UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT CLAIM 1 OF U.S. PATENT NO. 5,995,422 IS INVALID FOR INDEFINITENESS AND LACK OF WRITTEN DESCRIPTION, AND DEFENDANTS' OPPOSITION TO AMGEN'S ALTERNATIVE MOTION TO STRIKE

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Dated: Boston, Massachusetts
July 31, 2007

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STATUTES

Defendants F. Hoffmann-La Roche, Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively "Roche") submit this reply memorandum in further support of their motion for summary judgment that claim 1 of U.S. Patent No. 5,995,422 (the '422 patent) is invalid under 35 U.S.C. § 112 because it is indefinite or violates the written description requirement. Defendants also oppose Amgen's motion to strike.

INTRODUCTION

This Court and the Federal Circuit have held that claim 1 of the '422 patent is a pure product claim "directed to a structural entity not defined or limited by how it was made."[1] Roche's motion raises a seemingly simple question: *how can one tell what the structural entity of the '422 patent claim 1 is* ? Amgen's opposition brief provides no answer. Rather, Amgen suggests one of skill in the art need not know the answer, instead proposing a legally incorrect test for definiteness that "one of skill need only know the source from which the human EPO is obtained in order to know whether he or she practiced the claimed invention."[2] Amgen's test misstates the law because under section 112, the physical attributes of Amgen's "claimed" product must be clearly defined to a person of ordinary skill in the art reading the patent in November 1984.[3] The structural features must be defined because both the prior art and a

[1] *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) ("Amgen II").

[2] Amgen Inc.'s Opposition to Roche's Second Motion for Summary Judgment that Claim 1 of the U.S. Patent No. 5,995,422 is Invalid for Indefiniteness and Lack of Written Description, or Alternatively, Amgen's Motion to Strike ("Amgen Opp.") at 9 (D.N. 711).

[3] *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1973) ("The function of the description requirement is to ensure that the inventor had possession, *as of the filing date of the application relied on*, of the specific subject matter later claimed by him; how the specification accomplishes this is not material.") (emphasis added).

competitor's products must be compared against the physical elements of the product recited in the claim to determine patentability[4] and infringement, respectively.

It is obvious why Amgen avoids making any definitive statement about structural attributes imparted by the source limitation in the '422 patent claim 1. First, if Amgen were to define a limitation on structure it would have to prove that element is present in Roche's product for infringement. Second, the limitation would have to distinguish all prior art human erythropoietin in all of its various forms. There is no clear structural feature recited in the claim or disclosed in the specification that can accomplish either of these requirements. Furthermore, Amgen cannot point to glycosylation differences because it is collaterally estopped by prior rulings of this Court from arguing that glycosylation differing from that of human urinary erythropoietin is a definite claim element.[5]

Amgen's dilemma is that it cannot argue that the "source" limitation imparts structural limitations to human erythropoietin, already construed by this Court as just the amino acid sequence of human erythropoietin, in such a way as to distinguish prior art while still preserving its current infringement argument. Instead of explaining the physical attributes of the claimed structural entity, or admitting that there are none beyond the amino acid sequence (and possibly glycosylation), Amgen points to alleged differences between "recombinant and urinary erythropoietin" that are not the result of glycosylation and were not known in 1984. Conveniently, Amgen argues as though claim 1 of the '422 patent were limited to "recombinant"

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[4] *See*, *e.g.*, *In re McDaniel*, 293 F.3d 1379, 1385-86 (Fed. Cir. 2002) (quoting *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("It is well settled that anticipation is the epitome of obviousness.").

[5] *See Amgen v. Hoescht Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 156-157 (D. Mass. 2001), *aff'd* by, 314 F.3d 1313, 1342 (Fed. Cir. 2003) ("HMR").

human EPO. The claim has no such limitation and characteristics of "recombinant EPO" cannot be read into the claims. If, as Amgen argues, the general characteristics of commercial recombinant EPO that distinguish the prior art are limitations on the claim, those characteristics need to be present in CERA to establish infringement, and they are not. Amgen apparently cannot explain how the claims it drafted can simultaneously meet all the requirements of patentablity if read as broadly as Amgen urges in an attempt to entrap Roche's novel product.

At bottom Amgen has failed to come forward with any evidence that a person of skill in the art reading the specification in November 1984 would be able to determine the metes and bounds of the '422 patent claim 1 so as to determine whether a given structural entity falls within the scope of the claim. Therefore the Court should grant Roche's motion for summary judgment that the '422 patent claim 1 is invalid for indefiniteness and lack of written description.

Amgen's motion in the alternative that Roche should have combined all of its summary judgment motions into a single brief should be denied. In arguing against the application of collateral estoppel Amgen says the indefinite claims of the '933 patent are unrelated to the '422 patent because each claim has distinct limitations. As discussed below, under Amgen's interpretation of the claims, the limitations are not distinct. But if they are somehow seen to be distinct, there is no reason Roche's motions for lack of written description and indefiniteness of the '422 patent and the '933 patent must be decided wholesale in a single motion.

ARGUMENT

A. Amgen Uses the Phrase "*wherein said erythropoietin is purified from mammalian* cells *grown in culture*" as a Surrogate for "*having glycosylation that differs from that of human urinary erythropoietin*".

In its opposition brief Amgen takes the position that it is wrong to draw an analogy between the invalid claims of the '933 patent and claim 1 of the '422 patent because the '422 patent claim does not include the phrase "having glycosylation that differs from that of human

urinary erythropoietin".[6] While it is true that the '422 patent does not use that exact language, Roche's argument is still appropriate because "having glycosylation that differs" is implicit in the "purified from mammalian cells grown in culture" limitation of the '422 patent, as interpreted by Amgen. The chart below shows the elements of the patent claims have a high degree of overlap.

'933 Patent Claims Previously Invalidated For Indefiniteness	'422 Patent Claim 1 in the Instant Motion for Summary Judgment
A pharmaceutical composition comprising	A pharmaceutical composition comprising
an effective amount effective for erythropoietin therapy of a	a therapeutically effective amount of
non-naturally occurring	
erythropoietin glycoprotein product	human erythropoietin
having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells	
and having glycosylation which differs from that of human urinary erythropoietin	wherein said erythropoietin is purified from mammalian cells grown in culture
and a pharmaceutically acceptable diluent, adjuvant or carrier.	and a pharmaceutically acceptable diluent, adjuvant or carrier,

While Amgen now seeks to disavow the position that "wherein said erythropoietin is purified from mammalian cells grown in culture" imparts a structural limitation on the claim based on glycosylation, this is exactly the position that Amgen has taken in the past.[7] For example, Amgen has argued in its claim construction brief that the source limitation "defines the

[6] Amgen Opp. at 3 (D.N. 711).

[7] Amgen Opp. at 7 n.7 (D.N. 711)

carbohydrate structures, (i.e. glycosylation) that may be attached to the sequence of amino acid residues that constitute human erythropoietin."[8] Amgen's expert on glycosylation, Dr. Varki submitted an expert report in this case that states with regard to the '933 and '422 patents that

> It is my opinion that the process and **source limitations confer specific structures** to the claimed products and that those specific compositions are different from the structure of the EPO that was purified from human urine before Dr. Lin made his invention (emphasis added)[9]

Dr. Varki further states that in his opinion, glycosylation differences can be imparted to recombinant human erythropoietin as result of the source limitation "purified from mammalian cells grown in culture" and summarizes the differences in six bullet points.[10] Dr. Varki also testified at his deposition that "the differences are related to things that are components of the glycans that are attached to the polypeptide. **That is the way of summarizing all of the difference I looked at**. So everything beyond the glyco -- peptide -- polypeptide itself."[11] Dr. Varki apparently intends to offer these opinions at trial to distinguish prior art human urinary erythropoietin from the structures of '422 patent claim 1 based on differences in glycosylation. Thus, Amgen undeniably uses the phrase "wherein said erythropoietin is purified from mammalian cells grown in culture" as a substitute or surrogate for "having glycosylation that differs from that of human urinary erythropoietin." The Federal Circuit has already determined that comparisons between the prior art urinary EPO and a claimed product based on

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[8] Amgen Inc.'s Response to Defendants' Claim Construction Brief at 7 (D.N. 323).

[9] Declaration of Jennifer R. Moore in Support of Reply Memorandum in Further Support of Defendants' Motion for Summary Judgment that Claim 1 of U.S. Patent No. 5,995,422 is Invalid for Indefiniteness and Lack of Written Description, and Defendants' Opposition to Amgen's Alternative Motion to Strike ("Moore Decl."), filed herewith, Ex. A at ¶ 10

[10] *Id*. at ¶ 25.

[11] Moore Decl., Ex. B at 208:21-209:1 (emphasis added)

glycosylation differences are indefinite.[12] Given the interpretation of the source limitation "purified from mammalian cells grown in culture" that Amgen advances here, this Court can and should hold the '422 patent claim 1 is also invalid as a matter of law.

B. Preclusion Applies When The Same Factual Issue Has Already Been Decided

Amgen's argument that there is no preclusive effect to this Court and the Federal Circuit's prior determination concerning whether glycosylation differences could serve as a basis to distinguish Amgen's claimed EPO products from naturally occurring EPO is unavailing. For issue preclusion to apply, the following requirements must be met: (1) both proceedings involved the same issue of law or fact; (2) the parties actually litigated the issue in the prior proceeding; (3) the first court actually resolved the issue in a final and binding judgment; and (4) its resolution of that issue of law or fact was essential to its judgment.[13] Amgen does not dispute that the latter three elements apply but argues that the first requirement is not met because a different claim term was involved in the prior determination.

Amgen's suggestion that preclusion cannot apply merely because the claim term at issue here is different from the one relating to the previous judgment ("glycosylation which differs...") has no support in the law. Contrary to Amgen, collateral estoppel or issue preclusion may apply to claims of a patent not litigated in the prior determination. Two patent claims should never have exactly the same language which is why "[i]t is the issues litigated, not the specific claims around which the issues were framed, that is determinative."[14] As the Federal Circuit has noted,

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[12] *HMR*, 314 F.3d at 1342 (Fed. Cir. 2003).

[13] *Global Naps, Inc. v. Mass. Dept. of Telecomm. and Energy,* 427 F.3d 34, 44 (1st Cir. 2005).

[14] *Westwood Chem., Inc. v. U. S.*, 525 F.2d 1367, 1372, 207 Ct. Cl. 791 (1975). The Federal Circuit has expressly adopted the decisions of its predecessor courts including the United States Court of Claims and the United States Court of Customs and Patent Appeals, as binding precedent. South Corp. v. United States, 690 F. 2d 1368 (Fed. Cir. 1982).

"in determining the applicability of the estoppel, the first consideration is 'whether the issue of invalidity common to each action is substantially identical.'"[15]

Regardless of which particular claim or claim term was involved in this Court's prior adjudication, the issue was precisely the same as the one presented by the term "purified from mammalian cells grown in culture" -- whether one can distinguish claimed EPO products from unclaimed EPO on the basis of structure. To meet the limitation "purified from mammalian cells grown in culture" of the '422 patent a product must be determined to have novel and non-obvious structural characteristics in terms of glycosylation. The Court and the Federal Circuit has already held that such a determination is not possible and that Amgen's claimed EPO cannot be distinguished from prior art EPO in terms of glycosylation because there is no reliable standard for comparison. Thus, Amgen is precluded from relitigating this issue and the '422 patent must be invalid under § 112.

C. Human Erythropoeitin Is Defined By Amino Acid Sequence and Nothing Else

This Court has construed '422 patent claim 1 "*human erythropoietin"* as "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine."[16] This Court expressly rejected Roche's construction which

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[15] *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1136 (Fed. Cir. 1985); *Carter-Wallace, Inc. v. United States*, 496 F.2d 535, 538, 204 Ct. Cl. 341, 182 USPQ 172, 175 (1974).

[16] This Court did not indicate what it considered the amino acid sequence of human EPO to be or where to locate this information. However, immediately before construing "human erythropoietin", this Court cited the en banc decision of the Federal Circuit in *Phillips* which holds that claims should be interpreted as having the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). From this Roche takes it that this Court was leaving open the determination as a question of fact for the jury, the decision as to what the amino acid sequence was thought to be by those of skill in the art in 1984. Certainly if a new protein were discovered tomorrow that people named human erythropoietin, it could not govern the scope of the claims.

included reference to human erythropoietin being a "glycoprotein" and having "structure that would be produced in mammalian cells as of the invention date." In its written opinion explaining its claim construction the Court found by implication from the specification that "additional molecules are not part of the amino acid structure that comprises the claimed product". [17]

Amgen interprets the Court's Order concerning "human erythropoietin" to encompass ***both*** a protein having a sequence of amino acid residues ***and*** all products produced by the action of chemicals or enzymes on those amino acid residues, regardless of whether a residue has been changed.[18] Amgen's interpretation is an apparent effort to create a make-weight argument to bolster its infringement position. Predictably, Amgen argued in its reply brief on its summary judgment motion for infringement that the amino acid sequence is "the only relevant inquiry based upon the Court's claim construction" and that "the Court's claim construction of "human erythropoietin is a structural definition that does not limit the scope of the claim based upon functional characteristics."[19]

However, as defined, the claimed product is not distinct from endogenous human EPO circulating in the human body, human EPO isolated from human urine by Miyake et al. and used in animal and human trials by Drs. Goldwasser and Baron; or the human EPO produced by human tumor cells grown in culture. The claim phrases "therapeutically effective amount"; and "pharmaceutical composition comprising . . . pharmaceutically acceptable diluent, adjuvant or

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[17] Memorandum and Order dated July 3, 2007 ("Markman Order") at 14 (D.N. 613).

[18] Amgen Inc.'s Reply in Support of Its Motion for Summary Judgment on Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 at 8 ("[P]egylation creates a new bond between EPO and PEG that displaces a hydrogen atom to form the bond.") (D.N. 664).

[19] *Id.* (D.N. 664)

carrier" as defined by the Court fail to distinguish prior art.[20] This leaves Amgen with only the language "wherein said erythropoeitin is purified from mammalian cells in culture" to distinguish the claimed product from the numerous prior art forms of human erythropoietin. Amgen's predicament undoubtedly explains its determined efforts to persuade the Court that source limitations can define structure[21] "where such limitations are the best means to distinguish a claimed product over the prior art"

Given that the claim is directed to a structural entity defined only as an amino acid sequence, the structural limitations that are imparted by the source, if there are any, would have to be evident from the specification.[22] Moreover, the source limitation must impart limitations on the amino acid sequence of human erythropoietin because under both this Court's claim construction and Amgen's infringement theory, the only claimed feature of human erythropoietin is the amino acid sequence. In short, if the only thing that matters for infringement is the amino acid sequence, then the source limitation must impart structural limitations to the amino acid sequence to distinguish prior art and have relevance. Since Amgen has not come forward with

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[20] Declaration of Keith E. Toms in Support of Defendants' Opposition to Amgen's Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6, Ex. 117, Goldwasser Tr. 210-213 (D.N. 593).

[21] Markman Order at 18 (citing *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973)) (D.N. 613).

[22] *See Smithkline Beecham v. Apotex*, Civ. Action No. 99-CV-2926, U.S. Dist. LEXIS 25275 at *1, *20, *26-27 (E. D. Pa. Dec. 20, 2002) ("[W]e decline to recognize product properties that are not required by the patent claims or specification"; "In our view, [patentee] may not use process claims to define its product based on distinguishing characteristics identified after the fact."). (citing *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1433 (Fed. Cir. 1988)*; McCarty v. Lehigh Valley R. Co.,* 160 U.S. 110, 116, 16 S. Ct. 240, 242-43, 40 L. Ed. 358, 1895 Dec. Comm'r Pat. 721 (1895) ("We know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim, in order to limit such claim and avoid a defense of anticipation, we should never know where to stop.").

any evidence that a person of ordinary skill in the art in 1984 could determine any implicit physical limitation of the claimed structural entity from the claim language or the written description, the claim is invalid under section 112.

Moreover, the source limitation must impart limitations on the amino acid sequence of human erythropoietin because under the Court's claim construction, and Amgen's infringement theory the only claimed feature of human erythropoietin is the amino acid sequence. To draw an analogy, a claim to "a car purchased from the Ford Motor Company" would be anticipated by a prior art "car purchased from General Motors" unless the cars purchased from Ford are physically different than cars purchased from GM. If a car is defined only as a four-wheeled vehicle having an engine, then the fact that Fords have different paint colors than GM is not a basis to avoid anticipation. If prior art GM cars are truly excluded it must be possible to determine how a car purchased from Ford is physically different, otherwise the claim is indefinite.

Here, Amgen has not come forward with any evidence that a person of ordinary skill in the art in 1984 could ascertain the structural limits of the product claimed by '422 claim based on either the claim language or the patent specification. In fact, given Amgen's position that each mammalian cell can produce a different EPO structure that can be further varied by cell culture conditions,[23] which can be even further altered by chemical or enzymatic means after being purified from mammalian cells,[24] the potential structures encompassed by this claim would be limitless and the claim itself legally indefinite.[25]

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[23] Moore Decl., Ex. C at ¶¶ 36-42, 239.

[24] *Id.*

[25] Amgen Inc.'s Response to Defendants' Claim Construction Brief at 5-7 (D.N. 323).

The *Genentech v. Wellcome*[26] case is particularly instructive on the issues of claim construction, validity, and infringement of a patent directed to a protein. In the *Genentech* case the Court was called on to construe the claim term "human tissue plasminogen activator." Human tissue plasminogen activator or "t-PA"] PA is a human protein the gene for which was cloned shortly before EPO was cloned. The patentee Genentech argued that the protein should be defined functionally or to allow permutations of the natural amino acid sequence. The Federal Circuit considered the argued constructions "hopelessly overbroad" and held that they would lack enablement if adopted. The Court explained that "there may also be a problem with satisfaction of the definiteness and description requirements of *35 U.S.C. § 112* in relation to these other definitions, especially the fourth functional definition ... would give rise to a definiteness problem because a competitor could not then reasonably determine what DNA sequences are within the scope of the claims and which are not."[27] Similarly, "human erythropoietin" as construed here is indefinite.

Amgen asserts that the "exclusionary powers" of claim 1 extends "only to compositions that contain EPO that has been purified from mammalian cells grown in culture."[28] Amgen's position is legally flawed. Imagine two competitors having the exact same product, one purified from a mammalian cell grown culture and the other purified from a non-mammalian cell grown culture. Since the products are identical, either both of these competitors infringe or neither one infringes Amgen's claim. Yet Amgen's view would lead to the absurd result that one competitor infringes the product claim while the other competitor with a structurally identical

[26] 29 F.3d 1555 (Fed. Cir. 1994).

[27] *Id*. at 1565 n.25.

[28] Moore Decl., Ex. F at ¶ 134, Ex. G.

product does not. This is not how infringement of a product claim is determined. The analysis is properly conducted by comparing the physical attributes of a product against the physical elements of the claim as set forth by the terms of the claim.[29] Just as a pure source limitation cannot distinguish prior art structures, a source limitation cannot be the reason that one product infringes and the identical product does not infringe.[30]

To this day Amgen and its expert's are still unable to provide a description of the physical structural elements of human erythropoietin . . . purified from mammalian cells grown in culture" that distinguish the claimed substances from the human erythropoietin in the prior art. Certainly a person of skill in the art in 1984 could not have been put on fair notice of the metes and bounds of the claim or of what Dr. Lin considered to be his invention. Therefore the Court should find the claim is invalid for indefiniteness and lack of written description.

D. '422 Patent Claim 1 Is Not Limited To Recombinant Erythropoietin

Claim 1 of the '422 patent is simply directed to "human erythropoietin" purified from "mammalian host cells grown in culture." There is no requirement that the protein be produced by recombinant techniques. Nor does the claims specify any particular host cell or growth conditions. As drafted, the claim encompasses *any* mammalian host cell and *any* growth conditions. The enormous number of potential structures coupled with the unpredictability in the art look to the conclusion the claims are indefinite and lack written description.[31] As such,

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[29] *Amgen v. Hoechst* 126 F. Supp.2d 69, 101-102 (D. Mass 2001) (comparing product patents to process claims).

[30] *Scripps Clin. & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1390 (N>D. Cal. 1987), *aff'd in part by*, 927 F.2d 1565 (Fed. Cir. 1991) ("Human factor VIII:C as claimed in the [product claims] therefore applies to any Factor VIII:C preparation, *regardless of how produced, having the same material structural and functional characteristics* as the plasma-derived preparation.") (emphasis added).

[31] *Genentech*, 29 F.3d at 1565 n.25.

Amgen's efforts to distinguish the claimed product based on properties that are purportedly unique to EPO produced recombinantly, are entirely misplaced.

Amgen points to the specification disclosure that EPO would be free of pyrogens, "by virtue of their production by recombinant methods" as a source of distinction. Whether or not this would be true of recombinantly produced EPO is irrelevant since the '422 claims are not so limited. Similarly, the purported "additional evidence" "now available" distinguishing Dr. Lin's claimed products from urinary EPO based on "charge and sulfation[32]" and "differences between recombinant and urinary erythropoietin, such as "specific activity" and "the way the molecules of each are folded." are simply irrelevant given the scope of claim 1.

Moreover, none of these later discovered purported differences is disclosed in the specification and none would be recognized as limiting the claim as of 1984. Amgen admits that the tests on recombinant EPO have been recently developed and are only "now available" as a result of doping in sports. Amgen makes no effort to show these tests would have given definiteness to the claim as understood by a person of skill in the art in 1984. Apparently Amgen hopes to avoid collateral estoppel by implying that it could not have disclosed these differences in the specification. However, this just another apparent contradiction by Amgen since it argues in context of distinguishing prior art that IEF was known technique in 1984[33] and these new tests are based on IEF.

Finally, if it is Amgen's position that the product of '422 claim 1 is defined by these purportedly unique characteristics, it is worth noting that Amgen's motion for summary judgment of infringement of '422 patent claim 1 is utterly lacking in any evidence that CERA

[32] Amgen Opp. at 8-9 n. 25. (D.N. 711)

[33] Moore Decl., Ex. C at ¶¶ 101-124.

has required "charge", "specific activity", or conformational "fold." In fact, in arguing infringement Amgen asserts that these characteristics are irrelevant to deciding if a protein satisfies the claim. Amgen cannot have it both ways. Either "charge", "specific activity", "fold" and the like, limit the claimed structures or they do not.[34] That aside, since there is no way a person of skill in the art would be able to apply these characteristics to any given product the claims are indefinite.

E. The '422 Patent Does Not Describe "*human erythropoietin … wherein said erythropoietin is purified from mammalian cells grown in culture*" as interpreted by Amgen

Amgen's opposition brief inaccurately creates the impression that Dr. Lin or Amgen had actual physical possession of human erythropoietin that was purified from mammalian cells grown in culture and that such a product is described in the '422 patent. Amgen goes so far as to say that "Roche does not appear to challenge this immutable truth."[35] The immutable truth is that Amgen did not purify human EPO from mammalian cells grown in culture until at least 1985 and the specification provides no working example of purification or any characterization of a purified product. Amgen's expert Dr. Bradshaw confirmed that there is no indication in the patent that purification was actually carried out by anyone at Amgen.[36] Moreover, the '422 patent only provides a person of skill in the art reading that patent with inaccurate information about the structure of human erythropoietin purified from mammalian cells grown in culture.

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[34] *Scripps*, 927 F.2d at 1583 ("Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.").

[35] Amgen Opp. at 4 (D.N. 711).

[36] Moore Decl., Ex. D at 114:2-21.

The undisputed fact is that the amino acid sequence information in Fig 6 and Table 1 of the patent specification which purportedly describes human erythropoietin is wrong, as are the data on carbohydrate composition and molecular weight of the glycoprotein. Amgen rushed to file a patent specification before it analyzed a purified sample of human erythropoietin protein. It should not be able to rewrite history now to reflect what Amgen wishes had happened rather than what happened in truth.

F. Roche Was Correct to File Separate Motions So That The Court Can Decide On a Clear Record of What the Parties Are Arguing.

The claims of the '933 patent are product-by-process claims.[37] Amgen's desire to treat the '933 patent and the '422 patent together is an attempt to blur the critical distinction between them. Amgen objects that Roche filed three summary judgment motions, each focused on a separate claim element. According to Amgen all of these motions should have been filed together and all on the same grounds.[38] It is hornbook law that the invalidity of each claim be judged individually, each on its own words and form. Roche has complied with local rule 7.1 for all its motions and filed distinct summary judgment motions in an effort to separate out the relevant claim terms for the sake of clarity. Thus Amgen's motion to strike should be denied.

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[37] Moore Decl., Ex. E, AM-ITC 00941166 - 72 at 67-68 ("All product claims in the subject application are now product-by-process claims. . . .These product-by-process claims are presented . . . to further define the product of the subject invention since the recombinant erythropoietin claimed cannot be precisely defined except by the process by which it is produced.").

[38] Amgen Opp. at 15 ("Plainly, Roche should have filed these separate motions together[.]") (D.N. 711)

CONCLUSION

For all of the foregoing reasons, this Court should grant summary judgment in Roche's favor holding all '422 patent claim 1 is invalid, under 35 U.S.C. § 112, for indefiniteness and lack of written description.

Dated: July 31, 2007
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Respectfully submitted,

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By their Attorneys,

/s/ Keith E. Toms

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