UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S OPPOSITION TO AMGEN'S MOTION *IN LIMINE* NO. 12: TO EXCLUDE REFERENCE TO AMGEN'S "MONOPOLY" AND THE PATENTS-IN-SUIT AS LIMITING CONSUMER CHOICE

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") submit this opposition to Amgen's motion *in limine* no. 12 to exclude reference to Amgen's "monopoly" and the patents-in-suit as limiting consumer choice.

I. INTRODUCTION

Amgen's attempt to preclude Roche's use of the word "monopoly" at trial aims to undermine Roche's presentation of its defenses of inequitable conduct and obviousness-type double patenting. The key to both defenses is that Amgen had a valuable EPO monopoly and was highly motivated to extend improperly that monopoly beyond the expiration of Amgen's original '008 patent. As shown below, Amgen's motion fails to demonstrate -- as required under F.R.E. 403 -- that the probative value of evidence of Amgen's monopoly is "substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." In fact, it is Roche that will be prejudiced if this Court limits Roche's ability to present fully and fairly its inequitable conduct and obviousness-type double patenting defenses to the jury.

Furthermore, in seeking to prevent Roche from mentioning that Amgen's patents limit consumer choice, Amgen seeks to interfere with Roche's defense to infringement under 35 U.S.C. § 271(g). Roche's position is that even assuming, *arguendo*, that it practices a patented process outside of the U.S., there is no infringement, under § 271(g), because the product of the process was "materially changed by subsequent processes" before being imported into the U.S. An important aspect of the material change is reflected in the fact that Roche's MIRCERA® has a longer half-life than EPO and thus is dosed less frequently than EPO. In this sense, the advantage to consumers of Roche's alternative product bears on the materiality of the change prior to importation and, therefore, on the issue of infringement under § 271(g).

II. ARGUMENT

A. Amgen Has Not Shown As Required Under F.R.E. 403 That The Probative Value Of References To Amgen's Patent "Monopoly" Is Substantially Outweighed By The Danger Of Unfair Prejudice

Notwithstanding the 1870 decision relied upon by Amgen to support its assertion that "it is improper to characterize a patent as a monopoly" (Amgen Br. at 2), the fact is that the courts often refer to patents as "monopolies." *See Illinois Tool Works Inc. v. Independent Ink, Inc*., 126 S. Ct. 1281, 1286 (2006) (discussing improper extensions of "patent monopoly"); *Dastar Corp. v. Twentieth Century Fox Film Corp*., 539 U.S. 23, 33-34 (2003) ("The rights of a patentee . . . are part of a 'carefully crafted bargain,' . . . under which, once the patent . . . monopoly has expired, the public may use the invention."); *Festo Corp. v. Shoketsu Kinzoku Kogyu Kabushiki Co., Ltd.*, 535 U.S. 722, 727 (2002) (discussing the danger of the doctrine of equivalents in creating "substantial uncertainty about where the patent monopoly ends"); *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 63 (1999), ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."). As the Federal Circuit has stated: "The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent *monopoly* is the benefit derived by the public from an invention with substantial utility." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (emphasis added).

Moreover, this Court has frequently referred to patents as creating a monopoly. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp. 2d 69, 136-37 (D. Mass. 2001) (noting that a narrow claim construction would have left "TKT free and clear as a non-infringer and Amgen . . . would have retained its patent *monopoly* against all other comers"; "it can be claimed that Amgen's broad patent *monopoly* serves as a 'blocking' patent to prevent advances in

research and development by others") (emphasis added); *MediaCom Corp. v. Rates Tech., Inc.*, 4 F.Supp. 2d 17, 23 (D. Mass. 1998) (describing "intrinsic evidence" as "the public record of the government granted patent *monopoly*") (emphasis added); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F.Supp. 2d 104, 113 (D. Mass. 1998) ("The statutory *monopoly* is nowhere near expiring, and Amgen may legitimately apply to the courts to enforce that monopoly") (emphasis added); *Amgen, Inc. v. Genetics Institute, Inc.*, 877 F.Supp 45, 52 (D. Mass. 1995 ("From the early days of the republic, our patent law has required that in exchange for a government-sanctioned *monopoly* on the rights to an invention or discovery, the invention must teach the world the secret behind the method or device."); *Avco Corp. v. PPG Indus., Inc.*, 867 F.Supp. 84, 94 (D. Mass. 1994) (describing the "underfunded" PTO as "straining fairly to draw that complex line which will ensure invention and progress and at the same time not improperly, not excessively, confer the legal *monopoly* of a patent") (emphasis added).[1]

Contrary to Amgen's assertion, the fact of Amgen's EPO monopoly is unquestionably relevant here. Indeed, Amgen's interest in extending its monopoly is at the heart of Roche's inequitable conduct defense. According to the Federal Circuit, "[a] patent may be held unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." *McKesson Info. Solutions v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007). The requisite intent "need not, and rarely can, be proven by direct evidence."

[1] Amgen cites no cases in which a court granted the relief it seeks here. Contrary to Amgen's assertion (Amgen Br. 5 n.16), the court in *Novo Nordisk A/S v. Becton Dickinson & Co.*, 304 F.3d 1216, did *not* describe as "unduly prejudicial" the defendant's reference to patents as monopolies. That was the plaintiff's characterization. *Id*. at 1220. The court deemed the defendant's use of the term "monopoly" to be "less inflammatory" than the plaintiff maintained. *Id*.

Ferring BV v. Barr Labs. Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006). "[I]ntent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Id.*

Here, a significant aspect of the "facts and circumstances" surrounding Amgen's inequitable conduct during prosecution of the patents-in-suit is Amgen's EPO monopoly and Amgen's strong economic interest in protecting that monopoly. In other words, Amgen's need and desire to maintain its EPO monopoly -- which would have evaporated already absent the patents-in-suit -- is the motive behind Amgen's inequitable conduct and is evidence from which intent may be inferred.

Furthermore, Roche will present evidence that the process patents-in-suit are invalid for obviousness-type double patenting over Amgen's already expired '008 patent. The thrust of Roche's argument is that those inventions are not patentably distinct over the invention of the '008 patent, and were obtained by Amgen in an attempt to extend its valuable EPO monopoly. Significantly, the "underlying rationale of double patenting" is "to prevent inventors from artificially extending their patent monopolies." *Affymetrix, Inc. v. PE Corp.*, 66 U.S.P.Q.2d 1184, 1187 n.8 (S.D.N.Y. 2002) (unreported).

In sum, Amgen's existing EPO monopoly and its interest in extending that monopoly have significant probative value with respect to Amgen's inequitable conduct and obviousness-type double patenting defenses. Amgen's expressed concerns to any pejorative nature of the term "monopoly" fail to establish -- as F.R.E. 403 requires -- that in this particular case the probative value of evidence of Amgen's monopoly is "substantially outweighed by the danger of unfair prejudice."

B. Amgen Has Not Shown That The Probative Value Of References To The Patents-In-Suit As Limiting Consumer Choice Are Substantially Outweighed By The Danger Of Unfair Prejudice

One of Roche's defenses to claims that it infringes under 35 U.S.C. § 271(g) by importing into the United States the product of a patented process practiced outside of the U.S. is that the product is "materially changed" before being imported into the United States. Indeed, Roche will show that the crude isolate obtained from cell culture is purified, chemically reacted with an activated polyethylene glycol molecule, and formulated into MIRCERA® before being imported. One significant indication of the material change is the fact that Roche's MIRCERA® has a much longer half-life than epoetin and thus allows patients to enjoy substantially longer intervals between doses. Hence, it is vital to Roche's noninfringement defense under § 271(g) that the jury appreciate that MIRCERA® has to be administered less frequently than Amgen's epoetin product and, in that respect among others, is materially different from epoetin beta. Yet, Amgen's motion seeks to prevent Roche from presenting this evidence to the jury.

Moreover, Amgen has not shown that a risk of unfair prejudice or confusion would substantially outweigh the probative value of evidence that patients would benefit from the use of MIRCERA® as an alternative to EPO.

III. CONCLUSION

For the foregoing reasons, Amgen's motion *in limine* no. 12 should be denied in all respects.

Dated: September 3, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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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 (NEF) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

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