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 MEMORANDUM IN SUPPORT OF ITS MOTION TO ENFORCE THE COURT'S JANUARY 23, 2007 ORDER COMPELLING ROCHE TO PRODUCE ITS CELL LINE AND TO EXTEND THE TIME FOR AMGEN TO SUBMIT ITS INFRINGEMENT EXPERT REPORT REGARDING THE TESTING OF ROCHE'S DN2-3(A)3 CELL LINE

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I. INTRODUCTION.

On January 23, 2007, the Court granted Amgen's motion to compel[1] and ordered Roche to produce the cell line that Roche uses to make its accused peg-EPO product, subject to the existing Protective Order in this case.[2] Now, a month later, Roche has still not complied with this Court's January 23, 2007 Order, despite repeated requests from Amgen, and has failed to produce its EPO-producing cell line ***unless*** (1) Amgen agrees to produce its own EPO-producing cell line and (2) Amgen agrees to additional restrictions on the usage and handling of any cells produced.[3] Even on the eve of this filing, Roche would not provide a date certain for the production of its EPO-producing cell line or even confirm that it would produce its cell line without prior agreement by Amgen to produce its own EPO-producing cell line.[4]

Roche's continued delays in producing its cell line directly contravenes this Court's January 23, 2007 Order and prejudices Amgen's ability to prepare and submit timely expert reports. Nothing in the Court's January 23, 2007 Order authorizes Roche to withhold its cell line unless Amgen agrees to produce its EPO-producing cell line. And nothing in that Order requires or justifies Roche's demand that Amgen comply with Roche's additional, unreasonable

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[1] Docket No. 223 (Amgen's Memorandum in Support of Its Motion to Compel Production of Roche's Cell Line and Related Documents).

[2] Declaration of Krista M. Carter in Support of Amgen's Motion to Enforce the Court's January 23, 2007 Order Compelling Roche to Produce Its Cell Line (Hereafter "Carter Decl.") Exh. 10 (1/23/07 Court Order).

[3] Carter Decl., Exh. 1 (1/29/07 P. Carson letter to D. Fishman); Exh. 2 (2/1/07 D. Fishman letter to P. Carson); Exh. 3 (2/16/07 P. Carson letter to D. Fishman).

[4] In a last-ditch effort to delay resolution of this issue, Roche agreed that it would start the process of importing its cells (notwithstanding the fact that Roche has been under Court Order since January 23 to do so), but failed to provide a date certain to Amgen for its production or even confirm that its EPO-producing cell-line would be produced to Amgen once imported by Roche. *See* Carter Decl., Exh. 12 (1/23/07 P. Carson letter to D. Fishman) and Exh. 13 (1/23/07 D. Fishman response e-mail to P. Carson). Having delayed more than two months in its production, and having failed to produce after being under Court Order for more than a month to do so, even if Roche now does produce its EPO-producing cell line, Amgen still requires the Court's intervention to provide it with adequate time to grow and test those cells in furtherance of its initial expert report on infringement.

limitations on the handling and use of its cell line. In fact, the Court specifically rejected the additional restrictions proposed by Roche in favor of proceeding under the provisions of the parties' extant Protective Order.[5]

Roche argues that this Court's January 23, 2007 Order stating that "the Court expects Amgen will afford reciprocal discovery without the necessity of a motion" makes production of Roche's cell line contingent on the production of Amgen's cell line. Roche's argument ignores the fact that Amgen has already produced the "reciprocal discovery" sought by Roche by producing the Amgen documents describing its cell line that Roche specifically requested in its Requests for Production. By contrast, Roche refused to admit Amgen's Requests for Admission regarding whether Roche's cells satisfy the EPO production rate limitations in Amgen's asserted '349 Patent claims, and refused to produce documents demonstrating those production levels. These refusals prompted Amgen's original motion to compel Roche to produce its cell line and the instant motion to enforce this Court's January 23, 2007 Order.

The relevance of Roche's EPO-producing cell line is clear—it is accused of infringing Amgen's asserted '349 Patent claims, and provides the best evidence that Roche's cells satisfy the EPO production rates recited in those claims. By contrast, Roche has yet to articulate how the cell line that Amgen uses to produce its Epogen® product is relevant to any claim or defense in this case. Amgen's manufacturing cell line for producing Epogen®—a commercial embodiment of the patents-in-suit—is not relevant to the infringement inquiry (since it is not the accused product) and is also not relevant to any validity inquiry. Roche's insistence on production of Amgen's cell line as a precondition to its own production is little more than a delay tactic to avoid complying with the Court's January 23, 2007 Order.

The consequence of this delay is that Roche has been able to run down the clock on

[5] Carter Decl., Exh. 10 (1/23/07 Court Order).

Amgen's ability to test Roche's cell line and marshal proof of infringement in time for submission of its initial expert reports—due on April 6. By withholding its cell line, Roche is foreclosing discovery into the best evidence that its accused cell line meets the EPO production rate limitations in Amgen's '349 Patent claims and is reducing the window of time that is available for Amgen's experts to grow and test those cells for purposes of submitting an expert report. Amgen is left in the unfair position of having the burden to prove infringement without having access to the best evidence to do so.

Because the Court has ordered the production of Roche's cell line and the cell line provides the best and most direct evidence that Roche's cells meet the EPO production levels recited in Amgen's '349 Patent, Amgen respectfully requests that the Court enforce its January 23, 2007 Order and order Roche to produce two 4-milliliter frozen viable samples of its DN2-3(*a*)3 cell line used to make the accused peg-EPO product within 5 days of entry of the Court's Order. Additionally, since Roche's unjustified delay of production has deprived Amgen of virtually all of the time originally allotted for expert discovery on this issue, Amgen respectfully requests that the Court allow Amgen two additional weeks to complete its infringement expert report. Lastly, if Roche fails to produce its EPO-producing DN2-3(*a*)3 cell line within 5 days of the Court's Order, Amgen respectfully requests that the Court deem Roche to have admitted that its cell line satisfies the EPO-production levels recited in Amgen's '349 Patent claims.

II. ROCHE SHOULD BE ORDERED TO PRODUCE ITS CELL LINE AND RELATED DOCUMENTS IMMEDIATELY OR, IT SHOULD BE DEEMED ADMITTED THAT ROCHE'S EPO-PRODUCING CELL LINE SATISFIES THE EPO PRODUCTION LEVELS RECITED IN AMGEN'S '349 PATENT CLAIMS.

On January 23, 2007, the Court ordered Roche to produce its cell line and related documents. In particular, the Court granted Amgen's motion to compel Roche's compliance with the following Requests for Production of Documents and Things:

> **REQUEST NO. 11:** A viable sample of each cell line used by ROCHE to produce the EPO component of MIRCERA (including the "DN2-3α3" cell line), and such documents and things as are sufficient to identify the origin, DNA composition, the growth characteristics and the quantity of EPO produced by each such cell line, including all results of all analytical tests performed on each such [c]ell line.
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> **REQUEST NO. 12**: The production record of each cell line produced in response to Request 11, above.
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> **REQUEST NO. 13:** For each cell line used by ROCHE to produce the EPO component of peg-EPO (including DN2-3a3 cells), documents and things sufficient to show how ROCHE stores and cultures each such cell line to produce the EPO component of MIRCERA, including all directions, materials and instructions needed to store, thaw, prepare culture media, and culture each such cell line.

Roche has not complied with the Court's Order. Instead, Roche has engaged in stalling tactics by conditioning its compliance with that Order on Amgen's production of Amgen's own cell line, thereby disregarding the reciprocal discovery already provided by Amgen, and further conditioning compliance on the imposition of additional, unreasonable restrictions on the handling of its cell line. After weeks of negotiating to reach a reasonable compromise with Roche, Amgen is unfortunately left with no option but to ask the Court to intervene once again. It has now been four months since Amgen first requested the production of Roche's EPO producing cell line. Per the Court's January 23, 2007 Order, Roche should be ordered to produce its DN2-3(*a*)3 cell line and related documentation immediately.

A. DESPITE THE COURT'S ORDER, ROCHE HAS FAILED TO PRODUCE ITS CELLS AND DOCUMENTS SUFFICIENT TO SHOW THE EPO PRODUCTION LEVELS OF ITS CELL LINE AS DETERMINED BY RADIOIMMUNOASSAY.

Roche cannot dispute that its EPO-producing cell line is relevant to demonstrate whether Roche's cells infringe Amgen's asserted process claims. However, Roche has failed to produce any evidence by which Amgen can discern the EPO production levels of its DN2-3(*a*)3 cell line as determined by radioimmunoassay despite Amgen's Requests for Production and Requests for

Admission calling for precisely this evidence.[6] Roche has, at times, claimed that this information is in Roche's document production. However, Roche has failed to identify any document or source of discovery produced to date that provides the EPO production levels of Roche's cell lines as determined by radioimmunoassay, as required by Amgen's '349 Patent claims. Amgen has asked Roche to identify where this information is located in its production,[7] but Roche has failed to respond.

As an alternative to producing its DN2-3(*a*)3 cell line, Amgen proposed that Roche stipulate to the EPO production levels of its cell line.[8] Roche has declined to do so on multiple occasions. Roche first refused to admit to that its cells produce the claimed amounts of EPO in response to Amgen's Requests for Admission, where it denied this and other basic facts about its cell line that are evident from the data in its BLA. Most recently, and since the Court's January 27, 2007 Order compelling production, Amgen offered to forego production of Roche's cell line in exchange for a stipulation from Roche that its cell line satisfies the EPO production rate limitations in the '349 Patent claims.[9] Negotiations reached an impasse when Roche insisted that notwithstanding its admission that its accused cells satisfy the claim limitation of Amgen's '349 patents-in-suit, Roche should be free to argue that the claim limitations are indefinite while Amgen should be precluded from using the fact of the stipulation to rebut such an argument.[10]

The stipulation speaks for itself, and it should be available for any evidentiary purpose. By entering into the stipulation, Amgen would be foregoing discovery of Roche's cell line to

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[6] *See, e.g.*, Docket No. 156, Exh. 11 (Amgen's First Set of Request for Production Nos. 1-224) at Request for Production No. 11; Docket No. 277, Exh. 1 (Amgen's First Set of Request for Admission Nos. 1-22) at Request for Admission No. 21.

[7] Carter Decl., Exh. 4 (2/15/07 K. Carter letter to P. Carson).

[8] Docket No. 261, Exh. B (1/05/07 D. Fishman letter to P. Carson); Carter Decl., Exh. 4 (2/15/07 K. Carter letter to P. Carson), Exh. 11 (2/22/07 K. Carter letter to P. Carson).

[9] Carter Decl., Exh. 5 (Amgen's proposed stipulation).

which it is entitled by the Court's January 23, 2007 Order, while preserving Roche's ability to make its arguments regarding the alleged invalidity of the asserted claims. By injecting its proposed restriction on the use of the stipulation, Roche is simply further delaying resolution of this issue and further prejudicing Amgen's ability to adduce this evidence of infringement.

Having foreclosed all other, potentially less burdensome, means of demonstrating that Roche's cells satisfy the EPO-production rate limitations of Amgen's '349 Patent claims, Roche should be ordered to produce its cell line and corresponding documentation immediately. In the alternative, should Roche fail once again to comply with the Court's Order, Amgen respectfully requests that it be deemed admitted that Roche's DN2-3(*a*)3 cell line satisfies the EPO-production rate limitations of Amgen's '349 Patent claims.

B. AMGEN LONG AGO PRODUCED THE "RECIPROCAL DISCOVERY" REGARDING ITS OWN CELL LINES.

In stark contrast to Roche's deficient production, Amgen has already produced reciprocal discovery to Roche with respect to ***Amgen's own*** EPO-producing cell lines. Namely, Amgen has produced regulatory filings and laboratory notebooks that demonstrate that its EPO-producing cell lines meet the EPO-production rate limitations of its '349 Patent claims. This is precisely the type of information that Roche continues to refuse to produce to Amgen, thus necessitating both the original motion to compel and the instant motion. Moreover, Amgen produced this reciprocal discovery months ago during the related ITC action and has since pointed Roche to examples of documents in Amgen's production containing the relevant evidence.[11]

Even though: (1) the Court's Order compelling Roche to produce its cells was not contingent on the production of Amgen's cell line; (2) Amgen has already provided the

[10] Carter Decl., Exh. 9 (2/22/07 P. Carson letter to K. Carter).

reciprocal discovery sought by Roche; and (3) Roche's Requests for Production do not expressly call for the production of Amgen's cell lines, Roche still demands that Amgen agree to produce its EPO-producing cell lines before Roche will produce its DN2-3(*a*)3 cell line to Amgen. This demand is baseless.

While the relevance of Roche's EPO-producing cell line used to make the accused peg-EPO product is undisputed, it is still unclear why Roche demands production of Amgen's cell lines. Amgen's previously produced and identified documents provide the reciprocal evidence of the EPO production levels of Amgen's EPO-producing cell lines, and Roche has failed to demonstrate any deficiencies in this evidence. Amgen has informed Roche that it does not understand how Amgen's cell lines are relevant to any of Roche's defenses or counterclaims,[12] to which Roche has yet to respond. Amgen's Epogen® cell line is not relevant to the infringement analysis, as it is not an accused product, nor is it relevant to any invalidity inquiry.

Roche's demand for production of Amgen's cell line as a precondition to producing its own cell line is simply another delay tactic, meant only to deprive Amgen of the time it needs for its experts to conduct the experiments necessary to obtain the discovery Roche has otherwise refused to produce. Unless and until Roche articulates a relevance and need for Amgen's EPO producing cell line that has not been satisfied by other discovery provided by Amgen, its demand for Amgen's cell line is baseless and should be rejected. Furthermore, since Roche's delay tactics have been successful in running down the clock on Amgen's ability to test Roche's cell line in time to include that information in Amgen's initial expert reports (due April 6), Amgen should be allowed two additional weeks to complete its infringement expert report relying on such testing.

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[11] Carter Decl., Exh. 7 (1/26/07 D. Fishman letter to P. Carson).

[12] Carter Decl., Exh. 8 (2/5/07 D. Fishman letter to P. Carson).

C. AMGEN AGREES TO TAKE ADDITIONAL PRECAUTIONS TO ENSURE PROPER HANDLING OF ROCHE'S CELL LINE.

The Court's January 23, 2007 Order expressly rejected Roche's proposed special handling requirements and deemed the provisions of the existing Protective Order adequate to protect the confidentiality and security of the produced cells.[13] Nevertheless, in the spirit of cooperation, Amgen has agreed to treat Roche's cell line as Highly Confidential Discovery Material under the existing Protective Order and to abide by the additional handling restrictions in the attached proposed order.[14] These additional restrictions go beyond those provided to the cell lines produced in the *Amgen v. HMR/TKT* case, as Amgen has agreed that its in-house counsel will not have access to the cell line.

Considering the Court's rejection of Roche's additional proposed handling restrictions, Amgen has been more than accommodating and reasonable by agreeing to the special handling restrictions, as described in Attachment A. Those additional safeguards more than adequately protect Roche's cell line and, in fact, go beyond what is required in the Court's Order and the existing Protective Order.

Because Amgen has agreed to take additional precautions to ensure the safe handling and treatment of Roche's cell line, and because Roche has resisted other forms of producing the probative infringement discovery regarding its cell line, Roche should be compelled to produce its DN2-3(*a*)3 cell line immediately, subject to the special handling restrictions in Attachment A.

III. CONCLUSION.

For each of the foregoing reasons, Amgen respectfully requests that the Court:

(1) Order Roche to produce at least two 4-milliliter viable samples of its current DN2-3(*a*)3 cell line and documents responsive to

[13] Carter Decl., Exh. 10 (1/23/07 Court Order).

[14] Attached hereto as Attachment A is Amgen's proposed Special Handling Restrictions for the Use and Handling of Roche's Cell Line.

Amgen's Requests for Production Nos. 11-13 within 5 days of the Court's Order;

(2) Grant Amgen two additional weeks (until April 20, 2007) to submit its infringement expert report regarding the testing of Roche's DN2-3(*a*)3 cell line; and

(3) In the event Roche fails to comply with (1) above, deem admitted that Roche's DN2-3α3 cells are "capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 1000 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay."

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on February 23, 2007.

/s/ Michael R. Gottfried
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