

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**BRIEF IN SUPPORT OF AMGEN'S MOTION IN LIMINE NO. 7:
EXCLUDE ROCHE FROM REFERENCING THE PROFITS OR REVENUES FROM
AMGEN'S EPOGEN® AND ARANESP® PRODUCTS**

I. INTRODUCTION

Plaintiff Amgen moves to exclude any argument, evidence or reference by Roche in front of the jury to Amgen's profits or revenues from the sale of Amgen's EPOGEN[®] and Aranesp[®] products. Because Amgen is not seeking damages in this trial, evidence of Amgen's profits and revenues is not relevant to any issue to be heard by the jury. The only issue that it might be relevant to is Amgen's right to an injunction to show the harm to Amgen from the loss of sales and profit caused by Roche's threatened infringement. Since the injunction issue will be heard and decided by the Court and not the jury, there is absolutely no reason for Roche to seek to introduce evidence of Amgen's profits and revenues before the jury.

The potential prejudice that Amgen could suffer is obvious. In support of its flawed obviousness type double patenting ("ODP") positions, Roche will likely argue that Amgen has been rewarded enough for its inventions, citing to Amgen's profits and revenues, and that the jury should invalidate Amgen's patents. Such an argument is highly prejudicial and improper. Accordingly, references by Roche to the profits and revenues from Amgen's sales of its erythropoiesis stimulating products, namely Epogen[®] and Aranesp[®], should be excluded as irrelevant under FRE 402 and also under FRE 403 as so prejudicial as to far outweigh any probative value of such information.

II. FACTUAL BACKGROUND

This patent infringement case involves Amgen's claim for a declaratory judgment that Roche's pegylated erythropoietin ("PEG-EPO") product infringes Dr. Lin's U.S. patents. Amgen is seeking an injunction prohibiting Roche from selling PEG-EPO in the United States, and is not seeking damages based on Roche's activities to date.¹ Roche has raised various defenses and

¹ Plaintiff Amgen Inc.'s Second Supplemental Disclosures Pursuant To Fed. R. Civ. P. 26(a)(1) at p. 15, Docket No. 726-4.

counterclaims, including counterclaims seeking a finding that the asserted patents are invalid, unenforceable for inequitable conduct, and that Amgen has committed anti-trust violations. At Amgen's request, this Court bifurcated the trial on the patent claims (infringement, invalidity and unenforceability defenses) and Roche's antitrust counterclaims.² Because Amgen is not seeking damages, and because the Court bifurcated the antitrust claims, evidence of the profits and revenues from Amgen's product sales is irrelevant to the substantive issues in the patent trial.

Nevertheless, in discovery responses, Roche referenced Amgen's sales of Epogen[®] and Aranesp[®] to support its defenses:

Given the annual revenue generated by Epogen[®] after its approval by the U.S. Food and Drug Administration in 1989, Amgen had every reason to secure additional patent claims. Since approval for Epogen[®], Amgen has reported sales of approximately \$25,186,300,000 in the United States. (Amgen Inc., 10K Filings 1991-2006; see also AM 44 1508568). Even, after the expiration of the '008 patent, Amgen reported another approximately \$2,455,000,000 in U.S. sales for 2005 and \$2,511,000,000 in U.S. sales for 2006. Similarly, its Aranesp[®] product -- which Amgen asserts is covered by the '698 patent-in-suit -- has generated over approximately \$7,718,600,000 in sales since 2001 with approximately \$4,894,000,000 of the total amount due to sales since the '008 patent expired (Amgen Inc., 10K Filings 1991 - 2006).³

These statements, as well as others expected to be made by Roche's counsel at trial, will prejudice the jury against or otherwise unfairly influence the jury's consideration of the patent issues.

² July 18, 2007 Order, Docket No. 762.

³ Roche's Second Supplemental Response to Amgen's Third Set of Interrogatories, at p. 90.

III. AMGEN'S PROFITS AND REVENUES ARE NOT RELEVANT TO ANY OF ROCHE'S PATENT DEFENSES, AND WILL LIKELY PREJUDICE THE JURY

The Federal Rules of Evidence restrict the admission of evidence to that which is “relevant.”⁴ Without a damage claim, Roche has no basis for seeking to introduce evidence of Amgen’s profits and revenues from the sales of its products. Evidence of Amgen’s sales could only be relevant to Amgen’s proof of commercial success of the patented product as a secondary consideration of non-obviousness, and thus the validity of the patents.⁵ Amgen will not seek to introduce evidence of its sales, however, because the commercial success of Amgen’s Epogen[®] and Aranesp[®] products is not in dispute. Roche is not contesting the success of Amgen’s Epogen[®] and Aranesp[®] products but instead asserts that there is no nexus between the commercial success of Epogen[®] and the inventions claimed in Dr. Lin’s patents-in-suit.⁶ Thus, Roche has no legitimate basis to introduce evidence of Amgen’s profit and revenues and should not be allowed to argue that Amgen has received enough benefit from the inventions of Dr. Lin.

Whatever limited relevance Roche may argue for Amgen’s sales and profit figures, this Court should exclude references to these figures because their probative value is substantially outweighed by the danger of causing unfair prejudice to Amgen and confusion of the issues.⁷ Roche’s reliance on Amgen’s sales will give the jury the impression that Dr. Lin’s patents have created an unfair financial windfall for Amgen, and that invalidating Dr. Lin’s patent will still leave Amgen with plenty of money. This is exactly the type of unfair prejudice and confusion that FRE 403 is designed to prevent.

In *La Plante v. American Honda Motor Co., Inc.*, 27 F.3d 731 (1st Cir. 1994), the First

⁴ FRE 402.

⁵ See, *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966).

⁶ See, e.g., Expert Report of Dr. Lowe, dated April 6, 2007, at ¶¶ 54-60.

Circuit held that the plaintiff's references to the defendant's profits generated by sales of the products at issue caused unfair prejudice since it led the jury to view the case as a battle between a rich defendant and a poor plaintiff.⁸ Here, Roche is attempting to create a similar juxtaposition between Amgen as a rich patentee, and Roche as the party trying to break Amgen's hold on the market. Roche's effort should be rejected because it will unfairly put Amgen in a negative light, and introduce prejudice into the jury's consideration of the patent claims and defenses. Accordingly, this Court should preclude Roche from offering evidence or arguments relating to Amgen's sales of Epogen[®] and Aranesp[®].

If Roche were allowed to refer to Amgen's revenues and profits from the sale of its products, Amgen would be forced to use precious trial time to explain and defend its pricing strategy – one of the very issues raised in Roche's antitrust claims. Amgen would have to put on evidence to explain that EPOGEN's reimbursement price has been set by statute and that Amgen's price to its customers has always been below the statutory rate. Amgen would also have to put on evidence to explain that for innovative biopharmaceutical companies like Amgen, the one successful product must pay for the research and development cost of nearly a hundred product failures. Introduction of such evidence would be necessary to attempt to redress the prejudice that would be caused by Roche referring to Amgen's profits and revenues, but these issues are far removed from the real issues the jury will decide.

Without a damage claim in the case, Amgen's position is that Roche has no right to a jury trial. Apparently, Roche is pushing for a jury so that it can confuse and mislead the jury to decide the case, not on the law or the relevant facts, but on emotional reactions to irrelevant facts. The Court should reject Roche's attempt to do so.

⁷ FRE 403.

IV. CONCLUSION

This Court should prevent Roche from offering evidence or arguments relating to Amgen's profits or revenues from the sale of Amgen's EPOGEN[®] and Aranesp[®] products because Amgen's profits and revenues are irrelevant to the patent issues before the jury (infringement, invalidity, and unenforceability), and would likely unfairly prejudice the jury against Amgen and Amgen's case for infringement.

⁸ *La Plante*, 27 F.3d at 740.

Dated: August 20, 2007

Respectfully Submitted,

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/s/ Michael R. Gottfried

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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 on August 20, 2007.

/s/ Michael R. Gottfried
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