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

ROCHE'S BENCH MEMORANDUM: AMGEN SHOULD BE PRECLUDED FROM CROSS-EXAMINING DR. BERTOZZI ON COMPARISONS BETWEEN URINARY EPO AND RECOMBINANT EPO

Amgen should be precluded from cross-examining Dr. Bertozzi on any alleged differences between Dr. Goldwasser's prior art urinary EPO and Dr. Lin's EPO (or, for that matter, any other specific embodiments of the claims). Such comparisons are legally irrelevant and will only serve to confuse the jury.

During the cross-examination of Dr. Bertozzi, Amgen's counsel repeatedly asked questions directed at comparing Dr. Goldwasser's urinary EPO to Dr. Lin's recombinant EPO or to other recombinant EPO molecules. (*See, e.g.*, Trial Tr. 1067:6-1068:8). Thus, Amgen has divorced its line of questions from the asserted claims and focused improperly on specific embodiments within the claims. However, the law is clear that "[t]he *claims*, not particular embodiments, must be the focus of the obviousness inquiry." *Jackson Jordan, Inc. v. Plasser Am. Corp.*, 747 F.2d 1567, 1578 (Fed. Cir. 1984) (emphasis in original). Indeed, this Court recognized this very point. (Trial Tr. 1068:17-1069:2). The same principle holds true with

respect to anticipation. *See OKI Am., Inc. v. Adv. Micro Devices, Inc.*, 2006 WL 2711555, *6 (N.D. Cal. Sept. 21, 2006).

Accordingly, the fact that, as Amgen asserts, there may be differences between Goldwasser's prior art EPO and Lin's recombinant EPO says nothing about whether Goldwasser's prior art EPO renders the asserted clams obvious or anticipated. For example, claim 1 of the '422 patent does not recite a particular human EPO structure. Rather, the claim covers *all* pharmaceutical compositions containing *all* human EPOs produced in *all* types of cells, from *all* mammalian species, grown under *all* possible culture conditions, and purified using *all* possible techniques. The appropriate inquiry is whether Dr. Goldwasser's EPO falls within the broad language of the claims, not whether particular recombinant EPO molecules that also fall within the claims differ in some way from Dr. Goldwasser's EPO.

What matters here, in terms of obviousness and anticipation, is that -- as Roche has shown by clear and convincing evidence -- Dr. Goldwasser's prior art EPO is indistinguishable from what is *claimed.* The *claims*, therefore, encompass a pharmaceutical composition that existed in the prior art. *See Door-Master Corp. v. Yorktowne, Inc.*, 256 F.3d 1308, 1312 (Fed. Cir. 2001) ("[t]hat which infringes, if later, would anticipate, if earlier").

As such, Roche respectfully requests that the Court preclude Amgen from continuing to pursue this highly misleading line of questioning. Moreover, the Court should issue a corrective instruction explaining that differences between the prior art and particular embodiments of the claims are irrelevant to the jury's determination.

DATED: Boston, Massachusetts
September 23, 2007

Respectfully submitted,

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

By their Attorneys,

/s/ Keith E. Toms
Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO # 663853)
Kimberly J. Seluga (BBO# 667655)
ROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel: (617) 443-9292
ktoms@bromsun.com

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

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.

/s/ Keith E. Toms
Keith E. Toms

3099/501 744384.1