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. 8: EXCLUDE ROCHE FROM RELYING ON COMPARISONS BETWEEN ROCHE'S PEG-EPO PRODUCT AND AMGEN'S ARANESP® PRODUCT

I. INTRODUCTION

Plaintiff Amgen moves to exclude Roche's reliance on evidence comparing Roche's accused peg-EPO product (CERA) and Amgen's Aranesp® product in support of Roche's noninfringement arguments because a comparison of Roche's and Amgen's products is irrelevant to the issue of patent infringement and likely to confuse the jury. Comparisons between Roche's peg-EPO product and Amgen's Aranesp® product are inadmissible under FRE 402 because such comparisons have no bearing on whether Roche's product infringes the asserted claims of the Lin patents. The only relevant comparison is between Roche's product and the claims of the Lin patents. Moreover, allowing Roche to present comparisons of its product and Amgen's product would serve only to mislead and confuse the jury. Even if this evidence has any relevance, because it is likely to mislead and confuse the jury, the Court should exclude it under FRE 403.

II. FACTS

Roche has attempted to rely on comparisons of its products and Amgen's products to argue that peg-EPO does not infringe the claims of the Lin patents.[1] For example, Roche's expert, Dr. Klibanov, opined that "the structure and properties of Aranesp® are more like the subject of the Asserted Product Claims than CERA is. Since Amgen has maintained the [sic] Aranesp® is not covered by any of the Asserted Claims of the Lin patents, it follows that CERA should not be covered by those of the Asserted Claims either."[2] Similarly, Dr. Klibanov said that, "based on the substantial difference between MIRCERA and the subject matter of the asserted claims, and based on Amgen's position that Aranesp® is not literally, or the equivalent of, the subject matter of the asserted claims, it is [his] opinion that Roche does not infringe under

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[1] *See* Klibanov Expert Rebuttal Report, ¶¶ 277-98.

[2] *Id.* ¶ 289.

the reverse doctrine of equivalents."[3] Amgen expects Roche's counsel and experts to offer such opinions and arguments at trial.

III. ROCHE SHOULD NOT BE PERMITTED TO SUPPORT ITS NONINFRINGEMENT ARGUMENTS BY RELYING ON COMPARISONS BETWEEN PEG-EPO AND AMGEN'S COMMERCIAL PRODUCTS

A. The Only Permissible Comparison for Infringement Analysis Is Between the Patent Claims and the Accused Product

In patent infringement analysis, the only relevant comparison is between the claims of the patent and the accused product. Other product comparisons are irrelevant. The Federal Circuit has consistently held that a court's infringement analysis may consist only of comparisons between the asserted claims and the accused product.[4] As the Federal Circuit has "repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent."[5] In *Zenith*, the Federal Circuit reversed the district court's decision because the district court had relied on a comparison of the accused product with the patentee's commercial embodiment of the patented invention.[6] In another case in this District, this Court has said that "[t]o determine literal infringement, as well as equivalence, the accused product is not compared with a preferred or commercial embodiment of the patent, but rather with the language of the claims."[7]

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[3] *Id.* at 102, ¶ 297.

[4] *See, e.g., Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1286 (Fed. Cir. 2002) ("[I]nfringement is to be determined by comparing the claim to the accused device…").

[5] *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (citing *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985)).

[6] *Id.* at 1423-24.

[7] *Atlantic Thermoplastics Co. v. Sullivan*, 1990 U.S. Dist. LEXIS 20050, *10 (D. Mass. 1990); *see also King Instrument Corp. v. Perego*, 737 F. Supp. 1227, 1231 (D. Mass. 1990) ("The accused product is not compared with an embodiment of the patent, but rather with the language of the claims.").

B. Product Comparisons Involving Aranesp® Are Irrelevant and Should Be Excluded Under FRE 402 and FRE 403

The only relevant analysis for patent infringement purposes is a comparison of Roche's peg-EPO product with the claims of the Lin patents. Similarities and differences between Roche's product and Amgen's product are irrelevant. Also irrelevant are any comparisons of Amgen's Aranesp® product with the claims of the Lin patents. Under FRE 402, "evidence which is not relevant is not admissible." Reliance on comparisons involving Amgen's commercial products have no place in Roche's noninfringement arguments. Comparisons involving Amgen's Aranesp® product serve no legitimate purpose. Allowing Roche to introduce such evidence could only serve to confuse and mislead the jury. Accordingly, under FRE 403,[8] the substantial likelihood of this evidence to mislead and confuse the jury provides an additional reason to exclude this evidence, even if it were to have some marginal relevance.

IV. CONCLUSION

Comparisons of Roche's products and Amgen's products are irrelevant to the issue of patent infringement. Evidence comparing Roche's products with Amgen's products would serve only to mislead and confuse the jury. Accordingly, the Court should exclude Roche from supporting its noninfringement position with any evidence comparing its peg-EPO products with Amgen's products.

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[8] FRE 403 ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.").

Dated: August 20, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/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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