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-12237WGY

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM ARGUING THAT THE MANUFACTURE OF CERA OR MIRCERA® OUTSIDE OF THE UNITED STATES IS IN ANY WAY IMPROPER AND FROM RELYING UPON ROCHE'S STATUS AS A FOREIGN COMPANY

I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this motion *in limine* to preclude Amgen from suggesting to the jury that it is in any way improper for Roche to manufacture its accused product CERA (or the formulated drug substance MIRCERA®) outside of the United States or that the fact that two of the Roche defendants are foreign companies is relevant to any issue in the case. Any such argument would unfairly prejudice Roche and would also confuse and mislead the jury.

II. RELEVANT FACTS

Roche manufactures CERA, the active ingredient in Roche's MIRCERA® product, in Penzberg, Germany. MIRCERA® is formulated in Basel, Switzerland.

Roche does not manufacture either CERA or MIRCERA® in the United States, nor does Roche have plans to do so. Roche does not currently import either CERA or MIRCERA® into the United States save for the purpose of seeking approval of the products by the Food and Drug Administration.

III. ARGUMENT

A. Amgen Should be Precluded from Suggesting that the Manufacture of CERA or MIRCERA® Outside the United States Is in Any Way Improper

The manufacture of an otherwise infringing product outside of the United States is not an act of infringement under 35 U.S.C. § 271(a). Section 271(g) of the patent law imposes patent infringement liability on one who "without authority imports into the United States. . . a product which is made by a process patented in the United States." Two elements must be shown under this section: 1) the manufacture of an infringing product outside the United States; and 2) the importation of that infringing product into the United States for a non-approved purpose. *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1348 (Fed. Cir. 2000) ("When the process used abroad is the same as the process covered by a United States patent, liability for infringement arises only upon importation, sale or offers, or use in the United States as set forth in § 271(g)"); *Bio-Technology General Corp. v. Genentech Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996). Thus, even if the party seeking to prove infringement under §271(g) is able to demonstrate that a product is made outside the United States by a process patented in the United States, if the accused infringer does not import the product into the United States—or only imports it for an allowable purpose such as provided by 35 U.S.C. §271(e)—there is

no infringement.[1] *See Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991). The mere act of manufacturing an accused product outside the United States creates no liability under 35 U.S.C. § 271(g). *See Synaptic Pharmaceutical Corp. v. MDS PANLABS Inc.*, 265 F. Supp. 2d 452, 458 (D. N.J. 2002) ("§271(g) does not prohibit the unauthorized use of process patents in foreign jurisdictions.").

Under Federal Rule of Evidence 403, 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." As the Advisory Committee Note to Rule 403 explains, unfair prejudice means an "undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." *See* also *Dirico v. City of Quincy*, 404 F.3d 464, 468 (1st Cir. 2005) ("Evidence is unfairly prejudicial if it invites the jury to render a verdict on an improper emotional basis") (internal quotations omitted). Unfair prejudice can exist both in evidence that may cause a jury to base its decision on something other than the established law and in evidence that is designed to elicit a response from the jurors that is not justified by the evidence. *See La Plante v. American Honda Motor Co.*, 27 F.3d 731, 740 (1st Cir. 1994) (evidence of Honda's profits from sales of ATVs was relevant in that it offered a possible explanation for their failure to warn consumers of the danger of its product but was rightfully excluded because "the risk that the jury would be prejudiced by this reference to the enormous

[1] 35 U.S.C. §271(e)(1) provides that "It shall not be an act of infringement to...import into the United States a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

profitability of Honda's ATVs was almost inescapable"). *See also* Weinstein's Federal Evidence §403.04 (2006).

Plainly, even if, contrary to fact, Roche practiced a patented process outside the United States in manufacturing CERA or MIRCERA®, an argument or suggestion by Amgen that it is in any way improper for Roche to manufacture CERA or MIRCERA® outside the United States would be flatly inconsistent with the patent law.[2] Allowing Amgen to suggest otherwise would mislead and confuse the jury. Indeed, Amgen would be inviting the jury to render its verdict on an improper basis — precisely what FRE 403 is designed to prevent. Amgen would be asking the jury to find misconduct where none has occurred and to punish Roche *in spite of* the established law.

B. Amgen Should be Precluded from Suggesting that the Fact that Two of the Defendants are Foreign Entities is Relevant

For essentially the same reasons, Amgen should not be permitted to suggest to the jury that there is any relevance in this case to the fact that two of the defendants are foreign corporations. Plainly, under the patent law, the foreign status of the defendants is of absolutely no consequence. Allowing Amgen to emphasize the Roche entities' status as foreign companies importing a product made abroad creates a significant danger of unfair prejudice unjustified by any factual or legal relevance. The likelihood of confusing and misleading the jury is high.

V. CONCLUSION

For the foregoing reasons, pursuant to FRE 402 and 403, the Court should preclude Amgen from suggesting to the jury that the manufacture of CERA or MIRCERA® outside the United States is in any way improper or that the status of two of

[2] At trial Roche will show that it does not practice all the elements of Amgen's process claims.

the Roche defendants as foreign companies is relevant.

Dated: August 20, 2007
Boston, Massachusetts

Respectfully submitted,

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

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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