and received licenses” of the patents in suit, Amgen has produced no documents or any other evidence of any such activity with any other third party. There is no evidence produced by Amgen of discussions with other entities about licensing the patents, and certainly no evidence that Amgen has actually licensed the patents in suit, despite Roche demands for such information. *See, e.g.*, Roche Request for Production No. 55 (demanding documents concerning “any effort or attempt,

successful or otherwise, to license or grant rights” under the patents in suit). Nor did Amgen reveal that it was relying on any actual or potential licensing of the patents in suit as a component of any secondary consideration evidence of non-obviousness. In response to Roche’s interrogatory asking for the details for any contention of secondary considerations of non-obviousness, Amgen, in an 11-page response, did not once say anything about licenses of the patents in suit, or the interest of other parties in such licenses. Plaintiff Amgen’s Responses To Defendant’s Third Set of Interrogatories, Response to Interrogatory No. 21, dated April 2, 2007. Amgen never supplemented this interrogatory response to claim that licensing has anything to do with its secondary considerations defense.

Having clearly withheld evidence concerning licensing of the patents in suit during discovery, and indeed affirmatively representing that this issue had no bearing on its secondary considerations defense, Amgen must not now be permitted to present any such evidence to the jury.

III. CONCLUSION

As Amgen has already made an argument before this court cutting against the relevance of the PLA (which, if anything, would only be secondary indicia for the expired ‘008 patent), and as Roche was denied meaningful discovery directly related to the PLA, Roche respectfully asks the Court to preclude Amgen from proffering a contradictory argument now in its attempt to offer the PLA into evidence at trial. Amgen should be precluded both from making the argument to the jury and/or from offering the PLA as evidence relevant to any of the patents-in-suit.

In addition, Amgen should be precluded from introducing evidence regarding, or referring to, licensing of the patents-in-suit.

Dated: August 31, 2007
Boston, Massachusetts

Respectfully submitted,

F. Hoffmann-La Roche Ltd, Roche
Diagnostics GmbH, and Hoffmann-La
Roche Inc.

By their Attorneys,

/s/ Keith E. Toms

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CERTIFICATE OF SERVICE

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/s/ Keith E. Toms

Keith Toms

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