

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EXHIBIT A

AMGEN INC.,)
)
 Plaintiff,)
)
 v.)
)
)
 F. HOFFMANN-LAROCHE)
 LTD., a Swiss Company, ROCHE)
 DIAGNOSTICS GmbH, a German)
 Company and HOFFMANN LAROCHE)
 INC., a New Jersey Corporation,)
)
 Defendants.)
 _____)

Civil Action No.: 05-12237 WGY

**[PROPOSED] AMGEN’S REPLY IN SUPPORT OF AMGEN’S MOTION
IN LIMINE NO. 1 TO EXCLUDE ROCHE FROM REFERRING
TO ITS OWN PATENT ON PEGYLATED ERYTHROPOIETIN**

Roche does not contest that its receipt of a patent (U.S. Patent No. 6,583,272) that covers its accused peg-EPO product is not a defense to literal infringement. The Federal Circuit has made clear that “where defendant has appropriated the material features of the patent in suit, infringement will be found ‘even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement.’”¹ Since Roche’s patent on peg-EPO is not relevant to literal infringement and would likely mislead and confuse the jury from the proper legal inquiry – whether Roche’s product and processes satisfy the limitations of the asserted claims of Amgen’s patents-in-suit, Amgen seeks and order excluding all references to Roche’s patent on its peg-EPO product.

In its opposition, Roche argues that the Roche patent is nevertheless relevant and admissible because it would tend to prove that (1) Roche will not infringe under the doctrine of equivalents; (2) Roche will not infringe based upon a reverse doctrine of equivalents defense; and (3) the product of Amgen’s patented processes are “materially changed” under 35 U.S.C. § 271(g) prior to importation into the United States. Given that the award of the Roche patent has, little, if any, probative value to those issues and would pose a high danger of confusing or misleading the jury, the Court should exclude all references to the Roche patent under FRE 403.²

¹ *Fiskars, Inc. v. Hunt Mfg Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000) (quoting *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984)); see also *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1582 (Fed. Cir. 1996).

² Roche also argues that it should be allowed to reference the Roche patent if Amgen witnesses rely on the patent as evidence of infringement. If Amgen opened the door by referring to such evidence, Amgen agrees that Roche would be entitled to respond, subject to an appropriate limiting instruction. In the event that Amgen’s motion is granted, Amgen will not seek to elicit testimony from its witnesses regarding the Roche patent.

As Roche acknowledges, the Federal Circuit held in *Fiskars, Inc. v. Hunt Mfg Co.* that a trial court did not abuse its discretion to exclude references to the separate patentability of the accused device. *Fiskars* involved a claim for infringement under the doctrine of equivalents. The defendant complained that the trial court did not allow it to introduce evidence that the accused device was separately patentable. The Federal Circuit, however, noted that “Since it is well established that separate patentability does not avoid equivalency as a matter of law, we do not intrude upon the trial court’s evidentiary ruling.”³

While receipt of a patent may be relevant to the doctrine of equivalents inquiry in some cases, it is not relevant here. First, while one of the patents-in-suit is mentioned in the background section of the Roche patent, it was not cited by the applicant or the Patent Office as relevant prior art, so there was no specific determination or discussion by the Patent Office distinguishing Roche’s claimed invention from the patents-in-suit. Second, the determination of patentability is a distinct legal inquiry from the determination of infringement. While an improvement may be separately patentable, that determination does not mean that use of the prior invention is excused. The fact that the Patent Office determined that Roche is entitled to a patent does not answer whether Roche’s peg-EPO product infringes Amgen’s patents literally or equivalently.

Roche’s argument regarding the reverse doctrine of equivalents similarly fails. In fact, this Court rejected an almost identical argument in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* observing, “While attainment of a patent *may* aid in making a prima facie case in support of the reverse doctrine of equivalents, *it does not necessarily equate to such a determination.*”⁴ As the Court explained, “an improvement which is nonobvious in view of the prior art can still

³ *Fiskars*, 221 F.3d at 1324 (citations omitted).

⁴ 339 F. Supp. 2d 202, 267 (D. Mass. 2004) (citations omitted) (emphasis added).

infringe on a patent which is part of that prior art.”⁵ The receipt of narrow claims to an improvement do not establish noninfringement of an earlier patent with claims encompassing the accused product or process.

That is precisely the situation here. This Court has already rejected Roche’s reverse doctrine of equivalents defense with respect to infringement of ‘422 claim 1 when it granted summary judgment of infringement in favor of Amgen. In fact, Roche expressly argued that the existence of the Roche patent on peg-EPO supported its reverse doctrine of equivalents defense.⁶ Because the Court previously held that Roche’s reverse doctrine of equivalents defense failed as a matter of law with respect to ‘422 claim 1, the Court should preclude Roche from mentioning its patent on peg-EPO with respect to the other asserted claims-in-suit, particularly since Roche has failed to show why the mere existence of a patent would establish the showing required for non-infringement under the disfavored reverse doctrine of equivalents defense.

Finally, Roche cites no authority to support its claim that its patent on peg-EPO is relevant to the “materially changed” inquiry under § 271(g). Again, the fact that Roche’s peg-EPO product may be a patentable composition does not answer the relevant legal inquiry under § 271(g). The legally relevant inquiry is whether Roche practices Amgen’s patented processes outside the United States and whether Roche has performed subsequent processing steps on the product of those patented processes that materially change such product prior to importation. The Patent Office did not make such a determination, and the jury is likely to be confused or misled if the Roche patent is introduced at trial.

Amgen, therefore, requests that the Court enter an order precluding Roche from (1) referring to, or presenting evidence of, its peg-EPO patent (U.S. Patent No. 6,583,272) or (2)

⁵ *Id.* (quotations omitted).

⁶ Defendants’ Opp. to Amgen’s Motion for Summary Judgment of Infringement of ‘422 Claim 1, ‘933 Claim 3, and ‘698 Claim 6 at 19 n. 112.

arguing or suggesting that infringement is avoided, excused, or mitigated because peg-EPO is separately patentable.

September 3, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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CERTIFICATE OF SERVICE

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/s/ Michael R. Gottfried

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