

UNITED STATES DISTRICT COURT
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-12237WGY

**ROCHE’S BENCH MEMORANDUM REGARDING AMGEN’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.

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.”). A patent applicant can provide evidence of an earlier invention date to avoid potentially invalidating prior art or to establish priority of invention. *See 37 C.F.R. §1.131; Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169 (Fed. Cir. 2006).

Once a patent challenger 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)).

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)).

In order to establish actual reduction to practice, “an inventor must demonstrate that the invention is suitable for its intended purpose.” *Mahurkar*, 79 F.3d at 1578. In *Mycogen Plant science, Inc. v. Monsanto Co.*, 61 F. Supp. 2d 199, 238 (D. Del. 1999), the court stated that “[a]n actual reduction to practice occurs when the inventor: (1) constructs a product that is within the scope of the claimed invention; and (2) demonstrates that his invention actually worked for its intended purpose.” The court explained that “reduction to practice of an invention cannot occur unless the party claiming to be the inventor actually understood and appreciated at that time that the results were in fact the practicing of the later-claimed invention.” *Id.*

Furthermore, 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. Consequently, the earliest priority date Amgen can claim is the effective filing date of the patents; November 30, 1984.

DATED: October 3, 2007
Boston, Massachusetts

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

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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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