UNITED STATES DISTRICT COURT
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 INC.'S MOTION FOR JUDGMENT AS A MATTER OF LAW THAT THE BARON-GOLDWASSER EPO STUDIES AND THEIR NIH AND FDA GRANT APPLICATIONS ARE NOT PRIOR ART

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I. INTRODUCTION

Roche failed to clearly and convincingly show that Dr. Goldwasser's NIH Grant Applications and Dr. Baron's IND Application (collectively "Grant Applications") are prior art under 35 U.S.C. §§ 102(a), (b), (f), or (g).[1] Roche has not established a fundamental predicate from which a reasonable jury could find that the claims of the '422 or '933 patent are anticipated or obvious based upon Dr. Baron's and Dr. Goldwasser's experimental administration of urinary EPO to three patients. As such, in addition to the reasons stated in Amgen's Motion for Judgment As A Matter of Law,[2] there is further a fundamental failure of proof on this separate ground. The evidence of record fails to establish a *prima facie* clear and convincing showing that these Grant Applications constitute prior art. As such, these Grant Applications cannot be used to support Roche's obviousness or anticipating defenses to the '422 and '933 patents. In conjunction with its previous motion,[3] Amgen respectfully submits this additional Motion for Judgment As A Matter of Law.

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 50(a)(1) provides:

> If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may: (A) resolve the issue against the party; and (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

In order to warrant submission of an issue to the jury, Roche must present "more than a mere scintilla" of evidence and may not rely upon conjecture or speculation.[4] In addition, the Court should take into account the underlying burden of proof in ruling on the motion for

[1] TRX 2004, 2043, 2045, 2049, 2050.

[2] (D.I. 1137-2 at pp. 26-31.)

[3] (D.I. 1137-2 at pp. 26-27 fn. 92.) (Amgen alerted the Court it would "separately move for judgment as a matter of law on the basis that the Baron/Goldwasser experiment is not prior art under 35 U.S.C. §§ 102(a), (b), (f) or (g).")

[4] *Richmond Steel v. Puerto Rican American Ins. Co.*, 954 F.2d 19, 22 (1st Cir. 1992).

judgment.[5] Thus, the relevant inquiry is whether a jury applying the clear and convincing evidence standard could reasonably find for Roche.[6]

III. ARGUMENT

A. ROCHE HAS FAILED TO PRESENT CLEAR AND CONVINCING EVIDENCE THAT DR. BARON'S IND APPLICATION AND DR. GOLDWASSER'S NIH GRANT APPLICATIONS (COLLECTIVELY "GRANT APPLICATIONS") ARE PRIOR ART

1. Neither This Court Nor The Federal Circuit Have Held That The Baron-Goldwasser Study Or The Grant Applications Are Prior Art For The Purpose Of Anticipation Or Obviousness

The question of whether the Grant Applications constitute prior art has been raised several times in this case, and remains unresolved. Both parties have filed briefs on this issue.[7] Roche has mischaracterized many of the prior statements and adjudications made by this Court and the Federal Circuit.[8]

This Court has ***not*** already determined that these Grant Applications are clearly and convincingly prior art.[9] In *HMR/TKT*, this Court found that the experiment conducted in 1979-80 pre-dated Dr. Lin's patent application.[10] This Court made no finding with respect to public availability and was careful to say only that the Baron-Goldwasser study "appears to be prior

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[5] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) ("[W]e conclude that the determination of whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary standards that apply to the case. This is true at both the directed verdict and summary judgment stages.")

[6] *Id.* at 255-56.

[7] (D.I. 1055, 1091.)

[8] (D.I. 1091 at 1-2.)

[9] While this Court did state that "the Goldwasser study is prior art," (Trial Tr. at 579:3-5), the Court qualified this earlier statement by requesting additional briefing on whether the Baron-Goldwasser Grant Applications ("materials") constituted prior art. (Trial Tr. at 811:25 – 814:25). Roche's assertion that these applications have "already been admitted into evidence without objection" is equally irrelevant to whether these Grant Applications legally constitute evidence of prior art, and Amgen has consistently maintained an objection to these Grant Applications as prior art. (D.I. 1091 at 1.)

[10] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 111 (D. Mass. 2001) ("Because the documents submitted as exhibits in this case reveal that Dr. Goldwasser began this clinical study in 1979-80 at the University of Chicago in Illinois . . . it could fairly be said that it predates Amgen's patent application . . . That ***it appears*** to be prior art is only part of the analysis, for the only prior art that renders Amgen's claims invalid is that which anticipates Amgen's claims." (emphasis added)).

art."[11] Nor has the Federal Circuit held that the Baron-Goldwasser study was prior art.[12] The question of whether HMR/TKT has clearly and convincingly shown that Baron-Goldwasser's experiment is anticipating prior art is presently pending before this Court.[13]

2. Roche Has Not Shown That the Grant Applications are "Printed Publications" Under Section 102(a) or 102(b)

Roche has not presented clear and convincing evidence that Dr. Goldwasser's NIH Grant Applications, including one submitted on August 31, 1984, constitute prior art publications under 35 U.S.C. §§ 102(a) and (b).[14] Roche has failed to show that prior to Lin's date of invention for each of the claimed inventions, many of which are earlier than August 31, 1984, (or even by the time of Lin's final priority patent filing on November 30, 1984), these applications, and the information contained therein, were "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, [could] locate [them] and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation."[15]

Publications are not accessible to the public if such publications are subject to confidentiality or secrecy restrictions.[16] NIH Policies state that records and information regarding ***pending*** grant applications will not be released under a Freedom of Information Act (FOIA) request. Further, even when grants are approved, portions of the application may be kept

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[11] *Id.*

[12] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) ("If the claim term 'therapeutically effective' encompasses the patient responses described in the specification, as it appears to us it does, then the Goldwasser study ***may constitute*** invalidating prior art under § 102(a) or § 103 even if he did not achieve his intended result. We therefore vacate the trial court's determination that Goldwasser cannot constitute prior art because the study was a failure." (emphasis added)).

[13] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, Civil Action No. 97-cv-10814-WGY (D. Mass) (D.I. 862, 868) (TKT/HMR's Memorandum For Judgment That Claim 1 of the '422 Patent is Anticipated By the Goldwasser Pharmaceutical Compositions; and Amgen Inc.'s Reply Brief in Opposition.)

[14] *See Sandt Tech. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001) ("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.").

[15] *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006).

[16] *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1306-07 (Fed. Cir. 2002).

permanently confidential, such as portions containing patentable or commercially valuable information.[17] Roche has not shown that Dr. Goldwasser's August 31, 1984 Grant Application ceased to be pending by the November 30, 1984 final priority date, let alone by Lin's invention dates which were months earlier. Roche's retrieval of the Goldwasser Grant Application through a FOIA request in 2005 does not prove the applications were publicly available anytime in 1984.[18] Dr. Spinowitz's conclusory testimony on this issue further does not amount to a legitimate clear and convincing showing.[19]

Roche likewise has not clearly and convincingly shown that Dr. Baron's IND Application and related documents constitute a prior art publication. Dr. Spinowitz's conclusory statement that the data was known in the prior art because Dr. Baron filed an IND and submitted "follow-up letters to the FDA" is legally insufficient.[20] Dr. Baron's IND Application was confidential as Federal Law prevented the FDA from disclosing even the existence of the IND unless that existence was already made public.[21] Moreover, many of Dr. Baron's "follow-up letters" that Roche points to were submitted confidentially to the FDA well after November 30, 1984.[22] Finally, as of 1979/1980, Illinois patient confidentiality law similarly required the results of Dr. Baron's experiment to remain confidential.[23]

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[17] (D.I. 1055 – Attachment 4) (NIH Preaward Policies and Considerations, April 1994 (PHS GPS 9505) at 17-18); *see also* 45 C.F.R. § 5.65.

[18] (D.I. 1091 - Ex. 5.) This document is not in evidence. Roche's reliance on the fact that it and Amgen obtained Dr. Goldwasser's Grant Application through a FOIA request fails to address that the Grant Applications were not available until they were approved. This document is not clear and convincing evidence that the Grant Applications were approved, indexed, or publicly available before November 30, 1984.

[19] Trial Tr. at 810:22 - 811:16; *See Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1317 (Fed. Cir. 1999) (citing *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1988)) (conclusory expert testimony devoid of facts upon which the conclusions are based do not raise a genuine issue of material fact).

[20] Trial Tr. at 810:22-811:16. *See Zelinski*, 185 F.3d at 1317.

[21] D.I. 1055 – Attachment 1 (21 C.F.R. § 312.130); D.I. 1055 – Attachment 2 (21 C.F.R. § 601.50); D.I. 1055 – Attachment 3 (21 C.F.R. § 601.51).

[22] *See, e.g.*, TRX 2004 at AM-ITC 01006616 (Letter submitted to FDA on June 16, 1988).

[23] Illinois law requires medical study data to be "strictly confidential" and disclosure of such data is a misdemeanor. *See Memorial Hospital for McHenry County v. Shadur*, 664 F.2d 1058, 1060 n.2 (7th Cir. 1981) (citing the Illinois Medical Studies Act, Ill.Rev.Stat., Ch. 51 §§ 1, 2, 5 (1979)(amended 1981)).

Roche's reliance on *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*,[24] as proof that the Grant Applications were available printed publications anytime in 1984 is misplaced. Unlike here, in *E.I. Du Pont*, the NSF and NIH grant applications in question were not ***pending*** as of the date of the patent application.[25] Further, in *E.I. Du Pont*, the plaintiff provided a detailed factual showing, including deposition testimony of the Section Head of Grants and Awards for the NSF. That Section Head testified that prior to the date of the patent application, the NSF grant application had been filed, indexed by title, author, institution and grant number in the NSF's published indices of grants and awards.[26] The court concluded that "the emphasis [for determining whether an NSF grant application is a printed publication] is on systematic indexing and availability upon request."[27]

In stark contrast to *E.I. Du Pont*, Roche has not made any necessary evidentiary showing: that the Grant Applications were approved, that the FDA and NIH indexed and made these Grant Applications publicly available anytime in 1984, or any testimony from a Section Head. Roche failed to establish clearly and convincingly that the Grant Applications satisfy publication requirement of Section 102(a) and (b).

3. Dr. Goldwasser's and Dr. Baron's Urinary EPO Study is not a Prior Public Use Under 35 U.S.C. § 102(a) or (b), nor do the Grant Applications Evidence any Prior Public Use or Knowledge

Prior knowledge or use under Section 102(a) or (b) requires that the knowledge or use be available to the public.[28]

Roche offered no evidence that the patients involved in the Baron-Goldwasser study did not sign confidentiality agreements and that the experiments were conducted in public hospitals and subject to viewing by hospital staff.[29] Moreover, by Illinois law, the data generated and

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[24] *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 U.S. Dist. LEXIS 18382 (N.D. Cal. Dec. 11, 1990).
[25] *Id.* at *2-3, *6.
[26] *Id.* at *6.
[27] *Id.* at *7.
[28] *Minnesota Mining. & Mfg. Co.*, 303 F.3d at 1306-07; *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (citations omitted).
[29] (D.I. 1091 at 6 n.7.)

collected was confidential.[30] However, even if there was some viewing of the three subjects by the hospital staff, this is not clear and convincing evidence that this experimental study was a "public use." "[N]on-secret use is not *ipso facto* 'public use' activity."[31] Roche has not identified any specific public disclosure of this study prior to Lin's dates of invention in 1984.

Roche contends that Amgen's alleged knowledge of the Grant Applications makes their contents public. That is erroneous. "[I]n order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public."[32] Roche points to three internal Amgen documents.[33] Only one of these documents was admitted into evidence, namely a July 24, 1984, letter from Dr. Vapnek requesting that Dr. Goldwasser avoid disclosing confidential protein sequence information when he drafted his Grant Application.[34] It does not show that Dr. Vapnek, Amgen, or the public were aware of what Dr. Goldwasser subsequently put into his August 31, 1984 Grant Application. In fact, Dr. Vapnek cautioned Dr. Goldwasser

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[30] *See Memorial Hospital*, 664 F.2d at 1060 n.2 (*citing* Illinois Medical Studies Act, Ill.Rev.Stat., Ch. 51 §§ 1, 2, 5 (1979) (amended 1981)) (Illinois law requires medical study data to be "strictly confidential" and disclosure of such data is a misdemeanor.).

[31] *TP Labs., Inc., v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984) (*citing City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877)) (The Court in *TP Laboratories* held that although a dentist had not obtained any express promise of confidentiality from his patients, the use was not "public" because the dentist-patient relationship itself was tantamount to an express vow of secrecy. "[I]f a use is experimental, even though not secret, 'public use' is negated."); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1381 (Fed. Cir. 2005) (noting that "[i]n some cases, this court has determined that a use before the critical period was not public even without an express agreement of confidentiality); *See also Memorial Hospital*, 664 F.2d at 1060 n.2 (Illinois law requires medical study data to be "strictly confidential" and disclosure of such data is a misdemeanor.).

[32] *Minnesota Mining. & Mfg. Co.*, 303 F.3d at 1306-07; *Woodland Trust*, 148 F.3d at 1370.

[33] (D.I. 1091. - Exs. 4, 6, and 7 attached to D.I. 1092).

[34] TRX 2044. Contrary to Roche's assertion that this letter is proof that Amgen was aware of the contents of each of Dr. Goldwasser's and Dr. Baron's Grant Applications, this letter only addresses Dr. Goldwasser's NIH Grant Application that had yet to be drafted. Dr. Vapnek acknowledges that the Grant Application had not even been drafted by July 24, 1984, and thus it cannot show that Dr. Vapnek was aware of the Grant Application's contents.

about putting information on the EPO sequence in the NIH Grant Application even though Dr. Vapnek acknowledged that the to-be-drafted application would be "confidential."[35]

Roche's citation to *Baxter Int'l, Inc. v. COBE Lab. Inc.*, does not help its case.[36] In *Baxter*, two doctors with ***no relationship or connection*** with the inventor, (1) made modifications to a similar device before the patent at issue was filed,[37] (2) were actively using the invention in public, and (3) were showing it to independent 3rd parties under no duty of confidentiality before the critical date.[38] Unlike in *Baxter*, Dr. Spinowitz admitted that the Baron-Goldwasser data was not available prior to 1984 and further admitted that he was unaware if the data was made available to anyone.[39] Roche has made no showing that data from the Baron-Goldwasser studies was publicly available before Lin's invention dates.

4. Roche Has Not Shown That The Grant Applications Are Section 102(g) Prior Art

In order for the Baron-Goldwasser study to be Section 102(g) prior art, Roche must show that (1) another inventor (Dr. Baron or Dr. Goldwasser) did not abandon, suppress or conceal their invention, (2) reduced to practice their invention before the inventions by Dr. Lin, or conceived of an invention before Dr. Lin and diligently reduced it to practice, and (3) the prior reduction to practice or prior conception is supported by independent corroborating evidence.[40] "As between an earlier inventor who has not given the public the benefit of the invention, *e.g.*, because the invention has been abandoned without public disclosure, suppressed, or concealed,

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[35] The other two documents Roche relies upon are not in evidence, nor do they show that Amgen employees were aware of the results of the Baron-Goldwasser studies before November 30, 1984. (D.I. 1091 - Ex. 7) is an internal Amgen memorandum created and sent on *December 3, 1984, after November 31, 1984*. (D.I. 1091 - Ex. 6) is a September 17, 1984 memo attaching Dr. Baron's proposed protocol for human testing with EPO, but this protocol does not contain detailed results from Dr. Baron's three-patient experiment. This document is also marked as confidential which is further evidence that this information was not "public" knowledge."

[36] *Baxter Int'l, Inc. v. COBE Lab. Inc.*, 88 F.3d 1054 (Fed. Cir. 1996).

[37] *Id.* at 1056.

[38] *Id.* at 1057.

[39] Trial Tr. at 809:3-9.

[40] *See Sandt Tech.*, 264 F.3d at 1350.

and a subsequent inventor who obtains a patent, the policy of the law is for the subsequent inventor to prevail."[41]

Roche has not identified what invention, if any, that Dr. Baron or Dr. Goldwasser conceived of, nor when they conceived of it.[42] There is no evidence from Dr. Baron or Dr. Goldwasser that they believed they had made an invention. Nor has Roche identified when they reduced their conception to practice. It is black letter law that inventions cannot be established *nunc pro tunc*.[43]

Tellingly, Roche has not shown that Dr. Baron and Dr. Goldwasser did not abandon their experiments. Abandonment vitiates any alleged reduction to practice.[44] Neither Dr. Baron nor Dr. Goldwasser published the results of their urinary EPO clinical studies.[45] Roche did not address testimony from Dr. Baron that they considered that the results of their experiment were clinically insignificant and discontinued further studies.[46] Roche has failed to clearly and convincingly show that Dr. Baron or Dr. Goldwasser: (1) conceived of an invention; (2) reduced that invention to practice; and (3) did not abandon this invention. Thus, Roche failed to make a *prima facie* showing that the Baron-Goldwasser studies and the Grant Applications constitute Section 102(g) prior art.

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[41] *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997) (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983)).

[42] *See Burroughs Wellcome Co. v. Barr Labs, Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994) (Conception "is the formation in the mind of the inventor, or a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.") (citation omitted).

[43] *Estee Lauder, Inc. v. L'Oreal. S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997) ("[I]t is well-settled that conception and reduction to practice cannot be established *nunc pro tunc*.").

[44] *See Scimed Life Systems, Inc. v. Johnson & Johnson*, 2001 U.S. Dist. LEXIS 12862, *11-12 (D. Del. Aug. 15, 2001) (citing *In re Costello*, 717 F.2d 1346, 1350 (Fed. Cir. 1983) ("It has long been settled, and we continue to approve the rule, that an abandoned application, with which no subsequent application was co-pending, cannot be considered a constructive reduction to practice.")).

[45] Trial Tr. at 669:14-669:20; 877:4-878:13.

[46] Trial Tr. at 668:23-669:11.

5. Roche Has Not Shown That The Grant Applications Are Section 102(f) Prior Art

The Grant Applications likewise are not §102(f) prior art. Roche clearly misapprehends the application of §102(f) and has not clearly and convincingly shown what, if any, conception that either Dr. Baron or Dr. Goldwasser had coupled with a clear communication of this invention to Amgen.[47] Roche failed to clearly and convincingly show that Dr. Baron or Dr. Goldwasser conceived of any invention. The use of uEPO in an experimental study is not an invention, and is certainly not anything that Lin claims in his patents. Rather, the evidence shows that the experiment was clinically insignificant and that they abandoned further experimentations with urinary EPO treatment. Because Roche has failed to show a conception, the issue of whether Dr. Baron or Dr. Goldwasser clearly communicated this invention to Amgen is moot.[48] Even so, Roche failed to clearly and convincingly show that the details from the Baron-Goldwasser studies were communicated to Amgen such that it enabled one of ordinary skill in the art to make the patented invention.[49] Lacking a clear and convincing showing that these Grant Applications constitute § 102(f) prior art, Roche cannot combine these Grant Applications with other prior art for a § 103 obviousness inquiry.

[47] *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003).
[48] *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1376-77 (Fed. Cir. 2004).
[49] *See Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1578 (Fed. Cir. 1997) (To constitute Section 102(f) derivation, the communication of the invention must be sufficient to enable one of ordinary skill in the art to make the patented invention.)

IV. CONCLUSION

Based upon the foregoing, Roche failed to clearly and convincingly show that the Baron-Goldwasser study and the Grant Applications, and the details therein, constitute prior art under Sections 102(a), (b), (g), or (f), Amgen Inc. respectfully requests that the Court grants this Motion for Judgment as a Matter of Law.

DATED: September 29, 2007

Respectfully Submitted,

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