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.: 1:05-cv-12237 WGY

AMGEN INC.'S OPPOSITION TO DEFENDANTS' MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS, AND DEPOSITION TESTIMONY UNDER RULE 30(b)(6), RELATING TO PEGYLATION AND ARANESP®

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I. INTRODUCTION

On January 3, this Court denied Defendants' December motion to compel far-ranging document discovery into Amgen pegylated proteins other than pegylated EPO, including peg-NESP that is the subject in part of this motion. In doing so, the Court rejected Defendants' fundamental desire to elevate "peg" over EPO, in an attempt to divert this Court's attention from the indisputable fact that their peg-EPO product comprises EPO. The Court rejected Defendants' position, stating: "***The case involves EPO, including Pegylated EPO, Not Other Pegylated Compounds.***"[1] The Court also denied Defendants' motion to compel far-ranging document discovery into the research and development of Aranesp®, a compound that contains a different amino acid sequence and glycosylation structure from Amgen's claimed EPO of the Asserted Claims from Dr. Lin's Patents. Instead, the Court accepted Amgen's proffer to produce a limited scope of Aranesp® documents, which Amgen produced.

Defendants failed to move for reconsideration of the January 3 Order, and have waited until almost the close of fact discovery to bring this motion that rests largely on the same facts concerning the same document requests before the Court last December. With fact discovery closed on April 2, 2007, no good cause exists for Defendant's waiting eighty days after the Court's January 3 ruling to bring this motion, and the articulated grounds simply re-hash earlier arguments and/or do not withstand scrutiny.

Moreover, granting Defendants' motion at this late date without justification for waiting would be highly prejudicial to Amgen when Defendants have (1) designated 47 experts and expert reports due on April 6, (2) have dumped literally millions of pages of documents on Amgen within the last month, making a mockery of the Court's scheduling order, and (3) have failed to disclose with specificity their invalidity contentions that Amgen in effect will only learn about for the first time in Defendants' expert reports to be served on April 6 after fact discovery closed on April 2. Subjecting Amgen at this late date to additional burdensome and irrelevant

[1] This Court's Order of January 3, 2007 ("January 3 Order") (emphasis added).

discovery will only increase the prejudice that Amgen has suffered due to Defendants' tactics. The motion should be denied.

A. AMGEN'S BELIEF THAT ARANESP® IS COVERED BY *UNASSERTED* CLAIM 1 OF THE '698 PATENT DOES NOT MAKE ALL DOCUMENTS REGARDING ARANESP® AND PEG-ARANESP® RELEVANT

Defendants argue that a January and early February supplemental Amgen interrogatory response stating that Aranesp® is an embodiment within the scope of ***unasserted*** claim 1 of the '698 Patent somehow puts "the pegylation of Aranesp® squarely at issue in this case."[2] Defendants studiously ignore that they raised the same argument in their December motion, where they argued that the Aranesp®'s product label identifies Aranesp® as being covered by at least one claim of the '698 Patent so as to justify discovery of pegylated Aranesp® ("peg-NESP").[3] The Court effectively rejected that argument, denying Defendants' motion to compel. Just because Amgen in January and early February provided an interrogatory answer effectively providing the same information does not inject new facts so as to constitute good cause for revisiting the Court's previous January Order on "other pegylated compounds," such as peg-NESP that is the subject of this motion.

As addressed in opposing Defendants' December motion to compel, the Asserted Claims and the accused product define the proper scope of discovery.[4] Defendants' motion (again) ignores that a proper infringement analysis turns on a comparison of the accused peg-EPO product to the properly construed Asserted Claims, not a commercial embodiment that Amgen has not contended is within the scope of the Asserted Claims.[5] Defendants contend that Amgen's efforts to pegylate Aranesp® to create pegylated NESP is relevant to non-infringement and/or invalidity. Tellingly, their non-infringement and invalidity interrogatory responses make no such contention,[6] highlighting the lack of credibility to their rhetoric, and Amgen's success or

[2] Roche Memo at 2.
[3] Docket No. 172 at 14.
[4] Amgen 12/29/06 Opposition, Docket No. 201 at 6-7, 10.
[5] Roche Memo at 4-5.
[6] Lee Decl., Ex. 1 at 20-29.

failure of pegylating Aranesp® is irrelevant to the question of whether Defendants' product comprises EPO and methods of Lin's Asserted Claims.[7]

Defendants cannot conceal the inadequacy of their position by resorting to the overreaching phrase "patents-in-suit" because (1) Amgen has not put at issue each claim of the Asserted Patents (including unasserted claim 1 of the '698 Patent that Amgen believes covers Aranesp®), (2) Defendants have not put at issue unasserted claim 1 of the '698 patent for purposes of its invalidity defenses and declaratory relief validity counterclaims, and (3) infringement and validity rest on a claim-by-claim analysis, and thus generalizations to the "patents-in-suit" cannot form the basis of a proper relevance argument.

Finally, there is the broad scope of the requested documents that the Court previously denied. Defendants' motion seeks to demand full production of all documents to pegylate Aranesp that exist pursuant to their Document Requests Nos. 19, 20, 31, 33-35, and 105-112. Defendants' memorandum avoids discussing the breadth and depth of these requests that the Court previously denied compelling Amgen upon. These requests seek Amgen broad ranging and burdensome discovery. Unasserted claim 1 of the '698 Patent does not provide good cause to open the door to this burdensome and irrelevant discovery.

B. PEGYLATION OF ARANESP® IS NOT WITHIN THE SCOPE OF DOCUMENTS COMPELLED IN THE COURT'S JANUARY 3 ORDER

The Court's January 3 Order states clear that the case involves pegylated EPO, not "other pegylated compounds," which plainly peg-NESP is. Amgen's subsequent act of stating in its January interrogatory response that it believed that Aranesp® was within the scope of unasserted claim 1 of the '698 Patent does not place it within the scope of discovery as stated by the Court. It is another pegylated compound. Defendants' argument that peg-NESP is within the scope of "pegylated EPO" to avoid showing good cause based on new facts is without merit.

[7] To the extent the question has even minimal relevancy, the lack of credibility to Defendants' arguments about success or failure of Amgen being able to pegylate Aranesp® is belied by Defendants' liberal reference throughout its motion to Amgen's issued patent on peg-NESP. *See* U.S. Patent No. 6,586,398.

C. AMGEN PRODUCED RELEVANT EXCERPTS OF ITS ARANESP® BLA

Defendants urge the Court to compel production of the full Aranesp® BLA because: (1) Amgen allegedly did not produce relevant sections of the BLA in accord with its proffer; and (2) Defendants produced their MIRCERA™ BLA. Amgen produced relevant portions of the Aranesp® BLA that describe Aranesp®'s structure, activity, methods of manufacture, pharmaceutical composition and FDA-approved methods of use and has also provided deposition testimony on such structure, function and approved uses.[8] Defendants have not shown how the information disclosed is not sufficient for the purposes they require to examine the structural and functional issues that are relevant to the public health and market substitutability needs that their motion generally states, but does not examine or specify.[9]

Defendants' argument that their production of the MIRCERA™ BLA requires production of the full Aranesp® BLA is meritless: MIRCERA™, not Aranesp®, is the accused product, and the Asserted Claims must be compared to the accused peg-EPO product.[10] Defendants have come forward with no new theories, evidence, or otherwise to legitimize their attempts to undo the Court's January 3 Order.

D. AMGEN PRODUCED ITS PEG-EPO DOCUMENTS

Defendants' remaining complaints about lab notebooks and Dr. Boone's documents concerning Amgen's production of peg-EPO are meritless. Contrary to Defendants' contentions, Amgen has produced relevant excerpts of lab notebook nos. 2112 and 1041.[11] Lab notebook no. 1938 has been reviewed and determined to be non-responsive to Defendants' document requests.[12] Dr. Boone is not in possession of any peg-EPO documents that have not been produced. However, Amgen has produced the lab notebooks of Craig Crandall, who

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[8] Lee Decl., ¶ 3 (AM44 0220474-AM44 0220503).

[9] Roche Memo at 8. Further, the only data on a head-to-head comparison between Aranesp and Defendants' peg-EPO is found in Defendants' MIRCERA BLA.

[10] *Zenith Labs. v. Bristol-Myers Squibb*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) ("[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.").

[11] Lee Decl., ¶¶ 4 and 5.

[12] *See* Whiteford Decl., ¶ 3.

prepared EPO for pegylation under Dr. Boone's direction.[13] Amgen has undertaken a diligent search to locate peg-EPO documents in its possession, and an order compelling production of peg-EPO documents is unnecessary.

In sum, Defendants reprise of unsuccessful arguments from its December motion to compel and mischaracterization of Amgen's discovery conduct provide no basis for granting Defendants' motion to compel. Defendants' motion is a tactic to delay or otherwise seek a delay of resolution of this dispute on the merits, namely on whether Defendants' peg-EPO product comprises EPO, which it does.

II. ARGUMENT

A. DEFENDANTS' MOTION IS AN IMPROPER MOTION FOR RECONSIDERATION

In December, Defendants asked this Court to grant them unfettered access to Amgen's highly proprietary protein pegylation and Aranesp® programs on the same document requests based on the same relevance theories articulated here.[14] The Court denied Defendants' motion, ruling that this case is about EPO and pegylated EPO, and accepted Amgen's proffer to produce a limited set of Aranesp® documents.[15] Instead of promptly moving for reconsideration of the Court's order, Defendants resurrect their motion now at the end of fact discovery, requesting voluminous documents relating to and a 30(b)(6) witness on peg-NESP as well as the full Aranesp® BLA.

Defendants' requested relief is the same as in their failed December motion resting on the same document requests at issue before the Court in December. The Court denied their motion then and should deny this motion now because Defendants' procedurally defective motion fails to show any good cause – be it new facts or theories – for the Court to revisit and overturn its January 3 Order.[16] Were the Court to grant Defendants' requested relief, Amgen will be prejudiced and the case delayed as explained immediately below.

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[13] Lee Decl., ¶¶ 6-8.
[14] Docket No. 172 at 5-6 (peg-NESP) and 12-14 (Aranesp®).
[15] Docket Nos. 172, 201 and January 3 Order.
[16] *See Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass. 2000).

B. DEFENDANTS' MOTION IS THE LATEST OF A LONG LINE OF TACTICS USED TO PREJUDICE AMGEN

The Court clearly ruled that this case is about EPO and pegylated EPO. Nonetheless, approximately ten days before the close of fact discovery, and seventy-nine days after the Court issued its January 3 Order, Defendants filed this motion to seek documents precluded by the Court's January 3 Order. This is just one of Defendants' many systematic attempts to prejudice Amgen and to delay this case given the following circumstances:

- On, January 9, 2007, Amgen produced to Defendants the Aranesp® documents cited in their Brief.
- Defendants could have immediately filed a motion shortly after Amgen's January 9, 2007 production**;**
- Instead Defendants waited almost 80 days before filing this instant motion.

Granting Defendants' motion to compel Amgen to produce effectively another million or more pages of documents regarding Aranesp® and peg-NESP will cause severe prejudice to Amgen because Amgen will have to devote a substantial amount of resources to provide the discovery previously denied while still having to:

- process and review Defendants last minute February 27 and March 16 dump of almost 5 ***million pages*** of documents before the close of fact discovery;
- prepare for the disclosure of its initial expert reports on April 6;
- complete all outstanding third-party discovery; and
- prepare for the claim construction hearing.

Defendants' other tactics include:

- filing a March 28, 2007 motion seeking production of all Amgen privileged documents with respect to "inventorship, patentability, prior art, prosecution strategy, infringement, and claim construction."
- designating 47 experts that Defendants may call to testify at trial, with the very real possibility that Defendants will submit reports from all those experts on April 6, when Expert Reports are due; and

- refusing to provide Amgen its bases for invalidity and inequitable conduct even though fact discovery is about to close in a few days and fact discovery has been open since October 30, 2006.[17]

The Court should reject Defendants' latest attempt to further prejudice Amgen and to delay this case.

C. AMGEN'S BELIEF THAT ARANESP® IS COVERED BY *UNASSERTED* CLAIM 1 OF THE '698 PATENT DOES NOT MAKE ALL DOCUMENTS REGARDING ARANESP® AND PEG - ARANESP® RELEVANT

Defendants contend that Amgen's January and early February supplemental discovery response identifying Aranesp® as within the scope of unasserted claim of 1 of the '698 Patent justifies wholesale discovery into pegylation and attempted pegylation of Aranesp®. Defendants attempt to cast the interrogatory answer as a new development, but gloss over the fact that the Court circumscribed discovery into Aranesp® and peg-NESP upon consideration of this precise argument. Indeed, in their December motion to compel, Defendants argued that Aranesp®'s product label identifies it as being covered by at least one claim of the '698 Patent and that such fact justified this discovery of Aranesp®.[18] That contention still does not withstand scrutiny as Defendants have failed to establish that this discovery is relevant to the "claim or defense of any party," under Rule 26.

First, Defendants' motion bases relevancy on an improper infringement analysis. Aranesp® and peg-NESP are not accused products. The proper analysis requires the application

[17] Amgen recognizes that the Court issued an order in response to Amgen's motion to compel Defendants to answer further Interrogatories Nos. 9-11 stating that Roche must provide a claim-by-claim, limitation-by-limitation, response 30 days after the Court' claim construction order issues. Defendants have been able to vet and engage 47 experts within the last two months, but have been unable to provide Amgen with their claim-by-claim validity invalidity contentions. Defendants expert reports on validity are due on April 6. The prejudice to Amgen is that Amgen will learn of for the first time on April 6 exactly what Defendants' invalidity contentions are, have to digest them, and then issue opposing expert reports on Defendants' validity contentions three weeks later. Notions of justice and fair play are not served under this schedule, and Amgen anticipates that it will be seeking relief from the Court due to Defendants' prejudicial tactics.

[18] Docket No. 172 at 14.

of the Asserted Claims to the accused product (peg-EPO) and methods, not between Amgen's Aranesp® or peg-NESP products and Defendants' peg-EPO.[19]

Second, Defendants disregard the import of Amgen stating that Amgen believes that Aranesp® is within the scope of claim 1 of the '698 Patent. Amgen ***has not asserted*** that claim against Defendants. Relevance for infringement discovery does not rest upon comparing that unasserted claim to Amgen's Aranesp® product and its pegylation, or that unasserted claim to Defendants' accused product. Proper analysis that frames the Rule 26 relevance inquiry rests upon applying the construed Asserted Claims to the accused Defendants peg-EPO.

Third, Defendants fundamentally obfuscate the distinction between the limited set of Asserted Claims at issue, the "patents-in-suit" containing many other unasserted claims, and that Amgen has contended that only ***one*** unasserted claim from one patent covers Aranesp®.[20] Amgen has made no contention in this lawsuit on whether Defendants' peg-EPO product is or is not covered by claim 1 of the '698 Patent. And in response to Defendants' interrogatory, in early February, Amgen asserted only that its product Aranesp® is covered by unasserted claim 1 of the '698 Patent.[21] Defendants' obfuscation and terminology cannot hide their fundamental failure to tie discovery of peg-NESP to the Asserted Claims.

Fourth, Defendants' argument is flawed that somehow the unasserted '698 Patent claim 1 term "erythropoietin product" renders discovery relevant into pegylated-NESP.[22] Defendants' claim construction brief (and Amgen's) did not identify this unasserted claim term as relevant to construction of the disputed terms within the Asserted Claims.[23] Thus, the discovery is not

[19] *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd,* 517 U.S. 370 (1996).
[20] Roche Memo at 7.
[21] Lee Decl., Ex. 2.
[22] Roche Memo at 5.
[23] *See* Docket No. 311.

relevant to claim construction (assuming such extrinsic evidence of peg-NESP were even proper to consider).[24]

Fifth, and effectively conceding the infirmity in its "infringement" arguments, Defendants fall back to contending that "it is irrelevant that Amgen has not asserted this particular claim in the present litigation because this discovery remains relevant to Roche's asserted counterclaims of invalidity against all the claims of the asserted patents."[25] But that is not true: Defendants' second supplemental interrogatory responses to Amgen's contention invalidity interrogatories ***do not assert that claim 1 of the '698 Patent is invalid***.[26] Specifically, they do not contend that claim 1 is invalid on "the issues of enablement and written description under 35 U.S.C. § 112," as Defendants' motion implies.[27] Moreover, any such contention that the enablement/written description of unasserted '698 Patent claim 1 is relevant to the Asserted Claims is legally-flawed. The proper analysis is to assess independently the validity of each claim on its own.[28] Defendants cannot justify discovery at this late date on an invalidity theory that they have not asserted and/or concealed.

Defendants' vague and unsubstantiated allegations of relevance fall far short of the showing necessary for the Court to overturn its previous ruling stating that pegylated compounds other than EPO are not at issue in the litigation.

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[24] *See* Defendants' Opening Memorandum in Support of Their Proposed Claim Construction, Docket No. 311. Defendants' Memorandum at 6 makes too much of Amgen's passing and short-hand reference to "erythropoietin products" in Amgen's Response to Defendants' Claim Construction Brief at 2. That claim construction brief does not address or ask the Court to construe claim 1 of the '698 Patent. Further, the referenced language contains the additional language "as recited in the claims." Thus, the focus is on the claim language of the asserted claims, and Defendants are wrongly trying to imply that Amgen was construing "erythropoietin products" of claim 1 of the '698 Patent.

[25] Roche Memo at 6 n.3.

[26] Lee Decl., Ex. 1 at 68.

[27] Roche Memo at 5.

[28] *See* 35 U.S.C. § 282 (2000); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370 (Fed. Cir. 2003) ("each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; [and] dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim").

D. AMGEN PRODUCED OVER TWO MONTHS AGO RELEVANT SECTIONS OF THE ARANESP® BLA IN ACCORD WITH ITS PROFFER IN OPPOSITION TO DEFENDANTS' DECEMBER 5, 2006 MOTION TO COMPEL

The Court denied Defendants' first motion to compel production of the full Aranesp® BLA in its January 3, 2007 Order, leaving the door open for Defendants to renew their motion if Amgen's Aranesp® document production was not sufficiently comprehensive. Defendants do not challenge the sufficiency of Amgen's Aranesp® production. Nor have they raised new theories of relevance not previously considered by the Court. Instead, Defendants misleadingly assert that Amgen failed to produce relevant portions of its Aranesp® BLA to justify their request for production to the full Aranesp® BLA.[29] Amgen, in fact, produced relevant portions of the Aranesp® BLA in accord with its proffer: the produced excerpts describe Aranesp®'s structure, activity, methods of manufacture, pharmaceutical composition and FDA-approved methods of use and deposition testimony was provided in these areas as well.[30] Accordingly, Defendants' request for Amgen's voluminous, irrelevant and highly proprietary BLA should be denied.

E. AMGEN HAS PRODUCED PEG-EPO DEVELOPMENT DOCUMENTS

Defendants seek an order compelling production of all peg-EPO documents.[31] The two categories of allegedly missing documents, however, have either been produced, are irrelevant or do not exist.

First, Defendants complain that Amgen failed to produce lab notebook nos. 2112, 1041, and 1938.[32] To the contrary, Amgen has produced relevant excerpts of lab notebook nos. 2112 and 1041.[33] Lab notebook no. 1938, wholly unrelated to peg-EPO, is neither responsive to Defendants' document requests nor relevant to the instant action.[34]

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[29] Roche Memo at 8-9.
[30] *See* Lee Decl., ¶ 3 (AM44 0220474-AM44 0220503).
[31] Roche Memo at 9.
[32] *See* Lee Decl., ¶¶ 4, 5 (Notebooks 1041: AM77 002299 – 311, 2112: AM77 002312 – 315).
[33] Lee Decl. ¶¶ 4, 5.
[34] Roche Memo at 9-10; Whiteford Decl., ¶ 3.

Second, Defendants complain that Amgen has not produced peg-EPO work of Dr. Thomas Boone. Amgen produced the laboratory notebooks of Craig Crandall, who worked under Dr. Boone's supervision to prepare EPO used in some of Amgen's peg-EPO experiments.[35] As Defendants confirmed at Dr. Boone's March 30 deposition, Dr. Boone has no additional peg-EPO documents.

In sum, Amgen has conducted a reasonable search for and produced documents relating to its peg-EPO experiments. An order compelling production of such documents is unnecessary.

III. CONCLUSION

For all the stated reasons, Amgen requests that Defendants' motion to compel be denied.

DATED: April 6, 2007

Respectfully Submitted,

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[35] *See* Lee Decl., ¶ 6 (Notebooks 2699: AM87 016762 – 78, 3146: AM87 016779 – 81, 3715: AM87 016782 – 90).

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