

**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 REGARDING AMGEN'S (AND DR. LIN'S)
FAILURE TO ESTABLISH AN INVENTION DATE PRIOR TO THE
EFFECTIVE FILING DATE OF THE PATENTS-IN-SUIT**

Roche submits this bench memorandum to make clear to the Court that Amgen has not established an invention date earlier than the November 30, 1984 effective filing date of the patents-in-suit. Moreover, Amgen's failure to establish an earlier invention date is not remedied by the unsupported testimony of Dr. Lin.

Absent evidence of an earlier invention date, the invention date of a patent is presumed to be the date the application is filed. *Kopykake Enters., Inc. v. Lucks Co.*, 264 F.3d 1377, 1383 (Fed. Cir. 2001); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) ("Had Bard [sic] not come forward with evidence of an earlier date of invention, the [publication] would have been anticipatory prior art under section 102(a) because Dr. Mahurkar's invention date would have been the filing date of his patent.").

Once a patent challenger, as here, has made a *prima facie* case of invalidity, the patentee bears the burden of coming forward with rebuttal evidence of an earlier invention date.

Innovative Scuba Concepts, Inc. v. Feder Indus., Inc., 26 F.3d 1112, 1115 (Fed. Cir. 1994). In

order to prove an earlier invention date, the patentee must demonstrate an earlier reduction to practice or an earlier conception followed by a diligent reduction to practice. *Purdue Pharma Co. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359,1365 (Fed. Cir. 2001) (citing *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)).¹

However, inventor testimony alone cannot suffice to establish conception or reduction to practice. The Federal Circuit requires corroborating evidence when an inventor seeks to prove conception through his or her own testimony. *Id.* at 1577. Courts apply a “rule of reason” analysis to assess corroborative evidence. “[A]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor’s story may be reached.” *Mahurkar*, 79 F.3d at 1577 (quoting *Price*, 988 F.2d at 1195).

As reflected in the asserted claims, the intended purpose of the patented inventions was the production of glycoproteins having the biological activity of human erythropoietin and pharmaceutical compositions containing such glycoproteins. However, the record is devoid of evidence that, prior to the filing of the patent applications, Dr. Lin actually reduced his invention to practice by demonstrating that the invention worked for its intended purpose. Nor is there evidence that prior to the filing of the applications Dr. Lin “had a definite and permanent idea of the complete and operative invention” that would constitute conception.

Moreover, under *Mahurkar*, Amgen’s failure is not remedied by the unsupported testimony of Dr. Lin. While Dr. Lin may have testified that he cloned the EPO gene before November of 1984, Amgen has failed to introduce into the record any corroborating evidence of this testimony. *See*,

¹ Conception requires proof that the inventor formed in his or her mind “a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice,” and that the invention is “so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.” *Purdue Pharma Co.*, 237 F.3d at 1365 (quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)). Similarly reduction to practice must be established by independent contemporaneous evidence. Amgen has failed to present such evidence here. *Id.*

e.g., Trial Tr. at 1688:24 - 1689:2. Similarly, Dr. Lin's testimony that he developed an *in vivo* biologically active EPO protein prior to November 1984 is also unsupported by any corroborating evidence of record. *See, e.g.*, 1756:2-4. Without corroboration, this inventor testimony is wholly insufficient to prove an invention date prior to November 30, 1984.

For all of the above reasons, Amgen cannot be afforded an invention date earlier than the November 1984 filing date of the patents-in-suit.

Dated: October 10, 2007
Boston, Massachusetts

Respectfully submitted,

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

By its attorneys,

/s/ Vladimir Drozdoff

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Christopher T. Jagoe (*pro hac vice*)
Vladimir Drozdoff (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the 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/ Vladimir Drozdoff

Vladimir Drozdoff