UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
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	)	Civil Action No.: 1:05-cv-12237 WGY
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F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation,	)	
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AMGEN'S MOTION *IN LIMINE* REGARDING FLAVELL NO. 1: AMGEN'S MOTION TO PRECLUDE RICHARD A. FLAVELL FROM TESTIFYING DURING THE INFRINGEMENT STAGE ON ISSUES PERTAINING TO INVALIDITY

Roche has closed its validity case. Thus, its expert Richard A. Flavell should not be allowed to repeat or introduce opinions based on the alleged invalidity of Amgen's patents. But under the guise of purported "infringement" opinions, Dr. Flavell intends to offer testimony that relies solely on his contention that certain claims in Amgen's patents are not valid, and thus could not be infringed. These opinions are inappropriate at this stage of the trial. Not only is this testimony untimely, it will serve only to confuse the jury. Accordingly, it should be excluded pursuant to Federal Rules of Evidence 402 and 403.

The two steps for determining infringement are (1) to define the claim language, which is a matter of law; and (2) to compare the accused product to the claim limitations.[1] It is well-

[1] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (Enumerating two step process of infringement analysis).

established that a patent is presumed valid.[2] Dr. Flavell cannot undermine this infringement analysis by basing his infringement opinions on arguments that, if accepted, render the asserted claims invalid.

In particular, Dr. Flavell's purported infringement analysis regarding the "radioimmunoassay" limitation in claim 7 of the '349 Patent inappropriately rests upon his conclusion that this limitation is indefinite. He opines that Roche could not infringe claim 7 of the '349 patent because, he contends, the claims should be interpreted to require a measurement of biological activity by radioimmunoassay, not immunological activity, and skilled artisans would readily appreciate that "radioimmunoassay cannot determine biological activity."[3] By construing the claims to require a type of measurement that those skilled in the art would have known the claims do not require, Dr. Flavell not only seeks to attack the validity of '349 claim 7, but also its infringement. Such claim construction contrivances do not constitute an appropriate infringement opinion.[4]

Similarly, Dr. Flavell opines that the "isolating" step of the asserted '868 and '698 process claims are not infringed based on his conclusion that the patent fails to enable the purification of human EPO. Professor Flavell opines that because "purification of erythropoietin sufficient to create a claimed pharmaceutical composition is not disclosed in [Lin's] patent specification,[5]" the patent covers "at best, a crude heterogeneous mixture of cell-derived

[2] *See* 35 U.S.C. § 282 (stating "[a] patent shall be presumed valid"). *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 236 (D. Mass. 2004).

[3] Non-Infringement Expert Report of Richard A. Flavell, Ph.D, pp. 59-60 (¶ 123-125). Attached hereto as Exhibit 2 to the Declaration of Linda Sasaki-Baxley ("Baxley Decl.").

[4] Notably, this Court has already found that the term radioimmunoassay, as used in claim 7 of the '349 patent, is definite. *See* Electronic Order of Aug. 27, 2007 granting Amgen's Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled (Docket # 531).

[5] Fourth Expert Statement of Richard A. Flavell, Ph.D., p. 34, (¶79). Attached hereto as Exh. 3 to Baxley Decl.

materials and cell culture medium." [6] But this Court's construction of the '868 and '698 Patents is not so limited.[7] Indeed, Dr. Flavell's opinion disregards the claimed processes enumerated in the patent specification, which describe recovering mammalian cell expression products (i.e., human EPO) in "substantially purified form."[8] His opinion is not an infringement opinion, but rather another attack on the written description and definiteness of Amgen's patents.

Finally, Dr. Flavell's non-infringement opinion regarding the asserted '933 claims, based on the limitation "non-naturally occurring," is a rehash of Roche's rejected invalidity contention that "non-naturally occurring" is indefinite because one of ordinary skill in the art could not distinguish between naturally and non-naturally occurring EPO. As elucidated by the Federal Circuit, this claim limitation "only excludes human EPO from specific sources."[9] Specifically, it "limit[s] only the source from which the EPO is obtained, not the methods by which it is produced."[10] Indeed, this Court ruled on August 27, 2007 that "non-naturally occurring" is not indefinite.[11] Ignoring this precedent, the entirety of Dr. Flavell's non-infringement argument is that peg-EPO does not infringe Amgen's patents because peg-EPO cannot be distinguished from "urinary EPO or other natural EPO because … there is no reliable standard available which is necessary in order to draw a distinction between natural and 'non-naturally occurring' EPO." [12]

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[6] Non-Infringement Expert Report of Richard A. Flavell, Ph.D, p. 35 (¶ 77). Baxley Decl. Exh. 2.

[7] *See* Flavell Motion *In Limine* No. 2: Amgen's Motion To Preclude Richard Flavell From Offering Opinions Based On A Claim Construction That Is Inconsistent With The Court's Claim Construction of the Claim Terms "Isolating" and "Comprising," As Set Forth in the Asserted '698 and '868 Claims.

[8] '933 Patent, column 28, lines 29-32.

[9] *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003).

[10] *Id.* at 1330 n.5.

[11] *See* Electronic Order of Aug. 27, 2007 granting Amgen's Motion for Summary Judgment that Dr. Lin's Asserted Claims are Definite, Adequately Described and Enabled (Docket # 531).

[12] Non-Infringement Expert Report of Richard A. Flavell, Ph.D, p. 74 (¶153). Baxley Decl. Exh. 2.

This opinion simply assumes Roche's validity opinions as the basis for finding non-infringement. Raising such an attack during the infringement phase of the trial is inappropriate and prejudicial.

Roche has rested its case on the alleged invalidity of Amgen's patents. It would be confusing and unfairly prejudicial to allow Roche another opportunity to attack the validity of Amgen's patents through infringement opinions that rest on the notion that the claims in Amgen's patents are invalid.

DATED: October 15, 2007

Respectfully Submitted,

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 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

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