UNITED STATES DISTRICT COURT
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.: 05-12237 WGY

AMGEN INC.'S SUPPLEMENTAL PROPOSED JURY INSTRUCTION AND OBJECTIONS TO ROCHE'S SUPPLEMENTAL PROPOSED JURY INSTRUCTION CONCERNING SOURCE AND PROCESS LIMITATIONS

Amgen Inc. respectfully requests that the Court instruct the jury that a claimed product that is novel, new, and different from the prior art can be rendered patentable on the basis of a source or process limitation to the claim. This instruction is consistent with the Court's *Markman* order applying Federal Circuit precedent[1] and the Court's rulings this week permitting Amgen to present evidence of the differences between prior art EPO products, such as Goldwasser's urinary EPO, and the claimed recombinant EPO products.[2] Amgen's proposed instruction additionally seeks to avoid confusion concerning (1) which party bears the burden of proof, and (2) the standard for assessing whether the product claimed by reference to source is new and different from any prior art products.

As the Court noted again on September 12, 2007, in the context of the '422 claim 1 and 933 claims 3, 7-9, 11, 12 and 14, the factual issue for the jury to resolve is whether the claimed product is novel as compared with the prior art:

> "The jury is going to have to resolve whether the prior art, which I have let in, all right, the so-called prior art, is in fact the same product. If it is, the source limitation won't save them. If it's not, the source limitation is part of the limitation . . . ."[3]

In allowing this evidence into the record, the Court rejected Roche's position presented in three motions in limine that the jury should not be permitted to receive and consider evidence concerning structural and functional differences between Amgen's claimed products and prior art

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[1] *Amgen, Inc. v. F. Hoffman-La Roche Ltd*., 2007 WL 1893058, *7-8 (D. Mass. 2007), citing *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312 (Fed. Cir. 2006).
[2] 9/12/07 Trial Tr. at 871:11-24.
[3] 9/12/07 Trial Tr. at 871:11-16.

products. Amgen respectfully requests that these three motions, Docket Nos. 1027, 1046, and 1047 be denied.[4]

In the context of '422 claim 1 and the asserted claims of the '933 patent, the jury must first decide if the claimed product is novel in comparison to the prior art. Roche seeks to argue that Amgen has the burden to prove novelty.[5] But the cases Roche cites concern patent applications rather than claims that have issued.[6] Once Amgen has discharged that burden before the Patent Office and the claims have been allowed, the burden falls to an accused infringer, such as Roche, to prove by clear and convincing evidence that the invention as claimed is not novel. Issued claims are presumed novel.[7] The finder of fact can only determine that the patent is invalid if Roche has proven by clear and convincing evidence that the claimed product was not novel when the invention was made.[8]

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[4] Amgen stands ready to provide further briefing on these issues should the Court desire. To the extent any uncertainty remains with respect to these three motions, Amgen believes it is best addressed by a specific objection by Roche to an exhibit or question.

[5] Docket No. 1046 at 2.

[6] *In re Moeller*, 117 F.2d 565, 568 (C.C.P.A. 1941); *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983)

[7] *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1445 (Fed. Cir. 1984) ("Because of the statutory presumption, a court is required to assume novelty and then 'must be satisfied ... that the party challenging validity has carried its burden of overcoming the presumption.'"), citing *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567 (Fed. Cir. 1983).

[8] *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001) citing *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) (the "presumption of validity, 35 U.S.C. § 282 (1994), requires those challenging validity to introduce clear and convincing evidence on all issues relating to the status of a particular reference as prior art.")

Amgen objects to Roche's instruction concerning source and process limitations.[9] Roche's instruction would reverse the burden of proof and confuse the jury in at least two respects.

First, Roche's instruction does not provide clear guidance as to which party has the burden of proof. As the party seeking to prove invalidity, Roche carries the burden of proof on all issues.[10] The jury should not be confused into thinking that the burden of proof on some factual issues relating to invalidity rests with Amgen.

Second, Roche's proposed instruction includes an analogy which may confuse the jury concerning the proper standard for determining whether the claimed product was identical or different from the prior art. Roche discusses an example relating to a claimed product, a car, claimed by referenced to the process of making the car. Roche's instruction notes that one could claim a new car that flies by reference to the process of making it. Roche also explains that one could not claim a car that is not new by a claim to a new process of making the car.

Roche's analogy is confusing in multiple respects. The example is not analogous to the facts at issue here. The car example involves an old product and a new product with functional differences but not structural differences. The law is clear. Roche must prove structural identity, not similarity, between Lin's claimed product and at least the prior art product. Any difference in structure and the claimed product is novel and not anticipated. *See, e.g.*, *Fritsch v. Lin*, 21 U.S.P.Q.2d 1719, 1742 (Bd. Pat. App. 1992). The facts of this case establish that Lin's claimed product has both functional and structural differences relative to the prior art.

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[9] Docket No. 1030.

[10] *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498-99 (Fed. Cir. 1992) ("The statutory presumption of validity under 35 U.S.C. § 282 puts the burden of proving invalidity on the party asserting it and the burden never shifts to the patentee.").

Additionally, the example of the flying car compared to the normal car could potentially confuse the jury concerning the extent to which the claimed product must differ from the prior art. Sections 102 and 103 of the Patent Act require no particular threshold difference between the prior art and a claimed product to establish novelty and non-obviousness. Although simple analogies can clarify complex concepts, Roche's car analogy would only add to the jury's confusion.

For the foregoing reasons, Amgen submits that its attached jury instruction concerning source and process limitations should be given, and Roche's proposed instruction should be rejected. A copy of Amgen's proposed instructions is attached as Ex. A.

Dated: September 14, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ *Patricia A. Rich*

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BB#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

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/s/ Patricia A. Rich

Patricia A. Rich