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 OPPOSITION TO ROCHE'S MEMORANDUM REGARDING BARON-GOLDWASSER PRIOR ART: BARON-GOLDWASSER CLINICAL STUDY, BARON-GOLDWASSER IND AND GOLDWASSER NIH GRANTS [D.I. 1141-5]

Roche failed to clearly and convincingly show that the Baron-Goldwasser study, 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. The evidence of record fails to establish a *prima facie* clear and convincing showing that these Grant Applications constitute prior art. As such, the Baron-Goldwasser study and these Grant Applications cannot be used to support Roche's obviousness or anticipating defenses to the '422 and '933 patents. Amgen files this Opposition in response to Roche's Memorandum Regarding Baron-Goldwasser Prior Art.[2]

[1] TRX 2004, 2043, 2045, 2049, 2050.
[2] (D.I. 1141-5.)

I. ARGUMENT

A. ROCHE HAS FAILED TO PRESENT CLEAR AND CONVINCING EVIDENCE THAT THE BARON-GOLDWASSER CLINICAL STUDY AND THE 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 Baron-Goldwasser study and the Grant Applications constitute prior art has been raised several times in this case, but remains unresolved. Both parties have filed briefs on this issue.[3] Roche has mischaracterized many of the prior statements and adjudications this Court and the Federal Circuit have made regarding the Baron-Goldwasser study.[4] Such mischaracterizations are irrelevant to whether Roche made a clear and convincing showing that the Baron-Goldwasser study and the Grant Applications legally constitute prior art. Roche's assertion that these applications have "already been admitted into evidence without objection" is equally irrelevant.[5]

This Court has ***not*** already determined that these Grant Applications are clearly and convincingly prior art in this case.[6] Nor has it determined so in prior adjudications. In *HMR/TKT*, this Court found that the experiment conducted in 1979-80 pre-dated Dr. Lin's patent application.[7] 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 art."[8] Nor has the Federal Circuit

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

[4] (D.I. 1141-5 at 1-2.)

[5] (D.I. 1141-5 at 1.)

[6] 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).

[7] *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)).

[8] *Id.*

held that the Baron-Goldwasser study was prior art.[9] 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.[10]

2. Roche Has Not Shown That the Baron-Goldwasser Study and 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).[11] 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."[12]

Publications are not accessible to the public if such publications are subject to confidentiality or secrecy restrictions.[13] NIH Policies state that records and information regarding ***pending*** grant applications will not be released under a Freedom of Information Act

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[9] *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)).

[10] *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.)

[11] *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.").

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

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

(FOIA) request.[14] Further, even when grants are approved, portions of the application may be kept permanently confidential, such as portions containing patentable or commercially valuable information.[15] Roche's assertion that "the presumption under FOIA is complete disclosure"[16] is just that, a presumption, that does not even apply to ***pending*** applications. Roche has not shown that any of Dr. Goldwasser's Grant Applications ceased to be pending by the November 30, 1984 final priority date, let alone by Lin's invention dates which were month earlier. Roche's retrieval of the Goldwasser Grant Application through a FOIA request in 2005 does not prove that the Grant Applications were publicly available anytime in 1984.[17] Dr. Spinowitz's conclusory testimony on this issue further does not amount to a legitimate clear and convincing showing.[18]

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.[19] 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.[20] Moreover, many of Dr. Baron's "follow-up letters" that Roche points to were submitted confidentially to the FDA well after November 30, 1984.[21]

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[14] (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.

[15] *Id*.

[16] (D.I. 1141-5 at 5)

[17] (D.I. 1141-5 - Ex. 5.) 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. (D.I. 1141-5 – Ex. 1.) Neither of these documents are in evidence nor clear and convincing evidence that the Grant Applications were approved, indexed, and publicly available before November 30, 1984.

[18] 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).

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

[20] (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).

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

Finally, as of 1979/1980, Illinois patient confidentiality law similarly required the results of Dr. Baron's experiment to remain confidential.[22]

Roche's reliance on *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*,[23] 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.[24] 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.[25] 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."[26]

In stark contrast to *E.I. Du Pont*, Roche has not made any of the necessary evidentiary showings: 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 simply listed for the Court several inapplicable cases where there, the defendants actually made clear and convincing factual showings that publications dissimilar to NIH and IND Applications were publicly available.[27] Roche failed to establish clearly and convincingly that the Grant Applications satisfy publication requirement of Section 102(a) and (b).

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[22] 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)).

[23] *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 U.S. Dist. LEXIS 18382 (N.D. Cal. Dec. 11, 1990).

[24] *Id.* at *2-3, *6.

[25] *Id.* at *6.

[26] *Id.* at *7.

[27] (D.I. 1141-5 at 2-4.)

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 contends that Amgen's alleged knowledge of the Grant Applications makes their contents public. This 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."[29] Any alleged disclosures by Dr. Goldwasser or Dr. Baron did not make any information public.[30] Roche points to three internal Amgen documents.[31] 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.[32] 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 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."[33]

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

[30] (D.I. 1141-5 at 5.) Roche's assertion that Dr. Goldwasser's testimony "suggests" that he showed Amgen his draft proposals to Amgen with no confidentiality agreement in place is disingenuous and unsupported by facts. (D.I. 1141-5 at p. 3.) Dr. Goldwasser testified that there was a confidentiality agreement with Amgen. (Trial Tr. at 547:2-3.)

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

[32] 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.

[33] 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."

Roche's citation to *Baxter Int'l, Inc. v. COBE Lab. Inc.*, does not help its case.[34] 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,[35] (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.[36] Unlike in *Baxter*, Roche has not provided any evidence of similar disclosures that could be public. In fact, 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.[37] Roche has made no showing that data from the Baron-Goldwasser studies was publicly available before Lin's invention dates.

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.[38] 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."[39] Moreover, by Illinois law, the data generated and collected was confidential.[40] Roche has not identified any specific public disclosure of this study prior to Lin's dates of invention in 1984.

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[34] *Baxter Int'l, Inc. v. COBE Lab. Inc.*, 88 F.3d 1054 (Fed. Cir. 1996).
[35] *Id.* at 1056.
[36] *Id.* at 1057.
[37] Trial Tr. at 809:3-9.
[38] (D.I. 1141-5 at 6 n.7.)
[39] *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.).
[40] *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.).

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.[41] "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, and a subsequent inventor who obtains a patent, the policy of the law is for the subsequent inventor to prevail."[42]

Roche has not identified what invention, if any, that Dr. Baron or Dr. Goldwasser conceived of, nor when they conceived of it.[43] There is no evidence from Dr. Baron or Dr. Goldwasser that they believed they had made an invention.[44] Nor has Roche identified when they reduced their "conception" to practice. It is black letter law that inventions cannot be established *nunc pro tunc*.[45]

Tellingly, Roche has not shown that Dr. Baron and Dr. Goldwasser did not abandon their experiments. Abandonment vitiates any alleged reduction to practice.[46] Neither Dr. Baron nor

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

[42] *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)).

[43] *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).

[44] Roche's assertion that filing an IND or an NIH grant application is *per se* evidence of a conception is spurious and unsupported. (D.I. 1141-5 at 10.)

[45] *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*.").

[46] *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.")).

Dr. Goldwasser published the results of their urinary EPO clinical study.[47] Roche did not address testimony from Dr. Baron that they considered that the results of their experiment were clinically insignificant and discontinued further studies.[48] While Roche asserts that both Dr. Baron and Dr. Goldwasser at one point expressed a desire to resume experiments with urinary EPO,[49] Roche provided no evidence that either ever resumed their urinary EPO studies.

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.

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.[50] Roche failed to clearly and convincingly show that Dr. Baron or Dr. Goldwasser conceived of an 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 their 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.[51] 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

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[47] Trial Tr. at 669:14-669:20; 877:4-878:13.
[48] Trial Tr. at 668:23-669:11.
[49] (D.I. 1141-5 at 10-11.)
[50] *See Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1344 (Fed. Cir. 2003).
[51] *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1377 (Fed. Cir. 2004) ("[W]e determine as a matter of law that the prior conception prong cannot be met. We need not and do not address the communication prong.")

skill in the art to make the patented invention.[52] 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.

B. WHETHER THE GRANT APPLICATIONS ARE PROPERLY ENABLED IS IRRELEVANT TO WHETHER THEY CONSTITUTE PRIOR ART

Roche's assertion, that non-enabled references "may qualify" as prior art for the purpose of obviousness,[53] is a red-herring. Roche must first clearly and convincingly show that the Baron-Goldwasser study and the Grant Applications constitute prior art, and Roche has not met this threshold requirement.

II. 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.

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Respectfully Submitted,

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[52] *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.)

[53] (D.I. 1141-5 at 6-7.)

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