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 RELEVANCE OF DR. BARON AND DR. GOLDWASSER'S FAILURE TO PUBLISH THEIR WORK

Roche has proffered Dr. Baron and Goldwasser's IND Application and Dr. Goldwasser's Grant Applications as prior art. In raising such references as potential Section 102 prior art, Roche has opened the door to their exacting scrutiny into whether they clearly and convincingly satisfy the requirements of Section 102. Particularly, the very failure to publish the data raises a host of relevant issues for inquiry during Dr. Spinowitz further examination.[1] This is true regardless whether the reference is being offered for anticipation or obviousness.

In the first instance, 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] This burden places on the defendant a high standard to prove that all the requirements are met under Section 102, which necessarily means that the art reference itself is subject to the same exacting scrutiny as the asserted patents.

[1] Trial Tr. 814:8-9 ("searching examination" of Dr. Spinovitz will be permitted).
[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).

Section 102(a) or (b) anticipation requires "'the presence in a single prior art disclosure of all elements of a claimed invention arranged as in that claim.'"[3] Issues that must be looked at for purposes of whether the single reference anticipates include inherency and enablement. "A claim limitation is inherent in the prior art if it is necessarily present in the prior art, ***not merely probably or possibly present***."[4] Thus, inquiry into whether the prior art reference contains an inherent limitation that is only probably or possibly present is a highly relevant inquiry to disproving that the reference contains an inherent limitation.

Moreover, a claim "cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled."[5] "The standard for enablement of a prior art reference for purposes of anticipation under Section 102 differs from the enablement standard under 35 U.S.C. § 112. . . . [A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." [6] "Whether a prior art reference is enabling is a question of law based upon underlying factual findings."[7]

Further, if Roche wishes to assert Dr. Goldwasser's IND Application to the FDA or NIH Grant Application 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.[8] The accompanying bench memorandum Amgen filed today addresses this issue that the Court specifically requested briefing on, however, in summary form, there must be a showing that:

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[3] *Carella v. Starlight Archery & Pro Line Co*., 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1998) quoting *Panduit Corp. v. Dennison Mfg. Co*., 774 F2d 1082, 1101, 227 USPQ (BNA) 337, 350 (Fed. Cir. 1985)) (additional citations omitted).

[4] *Akami Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003)(emphasis added).

[5] *Elan Pharms., Inc. v. Mayo. Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

[6] *Novo Nordisk Pharm., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005).

[7] *SmithKline Beecham*, 403 F.3d at 1342-43.

[8] *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)

> [S]uch 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.[9]

For example, 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."[10]

Roche has further argued that the IND and the Grant Applications qualify as Section 102(g)(2) prior art. Such an assertion is subject to no less scrutiny. A patent is valid over Section 102(g)(2) unless the defendant proves clearly and convincingly that "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."[11] Section 102(g) thus requires corroborated evidence of conception and reduction to practice, with all aspects of that being proved through evidence.[12] "It is well-settled that conception and reduction to practice cannot be established *nunc pro tunc*. There must be *contemporaneous recognition and appreciation* of the invention," by the inventor.[13] "[T]here is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the [invention]."[14] The failure to publish is highly relevant evidence that Dr. Goldwasser and Dr. Baron themselves recognized that they had not achieved conception necessary to establish that *prima facie* showing under Section 102(g) inquiry.

The failure to publish is no less relevant to Section 103. "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."[15] Such a

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[9] *Bruckelmyer*, 445 F.3d at 1374; *In re Wyer*, 665 F.2d 221, 226 (C.C.P.A. 1981)
[10] *Norian*, 363 F.3d at 1330.
[11] 35 U.S.C. § 102(g)(2) (2000); *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1339, 60 USPQ2d 1519, 1522 (Fed. Cir. 2001).
[12] *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001)
[13] *Rosco Inc. v. Mirror Lite Co*., 304 F3d 1373, 64 USPQ2d 1676 (Fed. Cir. 2002).
[14] *Dow Chem. Co.*, 267 F.3d at 1341.
[15] *In re Spormann*, 363 F.2d 444, 448 (CCPA 1966).

retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.[16]

Moreover, "Prior art . . . cannot be evaluated in isolation, but must be considered in the light of the secondary considerations bearing on obviousness."[17] In *Alco Standard*, the Federal Circuit held that a patent was not obvious even though the prior art standing alone provided significant support for finding the patent obvious.[18] The *Alco Standard* Court instead held that "[e]vidence of secondary considerations . . . is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art."[19] So too here, the failure to publish is highly relevant evidence that the medical need remained unmet after Dr. Baron and Dr. Goldwasser performed their three patient trial.

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Respectfully Submitted,

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[16] *See In re Newell*, 891 F.2d 899, 901 (Fed.Cir.1989); *See also, In re Rijckaert*, 9 F.3d 1531 C.A.Fed.,1993 (November 23, 1993).
[17] *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1499-500 (Fed. Cir. 1986).
[18] *Id.*
[19] *Id.* (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)).

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