Amgen Inc. v. F. Hoffmann-LaRoche LTD et al

Doc. 297 Att. 4

Case 1:05-cv-12237-WGY

Document 297-5

Filed 02/26/2007 Page 1 of 8



Patricia Carson 212 836-7466 Fax 212 836-6355 pcarson@kayescholer.com

425 Park Avenue New York, New York 10022-3598 212 836-8000 Fax 212 836-8689 www.kayescholer.com

January 24, 2007

BY EMAIL and FAX

Deborah Fishman
Day, Casebeer, Madrid & Batchelder LLP
20300 Stevens Creek Blvd.
Suite 400
Cupertino, CA 95014

Re: Amgen, Inc. v. F. Hoffman-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-LaRoche Inc., Civ. No. 05-CV-12237WGY, D. Mass

Dear Deborah:

I write in response to the Court's order of January 23 regarding Roche's opposition to Amgen's motion to compel production of Roche's cell line, and your letter of yesterday to Howard Suh regarding production of Roche's cell line. As you know, the Judge treated Roche's Motion for Reconsideration on the cell line issue as an opposition to Amgen's motion. In addition to allowing Amgen's motion, the Court ordered Amgen to produce reciprocal discovery, hopefully without necessity of a motion to compel. Roche has identified Amgen cell lines that are relevant to this case, and which we expect Amgen to produce in concert with receiving Roche's cell line. Specifically, Defendants' Requests for Production 378-380 seek each cell line used by Amgen to produce erythropoeitin covered by Amgen's EPO Patents, each cell line used by Amgen to produce Epogen®, and each cell line used by Amgen to produce Aranesp®. Requests 396-399 seek each cell line covered by the asserted claims of Amgen's EPO Patents that Amgen possessed in certain relevant time periods including on or before December 13, 1983, February 21, 1984, September 28, 1984, and November 30, 1984.

As you point out in your letter, the time for performing and validating testing on the cell lines is short, so the production of Amgen's cell lines must occur quickly and at the same time as production of Roche's cell line. Of course, Roche will require reciprocal information and documents regarding storage and culture of Amgen's cell lines as you request from Roche in your letter. Additionally, in your letter, you request that we send the sample of our cell line to the University of Chicago. We do not think this is appropriate as the University of Chicago has produced documents pursuant to subpoena in this case, and is a potential witness. We are available to discuss the specifics of the information transfer, plus the timing, place and manner of

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KAYE SCHOLER LLP

2

January 24, 2007

production of each parties' cell lines, including a discussion of the conditions for protection of the lines similar to those set forth in the Proposed Order submitted January 22 with Roche's Motion for Reconsideration, a copy of which is enclosed with this letter.

Very truly yours,

Patricia Carson

Enclosure

cc: Michele E. Moreland, Esq. (via fax w/out encl.)
Mark Izraelewicz, Esq. (via fax w/out encl.)
Julia Huston, Esq. (via fax w/out encl.)
Leora Ben-Ami, Esq. (via fax w/out encl.)

EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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

[PROPOSED] ORDER REGARDING PRODUCTION OF ROCHE'S CELL LINE AND APPLICABLE RESTRICTIONS OF USE

In light of Amgen's professed need for discovery into samples of Roche's DN2-3(α)3 cell line to determine protein production levels relevant to the '349 patent, balanced against the extremely sensitive nature of this trade secret material and the need for a heightened precautions to protect Roche's proprietary material, the Court hereby orders that Roche will produce a limited amount of sample DN2-3(α)3 cells to a mutually agreed upon third party expert solely for testing relevant to the claims and defenses in this action. In addition, the following restrictions of use and access will govern the production and handling of this material:

1. Roche will provide a 4ml frozen vial sample of its DN2-3(α)3 cells containing approximately 3.3 x 10^7 cells to a designated independent third party expert qualified to render an opinion as to the properties and characteristics of such cell lines and their protein production capacities. This expert may perform all necessary experiments on the DN2-3(α)3 cells relevant to the limitations of the claims of the '349 patent or any other issue both parties stipulate is

relevant to this litigation, in all instances subject to all restrictions of use set forth elsewhere in this order.

This expert must not be in the employ of either party to this action or any parent, subsidiary or other affiliate thereof, nor receive any monetary compensation or other incentive from either party or any parent, subsidiary or other affiliate thereof outside of that related to the experiments he is authorized to perform under this order on the DN2-3(α)3 cells,

This expert must also be approved by Roche to be the recipient of the DN2-3(α)3 cells. Such approval may be withheld based on bias, incompetence or untrustworthiness of the expert or for any other legitimate reason but such approval must not be unreasonably withheld.

- 2. All of Roche's DN2-3(α)3 cells provided under this order must be maintained by the designated expert in a single, secured location, such as a locked laboratory or other room, access to which is restricted to the designated expert, lab assistants and members of the expert's staff, no more than two members of Amgen's outside counsel team and the Roche personnel designated in Section 14 below. Any of the aforementioned persons that will be permitted in the location in which the DN2-3(α)3 cells are kept must sign the consent form attached to this order as Appendix A.
- 3. Propagation of any of the DN2-3(α)3 cells produced under this order must be limited to the amount necessary to run the tests described in Section 1.
- 4. Neither the designated expert nor any other person with access to the cells produced under this order shall make any frozen samples of said cells.
- 5. The cells produced under this order must be maintained in a dedicated incubator and working area.

605232 1 2

Case 1:05-cv-12237-WGY Document 258 Filed 01/22/2007 Page 3 of 6

6. For every cell culture grown from the cells produced under this order, sufficient accounting shall be kept documenting the creation and use of such culture. On any day during which any testing or other use is conducted of either cells produced under this order or of any material derived from those cells, both the technical representative and legal representative of Roche identified in Section 14 shall have the opportunity, both at the beginning of the work day, and at the end of the work day, to inspect and review any laboratory notebooks and/or any other documentation of such testing or other use, including any data generated during the course of such testing or other use.

- 7. As successive cultures are produced of any of the cells produced under this order, all remaining cells must be destroyed.
- 8. Any cells propagated under this order shall not be grown in a bioreactor.
- 9. Any cells produced or propagated under this order that are no longer used in studies performed pursuant to this order or needed for propagation of cells for use in studies performed pursuant to this order must be immediately destroyed and the destruction of these cells must be accounted for in documentation.
- 10. Any cells provided under this order shall not be transferred to any third party or any other person not allowed access to the cells under Section 2.
- 11. No genetic material shall be removed or extracted from any cell produced under this order.
- 12. All information generated from or based upon the studies performed under this order and documentation relating to such information shall be maintained as Highly Confidential within the meaning of the Protective Order entered in this case on December 21, 2006.

605232_1 3

Case 1:05-cv-12237-WGY Document 297-5 Filed 02/26/2007 Page 6 of 8

13. The cells provided under this order or any cells propagated from those cells shall not be

used for any purpose other than the studies related to this litigation described in Section 1.

14. One legal and one technical representative from Roche may be present at all times during

testing or other use of the cells produced in this order.

15. At the conclusion of this litigation all cells produced under this order and any reports,

opinions, data sets or other documentation generated from or about the produced cells shall be

destroyed and the destruction accounted for in documentation.

16. To the extent not amended or modified by this order, the Protective Order entered in this

case on December 21, 2006 shall otherwise govern the use of the cells produced under this order

and any documentation relating to the cells produced under this order.

SO ORDERED on this	_ day of	, 2007.
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SO ORDERED:

The Honorable William G. Young United States District Court District of Massachusetts

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ATTACHMENT A

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
Plaintiff,)
VS.) C.A. No.: 05-cv-12237WGY
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH AND HOFFMANN-LA ROCHE INC., Defendants.)))
	ORDER REGARDING PRODUCTION OF APPLICABLE RESTRICTIONS OF USE
The undersigned represents that	he or she is outside counsel representing Plaintiff
Amgen Inc. in the above-identified litig	ation. The undersigned has read the protective
order issued on December 21, 2006 by	the Honorable William G. Young in this matter
and signed the agreement to be bound b	by its terms on The undersigned has
further read the Order Regarding Produ	ction of Roche's Cell Line and Applicable
Restrictions of Use issued on	("Order") by Honorable William G.
Young in this matter, and in accordance	e with that Order, further agrees to be bound by
the restrictions set forth in ¶¶ 2-16 of th	at Order.
Dated:	Respectfully submitted,
	Name Employer Address

ATTACHMENT B

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
Plaintiff,)
VS.) C.A. No.: 05-cv-12237WGY
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH AND HOFFMANN-LA ROCHE INC., Defendants.)))))
AGREEMENT TO ABIDE BY OF	RDER REGARDING PRODUCTION OF PPLICABLE RESTRICTIONS OF USE
The undersigned represents that h	e or she is an independent third party expert, as
set forth in ¶1 of the Order Regarding Pro	oduction of Roche's Cell Line and Applicable
Restrictions of Use issued on	("Order") by Honorable William G.
Young in the above-identified litigation,	or a member of said designated third party
expert's staff. The undersigned has read	the protective order issued on December 21,
2006 by the Honorable William G. Youn	g in this matter and signed the agreement to be
bound by its terms on The un-	dersigned has further read the Order in this
matter, and in accordance with that Order	r, further agrees to be bound by the restrictions
set forth in ¶¶ 2-16 of that Order.	
Dated:	Respectfully submitted,
	Name Employer Address