UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN'S BENCH MEMORANDUM CLARIFYING CASE LAW CONCERNING SOURCE AND PROCESS LIMITATIONS

Amgen respectfully submits this bench memorandum to clarify that the Court should continue to apply the case law concerning source and process limitations that this Court relied on its *Markman* order. In it latest bench memorandum concerning source and process limitations, Roche has attempted to circumvent that case law by pointing to the district court opinion in *SmithKline v. Geneva Pharma, Inc.*[1] In so doing, Roche ignored the fact that *Smithkline v. Apotex*, the Federal Circuit opinion in the very same case as the district court decision in *SmithKline v. Geneva Pharma, Inc.*, makes clear that process limitations may impart novel structure to a product claim and therefore serve to distinguish a product from the prior art.[2]

In its *Markman* ruling in the *Roche* matter, the Court recently determined that "purified from mammalian cells grown in culture" is a permissible source limitation in '422 claim 1 for

[1] Docket No. 1233 at 1-2.

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purposes of distinguishing the claimed product over the prior art.[3] In so holding, the Court properly applied *SmithKline Beecham Corp. v. Apotex Corp*. to reject the argument made by Roche that Lin could not distinguish the product claim in '422 claim 1 from prior art solely on the basis of a source limitation:

> [Roche's] argument is based on *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312 (Fed. Cir. 2006), where the Federal Circuit affirmed the invalidation of a patent to a pharmaceutical composition that recited process steps as the only distinguishing feature over a prior art tablet . . . Roche/Hoffmann's citation to SmithKline Beecham Corp. is misplaced since it omits the next passage, which recognizes that process limitations may impart novel structure to a product claim.[4]

Now, having already lost with its attempt to cite the Federal Circuit decision in *SmithKline v. Apotex*, Roche resorts to citing the district court opinion for the same proposition that the Federal Circuit opinion failed to adopt in its opinion – the notion that process limitations in a product claim are not relevant to the anticipation and obviousness analysis.[5]

The district court's holding *SmithKline v. Geneva Pharma, Inc*. should only be read in light the of the Federal Circuit decision in *SmithKline v. Apotex*. The district court decision ignores the *In re Luck* on the basis that the Federal Circuit's decision in *Scripps v. Genentech* post-dated *In re Luck*.[6] But the Federal Circuit's decision in *Smithkline v. Apotex* reaffirmed that

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[2] *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1319 (Fed. Cir. 2006).

[3] *Amgen, Inc. v. F. Hoffman-La Roche Ltd*., 2007 WL 1893058, *7-8 (D. Mass. 2007) ("In this case, Dr. Lin has testified that at the time, 'the only way [to] characterize [his claimed] product is by the way they were making ...' Def.'s Mem. Opp'n Amgen's Claim Construction. [Doc. 322] at 11-12 (citing Trial Transcript at 965:8-14, *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 457 F.3d 1293 (Fed. Cir. 2006)). Accordingly, the Court deems it appropriate to include the "source limitation" in a product claim.").

[4] *Id.* at *7.

[5] Docket No. 1233.

[6] *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1323 (Fed. Cir. 2006) ("These early cases nicely illustrate the fundamentals of modern-day claim construction in light of the specification; they are not a pronouncement that it is proper to ignore process limitations in product claims. To the contrary, all of these cases state the obverse of the panel majority's view. These long-standing rules of claim construction have had many iterations, such as summarized

In re Luck is valid precedent for the principle that a product different from a prior art product can be distinguished on the basis of process limitations.[7] Likewise, the dissent in *Smithkline v. Apotex*, authored by the same judge who authored *Scripps*, highlights the importance of *In re Luck* in noting that process limitations in product-by-process claim should be given meaning.

Additionally, the district court's decision in *Smithkline v. Geneva Pharma, Inc*. is factually distinguishable. In *Smithkline v. Geneva Pharma, Inc*., the district court found that process steps in the product-by-process claims did not distinguish the claimed compound over prior art compounds because the specification noted that the supposedly distinguishing properties were present in both the claimed compound and the prior art compound.[8] By contrast, here, the differences between the prior art urinary EPO compounds and the claimed compound purified from mammalian cells grown in culture are documented through extensive evidence already presented in interference proceedings, where the Board of Patent Appeals and Interferences found that Fritsch failed to prove that Goldwasser's EPO and Lin's EPO were identical, and the Board noted that the outcome would have been the same even if Lin had presented none of his extensive rebuttal evidence.[9]

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by our predecessor court in *In re Luck, 476 F.2d 650, 653 (CCPA 1973)*, that 'to the extent these process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics.' That is, the process limitations cannot be ignored.")

[7] *SmithKline Beecham Corp. v. Apotex Corp*., 439 F.3d 1312, 1319 (Fed. Cir. 2006).

[8] *Smithkline Beecham Corp. v. Geneva Pharm., Inc*., 2002 U.S. Dist. LEXIS 25275, *22 n. 14 (E.D. Pa. 2002) ("the '944 Patent specification states that the tablets of the prior art process "often" -- not always -- developed the undesirable pink hue. Id. at lines 35-36. The specification thus expressly reveals that some of the paroxetine tablets made according to the prior art wet granulation process shared the non-pink characteristic that SmithKline claims is a distinguishing property of the '944 Patent process. In other words, even considering the process limitations of the '944 Patent, it is clear that non-pink paroxetine tablets existed in the prior art.")

[9] *Fritsch v. Lin*, 21 U.S.P.Q.2D 1739, 1742 (Bd. Pat. App. & Inter. 1991) ("Even if we had found all the evidence relied upon by Lin to have been entirely discredited by Fritsch, and we do not so find, this would have only led us to conclude that differences in average carbohydrate composition may or may not exist, i.e., that the evidence as a whole is inconclusive, and that Fritsch has not satisfied its burden of establishing that there are no differences. It is particularly telling that Fritsch has presented no affirmative evidence of its own in the form of test data to

The Court should not permit Roche's attempt to mislead the Court by citing to a factually inapposite district court case that has been superseded by important Federal Circuit precedent in the very same litigation concerning the very same product-by-process claims. Roche's bench memorandum should be seen for what it is – another attempt to dodge and ignore well-established case law allowing source and process limitations as means to distinguish a novel product that is otherwise not as easily definable using traditional product characteristics.

support the assertion that r-EPO and u-EPO are identical in terms of average carbohydrate composition").

Dated: October 2, 2007

AMGEN INC.,

By its attorneys,

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