UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN INC.'S OPPOSITION TO ROCHE'S SECOND MOTION FOR SUMMARY JUDGMENT THAT CLAIM 1 OF U.S. PATENT NO. 5,995,422 IS INVALID FOR INDEFINITENESS AND LACK OF WRITTEN DESCRIPTION (DOCKET NO. 614), OR ALTERNATIVELY, AMGEN'S MOTION TO STRIKE

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I. INTRODUCTION

Rather than narrowing the issues for trial, Roche's recent spate of motions for summary judgment, filed on July 3, evidence that it is doing everything it can to compound and expand the issues to be heard at the July 17 Hearing and at trial.[1] As discussed in Amgen's oppositions to two of Roche's July 3 motions, both directed to whether Amgen is estopped from asserting infringement under the doctrine of equivalents, Roche simply ignores the fact that its motions conflict with the Court's prior claim constructions and the doctrine of *stare decisis*.[2] Roche's second Motion for Summary Judgment that '422 Claim 1 is Invalid Under § 112 is no better.

In this motion, Roche seeks to extend a previous ruling from the *TKT* case regarding the limitation "having a glycosylation which differs from that of human urinary erythropoietin" to '422 claim 1 despite the fact that this limitation does not appear in the claim. But this is not the first time that Roche has been unconstrained by the claim language. Roche attempts to read this same limitation into `933 claim 3 despite the fact that it does not appear in that claim either. In a nutshell, Roche argues that the Court's should in effect substitute "glycosylation which differs from that of human urinary erythropoietin" for the claim limitation "purified from mammalian cells grown in culture" to render '422 claim 1 invalid as indefinite and inadequately described. Roche's argument, and thus its motion, is merely a rehash and consolidation of assertions made

[1] *See also* Docket No. 449 (Amgen's 5/24/07 Emergency Motion For Expedited Case Management Conference).

[2] For example, the Court has already construed the limitation "DNA encoding the mature amino acid sequence of FIG. 6" and, as set forth in the Court's 7/3/07 Claims Construction Order, this construction acts as *stare decisis* here. (Docket No. 613 at 8-9). Notwithstanding this Order, Roche's motion (directed to whether Amgen is estopped from claiming equivalents under its process claims) (Docket No. 620) assumes a different construction, one that was already considered and rejected by this Court and the Federal Circuit. *See* Amgen's Opposition to Roche's Motion for Summary Judgment that Amgen is Estopped from Asserting Infringement Under DOE of the '868 and '698 Claims, filed concurrently herewith

in two of its other motions for summary judgment of invalidity under 35 U.S.C. § 112.[3]

Roche filed its two related motions seeking to invalidate Amgen's claims under § 112 on June 11 and 14, 2007. In the motion filed June 11 (the "first '422 motion"), Roche moved for summary judgment that '422 claim 1 is invalid under § 112 on the ground that the limitation "human erythropoietin" is not described and indefinite.[4] In the motion filed on June 14 (the "'933 motion"), Roche argued that this Court's finding in the *TKT* litigation that the limitation "glycosylation which differs from human urinary erythropoietin" was indefinite should be applied to the term "non-naturally occurring" in other '933 claims, such as claim 3.[5] Amgen filed its oppositions to both motions on June 29.

Five days later, on July 3, Roche filed the motion that is the subject of this opposition.[6] In this motion (the "second '422 motion"), Roche again seeks summary judgment that '422 claim 1 is invalid under § 112 by attacking the same limitation that was the subject of its first '422 motion ("human erythropoietin," as further modified by the limitation ". . . wherein said erythropoietin is purified from mammalian cells grown in culture"). In support of its motion, Roche relies on the same legal and factual arguments raised in its '933 motion.

The reasons for Roche's second '422 motion are obvious. Having filed its opposition to Amgen's motion for summary determination of the definiteness, enablement and written description of Lin's '422 and '933 claims, Roche seeks yet another vehicle by which to reargue

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[3] In addition to the three Roche motions for summary judgment of invalidity based on § 112 discussed here, Roche has filed two additional summary judgment motions under the same statute (*see* Docket Nos. 473 and 539), bringing the total number of § 112 motions filed by Roche to five.

[4] Docket Nos. 482, 483, 484.

[5] *See* Docket Nos. 505, 506, 508 (Roche's Motion for Summary Judgment that the limitation "non-naturally occurring," as it appears in the '933 Patent claims, are invalid as indefinite or not adequately described on the ground that an ordinarily skilled artisan could not determine what constituted a "naturally occurring" EPO).

[6] Docket Nos. 614, 615, 616.

the substance of its opposition, thereby multiplying the resources, distraction, and effort Amgen and the Court must dedicate to address Roche's filings, while hopefully avoiding summary judgment based on Amgen's motion.[7]

Like its other two motions on the subject, Roche's second '422 motion should be denied. As with Roche's '933 motion, Roche's second '422 motion improperly conflates the definiteness requirement of 35 U.S.C. §112 ¶ 2 with the novelty requirement of §102. Under §112 ¶ 2 the limitations of a patent claim must be "sufficiently precise to permit a potential competitor to determine whether or not he is infringing."[8] Roche's motion is not directed to this standard. Rather, its focus is on whether '422 claim 1 is distinguishable from the prior art based on a single limitation. But whether the claimed invention is distinct over the prior art is a determination made under 35 U.S.C. §102, not § 112. Moreover, that determination is a question of fact that is not particularly susceptible to summary judgment. And it is based on the claimed invention taken as a whole, not on a single limitation such as "human erythropoietin . . . purified from mammalian cells grown in culture."

Roche's attempt to analogize the limitations of '422 claim 1 to the "glycosylation ***which differs from that of human urinary erythropoietin***" limitation of '933 Claim 1 is simply wrong. '933 claim 1 was held indefinite because the specification failed to identify which among many possible urinary EPO preparations provided ***the*** standard for ***comparison***. However, no such comparative standard is required by '422 claim 1. And contrary to Roche's arguments, a finding of invalidity of an unrelated claim based on a distinct limitation cannot properly serve as basis

[7] As set forth below Amgen also moves to strike Roche's motion on the ground that, taken together, Roche's motions seeking summary judgment that '422 claim 1 is invalid under § 112 exceeds the twenty-page limit set by the Court's Local Rules. LR, D. Mass 7.1(b)(4).

[8] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314. F.3d 1313, 1342 (Fed. Cir. 2003) (*Amgen II*) (citation omitted); Roche's Brief at 14-15.

for arguing that Amgen is somehow collaterally estopped from asserting that '422 claim 1 is valid.

Roche's arguments that Dr. Lin's specification does not adequately describe "human erythropoietin . . . purified from mammalian cells grown in culture" are equally flawed. Not only does Dr. Lin's specification plainly describe a human erythropoietin purified from mammalian cells grown in culture, but a skilled artisan reading Lin's disclosure at the time of the invention would readily appreciate that Lin possessed the invention he claimed. Roche does not appear to challenge this immutable truth. Rather, Roche's written description argument begins with the erroneous assumption that Dr. Lin's specification should describe a test for "glycosylation which differs from that of human urinary erythropoietin" in order to describe adequately "human erythropoietin . . . purified from mammalian cells grown in culture." But unlike '933 claim 1, which specifically references "glycosylation which differs from that of human urinary erythropoietin," '422 claim 1 does not contain any such reference and thus there is no statutory requirement that Dr. Lin's specification describe such differences in order to be a valid claim. Regarding its argument that Amgen is collaterally estopped from asserting that '422 claim 1 is adequately described, in addition to different issues being considered, there is no actual affirmed finding that '933 claim 1 was invalid for inadequate written description.[9]

Roche has not shown — and indeed, it cannot show — by clear and convincing evidence that '422 claim 1 is either indefinite or lacks adequate written description. Under these circumstances, Roche's motion should be denied. [10]

[9] The Federal Circuit vacated the District Court's finding of infringement, or in the alternative, inadequate written description, when finding '933 claims 1, 2, and 9 (as it depends on claim 1) indefinite. *Amgen II*, 314 F.3d at 1342.

[10] *See Intel Corp. v. VIA Techs.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003) ("Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence."); *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005)

II. ARGUMENT

A. The limitation "human erythropoietin," as modified by "purified from mammalian cells grown in culture" is not indefinite.[11]

1. A claim is indefinite only if its meaning is insolubly ambiguous.

35 U.S.C. § 112 ¶ 2 requires that claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention" in order to be valid.[12] This requirement is satisfied when one of ordinary skill in the art would "understand the scope of the subject matter that is patented when the claim is read in conjunction with the rest of the specification."[13] The purpose of the definiteness requirement is to "ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude."[14] Claims are considered indefinite only when they are "not amenable to construction or [are] insolubly ambiguous."[15] Claims need not be "plain on their face in order to avoid condemnation for indefiniteness."[16] Rather, a claim is definite so long as it is "amenable to construction, however difficult that task may be."[17] To this end, the amount of

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("[I]nvalidating a claim requires a showing by clear and convincing evidence that the written description requirement has not been satisfied.").

[11] If Roche's Motion is not stricken, *see below*, Amgen incorporates by reference its oppositions to Roche's two earlier filed motions (Docket Nos. 565 and 580) since those oppositions are directed to substantially the same arguments as raised in Roche's current motion.

[12] 35 U.S.C. § 112.

[13] *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1367 (Fed. Cir. 2001).

[14] *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

[15] *Datamize*, 417 F.3d at 1347 (citation omitted).

[16] *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

[17] *Id.; Aero Prods. Int'l v. Intex Rec. Corp.*, 466 F.3d 1000, 1016 (Fed. Cir. 2006) (holding that claim was not indefinite because it was capable of being construed).

detail required of claim language depends on the particular invention[18] and the detail provided by the written description.[19]

In other words, "[i]f the meaning of a claim is discernable, even though the conclusion may be one over which reasonable persons will disagree," a claim will be held not indefinite.[20]

2. Roche fails to show by clear and convincing evidence that '422 claim 1 is insolubly ambiguous.

a. Because one of ordinary skill in the art could readily determine whether an accused recombinant human erythropoietin is purified from mammalian cells grown in culture, '422 claim 1 is not indefinite.

As this Court has held and the Federal Circuit has affirmed, "purified from mammalian cells grown in culture" means "obtained in substantially homogeneous form from the mammalian cells . . . which have been grown in the *in vitro* culture" and limits the source from which the "human erythropoietin" of '422 claim 1 can be obtained.[21] At *Markman*, Roche did not challenge this construction and that construction is set forth in the Court's July 2 Order.

Based on this construction, to assess whether '422 claim 1 reads on the pharmaceutical composition of '422 claim 1, ordinarily skilled artisians need only ask themselves, "where did the human EPO contained in this pharmaceutical composition come from?" No further inquiry as to the meaning of the limitation need be made. It is difficult to imagine how this task, which

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[18] *See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1575-1576 (Fed. Cir. 1986) (holding that the claim language describing a part of a wheelchair to be "so dimensioned" so as to fit through the door of an automobile was definite because the claims were intended to cover the use of the invention in a variety of automobiles and one of ordinary skill would know how to determine the appropriate dimensions).

[19] *See, e.g., Howmedica Osetonics Corp. v. Tranquil Prospects, Ltd.*, 401 F.3d 1367, 1371-72 (Fed. Cir. 2005) (concluding that an ordinary skilled artisan "would readily ascertain from the written description of the patents" the meaning of the disputed term and reversing the district court's finding of indefiniteness).

[20] *Bancorp Services, L.L.C. v. Hartford Life Insurance Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004) (citing *Exxon*, 265 F.3d at 1375).

[21] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp.2d 69, 89 (D. Mass. 2001) (*Amgen*

only requires knowledge of the source from which the human EPO was obtained, can reasonably be said to be anything other than trivial for a person of ordinary skill in the art.

b. Roche's arguments about distinguishing the prior art are not relevant to whether '422 claim 1 is definite.

Roche's arguments are premised on a sleight of hand. Roche urges the Court to assess the written description and definiteness of Claim 1 of the '422 patent by focusing on the phrase "glycosylation which differs from that of human urinary erythropoietin" even though those words appear nowhere in the claim. Roche's through-the-looking-glass argument begins with its premise that the actual claim term – "purified from mammalian cells grown in culture" – is insufficient for § 102 purposes to confer structure to the claimed "human erythropoietin" and that the Court must read in "glycosylation which differs" to preserve the validity of '422 Claim 1. Therefore, says Roche, the sufficiency of Dr. Lin's disclosure for supporting Claim 1 of the'422 patent must be measured against the phrase "glycosylation which differs" and not the actual language of the claim.[22] Roche's argument is flawed for many reasons.

First, Roche's motion is premised on the contention that the only distinction between Dr. Lin's claimed pharmaceutical composition and prior art preparations, as set forth in Dr. Lin's specification, relates to glycosylation differences between recombinant human erythropoietin and human urinary erythropoietin.[23] But this has never been Amgen's position. Each of the asserted

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I); *Amgen II*, 314 F.3d at 1329-1330.

[22] *See* Docket No. 615 at 4-5, 8-12.

[23] *Id*. at 9-10. Roche also erroneously characterizes Amgen's position regarding the limitation "purified from mammalian cells grown in culture" in stating that the limitation "recites structure," as if Amgen, and not Roche, is seeking to redraft '422 claim 1. Amgen does not seek to re-write the claims. Rather, Amgen is acknowledging that the source from which a material comes can confer or impart unique attributes. Docket No. 613 at *citing In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973) and *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006).

claims, considered as a whole, is distinct from the prior art based on multiple grounds, as for example, Dr. Lin's specification describes when distinguishing his claimed pharmaceutical compositions over the prior art. For example, Dr. Lin states that, by virtue of the source from which his claimed compositions are obtained, his products, unlike prior art products, are free of contaminants and inhibitory substances:

> Products of the invention, by virtue of their production by recombinant methods, are expected to be free of pyrogens, natural inhibitory substances, and the like, and are thus likely to provide enhanced overall effectiveness in therapeutic processes vis-à-vis naturally derived products.[24]

Based in part on these identified differences, Amgen argued in the *TKT* litigation that '422 claim 1 was not only patentable over Dr. Goldwasser's urinary preparation based on the limitation "therapeutically effective amount," but also based on differences in the "pharmaceutical composition" conferred by virtue of the "human erythropoietin" being "purified from mammalian cells grown in culture."[25]

Roche's reliance on the expert reports of Drs. Varki and Catlin is equally selective. In their reports, Drs. Varki and Catlin discuss not only compositional differences between urinary EPO and Dr. Lin's claimed products (*i.e.*, the differences in the composition of the sugars), but also structural differences between the two compositions' based on their charge and sulfation.[26] As set forth in Dr. Varki and Dr. Catlin's reports, as a consequence of increasing interest in the

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[24] *See e.g.* Ex. 1 ('933 Patent) at col. 33:39-48; *see also id.* at 12:1-7.

[25] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F.Supp. 2d 202, 335, n. 163 (D. Mass. 2004) (*Amgen III*) (in context of obviousness, recognizing that Amgen presented evidence that '422 claim 1 was patentable over the prior art based on structural and functional differences attributable to the source from which Dr. Lin's products are obtained). As set forth below, in addition to the evidence presented in the TKT litigation, additional evidence is now available that structurally distinguishes Dr. Lin's recombinantly derived EPOs from EPO obtained from human urine.

[26] *See* 6/1/07 Supplemental Expert Report of Ajit Varki, M.D. (Docket No. 507-9, Exhibit D at ¶ 14).

use of recombinant EPO in sports, and in particular doping in the arena of cycling, various tests have been developed and are now available that accurately distinguish between urinary human EPO and recombinant human EPO, based on glycosylation, including differences in charge and sulfation.[27]

Second, even Roche's § 102 argument assumes that structural differences are conferred by virtue of the source limitation "purified from mammalian cells in culture." In other words, simply by obtaining human EPO from the claimed source, an ordinarily skilled artisan would obtain human EPO that necessarily possessed the attendant structural characteristics distinguishing it from naturally occurring EPO. Therefore, even in light of Roche's § 102 argument, the inquiry to discern the metes and bounds of the claim for purposes of definiteness would remain unaffected: 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.

Third, Roche's argument fails even as a § 102 argument. The novelty requirement of § 102 applies to claims as a whole, not to individual limitations.[28] Thus, rather than considering the limitation "human erythropoietin . . . purified from mammalian cells grown in culture" in a vacuum, the whole of '422 claim 1 must be considered. As such, Roche's initial premise — that the only way for Amgen to distinguish '422 claim 1 over the prior art is based on glycosylation differences — is erroneous. But irrespective of Amgen's bases for distinguishing the pharmaceutical compositions of '422 claim 1 from prior art preparations, Roche's prior art argument is simply irrelevant to the issue of whether '422 claim 1 meets the requirements of

[27] Ex. 2 (5/11/07 Varki Report) at ¶¶ 99-124 (regarding use of isoelectric focusing (IEF) analyses to determine whether doping has occurred), and ¶¶ 125-130 (regarding use of IEF to determine sulfation diffrences between uEPO and recombinant EPO). *See generally* Ex. 3 (5/11/07 Catlin Report) at ¶¶ 19-69.

[28] *See e.g.*, *Hakim v. Cannon Advent Group, PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 2007) (a claim is anticipated when "all of the elements and limitations of the claim are described in a single prior art reference") (citation omitted).

§ 112 ¶ 2.[29] All that is required for a claim limitation to be definite under § 112 ¶ 2 is that it "give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe."[30] As discussed above, "human erythropoietin . . . purified from mammalian cells grown in culture" readily gives notice to the public that '422 claim 1's exclusionary powers extend only to compositions that contain EPO that has been purified from mammalian cells grown in culture.

In any event, Roche's suggestion that Amgen must establish that the glycosylation of all possible recombinant human EPOs differ from the glycosylation of all possible natural source human EPOs is simply false. The legally relevant comparison is with the prior art and it is Roche's burden, not Amgen's, to prove that the prior art anticipated Dr. Lin's claimed invention.[31]

Finally, even if the source limitation of '422 claim 1 were the only basis for distinguishing the claimed compositions from prior art preparations, the record, considered as a whole, is replete with evidence that the claimed pharmaceutical compositions of '422 claim 1 are structurally distinct from prior art EPOs. For example, as Dr. Goldwasser testified at length at deposition in this matter, experiments reported in a paper published in 1997[32] demonstrate

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[29] *See* Roche's Brief at 1-3, 7-8, 15-16.

[30] *Default Proof Credit Card System, Inc. v. Home Depo U.S.A., Inc.*, 412 F.3d 1291, 1302-03 (Fed. Cir. 2005).

[31] Roche's note that Dr. Varki fails to opine on the differences between EPOs purportedly produced in human tumor cells grown in culture and the human erythropoietin in the compositions claimed in '422 claim 1(Docket No. 615 at 11) is likewise misleading. As Dr. Varki testified at his deposition, he was never asked to even consider the issue since Roche's experts did not offer any opinion on it. Ex. 4 at Varki Depo. Tr. at 278-280.

[32] 6/29/07 Bier Declaration in Support of Amgen's Opposition to Roche's Motion for Summary Judgment regarding the asserted '933 claims (Docket No. 582) at Ex. 2 (2/26/07 Goldwasser Tr. at 468:10-469:8); *id.* at Ex. 3 (C. Kung and E. Goldwasser, "A Probable Conformational

numerous other differences between recombinant and urinary erythropoietin.[33] These differences, including accessibility to iodination,[34] inactivation by iodination,[35] trypsin inactivation,[36] specific activity,[37] and circular dichroism,[38] all indicate that recombinant and urinary erythropoietin differ conformationally, *i.e.*, in the way the molecules of each are folded, a structural difference.[39] Under these circumstances, even if Roche had moved for summary judgment under § 102, rather than under the guise of a § 112 motion, summary judgment would be inappropriate.

3. Amgen cannot be collaterally estopped by a prior ruling on an unrelated structural limitation of a different claim in a different patent.

In order for a party to be precluded from relitigating an issue by collateral estoppel: (1) the issue sought to be precluded must be the same as that involved in the prior action; (2) the issue must have been actually litigated; (3) the issue must have been determined by a valid and binding final judgment; (4) the determination of the issue must have been essential to the judgment; and (5) the party to the second action must be the same as or in privity with the parties

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Difference Between Recombinant and Urinary Erythropoietins," *Proteins: Structure, Function, and Genetics*, 28(1):94-98 (1997)).

[33] Roche's citation to *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 1989 WL 169006 (D. Mass., December 11, 1989) is misleading. At issue there was whether rEPO and and uEPO were sufficiently different to render Genetics Institute's product claims not enabled based on an argument that the purification process set forth in the Genetics Institute specification could not be applied to recombinantly produced product to attain the claimed potency levels. *Id.* at *83-84.

[34] *Id.* at Ex. 2 (2/26/07 Goldwasser Tr. at 471:19-473:8).

[35] *Id*. (at 474:1-475:13).

[36] *Id.* (at 475:15-476:16).

[37] *Id.* (at 461:8-464:6); *see also* Docket No. 502, Ex. E-4 at 5563 (Miyake et al., "Purification of Human Erythropoietin," *J. Biol. Chem.*, 252(15):5558-5564 (1977)) (reporting specific activity for urinary EPO of 70,400 unites/mg of protein).

[38] Docket No. 582 at Ex. 2 (2/26/07 Goldwasser Tr. at 476:21-478:18).

in the first action.[40]

The definiteness of the source limitation "purified from mammalian cells grown in culture," as found in '422 claim 1 was not at issue in the prior *HMR/TKT* litigation. Rather, this Court[41] and the Federal Circuit[42] each concluded that independent Claims 1 and 2 and Claim 9, as it depended on Claims 1 and 2 were rendered indefinite because of the limitation "having a glycosylation which differs from that of human urinary erythropoietin." ***But this limitation is not found in any of the claims asserted in the present action***. The first requirement of collateral estoppel is therefore unsatisfied.

As explained above, the issue posed by Roche is thus wholly irrelevant to whether '422 claim 1 is invalid due to the indefiniteness. Like the faulty substantive indefiniteness arguments upon which it is premised, Roche's collateral estoppel argument must fail.

B. Dr. Lin's specification adequately describes "human erythropoietin . . . purified from mammalian cells grown in culture."

35 U.S.C. § 112 ¶ 1 requires that a patent's written description "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."[43] Here, in order for a claim containing the limitation "human erythropoietin . . . purified from mammalian cells grown in culture" to be valid, the claim must be supported by a specification that demonstrates to the ordinarily skilled artisan that Dr. Lin actually invented a human erythropoietin purified from cells grown in culture.

In basing its written description position on the Court's § 112 ¶ 1 analysis of '933 claims

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[39] *Id.* (at 463:12-464:6).

[40] *Boston Scientific. Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 255 (D. Mass. 1997).

[41] *Amgen I*, 126 F. Supp. 2d at 156-67.

[42] *Amgen II*, 314 F.3d at 1342.

[43] *Amgen I*, 126 F. Supp. 2d at 147 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)).

1 and 2 in the prior litigation, Roche simply repackages its indefiniteness arguments. Conspicuously, Roche makes no attempt to explain substantively why it contends the § 112 ¶ 1 written description requirement is not met for the source limitation of '422 claim 1 where Dr. Lin's specification explains in great detail the methods used by the inventor to obtain, for the first time, therapeutically effective amounts of erythropoietin from cells grown in *in vitro* culture.

Rather, Roche directs attention to this Court's statement in the *TKT* litigation that "if [its] finding of non-infringement [of the '933 claims] were ruled in error, this Court would, in the alternative, rule that all three asserted claims of the '933 patent are invalid for lack of written description."[44] Based on this statement, Roche asserts that "Amgen is collaterally estopped from arguing the contrary." But: (1) as set forth above, '422 claim 1 does not include the same limitations as the '933 claims at issue in the *TKT* litigation; and (2) '422 claim 1 was found to be adequately described in that litigation. Moreover, this Court's "alternative" finding was vacated when the Federal Circuit vacated this Court's non-infringement rulings in favor of its decision that '933 claims 1, 2, and 9 (as it depended on claims 1 and 2) were indefinite.

C. Roche's motion should be stricken for failing to comply with LR 7.1(b)(4).

The Local Rules for the District Court of Massachusetts, LR 7.1(b)(4) provides:

> *Length of Memoranda.* Memoranda supporting or opposing allowance of motions shall not, without leave of court, exceed twenty (20) pages, double spaced.

Pursuant to LR 7.1(b)(4), a Court may strike an oversized motion.[45]

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[44] Docket No. 615 at 15.

[45] *Watson v. Trevino*, 2007 U.S. Dist. LEXIS 14758, *7 (E.D. Mich. 2007) (striking plaintiff's oversize motion and supplemental motion in support of its oversized motion). In striking the oversized brief, the Court cautioned that filing of multiple pleadings on same issue may violate Rule 11:

> "This Court has the authority under Federal Rule of Civil Procedure 11(c) and 28 U.S.C. § 1927 to sanction attorneys who multiply the proceedings

Roche has filed a total of nine motions for summary judgment, five of which purportedly address Roche's different § 112 arguments.[46] At issue here are three of Roche's five § 112 motions:

(1) Roche's first "Motion for Summary Judgment That Claim 1 of the '422 Patent is Invalid Under 35 U.S.C. Sec. 112,"[47]

(2) Roche's "Motion for Summary Judgment that the Asserted Claims of the '933 Patent Are Invalid for Indefiniteness and Lack of Written Description,"[48] and

(3) Roche's second "Motion for Summary Judgment that Claim 1 of U.S. Patent No. 5,995,422 Is Invalid for Indefiniteness and Lack of Written Description,"[49] currently at issue, and

The similarities between these motions are readily apparent when they are considered side-by-side:

	First '422 Claim 1 Motion for Invalidity	***'933 Motion for Invalidity***	***Second '422 Claim 1 Motion for Invalidity***
Theory of Invalidity	35 U.S.C. § 112 (indefiniteness and lack of written description)	35 U.S.C. § 112 (indefiniteness and lack of written description)	35 U.S.C. § 112 (indefiniteness and lack of written description)
Limitation at Issue	"human erythropoietin"	"non-naturally occurring"	"human erythropoietin . . . purified from mammalian cells grown in culture"
Underlying Basis	Court's construction of	*TKT* decision that '933	*TKT* decision that '933

unreasonably, and vexatiously, including the filing of frivolous pleadings. *Roadway Express, Inc. v. Piper*, 447 U.S. 752, 765, 100 S. Ct. 2455, 65 L. Ed. 2d 488 (1980), *cited with approval, Marrama v. Citizens Bank of Massachusetts*, 127 S. Ct. 1105, 1112 (2007)."

Id. at *3-4.

[46] Roche's remaining motions are directed to its non infringement arguments (3 motions) and its assertion of invalidity based on obviousness type double patenting (1 motion).

[47] *See* Docket No. 482.

[48] *See* Docket No. 505.

[49] *See* Docket No. 614.

	First '422 Claim 1 Motion for Invalidity	***'933 Motion for Invalidity***	***Second '422 Claim 1 Motion for Invalidity***
for Motion	"human EPO" renders '422 claim 1 indefinite and not described	claim 1 is indefinite renders asserted '933 claims indefinite and not described	claim 1 is indefinite renders '422 claim 1 indefinite and not described

Rather than file a single 20-page motion as to all of the issues covered in these motions,[50] Roche chose instead to file three separate motions, the last of which (Docket No. 614) was filed only after Amgen had filed its oppositions to the Roche's first two filed motions. Taken together, the motions total 58 pages in length. Plainly, Roche should have filed these separate motions together, two of which are directed to the same claim and the same theory of invalidity. As one motion, Roche has exceeded the page limit dictated by the Local Rules by a factor of three. As three motions, Roche has effectively multiplied the amount of paper and work that Amgen and this Court must deal with by the same factor. Roche's most recent motion should be stricken on these bases.

III. CONCLUSION

Amgen respectfully requests that the Court deny Roche's Second Motion for Summary Judgment That '422 Claim 1 Is Invalid for Indefiniteness and Lack of Written Description and as more fully set forth in Amgen's Motion for Summary Judgment of Validity (Docket No. 531), find that '422 claim 1 is definite and adequately described. In the alternative, Amgen respectfully requests that the Court strike Roche's motion on the ground that Roche's briefs attacking the validity of '422 claim 1, considered together, do not comply with LR 7.1(b)(4).

[50] *Compare* Docket No. 531 (Amgen's Motion for Summary Judgment That Dr. Lin's Asserted Claims Are Definite, Adequately Described, and Enabled).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Patricia R. Rich

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