

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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

**DECLARATION OF DR. REINHARD FRANZE IN OPPOSITION TO AMGEN’S  
MOTION TO COMPEL PRODUCTION OF ROCHE’S CELL LINE**

I, Dr. Reinhard Franze, declare as follows:

1. I am the Head of Pharmaceutical Biotechnical Development Fermentation within the Pharmaceutical Biotech Production at Roche Diagnostics GmbH (“Roche”). I have been an employee of Roche and formerly Boehringer Mannheim GmbH since 1986. My educational background includes a Ph.D. in Microbiology from the University of Tübingen, Germany.

2. I make this declaration in opposition to Amgen’s “Motion to Compel Production of Roche’s Cell Line and Related Documents,” filed January 10, 2007, based upon my personal knowledge and company information.

3. My duties include supervision of the optimization of cell culture and fermentation process.

4. I have been informed by counsel that Amgen Inc. seeks to discover Roche’s confidential and proprietary DN2-3a3 cell line. Roche has instructed its outside counsel to

oppose any and all attempts by any outsider to gain access to these valuable cells, which constitute highly confidential and protected trade secrets.

5. Roche uses the DN2-3 $\alpha$ 3 cell line to produce the rhEPO material used in its manufacture of MIRCERA. The cell line is also used to produce Recormon and NeoRecormon. NeoRecormon is sold in the European market, in direct competition with Amgen's anemia products.

6. Roche and its subsidiaries store and use their DN2-3 $\alpha$ 3 cells only in a strictly confidential and exclusive manner. Use and storage of these cells takes place only in secure locations, for which Roche maintains security 24 hours a day, seven days a week. Roche restricts access to these cells only to approved members of its internal organization.

7. Roche protects the DN2-3 $\alpha$ 3 cell line as extremely sensitive trade secrets because the company and its subsidiaries would all suffer great harm if the cells were misappropriated by a competitor, including Amgen Inc. Any divulgence of the cells to a third party would ruin the cell line's status as a trade secret, inflicting an enormous loss to Roche's intellectual property portfolio. In particular, by misappropriating the cells, a competitor would not only gain use of the cells themselves, but additionally, through the sophistication of today's genetic engineering technology, within a matter of weeks, the competitor could compile critical trade secret information regarding the genetic makeup of the cells, which could be used in reverse engineering similar production cell lines.

8. For this reason, if even a small amount of these cells were to find their way into the hands of a party intending to market rhEPO in the European Market, it is likely that Roche would sustain sudden harm because rhEPO has now gained generic status there. New generics

would be able to enter the rhEPO market bypassing the substantial research and development costs incurred by Roche to develop the cells.

9. In this regard, Roche, and their predecessors in interest, have spent millions of dollars total developing the DN2-3 $\alpha$ 3 line of cells. This enormous and expensive research and development task has taken more than 10 years to complete.

10. Given that potential competitors would have great interest in obtaining any sample of the DN2-3 $\alpha$ 3 cells, what concerns Roche most is the extreme ease with which an interested person may misappropriate the cells, and in doing so obtain possession of all trade secrets embodied in those cells. In particular, such cells may be grown in laboratory scale in small-sized cell culture flasks, each of which can easily contain more than 100 million cells suspended in approximately a pint of liquid culture medium. Such cells may be propagated simply by removing a small volume of the culture medium containing the cells and transferring that volume into a new flask, where they will continue to multiply. A few tablespoons of the culture medium could easily be removed, placed into a small sterile vial, and removed from the experimental site in a shirt or coat pocket without being detected.

11. For these reasons, among others, Roche maintains the DN2-3 $\alpha$ 3 cell line in such total secrecy that it does not, and would not, trust an outside third party with the possession, production or maintenance of the cells.

12. I have reviewed the safeguards set forth in the proposed order submitted with Roche's opposition. It is Roche's position that while no safeguard would be strong enough to prevent a motivated or even an unintentional misappropriation, given the considerations enumerated above, these safeguards will at least provide some level of protection.

Signed under the penalties of perjury pursuant to 28 U.S.C. Sec. 1746 this 22<sup>nd</sup> day of January, 2007.

/s/ Reinhard Franze  
Dr. Reinhard Franze

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically on the above-referenced date 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 January 23, 2007.

/s/ Keith E. Toms  
Keith E. Toms

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