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 THE RELEVANCE AND ADMISSIBILITY OF GENENTECH'S 1986 PLA

At the time of Dr. Lin's inventions in 1983-84, a person of ordinary skill in the art was unaware of any data showing that Genentech's recombinant tPA was biologically active *in vivo*. Because there was no such data in Genentech's tPA patent filings (as Amgen correctly told the Patent Office) or in any prior art publication, Roche wants to use Genentech's 1986 Product License Application ("PLA") to the FDA to demonstrate that *in vivo* biological activity was known in 1983-84. Plainly, the submission of clinical data to the FDA in 1986, does not establish what was known in the art in 1983-84.

On September 7, 2007, Roche submitted to this Court a Bench Memorandum asserting that Genentech's 1986 PLA was (1) relevant as prior art under a contorted application of 35 U.S.C. §§ 102(g)/103, and (2) evidence to show the tPA Patents (the '075 Patent and the '619 Application) were enabled.[1] Roche filed an additional brief on September 10, contending that Mr. Day's questions about what the tPA patents teach one of ordinary skill in the art somehow made this 1986 PLA document evidence of the prior art (it is not prior art).[2] Genentech's 1986

[1] Trial Tr. (9/7/07) at 340:15 to 343:8.

[2] Roche has further provided marked pages from the PLA, contending that these are somehow relevant to the obviousness inquiry.

PLA and any specific pages should be excluded because (1) on its face, the 1986 PLA is clearly not prior art and Roche's allegation that it qualifies as relevant prior art under 35 U.S.C. §§ 102(g)/103, is legally erroneous, and (2) Roche's allegation that the 1986 PLA is relevant to enablement of the tPA Patents is irrelevant to the obviousness inquiry of the patents-in-suit.[3]

A. THE 1986 GENENTECH PLA SHOULD BE EXCLUDED BECAUSE IT IS NOT SECTION 102(G) PRIOR ART

To establish that Genentech's 1986 PLA is Section 102(g) prior art, Roche must establish by clear and convincing evidence that (1) another inventor who had not abandoned, suppressed or concealed it, (2) reduced to practice an invention before the invention by Dr. Lin, or conceived of an invention before the invention by Dr. Lin followed by diligence to a reduction to practice, and (3) the prior reduction to practice or prior conception is supported by independent corroborating evidence.[4] Roche has not met this burden.

First, characterizing Genentech's alleged acts in 1984 as evidence of actual reduction to practice is legally erroneous and this does not justify relevance. The inventions claimed in Genentech's patent filings were actually or constructively reduced to practice either on or before Genentech filed these applications. Reduction to practice occurs either actually prior to the filing of the patent application, or constructively upon the filing of the application.[5] For purposes of patent law, post-filing activities cannot serve as evidence of a reduction to practice of these inventions. Roche contends that somehow Genentech's acts filing the '075 Patent and the '619 EP application evidence an actual reduction to practice of inventions claimed therein for purposes of Section 102(g). Whatever is reduced to practice by the date of the application, and what that teaches to one of ordinary skill in the art, is defined by the four corners of the document. The 1986 PLA document and work therein may not expand the teaching of the

[3] The exhibits in question are designated as Exhibits OUX, PXY and PNT.

[4] *See Sandt Technol. Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350 (Fed. Cir. 2001).

[5] *See Cooper v. Goldfarb*, 154 F.3d 1321 (Fed. Cir. 1998); *Medichem, v. Rolabo*, 437 F.3d 157, 1169 (comparing reliance on constructive reduction to practice of patent application with actual reduction to practice before the filing date).

earlier-filed tPA Patents. Instead, the relevant question is what that patent application teaches *as of the filing date* to one of ordinary skill in the art.

Second, even if Genentech had a tPA related invention that was not described in its patents, Roche has failed to make a *prima facie* showing that it is prior art. Roche has not shown (1) what this invention is, (2) when the conception of that invention occurred, nor (3) how the 1986 PLA qualifies under Sections 102(g)/103 as potential prior art. Roche has failed to identify the prior inventor, the prior inventor's acts of conception (and diligence) or reduction to practice, the date(s) the prior inventor(s) performed these acts, and the corroborating evidence for the unknown prior inventor's conception or reduction to practice. Moreover, Roche has failed to make a detailed *prima facie* showing that the specific work therein was disclosed to the public. Information submitted in a PLA to the FDA is confidential. Indeed, Roche produced the document as confidential in this action.

For all these grounds, the Court should see Roche's action for what it is: An attempt to bring unknown and secret acts showing biological activity of recombinant tFA into the obviousness analysis under the guise of an ill-defined Section 102(g) allegation. Admitting the Genentech PLA into evidence "expand" the teaching of the Genentech '075 Patent and '619 Application beyond their four corners. This would only confuse the jury as to what a person of ordinary skill in the art knew, and is improper under Section 103.

B. ROCHE'S ALLEGATIONS THAT GENENTECH'S PLA SHOWS ENABLEMENT IS IRRELEVANT

Roche further contends that the evidence of the subsequent unknown acts are relevant to Amgen's supposed contention of nonenablement of the two applications. But Amgen has made no such contention. The legally relevant question before the Jury and this Court under Section 103, is what is the scope and content of the prior art, *i.e.*, what do the tPA Patents teach to one of skill in the art.[6] Roche has confused the Section 103 inquiry into reasonable expectation of success with the separate enablement inquiry under Section 112, and boot-

[6] *See Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966).

strapped this confusion into the legally erroneous argument that a document which is not prior art under Section 102, Genentech's 1986 PLA, can supplement the proper prior art to show that Amgen's Patents were obvious as of 1983-1984. This is legally erroneous because all art asserted under Section 103 must qualify in the first instance as prior art under Section 102, or be an admission.[7] Neither criterion is satisfied here.

Obviousness does not ask if an invention is enabled, but rather whether there is a reasonable expectation of success at the time of invention using an objective standard, the person of ordinary skill in the art.[8] Roche uses its enablement argument to ask a legally irrelevant question under obviousness, namely whether the tPA Patent disclosure actually did work in 1986, and not whether a person of ordinary skill in the art would objectively expect them to work at the time of the invention.[9]

Moreover, that "which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."[10] Such a retrospective view of inherence is not a substitute for some teaching or suggestion supporting an obviousness rejection.[11]

Roche's non-prior art document is also in conflict with the contemporaneous expectation in the art. A publication from 1984 shows it was unknown whether human proteins would need proper glycosylation for *in vivo* biological activity, and whether animal or other cells could make this proper glycosylation if it was needed.[12]

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[7] *See Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003).

[8] *See* 35 U.S.C. §103 (". . . the subject matter as a whole would have been obvious at ***the time of the invention*** to a person of ordinary skill in the art . . .")

[9] Roche cites to several cases for the proposition that post-invention references can be used to show that a patent specification enables a claim. (Roche Bench Memo at 3.) These citations are inapposite because the post-invention references in the cited cases were used to show that an anticipatory reference under Section 102 met all the limitations of a claim, *i.e.*, these references proved that the public was already in possession of the invention. These non-prior art references cannot be used under obviousness to show that a person of skill in the art would have a reasonable expectation of success at the time of the invention.

[10] *In re Sporman*, 363 F.2d 444, 448 (CCPA 1966).

[11] *See in re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989).

[12] Plaintiff's Ex. 11 at AM-ITC 00355672, 74 (Attachment A hereto). (Roche stated in this January 1984, publication: "We don't know if non-glycosylation in *E. coli* is a major problem . . . so ways such as this of producing it in glycosylated forms are of great interest." Ciba stated in this same January 1984, publication: "The TPA synthesis method Ciba settles on – bacterial (continued…)

Roche cannot supplement the four corners of the obviousness prior art with information that is not prior art. Section 102 of the Patent Statute defines all prior art that can be used to prove obviousness, and there is no category that includes Genentech's 1986 PLA. Genentech's PLA is too late in time to be prior art, and Roche has not made the necessary foundational showing that would even qualify the PLA as Section 102(g) prior art. Thus, Genentech's PLA cannot be used as prior art in the Jury's obviousness analysis and should be excluded.

Roche repeats this enablement allegation in its Addition to Bench Memo filing of today. Roche misconstrues Amgen's evidence. Mr. Day elicited admissions from Dr. Lowe relevant to the scope and content of the prior art, and the reasonable expectation of success that persons of ordinary skill would have based on the content of this art. Enablement is not relevant under Section 103, and Roche cannot leverage this irrelevant legal argument into a new, non-statutory category of secret, post-filing prior art. Even if the enablement of Genentech's patents were an issue here, Genentech's PLA is irrelevant to that inquiry because the issue is whether a person of ordinary skill in the art could practice the patent disclosure and not whether the patent applicant itself could practice the disclosure.

CONCLUSION

In view of the foregoing, Amgen respectfully requests that this Court exclude Roche from using Genentech's 1986 PLA as prior art.

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Respectfully Submitted,

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cloning or mammalian-cell culture – will depend, Nüesche explains, on how important glycosylation of the native molecule turns out to be (*see* also story on page 1).")

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