IN THE UNITED STATES DISTRICT COURT
FOR THE 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 U.S. District Judge Young

ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM ARGUING THAT EXAMPLES IN THE LIN SPECIFICATION INHERENTLY PRODUCE HUMAN EPO WITH 165 AMINO ACID RESIDUES

Amgen apparently intends to argue that Dr. Lin's specification adequately describes human EPO protein as now claimed because Example 10 "inherently" produces a protein with 165 amino acid residues "such as the amino acid sequence of EPO isolated from urine.[1]" Amgen defines urinary EPO as having the amino acid sequence of 1-165 of Figure 6. However, argument and evidence relating to the amino acid sequence produced by the examples set forth in the Lin specification should be precluded because the "inherent" amino acid sequence of any such product is irrelevant as a matter of law and fact to the written description inquiry here.

Amgen previously admitted that "[e]ven though 165 human EPO was inherently produced in Example 10, it was not expressly recited as being Amgen's invention in the [Lin] specification." (D.I. 485-5 - 485-8 at 9 (AM-ITC 00852571)). Amgen further admitted that "[a]lthough the

[1] While Amgen has only cited example 10 in support of this argument, any attempt to rely on any other patent example is also improper for the reasons explained in this motion.

amino acid sequence of 165 human EPO is depicted within the 166 amino acid sequence shown in Figure 6, that fact alone is not sufficient to support a claim that recites the 165 human EPO sequence." (D.I. 485-5 - 485-8 at 6 (AM-ITC 00852568)).[2] Thus, Amgen admitted that "to subsequently add a description of the later-discovered equivalent — in this case, the fact that the product of example 10 has only, 165 amino acids — would violate the statutory prohibition against adding new matter to the application" because there was no adequate written description. (D.I. 485-5 - 485-8 at 5 (AM-ITC 00852567)). Amgen seeks to reverse its position in this litigation.

Each of the cases relied upon by Amgen in its opposition to summary judgment (D.I. 565) to back-track from its previous admissions stand merely for the proposition that one may rely on inherency to support the written description requirement if, and only if, the inherent structure is necessarily found within the claimed product. Amgen cannot make any such claim here because some mammalian cells do express human EPO with 166 amino acid residues. *Amgen v. HMR/TKT*, 287 F.Supp.2d 126, 157 n.14 (D. Mass. 2004).[3] In addition, because the construction of claim 1 of the '422 patent allows the human EPO to be taken "from the cells" before secretion as well as from the cell culture medium, *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 494 F. Supp.2d 54, 64 (D. Mass. 2007), the human EPO produced in CHO cells of Example 10 at the very least may have 166 amino acid residues. Thus, the disclosed human EPO is not inherently

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[2] Amgen also admitted that under controlling law Lin's "references to a genus of fragments or to DNA sequences of different lengths cannot constitute 'blazemarks' pointing to the particular 165 amino acid EPO." (D.I. 485-5 - 485-8 at 8 (AM-ITC 00852570)).

[3] Only claim 2 of the '868 patent and claim 8 of the '933 patent limits human EPO to the product expressed from CHO cells, which is not necessarily 165 amino acids. The remaining 13 claims asserted by Amgen broadly claim the product of "mammalian cells", "non-human mammalian cells" or "vertebrate cells."

165 residues as Amgen now claims.

The facts here align with *Chen v. Bouchard*, 347 F.3d 1299 (Fed. Cir. 2003), a Federal Circuit case that was decided subsequent to any case cited by Amgen. *Chen* demonstrates that inherency will not support adequate written description where the procedures disclosed in the specification actually produce the structure expressly disclosed as well as the structure allegedly inherently disclosed. *Chen*, 347 F.3d at 1305 (no written description of inherently produced 7,8-cyclopropataxols where specification expressly disclosed 7-a flurotaxol derivatives made by same process). Here, even assuming Example 10 inherently produces a product with 165 amino acids under some conditions, Lin expressly described human EPO as 166 amino acids and set forth procedures that will produce a product with 166 amino acids. Thus, Amgen's inherency theory cannot support adequate written description.

Moreover, even if Example 10 may inherently produce erythropoietin with 165 amino acid residues under some process conditions and from some mammalian cell lines (but not all), Amgen's argument that Dr. Lin therefore "possessed" human EPO as now claimed is irrelevant as a matter of law. Federal Circuit precedent states that "[a]pplication of the written description requirement ... is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the ***statutory mandate*** that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002) (emphasis in original). As the Federal Circuit has already held: "At the time the patent was drafted, it was believed that the sequence included 166 amino acids, and this belief is depicted in Figure 6." *Amgen, Inc. v. HMR/TKT*, 314 F.3d 1313, 1343 (Fed. Cir. 2003).

Here, upon reading the specification, one of skill in the art in 1983-84 would have understood that Dr. Lin "possessed" the product with the 166 amino acid sequence expressly described in the specification, rather than the 165 residues now claimed. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) ("one cannot describe what one has not conceived"). Amgen previously admitted that "the record indisputably establishes that at the time Dr. Lin filed his application, neither he nor anyone of ordinary skill could have foreseen that the mature human erythropoietin glycoprotein produced by Example 10 would contain only the 1-165 amino acid sequence of Figure 6." (D.I. 485-5 - 485-7 at 5 (AM-ITC 00852567). Indeed, it was "later research" that reported human EPO as 165 amino acids. *Amgen*, 314 F.3d at 1343.

Amgen's argument also invites legal error by conflating the written description requirement with enablement, and its arguments will only serve to confuse the jury. The law is clear: adequate written description is a requirement separate and distinct from enablement. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 921 (Fed. Cir. 2004) ("an invention may be enabled even though it has not been described"). The specification must describe each claim element and "proof of a reduction to practice, absent an adequate written description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of §112, 1." *Enzo*, 323 F.3d at 969. That is because the law requires that "adequacy of the written description (i.e., the disclosure) ***is measured from the face of the application***; the requirement is not satisfied if one of ordinary skill in the art must first make the patented invention before he can ascertain the claimed features of that invention." *New Railhead Mfg. LLC v.*

Vermeer Mfg., 298 F.3d 1290, 1295 (Fed. Cir. 2002) (emphasis added).[4] Here, Amgen would require one of skill in the art to make and analyze the product in 1983-1984 to determine what the amino acid sequence of the product actually is and then realize he made the correct 165 product rather than the disclosed and described 166 amino acid product (even though, as discussed above, Amgen admits one of skill in the art could not have made this determination in 1983-84). Amgen's position is squarely in conflict with controlling law that requires actual description of each feature that is included as a claim limitation.

For all these reasons, Amgen should be precluded from presenting evidence and arguing that the examples in the Lin specification may inherently produce a human EPO with 165 amino acid residues. Such evidence is contrary to the claims and irrelevant to Roche's asserted defenses as a matter of law, and will be confusing to the jury.

[4] In contrast, the enablement requirement requires that the specification teach one of skill in the art how to make and use the claimed invention as of the date that the patent application was first filed. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999).

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

DATED: September 13, 2007

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

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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.

/s/ *Thomas F. Fleming*
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