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 COMPEL PRODUCTION OF ROCHE'S CELL LINE AND RELATED DOCUMENTS

I. INTRODUCTION.

To produce the EPO used in Roche's accused peg-EPO product, Roche uses an EPO-producing Chinese Hamster Ovary (CHO) cell line designated DN2-3α3. Amgen requires discovery of Roche's cell line to demonstrate infringement of its asserted claims. In particular, the claims of Amgen's asserted '349 Patent require that the claimed vertebrate cells are capable of producing 100, 500, or 1000 units of EPO as measured by radioimmunoassay (RIA) per 10^6 cells in a 48-hour period. Yet, Roche has refused to stipulate to the claimed production levels in response to requests for admission and has failed to produce documents that provide those production levels in response to requests for production, leaving Amgen's request for production of Roche's cell line the only viable avenue for Amgen to obtain this plainly relevant discovery.

Amgen first requested Roche's cell line on October 30, 2006, to which Roche responded with an outright refusal. Since that time, Amgen has tried to resolve this issue amicably on numerous occasions, including trying to reach a compromise that would have obviated the need to produce the cell line. Roche, on the other hand, has delayed and forestalled agreement, depriving Amgen of its limited and valuable time to develop its case. Regrettably, Amgen is left with no choice but to seek the Court's intervention.

Amgen has already agreed to undertake safeguards for the handling and use of Roche's cell line to allay any concerns Roche may have about producing its proprietary cell line. Notably, the Court addressed the same issue in *Amgen v. HMR/TKT*, where Amgen agreed to similar handling safeguards, and the Court ordered that Defendants produce their proprietary cell line to Amgen.[1] Because Roche's cell lines are responsive to Amgen's pending discovery requests, provide the best and most direct evidence for Amgen's infringement case, and are not

[1] See Exh.13 to the accompanying Declaration of Deborah E. Fishman (hereafter "Fishman Decl.") at Docket No. 288 from *Amgen v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, USDC District of Massachusetts Civil Action No. 97-10814-WGY.

cumulative of other discovery, Roche should be ordered to produce its cell lines immediately.

II. ROCHE SHOULD BE ORDERED TO PRODUCE ITS CELL LINES AND RELATED DOCUMENTS.

On October 30, 2006, Amgen served requests for production of samples of Roche's cell line and documents sufficient to identify the characteristics of the cell line, its production records, and instructions for growing those cells. In response, on December 4, Roche objected to the production of its cell lines and related documents, contending that the requested materials are unnecessary and irrelevant. Since then, counsel for Amgen has met and conferred with Roche on numerous occasions to try to reach agreement on the production of its cell lines. Although Amgen acceded to Roche's panoply of demands, in each instance Roche backed away from compromise while simultaneously foreclosing other means for Amgen to obtain the same discovery regarding the production levels of Roche's cell line. With the time for fact discovery dwindling rapidly, Amgen seeks the Court's assistance to resolve this matter promptly.

A. AMGEN HAS REPEATEDLY TRIED WITHOUT SUCCESS TO AMICABLY RESOLVE THE DISPUTE OVER PRODUCTION OF ROCHE'S CELL LINE.

Amgen's original Requests for Production relevant to Roche's cell line (Nos. 11-13) and Roche's responses are set forth below:

> **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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> **RESPONSE TO REQUEST NO. 11:** Roche objects to this Request as overly broad, unduly burdensome, vague, ambiguous, harassing and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Roche also objects to this Request to the extent it seeks production of material that could constitute a non-exempt use under 35 U.S.C. § 271(e)(1) and subject Roche to potential liability. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No.

337-TA-568 for information concerning the production, composition, characteristics and relevant analytical test results of MIRCERA™. ***Roche will not produce any samples of cell lines to Amgen as such samples are unnecessary and irrelevant***. (Emphasis supplied)

REQUEST NO. 12: The production record of each cell line produced in response to Request 11, above.

RESPONSE TO REQUEST NO. 12: Roche incorporates herein by reference its Response to Request No. 11 above.

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.

RESPONSE TO REQUEST NO. 13: Roche objects to this Request to the extent it is overly broad, unduly burdensome, vague, ambiguous and not reasonably calculated to lead to the discovery of admissible evidence. Roche objects to this Request as seeking materials and information that have no relevance to any claim or defense in this action as EPO is not the accused product in this case. Roche also objects to this Request's use of the term "EPO component" as misleading, inaccurate and undefined. Roche also objects to this Request's use of the term "peg-EPO" as vague, ambiguous and misleading. Roche also objects to this Request to the extent it seeks information regarding cell lines other than those used to create Roche's MIRCERA™ product for which commercial approval is sought in Roche's BLA No. STN 125164/0. Roche refers Amgen to Roche's BLA No. STN 125164/0 already produced to Amgen in ITC Investigation No. 337-TA-568 for information concerning the cell lines used to produce MIRCERA™.

On December 11, Amgen met and conferred with Roche regarding the production of samples of its cell line and the EPO made from that cell line. During that discussion, counsel for Roche agreed to produce samples of its EPO product and to confer with the client regarding production of its cell line, subject to an appropriate immunity agreement.[2] On December 13, counsel for Roche told Amgen: "With respect to samples of cell lines, we are still consulting with our client regarding the feasibility of our production and will get back to you when we have

[2] Fishman Decl., Exh. 1 (12/11/06 D. Fishman letter to H. Suh).

Roche's final position. In any event, such production would also have to be the subject of a proper non-assert and use-restriction agreement."[3] The very next day, on December 14, Amgen sent Roche a non-assert agreement that addressed Roche's concerns about providing samples of its accused product and cell lines and also addressed certain use restrictions for those samples as set forth in the parties' Protective Order.[4] And then Amgen waited, and waited, and heard nothing from Roche.

Worse yet, on December 20, Roche served Responses to Amgen's Requests for Admission in which it denied certain basic characteristics about its cell line, including the amount of EPO made by its cell line.[5] In response and on the same day, Amgen requested an immediate meet and confer on Roche's insufficient responses and denials. Roche could not meet and confer until December 29.[6] On December 29, Amgen told Roche that its denials placed Amgen in an untenable position: Amgen was given an unsupported denial and was deprived of the discovery necessary either to verify or to challenge Roche's surprising denials.[7] During that December 29 meeting, Amgen asked Roche for its position on production of its cell line and counsel for Roche promised to provide an answer by the following week (Wednesday).[8]

The following week, rather than providing its response (as promised), Roche instead refused to take a position on whether or not it would produce its cell line, apparently in an effort to stall Amgen's ability to file a motion to compel on the subject.[9] Instead, for the first time,

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[3] Fishman Decl., Exh. 2 (12/13/06 H. Suh letter to D. Fishman).

[4] Fishman Decl., Exh. 3 (12/14/06 D. Fishman letter to H. Suh); Exh. 4 (12/14/06 K. Carter letter to H. Suh).

[5] Fishman Decl., Exh. 5 (Roche's Responses to Requests for Admission Nos. 18-21).

[6] Fishman Decl., Exh. 6 (1/3/07 D. Fishman letter to P. Carson).

[7] Fishman Decl., Exh. 7 (12/29/06 D. Fishman letter to P. Carson).

[8] Fishman Decl., Exh. 7 (12/29/06 D. Fishman letter to P. Carson).

[9] Fishman Decl., Exh. 6 (1/3/07 D. Fishman letter to P. Carson).

Roche suggested a compromise whereby it would admit or stipulate to certain characteristics regarding its cell line in exchange for Amgen withdrawing its request for the cell line itself. Amgen agreed that if Roche stipulated that its cell line made the amount of EPO as set forth in Amgen's claims (capable of producing in excess of 1000 units of EPO per 10^6 cells in 48 hours as measured by RIA), then Amgen would withdraw its request for production of Roche's cells. Counsel for Roche agreed to respond by the end of the day as to whether its client would agree in principle to the stipulation. At the end of the day Friday, Roche's counsel sought additional time (until Monday) to receive its client's sign-off on the proposed stipulation.

On Monday, Roche reversed course. Rather than pursuing the brokered-compromise—which Roche had originally proposed—Roche instead served Supplemental Responses to Amgen's Requests for Admission that, among other things, refused to answer Amgen's RFA regarding production levels of EPO. Amgen's attempts to resolve this matter with the cooperation of opposing counsel have failed and it seeks the Court's intervention.

Because Roche's cell line provides the best and most direct evidence that Roche's cells meet the EPO production levels claimed in Amgen's asserted '349 Patent, and because Roche has foreclosed all other practicable means of Amgen obtaining this evidence, Roche should be ordered to produce its cell lines immediately.

B. BECAUSE ROCHE'S CELL LINE IS HIGHLY PROBATIVE AND NON-CUMULATIVE EVIDENCE OF INFRINGEMENT, IT SHOULD BE PRODUCED.

Roche does not dispute that its cell line may be relevant to demonstrating whether Roche's cells meet the EPO production levels specified in Amgen's claims.[10] Likewise, Roche was unable to identify any other document or source of discovery information produced to date that would provide Amgen with the production levels of Roche's cell lines as measured by RIA,

[10] Fishman Decl., ¶ 3.

as required by Amgen's '349 Patent claims.[11]

In fact, at the same time Amgen served these requests seeking Roche's cell line, Amgen also served Requests for Production specifically seeking documents regarding the amount of EPO produced by Roche's cell line as measured by RIA (Request Nos. 14 and 15). Roche refused to produce documents responsive to either request,[12] Amgen moved to compel this production,[13] and the Court ultimately ordered Roche to produce documents responsive to these requests.[14]

Notwithstanding the Court's Order, Roche has yet to produce any documents that identify the amount of EPO produced by Roche's cell line as measured by RIA. Whether Roche's failure to produce responsive documents is in defiance of the Court's order or simply a reflection that Roche has no such documents in its possession, the fact remains that Amgen has been unable to obtain this information by other means.

Likewise, Roche has refused to stipulate or admit to the production levels specified by Amgen's Request for Admission and has denied other basic facts about Roche's cell line that appear contrary to facts specified in its BLA. Roche cannot have it both ways. It cannot provide baseless denials and then foreclose Amgen the discovery necessary to test or verify its responses.

Having foreclosed other, potentially less burdensome, means of demonstrating the production levels of Roche's cell line as measured by radioimmunoassay, any contention of burden by Roche should be rejected. Because Roche's cell line is not cumulative of other

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[11] Fishman Decl., ¶ 3.

[12] Docket No. 177, Exh. 4 (Roche's Responses to Amgen's First Set of Requests for Production Nos. 14 and 15).

[13] Docket No. 174 (Amgen's Motion to Compel Production of Documents). By contrast, because at all times, Roche provided the false assurance that it would work toward a compromise solution on production of its cell line, Amgen did not include the cell line samples issue in its original motion to compel.

[14] 12/29/06 Electronic Order on Amgen's Motion to Compel.

discovery already obtained, and not available from another source, Roche should be ordered to produce its cell line and corresponding documentation.[15]

C. BECAUSE AMGEN HAS TAKEN PRECAUTIONS TO ENSURE PROPER HANDLING OF ROCHE'S CELL LINE, ANY BURDEN ON ROCHE CAUSED BY PRODUCTION IS OF ITS OWN MAKING.

Amgen appreciates that Roche's cell line is proprietary and confidential and has taken reasonable precautions to ensure its safe handling and treatment. As discussed above, Amgen has already provided Roche with its agreement not to assert infringement for the supply of its cell line and also agreed to treat Roche's cell line as Highly Confidential Discovery Material under the parties' Protective Order.[16]

This Court has addressed an analogous situation in the *Amgen v. HMR/TKT* case. There, Amgen served requests for production seeking HMR/TKT's proprietary cell line, which was in the possession of a third party named Lonza Biologicals, Inc.[17] As in this case, Defendants' cell line was the best and most direct evidence that the accused cells made the production levels of EPO claimed in Amgen's '349 Patent.

During a hearing on Amgen's Motion for Summary Judgment of Infringement, the Court learned that Defendants had failed to produce their cell line, leaving Amgen to rely on indirect evidence (by way of an expert declaration) correlating the ELISA production values from TKT/HMR's FDA submission with the claimed RIA units. The Court ordered Defendants to produce their cell line within five days of that hearing.[18]

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[15] *See Caterpillar, Inc. v. Deere & Co.*, 1997 U.S. Dist. LEXIS 10155 *5 (N.D. Ill. 1997) (finding the requested product relevant and non-cumulative, the court compelled production and noted, "[a]s Caterpillar may obtain an 8000T tractor for testing only if the Court compels a sale by Deer, the discovery sought is not obtainable from another source.").

[16] Fishman Decl., Exh. 3 (12/14/06 D. Fishman letter to H. Suh); Exh. 4 (12/14/06 K. Carter letter to H. Suh).

[17] Fishman Decl., Exh. 8 (10/5/99 C. Stretch letter to D. Gilbert).

[18] Fishman Decl., Exh. 12 (12/15/99 Summary Judgment Hearing Tr. at 12:10-22); Exh. 13 at

In *Amgen v. HMR/TKT*, the parties' amended their stipulated protective order to include third party Lonza's production of its cell bank samples, cell culture media, and corresponding documentation, and they limited access to outside counsel, five designated in-house counsel for each party, independent experts, and the Court and its staff. Likewise, the parties agreed that the cell line could only be used for purposes related to the preparation of the lawsuit.[19] Under those terms, the parties reached agreement and Lonza agreed to provide HMR/TKT's cell line used to make its accused product.[20]

Amgen has agreed to the same access and use limitations with respect to Roche's production of its cell line.[21] In fact, Amgen's non-assert agreement offers to treat Roche's cell line as Highly Confidential thereby precluding even designated in-house counsel from having access to the cell line. Notably, Amgen provided this non-assert agreement nearly a month ago and Roche has not once raised issues regarding the inadequacy of the access and use restrictions offered by Amgen in that agreement.

Because Amgen has taken precautions to ensure the safe handling and treatment of Roche's cell line, and because Roche has resisted other forms of producing this probative information, Roche cannot be heard to complain that production of its cell line is onerous or unduly burdensome.

III. CONCLUSION.

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

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Docket No. 288 ("The Court further Orders the following: The dft is to produce the cells no later than Mon. Dec. 20, 1999…").

[19] Fishman Decl., Exh. 10 (11/3/99 Joint Motion to Amend Stipulated Protective Order and Exhibit A).

[20] Fishman Decl., Exh. 11 (12/2/99 C. Stretch letter to DiLello).

[21] Fishman Decl., Exh. 9, (11/16/99 R. Galvin letter to E. DiLello); Exh. 4 (12/14/06 K. Carter letter to H. Suh).

Roche to produce cells and documents response to Amgen's Requests for Production Nos. 11-13.

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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 January 10, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried