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 Civ. 12237 WGY **ROCHE'S RESPONSE TO AMGEN'S BENCH MEMORANDUM REGARDING PUBLICATION REQUIREMENTS FOR SECTION 102 PRIOR ART**

Defendants respectfully submit this memorandum of law to respond to Amgen's bench memorandum (D.I. 1055) and to clarify the legal standards to be applied in considering what constitutes prior art under §§ 102(a), (b) and (g) and what constitutes publication under §§ 102(a) and (b). Earlier this week, the Court granted Roche's motion in limine to preclude plaintiff from arguing that the Goldwasser clinical study is not prior art (D.I. 1028). Nevertheless, in its bench memorandum, Amgen objects that the Baron-Goldwasser IND and the Goldwasser NIH grants, which have already been entered into evidence as TRX 2004, TRX 2043, and TRX 2045, do not constitute prior art because they were not sufficiently public. Amgen is incorrect.

Under 35 U.S.C. § 102(a) and (b), which require prior art that is "public," subject matter is sufficiently "public" if it is known to a third party. Case law makes clear that "public" does not mean wide dissemination. *See Baxter Int'l, Inc. v. Cobe Labs, Inc.*, 88 F.3d 1054, 1058-59 (Fed. Cir. 1996) (art "was in public use" under § 102(b) when disclosed to a select few in a laboratory); *Mazzari v. Rogan*, 323 F.3d 1000, 1005-06 (Fed. Cir. 2003) (German language reference available in Germany was prior art under § 102(b)); *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985) (where existence of reference was made known to

50 to 500 persons of ordinary skill, with actual reference disseminated to 6 people, reference was prior art under § 102(b)); *In re Hall*, 781 F.2d 897, 900 (Fed. Cir. 1986) (thesis that was cataloged in one library was prior art under § 102(b)).

Grant proposals and grant applications, such as those submitted to the National Science Foundation and the National Institutes of Health are considered public and constitute prior art. *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 Dist. LEXIS 18382, *6-*8 (N.D. Cal. 1990) (unreported). For prior art purposes, "[p]ublication does not require dissemination in books or journals." *Cetus,* 1990 Dist. LEXIS 18382 at *4. Additionally, publicly accessible submissions to government entities constitute printed publications. *See Amer. Stock Exchange, LLC v. Mopex, Inc.*, 250 F. Supp. 2d 323, 329-30 (S.D.N.Y. 2003) (finding World Equity Benchmarks Application submitted to the SEC to be prior art).

Just as the NIH grant application in *Cetus* was held to be prior art, the Goldwasser NIH at issue in this case is also prior art. As Amgen concedes in its bench memo, the Goldwasser NIH grants are available upon request from the Department of Health and Human Services under FOIA. Amgen states, however, that NIH Policies leave uncertain what parts of NIH grant applications can be released via FOIA and that because Roche cannot prove what would be available and what wouldn't, the applications should be precluded. This argument is spurious as Amgen's own production includes Roche counsel's own FOIA request (produced ***by Amgen*** at AM-ITC 00040201-03) and the resulting production of Goldwasser grant applications (again produced ***by Amgen*** starting at AM-ITC 00039848, specifically at AM-ITC 00039895).

As for the FDA-submitted Baron-Goldwasser IND, Amgen's own production again shows that a FOIA request was exactly how the produced IND was attained in the first place. (See Attachment A, August 23, 2000 Castle letter to Safir, AM-ITC 01006756). Accordingly,

Amgen's arguments that "Federal Rules prevented the FDA from disclosing even the existence of the IND" are similarly without merit. As both the Baron IND and Goldwasser NIH grants were "publicly accessible" submissions to a government entity and one of skill in the art could attain it, the IND and NIH grants constitute prior art under §§ 102(a) and (b).

Additionally, § 102(g) states that "[a] person shall be entitled to a patent unless . . . another inventor . . establishes . . . that before such person's invention . . . the invention was made in this country by such other inventor who had not abandoned, suppressed or concealed it." Under this subsection, a reference need not be disclosed and disseminated widely to the public in order for it to be considered "known" prior art to the hypothetical person of ordinary skill in the art at the time of the invention of the asserted patent. Courts have made clear that § 102(g)(2) does not require knowledge or use of a prior invention that was publicly accessible at the time the patented invention was made. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969); *see also E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir. 1988) ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment"). In *E.I. Du Pont*, the Federal Circuit made clear "that certain prior work at issue, solely because it satisfied § 102(g) (i.e. it was reduced to practice and had not been abandoned, suppressed or concealed), could be used for § 103 purposes." *Id.* The court acknowledged that such art, like § 102(e) art, was "secret prior art" and not known to the public. *Id.* Accordingly, under § 102(g), public accessibility is not a requirement for admission and evidence offered pursuant to this subsection can properly be considered prior art regardless of whether or not it was "public."

To the extent that Amgen may argue that Baron "abandoned" his study of purified human erythropoietin, the June 16, 1988 letter in the Baron-Goldwasser IND clearly shows Baron

requesting his IND "be put on inactive status" but that he wishes "to have the opportunity to re-open this study by submission of a protocol amendment with proposed investigational plan for the coming year." (see Attachment B, June 16, 1988 Baron letter to Department of Health and Human Services, AM-ITC 01006614) Accordingly, the study was not abandoned and the IND was indeed open at least as late as the summer of 1988.

Accordingly, Amgen's objections to the Baron-Goldwasser IND and Goldwasser NIH are spurious and contrary to the Court's own holding; under §§ 102(a), (b) and (g), the IND and NIH grant meet the standard for prior art and should properly be considered by the jury.

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Boston, Massachusetts

Respectfully submitted,
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