UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMAN-LAROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMAN-LA ROCHE INC. Defendants.	CIVIL ACTION No: 05-CV-12237WGY

OPPOSITION TO 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

Roche's motion *in limine* to preclude Amgen from arguing that the manufacture of peg-EPO outside the United States is improper and from relying upon Roche's status as a foreign company ignores that this evidence is an essential element of Amgen's claims and directly relevant to Roche's purported defenses. Roche cannot sustain its burden to show that this evidence would be substantially outweighed by unfair prejudice. Amgen does not intend to argue that the jury should hold against Roche because it is a Swiss company that manufactures peg-EPO in Germany. But Roche's motion is far broader than a simple request that Amgen not invoke nationalistic arguments. It seeks to preclude Amgen from arguing an essential element of its claims: that Roche's manufacture of peg-EPO outside the United States is illegal and improper because of Roche's importation into the United States. Indeed, Roche's motion acknowledges that its manufacture outside the United States is one of the two elements of

Amgen's claim of infringement under 35 U.S.C. §271(g).[1] It is Roche's manufacturing — in conjunction with Roche's importation — that gives rise to Amgen's §271(g) claim. The two elements cannot be conveniently separated as Roche claims.

Furthermore, Roche's manufacture of peg-EPO outside of the United States is relevant to its hollow claim that its importation falls within a safe harbor. One of Roche's foreign companies is currently selling peg-EPO to one of Roche's United States subsidiaries so that Roche can use peg-EPO to conduct clinical trials in the United States that do not fall under the safe harbor. Moreover, Roche has acknowledged throughout discovery that when it gets FDA approval it will sell peg-EPO in the United States, regardless of whether this lawsuit is resolved. Roche's current stockpiling of peg-EPO in Europe shows Roche's improper intent and that its safe harbor defense is baseless.

Finally, implementation of Roche's request would be a logistical impossibility. Roche's documents and deposition testimony state throughout that Roche is a foreign company that manufactures peg-EPO in Germany. The parties cannot simply remove this information from the case.

I. Roche Cannot Use FRE 403 To Exclude Highly Relevant Evidence That Is Not Unfairly Prejudicial

Federal Rule of Evidence 403 is an extraordinary remedy that should be used sparingly.[2] The "general rule is that the balance should be struck in favor of admission.[3]" Moreover, where a party seeks to exclude the essential elements of a claim based on FRE 403, the burden on the

[1] *See* Roche's Memorandum of Law in Support of Motion *in Limine*, p. 2 *citing Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1348 (Fed. Cir. 2000).

[2] *United States v. King*, 713 F.2d 627, 631 (11th Cir. 1983) *quoting United States v. Thevis*, 665 F.2d 616, 633 (5th Cir. Unit B 1982).

[3] *Dente v. Riddell, Inc.*, 664 F.2d 1, 6 (1st Cir. 1981).

requesting party is significant and the Court should exclude the evidence only if "the danger of unfair prejudice is substantially outweighed by its probative value.[4]"

Roche has not met its burden to show that the evidence Amgen will present at trial is unfairly prejudicial.[5] Although Roche's motion implies that Amgen may make some type of nationalistic argument, this is simply incorrect and not Amgen's intent. The mere fact that Roche manufactures peg-EPO in Germany or that its headquarters are in Switzerland is not unfairly prejudicial. Indeed, Roche's own website boasts about its international status and Swiss headquarters stating "Roche's multinational presence reinforces our ability to offer our healthcare solutions world-wide and to anticipate needs in all regions of the world[6]"

Moreover, Roche incorrectly claims that its foreign manufacture of peg-EPO is not improper. As Roche acknowledges in its motion, its foreign manufacture of peg-EPO is the first of two essential elements that Amgen must establish to show infringement under 35 U.S.C. §271(g).[7] It is Roche's foreign manufacture of peg-EPO and its importation into the United States that is illegal under §271(g). The two parts of this claim cannot be separated. A product that infringes a patent because it is imported into the United States must, by definition, be manufactured outside the United States. Precluding "Amgen from suggesting to the jury that it is in any way improper" for Roche to manufacture peg-EPO outside the United States would

[4] *Espeaignnette v. Gene Tierney Co.*, 43 F.3d 1, 8 (1st Cir. 1994) (Finding that trial court abused its discretion when it excluded evidence that "bore directly on an essential element of the plaintiff's prima facie case"); *Swajian v. General Motors Corp*, 901 F.2d 1319, 1320-21 (reversing exclusion under FRE 403 where evidence "[went] to the fundamental question of the case").

[5] *Espeagnette*, 43 F.3rd at 8 ("the Company's failure in its brief to illustrate how the excluded evidence would be 'unfairly' prejudicial to its case confirms our conclusion [that the evidence was improperly excluded]").

[6] *See* http://www.roche.com/home/countries.htm.

[7] Roche Motion, p. 2 (stating "Two elements must be shown [to impose patent infringement liability] under [35 U.S.C. s. 271(g)]: 1) 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" *citing Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1348 (Fed. Cir. 2000).

preclude Amgen from showing the essential elements of Roche's infringement of Amgen's patents.

Furthermore, Roche's improper manufacture of peg-EPO is also relevant to Roche's claim that it uses peg-EPO in the United States under a safe harbor.[8] Amgen will show that Roche's United States entity is purchasing peg-EPO from Roche's foreign manufacturing company and using peg-EPO for clinical trials that do not fall under a safe harbor.[9] Moreover, even if, contrary to fact, Roche could show that its current activities fall under a safe harbor, Amgen's claims for declaratory relief also relate to the fact that Roche will imminently infringe Amgen's patents under §271(g).[10] Indeed, Roche's witnesses have boldly proclaimed throughout discovery that Roche will sell peg-EPO — a product this Court has already held infringes in an Amgen patent claim — in the United States when Roche gets FDA approval, regardless of Amgen's patent infringement claims or this lawsuit.[11] Roche is currently stockpiling peg-EPO in Europe for this very purpose.[12] Thus, evidence of Roche's improper

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[8] *See* Defendants' First Amended Answer and Counterclaims to Plaintiff's Complaint, p. 4 (Fourth Defense – Safe Harbor). Docket # 344.

[9] Deposition of Peter Schupbach at 15:23 – 16:3 (Roche companies pay a transfer price when they get product from a production site).

[10] *See* Amgen's Amended Complaint for Declatory Judgment of Infringement, ¶ 26 (stating Roche "currently infringes or will imminently infringe the claims of [Amgen's patents]").

[11] *See* Statement of Undisputed Material Facts In Support of Amgen's Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims, pp. 2-3. Docket # 520(describing: Deposition of Chrys Kokino at 256:24-257:9 ("Q. [I]n what way has Roche reevaluated its entering the U.S. market as a result of Amgen's alleged conduct? A. Roche's intent has always been to enter the U.S. market. It's now much more difficult. Q. But . . . no determination has been made that Roche will stop trying to enter the U.S. market, correct? . . . A. I'm unaware of that discussion if that has occurred."); Deposition of Sonders Beimfohr at 43:12-15 ("Q. Was there any discussion about not entering the U.S. market with MIRCERA if you were not able to get [a Large Dialysis Organization as a customer]? A. No."); Deposition of George Abercrombie at 32:24-33:2 (Q. So if Roche receives FDA approval to market and sell MIRCERA in the United States, do you currently plan to do so? A. Yes, absolutely. Q. . . . Roche is still planning to import and sell MIRCERA in the Unites States, even though that lawsuit has been brought, right? A. Absolutely . . . .").

[12] Deposition of Peter Schupbach at 26: 15 – 27:14; 28:11 – 4; 31: 4 – 15 (Roche has several hundred grams of unpackaged peg-EPO, as well as filled syringes in storage for clinical studies and commercial use.)

foreign manufacture is critical to show that Roche is misleading the jury when it asserts its hollow claim about selling under a safe harbor.

II. It is Logistically Unworkable to Provide Roche's Requested Relief.

It would also be logistically unworkable to provide Roche the relief it requests. Roche is headquartered in Switzerland and manufactures peg-EPO in Germany. The document and deposition evidence in this case refers throughout to Roche's foreign status and German manufacturing plant. Removing these references would be impracticable, if not impossible. There is simply no basis for the parties, or this Court, to go through this extraordinary exercise.

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Respectfully Submitted,

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