

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**BRIEF IN SUPPORT OF AMGEN'S MOTION *IN LIMINE* NO. 1:  
EXCLUDE ROCHE FROM REFERRING TO ITS OWN  
PATENT ON PEGYLATED ERYTHROPOIETIN**

## I. INTRODUCTION

Amgen moves to preclude Roche from presenting evidence that the accused peg-EPO product is the subject of a Roche patent, because this evidence is irrelevant and likely to confuse the jury's consideration of the infringement issue. It is axiomatic that infringement of a dominant patent is not avoided by a variation or improvement which becomes separately patented. Any suggestion by Roche's experts and counsel relying on Roche's patent covering the accused peg-EPO product (Bailon, U.S. Patent No. 6,583,272) will cause the jury to ask the erroneous question when considering the infringement issue: how can peg-EPO infringe a claim in the Lin patents, if Roche has a patent of its own? It is this flawed reasoning that must be avoided by excluding Roche from referring to its Bailon patent. And, Amgen expects that Roche will introduce and refer to its Bailon patent to advance its non-infringement argument because Roche's expert reports contain references to the Bailon patent.<sup>1</sup> To avoid confusing and misleading the jury, Roche should be precluded from referring to its patent on peg-EPO because the jury is likely to wrongly conclude that peg-EPO does not infringe the Lin patents because it is separately patented.

## II. ARGUMENT

### A. Evidence of separate patentability is not relevant to the issue of infringement

The Supreme Court long ago established the principle that "the introduction of an improvement gives no title to use the primary invention upon which the improvement is based."<sup>2</sup>

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<sup>1</sup> Spinowitz Expert Report (6/13/07) ¶ 74 ("the fact that CERA is patented is further evidence that it is materially different than epoetin beta. In order to obtain a patent on a chemical entity, the chemical must be new"); Jorgensen Expert Report (5/11/07) ¶ 63, n.9 ("Roche has a United States Patent [ ] to CERA. This further supports my opinion that CERA is a new molecule"); *see also* Imperiali Expert Report (5/11/07) ¶ 164; Flavell Expert Report (5/11/07) ¶ 144; Longmore Expert Report (5/11/07) ¶ 85.

<sup>2</sup> *Tilghman v. Proctor*, 102 U.S. 707, 732 (1880).

It is now well established that the grant of a patent on an improvement over a prior invention does not avoid, excuse, or mitigate infringement of the prior patent.<sup>3</sup>

For example, in *Vulcan Engineering Co. v. Fata Aluminum, Inc.*,<sup>4</sup> an accused infringer argued that it did not infringe a patent on a “lost foam casting system” because the accused embodiment possessed capabilities beyond those listed in the asserted claim. The Federal Circuit rejected this argument. In affirming the lower court’s finding of infringement, the Federal Circuit stated that “[i]t is irrelevant whether an element has capabilities in addition to that stated in the claim. When the claimed function is performed in the accused system, by the same or equivalent structure, infringement of that claim is established.”<sup>5</sup> The issue remains whether the accused embodiment contains each limitation recited in the asserted claim.<sup>6</sup>

Only relevant evidence should be presented at trial – that is, evidence that has “any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.”<sup>7</sup> The question of infringement requires a comparison only between the accused product and the asserted claim.

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<sup>3</sup> See *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000) (upholding district court refusal to allow evidence of separate patentability of accused device in infringement suit); *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1582 (Fed. Cir. 1996) (“an improvement in a step of a patented method, even if separately patentable, may not avoid infringement”); *Nat’l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1191-92 (Fed. Cir. 1996) (“Improvements or modifications may indeed be separately patentable if the requirements of patentability are met, yet the device may or may not avoid infringement of the prior patent.”); see also *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928) (“One who practices an improvement invention without a license under the basic patent of another is an infringer.”).

<sup>4</sup> 278 F.3d 1366 (Fed. Cir. 2002).

<sup>5</sup> *Id.* at 1375.

<sup>6</sup> *Id.* at 1376 (“[W]hen all of the claimed features are present in the accused system, the use of additional features does not avoid infringement.”).

<sup>7</sup> FRE 401, 402.

Evidence that the accused product represents a patented improvement is not of consequence to the determination of infringement on the underlying patent. Because separate patentability is irrelevant to the determination of infringement, Roche should be precluded from presenting such evidence at trial.<sup>8</sup>

**B. Allowing evidence of separate patentability would prejudice Amgen because it is likely to confuse and mislead the jury**

Under FRE 403, the court may exclude evidence from trial if the evidence poses a danger of confusing or misleading the jury, or is likely to create an “undue tendency to suggest decisions on an improper basis.”<sup>9</sup> In this case, the Court should exercise its discretion to exclude references to the separate patentability of peg-EPO because such references are likely to mislead the jury to focus on irrelevant additional features of the accused product.

Whether an accused product modifies or improves upon the claimed invention is legally irrelevant and tends to confuse finders of fact on the issue of infringement. For instance, in *Stiftung v. Renishaw PLC*, the Federal Circuit reversed a district court ruling of noninfringement after a bench trial, finding that the judge focused improperly on an improvement in the accused product:

The district court seems to have focused on the fact that [the] element is an improvement upon the patented invention. Indeed, ... this superiority appears to

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<sup>8</sup> See *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000) (upholding district court’s refusal to allow evidence of separate patentability of accused device in an infringement suit, noting that “where 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’”) (quoting *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984)); see also *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 836 (D. Minn. 2007) (barring defendant from arguing that its patent grants it the affirmative right to use, develop or manufacture the invention).

<sup>9</sup> *CPC Int’l, Inc. v. Northbrook Excess & Surplus Ins. Co.*, 144 F.3d 35, 45 (1st Cir. 1998) (citing Notes of Advisory Committee, FRE 403).

be undisputed. But an improvement upon a patented device does not necessarily avoid infringement.<sup>10</sup>

A lay jury is even more likely to mistakenly focus its infringement analysis on the presence of alleged improvements in the accused product, rather than considering whether the accused product meets all the limitations of the asserted claim. The danger of confusing or misleading the jury can be minimized by precluding references to the separate patentability of peg-EPO.<sup>11</sup>

### III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that (a) Roche be precluded from referring to, or presenting evidence of, its patent on peg-EPO, and (b) Roche be precluded from

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<sup>10</sup> *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1179 (Fed. Cir. 1991).

<sup>11</sup> At a minimum, the jury should be clearly instructed that separate patentability is not a defense to infringement. The jury should be reminded that the test for infringement is whether peg-EPO meets every limitation of at least one asserted claim. Such instructions are routinely given when allegedly infringing embodiments are separately patented. *See* Uniform Jury Instructions for Patent Cases in the United States District Court for the District of Delaware 3.16 (regarding improvements):

You may find that defendant's accused product [apparatus or method] represents an improvement over the invention defined in plaintiff's patent claims. You have even seen and heard evidence that defendant obtained a patent on the improvement. However, you are not to presume that these facts mean that defendant cannot infringe plaintiff's patent claims. As long as defendant's accused product [apparatus or method] includes all of the elements of at least one of plaintiff's patent claims, or if defendant's accused product is found to be equivalent under the doctrine of equivalents, then plaintiff's patent claims are infringed by defendant's product [apparatus or method] despite defendant's improvements and patent.

*See also* Federal Circuit Bar Association Model Patent Jury Instructions 8.11 (regarding improvements):

[Defendant] has presented evidence that its [product or process] accused of infringement represents an improvement of the invention described in the \_\_\_ patent claims. Proof of this fact does not necessarily mean that the accused [product or process] does not infringe [plaintiff's] patent claims. The tests for infringement remain as I have instructed you. As long as you find that [defendant's] accused [product or process] includes all of the limitations of at least one of \_\_\_ patent claims, either literally or under the doctrine of equivalents, then you must find that the \_\_\_ patent claims are infringed by [defendant's] accused [product or process], despite defendant's improvement.

suggesting that infringement is avoided, excused, or mitigated because peg-EPO is separately patented or because peg-EPO represents a patentable improvement over EPO.

Respectfully Submitted,

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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 and paper copies will be sent to those indicated as non-registered participants on August 17, 2007.

*/s/ Michael R. Gottfried*  
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