IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE 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.: 1:05-CV-12237 WGY

AMGEN'S MOTION FOR A CORRECTIVE INSTRUCTION REGARDING ROCHE'S PATENT ON PEGYLATED ERYTHROPOIETIN

Amgen requests that this Court provide a corrective instruction to the Jury regarding the relevance to infringement of Roche's patent (the "Bailon Patent") on peg-EPO. Roche's opening statement revealed that it will rely on its peg-EPO patent as a defense to infringement. However, Roche's patent is irrelevant to literal infringement, and it is likely to confuse and mislead the jury in the absence of a corrective instruction. Amgen respectfully requests that this Court give the following corrective instruction to the Jury prior to Roche commencing its case for noninfringement:

> Roche contends that its MIRCERA (peg-EPO) product and process accused of infringement represents an improvement to the inventions described in the Lin patent claims. Proof of this fact does not necessarily mean that Roche's accused MIRCERA product and process do not infringe Dr. Lin's patent claims. Furthermore, MIRCERA may infringe the Lin patent claims whether or not Roche has a patent on MIRCERA. Improvements may be separately patentable, yet still infringe another's patent.
>
> The tests for infringement remain as I have instructed you. As long as you find that Roche's MIRCERA product and process include all of the elements of at least one of the asserted patent claims, either literally or under the doctrine of equivalents, then you must find that the patent claim(s) will be infringed by Roche's

> product and process, despite what Roche contends to be improvements.

Courts have properly excluded evidence of separate patentability as prejudicial when Defendants cannot make the requisite showing of legal relevance.[1] In addition, the Federal Circuit Bar Association has promulgated a model Jury instruction (recited above) to moderate the potential prejudice from arguments of separate patentability for a product accused of infringement.

Separate patentability is not relevant to the issue of literal infringement, and is relevant under only limited circumstances to infringement under the doctrine of equivalents not applicable here.[2] Separate patentability is probative of insubstantial differences when the literal limitations of a claim are not met and the accused equivalent element lends patentable distinction to the product accused of infringement because of unexpected results.[3] This Court has already determined that Roche's peg-EPO infringes claim 1 of the '422 Patent, and Amgen is asking the Jury to find literal infringement of the other claims in the other asserted patents.

The facts surrounding the Bailon Patent also negate any relevance to Roche's Reverse Doctrine of Equivalence defense. The Bailon Patent admits that peg-EPO works in the same way as EPO:

> The conjugates of this invention have the ***same uses*** as EPO. In particular, the conjugates of this invention are useful to treat patients by stimulating the division and differentiation of committed erythroid progenitors in the bone marrow in the ***same way*** EPO is used to treat patients.[4]

The BLA for MIRCERA also admits that peg-EPO works in the same way as EPO:

> The mode of action for RO0503821 is described by the following key mechanism: ***receptor binding and stimulation of production of erythroid progenitor cells in the bone marrow.***[5]

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[1] *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000).
[2] *Atlas Powder Co. v. E. I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984).
[3] *Id*.
[4] The Bailon Patent at col. 2:22-27 (emphasis added)
[5] Mircera BLA Sec. 3.2.S, ITC-R-BLA-00004024 - 649 at 4200 (emphasis added)

Thus, the separate patentability of the Bailon Patent cannot establish the Reverse Doctrine of Equivalence because the Bailon Patent itself states that the way in which peg-EPO functions is the same as the invention claimed by the Lin Patents. This Court also rejected Roche's argument of noninfringement under the Reverse Doctrine of Equivalents when it granted Amgen's motion for summary judgment of infringement for claim 1 of the '422 Patent.[6]

Finally, Roche may argue that the Bailon Patent is relevant to whether the EPO made in Germany is materially changed by PEGylation. The EPO made in Germany is materially changed if PEGylation imparts a significant change to the structure and properties of the EPO which changes it's basic utility.[7] As Roche's admissions cited above show, the function and utility of EPO has not been changed by PEGylation, and this Court's prior decision that peg-EPO contains human erythropoietin shows that the structure of EPO has not been changed by PEGylation.

The Model Jury Instructions for the Federal Circuit Bar Association set out a specific corrective instruction for those cases in which separate patentability is relevant, and admitted as evidence into a case. Courts readily provide such corrective jury instructions to prevent juror confusion over the import of separate patentability. For example, in *The Read Corp., v. Powerscreen of America, Inc., No. 96-11025*, the Court instructed the jury that

> [i]f there are other things added, made more sophisticated, made better, it still infringes so long as it has every element of what's claimed. Miss an element and there's no infringement. But add to the elements, make the elements better, is still infringement so long as it has every element of the claim.[8]

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[6] August 28, 2007 Order ("Amgen's Motion for Summary Judgment is ALLOWED as to infringement of the '422 patent.")

[7] *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1573 (Fed. Cir. 1996)

[8] *Read*, Feb. 23, 2001 Tr. at 15. *See also, Amstar Corp., v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984) ("Modification by mere addition of elements or functions, whenever made cannot negate infringement . . . ."); *Nat'l Presto Indus., Inc.* v. *W. Bend Co.*, 76 F.3d 1185, 1191-92 (Fed. Cir. 1996) ("The grant of a separate patent on the accused device does not automatically avoid infringement either literal or by equivalency. Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may not avoid infringement of a the prior patent."); *Hoechst Celanese Corp.* v. *BP Chems. Ltd.*, 78 F.3d 1575, (continued…)

A corrective instruction is appropriate in this case because Roche's evidence of separate patentability will likely confuse and mislead the jury on literal infringement.

Amgen requests that the Jury receive the Federal Circuit Bar Association model instruction on separate patentability before Roche commences its defense on infringement.

DATED: October 15, 2007

Respectfully Submitted,

AMGEN INC.,

/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

William G. Gaede III (pro hac vice)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

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

1582 (Fed. Cir. 1996) ("[t]he fact of separate patentability presents no legal or evidentiary presumption of noninfringement").

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 Electronic Case Filing (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.

/s/ Michael R. Gottfried
Michael R. Gottfried