IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 1:05-cv-12237 WGY

AMGEN'S BENCH MEMORANDUM REGARDING PUBLICATION REQUIREMENTS FOR SECTION 102 PRIOR ART

The Court requested at the close of evidence yesterday briefing on the legal definition of publication for purpose of Section 102.[1] "The presumption of validity, 35 U.S.C. § 282 (1994), requires those challenging validity to introduce clear and convincing evidence on all issues relating to the status of a particular reference as prior art."[2]

If Roche wishes to assert Dr. Goldwasser's IND application[3] or NIH grant application[4] as prior art publications under 35 U.S.C. §102(a) or (b), Roche must prove by clear and convincing evidence that these documents were publicly accessible.[5] The test for public accessibility requires:

[1] Trial Tr. (September 11, 2007) at 814:8-11.
[2] *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001), *citing Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576, (Fed. Cir. 1996).
[3] Trial Ex. 2050.
[4] Trial Exs. 2043 & 2057.
[5] *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006); *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330 (Fed. Cir. 2004).

> [U]pon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.[6]

In *Norian*, the Federal Circuit affirmed a holding that a document was not a printed publication "because it was available only upon individual request to the authors, and . . . such request and dissemination had not been shown."[7] Similarly, in *Cronyn*, the Federal Circuit held that a thesis presented to a handful of faculty members and later indexed but not made publicly available was not sufficiently publicly accessible to be a printed publication.[8] On the other side of the coin, the Federal Circuit has held that foreign patent applications laid open to public inspection are publicly accessible and so are printed publications under Section 102.[9]

By rule, Dr. Goldwasser's IND application was confidential, and Federal Rules prevented the FDA from disclosing even the existence of the IND unless that existence was already made public. *See* 21 C.F.R. §312.130 (Attachment 1 hereto)[10]; 21 C.F.R. §601.50 (Attachment 2 hereto)[11]; 21 C.F.R. §601.51 (Attachment 3 hereto).[12] Thus, under the FDA rules, Dr.

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[6] *Bruckelmyer*, 445 F.3d at 1374; *In re Wyer*, 665 F.2d 221, 226 (C.C.P.A. 1981).

[7] *Norian*, 363 F.3d at 1330.

[8] *See In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989).

[9] *See Bruckelmyer*, 445 F.3d at 1378-79; *Wyer*, 665 F.2d at 226; *see also, In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004) (There, the court held that a slide presentation given at a meeting of the American Association of Cereal Chemists was a "printed publication." While the court acknowledged that the presentation was never distributed to the public, nor indexed, and was temporarily displayed, the court considered relevant the facts that the presentation was exhibited, to an audience of people skilled in the art, and the ease with which the material could have been copied. Balancing all the factors, the court held that the presentation was a "printed publication" under section 102(b).)

Goldwasser's IND application was not publicly accessible. Roche has not made a clear and convincing showing that Dr. Goldwasser's IND application was otherwise publicly accessible, and so, it cannot be a prior art publication.

The NIH Grant award web-page states that information in Grant Applications can be released upon a FOIA (Freedom of Information Act) Request.[13] The NIH Policies also state, however, that in general, records and information regarding pending grant applications will not be released, and some information in funded grant applications may also be kept confidential, such as patentable or commercially valuable information.[14] Roche must prove by clear and convincing evidence what information is available, if any, and when such information was available to make out a *prima facie* case of publication of the grant applications.

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[10] Sec. 312.130 Availability for public disclosure of data and information in an IND.

(a) The existence of an investigational new drug application will not be disclosed by FDA unless it has previously been publicly disclosed or acknowledged.

[11] Sec. 601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

(a) The existence of an IND notice for a biological product will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for a biological product shall be handled in accordance with the provisions established in 601.51.

[12] Sec. 601.51 Confidentiality of data and information in applications for biologics licenses. * * *

(c) If the existence of a biological product file has not been publicly disclosed or acknowledged, no data or information in the biological product file is available for public disclosure.

[13] *See* NIH Preaward Policies and Considerations (PHS GPS 9505) at pp. 17-18 (April 1994) (Attachment 4 hereto).

[14] *Id*. at 18; 45 C.F.R. § 5.65 (Attachment 5 hereto).

In short, the rules require Roche to make a specific showing of publication by clear and convincing evidence that the document was disseminated or otherwise made available before the priority date. Simply submitting the documents to the NIH or the FDA fails to meet this standard.

DATED: September 12, 2007

Respectfully Submitted,

AMGEN INC.,

/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 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