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

AMGEN INC.'S MOTION *IN LIMINE* TO PRECLUDE ROCHE FROM CLAIMING DURING THE INFRINGEMENT CASE THAT (1) MIRCERA® DOES NOT COMPRISE HUMAN EPO, IN CONTRADICTION OF THIS COURT'S FINDING OF INFRINGEMENT ON CLAIM 1 OF THE '422 PATENT AND (2) THAT EUROPEAN REGULATORY APPROVAL HAS ANY RELEVANCE TO THE CLAIMS IN THIS LAWSUIT.

Roche's demonstratives for its opening argument as to infringement show that it plainly intends to argue irrelevant and prejudicial information to the jury. In particular, Roche intends to argue that MIRCERA® does not comprise human EPO, *i.e.*, a protein having the amino acid sequence of human EPO. The Court's adjudication that Roche's MIRCERA® meets this limitation is the law of the case.[1] Further, Rule 56(d) specifies that where there has been a partial adjudication of "facts that appear without substantial controversy . . . . Upon the trial of the

[1] *United States v. Medina*, 219 Fed. Appx. 20, 21-22 (1st Cir. 2007) (Under the relevant branch of the law of the case doctrine, "a legal decision made at one stage of a civil or criminal proceeding . . . remain[s] the law of that case throughout the litigation, unless and until the decision is modified or overruled by a higher court.") (citing *United States v. Moran*, 393 F. 3d 1, 7 (1st Cir. 2004)).

actions, ***the fact so specified shall be deemed established, and the trial shall be conducted accordingly.***"[2]

In addition, Roche intends to publish to the jury documents related to European approval of MIRCERA in an attempt to claim that this foreign approval has some relevance to whether MIRCERA infringes Amgen's U.S. patents. It is patently inappropriate for Roche to publish this information to the jury. European regulatory approval of MIRCERA has no relevance to the infringement of the patents-in-suit. European regulatory officials operate under different regulatory and patent laws than the U.S., and their decisions are not only irrelevant, but will prejudice and confuse the jury. Indeed, during discovery, Roche refused to provide Amgen documents related to submissions to foreign governmental agencies claiming "documents and things concerning foreign governmental agencies and bodies … have no relevance to any claim or defense in this action. [3]" As a subset of the European approval, Roche apparently intends to assert that MIRCERA has potential advantages in longer dosing intervals than other commercial products. Again, this fact, even if true, is irrelevant to the infringement in the U.S. because none of the claims at issue are restricted to any particular dosing schedule.

Finally, this Court has already granted Amgen's MIL No. 13 (Docket No. 856) on September 24, 2007 precluding Roche from relying on "[e]vidence and arguments relating to the potential FDA approved label and uses for peg-EPO" because Roche persistently denied Amgen's discovery of this information. Plainly, Roche should not be allowed to substitute European regulatory documents — which it also refused to produce — when the Court has already precluded the U.S. regulatory documents. The slides Roche intends to use in its

[2] Fed. R. Civ. P. 56(d) (emphasis added).

[3] *See* Responses 43 and 44 of Roche's Responses and Objections to Amgen's First Set of Requests for Production of Documents and Things (Nos. 1 to 224), attached hereto as Exhibit A to Declaration of Daniel A. Curto.

infringement opening are directed to exactly what the Court has already precluded – potential label and uses for peg-EPO.

I. Roche Cannot Contradict Finding of Fact Necessary For This Court's Finding That Peg-EPO Infringes Claim 1 of the '422 Patent.

The Court's adjudication that MIRCERA® comprises "human erythropoietin" is factually established in this case and the trial should be conducted accordingly. The Court has construed "human erythropoietin" to mean *"a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine."*[4] When the Court determined that MIRCERA® infringed claim 1 of Amgen's '422 patent, it necessarily determined that as a matter of law MIRCERA®'s composition comprises a protein having the amino acid sequence of human EPO.

Roche's graphics for its opening argument show that it is plainly intends to argue that MIRCERA does not comprise human EPO. For example, Roche's graphics contend that one molecule cannot contain another molecule, when the Court has ruled that MIRCERA comprises human erythropoietin. Other Roche slides argue that modification of an amino acid changes the amino acid, when the Court has already considered and rejected such arguments in granting summary judgment. Indeed, rife through Roche graphics are immaterial factual arguments that were presented and rejected by this Court. Roche is precluded from contradicting the Court's factual determination as a matter of law that MIRCERA® comprises "human erythropoietin."

If Roche is permitted to make such arguments during its opening, Amgen should be permitted to inform the Jury of this Court's adjudication to the contrary.

[4] *Amgen Inc., v. F. Hoffman-La Roche Ltd.*, 494 F. Supp. 2d 54, 64 (D. Mass. 2007) (the Court's Claim Construction Order).

II. European Regulatory Approval of MIRCERA® is Irrelevant to the Patents-In-Suit and Prejudicial.

It is also inappropriate for Roche to discuss European regulatory approval of MIRCERA® during the infringement case. The European Commission's approval of MIRCERA® has no relevance to whether MIRCERA® infringes Amgen's patents. Nevertheless, Roche intends to show excerpts from the Commission's decision that are designed to mislead the jury. For instance, under a demonstrative entitled "Active Ingredient in MIRCERA is Not EPO," Roche cites to the European Commission's description of the pharmacodynamic properties of MIRCERA®. But the European Commission has not made a determination, relevant to this patent case, that MIRCERA's® "active ingredient" is not EPO. Indeed, not only has the European Commission never made such a determination, it is not qualified to make that judgment.

Furthermore, Roche refused to produce during discovery documents it submitted to foreign governmental agencies and bodies claiming "documents and things concerning foreign governmental agencies and bodies … have no relevance to any claim or defense in this action." Thus, Roche has already acknowledged that European approval of MIRCERA is irrelevant. Moreover, it has been well-established during this trial that the parties cannot use documents and information not produced in discovery. Roche's refusal to produce documents concerning foreign governmental agencies and bodies precludes their use of such information.[5]

Finally, it would be unfairly prejudicial to allow Roche to confuse the jury with information about the European Commission's approval of MIRCERA®. This information has no probative value at trial. Moreover, the jury will not understand that the European

[5] *See Texas Instruments Inc. v. PowerChip Semiconductor Corp*. 2007 WL 1541010 (S.D.N.Y. May 24, 2007) (precluding documents as a result of belated production).

Commission's decision has no relevance to U.S. patent laws. Nor will the jury understand that the European Commission is not opining, in any way, on whether MIRCERA® infringes Amgen's U.S. patents. Roche clearly intends to confuse the jury by implying that the European Commission somehow endorses the position it takes in this litigation. This is precisely the type of unfair confusion that FRE 403 prohibits — it encourages the jury to decide the case based on irrelevant and misleading information. As such, this information should be excluded.

Dated: October 1, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO# 542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

Lloyd R. Day, Jr. (*pro hac vice*)
DAY CASEBEER, MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

Michael Kendall (BBO#544866)
Daniel A. Curto (BBO #639883)
McDERMOTT WILL & EMERY
28 State Street
Boston, MA 02109
Telephone: (617) 535-4000
Facsimile: (617) 535-3800

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
Kimberlin L. Morley
Erica S. Olson
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 October 1, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried