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

[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).