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 BRIEF ON DOCUMENTS ALREADY IN EVIDENCE THAT DEMONSTRATE A NEXUS BETWEEN EPOGEN® AND AT LEAST ONE CLAIM OF A PATENT-IN-SUIT

Evidence offered by Defendants in their case-in-chief and admitted in this trial demonstrates a nexus between Amgen's EPOGEN® product and at least one claim of a patent-in-suit. Accordingly, there is more than an adequate basis to allow evidence and testimony of secondary considerations of non-obviousness which evidence is based in whole or in part on the introduction of EPOGEN® as a treatment for anemia of chronic renal failure. Secondary considerations of non-obviousness are relevant to the jury's determination of whether the asserted claims of the patents-in-suit were obvious. By way of example, the following chart directs the Court's attention to specific pages of Trial Exhibit 2056, which demonstrate that EPOGEN® satisfies every limitation of U.S. Patent No. 5,955, 422, claim 1:

A pharmaceutical composition comprising	It is not in dispute that EPOGEN is a pharmaceutical composition and has been approved by the FDA.
a therapeutically effective amount of	"The two Amgen-sponsored clinical studies presented in this application involved 276 chronic renal anemia patients on hemodialysis . . . . These studies demonstrate r-HuEPO's effectiveness in correcting or ameliorating symptomatic anemia through a sustained increase in hematocrit, hemoglobin, and red blood cell parameters. In addition, transfusion dependence was reduced or eliminated in patients who were heavily transfusion dependent prior to study entry." Trial Ex. No. 2056 at AM-ITC00092311.
human erythropoietin . . . purified from mammalian cells grown in culture	"The CHO KI (DHFR$^-$) cell line was used as the host cell strain for transformation by the pDSVL-gHuEPO construct…" Trial Ex. No. 2056 at AM-ITC 00092414. "Recombinant human erythropoietin (r-HuEPO) is secreted by genetically engineered mammalian cells in culture." Trial Ex. No. 2056 at AM-ITC 0092249. "Following concentration and diafiltration of the cell-conditioned media, purification of r-HuEPO is accomplished via a four-step colum chromatography procedure." Trial Ex. No. 2056 at AM-ITC 00092265. "Recombinant human erythropoietin is a 165 amino acid glycoprotein manufactured by recombinant DNA technology." Trial Ex. No. 2056 at AM-ITC00092249. "the amino acid sequence of r-HuEPO is identical to naturally derived erythropoietin." Trial Ex. No. 2056 at AM-ITC 00092263. "results of complete amino acid sequence analysis of u-HuEPO were identical to the complete amino acid sequence of r-HuEPO, demonstrating that the erythropoietin gene clone producing the r-HuEPO gene product correctly reflects natural human erythropoietin." Trial Ex. No. 2056 at AM-

	ITC 00092425.
and a pharmaceutically acceptable diluent, adjuvant or carrier.	"r-HuEPO is formulated in an Albumin containing sodium chloride-sodium citrate buffer at neutral pH. Trial Ex. No. 2056 at AM-ITC 00092261.

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Respectfully Submitted,

AMGEN INC.,

/s/ Michael R. Gottfried

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Michael R. Gottfried

Michael R. Gottfried