UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

PLAINTIFF AMGEN INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO ENFORCE THE COURT'S DECEMBER 29, 2006 ORDER AND TO COMPEL THE FURTHER PRODUCTION OF DOCUMENTS

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I. INTRODUCTION.

Amgen seeks a permanent injunction to preclude Roche from infringing Amgen's patents by making, importing, using, selling or offering to sell Roche's accused peg-EPO product in the United States. Roche counters that its accused peg-EPO product does not infringe Amgen's patents-in-suit, and that even if its peg-EPO product does infringe a valid Amgen patent claim, no injunction should issue because "an injunction precluding Roche from importing into, making, using, or selling CERA in the U.S. is contrary to the public health and welfare."[1] Yet, Roche refuses to produce the supplemental BLA filings it has submitted to FDA since April 2006 or any of the correspondence between FDA and Roche regarding its BLA—the very documents most probative of issues on which Amgen's right to injunctive relief and Roche's defenses depend. Roche's "heads-I-win, tails-you-lose" approach to discovery should be rejected.

On December 29, the Court directed Roche to produce its peg-EPO BLA and each supplement filed with the FDA in the electronic format in which Roche submits those filings to FDA.[2] Indeed, when Roche opposed Amgen's motion to compel production of documents, it expressly told the Court and Amgen that it would produce its supplemental BLA filings and all clinical data underlying them as a "compromise position" in lieu of producing the broader production requested by Amgen.[3] In reliance on Roche's representation, the Court denied

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[1] Docket No. 140 (Roche's Answer and Counterclaims).

[2] 12/29/06 Order attached as Exhibit 1 to the Declaration of Deborah E. Fishman in Support of Amgen Inc.'s Memorandum of Points and Authorities of its Further Motion to Compel Production of Documents (hereafter "Fishman Decl.").

[3] Docket No. 199 (Roche's 12/28/06 Opposition to Amgen's Motion to Compel the Production of Documents) at 2. In fact, at the time Roche offered its "compromise position," it had already submitted at least two supplemental BLA filings to FDA in support of its original April 18, 2006 BLA filing on Mircera. *See* Fishman Decl., Exh. 2 (indicating that Roche would be providing a 4-month safety update following a March 6, 2006 meeting with FDA); Fishman Decl., Exh. 3 (Roche website: Investor update – Roche offers the FDA additional Mircera data); and 12/15/06 Roche press release at http://www.roche.com/inv-update-2006-12-15 ("Roche today announced

Amgen's request to compel even broader discovery of Roche's clinical program, and ordered Roche to produce documents in accordance with its compromise position, and to do so by January 29.[4]

But Roche has now reneged on that promise. Although Roche did subsequently produce an electronic copy of its April 18, 2006 BLA submission in the format ordered by the Court, it refuses to produce the supplemental BLA filings it has submitted to FDA since April 2006. According to Roche's latest position, it will not produce its supplemental filings with FDA unless and until FDA finally approves its peg-EPO BLA (which isn't expected by Roche before its May 2007 PDUFA date).[5] In other words, Roche refuses to produce its supplemental BLA filings before the April 2 close of fact discovery, the April 6 submission of initial expert reports, and the April 27 submission of rebuttal expert reports.[6]

Roche's intransigent refusal to produce its supplemental BLA filings flies in the face of this Court's December 29 Order and severely prejudices Amgen's preparation of its case. The supplemental BLA filings submitted to FDA since April 2006 are highly probative, not only to Amgen's claim for declaratory relief and Roche's non-infringement defense, but even more significantly to Amgen's claim for injunctive relief and Roche's asserted defenses to that claim.

When Roche made its original BLA filing in April 2006, Roche characterized the data it submitted to FDA as incomplete because its filing did not include complete safety data for many

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that it has submitted additional data to the FDA to support its Biologic License Application (BLA) for Mircera.

[4] Fishman Decl., Exh. 1 (12/29/06 Order).

[5] Fishman Decl., Exh. 4 (2/8/07 D. Fishman letter to T. Fleming); Fishman Decl., Exh. 5 (2/9/07 T. Fleming letter to D. Fishman).

[6] In December 2006, when Roche supplemented its BLA with additional data, it also agreed to postpone any decision by FDA on its pending BLA from February 20, 2007 until May 20, 2007. *See* Fishman Decl., Exh. 3 (12/15/06 Roche press release at http://www.roche.com/inv-update-2006-12-15).

patients whose results could not be collected in time for Roche's April 2006 filing[7] Consequently, the clinical analyses Roche submitted in April were also presented as preliminary and incomplete. Roche told FDA that it would supplement its filing with completed data for the clinical trials it had conducted in a supplemental filing four months after the original filing.[8] Then, in December 2006, Roche publicly announced that it had filed yet more data and analyses with FDA in support of its BLA.[9] None of these supplemental filings has been produced to Amgen, and Roche now refuses to do so.

At the same time, however, Roche contends that its peg-EPO product differs from Amgen's claimed inventions, and provides clinical and economic benefits not achievable with currently available therapies. Because Roche alone has access to its peg-EPO product, it alone has had the ability to conduct clinical trials comparing the clinical effects of peg-EPO to other commercially available ESPs, including Amgen's recombinant human EPO. The studies Roche has submitted to FDA include clinical trials in which the effect of peg-EPO is compared to the effect of EPO therapy in corresponding patient groups. In fact, Roche's BLA filings with FDA contain the only comparative studies of peg-EPO and EPO in human patients and, as such, they are highly probative of the truth or falsity of the comparative claims Roche makes regarding its accused product.

The supplemental clinical information and analyses submitted to FDA, some at FDA's request, are directly relevant to the assertions Roche makes about the safety and efficacy of its peg-EPO product, as well as any alleged benefits or risks associated with its use. All of these

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[7] *See* Fishman Decl., Exh. 2 (indicating that Roche told FDA at a pre-BLA meeting that safety information for its Phase IIIb would not be included with its BLA submission but would instead be provided as a 4-month safety update) at ITC-R-BLA-00000009-010.

[8] *Id*.

[9] Fishman Decl., Exh. 3 (12/15/06 Roche press release at http://www.roche.com/inv-update-2006-12-15 containing investor update: "Roche offers the FDA additional Mircera data").

issues are relevant to the merits of Amgen's claim for injunctive relief as well as Roche's asserted non-infringement and public interest defenses. Yet none of Roche's BLA filings since April 18, 2006 has been produced to Amgen.

Amgen respectfully requests the Court to enforce its December 29 Order and to rectify the prejudice that Roche's refusal is causing Amgen—both in its completion of fact discovery by April 2 and in its preparation of initial expert reports by April 6, 2007. Without access to the complete set of data and analyses submitted to FDA, Amgen and its experts cannot assess whether and to what extent Roche's representations based on its partial data submitted in April 2006 are in fact correct or significant. Nor can it assess whether Roche has changed its representations based on the more complete and extensive data submitted in its supplemental filings. Given the vanishingly short time remaining to review and analyze Roche's supplemental data before the April 2 discovery cut-off, it is now more urgent than ever that Roche produce its filings in the electronic format in which they have been submitted to FDA.

In addition, Amgen moves the Court to order Roche to produce its communications between FDA and Roche since April 2006 regarding its pending peg-EPO BLA. Although the Court ordered Roche in December to produce its BLA filings to Amgen, the Court denied without prejudice Amgen's motion to compel Roche to produce all documents and things comprising or relating to Roche's communications with FDA.[10] In particular, the Court ruled that "Requests 37-40 are denied as overbroad without prejudice to their renewal upon drafting of more narrow and focused requests."[11] Amgen subsequently narrowed its requests to seek only those communications that have occurred between Roche and the FDA since April 2006 that

[10] Fishman Decl., Exh. 1 (12/29/06 Order).

[11] Fishman Decl., Exh. 1 (12/29/06 Order).

relate to Roche's pending BLA, peg-EPO, or EPO.[12] Roche, however, adamantly refuses to produce these communications to Amgen.[13]

Here again, Roche's refusal severely prejudices Amgen's preparation of its case. Since filing its BLA with FDA in April 2006, Roche and the FDA have engaged in extensive communications with one another regarding the wording and content of the package labeling requested for peg-EPO, as well as the significance, accuracy and completeness of the clinical and manufacturing data that Roche has submitted to FDA. Communications between Roche and the FDA regarding the proposed label for peg-EPO will evidence whether and when FDA may approve Roche's pending application, the patients for which the product may be approved, and the conditions or restrictions on the product's use and dosing. Roche's communications with FDA regarding its clinical studies submitted in support of product registration will evidence the questions and concerns FDA has posed to Roche—and the responses Roche has provided to FDA—about claims Roche is making in its license application and proposed labeling regarding the relative safety and therapeutic effect of peg-EPO as compared to other ESP products currently available to patients, as well as Roche's attempts to differentiate peg-EPO from EPO.

For its part, Amgen has already produced its FDA filings and correspondence between Amgen and FDA regarding Amgen's currently-marketing EPO product (EPOGEN®) from 1985

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[12] Amgen Request for Production 298 reads:

> "A copy of each electronic submission of ROCHE to FDA comprising its Biologics License Application (BLA) and/or Investigational New Drug Application (IND) for peg-EPO (in the electronic form and data format provided to FDA with all embedded links intact and operable), including each communication, update, supplement and patient data related thereto."

Amgen Request for Production 301 reads:

> "Documents sufficient to show each communication, meeting or exchange of information between ROCHE and FDA regarding peg-EPO or EPO since April 19, 2006."

[13] Fishman Decl., Exh. 6 (1/23/07 D. Fishman letter to T. Fleming); Fishman Decl., Exh. 7 (1/31/07 D. Fishman letter to T. Fleming; Fishman Decl., Exh. 11 (2/2/07 T. Fleming letter to D. Fishman).

through October 2005, and is currently collecting and will produce its regulatory filings and correspondence with FDA since October 2005 concerning the safety and efficacy of EPOGEN® and Aranesp® in the nephrology indication for which Roche's pending BLA seeks FDA approval. Because Roche's communications with FDA are directly relevant to Amgen's claims and Roche's defenses, as well as the propriety and need for injunctive relief, Amgen respectfully requests the Court to order Roche to produce on an expedited basis documents responsive to Amgen's narrowed Requests for Production Nos. 298-301.

II. ARGUMENT

A. ROCHE HAS REFUSED TO PRODUCE ITS SUPPLEMENTAL FDA FILINGS AS PREVIOUSLY ORDERED BY THE COURT.

Four months after the submission of its BLA in April 2006, Roche supplemented its original BLA filing with additional safety data requested by FDA.[14] Then, in December 2006, Roche publicly announced that FDA had requested Roche to submit still more clinical data and analyses in support of its application, and that Roche had agreed to extend the date for FDA action on Roche's pending peg-EPO BLA from February to May 2006.[15] While investor reports suggest that Roche's December submission to FDA was related to safety concerns over its peg-EPO product, this is mere speculation without discovery:

> We believe the additional data requested by the FDA are related to safety, possibly the link of high hemoglobin with complications which is a "class effect." There might also be data specific to CERA. Prior Phase 3 data on CERA suggest that there were more drug-related severe adverse events. However, the details

[14] *See* Fishman Decl, Exh. 2 (indicating that Roche would be providing a 4-month safety update following a March 6, 2006 meeting with FDA).

[15] Fishman Decl., Exh. 3 (Roche website: Investor update – Roche offers the FDA additional Mircera data). *See* http://www.roche.com/inv-update-2006-12-15: "Roche today announced that it has submitted additional data to the FDA to support its Biologic License Application (BLA) for Mircera. These data offered are intended to provide as comprehensive an understanding of Mircera as is possible to assist the FDA in completing the review process. As a result of this action, the FDA has granted Roche a three month extension to the review period."

have not been disclosed by Roche.[16]

On December 14, 2006 Amgen moved the Court for an order compelling Roche to produce its original and supplemental BLA filings, and to do so in the same electronic format in which the submissions were provided to FDA.[17]

Roche opposed Amgen's motion, but in so doing represented to the Court that "Roche has agreed that documents relating to clinical studies that have been completed and submitted to the FDA will be produced, but that production of ongoing communications with the FDA would be unduly burdensome to gain FDA approval."[18] Roche justified its compromise position by stating that:

> "[r]equests for unfinished and unanalyzed raw data from these studies are not reasonably calculated to lead to the discovery of any information relevant to whether the finished MIRCERA™ product infringes Amgen's patents. Only if and when these studies are completed and the data is processed for submission to the FDA will they become the subject of legitimate discovery and at that time Roche will produce any responsive associated documents."[19]

On December 29, the Court ordered Roche to produce "documents and things sufficient to configure correctly and execute properly each electronic copy of submissions made to FDA produced in response to Requests for Production Nos. 37-40."[20] The Court's Order on Amgen's Request for Production No. 40 expressly requires Roche to produce each electronic copy of its submissions made to FDA. Amgen's Request No. 37 clarifies that the FDA submissions to be produced in native format include supplemental filings and patient data:

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[16] Fishman Decl., Exh. 9 (1/22/07 Goldman Sachs Report).

[17] Docket No. 166 (12/14/06 Amgen's Memorandum in Support of its Motion to Compel Production of Documents).

[18] Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of Documents) at 2.

[19] Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of Documents) at 10.

[20] Fishman Decl., Exh. 1 (12/29/06 Order).

> **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. (Emphasis added)

In addition, the Court held Roche to its compromise position, ordering Roche to complete the production of it supplemental FDA filings by January 29, 2007.[21] Throughout January Amgen expressly relied on Roche's promise to produce its supplemental BLA filings and the Court's Order to do so by January 29. At no time – until last week – did Roche suggest that it would withhold its supplemental BLA filings.[22] When Amgen learned that Roche's January 29, 2007 production did not include Roche's supplemental BLA submissions, it immediately requested Roche to rectify the deficient production.[23] In response, and for the first time, Roche took the position last week that it was under no obligation to make a production of its supplemental BLA filings.[24]

Roche's newly-articulated position is contrary to the Court's December 29 Order and is also inconsistent with Roche's prior agreement to produce its supplemental BLA filings. Lest there be any doubt that Roche's "compromise position" includes its submissions to FDA, Roche repeatedly told Amgen in the parties' discovery conferences that it would be producing its supplemental BLA submissions to FDA.

Roche first offered Amgen its "compromise position" in early December in response to Amgen's request for production of all responsive documents created after April 18, 2006. In particular, counsel for Amgen summarized the parties' meet and confer in which Roche agreed

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[21] Fishman Decl., Exh. 1 (12/29/06 Order). The Court also ruled that Amgen was free to renew its motion to compel production of more narrowly defined documents.

[22] Fishman Decl., Exh. 4 (2/8/07 D. Fishman letter to T. Fleming).

[23] Fishman Decl., Exh. 10 (2/7/07 D. Fishman letter to T. Fleming).

to produce its on-going and future clinical trials at such time as Roche submitted data to FDA:

> ***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.[25] (Emphasis supplied)

Roche's counsel wrote back and confirmed that Roche would produce its supplements, amendments or updates to its BLA once they were actually submitted to FDA:

> ***Roche maintains its position that it will not produce documents created after April, 18, 2006, except completed amendments, supplements or updates to its BLA, or other correspondence relating to MIRCERA™, that have actually been submitted to the FDA, as well as relevant and responsive documents concerning completed clinical trials***. As stated in Roche's Responses to Amgen's Document Requests, production of other documents post-dating the filing of Roche's BLA is irrelevant, unnecessary and particularly disruptive in the context of unfinished or future clinical trials from which no conclusions concerning the properties of MIRCERA™ can be drawn.[26] (Emphasis supplied.)

Roche's about-face not only conflicts with its prior representations to the Court and to Amgen, but is highly prejudicial to Amgen. As discussed above, Roche alone has had the means to conduct comparative analyses of the safety and efficacy of its accused product and other currently-marketed ESPs. By purchasing Amgen's commercially available products, Roche has been able to conduct (and has in fact conducted) numerous human clinical trials in which it compares the safety and efficacy of its accused product with the safety and efficacy of Amgen's EPO and other commercially available ESPs. Because Amgen has not had access to Roche's peg-EPO product, it could not and has not performed such comparative studies. Consequently, the clinical data submitted to FDA by Roche are the only comparative human clinical data

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[24] Fishman Decl., Exh. 4 (2/8/07 D. Fishman letter to T. Fleming).

[25] Fishman Decl., Exh. 8 (12/11/06 D. Fishman letter to H. Suh).

[26] Docket No. 177, Exh. 30 (12/13/06 H. Suh letter to D. Fishman).

known to exist. Even more to the point, the supplemental data and analyses that Roche submitted to FDA after April 2006 are likely to be the only data and analyses that address the longer-term safety and efficacy of peg-EPO in humans.

Since December, more than one-third of the time available for fact discovery has expired. Having patiently waited for over a month for the filings Roche represented it would produce and was ordered to produce by January 29, Amgen must now move to compel Roche to do what Roche promised this Court and Amgen in December it would do. Roche's latest gambit means that even more time will now expire before Amgen will receive the highly complex, detailed and massive amount of data Roche promised to produce and was ordered to produce by January 29, leaving Amgen with little or no time to evaluate that information and use it effectively to conduct fact discovery by April 2 (fact discovery cut-off) or prepare expert reports by April 6 (submission of initial expert reports). In light of the vanishingly short time remaining to conduct fact discovery and prepare expert reports, any further delay in the Roche's production of its BLA supplements in the format provided to FDA as previously ordered by the Court only compounds the prejudice to Amgen and the preparation of its case.[27]

Amgen respectfully requests the Court to order expedited production of Roche's supplemental filings and amendments in the form submitted to FDA as previously ordered. In addition, Amgen asks the Court to sanction Roche for its dilatory discovery tactics by extending Amgen's time to complete fact discovery and to serve its initial expert reports on the subject of injunctive relief by whatever additional time Roche takes beyond January 29 to comply with the Court's order.

[27] *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d at 1446, 1458 (Fed.Cir. 1988) (citing *Smith Int'l*, 718 at 1581; *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986).

B. ROCHE'S COMMUNICATIONS WITH FDA REGARDING ITS PEG-EPO BLA ARE RELEVANT TO THE MERITS AS WELL AS AN INJUNCTION AND SHOULD BE PRODUCED.

On October 30, 2006, Amgen served document requests seeking Roche's communications with FDA regarding its peg-EPO IND and BLA submissions and, in particular, Roche's communications with FDA since April 18, 2006, the date on which Roche filed its BLA with FDA. When Roche refused to produce these documents, Amgen moved to compel on the following requests, among others:

> **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.
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> **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.
>
> **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.
>
> **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.
>
> **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.

Each of these requests seeks communications between Roche and FDA regarding Roche's peg-EPO IND, BLA, and all supplements or amendments thereto. In particular, Request No. 40 seeks all communications between FDA and Roche that post-date the filing of Roche's BLA. In its Opposition, Roche refused to produce any communications with the FDA after April 18, 2006

about its peg-EPO product, claiming that such production would be "unduly burdensome to Roche's efforts to gain FDA approval."[28]

The Court ordered Roche to fully produce in response to Amgen's Request No. 41, but did not order any specific relief with respect to Roche's communications with FDA after April 18, 2006. It denied the remainder of Amgen's motion without prejudice and with leave to re-propound narrowed requests.[29]

On January 8, Amgen served narrowed requests on Roche (Nos. 298-301), once again seeking Roche's on-going communications with FDA:

> **Request for Production No. 298:** A copy of each electronic submission of ROCHE to FDA comprising its Biologics License Application (BLA) 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 each communication, update, supplement and patient data related thereto.
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> **Request for Production No. 299:** Each IND filed by ROCHE with FDA for peg-EPO, including the original IND filed by ROCHE with FDA in November 2001, and each communication with the FDA related thereto, including each amendment, supplement or update thereto.
>
> **Request for Production No. 300:** Each supplement or amendment to ROCHE's BLA, including draft supplements and amendments of each, for peg-EPO since April 16, 2006, including each communication, update, analysis and patient data related thereto.
>
> **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.

Despite the narrowed requests served by Amgen, Roche has made it clear that it will not produce any communications with FDA after April 18, 2006 regarding its BLA.[30] According to

[28] Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of Documents) at 2.
[29] Fishman Decl., Exh. 1 (12/29/06 Order).
[30] Fishman Decl., Exh. 11 (2/2/07 T. Fleming letter to D. Fishman); Fishman Decl., Exh. 4 (2/8/07 D. Fishman letter to T. Fleming).

Roche, the Court's December 29 Order relieved it of any obligation to produce communications with the FDA that occurred after April 18, 2006.[31] In addition, Roche argues that the production of its post-April 2006 communications with FDA would be "unduly burdensome to Roche's efforts to gain FDA approval."[32]

Amgen respectfully submits that the Court's December 29 Order did not relieve Roche of the obligation to produce communications with FDA that occurred after April 18, 2006, and that any such ruling would severely prejudice Amgen's right and ability to discover and prepare its case for trial. Roche's communications with FDA regarding FDA's review and consideration of Roche's BLA are not only relevant but highly probative of Amgen's claims of infringement, Roche's defenses, and the propriety and urgency of injunctive relief.

For example, Roche's most recent communications with FDA provide the surest insight into whether and when FDA may approve Roche's pending application and are thus directly relevant to Amgen's claims of infringement and injunctive relief. Such communications are also relevant to Roche's defenses and claims of non-infringement, and particularly to the weight, if any, that should be placed upon the many self-serving attempts in Roche's BLA submission and proposed product labeling to differentiate its peg-EPO product from human recombinant EPO. Likewise, Roche's supplemental clinical information and analyses provide the most direct evidence of whatever clinical or economic benefits or detriments peg-EPO may have and are directly relevant to the merits of Amgen's infringement claims, Roche's defenses, and the propriety of injunctive relief. Indeed, Roche's Ninth Affirmative Defense (Public Welfare) is predicated on the contention that its peg-EPO product better serves the public health and welfare

[31] Fishman Decl., Exh. 11 (2/2/07 T. Fleming letter to D. Fishman); Fishman Decl., Exh. 12 (Roche's Responses and Objections to Amgen's Second Set of Requests for Production) at Responses to RFP Nos. 298-301.

[32] Docket No. 199 (Roche's Opposition to Amgen's Motion to Compel the Production of

than currently marketed ESPs; its on-going communications with FDA during the approval process are perhaps the most probative evidence of the truth or falsity of Roche's claim of public health benefit. The fact that Roche wishes to foreclose this discovery speaks volumes.

Significantly, and for good reason, Roche does not contend that its communications with FDA are not relevant to the issues in this case. Rather, other than its mischaracterization of the Court's December 29 Order, Roche claims that production of its communications with FDA be "unduly burdensome to Roche's efforts to gain FDA approval." But that objection is spurious. Under applicable FDA regulations, Roche is required to collect and maintain a written record of all communications with FDA during the registration process in order to comply with its reporting obligations.[33] There is neither burden nor hardship to Roche in making the production Amgen requests.

Because Amgen's original requests have been pending since October and because two-thirds of the time for fact discovery has already expired, Amgen respectfully requests the Court to order Roche to produce all documents responsive to Amgen's Requests for Production 298, 299, 300 and 301 on an expedited basis.

III. CONCLUSION.

For each of the foregoing reasons, Amgen respectfully requests the Court to order:

(1) Roche to produce all updates, supplements, and patient data comprising or in support of its BLA in the electronic form and data format provided to FDA;

(2) An extension of time for Amgen to take depositions and to prepare and submit expert reports on the subject of injunctive relief equal to the number of days from January 29 until Roche produces its BLA updates, supplements, and patient data in the previously ordered electronic format; and

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Documents) at 2.

[33] *See, e.g.*, 21 C.F.R. 312.33, 21 C.F.R. 312.50, and 21 C.F.R. 312.56.

(3) Roche to produce within seven (7) days of this Order all communications between Roche and FDA since April 18, 2006 regarding Roche's pending BLA for peg-EPO.

Dated: February 15, 2007

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on February 15, 2007.

/s/ Michael R. Gottfried
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