UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

AMGEN INC.'S MOTION TO PRECLUDE ROCHE FROM INTRODUCING EVIDENCE OR TESTIMONY REGARDING THE SAFETY OR EFFICACY OF PEG-EPO BECAUSE ROCHE HAS ASSERTED THAT THESE TOPICS ARE IRRELEVANT AND ON THAT BASIS DENIED AMGEN FULSOME DISCOVERY

From the outset of this case, Roche has sought to cherry-pick the issues and evidence that may be presented at trial by denying Amgen discovery into its filings and negotiations with the Food and Drug Administration regarding peg-EPO. At the same time, Roche has produced only belatedly that which is useful to it. For example, Roche fought for and won the right to withhold from discovery its communications with FDA that address and relate to the safety and efficacy data it submitted to FDA in support of its Biologics License Application for peg-EPO. As such, Roche never produced its product label negotiations or its communications with FDA (or any other governmental agency) regarding safety, efficacy and dosing — the information that is necessary for fulsome discovery of those issues. Having denied Amgen the benefit of this discovery, including insight into FDA's concerns about the safety and efficacy data presented by Roche in its April 2006 Biologics License Application and the ability to investigate the metes

and bounds of such concerns, Roche should be precluded from introducing evidence or argument regarding the safety or efficacy of its accused product, including its initially-proposed product label and package insert (the information Roche proposed accompany its product) to show any differences between EPO and peg-EPO.[1]

Amgen requested—and was granted relief—that precluded Roche from introducing evidence related to its potential approved uses and label, which necessarily includes dosing and other clinical usage guidelines.[2] Because Roche has maintained the position that such information is irrelevant to a patent trial before a jury, it should be precluded from introducing selective evidence and arguments related to the clinical uses of its pegylated EPO product.

In this same vein, Roche has consistently argued that Amgen should be precluded from offering evidence regarding the safety of its pegylated EPO product by stating that it has no relevance in this trial.[3] But, as evidenced by Roche's proposed opening statement demonstratives, it is clear that Roche will allege that other clinical parameters, such as dosing frequency, is relevant. As this Court has already ruled, Roche cannot have it both ways.

For example, in its September 3, 2007 Motion in Limine to Preclude Amgen from Introducing Evidence Regarding the Safety of Mircera,[4] Roche argued that Amgen should be precluded from offering evidence regarding the safety of Roche's peg-EPO product. In opposition, Amgen argued that Roche should not be allowed to argue, on the one hand, that Roche's efficacy data and information about peg-EPO is an improvement over EPO, and on the

---

[1] *See* 8/22/07 Amgen's Motion *in Limine* No. 13 to Exclude Evidence and Argument Regarding Roche's FDA Filings and Communications Withheld Throughout Fact Discovery (Docket Nos. 856, 857), granted by Electronic Order, September 24, 2007.

[2] *Id.* (excluding "evidence and arguments relating to the potential FDA approved label and uses for peg-EPO.").

[3] *See, e.g.*, 9/3/07 Roche's Mem. of Law in Supp. of Its Mot. in Limine to Preclude Amgen From Introducing Evidence Regarding the Safety of MIRCERA, at 1 (Docket No. 971) ("The issue of MIRCERA's safety profile is of no relevance to any issue at this jury trial.").

[4] Docket Nos. 970 (Motion), 971 (Memorandum).

other hand, preclude Amgen from presenting evidence comparing the safety of both products.[5] On September 24, the Court "allowed [Roche's motion] without prejudice to Amgen's renewal should Roche - in the infringement phase of the case - bring up supposed improvements in its product." Having won its motion, Roche is now seeking to introduce evidence about dosing frequency and the like to assert that it does not infringe Dr. Lin's claims.

In accordance with Fed. R . Civ. P. 37(c)(1), Roche should be precluded from introducing or making argument about evidence and information that was withheld from discovery. Furthermore, Roche's position and refusal to produce the most recent information related to clinical issues, such as drug efficacy, prevent Amgen from effectively cross-examining Roche on these issues. Permitting Roche to introduce any evidence related to the clinical applications, safety, or efficacy of its peg-EPO product will both confuse the jury and prejudice Amgen because it is incomplete and untested in discovery due to Amgen's inability to assess the truth and veracity of Roche's positions. Indeed, it is not relevant where Dr. Lin's claims do not expressly reference any of the information that Roche will likely present as a claim requirement (e.g., none of Dr. Lin's claims include a limitation directed to "dosing frequency" or the like). Roche, of course, is free to argue whether or not its peg-EPO product satisfies the asserted patent claims—that is, whether or not its peg-EPO product is capable of increasing reticulocytes, red blood cells, and/or a patient's hematocrit.

Amgen respectfully requests that Roche be precluded from: (1) introducing argument or evidence related to the safety and efficacy of its accused product—including dosing regimens, perceived clinical benefits, and clinical improvements over established ESAs; and (2) making reference to such evidence or testimony in its opening statement.

---

[5] Docket No. 1082.

Dated: October 3, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D.DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R.GOTTFRIED (BBO#542156)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS
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 91320-1889
(805) 447-5000

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 3, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried