

**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-CV-12237 WGY

**ROCHE'S BENCH MEMORANDUM REQUESTING THAT  
THE JURY BE INSTRUCTED THAT THE PROCESSES OF CLAIMS  
'868 1 AND 2 AND '698 4-9 CULMINATE IN ISOLATION,  
NOT PURIFICATION, OF THE RECITED POLYPEPTIDE**

Roche submits this bench memorandum to request that the Court instruct the jury, in accordance with the Court's construction, that the term "isolating said glycosylated erythropoietin polypeptide" in '868 claims 1 and 2 and '698 claims 4-9 does not encompass purification.

Roche asserts non-infringement of Amgen's process claims under 35 U.S.C. § 271(g). Under 271(g), a product made by a patented process will not be considered infringing if the end product "is materially changed by subsequent processes." In deciding infringement under 271(g), the jury first will have to decide what, if anything, made by Roche is "the product of a patented process" and then make a determination of whether or not the product to be imported by Roche (i.e Mircera) has been materially changed by subsequent processes. *See Bio-Technology Gen. Corp.*, 80 F.3d 1553, 1559-60 (Fed. Cir. 1996); *Genentech, Inc. v. Boehringer Mannheim*, 47 F. Supp. 2d 91, 111-12 (D. Mass. 1999) (finding non-infringement under 271(g) where

accused product was “not . . . made by a patented process because the additional process steps . . . were not themselves covered by the patent” and served to “change the physical and chemical properties [of the product] . . . in material ways.”) In *Genentech*, the Court specifically distinguished the patent doctrine that performance of additional steps not found in a patent does not absolve an infringer from liability; “reliance [on this doctrine] is misplaced in the context of an analysis . . . under Section 271(g).” Accordingly, the jury should be instructed that the patented process ends before purification, with mere isolation of the polypeptide from the cell material<sup>1</sup> and that the product at issue is the product of that process alone, without any subsequent purification step. Roche requests that Amgen be precluded from arguing otherwise.

In the Markman hearing on this issue, Amgen pressed a definition of “isolating said glycosylated erythropoietin polypeptide” that encompassed purification. (4/17/07 Markman Hearing Tr. 94:24-95:14) Counsel for Roche pointed out that in the *Fritsch v. Lin* interference Amgen argued *against* the very interpretation it now proffers. (4/17/07 Markman Hearing Tr. 94:11-22). Indeed, in the Interference, Amgen asserted that the term “isolating” means “nothing more than separating the expressed product from the cell,” flatly denying that the step of isolated includes “purification.” (Party Lin Interference Brief 102,097 at 48, 58) (“Fritsch et al again try to equate isolation with purification but, as noted earlier, these two are not the same.”) Counsel for Amgen could not deny such was Amgen’s position. (4/17/07 Markman Hearing Tr. 95:15-17) (“THE COURT: What do you say about the language in the interference? MR. DAY: It says what it says.”)

Recognizing that “what was said in the interference has got to be consistent with what’s presented to this Court” this Court struck Amgen’s purported phrase “recovering in pure form”

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<sup>1</sup> In the case of claim 7 of the ‘349 patent the patented process ends with “culturing”, and even “isolating” is not a recited process step.

from the construction of the applicable claims and substituted the word “separating.” (4/17/07 Markman Hearing Tr. 97:20-98:5)

Thus, the limitation “isolating said glycosylated erythropoietin polypeptide” in the ‘868 and ‘698 patent claims means separation of the glycosylated erythropoietin polypeptide from the cells and nothing more. Amgen should be precluded by this Court’s Markman decision and by its own prior representations to the contrary from arguing otherwise. The jury should be instructed accordingly.

DATED: October 12, 2007

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

By its attorneys,

/s/ Patricia A. Carson

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/s/ Thomas F. Fleming  
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