UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 05-12237 WGY
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.	)	
	)	

AMGEN INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT AMGEN IS ESTOPPED FROM ASSERTING INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS OF THE ASSERTED CLAIMS OF THE '698 AND '868 PATENTS

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I. INTRODUCTION

After reading Roche's latest addition to its towering stack of summary judgment motions, it is clear that Roche did not save the best for last. Ignoring this Court's claim construction order and the Federal Circuit's prior decisions in *Amgen v. Hoechst Marion Roussel*, Roche scrapes together the bizarre argument that the scope of equivalents for the asserted claims of the '698 and '868 patents is somehow narrower than the scope of the claims as literally construed by the Court. Roche contends that Amgen is estopped from contending that the claims of the '698 patent "capture a 'process for the production of glycosylated erythropoietin polypeptides' other than the 166 amino acid residue [sequence] set forth on Figure 6."[1] Similarly, Roche contends that "claim 1 of the '868 patent should be limited to the 166 amino acid sequence of human erythropoietin disclosed by the specification."[2]

Roche's argument is, on its face, inconsistent with the language of the claim and the Court's claim construction order. The Court has construed the term "human erythropoietin" to mean "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine."[3] Nothing in the claim language, specification, or prosecution history defines the term "glycosylated erythropoietin polypeptide" in the asserted claims of the '698 and '868 patents to be more narrowly limited to the production of EPO with 166 amino acids. Under the Court's claim construction, Roche's process literally infringes the claims of the '698 and '868 patents, and Amgen accordingly has moved for summary judgment

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[1] 7/3/07 Memorandum in Support of Defendants' Motion for Summary Judgment that Amgen is Estopped from Asserting Infringement Under the Doctrine of Equivalents of the Asserted Claims of the '698 and '868 Patents ("Memo.") at 2 (Docket No. 625).

[2] Memo. at 6 (Docket No. 625).

[3] 7/3/07 Memorandum and Order ("7/3/07 *Markman* Order") at 15 (Docket No. 613).

of infringement. By arguing estoppel under the doctrine of equivalents, Roche is simply attempting to confuse the application of the Court's claim constructions.

Roche claims that the Federal Circuit's prior prosecution history estoppel ruling regarding the limitation "mature erythropoietin amino acid sequence of FIG. 6" in the '080 patent applies equally to the '698 and '868 patents. But Roche improperly ignores that the '698 and '868 process patents contain very different claim language than the '080 patent, and different prosecution histories. In fact, this Court previously held, and the Federal Circuit affirmed, that the glycosylated EPO polypeptide produced by the processes of the '698 claims were ***not*** limited to EPO with 166 amino acids. Consequently, there is no basis for determining that prosecution history estoppel applies to limit the equivalents of the '698 and '868 claims to EPO having 166 amino acids.

Roche also has failed to show that the identified claim limitations were added to narrow the claims. Roche's cherry-picking of a hodge-podge of claims and amendments from the complicated prosecution histories fails to make the showing necessary to invoke the presumption of prosecution history estoppel. Roche's motion for summary judgment that Amgen is estopped from asserting infringement under the doctrine of equivalents for the asserted claims of the '698 and '868 patents should therefore be denied.

II. ROCHE'S MOTION FOR SUMMARY JUDGMENT OF PROSECUTION HISTORY ESTOPPEL SHOULD BE DENIED.[4]

A. PROSECUTION HISTORY ESTOPPEL

"[P]rosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent."[5] "Estoppel

[4] Amgen specifically addresses the "undisputed" material facts in 7/3/07 Roche's Rule 56.1 Statement (Docket No. 626) in its Response to Roche's Rule 56.1 Statement filed concurrently with this opposition.

arises when an amendment is made to secure the patent and the amendment narrows the patent's scope."[6] The burden is on the patentee to establish that the reason for the amendment was unrelated to patentability.[7] "If the patentee fails to meet this burden, the court must presume that the patentee had a substantial reason related to patentability for including the limiting element added by amendment."[8] Even if the amendment were related to patentability, the patentee may nevertheless rebut the presumption of estoppel by establishing that "one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."[9] The patentee rebuts the presumption of estoppel by "(i) showing that an equivalent was unforeseeable; (ii) demonstrating that the purpose for an amendment was merely tangential to the alleged equivalent; or (iii) establishing 'some other reason' that the patentee could not have reasonably been expected to have described the alleged equivalent."[10]

The issue of the doctrine of equivalents is not even reached if there is literal infringement.[11] Prosecution history estoppel is likewise irrelevant to claim construction.[12]

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[5] *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995).

[6] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002).

[7] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, No. 05-1492, 2007 U.S. App. LEXIS 15942, at *20 (Fed. Cir. July 5, 2007) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997)).

[8] *Id.* (internal quotations omitted).

[9] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1312 (Fed. Cir. 2006).

[10] *Id.* at 1310-11; *see also Festo*, 2007 U.S. App. LEXIS 15942, at *20-*21.

[11] *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1571 (Fed. Cir. 1983) ("If there be literal infringement . . . the doctrine [of prosecution history estoppel] is irrelevant.").

[12] *Southwall*, 54 F.3d at 1578 ("The limit on the range of equivalents that may be accorded a claim due to prosecution history estoppel is simply irrelevant to the interpretation of those claims.").

B. NOTHING ESTOPS AMGEN FROM ASSERTING THAT LIN'S '698 CLAIMS COVER A PROCESS FOR PRODUCING A GLYCOSYLATED EPO POLYPEPTIDE WITH 165 AMINO ACIDS.

1. Roche's estoppel argument ignores critical differences between the '698 claims and the estopped claims of the '080 patent.

Roche argues that Amgen should "be foreclosed from using the doctrine of equivalents to broaden the term 'mature erythropoietin amino acid sequence of FIG. 6' in the claims of the '698 patent to capture a 'process for the production of glycosylated erythropoietin polypeptides' other than the 166 amino acid residue [sequence] set forth in Figure 6."[13] Roche's argument rests on the fact that the phrase "mature erythropoietin amino acid sequence of FIG. 6" also appears in claims 2-4 of the '080 patent. The Federal Circuit in *Amgen IV* held that Amgen was foreclosed under the doctrine of equivalents from asserting that the "mature erythropoietin amino acid sequence of FIG. 6" limitation in claims 2-4 of the '080 patent could cover an EPO product containing 165 amino acids. Therefore, Roche argues, it must follow that "the term 'mature erythropoietin amino acid sequence of FIG. 6' limits Amgen to 'a process for the production of a glycosylated erythropoietin polypeptide' with the 166 amino acid residue set forth by Figure 6."[14]

Roche is wrong because its argument ignores a critical distinction between the claims of the '698 patent and the claims of the '080 patent. A side-by-side comparison of '080 claim 3 and '698 claim 6 illustrates the difference:

[13] Memo. at 2 (Docket No. 625).

[14] Memo. at 12-13 (Docket No. 625).

'080 CLAIM 3	**'698 CLAIM 6**
An isolated erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein **said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6**	"A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, comprising the steps of: (a) growing, under suitable nutrient conditions, **vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6**; and (b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.

In the '080 claims, the term "mature erythropoietin amino acid sequence of Fig. 6" modified the claimed erythropoietin glycoprotein. Since the term was construed to require 166 amino acids, the claimed EPO glycoprotein was therefore limited to 166 amino acids. By contrast, in the '698 claims, the relevant limitation is "**DNA encoding** mature erythropoietin amino acid sequence of Fig. 6." The recited phrase modifies the vertebrate cells used in the claimed process, not the glycosylated EPO polypeptide produced by the process. In other words, the recited cells must contain ***DNA*** encoding 166 amino acids identified in Figure 6 as the "mature erythropoietin amino acid sequence." The recited phrase does not modify the EPO glycoprotein product expressed by the cells. By repeatedly taking and using the phrase "mature erythropoietin amino acid sequence of Fig. 6" out of context from the '698 claims, Roche creates the false impression that the limitations in the '698 and '080 patents are the same, when, in fact, they are not. As shown in Amgen's pending motion for summary judgment of infringement, there is no genuine dispute that Roche uses vertebrate cells comprising ***DNA encoding*** the mature erythropoietin

amino acid sequence of Fig. 6 (i.e., positions +1 through +166) to make its glycosylated EPO polypeptide.[15]

This Court already addressed this very issue and was affirmed by the Federal Circuit in *Amgen Inc. v. Hoechst Marion Roussel*. HMR/TKT argued that the claims of the '698 patent were limited to the production of a 166 amino acid product based on the claim language relied upon by Roche. This Court rejected the argument, explaining:

> HMR/TKT's argument fails to persuade the Court because "the mature erythropoietin amino acid sequence of FIG 6" in the context of the '080 patent refers to the structure of the claimed glycoprotein whereas in the '698 claims it refers to the structure of a DNA in the claims. . . . In the '698 patent, however, the phrase is preceded by "DNA encoding," and thus the primary subject is the DNA whereas in the '080 patent the primary subject is the "erythropoietin glycoprotein" itself.[16]

On appeal, the Federal Circuit affirmed this Court's claim construction with respect to the '698 patent.[17] As this Court had recognized, the principles of *stare decisis* binds this Court to "follow the prior constructions of Amgen's patents adopted or affirmed by the Federal Circuit."[18] Roche's attempt to re-argue that the '698 claims must be construed, as a matter of law, to be limited to the production of a 166 amino acid EPO polypeptide should be rejected based upon *stare decisis*.

Moreover, in the context of '422 claim 1, the Court has construed the term "human erythropoietin" to mean a "protein having the amino acid sequence of human EPO, such as the

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[15] *See* 6/14/07 Amgen's Memorandum in Support of Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 at 5 (Docket No. 510); *see also* 6/14/07 Amgen's Statement of Material Facts in Support of Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 at ¶¶ 8-11 (Docket No. 512).

[16] *Amgen Inc. v. Hoechst Marion Roussel, Inc*., 339 F. Supp. 2d 202, 281-82 (D. Mass. 2004), *aff'd in relevant part*, 457 F.3d 1293 (Fed. Cir. 2006).

[17] *Amgen*, 457 F.3d at 1317.

[18] 7/3/07 *Markman* Order at 9 (Docket No. 613).

amino acid sequence of EPO isolated from human urine" and did not limit the term to a 166 amino acid protein. Given the absence of a basis in the intrinsic record to construe the related term "glycosylated erythropoietin polypeptide" in the '698 claims more narrowly than the term "human erythropoietin," Roche's argument is also inconsistent with this Court's claim construction order.

If the '698 claims are not literally limited to a process for producing a 166 amino acid EPO polypeptide, the scope of equivalents obviously cannot be narrower than the literal claim scope, [19] and Roche's motion for summary judgment should be denied.

2. Roche has failed to show that the limitation "DNA encoding the mature erythropoietin amino acid sequence of Fig. 6" was added to narrow the claims to preempt a double-patenting rejection.

An independent basis for denying Roche's motion for summary judgment of estoppel with respect to the '698 claims is the fact that Roche has failed to show that the limitation "DNA encoding the mature erythropoietin amino acid sequence of Fig. 6" was a narrowing amendment made for reasons related to patentability.

Tellingly, Roche tries to gloss over the prosecution history relating to the '698 claims by simply asserting that "the applicant agreed to add the claims which became claims 4 and 6 of the patent to avoid double patenting rejection" and by failing to identify the text of the claims that preceded the claims which issued as '698 claims 4 and 6.[20] A review of the prosecution history, however, reveals that there was no pending rejection to Amgen's claims and that the relevant limitation, "DNA encoding the mature erythropoietin amino acid sequence of Fig. 6" was introduced as part of the introduction of new claims addressed to different subject matter, not as part of a narrowing amendment.

[19] *Cf. Fromson*, 720 F.2d at 1571.

In a June 6, 1995 Preliminary Amendment, Amgen introduced, among other things, claims 68 and 69.[21] Representative claim 68 recited:

> A process for the preparation of a human erythropoietin comprising the steps of:
>
> > (a) growing, under suitable nutrient conditions, host cells which can be propagated *in vitro* outside the cavity of living organism and which upon growth in culture produce in the medium of their growth a human erythropoietin in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay; and
> >
> > (b) isolating said human erythropoietin therefrom.

Prior to receipt of any rejections on these pending claims, an interview was held with the Examiner on December 11, 1996. According to the Interview Summary, "[a]pplicant proposed replacing claims 68 and 69 with claims D and E."[22] The text of claims D and E is identical to issued claims 4 and 6 of the '698 patent. Representative claim E (now '698 claim 6) recited:

> A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, comprising the steps of:
>
> > (a) growing, under suitable nutrient conditions, **v**ertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and
> >
> > (b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.

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[20] Memo. at 8 (Docket No. 625).

[21] Declaration of Katie J.L. Scott in Support of Amgen Inc.'s Opposition to Defendats' Motion for Summary Judgment that Amgen is Estopped From Asserting Infringement Under the Doctrine of Equivalents of the Asserted Claims of the '698 and '868 Patents ("Scott Decl."), Ex. 1 ('698 patent file history, Paper 4, Preliminary Amendment).

[22] 7/3/07 Declaration of Nicole A. Rizzo is Support of Roche's Motion for Summary Judgment that Amgen is Estopped from Asserting Infringement Under the Doctrine of Equivalents of Asserted Claims of the '698 and '868 Patents ("Rizzo Decl."), Ex. 11 ('698 patent file history, Paper 7, 12/11/96 Interview Summary) (Docket No. 627).

Applicant also indicated that an amendment would be made to then-pending claim 62, and that a terminal disclaimer with respect to the '868 patent would be filed.[23] In a Second Preliminary Amendment dated December 20, 1996, pending claims 68 and 69 were cancelled, and a series of new claims, claims 70-75, were added.[24] New claim 70 (claim D) was identical to issued claim 4 of the '698 patent,[25] and new claim 72 (claim E), was identical to issued claim 6 of the '698 patent.

A comparison of cancelled claim 68 and new claim 72 (now '698 claim 6) makes clear that the claims were not narrowed for patentability. Claim 68 was directed to a process for making "human erythropoietin" using cells that produced certain recited amounts of EPO over a period of time. The new claims focused on the production of "glycosylated erythropoietin polypeptde" using cells defined by the presence of "amplified DNA" or "promoter DNA, other than human erythropoietin promoter DNA." The new claims were simply of a different scope based on different types of limitations. They were not "narrowing" amendments. Accordingly, the presumption of prosecution history estoppel does not apply.

C. AMGEN IS NOT ESTOPPED FROM ASSERTING THAT '868 CLAIMS COVER PROCESS FOR PRODUCING GLYCOSYLATED EPO POLYPEPTIDE WITH 165 AMINO ACIDS.

1. Roche's estoppel argument ignores the Court's Claim Construction Order.

Roche's estoppel argument for the '868 patent rests on a construction of "human erythropoietin" that is directly contrary to this Court's construction. Roche asserts that

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[23] *Id.*

[24] Scott Decl., Ex. 2 at 7 ('698 patent file history, Paper 9).

[25] New claim 70 (now '698 claim 4) is identical to claim 72 (now '698 claim 6) with the exception of the term "promoter DNA, other than human erythropoietin promoter DNA, operatively linked to" instead of the term "amplified."

"'[h]uman erythropoietin' as defined by the patent is a 166 amino acid protein"[26] and then funnels this improper construction through selected parts of the prosecution history to arrive at its conclusion that "the '868 patent should be limited to the 166 amino acid sequence of human erythropoietin disclosed by the specification."[27] Stripped of its incorrect construction of "human erythropoietin," Roche's conclusion that the '868 patent is limited to production of a protein with the 166 amino acid sequence falls away.

As Roche recognizes, two potentially relevant changes to the claim language occurred between file claim 65 and what issued as '868 claim 1. First, the language "an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin" was changed to "an isolated DNA sequence encoding human erythropoietin."[28] Second, the term "erythropoietin" was added to the preamble: "A process for the preparation of an *in vivo* biologically active glycosylated ***erythropoietin*** polypeptide comprising the steps of: . . . ."[29]

Neither of Roche's citations to the prosecution history support its view that the process of the '868 patent is limited to making a 166 amino acid protein. The change from a "glycosylated polypeptide" to a "glycosylated ***erythropoietin*** polypeptide" does not alter the plain meaning of those terms or specify a particular number of amino acids that the erythropoietin polypeptide must contain. Moreover, this Court has construed "human erythropoietin" as "[a] protein having

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[26] Memo. at 6 (Docket No. 625).; *see also id.* at 13. Roche's argument is also inconsistent with its own proposed construction for "human erythropoietin," wherein Roche agreed that "human erythropoietin" includes "[a] glycoprotein having the amino acid sequence of erythropoietin isolated from human urine having the structure that would be produced in mammalian cells as of the invention date." *See* 7/3/07 *Markman* Order at 13 (Docket No. 613).

[27] *Id.* at 6; *see also id.* at 13.

[28] Scott Decl., Ex. 3 at 1 ('868 patent file history, Paper 24).

[29] *See* Scott Decl., Ex. 4 at 2 ('868 patent file history, Paper 33).

the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine."[30] Unlike the term "mature erythropoietin amino acid sequence of FIG. 6," there is no basis in the intrinsic record for construing a "glycosylated erythropoietin polypeptide" to be limited to exactly 166 amino acids while construing "human erythropoietin" in a way that includes polypeptides having 165 amino acids.

The removal of the "sufficiently duplicative" language[31] also does not support Roche's contention that the product of the process should be limited to the 166 amino acid protein. This amendment addressed only the DNA sequence of the cells used in the process, not the resulting EPO product itself. Moreover, the term "encoding . . . human erythropoietin" language was already present in file claim 65. So just striking the "sufficiently duplicative" language from file claim 65 did not change the meaning of "human erythropoietin."

Thus, Roche's assertion that the claim was narrowed to "'an isolated DNA sequence encoding human erythropoietin,' which is disclosed by the patent to be 166 amino acids" directly contradicts this Court's claim construction of "human erythropoietin." In both file claim 65 and issued claim 1, "human erythropoietin" has its plain and ordinary meaning as construed by the Court: "[a] protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine."[32] It is not limited to only a 166 amino acid protein. Amgen should therefore not be estopped from asserting that the '868 claims cover a process for producing a glycosylated EPO polypeptide with 165 amino acids.

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[30] 7/3/07 *Markman* Order at 15 (Docket No. 613).

[31] *See* Scott Decl., Ex. 3 ('868 patent file history, Paper 24). The "sufficiently duplicative" language was removed to conform the claim to the pending interference count. *Id.* This language was not altered in response to a rejection by the Examiner, and had been allowed at the time it was amended. *See* Scott Decl., Ex. 5 ('868 patent file history, Paper 16).

[32] 7/3/07 *Markman* Order at 15 (Docket No. 613).

2. Roche's assertion that Amgen should be completely barred from asserting any equivalent to "an isolated DNA encoding human erythropoietin" is contrary to law.

Roche also suggests that Amgen should be completely barred from pursuing infringement by equivalents for the "isolated DNA sequence encoding human erythropoietin" limitation, not just for those equivalents that may have been surrendered.[33] However, that is not the law.[34] Even if the presumption of estoppel is not overcome, estoppel only applies to the scope of the surrender.

As the Supreme Court has made clear:

> [W]hen the court is unable to determine the purpose underlying a narrowing amendment-and hence a rationale for limiting the estoppel to the surrender of particular equivalents-the court should presume that the patentee surrendered all subject matter ***between the broader and the narrower language***.[35]

Thus, any estoppel with respect to equivalents to "an isolated DNA sequence encoding human erythropoietin" must be limited solely to "the territory between the original claim and the amended claim."[36] Given that the language "an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin" was changed to "an isolated DNA sequence encoding human

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[33] Memo. at 13-14 (Docket No. 625).

[34] *See Festo*, 535 U.S. at 737-38 ("Though prosecution history estoppel can bar a patentee from challenging a wide range of alleged equivalents made or distributed by competitors, its reach requires an examination of the subject matter surrendered by the narrowing amendment. The complete bar avoids this inquiry by establishing a per se rule; but that approach is inconsistent with the purpose of applying the estoppel in the first place-to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment.").

[35] *Id.* at 740.

[36] *Id.*

erythropoietin,"[37] the only subject matter potentially surrendered by this amendment was the difference between DNA sequences that encode "human erythropoietin," and DNA sequences that encode polypeptides "having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin" to perform the biological function of EPO. Roche's request for a complete bar to any equivalents to "an isolated DNA sequence encoding human erythropoietin" is far too broad as a matter of law.[38]

Moreover, aside from being overly broad, the relief sought is entirely irrelevant under the Court's current claim construction. The Court construed the limitation "cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin" to mean "cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions."[39] Roche's cells certainly contain the "genetic instructions for human erythropoietin" because they contain the DNA encoding the mature erythropoietin amino acid sequence of Fig. 6 (i.e., positions +1 through +166).[40] Thus, because Roche literally infringes this claim limitation, the doctrine of equivalents will be unnecessary and Roche's current arguments regarding estoppel will be moot.[41]

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[37] *Compare* Rizzo Decl., Ex. 9 ('868 patent file history, Paper 8) *with* Scott Decl., Ex. 3 ('868 patent file history, Paper 24).

[38] For example, such a broad estoppel would also preclude equivalents to the "isolated" limitation even though that term was not affected by the amendment in question.

[39] 7/3/07 *Markman* Order at 30 (Docket No. 613).

[40] *See* 6/14/07 Amgen's Memorandum in Support of Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 at 5 (Docket No. 510); *see also* 6/14/07 Amgen's Separate Statement of Undisputed Material Facts in Support of Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 at ¶¶ 8-11 (Docket No. 512).

[41] Amgen does not expect it will need to press at trial a claim of infringement under the doctrine of equivalents for the asserted claims of the '868 and '698 patents if the Court's current claim

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Respectfully submitted,

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construction rulings remain in force.

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