

**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. 05-12237 WGY

U.S. District Judge Young

**OPPOSITION TO AMGEN’S BENCH MEMORANDUM REGARDING
RESOLUTION OF DEFINITENESS AS A MATTER OF LAW (D.I. 1334)**

Amgen attempts to improperly bootstrap the indefiniteness inquiry to this Court’s role as the construer of patent claims. (D.I. 1334 at 1-2). It should not be allowed to do so. As the Federal Circuit has recognized, although definiteness is ultimately a question of law, the defense is amenable to resolution by the jury because it raises underlying issues that are factual in nature. *BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003).¹

Whether a claim is invalid for indefiniteness focuses on factual issues regarding whether one of ordinary skill in the art would understand the scope of the claim when read in light of the

¹ *BJ Services* was decided after each and every case cited by Amgen and states:

Indefiniteness is also a legal determination arising out of the courts performance of its duty construing the claims, *Personalized Media Communications*, 161 F.3d at 705, and is reviewed de novo. *Cardiac Pacemakers, Inc. v. St. Jude. Med., Inc.*, 296 F.3d 1106, 1113 (Fed.Cir.2002). “The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification.” *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed.Cir.2001) citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed.Cir.1986). Like enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature.

specification. *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002).

Indefiniteness generally arises when the claim language is “not sufficiently precise to permit a potential competitor to determine whether or not he is infringing.” *Morton Int'l. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993); *Semmler v. American Honda Motor Co.*, 990 F. Supp. 967, 975 (S.D. Ohio 1997); *Halliburton Energy Servs., Inc. v. MI, LLC*, 456 F. Supp. 2d 811, 817 (E.D. Tex. 2006).

Here, the Court has already fulfilled its duty and construed the claims-in-suit as a matter of law for application by the jury. Regarding its role in the judicial process, the jury will have received approximately 18 days of relevant testimony and will be charged with (1) determining the understanding of one of skill in the art at the time of the invention with respect to “the amino acid sequence of human EPO isolated from urine” and (2) determining whether or not Roche’s product meets the “human EPO” claim limitation as construed by this Court. Likewise, the jury has heard significant evidence concerning regarding the purported structures and properties of human EPO -- such as glycosylation, specific activity, etc. -- that Amgen now reads into the ‘422 and ‘933 source and process limitations in an attempt to overcome prior art. Because the jury already is obligated to consider these factual underpinnings that necessarily impact Roche’s indefiniteness defense during its deliberation regarding other invalidity defenses and infringement, it is well equipped to -- and should -- make the ultimate finding as to whether Amgen’s claims also are invalid under 35 U.S.C. §112, ¶2. There is no compelling reason to parse out this particular defense.

In fact, many courts properly have allowed the jury to determine whether patent claims are definite. *See, e.g., B.J. Services*, 338 F.3d 1368; *Northpoint Tech., Ltd. v. MDS Amer., Inc.*, 413 F.3d 1301, 1305 (Fed. Cir. 2005); *Mitsubishi Elec. Corp. v. Ampex Corp.*, 190 F.3d 1300,

1305 (Fed. Cir. 1999); *Texas Instr. Inc. v. Cypress Semiconductor Corp.*, 5 F.3d 1504 (Fed. Cir. 1993) (unpublished); *Syngenta Seeds, Inc. v. Monsanto Co.*, 409 F. Supp. 2d 536, 542 (D. Del. 2005); *Lucent Tech, Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 243-44 (D. Del. 2001); *GNB Battery Tech, Inc. v. Exide Corp.*, 876 F. Supp. 582, 596 (D. Del. 1995). If Amgen is disappointed by the jury's verdict the proper remedy is the appeal process, not the extreme prophylactic measure that Amgen requests with its erroneous assertion that definiteness is a determination solely for the Court rather than the jury.

For the foregoing reasons, the question of indefiniteness should be determined by the jury and included in the jury charge and verdict forms as submitted by Roche.

DATED: October 11, 2007

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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