Preliminary Amendment, Amgen cancelled those claims, amended two of the remaining claims, and added a new "product-by-process" claim.[31] None of these remaining pending claims were limited to "human" EPO.

Although there is no record evidence as to why Amgen changed the claims from straight product claims to a product-by-process claim and then back again, there can be no dispute that when Amgen made the Third Preliminary Amendment at issue here,[32] the pending '080 claims were ***not*** limited to human EPO.

Defendants' argument is also contradicted by Amgen's remarks accompanying its amendment, which expressly indicated that its amended '080 claims were distinguished from the issued '933 claims because its amended '080 claims were directed to EPO having the "mature ***human*** erythropoietin sequence of Figure 6."[33]

All of the record evidence indicates that Amgen amended its '080 claims to limit them to human EPO so as to avoid any potential double-patenting problem with its then recently-issued '933 patent claims. There is no evidence that Amgen's amendment was related in any way whatsoever to 165 human EPO, the "particular equivalent" and "insubstantial substitute" in question here. Consequently, as explained in its motion papers and at the July 28 hearing, Amgen has satisfied the second prong of *Festo* by showing that the rationale underlying its

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[31] *See* December 20, 1995 Second Preliminary Amendment (Trial Ex. 3, Tab 3 at 119-120) (adding "non naturally occurring" to claim 64, changing the dependency of claim 65, and adding claim 68 reciting "A ***non-naturally occurring erythropoietin product*** of the process comprising the steps of: a) growing, under suitable nutrient conditions, host cells transformed or transfected with an isolated DNA sequence encoding the human erythropoietin amino acid sequence set out in FIG. 6 or a fragment thereof; and b) isolating ***an erythropoietin product*** therefrom.") (emphasis added).

[32] *See* Amgen Motion App. Tab C (December 20, 1996 Third Preliminary Amendment) (Trial Ex. 2005) (canceling claims 64-68 and adding new claims 69-75).

[33] *See id.* (emphasis added).

amendment bears "no more than a tangential relation" to the particular 165 amino acid equivalent in question.

During the July hearings, the Court questioned why Amgen's amended '080 claims did not result in impermissible double-patenting over the '933 patent claims.[34] The simple answer is that no double patenting occurred because the two sets of claims are of different scope, thus avoiding "same invention type" double patenting, and "obviousness-type" double patenting was avoided by the filing of a terminal disclaimer so that the '933 and '080 patents expire on the same date. When questioned by the Court, Defendants agreed that their position on this issue is consistent with Amgen's position.[35]

Nevertheless, a brief discussion of double patenting may be helpful. In determining whether double patenting has occurred, the fundamental question is: "Is the same invention being claimed twice?"[36] The same invention cannot be claimed twice because 35 U.S.C. § 101[37] "prevents two patents from issuing on the same invention. . . . By 'same invention,' we mean identical subject matter."[38]

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[34] *See* 7/28/03 Hearing Transcript at p. 172, lines 4-9 and 7/31/03 Hearing Transcript at p. 79, lines 4-13.

[35] *See* 7/31/03 Hearing transcript at p. 80, lines 2-10.

[36] *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970).

[37] "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[38] *In re Vogel*, 422 F.2d at 441. ("Thus, the invention defined by a claim reciting 'halogen' is not the same as that defined by a claim reciting 'chlorine,' because the former is broader than the latter.").

In the context of double patenting, "[a] good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention."[39]

Here, the "same invention" is not claimed in the '080 and '933 patents because, *inter alia*, the '933 claims broadly encompass both human and non-human EPO, whereas the '080 claims are limited to human EPO. Thus, an EPO product could literally infringe the claims of one patent without literally infringing the claims of the other patent. For example, monkey EPO could literally infringe the '933 claims without literally infringing the '080 claims. Consequently, Amgen's '080 claims do not constitute double patenting over the '933 claims.[40]

C. There is "some other reason" suggesting that Amgen could not reasonably be expected to have described the 1-165 amino acid equivalent

Separate and apart from any other reason, Amgen can rebut the *Festo* presumption of estoppel if it shows "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question."[41] The prosecution history reveals that Amgen intended the Figure 6 sequence limitation of the '080 claims to literally cover 165 human EPO. Amgen informed the Patent Office that the inventions described by the amended '080 claims were distinguished from human urinary EPO, not on the basis of the Figure 6 sequence limitation, but rather by the inclusion of glycosylation and source limitations:

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[39] *Id.*

[40] Any potential question relating to "obviousness-type" double patenting was obviated by Amgen's filing of a terminal disclaimer over the '933 patent (*see* Trial Ex. 3 at Tab 5, pp. 153-155). Such a disclaimer does not act as an estoppel or constitute an admission that obviousness-type double patenting had occurred. *See Amgen*, 126 F. Supp. 2d at 161-162 (citing, *inter alia*, *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991)).

[41] *Festo*, 535 U.S. at 740-41.

> "Applicant notes that [the amended '080 claims] all differ in scope from glycoprotein claim 1 of U.S. 5,547,933 in specifying that the claimed subject matter comprises the mature ***human*** erythropoietin sequence of Figure 6. Claim [1 of the '080 patent] (like glycoprotein claim 1 [of the '933 patent]) recites carbohydrate differences in comparison to human urinary erythropoietin and claim [2 of '080] recites a negative limitation with respect to isolation from human urine."[42]

Since the amino acid sequence of human urinary EPO was then known to be the 1-165 amino acid sequence of Figure 6,[43] the only reasonable inference to be drawn from Amgen's contemporaneous explanation is that Amgen did not believe that the sequence limitation in its amended '080 claims excluded EPO compositions having the 1-165 amino acid sequence of Figure 6.[44] Otherwise it would have pointed to the addition of that limitation as yet another difference between human urinary EPO and the inventions claimed in the amended '080 claims.

The fact that this Court subsequently determined that Amgen was mistaken in its construction of the claim term "mature," and construed the scope of Amgen's '080 claims differently than did Amgen, does not obviate the fact that at the time it amended its claims, Amgen's statements to the Patent Office demonstrated its belief that the claims as amended would in fact literally encompass the particular 165 amino acid equivalent in question here.

Amgen submits that its evident belief — later held to be mistaken — that its claims as amended literally covered the 165 human EPO qualifies under the third prong of *Festo* as yet another reason why Amgen could not reasonably be expected to have literally claimed the 165 amino acid "insubstantial substitute." Since Amgen reasonably believed that its amended claims

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[42] Trial Ex. 2005 (December 20, 1996 Third Preliminary Amendment) at 9.

[43] *See, e.g.*, Trial Ex. 53 at 17156.

[44] Indeed, Mr. Borun, the author of the amendment, testified that he believed that the amended claims covered both 165 and 166 amino acid human EPO. *See* Borun Trial Tr. at 2884, line 23 to 2885, line 16.

encompassed the accused equivalent, and expressed that belief to the Patent Office at the time of the amendment, there is no basis to conclude that Amgen could or should have drafted any different claim language to encompass that equivalent.

III. CONCLUSION

The evidence of record shows that the particular equivalent in question was unforeseeable at the time of Dr. Lin's application, that the particular equivalent in question bears no more than a tangential relation to the rationale underlying Amgen's amendment, and that Amgen could not reasonably have been expected to describe or claim the particular equivalent in question. Amgen has therefore rebutted the *Festo* presumption of estoppel under each of the three ways identified in *Festo*. To exclude an "insubstantial substitute" such as Defendants' HMR 4396 erythropoietin product from the coverage of Amgen's '080 claims under the Doctrine of Equivalents would be "beyond a fair interpretation of what was surrendered."[45]

Because Amgen has rebutted the presumption of prosecution history estoppel under *Festo*, this Court should sustain its previous finding and grant Amgen's motion that claims 2-4 of the '080 patent will be infringed by Defendants' HMR 4396 erythropoietin product under the Doctrine of Equivalents.

[45] *Festo*, 535 U.S. at 738.

Dated: August 18, 2003

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CERTIFICATE OF SERVICE

I, Michael R. Gottfried, hereby certify that on August 18, 2003, I caused a copy of the following document:

a) Amgen Inc.'s Post-Hearing Memorandum in Support of its Fed. R. Civ. P. 52(C) Motion that '080 Claims 2-4 are Infringed Under the Doctrine of Equivalents.

to be served upon all counsel of record and in the manner indicated below:

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