

**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'S BENCH MEMORANDUM REGARDING APPLICATION OF THE
DOCTRINE OF EQUIVALENTS TO ESTABLISH INFRINGEMENT
UNDER 35 U.S.C. § 271(g)**

During the October 10, 2007 hearing, in discussing the structure of the jury verdict form, Roche indicated that the doctrine of equivalents does not apply to claims of infringement under 35 U.S.C. § 271(g).¹ Roche's assertion is wrong. Amgen submits this bench memorandum to explain how the doctrine of equivalents applies in the context of § 271(g).

Section 271(g) protects patentees from the importation, use, sale or offer for sale in the United States of products made overseas by a process patented in the United States. An infringement analysis under § 271(g) involves two separate inquiries: (1) whether the imported product was made by a process falling within the scope of the asserted process claim (i.e., whether the foreign process would infringe if practiced in the U.S.); and (2) if so, whether the product of the process is "materially changed" prior to importation or constitutes a "trivial and

¹ See 10/10/07 Trial Tr. at 2565:3-2569:8.

non-essential component” of the imported product. *See Genentech, Inc. v. Boehringer Mannheim GmbH*, 47 F. Supp. 2d 91, 107 (D. Mass. 1999).

Although the Federal Circuit has not directly considered the issue, several district courts, including this Court, have applied the doctrine of equivalents to decide the first step of the § 271(g) infringement analysis. That is, just as a patentee alleging infringement under § 271(a) may use the doctrine of equivalents to establish that a process practiced *within* the United States infringes its claimed process, a patentee alleging infringement under 271(g) likewise may use the doctrine of equivalents to prove that a process practiced *abroad* satisfies each limitation of its claimed process and therefore would infringe if practiced in the United States.²

For example, in *Genentech, Inc. v. Boehringer Mannheim GmbH*, 47 F. Supp. 2d 91 (D. Mass. 1999), Boehringer Mannheim (“BM”) argued that it did not infringe claim 1 of Genentech’s ‘832 patent under § 271(g) because, *inter alia*, BM’s overseas process for constructing Reteplase production plasmids involved replicated cDNA instead of reverse transcript cDNA and therefore did not literally satisfy step (b) of Genentech’s patented process. *See id.* at 109-10. This Court determined that even if BM did not literally practice step (b) of Genentech’s patented process, that limitation was nonetheless satisfied under the doctrine of equivalents:

Even if BM were correct on this point, Genentech would be easily saved by the doctrine of equivalents. As Genentech persuasively points out, under the doctrine of equivalents, replicated cDNA is the substantial equivalent of reverse transcript cDNA. *See Warner-Jenkinson*, 520 U.S. at 39-40. BM submits no evidence that they are not interchangeable, or that they are substantially different.

Genentech, 47 F. Supp 2d. at 110. Thus, although the Court ultimately held that BM’s process

² There do not appear to be any cases indicating that the doctrine of equivalents may apply to the “materially changed” inquiry. However, Amgen does not seek an instruction applying the doctrine of equivalents to this second step of the § 271(g) infringement analysis.

did not satisfy other limitations of Genentech's patented process and therefore did not infringe under 271(g), the Court's opinion clearly acknowledged that patentees may use the doctrine of equivalents in the first step of the § 271(g) infringement analysis to establish that a process practiced abroad satisfies one or more limitations of the claimed process.

In *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90 (D. Mass. 2002), this Court again acknowledged the availability of the doctrine of equivalents to establish the first prong of the § 271(g) infringement test: "Although GI did not literally infringe the unlinked cotransformation claims, the doctrine of equivalents could apply to GI's processes with respect to these claims." *Id.* at 102. The Court ultimately held that because GI's process "did not directly infringe any of the unlinked cotransformation claims of the Axel patents, either literally ***or through the doctrine of equivalents***," as to those particular claims, Roche was not liable under § 271(g) (or under § 271(b)) for importing the product of GI's process into the United States. *See id.* at 103 (emphasis added).

Other district courts have similarly applied the doctrine of equivalents in assessing whether a patentee has established the first requirement of infringement under § 271(g). *See, e.g., Taltech Ltd. v. Esquel Apparel, Inc.*, 2007 U.S. Dist. LEXIS 17005, at *56-72 (W.D. Wash. Mar. 9, 2007) (applying doctrine of equivalents in the context of § 271(g) infringement claim and holding no infringement); *Pfizer Inc. v. F & S Alloys & Minerals Corp.*, 856 F. Supp. 808, 815-16 (S.D.N.Y. 1994) (holding that plaintiff's showing of substantial likelihood that overseas process would infringe at least under the doctrine of equivalents was sufficient to shift burden to defendant to prove non-infringement under § 271(g)/§ 295); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 411 F. Supp. 2d 490, 495, 508-509 (D.N.J. 2006) (holding that plaintiff had not sufficiently established that foreign process would infringe under the doctrine of equivalents and therefore had not established a likelihood of success in proving its § 271(g) claim for purposes of a

preliminary injunction). Thus, there is no merit to Roche's contention that the doctrine of equivalents is inapplicable to claims of infringement under § 271(g).

In light of the foregoing, Amgen respectfully submits that, for all the claims-in-suit, including the process claims alleged to infringe under § 271(g), the jury verdict form should include a separate box for infringement under the doctrine of equivalents.

Dated: October 12, 2007

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 October 12, 2007.

/s/ Patricia R. Rich
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