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

DEFENDANTS' OPPOSITION TO AMGEN'S MOTION TO ENFORCE THE COURT'S JANUARY 23, 2007 ORDER AND MEMORANDUM IN SUPPORT OF DEFENDANTS' CROSS MOTION TO COMPEL PRODUCTION OF AMGEN'S CELL LINES AND RELATED DOCUMENTS

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") respectfully submit this memorandum in opposition to Amgen Inc.'s ("Amgen") Motion to Enforce the Court's January 23, 2007 Order, and in support of Roche's Cross Motion to Compel Production of Amgen's Cell Lines and Related Documents filed herewith. For the reasons discussed below, Roche's Cross Motion to Compel should be granted and Amgen's Motion should be denied.

I. INTRODUCTION

On January 23, 2007, the Court issued the following Order regarding the production of cell lines by the parties:

> Upon Careful Consideration All Of The Submissions, the Court Allows Amgen's Motion to Compel Subject To The Extant Protective Order.
> Naturally, The Court Expects Amgen Will Afford Reciprocal Discovery Without The Necessity of a Motion.

(emphasis added).[1] Amgen's blatant disregard of the Court's Order has brought about the very necessity the Court was concerned about, and indeed, has resulted in the filing of not one, but two separate motions. After repeated efforts to reach a resolution with Amgen, Roche is left with no alternative but to seek an order compelling Amgen to produce: (1) a sample of the cell lines it uses to produce its commercial products Epogen® and Aranesp®; (2) a sample of any erythropoietin-producing cell line that Amgen had in its possession as of the effective filing date of the patents-in-suit; and (3) the declarations submitted by Ronald McLawhon in *Amgen v. TKT*[2] and any documents he considered in their preparation.[3] These requests are reasonably calculated to lead to relevant evidence. As explained herein, testing of the requested cell lines may lead to evidence supporting Roche's non-infringement and invalidity defenses including obviousness, indefiniteness, nonenablement and lack of written description. Therefore Roche respectfully requests the Court's intervention and seeks an order compelling Amgen to produce the defined materials.

In addition, Roche respectfully requests that Amgen's Motion be denied as moot. Amgen seeks an order requiring Roche to produce samples of its EPO producing DN2-3(*a*)3 cell line. Roche is in the process of arranging to have the cell line transported from Germany by courier and alerted Amgen to that fact today.[4] Further, Roche respectfully requests that if the Court

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[1] The Court's order is attached as Exhibit ("Ex.") 1.

[2] Reference is made to *Amgen v. Hoechst Marion Roussel, Inc. & Transkaryotic Therapies, Inc.*, D. Mass. Civ. A. No. 97-10814-WGY.

[3] In a final attempt to reach an agreement with Amgen, and to prevent the necessity of filing its own motion, Roche again sought confirmation from Amgen that it would produce its cell lines, which Amgen refused to provide. *See* Ex. 2 (2/23/07 E-mail from P. Carson to D. Fishman).

[4] Roche informed Amgen today that the cell line would be shipped via courier from Penzberg this week. Although Amgen previously indicated that it would withdraw its motion to compel once it was provided with a date certain for production, Roche submits this motion in case

decides to extend the time for Amgen to submit its infringement expert report, that the Court grant Roche an equal extension of time to submit its own infringement and invalidity expert reports.

II. FACTS

A brief summary of the correspondence that has transpired between the parties since the Court's January 23rd Order is set forth for the Court to understand why no cell lines have been produced by either side to date.

Following receipt of the Court's order, Amgen wrote to Roche, noting that "the Court ordered Roche to produce the cell line(s) it uses to make the EPO starting material for MIRCERA™ . . . it is essential that Roche promptly comply."[5] The following day, Roche responded to Amgen, agreeing that production "must occur quickly." Noting that "the Court ordered Amgen to produce reciprocal discovery, hopefully without the necessity of a motion to compel," Roche stated that it was ready to make a reciprocal exchange.[6] Amgen's reply was that the Court's order does not require reciprocal discovery of the cell lines.[7] Without questioning the relevance of its own cell lines, Amgen postulated that it need not produce them because, "Amgen has produced regulatory filings and laboratory notebooks that demonstrate that its EPO-producing cell lines meet the production level requirements."[8]

Roche disagreed that Amgen's production of documents was sufficient for this parameter and overlooked numerous other reasons why the cell lines were relevant, but nonetheless offered

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Amgen unreasonably fails to withdraw its motion or to address any portion that is not withdrawn.

[5] *See* Ex. 3 (1/23/07 Ltr. from D. Fishman to H. Suh).

[6] *See* Ex. 4 (1/24/07 Ltr. from P. Carson to D. Fishman).

[7] *See* Ex. 5 (1/26/07 Ltr. from D. Fishman to P. Carson).

[8] *Id.*

Amgen a compromise. Noting that Amgen had repeatedly asserted that it needed Roche's cell line for one reason only, i.e., because Roche "refused to reach a stipulation regarding the [production] values" of Roche's cell line,[9] Roche offered Amgen just such a stipulation. Roche agreed to stipulate that the cells it uses in Germany to make epoetin beta "are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay," – i.e., meet the production levels required by claim 1 of the '349 patent – if Amgen would withdraw its request. In offering such a stipulation however, Roche insisted upon language reserving Roche's right to attack validity of the '349 claims on any ground, notwithstanding the stipulation.[10] In turn, Amgen requested and Roche agreed that the stipulation provide that Roche withdraw its request for Amgen's cell lines. When the parties agreed in principle to the compromise, Roche discontinued the procedures it had initiated to ship its cells.[11]

Efforts to finalize the stipulation were stymied when it became clear that Amgen wanted to use the stipulation for purposes other than originally represented. Despite expressly agreeing to language precluding any argument that the stipulation waived Roche's right to attack validity of the '349 claims, it became clear that Amgen intended to use the stipulation for precisely that purpose. Specifically, Amgen informed Roche that it must be able to use the stipulation as evidence that Roche had waived argument that the '349 claim language is indefinite. Unable to reach agreement, the parties went back to where they were immediately after the Court's order

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[9] *See* Ex 6 (2/5/07 Ltr. from D. Fishman to P. Carson); *see also* Ex. 7 (12/29/06 Ltr. from D. Fishman to P. Carson); Ex. 8 (1/5/07 Ltr. from D. Fishman to P. Carson).

[10] *See* Ex. 9 (2/7/07 Ltr. from P. Carson to D. Fishman).

[11] *Id.*

for reciprocal production. Amgen's refusal to compromise and refusal to produce its cells has made necessary Roche's instant motion.

Moreover, Amgen's actions alone are responsible for the delays it complains about in its Motion. As noted above, on the day after the Court's Order Roche instructed Amgen that it was ready and willing to produce its cells, provided Amgen agree to the reciprocal discovery ordered by the Court. Roche's alleged "continued delays" in producing its cell line are the direct consequence of the several weeks of negotiations between Amgen and Roche, which were entered into as a compromise because Amgen refused to produce its cells. Indeed, as soon as negotiations fell through, Roche immediately wrote to Amgen, reiterating that:

> Roche understands its obligations under the Court's order and will produce its cell line. We will ship it promptly from Penzberg however, we are at the mercy of at minimum, U.S. Customs and cannot tell you with certainty that the cell line will be in Amgen's expert's hands on Friday. Amgen's threatened motion is unnecessary and constitutes harassment.[12]

Yet within an hour, Amgen had filed its currently pending motion.

III. ARGUMENT

A. In Accordance with the Reciprocal Discovery Ordered by the Court, Both Parties Should Produce their Respective Cell Lines.

1. The Court Clearly Demanded that Discovery be Reciprocal

In its January 10th motion to compel, Amgen asserted that it needed Roche's cell line to prove production levels, because the "cell line is not cumulative of other discovery already obtained, and not available from another source." The "discovery already obtained" by Amgen included Roche's regulatory filings with the U.S. Food and Drug Administration ("FDA"), Roche's regulatory filings with the European Medicines Agency ("EMEA") for Roche's NeoRecormon® (epoetin beta), Roche's laboratory notebooks, as well as Roche's agreement to

[12] *See* Ex. 10 (2/23/07 Ltr. from P. Carson to D. Fishman).

produce additional documents regarding production levels as specifically requested by Amgen. Roche's regulatory filings contain entire sections devoted to the characteristics of Roche's cell line, including the source, structure, growth conditions and production levels. In particular, Roche's filings contain data, calculations and graphs describing the productivity of Roche's cell line calculated to µg EPO/10^6 cells per day – exactly the information Amgen alleged it needed. These documents indisputably provide all of the information Amgen sought regarding the production levels of Roche's cell line.

Nevertheless, on January 23, 2007, the Court ordered that Roche go one step further and provide Amgen with its EPO producing cell line. At the same time, the Court's Order clearly demanded that Amgen afford Roche reciprocal discovery. Yet, immediately following the Court's Order, Amgen wrote to Roche and maintained that Amgen's own regulatory documents and laboratory notebooks made production of its own cell lines unnecessary.[13] Amgen cannot have it both ways. After arguing successfully to this Court that these very types of documents are insufficient to show production levels, Amgen should be held to abide by its position and to abide by the Court's Order. Instead, Amgen has attempted to hold Roche alone to a higher burden of discovery, in contravention of the Court's mandate for reciprocal discovery. If Roche must produce its cell line, reciprocal discovery demands that Amgen produce its cell lines as well.

2. Amgen's Documents Alone are Insufficient "Reciprocal Discovery"

Even if the Court did not necessarily intend "reciprocal discovery" to mean that Amgen's cell lines must be produced, Amgen's document production on its own is entirely insufficient to constitute such discovery. Although Amgen identified certain documents to Roche which

[13] *See* Ex. 5 (1/26/07 Ltr. from D. Fishman to P. Carson).

allegedly discharge its duty of reciprocal discovery, these documents are wholly inadequate, and provide substantially less information than those produced by Roche.[14]

For instance, Amgen has failed to produce any documents which show how Amgen's cells satisfy the production level requirements of its '349 patent. Amgen merely pointed Roche to sections of its Product License Application ("PLA") disclosing the production rate for a seven-day cycle, with units in milliliters – unlike the '349 patent, the claims of which contain limitations based on a 48 hour period, with units in numbers of cells. Nothing Amgen produced describes how to translate the values in the PLA to the values in the '349 patent claims (if indeed those values are translatable at all), and Amgen will undoubtedly contest any method Roche attempts to use. Thus, Roche's best evidence is to turn to the cells themselves. Amgen should not be heard to complain otherwise, for Amgen maintains that it needs Roche's cells because the data in Roche's own regulatory filings are insufficient to determine production levels.

Moreover, Amgen's PLA, filed on October 30, 1987, provides no information to confirm that the production levels reported therein would correlate with results obtainable with materials and techniques available at the time the patent was filed. Likewise, Amgen's laboratory notebooks are equally insufficient to establish if and when Amgen possessed EPO-producing cell lines that meet the production level claimed in the '349 Patent, and provide absolutely no information about the cell lines used to produce Aranesp®.

Nonetheless, even if Amgen's data regarding its production levels could be authenticated and converted into the terms Amgen used in the claims of the '349 Patent, and even assuming the documents Amgen produced are sufficient to satisfy the rest of the discovery Roche is entitled to

[14] *See* Ex. 11 (1/29/07 Ltr. from P. Carson to D. Fishman) (noting deficiencies in Amgen's alleged "reciprocal production").

(they are not), under the Court's order for reciprocal production, Roche should be entitled to directly measure and evaluate the production levels and other characteristics of Amgen's cells.

B. Amgen's Epogen® and Aranesp® Cell Lines are Relevant to Invalidity.

1. The Cell Lines Used By Amgen to Make Its Commercial Products Are Highly Relevant to an Obviousness Analysis

Amgen has acknowledged that its cell line used to produce EPO is relevant but has taken issue with the Aranesp® cell line. As discussed herein, *both* of these cell lines are indisputably relevant to certain of Roche's claims and defenses. Roche's request for the cell lines that Amgen uses to produce its commercial products Epogen® and Aranesp® is reasonably calculated to lead to relevant evidence.[15] For instance, it is highly likely that Amgen will attempt to rebut the obviousness of its claims by pointing to the successes it has had with its commercials products. Amgen made arguments along these lines in the U.S. Patent and Trademark Office ("PTO") when securing the patents, and during its prior litigation with TKT. Thus Amgen is expected to allege that Example 10 of the Lin patents describes the creation of the cells used to produce the commercial product. While commercial success, satiating long felt but unmet need, and accolades can be indicia of non-obviousness, there must be a nexus to the specific claims at issue.[16] If the cells that Amgen uses to produce Epogen® or Aranesp® are not within the scope of the asserted claims, then facts such as commercial success cannot be used to show non-obviousness of that claim.[17] Roche therefore seeks a sample of the cells that Amgen uses to

[15] *See* Fed. R. Civ. P. 26(b)(1) (Discovery requests need only be "reasonably calculated" to lead to relevant information).

[16] *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.").

[17] Although to date Amgen has identified only one unasserted claim of the patents-in-suit as covering Aranesp, in that discovery is ongoing and claim construction has not yet occurred,

produce Epogen® and Aranesp® to test whether or not they meet the limitations of any of the claims of the Lin Patents.

2. Amgen's Cell Lines are Relevant to Enablement

Furthermore, one of the fundamental issues in the case is whether the claims of the Lin patents are so broad as to capture Roche's novel synthetic compound which is the active ingredient in the accused MIRCERA™ product. Amgen, of course, believes that the asserted claims are broad enough, and Roche disagrees. However, Roche further argues that if the claims are construed to cover its novel compound, then they must be invalid because the specification cannot enable the full scope of such claims.

Amgen argued successfully in the PTO that its claims to glycoproteins and glycosylated polypeptides were enabled because Dr. Lin had invented novel cells that allow the production of erythropoietin with glycosylation that differs from naturally occurring glycosylation. Thus, Roche seeks to examine Amgen's cells so that its experts can determine the ability of the cells to produce modified erythropoietin molecules.

An inventor should not be allowed to dominate future patentable inventions outside the scope of his contribution. Accordingly, to be properly enabled, a patent must contain a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims without undue experimentation. For example, in *Amgen v. Chugai*, the district court held that claim 7 of Lin's '008 patent was invalid for nonenablement based on evidence similar to that which Roche seeks to obtain from Amgen's cell lines. Claim 7 provided in relevant part: "A purified and isolated DNA sequence . . . encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the

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Roche has no definitive assurance that Amgen will not ultimately assert that any additional claims cover Aranesp.

[requisite] biological propert[ies] . . . ." Evidence was introduced showing that as late as five years after the patents were filed, scientists, including those at Amgen, were unable to predict the biological activity of EPO analogs. As the district court stated, "[b]ased on this evidence, the court concludes that defendants have provided clear and convincing evidence that the patent specification is insufficient to enable one of ordinary skill in the art to make and use the invention claimed in claim 7 of the 008 patent without undue experimentation." The Federal Circuit affirmed.[18] The question of what products can or cannot be made with Dr. Lin's cells is relevant to enablement. To produce Aranesp®, Amgen apparently expended significant effort to create a new cell line. The differences between these cells and those taught by Lin will provide evidence of the claim scope enabled by Lin.

3. The Cells Amgen Possessed on the Effective Filing Date Are Relevant to Indefiniteness, Written Description and Enablement

Roche has also requested a sample of the recombinant erythropoietin producing cells Amgen had in its possession as of the effective filing date of the patents. The evidence that Roche could derive by independently testing these cell lines has not been provided or is not available from Amgen, and is highly relevant to Roche's invalidity arguments.

For example, claim 1 of Amgen's '349 patent recites certain cells capable of "producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours." As noted above, Amgen has failed to produce documents sufficient to show how Amgen's cells satisfy this requirement. Amgen has merely produced information on the

[18] *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213-1214 (Fed. Cir. 1991) ("Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This 'disclosure' . . . represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.").

production rate it disclosed to the FDA, after the filing date of its patent, and given in entirely different units than those used in its claims. Roche should be allowed to directly measure and evaluate Amgen's cells, and to generate first-hand evidence of their production levels. Such evidence will avoid disputes over how to authenticate and convert the selective results that Amgen provided, and will be highly relevant to Roche's invalidity defenses of indefiniteness, lack of written description, and nonenablement.

Indeed, the difficulty of converting Amgen's results may be insurmountable. Roche has asserted the defense of indefiniteness, arguing in its interrogatory responses that "the phrase [U of erythropoietin] as used in the claims [of the '349 patent] is indefinite, cannot be properly defined in view of the patent specification and is otherwise scientifically inaccurate."[19] Specifically, Roche has contended that the limitation "U of erythropoietin . . . as determined by radioimmunoassay" is indefinite because radioimmunoassay alone cannot measure erythropoietin units ("U"). Neither does the specification define "U of erythropoietin" nor does it disclose any method for measuring "U of erythropoietin." Without further guidance that the specification fails to provide, the proper metes and bounds of this limitation cannot be determined, and hence the claims of the '349 patent are invalid as indefinite under § 112 for failing to distinctly claim the subject matter in a manner that enables one skilled in the art to understand its true scope. The best evidence of this defense comes from Amgen's own cells. If data from experiments with Amgen's cells shows that it is impossible to measure erythropoietin units based on Amgen's disclosure, such data would be highly probative for Roche's indefiniteness defense.

[19] *See* Roche Response to Amgen Interrogatory No. 9(J).

Furthermore, it is apparent from the specification of the Lin patents that Example 10 does not describe the cells Amgen developed for commercial production of erythropoietin. Example 10 of the Lin patents states that other procedures are being employed to meet the requirements of the FDA:

> The cells in the cultures described immediately above [Example 10] are a genetically heterogeneous population. Standard screening procedures are being employed in an attempt to isolate genetically homogeneous clones with the highest production capacity. See, Section A, Part 2, of "Points to Consider in the Characterization of Cell Lines Used to Produce Biologics", Jun. 1, 1984, Office of Biologics Research Review, Center for Drugs and Biologics, U.S. Food and Drug Administration.[20]

A sample of the actual cells could lead to evidence that something more than standard screening procedures were required to practice one or more of the claims in the Lin Patents. Moreover, it is clear that Amgen did not make a deposit of any cells, despite having claims to cells which are alleged to be inventive over its earlier expired patent. For at least these reasons, Amgen's cell lines are relevant to written description and enablement as well.

C. Amgen's Aranesp® Cell Lines are Relevant to Non-Infringement.

Amgen has alleged that the cells Roche uses as part of its manufacturing process for MIRCERA™ infringe a number of Amgen's process patent claims. In this litigation, Amgen has taken the position that the cells it uses to manufacture its Aranesp® product do not meet the limitations of those very same claims.[21] If Amgen's Aranesp® producing cells have certain characteristics that take them outside the scope of the asserted claims, then by Amgen's own admission, Roche's cells would also be outside of the scope of the claims if they share those

[20] *See* U.S. Pat. No. 5,547,933 at col. 26, ln. 66 – col. 27, ln. 7.

[21] For example, in Amgen's Supplemental Response to Roche Interrogatory No. 8, Amgen stated that "[a]s set forth in the ARANESP® product label, Amgen contends that the importing, making, using, offering to sell or selling of ARANESP® is covered (literally or equivalently) under unasserted claim 1 of the '698 Patent."

same characteristics. Because Amgen has refused to point Roche to why its process for producing Aranesp® falls outside every one of its asserted claims, Roche should be entitled to independently test Amgen's Aranesp® producing cells to determine precisely what these characteristics are.

For instance, Amgen has accused Roche's MIRCERA™ product of infringing claims 1 and 7 of its '349 patent. Together, the claims read:

> A process for producing erythropoietin comprising the step of culturing, under suitable nutrient conditions, vertebrate cells which can be propagated in vitro and which are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay, said cells comprising non-human DNA sequences which control transcription of DNA encoding human erythropoietin.

What is claimed by the '349 patent is therefore a "process for producing erythropoietin" using certain vertebrate cells "capable upon growth in culture" of specific production levels. Amgen's position is that making Aranesp® using the Aranesp® cell line is not covered by the claims of the '349 patent, either literally or under the doctrine of equivalents. Clearly, for this to be true, Aranesp® must not meet at least one of the limitations of each of the claims. Is it because Aranesp® is not "erythropoietin"? Is it because the Aranesp® cell line produces only limited amounts of product? Is it something else? Roche has specifically sought this information from Amgen in its requests to admit and its interrogatories, to no avail.[22]

Similarly, Amgen maintains that claims 4 and 6 of the '698 patent, both asserted against Roche, do not cover Aranesp®. By contrast, Amgen maintains that claim 1, unasserted against Roche, does cover Aranesp®. (Indeed, according to Amgen, claim 1 is the only claim of the Lin patents that Aranesp® is covered by.) Because Amgen has failed to provide adequate discovery

[22] For example, Roche specifically requested this information in Roche's First Set of Requests to Admit Nos. 1 & 2 and in Roche's First Set of Interrogatories No. 8.

regarding why claim 1 covers Aranesp®, while claims 4 and 6 do not, Roche should be entitled to test Amgen's Aranesp® cell line to gather evidence to enable Roche to make this determination on its own. For the Court's convenience, a chart comparing claims 1, 4 and 6 of Amgen's '698 patent is included below. As the chart makes readily apparent, the claims contain several limitations, any of which Amgen could be relying on to distinguish Aranesp®. For example, claim 1, which allegedly covers Aranesp®, is broader that claims 4 and 6, because it covers sequences beyond the specific amino acid sequence of human urinary erythropoietin, or the specific amino acid sequence of Fig. 6. But Roche should not have to rely on such educated guesses, and should be allowed to derive direct evidence from Amgen's Aranesp® cell line.

Claim 1 (unasserted) **COVERS ARANESP**	**Claim 4** (asserted) **DOES NOT COVER ARANESP**	**Claim 6** (asserted) **DOES NOT COVER ARANESP**
1. A process for the preparation of an in vivo biologically active erythropoietin product comprising the steps of: (a) growing, under suitable nutrient conditions, host cells transformed or transfected with an isolated DNA sequence selected from the group consisting of (1) the DNA sequences set out in FIGS. 5 and 6, (2) the protein coding sequences set out in FIGS. 5 and 6, and (3) DNA sequences which hybridize under stringent conditions to the DNA sequences defined in (1) and (2) or their complementary strands; and (b) isolating said erythropoietin product therefrom.	4. 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 promoter DNA, other than human erythropoietin promoter DNA, operatively linked to DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.	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.

Therefore, given that Amgen asserts that its Aranesp® producing cell line does not fall within any of the asserted claims, while at the same time denying Roche any reasonable discovery that would identify the precise reasons why, Roche should have the opportunity to test Amgen's cell line to identify what difference or differences put it outside of what Amgen

understands to be the scope of its claims. For if Roche can show that the same differences are present in its own cell line, then by Amgen's own admissions, Roche's MIRCERA™ product will be non-infringing. Clearly, such evidence would be highly relevant.

D. The Declarations of Dr. McLawhon are Relevant.

Amgen has indicated that Roche's cells should be produced to Dr. Ronald W. McLawhon at the University of Chicago.[23] Roche understands from this Court's published decision in *Amgen v. TKT* that Dr. McLawhon ran certain tests on cells produced to Amgen by TKT. From the text of the decision, Dr. McLawhon apparently submitted at least two declarations concerning the production of erythropoietin as determined by radioimmunoassay. The Court found these declarations "very influential."[24] Despite general and specific requests, Amgen has provided neither Dr. McLawhon's declarations nor the underlying documents McLawhon considered in drafting them. Further, Amgen has taken the position that Dr. McLawhon's results from the TKT litigation are not available to Roche. Because Dr. McLawhon's methods, analyses, and data are highly probative to both validity and non-infringement, as they show how Amgen determines production values, the Court should Order Amgen to produce the documents requested from him as well.

[23] *See* Ex. 3 (1/23/07 Ltr. from D. Fishman to H. Suh).

[24] *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 118 (D. Mass. 2001) ("[T]he Court ruled that [the] cells are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 units of erythropoietin per 10^6 cells in forty-eight hours as determined by radioimmunoassay ("RIA"). Dr. Ronald W. McLawhon's second declaration was very influential in this determination.") (emphasis added).

E. Amgen's Motion Should Be Denied as Moot.

Grounded in the fact that Roche is unable to meet Amgen's unreasonable demand that Roche guarantee the delivery of its cell line by a "date certain", regardless of circumstances outside Roche's control, including delays going through Customs, Amgen's Motion to Enforce the Court's January 23, 2007 Order is baseless and unwarranted.[25] Even before Amgen's motion was filed, Roche had already acknowledged that it must produce its cell line, and promised to use its best efforts to produce it promptly, going so far as to offer to allow an appropriate representative of Amgen to pick up the cell line in Penzberg.[26] By letter today, Roche confirmed that arrangements were being made to deliver the cell line by courier in an attempt to minimize delays at U.S. Customs. In that it is simply not within Roche's control however to make any guarantees as to exactly when the cell line will reach Amgen's expert, in an attempt to accommodate Amgen's "date certain" demand, Roche again offered to allow an appropriate Amgen representative pick up that sample in Penzberg.[27] In short, Amgen is seeking that the Court order Roche to do no more than that with which Roche has already made it clear it is ready to comply. As such, Amgen's Motion is utterly unnecessary and should be denied as moot.

F. Roche Should Be Equally Entitled to Additional Time to Complete its Expert Reports.

As explained above, Amgen's contention that Roche alone is responsible for unjustified delay of production is not based on reality. Roche was at all times after this Court's order willing to import and produce its cell lines, and the fact that it has not yet done so should be

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[25] Indeed, even the relief Amgen seeks in the alternative, that Roche be deemed to have admitted that its cells meet the production requirements of the '349 patent, Roche has been ready to stipulate to for several weeks, providing that the stipulation is not used as evidence for any purpose beyond infringement.

[26] *See* Ex. 2 (2/23/07 E-mail from P. Carson to D. Fishman)

[27] *See* Ex. 12 (2/26/07 Ltr. from P. Carson to D. Fishman)

attributed to Amgen's own actions. Moreover, the hardship posed by the limited time remaining until the completion of initial expert reports works to the disadvantage of Roche as well as Amgen. Therefore, should the Court choose to grant Amgen additional time to prepare its expert reports, it should extend the same benefit to Roche.

IV. CONCLUSION

For the foregoing reasons, Roche respectfully requests that the Court order Amgen to produce: (1) a sample of the cell lines it uses to produce its commercial products Epogen® and Aranesp®; (2) a sample of any erythropoietin-producing cell line that Amgen had in its possession as of the effective filing date of the patents-in-suit; and (3) the declarations submitted by Ronald McLawhon in *Amgen v. TKT* and any documents he considered in their preparation.[28] Further, Roche respectfully requests that Amgen's Motion be denied. If the Court decides to grant Amgen additional time to submit its expert report on infringement, Roche respectfully requests that the Court grant Roche an equal extension of time to submit its non-infringement and invalidity reports pertaining to the subject matter discussed herein.

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and that no agreement was reached.

[28] Although Roche believes that additional restrictions would be advisable, it is willing to agree to abide by the terms of Amgen's Proposed Special Handling Restrictions for the Use and Handling of Roche's Cell Line, and has therefore followed them verbatim in its own Proposed Order.

DATED: Boston, Massachusetts
February 26, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

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/s/ Nicole A. Rizzo
Nicole A. Rizzo

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