UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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 CV 12237 WGY

BRIEF IN SUPPORT OF AMGEN'S MOTION *IN LIMINE* NO. 6:
EXCLUDE REFERENCE TO AMGEN'S REQUEST FOR INJUNCTIVE RELIEF

I. INTRODUCTION

Amgen is seeking injunctive relief in this case, as is its right under 35 U.S.C. § 283, to prevent Roche from infringing the patents-in-suit by importing and selling its peg-EPO product in the United States. As this Court has made clear, Amgen's entitlement to an injunction will be determined by the Court after the liability phase of the case – i.e., the determination of infringement and validity. Roche has indicated, however, that it intends to argue portions of the injunction question in front of the jury, specifically the public interest factors.[1] On more than one occasion, Roche has publicly characterized this lawsuit as seeking to impinge on "America's right to choose" and "patients' choice."[2] The question of "patients' choice" and the fact that Amgen is seeking an injunction to stop Roche from selling peg-EPO are not relevant to any issue to be determined by the jury, and if argued, are likely to confuse or mislead the jury into deciding the liability issues on emotion rather than factual and legal bases.

For these reasons, Amgen moves to preclude any argument, evidence or other reference before the jury that: 1) Amgen is seeking injunctive relief, and 2) that Roche's peg-EPO product

---

[1] Document 807-3, Exhibit B Roche's Statement of Contested Issues of Fact ¶ 104; Document 807-5, Exhibit D Roche's Statement of Legal Standards and Burdens of Proof ¶¶ 147, 170 and 171.

[2] "Roche believes it is important for there to be competition and choice for U.S. patients, providers and physicians in the management of renal anemia." http://www.rocheusa.com/newsroom/current/2007/pr2007051801.html

William M. Burns, CEO Roche Pharma Division, said "The ITC's decision supports our long-term efforts to develop Mircera. **We want to offer doctors and patients in the United States the choice of a novel medicine** that has been created to allow longer dosing intervals up to every four weeks – something that currently does not exist in the United States. Our energies are focused on continuing our dialogue with health authorities regarding our filings which occurred in April this year and on further clinical trials to manage this oxygen-depriving condition." http://www.roche.com/inv-update-2006-09-01

presents a choice in anemia therapy for patients and physicians or that it potentially has any clinical benefits over existing therapies on the market.

II. ARGUMENT

Injunctive relief is an equitable question to be decided by the Court in the remedy phase of the trial, not during the liability proceedings. The Supreme Court's recent *eBay* decision makes clear that the issuance of an injunction upon a finding of patent infringement is separate from the determination of patent infringement and validity and must be based upon the district court's consideration of the traditional, four-part equity analysis.[3]

> "The creation of a [patent] right is distinct from the provision of remedies for violations of that right. Indeed, the Patent Act itself indicates that patents shall have the attributes of personal property '[s]ubject to the provisions of this title,' 35 U. S. C. §261, including, presumably, the provision that injunctive relief 'may' issue only 'in accordance with the principles of equity,' §283."[4]

Therefore, it is inappropriate for Roche to raise their "consumer choice" and "clinical advantage" arguments as a matter of public interest in the liability phase of this trial when they will have the opportunity to do so during the remedy phase.

While Amgen firmly believes that its patents will be infringed by the importing and selling of peg-EPO and that it is entitled to an injunction to prevent that infringement, arguing the injunction issue in front of the jury would be improper. Because the issuance of an injunction and the underlying questions of harm and public interest are not relevant to any issue to be decided by the jury during the liability phase of this trial, all references to the arguments and evidence related to these questions and issues should be excluded from the jury's hearing under FRE 402.

---

[3] *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1840 (2006).

[4] *Id.*

This principle has been recognized by a number of courts. For example, in *Computer Associates Intern., Inc. v. American Fundware, Inc.*,[5] [6] the court granted a motion *in limine* precluding the defendant from referring to plaintiff's request for injunctive relief, reasoning that since injunction is a question for the court alone, "[t]he jury need not be advised of [plaintiff's] equitable claim."[7]

Furthermore, under FRE 403, evidence should be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. Here, in addition to being irrelevant, references to injunctive relief and the public interest issue of choice are likely to confuse and mislead the jury and should be excluded.[8] Mention of these before the jury could lead the jury to improperly find invalidity or noninfringement in order to allow Roche's product on the market. The same is true if Roche attempts to argue that patient health might somehow be compromised if its peg-EPO product were not available. Courts have recognized the importance of minimizing confusion and prejudice by precluding parties from mentioning the possibility of an injunction.[9]

---

[5] *Computer Associates Intern., Inc. v. American Fundware, Inc*., 831 F.Supp. 1516 (D. Colo. 1993).

[6] *See also Ciena Corp. v. Corvis Corp.*, 352 F.Supp.2d 526, 529 (D. Del. 2005) (describing court order precluding defendant from referring to injunctive relief in the presence of the jury); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 2003 WL 1905636, at *1 (D. Del. 2003) (granting motion *in limine* precluding mention of injunctive relief).

[7] *Computer Associates*, 831 F.Supp 1516 at 1530.

[8] *CPC Intern*, 144 F.3d 35, 45 (1st Cir. 1998) (under Fed. R. Evid. 403, evidence should be excluded if it creates an "undue tendency to suggest decisions on an improper basis.")

[9] *U.S. Football League v. National Football League*, 1986 WL 7012, at *2-3 (S.D.N.Y., 1986) (granting a motion *in limine* precluding defendants "from referring to the possibility of injunctive relief in front of the jury, since such reference would needlessly confuse the issues and unfairly prejudice plaintiffs.")

While Roche's arguments against an injunction remain unclear, it might try to argue that peg-EPO provides some benefit to patients such as a more convenient dosing schedule or a slower rise in hematocrit.[10] It might even attempt to argue that peg-EPO might have a lower price thus saving money for the U.S. healthcare system, although its own documents show otherwise. These arguments and others relating to patient choice could only be relevant to the injunction question and have no relevance to whether Amgen's patent claims are valid and whether peg-EPO has all the limitations of those claims.[11] Because this evidence regarding injunctive relief, potential clinical benefits and product choice are irrelevant and prejudicial, Roche should be precluded from presenting such evidence before the jury at trial.

[10] Amgen is filing a companion motion in limine to preclude Roche from arguing or presenting any evidence that peg-EPO has any potential clinical benefit as compared to Amgen's anemia products. The bases for this motion include 1) the fact that the FDA has not yet approved Roche's product so any claim of potential clinical benefit would be speculation, and 2) Roche refused to provide discovery on all the communications with the FDA. Since Roche's clinical trials were not designed or intended to show product superiority as compared to Amgen's products, it is very likely that the FDA has told Roche that its peg-EPO product has no clinical advantages. Roche should not be allowed to argue otherwise.

[11] Although the issue of consumer choice (or patient choice) does sometimes arise in the context of antitrust claims, and also in the context of ascertaining the availability of non-infringing alternatives in connection with the determination of a reasonable royalty, neither of those issues is present in this case. As the Court has previously ruled, the antitrust issues in the current litigation are to be bifurcated and tried later, if necessary, and Amgen does not seek reasonable royalty damages in this case.

III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that Roche be precluded from presenting argument or evidence before the jury concerning:

1) The fact that Amgen is seeking injunctive relief; and

2) That Roche's peg-EPO product presents a choice for patients and physicians or that it has potential clinical benefits as compared to the current therapies.

Respectfully Submitted,

Date: August 20, 2007

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

WILLIAM 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

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 August 20, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried