UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN INC.,	
Plaintiff,	) Civil Action No. 05-CV-12237WGY
v.	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,	
Defendants.	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO COMPEL DEPOSITIONS, DOCUMENTS AND INTERROGATORY ANSWERS

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I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Hoffmann-La Roche Inc. (collectively, "Roche") respectfully submit this memorandum in support of its motion to compel various discovery that Amgen has continued to withhold through today, the fact discovery deadline. Specifically, Roche requests that Amgen be compelled to produce documents relating to Amgen's anticompetitive threats of potential Roche customers; documents relating to contracting and pricing practices in certain Amgen customer segments; and documents from the files of Mr. Marinelli, Amgen's designated 30(b)(6) on Amgen's gross revenue and incremental costs associated with its ESA products. Amgen should also be compelled to provide a properly prepared 30(b)(6) witness on the topic of the Ortho licensing agreement, as well as a knowledgeable witness on the topics in Roche's 3rd 30(b)(6) notice. Finally, Roche moves for an order compelling Amgen to provide complete and detailed supplemental responses to Roche's First Set of Interrogatories Nos. 1-12.

With today's cutoff looming, the parties have been working furiously to complete fact discovery. In the last week alone, over 25 depositions were taken. Initial expert reports are due at the end of this week. However, Amgen's unresolved discovery deficiencies have prompted Roche to file this motion to compel to address these issues. There may be more issues that arise after the final written discovery is served at the end of the day today by Amgen, and Roche respectfully requests the right to seek relief from the Court after it views those responses. For now, Roche submits this motion. Roche has struggled to complete its discovery even though Amgen held to the last two weeks in discovery before providing the majority of its witnesses for deposition. As a consequence,

Roche has had to be cautious in taking depositions to not exceed the 105 hours allocated by the Court, and at the same time to ensure that it had additional time should its motions be granted.

Although Amgen's discovery shortfalls are myriad, Roche identifies crucial areas below in which Amgen's recalcitrance has substantially prejudiced Roche during the discovery period and if not resolved will impede Roche's preparation of its case for trial. In particular, Amgen has blocked key document discovery into some of Amgen's market tactics and customer interactions that go right to the essence of Roche's antitrust counterclaims. With respect to the patent claims and defenses, Amgen has failed to provide the most basic discovery into its contentions by submitting interrogatory responses that omit requested information including *inter alia* all the intrinsic and extrinsic evidence supporting Amgen's claim construction; an explanation of Amgen's claims of contributory and induced infringement; the conception and reduction to practice dates for the invention claimed in the patent-in-suit and supporting evidence; a description of Dr. Lin's inventive contribution to these claims; whether Amgen will seek monetary damages and if so what kind; and any description of Amgen's pegylation work in connection with EPO. Plainly Amgen's withholding of such documents and information on both the antitrust and patent issues in suit is inconsistent with Amgen's discovery obligations. With discovery just about exhausted, Roche has no recourse but to seek to compel.

III. ARGUMENT

Roche is entitled to discovery of "any matter, not privileged, which is relevant to the claim or defense of any party . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible

evidence." Fed. R. Civ. P. 26(b)(1). "The plain language of Rule 26(b)(1) contemplates wide-ranging discovery to the fullest possible extent." *Klonoski v. Mahlab*, 156 F.3d 255, 267 (1st Cir. 1998).

In particular, "discovery in antitrust litigation is liberally granted." *Riedel Int'l, Inc. v. St. Helens Invest., Inc.*, 633 F. Supp. 117, 119 (D. Or. 1985); *see also, e.g., Columbia Steel Casting Co. v. Portland Gen. Elec. Co.*, 1992 U.S. Dist. LEXIS 3036 (D. Or. 1992) (quoting same, overruling defendant's objection that requests were overly burdensome, and requiring defendant utility to produce documents regarding prices paid to other, non-party utilities for power); *Trans World Airlines, Inc. v. Hughes*, 29 F.R.D. 523, 524 (S.D.N.Y. 1961) ("The scope of proof is quite broad in these [antitrust] cases and under the liberal federal rules wide latitude is permitted in the deposition-discovery proceedings."). Thus, while the scope of permissible discovery always is broad, it is especially important that, in cases with antitrust claims, discovery be permitted regarding all evidence going to central issues such as market definition, market and monopoly power, anticompetitive effects, and damages. Such discovery inevitably requires review of substantial documents beyond those required in many other cases. *See, e.g., Banana Serv. Co. v. United Fruit Co.*, 15 F.R.D. 106, 108 (D. Mass. 1953) (overruling defendants' objection that interrogatories were unduly burdensome, and observing that "[i]t is well known that the preparation and proof of anti-trust cases requires the study and investigation of a multitude of facts and documents").

Roche's antitrust counter-claims are based, among other things, on Amgen's efforts to tie up the market for drugs that stimulate the production of red blood cells ("erythropoiesis stimulating agents," or "ESAs"), which are used to treat patients suffering

from a number of life-threatening maladies. Amgen has sought to prevent Roche from entering the market through threats and contract provisions that directly or effectively prevent customers from purchasing ESAs from Roche. Amgen has employed long term sole-source contracts, exclusive dealing provisions, and rebate provisions that require customers to purchase significant quantities of Amgen's product in order to qualify for rebates that are essential to a successful business in the renal care market. This Court already recognized the core relevance of these customer contracts, communications, and relationships when it ordered Amgen to produce all documents concerning Amgen's customer contracts. (*See* January 29, 2007 Order.) Still, despite repeated requests Roche has been hampered in obtaining complete discovery from Amgen on these issues, as well as on the patent issues through glaring omissions from Amgen's interrogatory responses.[1]

A. Amgen Must Provide Complete Discovery of Documents Relating to Amgen's Admitted Threats to Customers Relating to MIRCERA™.

Among the prongs of Roche's antitrust claims is the fact that Amgen has been threatening customers that if the customer uses MIRCERA™, and then wishes to continue to use Amgen products, Amgen would refuse to offer those customers the same favorable pricing and contract terms that they currently have available to them. These threats have not only been confirmed in the deposition testimony of certain customers, but the fact of the threats have been acknowledged by Amgen. At the deposition of Helen Torley, Amgen's Vice President and General Manager of Amgen's Nephrology Unit, Ms. Torley acknowledged that an Amgen executive who reports to her, Leslie Mirani, another Amgen Vice President, was making threats and other inappropriate statements to intimidate

[1] Pursuant to LR 37.1 the parties have conferred on these issues by teleconference and letter and been unable to reach agreement.

customers from doing business with Roche in the renal anemia market. Ms. Torley testified:

Q And who did Mirani communicate it to?

MR. DAY: Objection. Vague as to time and person.

THE WITNESS: I'm aware that in 2006, Leslie did have a communication around legal uncertainty to some customers at the NRRA meeting. Leslie, at that time, did not communicate the appropriate message, and it was brought to my attention. And I gave her feedback on that and instructed her to take corrective action to make sure that even though nobody else was communicating the message, it would be understood we should not be talking about this topic.

Torley Trans. 124:13:125:2

* * * * *

Q: Was there any other aspect of her [Ms. Mirani] message that you learned about that simply was considered inappropriate?

A: Um, there was another comment that she [Ms. Mirani] had made that was reported that if you leave Amgen and go to CERA, I can't say what your contract will be when you come back.

Q: And did you also -- strike that. Did you learn that from the same two channels?

A: Yes, I did.

Q: And what did you tell her about that message?

A: I said no decisions have been taken on that at this point in time, and it's inappropriate to communicate that.

Torley Tr. 131:14-132:4

* * * *

Q Was she directed to have those communications with other people?
A No, she wasn't.
Q Was she directed to have those communications with the NRAA?
A No, she was not.
Q Did you talk to Ms. Mirani about what should be communicated to the marketplace, in terms of legal risk?
MR. DAY: Objection. Vague and ambiguous as to time.
THE WITNESS: Did not, until after the event go into detail with Leslie as to her understanding of what legal risks -- what she had said, how this could -- was interpreted by customers and gave her corrective action as to what Amgen's intent was with legal risk and how it should be communicated if it was communicated again.

Torley Tr. 126:19-127:12

* * * * *
Q And what did you tell Ms. Mirani?
A I explained to Ms. Mirani that the customers had indicated they were distressed by this. This wasn't a message that we had discussed, approved, or was it part of any planned communication; That she had left them with her own impression; That I wanted her to go back to speak to the customers to correct that misimpression.
Q Did you tell her how to correct the misimpression?
A Yes. I told her that in communicating about anything about that legal risk, it really related to waiting until the litigation was completed, rather than having to convert patients to Peg-EPO and then back.

Torley Tr. 129:5-23

Roche had already requested documents from Amgen regarding this conduct of intimidation. (*See* Roche's document requests nos. 126-130, 132, 287, 304-308, 418-422.) This Court should order Amgen to fully comply with these requests. In addition, subsequent to this deposition Roche repeated its demands for all documents (including internal email, memoranda or other materials) reflecting such communications whether discussing them internally at Amgen or externally with clients. (Attached as Ex. A is a copy of a March 23, 2007 letter from Theodore Maya to Deborah Fishman regarding Roche's request). Amgen has refused to acknowledge this request or produce all such documents. Roche respectfully asks this Court to compel Amgen to produce any and all documents reflecting or relating to such communications with customers regarding MIRCERA™ and Roche's internal discussions regarding such communications.

B. <u>Amgen Must Provide Complete Discovery of Documents Regarding Sales of ESA's For Use Among Patients In the Anemia Related Oncology Market.</u>

Roche also moves to compel documents and information from Amgen regarding its sales of ESAs for use in patients with anemia related to oncology. Roche's original requests for documents relating to Amgen's sales and marketing of ESAs did not distinguish between sales for oncology-related anemia and ESA sales for anemia related to

other diseases, such as chronic kidney disease. Amgen, however, refused to produce information regarding its sales for oncology-related anemia. After a meet and confer process, Roche agreed to a compromise wherein Amgen would provide certain data and information regarding its sales for oncology-related anemia, in particular "information on oncology sales, prices, profits and costs since January 1, 2000." (*See* Ex. B, Letter from Gaede to Mayell, Feb. 7, 2007). Amgen was also to produce similar information and data on its "sales, prices, profits, and costs" as to non-oncology use as well. But as late as March 6, 2007, Amgen acknowledged that it had not produced this information as to either oncology or non-oncology related sales in a comprehensive form. (Ex. C, W. Diaz email, March 6, 2007 to Mayell). Only after this date -- after Roche stated that it would need to file an emergency motion to compel -- did Amgen produce data in native format that it represented would contain sales, pricing, profit and cost data for both oncology and non-oncology use. *Id.*

That data received from Amgen, however, does not contain data or information enabling Roche to determine the pricing of ESAs sold for oncology uses in, as newly-amended Rule 34 of the Federal Rules of Civil Procedure requires, "reasonably usable form." Contrary to its agreement as part of the meet and confer process, Amgen has provided no documentation or data that enables Roche to determine the pricing of ESAs sold for oncology use, nor data from which that information can be derived. Amgen must produce this information immediately.

Amgen's failure to produce the pricing information on its oncology sales also negates the agreement to which Roche agreed during the meet and confer process. Because of Amgen's discovery failure, Roche further moves to compel Amgen to comply with

Roche's discovery requests as drafted regarding its contracts for the sale of ESAs to healthcare providers (Request 114).[2] On the assumption that Amgen would be providing data on prices of its sales of ESAs for oncology use, Roche agreed that Amgen did not have to produce documents concerning its contracts for the sale of ESAs for oncology uses. Because Amgen has reneged on its agreement to provide pricing information on such sales, Amgen should respond to document request 114 as originally drafted by producing its contracts, and related documents, for its sales of ESAs for oncology uses.

C. Amgen Must Supplement Its Responses To Roche Interrogatories Nos. 1-12.

Roche served its First Set of Interrogatories on Amgen on December 6, 2006, and despite repeated reiterations of its requests, Amgen has declined to address various deficiencies in its Response.

Roche first objected to deficiencies in Amgen's Responses to Roche's First Set of Interrogatories in late January, demonstrating with a chart showing bullet-point detail, deficiencies in Amgen's responses. (*See* Ex. D, 1/24/07 H. Heckel letter to W. Gaede). Amgen subsequently issued supplemental responses, which failed to address Roche's articulated concerns. (*See* Ex. E, 1/24/07 W. Gaede letter to H. Heckel).

Roche then, on March 1, requested for a second time that Amgen supplement its responses, again including a chart laying out in bullet-point detail deficiencies in Amgen's responses, and its subsequent supplementation. (*See* Ex. F 3/1/07 Letter from H. Heckel to W. Gaede). Amgen declined to further supplement its responses, leaving Roche with no

[2] Document Request 114 seeks "[a]ll Documents and Electronic Data Concerning contracts, agreements, negotiations or discussions between Amgen and any third party, Including any Health Care Provider, concerning the purchase, manufacture, source or supply of any ESA product, Including requirements contracts, exclusive dealing arrangements, discounts, bundled discounts across product lines, rebates and /or pricing."

choice but to seek the Court's intervention. The following deficiencies persist despite Roche's repeated requests for supplementation:

Interrogatory No.1

While Amgen in its Supplement, does vaguely identify a class of entities which they allege could be direct infringers, induced by Roche, it does not identify

- any specific customer or distributor,
- what acts would constitute the direct infringement, or
- any acts that may induce infringement.

Amgen also does not identify each document and thing that supports or otherwise refutes Amgen's proposed claim construction, including all intrinsic evidence and extrinsic evidence as requested in Roche's Interrogatory No. 1. Curiously, even with regards to intrinsic evidence, Amgen labels this request "overbroad and unduly burdensome."

Interrogatory No. 2

Amgen declined to supplement its response to this interrogatory, pointing generally to "produced documents" as a response, where the burden is greater on Roche to glean this information from the documents than Amgen pursuant to FRCP 33(d), while Amgen does not identify specifically the documents to which it refers. Roche repeats its request for the identity of "all current and former employees of Amgen likely to have knowledge of facts in connection to ... Amgen's assertions regarding:

- 'Dr. Lin's Pioneering Inventions,'
- 'Roche's Infringing Process and Product,' and
- Amgen's "First Cause of Action'"

Interrogatory No. 3

Amgen declined to supplement this interrogatory, and its response remains deficient in the following respects:

- does not provide conception and reduction to practice dates on a limitation-by-limitation basis,
- does not identify Dr. Lin's purported inventive contribution to the claimed subject matter of Amgen's EPO patents on a limitation-by-limitation basis, and
- fails to provide all corroborating evidence of Dr. Lin's purported conception and reduction to practice.

Interrogatory No. 4

Amgen asserts, in conclusory fashion, that "Dr. Lin invented the subject matter of the Asserted Claims." Notably, Amgen declines to describe

- Dr. Lin's role in developing any method for expressing DNA encoding EPO in mammalian host cells.

Interrogatory No. 5

Amgen declined to supplement its response to this interrogatory. The response remains deficient because it does not identify any particularized basis and/or evidence that Amgen contends demonstrates

- "that by September 1984, once one of skill in the art of the patents-in-suit had possession of the DNA sequence encoding human EPO, it would not have been routine and/or obvious for that person to express the DNA sequence encoding human EPO in mammalian host cells to produce a glycosylated protein and to

isolate the resulting EPO protein to make an *in vivo* biologically active product."

- Amgen also does not even define the predicate skill level of one of ordinary skill in the art that would be necessary to answer this interrogatory.

Interrogatory No. 6

Amgen continues to decline to state:

- whether it will be seeking monetary damages in this case,
- if so, what type of monetary damages it will seek, and
- the extent of such damages.

Amgen does state that it "is not seeking monetary damages for any past acts [of infringement]" but

- does not identify or describe any of the "past acts" to which it obliquely refers.

Interrogatory No. 7

- Amgen declines to describe all attempts at pegylation of EPO.[3]

Interrogatory No. 8

- Amgen does not identify whether Claim 1 of the '698 patent literally covers, or covers under the doctrine of equivalents, the making, using offering to sell, or selling ARANESP.
- Amgen does not state whether ARANESP is covered by any other claims of the patents-in-suit.

[3] Experiments regarding pegylation and Aranesp are currently subject of another Motion to Compel production of documents and 30(b)6) witness(es) filed by Roche and pending before this Court.

Interrogatory No. 9

- Amgen does not identify any evidence specifically supporting the statement "the addition of one or more peg molecules to the EPO does not alter the molecule on any relevant manner."

Interrogatory No. 10

- Amgen does not confirm that all claims within the patents listed are exempt from double patenting for the reasons stated in its supplement to this interrogatory; if not all claims are being asserted as exempt, Amgen does not identify which ones are.
- Amgen fails to provide any explanation of supporting evidence for the statement "the later issued claims are consonant with the examiner's restriction requirement."

Interrogatory No. 11

- Amgen declines to state whether it contends that claim 1 of U.S. Patent No. 5,955,422 is a "product-by-process claim." Nor does Amgen provide any evidence supporting such a position.

Interrogatory No. 12

- Amgen has not further supplemented its response to describe any reasons why the work of Goldwasser does or does not demonstrate a "therapeutically effective amount of human erythropoeitin."

Accordingly, after repeated attempts to reach out to Amgen, Roche respectfully requests that this Court compel Amgen's response to the above enumerated points.

D. Amgen Should Provide a Knowledgeable Witness Regarding The Ortho Licensing Agreement and Responsive Documents From the Files of Mr. Marinelli.

Amgen has also provided 30(b)(6) witnesses on key marketing and financial issues who were insufficiently prepared and for which Amgen failed to provide any document discovery. For example, Amgen's witness Mr. Daly was designated for Roche's 30(b)(6) Topic 15 regarding the terms of Amgen's product licensing agreement for Procrit. Amazingly, at his deposition Mr. Daly was not sure if he had ever seen this agreement before. (Daly Tr. 14). Amgen's attorney represented that in unnamed meet and confers it was agreed that "there was going to be a very high level discussion of the Licensing Agreement" at the deposition. *Id.* This was hardly an accurate characterization but clearly no matter what "level" a witness is testifying on with respect to an agreement, it goes without saying that the witness must at least have seen the document to be adequately prepared with respect to its contents.

Mr. Marinelli, Amgen's witness on Topic 28 regarding gross revenue and incremental costs associated with Amgen's ESA products testified at his deposition that his personal files contain "plan forecast and actual documents," "supporting analyses that reflect the results of operations," and maybe "a profit or loss or controllable margin statement." (Marinelli Tr. 36-37). While these documents are clearly responsive to Roche's document requests (and would inform Mr. Marinelli's testimony were he properly prepared), neither these nor *any* other document -- not a *single* document -- was produced from Mr. Marinelli's files.

Roche raised these issues at these depositions and by letter to Amgen but has received no response by this last day of discovery. (Ex G, 3/30/07, Letter of Heckel to

Moore). Roche respectfully submits that Amgen cure these deficiencies by producing responsive documents from Mr. Marinelli's files and provide a 30(b)(6) witness adequately prepared to testify regarding the Ortho product licensing agreement at least to the extent of having reviewed the document in order to understand and explain its terms.

E. Roche's Third Notice Under Rule 30(b)(6).

Finally, Roche's Third Notice of Deposition under Rule 30(b)(6) was served on Amgen seeking witnesses relating to discrete topics including Amgen's facts supporting its position on secondary indicia of non-obviousness; Amgen's practices and policy regarding the publication of scientific articles and presentations by Amgen employees and Amgen collaborators; and Amgen's strategies and tactics for countering or addressing Roche's MIRCERA™ in the United States. Amgen never served an objection to this Notice but instead merely sent a cursory letter from one of its lawyers claiming that all the topics were covered by other witnesses, without identifying whom or in what way. In other scheduling relating to a separate notice from Roche, Amgen had designated a witness weeks earlier, Dr. Brenner, to talk about issues related to the "public interest" and a deposition was scheduled in California. At the last minute, literally the night before the deposition of Dr. Brenner was to occur, Amgen announced that Dr. Brenner would be designated for topic 1 of Roche's Third Notice on secondary considerations. Without time to prepare, Roche asked to adjourn the deposition, and Amgen refused. Forced to go forward, and taking the deposition as best it could, it appeared that on the issue of commercial success, Dr. Brenner knew nothing about the sales of Amgen's ESA products, and hadn't even read the patents in suit. Clearly, this witness was not properly prepared to address the issue of facts relating to the nexus between sales of Epogen and the claims asserted, and was not a proper

witness, especially given the prejudice of such short notice.[4] While the witness claimed to be prepared to discuss, the praise of others, long felt need and copying, the lack of notice prejudiced Roche's attorney's ability to take a meaningful deposition on those topics.

Amgen offered no witness for the second category in Roche's Third Notice regarding the publication of scientific articles and presentations by Amgen employees and Amgen collaborators.

Thus, Roche respectfully requests that Amgen be made to produce properly prepared witnesses in response to its Topics Nos. 1 and 2 from its Third Notice of Deposition Pursuant to Rule 30(b)(6) to Amgen.

III. CONCLUSION

For the reasons set forth above, the Court should order all of the discovery requested herein including 1) production of documents relating to Amgen's anticompetitive threats of potential Roche customers; 2) production of documents relating to contracting and pricing practices in certain Amgen customer segments; 3) production of documents from the files of Mr. Marinelli, Amgen's designated 30(b)(6) on Amgen's gross revenue and incremental costs associated with its ESA products; 4) provision of a 30(b)(6) witness properly prepared for deposition on the topic of the Ortho licensing agreement; 5) provision of a witness properly prepared for deposition on the topics in Roche's 3rd 30(b)(6) notice and 6) provision of complete and detailed supplemental responses to Roche's First Set of Interrogatories Nos. 1-12.

[4] A practice followed by Amgen for other witnesses as well, where Amgen merely announced at the deposition that witnesses would also be acting as Rule 30(b)6 witnesses for Amgen, denying the Roche attorneys sufficient time to prepare.

Dated: April 2, 2007
Boston, Massachusetts

Respectfully submitted,
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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Nicole A. Rizzo
Nicole A. Rizzo