

# **EXHIBIT 1**

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

December 11, 2006

VIA EMAIL & FACSIMILE

Howard Suh, Esq.  
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 Howard:

I write to confirm our conversation of earlier today regarding Roche's Responses to Amgen's First Set of Requests for Production of Documents and Things.

**Roche's General Objections**

Amgen objected to Roche's position (General Response and Objection ¶ 7) that documents may be withheld based on privileges other than the attorney-client privilege and attorney work product immunity. To the extent that Roche withholds any documents based on a claim of privilege or immunity, you agreed to record the document and basis for withholding such document on your privilege log.

Roche objected generally to Amgen's Request for Production as calling for protected third-party information protected by third party confidentiality obligations (General Response and Objection ¶ 5). You confirmed that Roche is willing to reach agreement with respect to production of information protected by third party confidentiality obligations and protective orders in prior litigations. In particular, you agreed to produce documents responsive to Amgen's Requests for Production Nos. 100-109, pertaining to communications with customers and potential customers regarding the importation, use, offer for sale, or reimbursement of peg-EPO in the U.S, subject to such agreement.

In addition, you confirmed that notwithstanding Roche's general objections set forth in ¶ 7 (requested documents were disclosed and identified in Roche's Rule 26(a) statement), ¶ 10 (general requests shall be deemed limited by a more particular response), and ¶ 13 (Roche's objection to the use terms "EPO component," "DNA sequence encoding EPO," and "DNA

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encoding EPO”), Roche will not use any of these objections as a basis for withholding documents responsive to Amgen’s Requests for Production.

**Roche’s Objections to Amgen’s Definitions and Instructions**

Roche objected to the term “EPO” as overbroad, vague and ambiguous, and not likely to lead to the discovery of admissible evidence. (Objection to Definitions ¶ 2). You confirmed that notwithstanding Roche’s objection, it would not withhold documents regarding EPO based on this objection, except inasmuch as Amgen’s definition of “EPO” encompasses EPO analogs.

You confirmed that notwithstanding Roche’s objection to Amgen’s definitions for “ESP,” “PEG-EPO,” and “non-PEG component of peg-EPO,” Roche would not use its objection to any of these terms as a basis for withholding documents responsive to Amgen’s Requests for Production.

With respect to Roche’s Objection in ¶ 7, Roche’s attempt to limit its collection, review, and production obligation to the named defendants is unacceptable and unsupported by applicable case law. Roche has an obligation to conduct a reasonable search that includes subsidiaries and affiliates over which it has custody and control. Under Fed. R. Civ. P. 34, Defendants must produce documents which are under their control, whether or not in their possession.<sup>1</sup> “Control” is construed broadly and has been deemed to exist: (1) for a parent corporation for any documents retained by a wholly-owned or controlled subsidiary, (2) for a sister corporation, (3) where there is common ownership between a party and a non-party, and (4) where there is close coordination between the party and non-party.<sup>2</sup>

You have confirmed that notwithstanding Roche’s statement at ¶ 7, Roche will produce responsive documents for Roche Labs as well as Carolina Roche Inc. In addition, you have agreed to consider removing the language of ¶ 7 that “Roche objects to Amgen’s Definition No. 20 as including persons and entities that **do not control the corporate decisions or policy-making of the named parties and** possess no information bearing any relevance to any claim or

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<sup>1</sup> *In re Ski Train Fire of November 11, 2000 Kaprun Austria*, 2006 U.S. Dist. LEXIS 29987, \*14 (S.D.N.Y. 5/16/2006) (“[c]ourts have long construed the term ‘control as meaning more than simple possession.’); *Uniden America Corp. v. Ericsson Inc.*, 181 F.R.D. 301, 305 (N.D.N.C. 1998).

<sup>2</sup> *Id.* (granting motion to compel documents from a sister company where defendant had legal right to control or actual ability to control the production of documents); *Steele Software*, 237 F.R.D. at 565 (granting motion to compel where there was common ownership between party and affiliate); *Afros S.P.A. v. Krauss-Maffei Corp.*, 113 F.R.D. 127, 129 (D. Del. 1986); *In re Ski Train Fire of November 11, 2000 Kaprun Austria*, 2006 U.S. Dist. LEXIS 29987 at \*14-24.

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defense in this action. Based on our discussion, it is my understanding that Defendants will not limit their reasonable search for responsive documents to any affiliate or subsidiary that may possess information relevant to any claim or defense in this action, specifically including Chugai USA Inc. and Chugai Pharma USA LLC. If I am incorrect, please let me know immediately, identifying the name of each subsidiary or affiliate for whom Roche is withholding production.

You confirmed that Roche *will not* produce documents created after April 18, 2006. You stated that Roche would produce documents regarding its on-going or future clinical trials at such time as that data is submitted to the FDA, citing the reluctance to communicate with third parties until the clinical trials are closed. (Objection to Definitions ¶ 8). Based on your position, it is our understanding that Roche will produce all communication between Roche and the FDA after April 18, 2006, as requested in Amgen's RFP 40. Please let me know immediately if our understanding is incorrect.

In addition, with respect to each of Amgen's requests, wherever Roche agreed to either produce documents or to make them available for inspection and copying, you agreed that Roche will produce those documents to Amgen.

### **Roche's Responses to Amgen's Requests for Production**

#### ***Roche's BLA***

You confirmed that Roche will not produce its BLA to Amgen in the form it was provided to the FDA. (Requests No. 1, 37-42). We reiterated our concern that there remain several significant deficiencies in the BLA as it was produced to Amgen that have gone un-remedied and unanswered. In fact, Amgen made the request for an electronic copy as submitted to the FDA, just *one day* after the electronic copy of the BLA was produced, and many times thereafter. As we have detailed in our on-going correspondence, Roche must provide its BLA in native form in order to fully satisfy its production obligation. (See 6/04/06 V. Smith letter to H. Suh, 11/21/06 D. Fishman letter to T. Fleming; 11/08/06 K. Carter letter to P. Fratangelo; 6/30/06 D. Fishman letter to H. Suh; 6/06/06 D. Fishman letter to H. Suh)

While you offered to address gaps that we identify in your production, you continue to shift the burden to Amgen to identify those gaps, despite the fact that Amgen has repeatedly notified you that it cannot know the full scope of what is missing. As we have told you on several occasions, Amgen is prevented from identifying or confirming the gaps in your production because it is impossible to associate a hyperlink to the appropriate reference document. Beyond that, while you suggest that Roche is willing to work with Amgen to make a complete production, that statement ignores the fact that Amgen's past and on-going pleas to rectify production problems

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have gone unanswered. (See 11/21/06 D. Fishman letter to T. Fleming; 11/08/06 K. Carter letter to P. Fratangelo.)

***Structure and Activity of PEG-EPO***

You reconsidered and changed your position on the production of samples. You agreed to produce samples of Roche's MIRCERA and the EPO from which it is made (RFPs 2-4), subject to the parties reaching accord on an immunity and restricted access agreement for the production. Likewise, you agreed to confer with your client immediately regarding that production of the requested cell lines (RFPs 11-13). We look forward to your answer by Wednesday and we will in the meantime prepare an appropriate immunity agreement for your signature.

You maintained Roche's objection and refusal to produce documents relating to the characterization of the structure and activity of EPO from which MIRCERA is made beyond what was produced in Roche's BLA. (RFPs 5, 14-15). In addition, you refused to produce documents regarding Roche's naming efforts for its Mircera product based on a relevance objection, notwithstanding that such efforts are directly implicated by Roche's litigation position that its Mircera product – which it previously called peg-EPO – is not comprised of EPO (RFPs 218-220).

***Comparisons of Mircera to Other ESPs***

You reconsidered and changed your position on producing documents regarding comparisons between MIRCERA and other ESPs. You agreed to produce documents responsive to Amgen's RFPs 7, 9, and 28-36.

***Failed Attempts***

You maintained Roche's refusal to produce documents pertaining to the materials, cell lines, and processes that were considered or evaluated by Roche in its efforts to make Mircera. Notwithstanding the fact that Roche's failed attempts (as well as any successful attempts) are relevant to Amgen's infringement claims as well as Roche's invalidity defenses, you refused to produce documents responsive to Amgen's RFPs 16-24.

***On-Going and Imminent Infringing Acts***

In response to dozens of Amgen's Requests for Production regarding Roche's on-going and imminent acts of infringement and market preparations (RFPs 45-57, 60-64, 66, 69-81, 85, 88-90, 97-98, 100-103, 111, 148-150, 155, 158, 166, 214), Roche objected based on its contention that such information would only be relevant to the extent that they relate to a preliminary or

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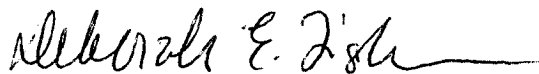
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permanent injunction or in the event that Amgen has a claim for damages. Today, during our discussion, you clarified that Roche's position is that it will not produce documents responsive to any of these requests unless Roche moves for a preliminary injunction or unless Amgen adds a claim for damages. In response, I explained that such documents were relevant to Amgen's claims of infringement, to the declaratory judgment jurisdiction of the Court, as well as to Roche's affirmative defense of non-infringement based on 35 U.S.C. § 271(e)(1). Notwithstanding these arguments, you maintained that Roche will not be producing responsive documents to these requests unless and until Amgen has a claim for damages. In light of your position on the foregoing, you also asked to change Roche's response to Amgen's RFP 65 from a "produce" response to a "will not produce" response.

Please let me know immediately if I have inaccurately stated our conversation of earlier today.

Very truly yours,

DAY CASEBEER  
MADRID & BATCHELDER LLP



Deborah E. Fishman

DEF:rlp

cc: Leora Ben-Ami  
Thomas F. Fleming  
Michelle Moreland  
Mark Israelewicz