

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LA ROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LA ROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**AMGEN’S BENCH MEMORANDUM REGARDING ROCHE’S DEFENSE OF NON-
INFRINGEMENT UNDER “THE REVERSE DOCTRINE OF EQUIVALENTS”**

Roche has raised the “reverse doctrine of equivalents” as an equitable, affirmative defense to Amgen’s assertions that Roche’s products and processes infringe Dr. Lin’s asserted patent claims in this action. Roche confirmed its intent to press this defense as recently as this week during the October 1, 2007 non-jury trial session regarding Roche’s remaining obviousness-type double patenting defense.¹ Amgen respectfully submits this bench memorandum to briefly summarize the law regarding this defense.

As described by the Supreme Court in *Graver Tank*, the reverse doctrine of equivalents may preclude literal infringement only where “a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim.”² The Federal Circuit has further described the doctrine as applicable only when “despite the asserted claims literally reading on the accused device, ‘it has been so changed that it is no longer the same invention.’”³

The reverse doctrine of equivalents comes into consideration only after literal infringement is found.⁴ Presenting the jury with arguments and a verdict form addressing Roche’s reverse doctrine defense without instructing the jury that literal infringement has already

¹ Trial Tr. (Hearing in re Obviousness-Type/Double Patenting) 73:6-7 (“Mr. Fleming: We of course, have interpreted it that we still have it.”). Roche represented that it would inform the Court of its decision as to whether it would run the defense by the morning of October 2, 2007 (*id.* at 74:23-25)(“Court: [S]o you want to think about that and tell me tomorrow. Mr. Fleming: First thing in the morning.”), but it failed to do so, and refused to respond to Amgen’s inquiry regarding Roche’s decision later that day.

² *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09 (1950).

³ *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1351 (quoting *Del Mar Avionics, Inc. v. Quinton Instr. Co.*, 836 F.2d 1320, 1325 (Fed. Cir. 1987)).

⁴ “When a patentee establishes literal infringement, the accused infringer may undertake the burden of going forward to establish the fact of non-infringement under the reverse doctrine of equivalents.” *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123-24 (Fed. Cir. 1985); see also *Texas Instruments, Inc. v. U.S. Intern. Trade Comm’n*, 846 F.2d 1369, 1372 (Fed. Cir. 1988).

been found by the Court could be misleading and is likely to result in juror confusion. Amgen therefore respectfully requests that if Roche is to be permitted to pursue its reverse doctrine of equivalents affirmative defense, Amgen should be permitted to tell the jury (including in its opening statement regarding infringement) that literal infringement of '422 claim 1 has already been found by this Court as a matter of law. Amgen also believes that an instruction by the Court on this point would be necessary.

It must be kept in mind that to date, the Federal Circuit has not found a single case where this doctrine should be applied.⁵ Among other reasons, this is because after *Graver Tank*, Congress enacted 35 U.S.C. § 112, which imposes explicit requirements for written description, enablement, and definiteness. These requirements severely limit the need for, and the reach of, the reverse doctrine of equivalents defense.⁶

Once literal infringement is found for an asserted claim, Roche bears the burden of making a *prima facie* showing that its accused products and processes fall outside the fair and equitable scope of Dr. Lin's asserted patent claims.⁷ At trial, Roche's reverse doctrine of equivalents defense will not be able to survive a motion for judgment as a matter of law since no reasonable juror could find that Roche's peg-EPO performs its function in a substantially different way from Dr. Lin's claimed EPO products. To the contrary, the evidence will show that Roche's peg-EPO stimulates the formation of red blood cells in the same way, by activating the

⁵ As the Federal Circuit has stated, this defense is an "anachronistic exception, long mentioned, but rarely applied." *Tate Access Floors Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002).

⁶ *Id.* at 1368. As this Court is well-aware, the claims of Dr. Lin's patents-in-suit have withstood intense attacks under each of these provisions of § 112.

⁷ *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123-24 (Fed. Cir. 1985) (*en banc*); *see also, generally, Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 283-289 (D. Mass. 2004).

same EPO receptors, to initiate the same signaling pathway in the body, as do Dr. Lin's claimed products. Nor may Roche rely on the presence of an unclaimed additional structure, peg, to avoid infringement under the reverse doctrine of equivalents, because the EPO in peg-EPO satisfies all of the limitations of Dr. Lin's asserted claims.⁸

Roche has generally asserted that its accused peg-EPO product is "improved" over commercial embodiments of Dr. Lin's claimed EPO products. But this assertion, even if it were true, would be insufficient, as a matter of law, to forestall judgment as a matter of law. In *Northern Telecom, Inc. v. Datapoint Corp.*,⁹ the Federal Circuit rejected a reverse doctrine of equivalents defense under similar circumstances. As the Federal Circuit explained, "[t]he addition of features does not avoid infringement, if all the elements of the patent claims have been adopted. Nor is infringement avoided if a claimed feature performs not only as shown in the patent, but also performs an additional function."¹⁰ Applying the reasoning of *Northern Telecom*, the District of Oregon recently granted summary judgment rejecting a reverse doctrine of equivalents defense, noting that the defendant could not avoid infringement merely by pointing to additional features not described in the asserted patent, if all the elements of the claimed invention had been adopted.¹¹

Here, Roche's accused peg-EPO product is, at best, an improvement over the EPO products described and claimed by Dr. Lin, based on the addition of peg. However, that does not

⁸ See *Seiko Epson Corp. v. Print-Rite Holdings, Ltd.*, 2005 U.S. Dist. LEXIS 43200 at *26 (D. Or. Mar. 5, 2005) (rejecting reverse doctrine of equivalents defense on summary judgment); see also *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990).

⁹ *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 944-45 (Fed. Cir. 1990).

¹⁰ *Id.* at 945 (internal citations omitted).

¹¹ *Seiko Epson Corp. v. Print-Rite Holdings Ltd.*, 2005 U.S. Dist. LEXIS 43200 at *26 (D. Or. Mar. 5, 2005).

avoid infringement because all of the elements of the claimed EPO products remain. Roche cannot establish that peg-EPO performs its function (stimulating red blood cell production) in a fundamentally different way than do Dr. Lin's claimed EPO glycoproteins. To the contrary, the evidence to be presented at trial will establish that peg-EPO performs its function by binding to the same EPO receptors in the body, to initiate the same signaling pathways, as do Dr. Lin's claimed EPO products.

Even if Roche's pegylation of Dr. Lin's claimed EPO products constituted an "improvement" of those products – which it does not – the case law over the last century has firmly established that an accused infringer, even if an innovator, cannot appropriate the claimed invention of another simply because he has improved upon it.¹² As the Supreme Court has stated, "[i]t is well established that an improver can not appropriate the basic patent of another, and that the improver without a license is an infringer, and may be sued as such."¹³

Consequently, even if Roche's pegylation of EPO were an "improvement," Roche would nevertheless be liable for infringement of Dr. Lin's patent claims because it has appropriated Dr. Lin's claimed inventions.

For all these reasons, Amgen respectfully requests that it be permitted to tell the jury (including in its opening statement regarding infringement) that Roche has already been found to infringe '422 claim 1 as a matter of law, and that the Court instruct the jury on that point.

¹² See *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984) (“[W]here defendant has appropriated the material features of the patent in suit, infringement will be found ‘even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement.’”); *Tilghman v. Proctor*, 102 U.S. 707, 732 (1880) (“[T]he introduction of an improvement gives no title to use the primary invention upon which the improvement is based.”).

¹³ *Temco Electric Motor Co. v. Apco Mfg. Co.*, 275 U.S. 328 (1928).

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Respectfully Submitted,

AMGEN INC.,
By its attorneys,

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 91320-1889
(805) 447-5000

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

LLOYD R. DAY, JR
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
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

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

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 and paper copies will be sent to those indicated as non-registered participants on October 3, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried