UNITED STATES DISTRICT COURT
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-12237WGY

BENCH MEMORANDUM CLARIFYING THAT PRODUCT BY PROCESS CLAIMS ARE LIMITED ONLY BY LIMITATIONS RECITED IN THE CLAIMS OR THE SPECIFICATION

Roche submits this memorandum to clarify for the Court that product by process claims are limited only by process limitations which are explicitly stated in the claims or the specification. As the court stated in *Smithkline Beecham Corp. v. Geneva Pharm. ,Inc*., 2002 U.S. Dist. LEXIS 25275 *20 (E.D. Pa. 2002): "[W]e decline to recognize product properties that are not required by the patent claims or specification."

Roche has emphasized to this Court that in previously construing the '422 patent, the Federal Circuit stated that "a claimed product shown to be present in the prior art cannot be rendered patentable solely by the addition of source or process claims." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F. 3d 1313, 1354 (Fed. Cir. 2003). Similarly, the Federal Circuit held invalid two product-by-process claims in a pharmaceutical composition patent, stating that "a prior art disclosure of a product precludes a future claim to that same product, even if it is made by an allegedly novel process." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 n.7 (Fed. Cir. 2006).

Amgen has nonetheless insisted that, for validity purposes, the claim term "purified from mammalian cells grown in culture" distinguishes the pharmaceutical composition of claim 1 of the '422 patent from prior art pharmaceutical compositions containing EPO purified from mammalian cells which were not grown in culture based on structural differences supposedly identified in the years that have passed since the filing of Amgen's patent applications. There is no dispute that the patents make no mention of any such differences.

In *Smithkline v. Geneva, supra*, the court rejected the very argument that Amgen makes here. In that case, Smithkline argued that products of its patented direct compression process for forming paroxetine tablets were distinguishable over prior art paroxetine tablets made by a wet granulation process on the grounds that "tablets made from a wet granulation process are more likely to develop an undesirable 'pink hue,' will retain identifiable remnants of the spherical granules used in the wet process and will have a different content uniformity than tablets made by a direct compression process." 2002 U.S. Dist. LEXIS 25275 at * 20. The court held that "the product characteristics now cited by Smithkline are insufficent to distinguish the product of the [asserted] patent" from prior art paroxetine. *Id*. at *22. The court explained that the asserted patent made no reference to the absence of spheres and the content uniformity that Smithkline cited as distinguishing characteristics of the patented paroxetine tablets. Moreover, the likelihood of a "pink hue," though "referenced in the specification, [did] not require a limitation of the patent's claims." *Id*. at 21. Thus, as set forth above, the court concluded: "[W]e decline to recognize product properties that are not required by the patent claims or specification." *Id. at 20.*

We note that this Court necessarily took the very same approach in granting summary judgment that Roche infringes the '422 patent in the absence of any evidence that Roche's

CERA satisfies the structural requirements that Amgen now claims distinguish the claimed erythropoietin that is "purified from mammalian cells grown in culture" from prior art erythropoietin purified from mammalian cells not grown in culture

DATED: October 1, 2007,

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

By its attorneys,

/s/ Thomas F. Fleming

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