

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE, LTD.,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE, INC.

Defendants.

Civil Action No. 05-CV-12237 WGY

**ROCHE'S BENCH MEMORANDUM THAT THE U.S. PATENT NO. 4,766,075 IS
RELEVANT PRIOR ART THAT IS PRESUMED TO BE ENABLED**

Roche presents this memo to clarify the relevance and prior art status of U.S. Patent No. 4,766,075 ("the '075 patent") (TRX 2030). Not only is the '075 patent relevant prior art to the patents-in-suit, it is also entitled to a presumption of validity. To the extent Amgen argues that the patent is not enabled, the burden of proof lies with Amgen; it must provide the court with persuasive evidence in support of that contention.

The '075 patent was filed April 7, 1983 and is therefore prior art to the patents-in-suit under 35 U.S.C. §102(e). As Dr. Lowe testified, the '075 patent, in combination with the tryptic fragments of Dr. Goldwasser and other prior art, renders obvious the claimed subject matter of the patents-in-suit. *See, e.g.* Lowe testimony at Trial Tr. 281:7-284:4. While a prior art reference need not be enabled to serve as evidence of obviousness, as discussed below, to the extent Amgen asserts otherwise, the '075 patent is entitled to a presumption of validity as to all subject matter asserted as 102(e) art. In particular, the '075 patent describes the use of CHO cells to produce an in vivo biologically active recombinant human glycoprotein, suitable for use

in pharmaceutical compositions for the treatment of human patients. *See, e.g.* Lowe testimony at Trial Tr. 281:7-284:4.

When “an accused infringer asserts that either claimed or unclaimed material in a prior art patent anticipates patent claims asserted against it, the infringer is entitled to a presumption that the allegedly anticipating material is enabled.” *Impax Labs, Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006). “A court cannot ignore an asserted prior art patent in evaluating a defense of invalidity for anticipation, just because the accused infringer has not proven it enabled.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Moreover, “proof of efficacy is not required for a prior art reference...to be enabling and thus anticipating.” *Impax Labs, Inc. v. Aventis Pharm. Inc.* at 1383. “Rather, the proper issue is whether the [prior art reference] is enabling in the sense that it describes the claimed invention sufficiently to enable a person of ordinary skill in the art to carry out the invention.” *Id*; *see also id.* at 1382 (stating “anticipation 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.”). A patentee therefore bears the burden of proof when rebutting the presumption of enablement. It must provide the court with persuasive evidence to meet this burden. *Id.*

There cannot be any credible argument that the ‘075 patent fails to disclose how one of skill in the art could use CHO cells to express human t-PA. *See, e.g.*, ‘075 patent at Col. 26, ln. 40 to Col. 27, ln. 58 (describing, in detail, the use of CHO cells to express human t-PA); *see also* Col. 27, ln. 54-58 (directing the person of ordinary skill to a sample of the specific CHO cell strain used, which the inventors deposited with the ATCC). Nor can it be credibly argued that the ‘075 patent does not describe use of the recombinant human t-PA product as a pharmaceutical composition and for treating cardiovascular diseases. *See, e.g.*, ‘075 patent Col.

27, ln. 60-65 (“The compounds of the present invention can be formulated according to known methods to prepare pharmaceutically useful compositions.”); *see also*, Col. 3, ln. 64-67 (“The product human t-PA is suitable for use, in all of its forms, in the prophylactic or therapeutic treatment of human beings for various cardiovascular conditions or diseases.”). Amgen has presented no evidence to the contrary.

For all of the foregoing reasons, U.S. Patent No. 4,766,075 must be presumed enabled for purposes of 35 U.S.C. §102.

Dated: October 2, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ Lee Carl Bromberg

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/S/ Thomas F. Fleming