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. 20: PRECLUDE ROCHE FROM MAKING STATEMENTS REGARDING THE DURATION OF AMGEN'S PATENT PROTECTION

Roche apparently intends to tell the jury that Amgen's patents-in-suit represent an improper extension of the term or duration of patent protection afforded Lin's inventions, and that the jury should remedy this situation by invalidating the claims-in-suit.[1] In granting Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting, the Court has determined that Amgen's claims-in-suit are not invalid for ODP over the claims of the Lai/Strickland '016 Patent. The Court has also determined that the '933, '422 and '349 claims-in-suit are exempt from ODP over the claims of the '008 patent pursuant to 35 U.S.C. § 121.[2] Consequently, Roche's rhetoric is legally irrelevant to the validity issues that the jury properly may decide, and instead asks the jurors to apply their subjective beliefs regarding the appropriate length of patent protection when assessing Roche's remaining ODP and other invalidity defenses. Accordingly, Amgen respectfully moves the Court for an order under FED. R. EVID. 402 and 403 precluding Roche from making irrelevant, confusing and unfairly prejudicial statements to the jury regarding the duration of Amgen's patent protection.[3]

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[1] *See, e.g.*, 4/6/07 Expert Report of Dr. Lowe, Demonstrative Nos. 100-101 (8/28/07 Declaration of Geoffrey M. Godfrey, Ex. A) (depicting and characterizing Amgen's patents-in-suit — including the '933, '422 and '349 patents — as an "improper extension of monopoly"); D.I. 494, at ¶ 46 ("To protect the public from an unwarranted extension of the patent monopoly, a terminal disclaimer limiting the patent terms of these patents to the full life of the earlier '016 patent should have been required."); D.I. 491, at 1 ("At the very least, with the expiration of the '016 patent in 2005, Amgen's right to exclude competitors from selling recombinant erythropoietin ('rEPO') has come to an end"); *Id.* at 2 (arguing Amgen should be prevented "from obtaining a 10-year extension of patent protection for the subject matter of the expired '016 patent").

[2] *See* Electronic Order, dated Aug. 27, 2007, granting Amgen's Motion for Summary Judgment of No Obviousness-Type Double Patenting (D.I. 498).

[3] FRE 402 provides, in pertinent part: "Evidence which is not relevant is not admissible." FRE 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

The term of the patents-in-suit is set by statute, 35 U.S.C. § 154. Although the current law provides for a 20 year term, this was a change adopted in 1995. Prior to this change, the term of patents was 17 years from the date of issuance. Because the patents-in-suit issued from applications filed before the change in the statute, the 17 year term applies. Each patent-in-suit is entitled to its own term. The '933 patent issued in August of 1996 and will expire in August of 2013. The '422 patent issued in September of 1999 and, because of a terminal disclaimer over the '933 patent, will also expire in August of 2013. The '349 patent issued in May of 1998 and will expire in May of 2015. The '868 and the '698 patents both expire in 2012 (the '698 patent was terminally disclaimed over the '868). Any arguments by Roche that the patents-in-suit "wrongfully" extend the term of the Lai/Strickland '016 patent, or that the '933, '422 and '349 patents "wrongfully" extend the term of the '008 patent, are legally irrelevant and should be precluded. All legally relevant questions involving these ODP defenses have been resolved by the Court on summary judgment.

Similarly, the Court, not the jury, must ultimately decide Roche's remaining ODP allegations that the '868 and '698 patent claims are invalid for ODP over Lin's '008 claims. The decision of that issue requires the Court to determine whether the process inventions claimed in the '868 and '698 patents are patentably distinct from the DNA and cell inventions claimed in the '008 patent, that is, whether the later-issued process claims would have been non-obvious at the time in view of the earlier-issued DNA and cell claims of the '008 patent. The PTO held that these inventions were patentably distinct. While it is Amgen's position that the Court should decide ***all*** issues regarding Roche's remaining ODP defense, at most, the jury's role in assessing this defense would be limited to determining whether a person of ordinary skill in the art in 1984 would have found the '868 and '698 claims-in-suit to be obvious over one of the '008 patent

claims. The Court, not the jury, must perform the first step of the ODP analysis, which is to construe the claims at issue. And even as to the '868 and '698 patents, it would be legally irrelevant and inappropriate for the jury to consider what term of patent protection is "appropriate" or "fair" or "too long." Thus, Roche should be precluded from making statements to the jury concerning the duration of Amgen's patent protection, or the length of Amgen's separate patent terms.[4]

Furthermore, because the term of all of the patents-in-suit is determined by the version of 35 U.S.C. § 154 in effect before 1995 (i.e., a term of 17 years from the date of issuance, subject to any terminal disclaimers or adjustments), the Court should preclude Roche from telling the jury about the 1995 change in the law regarding the term of patent protection, and about how the term of patents filed after 1995 is 20 years from the date of filing. Those facts are irrelevant to Roche's ODP defense in this case.

Roche's rhetoric concerning an improper extension of patent term and its inaccurate references to a 28-year term of patent protection are misleading and highly prejudicial to Amgen. Roche seeks to draw the jury's attention away from the one probative issue that resolves Roche's remaining ODP defense (i.e., whether an ordinarily skilled artisan in 1984 would have found the '868 and '698 claims-in-suit to be obvious over one of the '008 claims) and to focus the jury's attention instead on the legally irrelevant issue of whether the jury believes Amgen has enjoyed "enough" patent protection for its EPO inventions. Roche's arguments undermine the statutory presumption of validity by urging the jury to decide the validity of Amgen's patents based on a subjective, emotion-driven determination of the "appropriate" or "fair" duration of patent protection, rather than a structured application of the relevant law to the relevant facts. Roche's

[4] If the Court determines that the jury must be told the purpose of the ODP doctrine, the Court can communicate that purpose as part of its instructions to the jury.

improper appeals to the jury's emotional prejudices also risk undermining this Court's summary judgment order regarding ODP, because there is a significant danger that the jury, at Roche's urging, will decide that Amgen has enjoyed "enough" patent protection and therefore invalidate all of the claims-in-suit, including the '933, '422, and '349 claims that the Court held are exempt from Roche's ODP attack.

For the foregoing reasons, the Court should preclude Roche from making irrelevant, confusing and unfairly prejudicial statements to the jury regarding the duration of Amgen's patent protection and the current law that sets a term of 20 years from the date of filing.

Dated: August 28, 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 August 28, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried