EXHIBIT B

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.: 05-12237 WGY

REDACTED

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499. I disagree with Drs. Nunberg's and Kadesch's contentions for the seasons set forth below.

A. BASED IN PART ON MY TESTIMONY, THIS COURT AND THE FEDERAL CIRCUIT COURT OF APPEALS HAS ALREADY FOUND '349 CLAIM 7 TO BE ADEQUATELY DESCRIBED AND ENABLED

500. I testified extensively in the *Amgen v. Hoechst* case on the issue of whether the claims of the '349 patent were adequately described and enabled by Dr. Lin's patent specification. The claims of the '349 patent involve vertebrate cells that make high levels of erythropoietin protein as measured by radioimmunoassay, and the process for making erythropoietin using such cells. In that case, Hoechst and TKT made a number of arguments trying to establish that Dr. Lin had failed to describe or enable his '349 inventions, but in each instance, Judge Young and the Federal Circuit determined that Hoescht and TKT had not proven their case. I have read these portions of the Court's decisions and agree with their findings and conclusions:

Federal Circuit 2006 Decision Concerning the Enablement and Description of '349 claim 7.

> On appeal, HMR/TKT argues that the district court made various claim construction errors and also erred in its validity and infringement rulings in the case of both the '698 and '349 patents. We have carefully considered all of HMR/TKT's arguments relating to the '698 and '349 patents. Having done so, we see no error in the district court's legal conclusions; nor do we see clear error in its findings of fact. Accordingly, we affirm in all respects the court's rulings with respect to the '698 and '349 patents.[169]

[169] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1317 (Fed. Cir. 2006).

Judge Young's 2004 Decision Concerning the Enablement and Written Description of '349 claim 7.

> [T]he Court holds that HMR/TKT has failed to show by clear and convincing evidence that the process claims of the 349 and 698 patents were not enabled.[170]

The Federal Circuit's 2003 Decision Concerning the Enablement of '349 claims 1-6.

> We address the product claims of the '349 patent in more detail, as they differ slightly from the patents we discussed above. The '349 patent claims genetically manipulated "vertebrate cells" — a composition — having certain characteristics and properties, including an ability to produce the claimed levels of human EPO. n10. The enablement question thus posed is this: having disclosed one way to make the claimed EPO-producing cell, is Amgen entitled to claim all such cells that "can be propagated *in vitro*," comprise "non-human DNA sequences that control transcription," transcribe "DNA encoding human erythropoietin," and produce the claimed amount of EPO? While our precedent does hold that disclosure of one or two species may not enable a broad genus, e.g., In re Vaeck, 947 F.2d at 495-96, 20 USPQ2d at 1444-45, the district court made several fact-findings indicating that any gaps between the disclosures and the claim breadth could be easily bridged. See, e.g., Amgen, 126 F. Supp. 2d at 149, 57 USPQ2d at 1514 (crediting Amgen's expert Dr. Lodish's statement that "one of ordinary skill in the art, me, my students, would have understood this not to be limited to the specific types of cells that were used in this example, that other vertebrate cells, mammalian cells, could have been used"); cf. Enzo Biochem, 188 F.3d at 1367-68, 1372, 52 USPQ2d at 1133, 1136-37 (affirming nonenablement of claims to anti-sense DNA technology applied to all eukaryotic and prokaryotic organisms because anti-sense was a "highly unpredictable technology" and a "high quantity of experimentation" would be needed to practice the invention outside of the disclosed example); Vaeck, 947 F.2d at 495-96, 20 USPQ2d at 1444-45 (holding the examiner did not err in rejecting as nonenabled claims drawn to all genetically-engineered cyanobacteria expressing a given protein because the claimed 150 genera of cyanobacteria represent a vast, diverse, and poorly understood group; heterologous gene expression in cyanobacteria was

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[170] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 279 (D. Mass. 2004).

> "unpredictable"; and the patent's disclosure referred to only a genus). The district court found that a skilled artisan could readily have used various cultured vertebrate and mammalian cells to produce human EPO, and this fact was buttressed by numerous post-filing publications that demonstrated the extent of the enabling disclosure. Amgen, 126 F. Supp. 2d at 162, 57 USPQ2d at 1517 (citing Gould v. Quigg, 822 F.2d 1074, 3 U.S.P.Q.2D (BNA) 1302 (Fed. Cir. 1987) for the proposition that an expert may rely on post-filing publications to show enablement). The court also found that for those skilled in the art it was a relatively simple matter to determine whether a certain promoter would work within a specific vertebrate cell, whether a particular vertebrate cell would produce human EPO in culture, and whether a particular promoter could be operatively linked to control the transcription of the human EPO DNA. Id. In summary, the court once again chose to credit Amgen's witnesses, Drs. Lodish and Wall, on the issue of enablement:
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> Throughout the testimony of these witnesses, a theme becomes apparent: any challenge which one of ordinary skill in 1984 might have encountered in attempting to make and use the claimed invention using other cultured mammalian cells could be resolved by experimentation falling short of undue. Id. at 159, 57 USPQ2d at 1515.
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> With these factual findings before us, TKT cannot prevail simply by reasserting in a conclusory manner that Amgen's disclosure does not enable the transformation of all mammalian or vertebrate cells or the production of human EPO. The district court carefully considered these issues, finding in the end that TKT had not met its clear and convincing burden of proof. Finding no clear error in these factual determinations, and having been directed to no legal error committed by the trial court, we will not disturb its holding that the asserted patents are not invalid for failure to meet the enablement requirement of § 112 P 1.[171]

Judge Young's 2001 Decision Concerning the Enablement of '349 claims 1-6.

> As to the asserted claims of the '349 patent, the Court also concludes that the written description, when combined with the knowledge of those of ordinary skill in the art as of 1984, teaches skilled artisans how to make and use the claimed unique

[171] *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1336-1337 (Fed. Cir. 2003).

vertebrate cells. In analyzing TKT's written description challenges to the '349 patent, the Court considered various passages from the specification as well as helpful testimony from the witnesses. Much the same evidence undergirds the Court's enablement holding. See supra Section IV.F.2.c, at 207-11.

In sum, various passages of the specification provide important data regarding, for instance, promoter and regulator DNA sequences, the creation of vectors carrying transcription control DNA sequences and human EPO DNA, the primary structural conformation of human EPO, selection and amplification techniques, and methods to quantify the erythropoietin production rates of the cells. See, e.g., Trial Ex. 1 at 2:3-8, 2:10-13, 10:42-49, 21:40 to 22:67 (Example 6), 23:1 to 24:38 (Example 7), 25:29 to 29:7 (Example 10), Fig.6. Moreover, the art was already rich in certain aspects of these teachings. For example, as of 1984, ordinary skilled artisans had identified a variety of promoters that could be used to promote gene expression in a variety of mammalian and vertebrate cells. Determining whether a given promoter would operate within a particular cell type was a matter of routine experimentation. One skilled in the art at that time also would have understood that a variety of vertebrate cells adapted for growth in culture could be obtained from the ATCC. In addition, a number of cultured human cell lines were available. One skilled in the art of molecular biology would have understood that because all vertebrate cells produce and secrete hormones by the same fundamental processes, the teachings displayed in the '349 patent were readily applicable to the entire range of cultured vertebrate cells, including human cells. These aspects relating to the Lin patents were already well known in the art prior to Dr. Lin's disclosure.

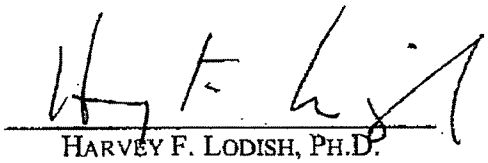
Building on this art, Dr. Lin's disclosure taught ordinary skilled artisans how to practice the claimed vertebrate cell inventions. In particular, the teachings enabled one of ordinary skill in the art to use various cultured vertebrate and mammalian cells, including human cells, to produce human EPO. With the assistance of the Amgen specification, a skilled artisan would have been able to determine with routine experimentation which cultured vertebrate cells would produce human EPO. The same is true with respect to whether certain of the various promoters could be operatively linked to control the transcription of the DNA encoding human EPO. The specification teaches how to use cultured vertebrate cells to make cells that contain non-human DNA sequences that control transcription of human EPO

DNA and, upon growth in culture, are capable of producing EPO at the levels recited in the claims. Among the many techniques described in the '349 patent for obtaining such cells are the use of (1) strong non-human promoters and enhancers; (2) selectable markers for isolation of cells capable of stable EPO expression in culture; (3) amplified markers for selection of cells containing amplified copies of EPO DNA under the control of non-human transcription control sequences; and (4) cell cloning. The patent also enables one of ordinary skill in the art to isolate EPO from EPO-producing cells and to measure such EPO.

The extent of the enabling disclosure is also demonstrated by a series of post-filing publications that describe the creation of EPO-producing cultured human, monkey, and hamster cells using the techniques taught in the Amgen specification. See Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) (explaining that an expert may rely upon post-filing publications that apply known techniques as of the filing date to show that the specification was enabling). Yanagi, for example, applied the teachings of the '349 patent to make cultured human cells capable of producing the claimed amounts of human EPO. Powell, similarly, made DHFR<+>, COS, and BHK (baby hamster kidney) cells containing amplified human EPO DNA under the control of non-human transcription control sequences that were capable of producing human EPO at the levels recited in the '349 claims. Ohashi, meanwhile, made EPO-producing DHFR<+> human cells that contained amplified human EPO DNA under the control of non-human transcription control sequences. The fact that these researchers were capable of making EPO-producing cells using non-human transcription control sequences and either amplified or non-amplified EPO DNA in various types of cultured cells including human cells further suggests that Amgen's specification was enabling.[172]

[172] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 161-163 (D. Mass. 2001) (internal citations omitted).

Executed this 11th day of May, 2007 at Boston, Massachusetts.



HARVEY F. LODISH, PH.D.