EXHIBIT L

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,

Plaintiff,

v.

HOECHST MARION ROUSSEL, INC.
and
TRANSKARYOTIC THERAPIES, INC.,

Defendants.

Civil Action
No. 97-10814-WGY

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

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I. INTRODUCTION

Prosecution history estoppel does not bar Amgen's claims for infringement of its '080 patent under the Doctrine of Equivalents. Amgen "could not reasonably be expected to have described the insubstantial substitute in question," either in its application as originally filed or in any claim amendment. In addition, the rationale underlying Amgen's amendment of its claims — to avoid a double-patenting rejection over the EPO glycoprotein claims in its '933 patent — bears "no more than a tangential relation" to the particular 165 amino acid equivalent in question. Finally, the record demonstrates that Amgen did not intend the sequence amendment to exclude or distinguish over EPO having the 1-165 amino acid sequence of Figure 6 ("165 human EPO"). For all of these reasons, the presumption of estoppel has been rebutted.

During the July 28 hearing, the Court questioned whether Amgen could have amended its '080 claims to expressly recite the 1-165 amino acid sequence of Figure 6.[1] As Amgen's counsel stated at the hearing, the answer to that question is no. When Amgen drafted and filed its patent application, it was unknown and unforeseeable that the human EPO product of example 10 in the patent had 165 amino acids rather than the deduced 166 amino acid sequence shown in Figure 6. Because this fact was unknown in 1984 when the written description of Amgen's specification was drafted and submitted, the specification did not expressly recite an EPO having the 1-165 sequence. As explained more fully in Section II(A) below, the absence of an express description of that specific sequence in Amgen's application made a later claim amendment reciting that specific sequence impermissible.

[1] *See, e.g.*, 7/31/03 Hearing Transcript at p. 81, lines 4-9.

The Court also questioned whether Amgen's amended '080 claims constituted "double patenting" over the EPO glycoprotein claims of the '933 patent.[2] Again, as Amgen's counsel stated at the hearing, the answer is no. Statutory "same invention"-type double patenting is not present when one set of claims can literally be infringed without literally infringing the other set of claims. Here, the '933 claims would literally be infringed by certain EPO compositions, such as monkey EPO, that would not literally infringe the '080 claims. Therefore, as explained more fully in Section II(B) below, Amgen's amended '080 claims did not result in double patenting.

At the date of the amendment, the prosecution history reveals that Amgen intended the sequence limitation to cover human EPO compositions having the 1-165 amino acid sequence. In making the amendment, Amgen stated that other limitations in the '080 claims, rather than the Figure 6 sequence limitation, distinguished its claimed EPO from human urinary EPO, which was then known to have the 1-165 amino acid sequence of Figure 6. For this reason as well, as explained more fully in Section II(C) below, Amgen has rebutted the presumption of estoppel.

Based on hindsight, Defendants argue that Amgen should have drafted different claim language to cover 165 human EPO without reciting or referencing its 1-165 amino acid sequence. At bottom, Defendants' argument merely leads to *Festo*'s rebuttable presumption. The fact that Amgen could have drafted a different, broader claim, yet chose not to do so, creates a rebuttable presumption of estoppel; it does not contradict Amgen's particularized showing that application of that presumption to the accused equivalent in this case is rebutted under one or more of the tests laid down in *Festo*. As the *Festo* Court held, amending a patent claim does not result in an absolute bar to the doctrine of equivalents. Rather, the scope of the estoppel depends

[2] *See, e.g.*, 7/31/03 Hearing Transcript at p. 79, lines 8-13.

on "the inferences that may reasonably be drawn from the amendment."[3] Nothing in the prosecution history supports the inference that by amending the '080 claims to refer to the Figure 6 sequence Amgen surrendered the 1-165 amino acid human EPO equivalent. In fact, the reasonable inferences from the prosecution history establish that the amended claims were intended to cover human EPO compositions having the 1-165 amino acid sequence.

When the Supreme Court's holding in *Festo* is applied in this case, judgment that Amgen has rebutted the presumption of prosecution history estoppel is fully justified. Since Defendants indicated at the hearing that they do not seek to present any further evidence on this issue,[4] this Court should therefore grant Amgen's Rule 52(c) motion.

II. AMGEN HAS REBUTTED THE PRESUMPTION OF ESTOPPEL UNDER THE CORRECT *FESTO* STANDARDS

Defendants' arguments in opposition to Amgen's Rule 52(c) motion are based on an incorrect reading of *Festo* that should be rejected. The Supreme Court in *Festo* set forth at least three separate and independent ways in which a patentee may overcome a presumption of estoppel, not the single standard argued by Defendants.[5] Even if, as Defendants argue, Amgen must show that at the time of the amendment that it "could not reasonably have been expected to have drafted a claim that would have literally encompassed the alleged equivalent," Amgen has made that showing here.

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[3] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722, 737 (2002).

[4] *See* 7/28/03 Hearing Transcript at p. 88, line 23 to p. 89, line 1.

[5] *See, e.g.*, Def's Opp. Mem. at p. 3 (quoting *Festo*, 535 U.S. at 741) and 7/28/03 Hearing Transcript at p. 89.

A. The particular equivalent in question was indisputably not foreseeable at the time of the application

In *Festo*, the Supreme Court held that the presumption of prosecution history estoppel can be rebutted where the equivalent in question was "unforeseeable at the time of the application."[6]

Defendants continue to argue that the Supreme Court's clear instruction "at the time of the application" really means "at the time of the amendment."[7] This assertion simply defies the plain language of the Supreme Court's express holding in *Festo* that the presumption is rebutted where the equivalent was "unforeseeable at the time of the application."[8]

As discussed at the July 28 hearing,[9] the reason foreseeability is judged as of the date of the application, and not at the date of an amendment, stems from the fact that the application date is the point in time when the written description of the invention is fixed. And it is that description — fixed in writing as of the application date — which later limits an applicant in drafting amended claims. When an applicant later seeks to amend its claims during prosecution, the words he must work with are the words that were set forth in the application at its filing date.

As the *Festo* Court stated, "What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue."[10] The applicant

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[6] *Festo*, 535 U.S. at 740.

[7] *See, e.g.*, 7/28/03 Hearing Transcript at pp. 92-93.

[8] *Festo*, 535 U.S. at 740 ("we hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question. . . . There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application. . . .").

[9] *See* 7/28/03 Hearing Transcript at pp. 65-68.

[10] *Festo*, 535 U.S. at 736.

cannot add new written description, whether in the specification or in the claims themselves, to describe a particular equivalent that became foreseeable after the application date but before the date of an amendment. The applicant is constrained by the original written description and drawings that were in the application at the filing date.[11] 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. That is why it is the date of the application, not the date of the amendment, that is the appropriate point in time at which to judge whether the applicant could have foreseen, and therefore could have described, a particular equivalent.[12]

Here, as shown in Amgen's motion and as explained at the July 28 hearing, 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 in Example 10 would contain only the 1-165 amino acid sequence of Figure 6. Defendants do not dispute this fact. Amgen's Rule 52(c) motion can be granted on this ground alone.

The fact that 165 human EPO was not foreseeable at the date of the application, and therefore not literally described in Amgen's specification, also explains why, even under Defendant's test, Amgen could not reasonably have been expected to submit a claim amendment

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[11] *See, e.g.*, M.P.E.P §§ 608.01(g) and (o), 2163(B) and 2163.05-.06.

[12] Defendants' fall-back position, that foreseeability should be judged as of the June 6, 1995 filing date of the '556 application that issued as the '080 patent, should also be rejected. Under 35 U.S.C. § 120, the effective filing date, *i.e.*, "time of the application," for the '556 application is at least as early as the filing date of the last priority application from which it is a direct continuation, *i.e.*, the November 30, 1984 filing date of application Ser. No. 06/675,298 ("An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application. . . . ").

that literally recited that sequence. Although the 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. Where a specification describes a genus of compounds, such as EPO having the sequence of Figure 6 and fragments thereof, a claim reciting a specific single species within that genus (e.g., 1-165) is not supported unless the specification expressly recites that species as the applicant's invention.[13]

Both the Federal Circuit and the Court of Customs and Patent Appeals, its predecessor court, have applied the principle enunciated in *Ruschig* to reject species and sub-genus claims in a number of cases in the chemical and biotechnological arts:

> Simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses. . . . Were we to extend *Ruschig's* metaphor to this case, we would say that it is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail to find the tree is well marked. Wattanasin's preferred embodiments do blaze a trail through the forest; one that runs close by Fujikawa's proposed tree. His application, however, does not direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it."[14]

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[13] *In re Ruschig*, 379 F.2d 990, 994 (C.C.P.A. 1967) ("Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that *naming* is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given enough time, a chemist could name (especially with the aid of a computer) all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed.") (emphasis in original).

[14] *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) (holding that the disclosure of a "C_{1-6} alkyl" chemical genus is insufficient to support a claim limited to "C_3 cycloalkyl"); *see also In re Wako Pure Chem. Indus. Ltd.*, 4 Fed. Appx. 853, 855-57 (Fed. Cir. 2001) (holding that claim limiting a chemical moiety to "3 to 8 carbon atoms" was unsupported by specification's description of seven categories of such moieties, even where one such category encompassed the claimed range); *Bigham v. Godtfredsen*, 857 F.2d 1415 (Fed. Cir. 1988); *Application of Lukach*, 442 F.2d 967, 969-70 (C.C.P.A. 1971); and *Application of Ahlbrecht*, 435 F.2d 908, 911-12 (C.C.P.A. 1971).

This black-letter patent law has also specifically been applied by the PTO's Board of Patent Appeals and Interferences in holding that claims in pending applications directed to specific fragments of a disclosed protein are not supported by a specification disclosing a genus encompassing those fragments. For example, in *Forssmann v. Matsuo*, the patentee sought to rely upon a parent application directed to a 126 amino acid hormone "cardiodilatin" to support a claim to a specific fragment of that protein (the fragment containing amino acids 99-126).

The parent application disclosed that (i) fragments of the peptide could be therapeutically useful; (ii) at least two cleavage methods could be used to prepare such fragments; and (iii) at least 20 such fragments (including the 99-126 fragment). The parent application also included an original claim directed to such fragments.[15]

The *Forssmann* court held that despite this extensive disclosure of the genus of potential peptide fragments, a claim to the 99-126 fragment was not supported by the specification's description of a larger peptide fragment embracing the 28 amino acid sequence of claim 28 because the specification did not provide any direction to that specific fragment nor did it "indicate any recognition by the inventor of this specific sequence."[16]

At the July 28 hearing, Defendants pointed to certain language in Amgen's specification as purportedly providing written support for a claim to 165 human EPO.[17] But the specification only speaks of generic "fragments" of EPO or "DNA sequences encoding part or all of" the EPO sequence. Such references to a genus of fragments or to DNA sequences of different lengths

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[15] *Forssmann v. Matsuo*, 23 U.S.P.Q.2d 1548, 1550 (Bd. Pat. App. & Int. 1992).

[16] *Id.* at 1552. *See also Yamada v. Aggarwal*, 57 U.S.P.Q.2d 2002 (Bd. Pat. App. & Int. 2000).

[17] *See* 7/28/03 Hearing Transcript at p. 98, line 19 to 99, line 2.

cannot constitute "blazemarks" pointing to the particular 165 amino acid EPO equivalent in question here, and therefore could not support a claim specifically to such a species.

Consequently, although Amgen's specification provides written support for broader claims drawn to EPO glycoproteins and generically to fragments,[18] Amgen could not reasonably be expected to have described, or drafted a claim to, an EPO composition having only the 1-165 amino acid sequence of Figure 6, *i.e.*, the "particular equivalent" and "insubstantial substitute" in question here.[19]

Defendants argue that Amgen cannot rebut the presumption of estoppel unless it shows that it could not have drafted a claim that encompasses 165 human EPO. As Amgen has explained, the dispositive issue is not whether Amgen could have drafted ***any*** claim that would cover 165 human EPO. If that were the dispositive issue, the Federal Circuit would not have remanded the issue of rebuttal for decision by this Court. As this Court previously found and the Federal Circuit affirmed, Amgen drafted another claim that encompasses Defendants' 165 amino acid EPO product (claim 1 of the '422 patent). If the only question was whether Amgen could

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[18] *See, e.g., Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1582, fn. 7 (Fed. Cir. 1996) ("[T]he district court confused a claim not supported by the specification, which is not allowable, with a broad claim, which is. Claim 1 was properly rejected because it *recited* an element not supported by Fox's disclosure, i.e., a lockout 'on the stapler.' It does not follow, however, that Fox's disclosure could not support claims sufficiently broad to read on a lockout off of the cartridge. *See, e.g., In re Vickers*, 141 F.2d 522, 525 (C.C.P.A. 1944) ('an applicant . . . is generally allowed claims, when the art permits, *which cover more than the specific embodiment shown.*"). If Fox did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly . . . .") and *Application of Smith*, 458 F.2d 1389, 1395 (C.C.P.A. 1972) ("We see nothing inherently wrong with a particular principle of patentability which under certain circumstances operates to defeat the patentability of a narrow, but not a broader, claim, and, ordinarily, the mere fact that under such a principle a broader claim would pass muster is not a basis for adjusting the principle to render the narrower claim patentable.")

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

have drafted a claim that encompassed 165 human EPO, the Federal Circuit would have held that Amgen had already done so in '422 claim 1 and therefore could not rebut the presumption.

Rather, the relevant inquiry is whether Amgen could have literally claimed mature human EPO having the specific 1-165 amino acid sequence of Figure 6. That is the "particular equivalent" and "insubstantial substitute" to which the Supreme Court's *Festo* standards are directed. As demonstrated above, Amgen could not have claimed that particular equivalent at the time of its amendment. Even though 165 human EPO was inherently produced in Example 10, it was not expressly recited as being Amgen's invention in the '080 patent specification. Moreover, as shown below, simply because Amgen could have sought broader claims that literally "encompassed" 165 human EPO, and did in fact do so in the '422 patent, does not foreclose equivalents to the '080 claims because the amendment was made for an unrelated purpose and did not distinguish 165 human EPO from 166 human EPO.

B. The rationale underlying Amgen's amendment was not related to the particular equivalent in question

Amgen can also rebut the presumption of estoppel by showing that the rationale underlying its amendment bears "no more than a tangential relation to the equivalent in question."[20] As explained in Amgen's motion papers and at the July 28 hearing, Amgen has rebutted the presumption under this second prong of *Festo* because the rationale underlying Amgen's amendment, which was to avoid any double-patenting between its '080 claims and the claims of its then-recently issued '933 patent, was not even tangentially related to the particular "equivalent in question" (HMR 4396, a 165 human EPO product).

Defendants cannot dispute the following facts:

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[20] *Festo*, 535 U.S. at 740.

(1) There was no prior art disclosing the sequence of 165 human EPO, and thus no need for Amgen to distinguish its claims over any such equivalent;[21]

(2) Claim 1 of the '933 patent encompasses both human and non-human EPO,[22] whereas the amended '080 claims are limited to human EPO;

(3) Amgen voluntarily added the limitation "comprises the mature erythropoietin amino acid sequence of Figure 6" to each of the asserted claims of the '080 patent to distinguish those claims from claim 1 of its '933 patent;

(4) Amgen did not make the amendments in response to any rejection, objection, or observation by the patent examiner;[23]

(5) Amgen told the Patent Office that it amended its '080 claims to distinguish those claims from claim 1 of the '933 patent in "specifying that the claimed subject matter [of the new '080 claims] comprises the mature ***human*** erythropoietin sequence of Figure 6";[24]

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[21] As Amgen explained in its remarks accompanying its amendment, to the extent it needed to distinguish prior-art human urinary EPO, it did so by including limitations directed to differences in glycosylation or isolation from human urine. *See* Amgen's Motion App. Tab C (Trial Ex. 2005) (December 20, 1996 Third Preliminary Amendment) at p. 9 ("Claim 69 (like ['933] glycoprotein claim 1) recites carbohydrate differences in comparison to human urinary erythropoietin and claim 70 recites a negative limitation with respect to isolation from human urine.").

[22] *See, e.g.*, Amgen's Motion App. Tab D (Trial Ex. 2035 at col. 10:65-11:2; col. 38:17-21, Figure 5 (disclosing monkey EPO cDNA and amino acid sequences), and Figure 6 (disclosing human EPO genomic DNA and the deduced amino acid sequences)).

[23] *Amgen Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, 126 F. Supp. 2d 69, 135 (D. Mass. 2001), *aff'd in part, vacated in part*, 314 F.3d 1313, 1345 (Fed. Cir. 2003). *See also* 7/31/03 Hearing Transcript at p. 77, lines 1-8.

[24] Amgen's Motion App. Tab C (Trial Ex. 2005) (December 20, 1996 Third Preliminary Amendment) at 9 (emphasis added). *See also* 7/31/03 Hearing Transcript at p. 77.

(6) In doing so, Amgen further explained to the Patent Office that glycosylation and source limitations, not the Figure 6 sequence limitation, distinguished the EPO of its amended '080 claims from human urinary EPO;[25] and

(7) Human urinary EPO has the 1-165 amino acid sequence of Figure 6.[26]

Nevertheless, Defendants argue that Amgen could not have intended its amendment to distinguish the human erythropoietin of the amended '080 claims from the human and non-human erythropoietins of '933 claim 1 because the "original" '080 claims contained the word "human."[27] But that argument is contradicted by the fact that at the time Amgen made its amendment, the pending '080 claims were ***not*** limited to human EPO.

When the application which issued as the '080 patent was filed, it contained 60 claims.[28] None of the originally claimed EPO protein products in that group of 60 was limited to "human" EPO. In a Preliminary Amendment submitted with that application, those original 60 claims were canceled, and new claims 61-67 were added.[29] Some of these new claims (claims 61-63) were directed to "an isolated human erythropoietin glycoprotein product."[30] But in a second

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[25] *See* Amgen's Motion App. Tab C (Trial Ex. 2005) (December 20, 1996 Third Preliminary Amendment) at p. 9.

[26] *See, e.g.,* Trial Ex. 53 (Recny *et al.* (1987)) at 17156 ("Structural characterization of natural human urinary EPO (uEPO) . . . reveals that the urinary hormone is also missing the COOH-terminal Arg^{166} amino acid residue, a modification that remained undetected until now.") Amgen disclosed the Recny *et al.* reference to the Patent Office during prosecution (*see* Trial Ex. 3, Tab 3 at p. 140), and it is cited in the '080 patent disclosure as a reference reviewed by the Examiner. *See* Trial Ex. 3 ('080 patent), p. 8.

[27] *See, e.g.*, Defs. Opp. Br. at 8-9.

[28] *See* Trial Ex. 3, Tab 1 at 99-107.

[29] *See* TKT/HMR App. Tab E (June 6, 1995 Preliminary Amendment).

[30] *Id.*

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

For the Plaintiff, AMGEN INC.

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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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