EXHIBIT 12

Dockets.Justia.com

DAY CASEBEER MADRID & BATCHELDER LLP

20300 Stevens Creek Blvd., Suite 400 Cupertino, CA 95014 Telephone: (408) 873-0110 Facsimile: (408) 873-0220 Deborah E. Fishman (408) 342-4587 dfishman@daycasebeer.com

November 21, 2006

VIA E-MAIL & FACSIMILE

Thomas F. Fleming Kaye Scholer LLP 425 Park Avenue New York, NY 10022-3598

Re: Amgen Inc. v. F. Hoffmann LaRoche Ltd., et al. (05-CV-12237WGY)

Dear Tom:

I write in a spirit of cooperation to help Roche prioritize and accelerate its search for and production of highly relevant information responsive to Amgen's requests for production of documents. In drawing your attention to certain categories of documents that we know exist within Roche, I do not in any way narrow or alter the requests for production that we served on Roche in this case on October 30, 2006, for which timely and complete responses are due in early December. Rather, I simply wish to remind you of information that was previously requested in our ITC discovery requests, including certain categories of information that were specifically identified by Roche employees in deposition and thereafter requested in writing by Amgen, but never produced by Roche.

We understand that Roche has a highly coordinated infrastructure to plan, manage and oversee all activities relating to the manufacture, supply, development, testing, clinical investigation, regulatory approval, reimbursement, marketing, promotion and sale of CERA, including the preparation for commercial launch of the product in the United States. In particular, the CERA Life Cycle Team for Renal Anemia and the North America Operating Committee (as well as their respective subteams) prepare and establish goals, set and review milestones, and propose and revise operating budgets for the development and commercialization of CERA, both globally and specifically in the United States.

We understand that the goals, milestones and budgets of these organizations are subject to further periodic review and approval within Roche, including reviews by Roche's Life Cycle Committee (LCC), Pharma Business Management Team (PBMT), and Development Leadership Team (DLT) as well as Mr. Burns or his associates. Among the major planning documents that comprise the Life Cycle process for CERA, we understand that Roche has prepared a Full Development Decision

DAY CASEBEER MADRID & BATCHELDER LLP

Thomas F. Fleming November 21, 2006 Page 2

Plan, a Decision to File, a Strategic Positioning Statement, a Strategic Launch Concept Plan, and a Launch Plan, as well as possibly other comparable or similar documents focused specifically on the U.S. market. We understand that some or all of these documents are maintained or are accessible to various Roche employees through means of Roche's internal computer networks and systems, including its ShareWeb system. The foregoing documents and things are directly responsive to Amgen's Requests for Production Nos. 45, 46, 51-56, 154-155 and should be produced in early December.

Likewise, Roche's U.S. organization undoubtedly generates similar CERA-related planning and management documents as those listed above. For example, we understand that the U.S. organization annually prepares and approves a Plan of Action, a Marketing Plan, a Medical Affairs Plan, a Governmental Affairs Plan and a Sales Plan. We also understand that that Roche's U.S. organization has various CERA-related teams or groups, including marketing and sales teams, a CERA brand team, a CERA pricing team, a market analytics team and other teams that are involved in establishing a brand identity for CERA, pricing of CERA, establishing U.S. sales forecasts and quotas for CERA, reimbursement policies and guidelines for CERA and contracting policies and guidelines for CERA. We understand that Roche is profiling and evaluating potential U.S. customers for CERA, developing instructional and promotional materials for use with potential U.S. customers and dispensers of CERA, and forecasting and scheduling or planning to schedule its production and supply needs for commercial sale of CERA in the United States. In addition, we understand that Roche is recruiting and preparing to train or training a sales force, preparing various sales forecasts or quotas, and establishing metrics to measure sales force performance. These or other teams within Roche are developing and scheduling advertising for CERA and establishing distribution channels and commercial arrangements for the commercial sale and supply of CERA in the United States. Documents and things relating to all of these activities are directly responsive to Amgen's Requests for Production Nos. 72-139 and 166-167, and should be produced in early December.

It has also come to our attention that Roche is planning and arranging or conducting medical trials of CERA use in nephrology patients in the United States in addition to those studies included in Roche's April 2006 BLA submission to FDA. Documents and things relating to all such activities are directly responsive to Amgen's Requests for Production Nos. 72-76, 123-139 and should also be produced in early December.

Since April 2006, we believe that Roche has supplemented its original BLA submission to FDA with updated patient data and analyses for studies conducted or completed subsequent to the original data lock for the April 2006 submission. In addition, Roche has undoubtedly engaged in communications with FDA regarding FDA's review and approval of Roche's BLA. All such documents and things are directly responsive to requests 37-41 and should be produced with your initial production in early December.

DAY CASEBEER MADRID & BATCHELDER LLP

Thomas F. Fleming November 21, 2006 Page 3

Amgen also seeks a complete and electronically searchable production of Roche's prior BLA and IND submissions to FDA. The past production of Roche's BLA is incomplete and not "fully text searchable" as required by Judge Young's November 6 Order. We have identified several sections of the BLA that Roche submitted to FDA but failed to include in its production to Amgen (as represented in its "Reviewer's guide for BLA" at ITC-R-BLA-00000014 – 22). For example, the data sets and data definition files for the Phase I, II, and III studies and the Integrated Safety Dataset were not included in the material produced to date.

In addition, the electronic version of the BLA provided was produced in non-consecutive page order and included inactive hyper-text links, making it impossible to identify and locate the linked external files, data reports, and patient records, and thus impossible to fully understand the materials. Given the difficulty we have had using the format you produced, we cannot be certain that the identified gaps are the only gaps in your production of the BLA.

A complete, fully-text searchable electronic copy of the BLA and all communications with the FDA, updates, supplements, and patient data relating to Roche's regulatory submissions are highly relevant and directly responsive to Amgen's Requests for Production Nos. 37-41 and should be included in your production in early December.

We appreciate your attention to this matter look forward to your production in early December.

Very truly yours,

DAY CASEBEER MADRID & BATCHELDER LLP

Deborsh F. Jim

Deborah E. Fishman

DEF:rlp

cc: Michele Moreland Peter Fratangelo Mark Israelewicz