UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO AMGEN'S MOTION TO ENFORCE THE COURT'S DECEMBER 29, 2006 ORDER AND TO COMPEL THE FURTHER PRODUCTION OF DOCUMENTS

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Dated: March 1, 2007

I. Introduction

This motion is Amgen's third bite at the apple, as it essentially seeks reconsideration of this Court's Orders of December 29, 2006 and January 22, 2007 in which the Court adopted Roche's compromise position as to ongoing clinical trials and communications with the FDA. This compromise position requires Roche to provide data relating to the clinical trials that have closed and for which data has been submitted to the FDA, but not incomplete data or all communications with the FDA, as the production of such documents would be unduly burdensome, prejudicial and disruptive to Roche's efforts to gain FDA approval. After already seeking the Court's intervention and failing both times to dissuade the Court from a reasonable compromise position, Amgen now moves to "enforce" an order with which Roche has already complied. In full good faith compliance with this compromise position, as ordered by the Court, Roche has produced well over 350,000 pages of documents relating to the completed clinical trials that underlay the BLA and IND submissions for MIRCERA™, including over 7,000 pages related to the only two trials to have been completed after the cutoff date for Roche's April 2006 BLA submission (referenced in Roche's four-month BLA update). In all, to date, Roche has produced over *6 million pages of documents* in response to all of Amgen's over 400 document requests and is continuing to produce documents on a rolling basis as additional discoverable documents are available.[1] Having been twice rebuffed by the Court on this very issue, Amgen should not be permitted to expand the scope of what it was properly granted.

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[1] Roche has produced a far greater number of documents than Amgen, and Amgen's discovery responses are woefully deficient in many respects. Roche anticipates filing a motion to compel in the near future.

II. Amgen's Motion Is Moot Because Roche Has Already Complied With The Court's December 29, 2006 Order.

In Roche's December 28, 2006 Opposition to Amgen's Motion to Compel, Roche stated its compromise position that documents relating to ongoing discussions with the FDA were not relevant and extremely burdensome to Roche, but Roche would produce data from the clinical studies that have been completed and submitted to the FDA. The Court agreed with Roche and adopted this position in its December 29, 2006 Order.[2] Since then, Roche has fully complied with the Order as described above. Thus, Amgen's Motion is moot because Roche has complied both with the spirit and letter of the Court's December 29, 2006 Order to produce data related to completed clinical studies submitted to the FDA. Indeed, Roche has produced over 350,000 pages (the printouts of which would fill approximately 140 banker's boxes) of such documents in response to this Order. To date, Roche has produced over 7,000 pages of documents related to protocols included in its "Four Month Safety Update" to the FDA, BA16736 and BA16738, which are the only two studies to have closed after the cutoff date for the April 2006 submission.

In addition to Roche's complete BLA and two INDs for MIRCERA™ and many thousands of pages of data from the completed clinical trial studies that have been submitted to the FDA, Roche has gone further still and agreed to provide Amgen with any information submitted to the FDA that changes the Chemistry Manufacturing and Controls ("CMC") section of its BLA from the April, 2006 submission. This is the section which describes the relevant

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[2] Most recently, the Court denied Amgen's so-called motion for "clarification" wherein Amgen sought to gain access to the ongoing communications between Roche and the FDA regarding the accused product, and the Court maintained the compromise position which allows sufficient discovery into the completed clinical trials that form the basis of Roche's BLA submission, which describes the structure and properties of the accused product for which Roche seeks approval. *See* Court Order of 1/22/07**.** Roche has provided this discovery.

structure, properties, function and method of manufacturing of Roche's proposed product awaiting approval. Not satisfied with this discovery, Amgen continues to demand access to incomplete trials and ongoing discussions with the FDA which Amgen knows full well do not change or affect the attributes of the proposed product described in Roche's BLA. The production Roche has provided contains this information and fully complies with the Court's December 29 Order.

III. Amgen's Stance Regarding Roche's FDA Correspondence and Supplements To Its BLA Is Not Consistent With the Court-Adopted Compromise Position on This Issue.

Amgen's third and present motion seeks to reinvent the Court's December 29 Order, claiming it now stands for the proposition that Roche must produce each and every supplement or communication for its BLA. This is neither the position Roche posited nor the one this Court endorsed. The Court clearly adopted Roche's compromise position in that only a subset of the FDA post-BLA communications be produced, namely, the data from the completed clinical trials.

In a particularly tortured reading of the Court's Order of December 29, Amgen seeks to rely upon Amgen's Request for Production No. 39, a request this Court expressly *denied,* and which was referenced in Request No. 41. In its Motion to Enforce The Court's December 29, 2006 Order, Amgen laid out its BLA/IND related Requests Nos. 37-41. Amgen acknowledged that the Court *previously denied* as overbroad Request Nos. 37-40, reproduced below:

> **Request for Production No. 37:** A copy of each electronic submission of ROCHE to the FDA relating to or comprising its Biologics License Application and/or Investigational New Drug Applications (IND) for peg-EPO (in the electronic form and data format provided to FDA with all embedded links intact and operable), including all communications, updates, supplements and patient data related thereto.

> **Request for Production No. 38:** All INDs filed with the FDA relating to peg-EPO, including the original IND filed by ROCHE with FDA in November 2001 and all communications with the FDA related thereto, including any amendment, supplement or update thereto.
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> **Request for Production No. 39:** All documents and things comprising or relating to any supplement or amendment to ROCHE's Biologics License Application for peg-EPO since April 19, 2006, including all communications, updates, analyses and patient data related thereto.
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> **Request for Production No. 40:** All documents and things comprising or relating to any communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.

The Court granted Amgen's request to produce only in response to Request No. 41:

> **Request for Production No. 41:** Documents and things sufficient to configure correctly and execute properly each electronic copy of submissions made to FDA produced in response to Requests 37-40, above.

The Court's order was therefore simple: to the extent Roche had produced BLA/IND related documents responsive to Amgen's Request Nos. 37-40, Roche was now required to provide electronic copies of those documents in their native format as submitted to the FDA. Roche has fulfilled that obligation, providing the relevant documents in the electronic format Amgen preferred. The Court's granting of Request No. 41 was a matter of formatting of documents produced, not of additional substantive documents, and did not have the effect of reviving simultaneously denied requests or independently requiring production of all "submissions made to FDA," including documents contained in Requests the Court denied. Nevertheless, this is precisely the interpretation Amgen now asserts. Amgen's position is not consistent with the Court's December 29 Order and its motion to "enforce" the Order is unfounded and unnecessary.

Moreover, the Court has recognized that the production of ongoing communications with the FDA would be of no particular relevance to the current issues in this action and would be

unduly prejudicial and potentially disruptive to the ongoing discussions and negotiations between Roche and the FDA. There can be no dispute that such pre-approval communications have no relevance to the issues of infringement or invalidity.[3] Amgen's asserted claims in this case relate solely to the characteristics of the actual accused product, and then arguably to the processes by which it is made. Nothing in continuing FDA negotiations or incomplete clinical trial data (which is constantly changing as the trials progress) relate to those issues. In its prior motions, Amgen has consistently failed to articulate any meaningful basis of relevance for the production it seeks and offers no new arguments in its current motion that justify it now. At best, Amgen makes a general allusion to possible relevance in terms of the injunctive phase. As Roche told Amgen, absent approval, none of these discussions have any relevance at all to such issues.

Further, Amgen's argument that this discovery is necessary to the factors underlying injunctive relief is disingenuous in light of Amgen's continued refusal to produce the FDA filings and documents, including the BLA, relating to its own Aranesp® product which Amgen contends will be an adequate market substitute for MIRCERA™, and will meet the relevant public health and economic needs. The Court ruled in its Order of February 7, 2007 (Docket No. 274) that Amgen must produce a reasonable scope of documents related to Amgen's request for injunctive relief. Yet, Amgen has not produced its BLA regarding Aranesp®, and such documents are not only relevant to issues of infringement and validity in the underlying action, but particularly relevant under Amgen's reasoning to the injunctive phase, if required, as Amgen has positioned Aranesp® as an alternative to MIRCERA™ in the marketplace.

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[3] Roche has briefed the relevance issue at length in its Opposition to Amgen's Motion for Clarification of the Court's December 29, 2006 Order (Docket No. 246) and its Opposition to Amgen's Motion to Compel the Production of Documents (Docket No. 199).

Amgen has consistently maintained that Aranesp® is covered by at least one of the claims in the patents in suit (and discovery is ongoing -- although stymied by Amgen's noncompliance -- to determine if there are other claims) and Amgen has touted its product as an adequate market substitute for MIRCERA™, capable of meeting relevant public health and economic needs. Amgen implicitly asserts that comparisons between Aranesp® and MIRCERA™ in structure, composition, and mechanism of action are relevant to issues in this case, as Amgen's memorandum states that it is "currently collecting and will produce its regulatory filings and correspondence with FDA since October 2005 concerning safety and efficacy of . . . Aranesp® in the nephrology indication for which Roche's pending BLA seeks FDA approval." *See* Amgen Memorandum in Support of its Motion to Enforce at 6 (Docket No. 282). Notably, Amgen does not actually say it will produce its Aranesp® BLA and the actual Aranesp® BLA predates October 2005. Amgen should have produced this BLA long ago, as it has had Roche's BLA for almost nine months now. For all its qualifications and cut-outs, despite the fact that no regulatory filings have been produced for a product already approved and on the market, Amgen still impugns the completeness of Roche's production. It is disingenuous for Amgen to assert a need for supplements to Roche's BLA pursuant to its prayer for injunctive relief while continuing to deflect requests for its Aranesp® BLA. Amgen's refusal to produce these documents totally undermines its argument that the discovery it demands from Roche is needed in conjunction with the question of injunctive relief, especially in light of the Court's rulings that discovery be reciprocal. *See* Order of January 23, 2007 (Docket No. 298). For these reasons and those discussed below, Amgen's motion to reconsider, styled as a motion to enforce, should be denied in full.

IV. Amgen's Requests for Roche's Communications with FDA Regarding its MIRCERA™ BLA Are Unduly Burdensome and Have Already Been Denied.

Amgen further continues to ignore this Court's prior rulings by refusing to narrow the scope of its discovery requests. *See* Court's Order of December 29, 2006, denying Amgen's Motion to Compel Request for Production No. 40. Below is Amgen's *denied* Request No. 40 regarding communications with FDA, compared with its revised, purportedly "narrowed" Request No. 301:

> **Request for Production No. 40:** All documents and things comprising or relating to any communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.
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> **Request for Production No. 301:** Documents sufficient to show each communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006.

In addition to being completely inconsistent on the compromise position ordered by the Court, this purportedly "narrowed" request fails to follow the Court's prior rulings and instructions. Amgen has made it clear that it wants Roche to do more than merely identify its FDA communications, such as by providing a list, but instead seeks to discover the communications themselves. Amgen's renewed request is on its face substantively unchanged from its previous request and therefore cannot revive the previously denied request. Documents "sufficient to show" communications with the FDA encompass the same universe as "documents relating to" communications with the FDA. For example, if Roche were in possession of a presentation which included information which reflects a FDA communication, this document would be responsive to the "narrowed" request as a document "showing" a communication with the FDA, just as it would be responsive to the original request as a document "relating to" a communication with the FDA. Amgen has simply substituted synonymous words in its requests,

and has not effectively limited the universe of documents which the requests cover. This Court has denied this request once before due to the undue burden it would cause Roche, and Amgen has done nothing to overcome the Court's prior ruling or its adoption of the compromise position advanced by Roche. Such tactics are yet another example of Amgen attempting to circumvent and rewrite the Court's December 29, 2006 Order. In addition, it is not proper for Amgen to seek to "enforce" the Order with respect to requests such as this one that were never before the Court.

IV. Conclusion

For all of the foregoing reasons, the relief sought in Amgen's Motion to Enforce the Court's December 29, 2006 Order and to Compel the Further Production of Documents should be denied in full.

Dated: March 1, 2007
Boston, Massachusetts

Respectfully submitted,

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/s/ Nicole A. Rizzo
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