

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,
Plaintiff,
v.
F. HOFFMANN-LAROCHE
LTD., a Swiss Company, ROCHE
DIAGNOSTICS GmbH, a German
Company and HOFFMANN LAROCHE
INC., a New Jersey Corporation,
Defendants.
Civil Action No.: 05-12237 WGY

AMGEN'S BENCH MEMORANDUM CONCERNING THE RELEVANCE OF U.S.
PATENT 4,776,075 TO ROCHE'S OBVIOUSNESS DEFENSE

Amgen respectfully submits this bench memorandum in response to Roche's "Bench
Memorandum that the U.S. Patent 4,766,075 is Relevant Prior Art that is Presumed to be
Enabled." In essence, Roche's motion asks the Court to read into the Goeddel '075 Patent
(Exhibit 2030) evidence of in vivo biological activity, despite the fact that the document contains
no such disclosure - as Roche's own expert, Dr. Lowe conceded during his cross-examination.
Genentech's Bench Memorandum and its efforts in this regard should be denied because:

- The presumption of enablement applies only to what a patent
actually teaches;
The '075 patent does not disclose or teach in vivo biologically
active recombinant tPA; and
Inherent but unknown features are not properly part of an
obviousness inquiry.

Thus, whether or not the actually disclosed subject matter of the '075 patent is enabled is

irrelevant to the obviousness inquiry.

Roche's expert, Dr. Lowe, asserted during his direct testimony that the '075 "inventors were expecting to use this material [recombinant tPA] in human beings for clinical use and obviously they're not going to do that unless it's going to have activity."² Yet, on cross-examination, Dr. Lowe admitted that the '075 patent did not anywhere disclose *in vivo* biological activity for a recombinant human tPA:

Q Is there any demonstration, any experiment or data presented in the Genentech patent disclosure to show that the product produced from CHO cells was active *in vivo*; yes or no?

A So you want a yes or no answer?

Q Yes.

A No, there isn't.³

Because the patent does not teach or disclose *in vivo* biologically active tPA, it cannot be presumed enabled for this undisclosed subject matter.

Because the the '075 patent does not disclose *in vivo* biologically active recombinant tPA, Roche is desperately trying to backdoor later evidence of *in vivo* activity into the '075 prior art reference. First, Roche tried to read-in *in vivo* biological activity in an earlier motion (Docket No. 1245), whereby it sought to prove inherency of the *in vivo* biological activity of the tPA disclosed in the '075 patent via the post-dated 1986 Genentech PLA.⁴ Having failed in that approach, Roche now attempts to read-in evidence of *in vivo* biological activity through the presumption of enablement. But Roche's the '075 patent is only a reference for what it actually

¹ Docket No. 1245.

² Trial Tr. 282:13-16.

³ Trial Transcript 389:13-20.

⁴ In its 9/10/07 bench memorandum (Docket No. 1024-2) Roche argued that the Genentech PLA was "relevant to rebut Amgen's contention that [the '075 patent is] not enabling." Roche's motion to admit the PLA was denied save for 4 pages that do not address the purported enablement of the '075 patent.

teaches.⁵ Since it does not teach *in vivo* biological activity of tPA, it cannot be presumed to enable *in vivo* biological activity.

At bottom, Roche is trying to augment the state of the art at the time of Dr. Lin's inventions by reading into the '075 patent perhaps inherent but then-unknown and unreported features of a recombinant human tPA protein. It is fundamental to the law of obviousness that "Obviousness cannot be predicated on what is unknown."⁶ Since the '075 patent does not disclose or teach *in vivo* biological activity, such activity cannot be read into the state of the art for purposes of an obviousness inquiry. Thus Roche's argument that subject matter of the '075 patent is entitled to a presumption of enablement is of no moment and should be denied.

Dated: October 2, 2007

AMGEN INC.,

By its attorneys,

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⁵ *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251 (Fed. Cir. 1989).

⁶ *In re Sporman*, 363 F.2d 444, 448 (CCPA 1966).

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/s/ Michael R. Gottfried

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