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 OPPOSITION TO AMGEN'S BENCH MEMORANDUM CONCERNING PROPOSED JURY INSTRUCTIONS REGARDING SOURCE AND PROCESS LIMITATIONS

Contrary to Amgen's assertions (*see* D.I. 1320), Roche's proposed jury instruction regarding source and process limitations, unlike Amgen's proposed instruction, represents the only proper instruction on these issues. Amgen's memorandum (and corresponding jury instructions) should be ignored because:

- Amgen repeatedly misstates the law regarding the pertinence of process and source limitations.
- Amgen, not Roche, has the burden of showing that the claimed source and process limitations impart novel structure.
- Amgen cannot rely on after-arising evidence to establish novelty.
- Roche's proposed instructions are entirely consistent with established precedent.
- Prior proceedings conclusively establish that Amgen cannot show a difference in glycosylation between the claimed recombinant EPO and all prior art urinary EPOs.

I. AMGEN'S PROPOSED INSTRUCTION IS WHOLLY INCONSISTENT WITH ESTABLISHED PRECEDENT

Amgen's proposed jury instruction misrepresents established precedent regarding source

and process limitations. For example, Amgen proposes that "[a] product claim that contains source elements or product-by-process elements must be given the same consideration as claims having traditional product characteristics." While a correct statement of law, this instruction improperly suggests that the source or process limitations themselves must be given equal consideration. In fact, even Amgen concedes that this is incorrect. Source and process limitations need only be considered if they impart novel structure to the claimed product. (*See* Trial Tr. 871:11-16 ("The jury is going to have to resolve whether the prior art, which I have let in, all right, the so-called prior art, is in fact the same product. *If it is, the source limitation won't save them*. It it's not, the source limitation is part of the limitation") (emphasis added)).

Moreover, Amgen's argument that "the product is presumed to be novel and thus different from prior art products" (D.I. 1320 at 1) completely misses the point regarding source and process limitations. While this is a correct statement of law, it has nothing to do with source or process limitations. The question here is whether the claimed product, irrespective of the process or source from which it is produced, is the same as a product in the prior art. Amgen recognizes as much in quoting this Court's statement, as noted above: "The jury is going to have to resolve whether the prior art, which I have let in, all right, the so-called prior art, is in fact the same product. *If it is, the source limitation won't save them*. It it's not, the source limitation is part of the limitation." (Trial Tr. 871:11-16) (emphasis added). Roche has presented clear and convincing evidence that the claimed products, irrespective of the source and process limitations, "is in fact the same product" as what is in the prior art. Accordingly, "the source limitation won't save" Amgen.

Moreover, Amgen quotes this Court's *Markman* opinion and asks the Court to instruct the jury consistent with this opinion. (D.I. 1320 at 2). However, the Court's *Markman* opinion

does not support the expansive reading that Amgen suggests -- namely, that source or process limitations are presumed to impart novel structure to product claims. As the Court plainly stated, "process limitations ***may*** impart novel structure to a product claim." *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 2007 WL 1893058, *7 (D. Mass. 2007) (emphasis added). As Roche has explained previously, and as explained below, this language plainly indicates that it is Amgen's burden, not Roche's, to present evidence that the process limitations ***do*** impart novel structure to the product claim. In other words, the presumption is that such limitations do not render a claimed product novel, but they "may."

Finally, Amgen's reliance on after-acquired evidence is wholly misplaced. Amgen argues that because Roche sought to present after-arising evidence regarding the state of the prior art, such evidence "must also be relevant to the difference between the claimed inventions and that same art." (D.I. 1320 at 4 n.14). Roche's after-arising evidence is simply contemporaneous evidence to show what was *actually known* prior to November 30, 1984. To the contrary, Amgen's evidence, including the Dionex experiments, is directed at experimental procedures that were not even available at the time. Therefore, Amgen's arguments are misplaced and contrary to law. *See Nat'l Research Development Corp. v. Great Lakes Carbon Corp.*, 410 F. Supp. 1108, 1124 (D. Del. 1975) ("[t]o satisfy the statue, there must have been a test available at the time of the filing of the patent application which could have been employed by a person skilled in the art"); *In re Wright*, 999 F.2d 1557, 1563 n.8 (Fed. Cir. 1993); *see also* D.I. 1274.

II. ROCHE'S PROPOSED INSTRUCTION SHOULD BE ADOPTED

Despite Amgen's arguments, the law is clear that Amgen -- not Roche -- has the burden of proof with respect to showing that its source and process limitations impart novelty to the claimed products. While issued claims are presumed novel, there is similarly a presumption that

source and process limitations cannot impart novelty to an old product. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006); *see also Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("In determining patentability we construe the product as not limited by the process stated in the claims"). Here, the claimed product is simply a human erythropoietin polypeptide, which even Amgen cannot reasonably dispute is the same as prior art human urinary EPO. Because such product claims are not construed as limited by the process stated in the claims, Amgen, not Roche, bears the burden of proving that stated source or process limitations impart a novel structure. Indeed, in *SmithKline Corp. v. Geneva Pharms. Inc.*, 2002 U.S. Dist. LEXIS 25275, *19-*22 (E.D.Pa. Dec. 20, 2002), the court implicitly recognized that the patentee bears this burden by granting summary judgment of anticipation on certain asserted claims because SmithKline, the patentee, could not prove that the process limitations imparted novelty to the claimed product. Accordingly, even if, as Amgen asserts, the cases relied upon by Roche solely relate to patent prosecution, and not litigation, *SmithKline* presents a clear and unambiguous rule of law that the burden resides with Amgen. Amgen cites no law to the contrary.

As to Amgen's concerns regarding the "merely descriptive" language in Roche's proposed instruction, as well as Roche's car analogy, neither the term nor the analogy appear in Roche's proposed jury instructions. Accordingly, Amgen's concerns are moot.

III. ROCHE'S PROPOSED INSTRUCTION REGARDING "ISSUES ESTABLISHED BY PRIOR PROCEEDINGS" SHOULD BE ADOPTED

Roche's proposed instruction regarding prior proceedings is entirely proper and should be adopted. Despite Amgen's argument, the question here is not "whether Roche can prove that Lin's claimed product has the same glycosylation as one particular prior art urinary product: Goldwasser's urinary EPO." (D.I. 1320 at 8). The issue is whether Amgen can prove that Lin's

claimed erythropoietin polypeptide is distinct from *all* prior art urinary EPOs, not just Goldwasser's urinary EPO.

Furthermore, when viewed in light of the true issue here -- i.e. whether Lin's recombinant EPO is different from all prior art urinary EPOs -- this Court's holding in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.* is entirely consistent with Roche's proposed jury instruction. This Court held in that proceeding that the "glycosylation of human urinary erythropoietin is a standardless standard... As a result, making comparisons between the glycosylation of recombinant EPO and that of human urinary EPO is virtually impossible." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 59, 155-156, 165 (D. Mass. 2001). This conclusion is entirely consistent with Roche's proposed instruction -- namely, that it cannot be shown (i.e. it is virtually impossible) that recombinant erythropoietin is distinguishable from urinary erythropoietin on the basis of glycosylation. Amgen presents no arguments to suggest any inconsistency between the language of Roche's instruction and this Court's prior holding.

Moreover, the fact that this Court took notice of certain experiments comparing urinary EPO to recombinant EPO is of no consequence to Roche's proposed instruction. As noted, the question is not whether one sample of recombinant EPO differs from one sample of urinary EPO. The question is whether the claimed recombinant EPO differs from *all* prior art urinary EPOs, and this Court's conclusion in *Amgen v. TKT* plainly supports Roche's proposed jury instruction on this issue.

IV. CONCLUSION

In accordance with this memorandum and Roche's proposed jury instructions, the Court should employ Roche's jury instructions regarding source and process limitations.

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F. HOFFMANN-LA ROCHE LTD,
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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 (NEF) on the above date.

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