

## **EXHIBIT 9**

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November 8, 2006

VIA FACSIMILE & U.S. MAIL

Peter Fratangelo  
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 Peter:

I write in response to your letter of yesterday to Rusty Day. We have also received Judge Young's order and we understand our obligations with respect to Amgen's in-house counsel. We further acknowledge that Roche's BLA/INDs are Highly Confidential pursuant to the pending two-tier Protective Order. However, we disagree with your interpretation of Judge Young's order on a few other counts.

First, the additional access restrictions placed on Roche's BLA/INDs do not extend to "FDA related documents," as your letter asserts. We are not aware of any basis for your assertion in either the Court's order or the side agreement in the ITC action. If we are mistaken, please specify where we can find grounds for the same treatment of the broad and ambiguous category of "FDA related documents" as for Roche's BLA/INDs.

Second, Judge Young's ruling is limited to the terms specified on pages 6-7 of Roche's cross-motion. We disagree with your suggestion that we limit *outside counsel's* access to and review of Roche's information. Since you provide no basis to mistrust outside counsel and the manner in which we have treated your confidential information over the past year, your proposal to limit outside counsel's access to Roche's information seems designed to interfere with our ability to prepare Amgen's case rather than a genuine effort to safeguard Roche's confidential information. Notably, Amgen produced its regulatory filings to Roche in the ITC action without such restrictions, relying on the Protective Order in place to protect those materials. The additional access restrictions endorsed by Judge Young, in addition to the protections provided in the pending Protective Order, are more than adequate to safeguard the confidential information in Roche's BLA/INDs in this action.

Third, we would like to discuss the definitions of "Confidential" and "Highly Confidential." While Judge Young agreed to a two-tiered Protective Order, he left the form and particulars of the Protective Order to the parties to negotiate. Roche's proposed definitions for what constitutes "Confidential" and "Highly Confidential" information are ambiguous and seem likely to lead to a *de facto* single tier Protective Order with "Highly Confidential" information encompassing all

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produced information. We do not believe that this was your intent or, more importantly, Judge Young's direction when he endorsed the terms on pages 6-7 of your motion. We welcome your suggestions in this regard.

Finally, Roche has not satisfied its obligations to produce complete copies of the FDA filings, and, as detailed in discovery correspondence from the ITC, the format of previously produced BLA/INDs was unacceptable. As was the subject of much discussion and debate in the ITC action, we are again requesting that Roche produce a complete, electronically searchable and hyper-linked copy of the BLA in the electronic form and data format as it was submitted to the FDA. Please see Request for Production Number 37 in Amgen's first set of requests propounded on October 30 for the specific request in this litigation.

The electronic copy of the BLA produced to Amgen in the ITC action was incomplete and contained several unacceptable discrepancies. For example, the previously produced BLA contained inactive hyper-text links with the BLA text to external files, data reports and patient records referenced in the text. Presumably, the linked documents are in the production, but Amgen has no way of identifying or locating any one of thousands of references made in the OCR version of the BLA provided to Amgen. As you are aware, Amgen has raised and documented other unacceptable issues regarding the produced copy of the BLA, such as described in the 6-4-06 letter from V. Smith to H. Suh and the 6-30-06 letter from D. Fishman to H. Suh and raised on a number of occasions.

Given the discrepancies in the incomplete copy of Roche's BLA previously produced to Amgen, please produce a complete, electronically searchable and hyper-linked copy of the BLA in the electronic form and data format as it was submitted to the FDA at your earliest opportunity, or suggest a practical and timely alternative solution.

We would like to schedule a mutually convenient time to discuss these issues with you to move forward on finalizing the pending Protective Order as soon as possible. We are available tomorrow or Friday to discuss. Please let us know what day and time works for you.

Very truly yours,

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cc: Deborah Fishman  
Michele Moreland  
Thomas F. Fleming