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 12237 WGY U.S. District Judge William G. Young

ROCHE'S OPPOSITION TO AMGEN'S MOTION *IN LIMINE* NO. 10: EXCLUDE EVIDENCE RELATED TO ROCHE'S ANTITRUST ALLEGATIONS

I. INTRODUCTION

Failing to recognize that evidence can relate both to the patent and antitrust issues in this case, Amgen moves to exclude "any evidence or arguments . . . that relate to Roche's antitrust claims," contending that some very limited material Roche has designated relating to Amgen's efforts to prevent Roche from ultimately being able to sell Mircera™ to dialysis center customers has "no relationship" to patent claims. (Amgen Br. 1). The most telling indication of the meritless nature of Amgen's motion is the fact that *every one* of the exhibits Amgen identifies as objectionable has been included on *Amgen's own exhibit list*. Indeed, some of the exhibits Amgen objects to were included *only* on Amgen's exhibit list, not on Roche's list. Amgen's own exhibit list is thus a tacit admission that the material it complains about here is relevant to the patent claims.

The evidence at issue pertains to Amgen's indirect infringement claims. In particular, this evidence is relevant to Amgen's claims that Roche indirectly infringes Amgen's U.S. Patent No. 5,547,933 (Lin) ("the '933 patent") by inducing dialysis centers to infringe Amgen's method patents for treating kidney dialysis patients. Because direct infringement is an element of any inducement claim, at trial Amgen has the burden to prove that the methods of treating kidney dialysis patients claimed in the '933 patent (claims 11 and 14) have been directly infringed by persons or entities who provide such treatment, which Roche does not. Thus, Amgen can only meet its burden of proving direct infringement by showing that dialysis centers purchase and use Roche's product to treat kidney dialysis patients. The limited Roche-designated evidence on this point

concerns Amgen's efforts to foreclose Roche's ability to sell Mircera to dialysis centers, and is therefore directly relevant to the issue of direct infringement.[1]

Significantly, Amgen itself has designated scads of deposition testimony and exhibits that relate to the antitrust case, including deposition testimony from several Roche sales and marketing employees regarding Roche's efforts to sell to dialysis centers, as well as Roche's business plans, forecasts, pricing, and reimbursement strategies. Amgen -- which disingenuously fails to mention its own "antitrust-related" designations in its motion -- can not have it both ways by affirmatively designating evidence regarding Roche's sales efforts and at the same time claiming that evidence that Amgen is blocking those efforts is irrelevant. Thus, the Court should reject Amgen's gamesmanship and reject its motion.

II. ARGUMENT

Roche's Evidence Is Relevant to Amgen's Inducement Claims

Amgen has asserted in this action that Roche is liable for inducing the infringement of its claims as to a method for treating kidney dialysis patients, as set forth in claims 11 and 14 of its '933 patent. Claims 11 and 14 of the '933 patent read as follows:

> 11. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 9 in an amount effective to increase the hematocrit level of said patient.
>
> 14. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 12 in an amount effective to increase the hematocrit level of said patient.

[1] Amgen must meet other prerequisites in order to meet its burden on the inducement claim against Roche, including intent. *See DMS Corp. v. JMU Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006).

Because Roche does not treat kidney dialysis patients, Amgen must argue that Roche induces infringement of these method claims when dialysis centers use Roche's Mircera to treat kidney dialysis patients. As the Federal Circuit has recently made clear in an *en banc* opinion on inducement claims, Amgen has the burden "to show direct infringement for each instance of indirect infringement." *DMS Corp. v. JMU Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006); *see also Dynacore Holdings Corp. v. U.S. Philips Corp.* 363 F.3d 1263, 1272 (Fed. Cir. 2004) ("[i]ndirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement, though the direct infringer is typically someone other than the defendant accused of indirect infringement"); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993) ("[l]iability for either active inducement of infringement or contributory infringement is dependent upon the existence of direct infringement").

Consequently, Amgen has designated testimony from Roche sales and marketing witnesses and exhibits concerning Roche's discussions with dialysis centers, including Fresenius and DaVita, which together control about 66% of the dialysis center market. In fact, astonishingly, *every one* of the exhibits listed in Amgen's brief and accompanying appendix as "relating to Roche's antitrust allegations" has been included by Amgen on its *own* proposed exhibit list.[2] Moreover, Amgen has also designated scores of other "antitrust-related" documents and testimony, the relevance of which are far more remote than any of Roche's targeted exhibits. For example, Amgen -- and only Amgen -- has included on its exhibit list the 2005 Year-End Performance Review of Lori Hickman, a

[2] Amgen incorrectly states that "Roche's proposed exhibit list includes over 7000 entries." (Amgen Br. 1, n.1). In fact, Roche's proposed exhibit list has only 3,191 entries, while Amgen's proposed list has 7,937 entries. Amgen is apparently, mistakenly, referring in footnote 1 to its own voluminous list and using its own list as the source for the purportedly objectionable documents it identifies in its appendix.

Roche senior marketing executive – a document bears no ostensible connection to any issues in either the patent or antitrust case other than a passing mention of Roche communications with DaVita. (Amgen Temp. Exhibit No. 5522). Likewise, Amgen -- and only Amgen -- has included on its exhibit list, *inter alia* (i) Roche presentations on potential prices for Mircera (Amgen Temp. Exhibit Nos. 3659, 5743, 5777, 5781-82, 5789, 7360), (ii) Roche draft presentations on Roche's "Medicare strategy" (Amgen Temp. Exhibit Nos. 3657, 3658, 6273, 6275), and (iii) a Roche presentation on the 2007 Mircera marketing budget (Amgen Temp. Exhibit No. 5745). Amgen has also designated extensive deposition testimony relating to Roche's antitrust claims, including testimony from the following Roche senior sales and marketing staff:

- Sonders Beimfohr, Director of Strategic Pricing, Renal Segment
- Suzanne Duncan, Product Director, Commercial Operations
- Susan Graf, Product Director, Mircera Marketing
- Lori Hickman (now Martin), Vice President, Marketing
- Richard Hinson, Vice President, Commercial Operations
- John Keefe, Product Director, Mircera
- Chrys Kokino, Vice President, Anemia Products.

Given Amgen's own voluminous proffer of extraneous and highly sensitive Roche business information, Amgen's transparent purpose in the instant motion is not, as it claims, to exclude "irrelevant," "prejudicial," or "confusing" evidence, but rather to gain unfair advantage by blocking Roche's limited rebuttal evidence. Such gamesmanship should not be indulged by the Court.

Roche's designations go to rebutting Amgen's inducement claims. Accordingly, Roche has designated a limited number of documents and depositions showing that Amgen has made substantial and extensive efforts to prevent Roche from making any sales to entities that treat kidney dialysis patients. For example, Roche has designated evidence regarding Amgen's exclusive contract with Fresenius, which precludes Roche from selling to the largest treater of kidney dialysis patients in the United States. Other evidence shows that Amgen is attempting to negotiate a similar exclusive arrangement with DaVita, the second largest dialysis center. The rest of the evidence concerns threats that Amgen made to key thought leaders among smaller kidney dialysis providers in the United States -- namely that those providers who purchased Roche's product would lose the ability to obtain vital discounts on Amgen products needed for the providers to stay in business. Were Amgen to succeed in these efforts, Roche would be unable to distribute its product to kidney dialysis providers, thus preventing precisely the alleged direct infringement that is the lynchpin for Amgen's inducement claims.

Roche does not propose trying the antitrust counterclaims as part of the patent case. What it seeks, however, is the ability to present evidence to rebut what Amgen plans to offer about Roche sales efforts to dialysis centers in order to demonstrate that Amgen's inducement claims are without merit. Because the limited evidence that Roche has designated goes precisely to that issue, Amgen's motion should be denied.

IV. CONCLUSION

For the reasons set forth above, Amgen's Motion in Limine No. 10 should be denied in all respects.

Dated: September 1, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH,
and HOFFMANN-LA ROCHE INC.

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CERTIFICATE OF SERVICE

I certify that, on the above date, 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.

/s/ Thomas F. Fleming
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