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 Civil 12237 WGY

ROCHE'S MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE TO AMEND ITS PLEADINGS TO CONFORM TO THE EVIDENCE

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I. INTRODUCTION

Roche respectfully seeks leave of the Court to conform the pleadings to the evidence under F.R.C.P. 15(b) and/or 16(c)(2) by including in its Answer certain inequitable conduct allegations on which Amgen has not opposed amendment. The present motion is simple; Roche explicitly disclosed these allegations during fact discovery and Amgen has already consented to inclusion of the allegations in Roche's pleadings. Thus, there can be no prejudice from allowing these amendments. The parties have litigated the issues relating to these amendments throughout discovery and therefore amendment under Rule 15(b) is warranted to better reflect the state of the evidence.

Roche previously sought leave to amend its Answer under F.R.C.P. 15(a) on May 23, 2007 to include various allegations that were developed during discovery and then disclosed to Amgen in a timely manner. Amgen *did not oppose* amendment of the particular allegations for which Roche now moves to amend. Amgen stated it only opposed "Roche's motion to amend to the extent that it seeks to add allegations of inequitable conduct submitted for the first time after the close of fact discovery on April 2, 2007."[1] The Court denied the motion. Roche has now limited the present motion to only those allegations which were disclosed to Amgen in interrogatory responses prior to the close of fact discovery. Since Amgen did not previously oppose these amendments and has also consented to their inclusion in the case by withdrawing two earlier motions to strike in order to pursue these and other issues more fully in discovery, Roche respectfully submits that there is no compelling reason not to allow amendment in this instance.

[1] Amgen's Memorandum In Opposition To Roche's Motion For Leave To Amend Its Answer, June 6, 2007, D.I. 468 at p. 1.

Roche also seeks leave to conform the pleadings to the evidence to include particular refinements of market definitions relevant to its antitrust claims. This amendment is uncontroversial; it reflects facts fully explored in discovery and in expert reports and was also previously unopposed by Amgen.

Roche has set forth all the amendments regarding inequitable conduct and market definitions for which it seeks leave to conform the pleadings to the evidence as well as consequent amendments to its Walker Process claims in the accompanying Proposed Second Amended Answer.

II. ARGUMENT

A. Amgen Has Consented To Roche's Proposed Amendments

Amgen has conceded that it has had proper notice of the allegations for which Roche seeks to amend and already acquiesced to their inclusion in the pleadings. When Roche previously moved to amend under Rule 15(a), Amgen explicitly did not oppose amendment with respect to allegations disclosed during the fact discovery period. Amgen expressly stated that it only opposed Roche's initial motion to amend to the extent it included "post-discovery allegations."[2] Every single one of the specific allegations Roche now seeks to incorporate into the pleadings were disclosed to Amgen during the fact discovery period (which closed on April 2, 2007) in Roche's responses to Amgen's Interrogatory No. 26. Thus, Amgen has consented that these allegations are properly noticed and at issue in this case. Amgen raised no objection to amending the pleadings accordingly and there can be no valid basis to preclude amendment to conform the pleadings to the evidence under Rule 15(b) to include them now. While the Court denied Roche's 15(a) motion, which included particular allegations developed during the

[2] *Id.* at p. 2.

discovery period and then promptly disclosed thereafter, Amgen's consent to amendment on those allegations *disclosed during discovery* should allay any concerns the Court previously had about Roche's proposed amendments. Roche's present 15(b) motion is limited to inequitable conduct allegations included in Roche's interrogatory responses during discovery. They are listed below with citation to the instance of their disclosure in discovery:

- failure to disclose the Baron-Goldwasser clinical study and related prior art (*see* proposed Second Amended Answer at pp. 55-67)[3].
- misrepresentations and omissions regarding differences in structure and molecular weight between r-EPO and u-EPO (*see* proposed Second Amended Answer at pp. 23-25, 29-43)[4];
- failures of disclosure relating to the standard used in radioimmunoassay (*see* proposed Second Amended Answer at pp. 43-46)[5];
- failure to disclose Amgen's work with the 1411 cell line (*see* proposed Second Amended Answer at pp. 46-48)[6];
- inequitable conduct to overcome the Lai double patenting rejection (*see* proposed Second Amended Answer at pp. 48-50)[7];
- inequitable conduct relating to the state of the art in recombinant expression of glycoproteins (*see* proposed Second Amended Answer at pp. 50-55)[8].

[3] See Roche's Supplemental Objections and Responses to Amgen's Interrogatory No. 26, dated April 2, 2007, Exhibit A to the Declaration of Alfred H. Heckel in Support of Roche's Motion to Amend Its Pleadings to Conform to the Evidence, ("Heckel Decl.") at pp. 25-29.
[4] See Heckel Decl., Ex. A at pp. 29-53.
[5] See *id.* at pp. 63-66.
[6] See *id.* at pp. 66-68.
[7] See *id.* at pp. 9, 12-13.
[8] See *id.* at pp. 14-25.

In its opposition to Roche's previous motion to amend the pleadings under Rule 15(a), Amgen argued that Roche's motion should be denied only "to the extent that it seeks to add allegations of inequitable conduct that were not disclosed by Roche prior to the close of fact discovery on April 2, 2007."[9] However, Amgen erroneously included in its list of allegations disclosed after the close of fact discovery "Inequitable Conduct Relating to the Baron-Goldwasser Clinical Study and Related Prior Art" and "Misrepresentations and Omissions Regarding Molecular Weight". (See Appendix A to D.I. 468). As noted above, these allegations were in fact disclosed in Roche's April 2, 2007 Response to Amgen's Interrogatory No. 26. For instance, Roche disclosed in detail in its interrogatory response its contention that Amgen and its attorneys intentionally concealed the Baron/Goldwasser clinical study with EPO pharmaceutical compositions from the Patent Office and that "but for Amgen's conduct, the claims of the '422 patent would not have issued."[10] Roche discussed extensively the evidence that individuals involved with prosecution such as Drs. Lin, Egrie, Strickland and Browne and Amgen's prosecuting attorney Odre all had knowledge of the Baron/Goldwasser clinical study and how it was even used within Amgen as a dosing guide for administering EPO and yet withheld it from the examiners.[11] Roche also disclosed in its April 2 interrogatory response, its contention that Amgen and its attorneys committed inequitable conduct by misrepresenting the molecular weight of its claimed recombinant EPO products as being

[9] Amgen's Memorandum In Opposition To Roche's Motion For Leave To Amend Its Answer, June 6, 2007, D.I. 468 at p. 7.
[10] See Heckel Decl., Ex. A at pp. 25-29.
[11] *Id.* at 27.

greater than that of human urinary EPO despite clear evidence to the contrary in declarations foreign patent proceedings and in Amgen's own regulatory documents.[12]

Thus, Roche clearly disclosed these allegations before the close of fact discovery and Amgen's previous opposition to amendment on these allegations appears to be the result of inadvertent mistake or inconsistency with its representation that it was only opposed to amendment on allegations disclosed after discovery. Either way, Amgen's representation that it did not oppose amendment on the allegations disclosed during discovery should control and necessarily includes inequitable conduct relating to the Baron/Goldwasser clinical study and the molecular weight of recombinant EPO. In any case, it is scarcely credible for Amgen to claim it was not aware that Roche contended that the Baron/Goldwasser clinical study was invalidating and therefore material prior art as Roche disclosed its argument that the clinical study was anticipating the claims of the '422 and '933 patents as far back as January 11, 2007 in Roche's First Set of Interrogatory Responses to Amgen.[13]

Roche also seeks leave to conform the pleadings to the evidence concerning particular definitions of markets relevant to its antitrust counterclaims as follows: 1) conform to the evidence those pleadings regarding the market for Erythropoiesis Stimulating Agent ("ESA") drugs sold for use by patients with chronic kidney disease not on dialysis (the "CKD ESA" market), 2) plead, in the alternative, an all-ESA market in which Amgen possesses monopoly power, and 3) define the market for white blood cell stimulators (the WBC Stimulator Market) and to plead Amgen's power in that market. When Roche previously sought to amend the pleadings to include these definitions,

[12] *Id.* at 50-53.
[13] See Heckel Decl., Ex. B, Defendants' Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-15), January 11, 2007 at pp. 57-58.

Amgen did not object. These market definitions are not new, as they were the subject of discovery and expert reports on both sides.

Amgen has repeatedly acknowledged that it has been on notice of the allegations Roche seeks to incorporate into the pleadings and that these issues are part of the litigation. Amgen not only assented to Roche's amendment with respect to inequitable conduct allegations disclosed during discovery but it has also consistently acted as if these allegations were at issue in this case. For example, on May 24, Amgen filed a motion to strike particular non-infringement, invalidity and inequitable conduct allegations it claimed were belatedly disclosed by Roche and subsequently withdrew the motion in light of the agreement by the parties to extend expert discovery and allow for limited additional supplemental expert reports.[14] Significantly, Amgen never claimed that the particular inequitable conduct allegations Roche now seeks to incorporate into the pleadings were belatedly disclosed and restricted that motion to additional contentions noticed during expert discovery. Also, although Amgen had previously moved in April to strike particular invalidity and inequitable conduct allegations from Roche's expert reports including those at issue in the present motion, Amgen never claimed that these allegations were not properly disclosed during discovery but only complained of the technical deficiency that they had not yet been added to Roche's Answer.[15] (At that time Roche had not yet formally moved to amend under Rule 15). Amgen subsequently withdrew that motion as well when the parties agreed to a time

[14] See Motion to Strike Roche's Non-Infringement, Invalidity, and Inequitable Conduct Allegations Disclosed after the Close of Fact Discovery or, in the Alternative, Motion for Leave to Supplement Amgen's Expert Reports and Motion for Protective Order to Postpone Depositions of Certain Witnesses, D.I. 447, May 24, 2007.

[15] See Memorandum in Support of Plaintiff Amgen, Inc.'s Motion to Strike Belatedly Disclosed Invalidity and Unenforceability Allegations and For More Time to Respond to Roche's Expert Reports, D.I. 386, April 13, 2007.

extension for rebuttal expert reports. Then, when Roche initially moved to amend under Rule 15(a), Amgen did not oppose the motion with respect to allegations disclosed during fact discovery. Thus, there is no basis for opposition to the present motion. The plain fact is that Roche disclosed in sufficient particularity each and every one of these allegations before the close of fact discovery.

All of Amgen's previous objections to Roche's disclosures of particular allegations are obviated by the present motion. Amgen opposed Roche's motion to amend on allegations which Roche developed during fact discovery and then timely disclosed thereafter in a supplemental interrogatory response. In the interests of judicial economy, Roche has not included those allegations in this motion under Rule 15(b) and includes only those allegations which were disclosed during fact discovery. It would serve no purpose to exclude these allegations from the pleadings.

Amgen had previously lodged procedural objections about the difficulty of addressing all the issues raised in the case during the tight schedule which it advocated. These concerns have all been resolved since, by agreement, Amgen has completed discovery of these issues and has submitted its own expert reports to rebut these allegations. After receiving Roche's expert, Mr. Sofocleous's report on these issues, Amgen has submitted in response at least two written expert reports from patent attorneys Kunin and Voight, totaling together to almost 300 pages. Amgen has also submitted numerous expert opinions impacting the materiality component of these allegations, including over 180 pages from Dr. Varki on purported structural differences between recombinant EPO and human urinary EPO in 3 reports, a combined total of over 120 pages from Drs. Goldwasser and McLawhon on RIA standards, a combined total of over

170 pages from Drs. Lodish and Berk regarding recombinant expression of glycoproteins prior to 1983/1984; a combined total of over 20 pages from Drs. Eschbach and Goldwasser on the Baron/Goldwasser clinical study (with a report from a new expert touching on this issue to follow) and a combined total of over 20 pages from Dr. Lodish and Mr. Kunin on Lai double patenting. Further, as recently as June 20, Amgen submitted a second supplemental report from Dr. Varki which specifically addresses Roche's inequitable conduct allegations regarding structural differences between human urinary EPO and COS EPO and also attached over 80 pages of new documents from Amgen pertaining to recently conducted experiments with COS EPO in support.[16]

It would not be credible for Amgen to argue now that it is in any way prejudiced or surprised by the requested amendments. Amgen expressly consented to Roche's previous motion to amend on the inequitable conduct allegations which Roche disclosed during discovery. Amgen also implicitly consented that these allegations were part of the case by withdrawing its motions to strike and has now taken advantage of the ample opportunity to respond through several rounds of expert discovery. The Court should therefore allow Roche's motion to conform the pleadings to the evidence in order to formally reflect the development of these issues through discovery.

B. Amgen's Consent Justifies Amendment Under Rule 15(b)

Rule15(b) provides a vehicle to amend the pleadings to conform to the evidence where issues not raised by the pleadings are litigated "by express or implied consent." Fed.R.Civ.P. 15(b. "Under [Fed.R.Civ.P.] 15(b), the trial court may and should liberally allow amendments to the pleadings if prejudice does not result." *Jones v. Pineda*, 22 F.3d

[16] See Second Supplemental Expert Report of Ajit Varki, M.D., June 20, 2007, at pp. 35-37.

391, 400 (1st Cir. 1994) (citations omitted).[17] The Federal Circuit has held, for example, that it is reversible error under Rule 15(b) to exclude evidence relating to an unpleaded claim for relief of patent infringement, which plaintiff attempted to add by insertion to the joint pretrial order and which plaintiff had previously raised in opposition to the defendant's motion for summary judgment. *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Company*, 112 F.3d 1561, 1566 (Fed. Cir. 1997).

A court should permit the amendment of a pleading to conform to the evidence if the nonmoving party has given "express or implied consent" and has adequate notice or should otherwise have expected that the claim, despite its omission from the initial pleadings, would be litigated. *Jones*, 22 F.3d at 400; *Lynch v. Dukakis*, 719 F.2d 504, 508-09 (1st Cir. 1983). As discussed above, Amgen has expressly consented to amendment of the pleadings to include Roche's inequitable conduct allegations disclosed during fact discovery when it opposed Roche's initial Rule 15(a) motion.

Pretrial activities including discovery and pretrial motions in relation to the issue not pleaded establish implied consent. *See Jones* 22 F.3d at 401 (1st Cir. 1994) ("Because the issue [not pleaded] was the subject of substantial pretrial activity, plaintiff had ample notice that the defense [not pleaded] would be litigated . . . Consequently, the district court's decision . . . to admit the [. . .] evidence and allow the issue to be litigated was proper"), *citing Pane v. RCA Corp.*, 868 F.2d 631, 637 (3d Cir. 1989) for the proposition "where unpleaded affirmative defense was referred to repeatedly in pretrial

[17] There is conflicting authority as to whether the Federal Circuit applies its own law or the law of the regional circuit on issues such as amendment of the pleadings with respect to inequitable conduct. *See Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1303 (Fed. Cir. 2001) (applying Federal Circuit law) *and Studiengesellschaft Kohle, M.B.H. v. Shell Oil Company*, 112 F.3d 1561, 1566 (Fed. Cir. 1997) (applying the law of the regional circuit). In any event, the standard is essentially the same.

motions and no unfair surprise resulted, district court did not abuse its discretion in allowing the issue to be litigated"; *see also Torry v. Northrop Grumman Corp.*, 399 F.3d 876, 879 (7th Cir. 2005) (discovery and other pretrial maneuverings sufficient to support trial of unpleaded defense). Amgen's activities through withdrawal of its motions to strike and submission of extensive expert opinions germane to the allegations on which Roche seeks to amend is also evidence of Amgen's implied consent that these allegations are part of the case.

Indeed, even in the absence of consent to litigate, implied or otherwise, Rule 15(b) by its terms allows admission of evidence which is not pleaded as long as the party, against which the evidence is offered, is not prejudiced. Fed.R.Civ.P. 15(b) ("[Even if] evidence is objected to at trial on the ground that it is not within the issues made by the pleadings, the court may allow the pleadings to be amended *and shall do so freely* when the presentation of the merits of the action will be subserved thereby and the objecting party fails to satisfy the court that the admission of such evidence would prejudice the party in maintaining the party's action or defense on the merits.") (emphasis added).

Additionally, F.R.C.P. 16(c)(2) also provides a basis for the Court to allow the requested amendments in order to formalize the scope of the issues that the parties have been diligently litigating before trial. Rule 16(c)(2) establishes the "necessity or desirability of amendments to the pleadings" among the matters to be considered at Rule 16 pretrial conferences. Fed.R.Civ.P. 16(c)(2). Because the Federal Rules "encourage litigants to plead only a simple statement, in sequence, of the events which have transpired, coupled with a direct claim by way of demand for judgment," the pretrial procedure set forth in Rule 16, "becomes the *principal means* of defining the issues in a

case and the legal theories upon which they are to be tried." *Meadow Gold Products v. Wright*, 278 F.2d 867, 868-69 (D.C. Cir. 1960) (emphasis added). Permitting such amendments is the only way to simultaneously maintain liberal pleading standards and, yet, ensure that no party is unjustly surprised by the subject matter of the litigation. *Id.* As the trial date rapidly approaches, Roche submits that the Court should take Roche's proposed amendments into account in preparing the issues for trial consistent with the evidence established through discovery to date.

C. The Allegations for Which Roche Seeks to Conform the Pleadings to the Evidence Are Not New or Belatedly Disclosed

Amgen's consent to litigating the allegations for which Roche seeks to amend should dictate granting the present motion. Amgen's consent eliminates any concerns relating to prejudice or surprise. However, other considerations of fairness and efficiency also favor for allowing amendment. Discovery under the federal rules requires a balancing between timely disclosure and the need for fact gathering to firmly substantiate particular allegations, under, for example, Rule 11. Roche has achieved that balance by disclosing during the discovery period and in extensive detail in interrogatory responses the factual inequitable conduct allegations it now seeks to incorporate into its pleadings. The limited allegations for which Roche now seeks leave to conform the pleadings to the evidence are not new, nor were they belatedly disclosed.

Roche fulfilled its discovery obligations by gathering as much evidence relating to these allegations as was possible during the expedited schedule in this case, including thorough review of Amgen's production documents such as file histories of the patents-in-suit and related foreign patents, relevant proceedings in the US and foreign patent offices, internal Amgen documents and prior art documents, as well as depositions of the

inventor Lin, key Amgen scientists that submitted relevant declarations during prosecution such as Thomas Strickland and Joan Egrie and Amgen's prosecuting attorneys Michael Borun, Stuart Watt and Steven Odre. It must be noted that the depositions of Egrie, Lin, Watt and Odre did not even occur until the final week of depositions, due to Amgen's scheduling. Roche took all of this relevant discovery and then disclosed the inequitable conduct allegations listed above as quickly as possible thereafter (later in the same day as the Odre deposition) and before the close of fact discovery. Thus, Amgen cannot reasonably complain of delay or lack of notice and has already admitted the propriety of including these allegations in the pleadings.

Amgen also could not have claimed surprise when it received Roche's interrogatory response on April 2. Some of the allegations listed above merely elaborate on specific factual inequitable conduct contentions Roche advanced in its Proposed First Amended Answer originally provided to Amgen back on December 8, 2006. In particular, that Amended Answer set forth Roche's contentions that during prosecution Amgen misrepresented and/or omitted material information concerning the differences in glycosylation structure and molecular weight of its claimed recombinant EPO compared to that of urinary EPO. After submission of that pleading, Roche uncovered and analyzed various documents further substantiating Amgen's inequitable conduct in this regard, including papers by Amgen's Dr. Egrie and Dr. Vapnek (both deposed in the final week of discovery). These documents form the basis for the particular allegations concerning the structure and molecular weight of CHO EPO and COS EPO which Roche disclosed in its April 2 interrogatory response and now seeks to incorporate in its answer.

Similarly, the other inequitable conduct allegations listed above should have come as no surprise to Amgen. The allegations concerning the deficiencies of radioimmunoassay ("RIA") mirror Roche's indefiniteness arguments concerning the claims of the '349 patent which Roche disclosed to Amgen in its first interrogatory responses disclosed back in January.[18] Roche also disclosed in its January interrogatory response its contention that the European Patent Application No. 093,619 published November 9, 1983, regarding recombinant expression of the obligate glycoprotein, tPA, is invalidating § 103 art.[19] Thus, Amgen had been on notice for some time of Roche's position regarding the materiality of the European '619 patent, which is central to Roche's inequitable conduct allegations regarding Amgen's misrepresentations of the state of the prior art. Further, Roche's argument that asserted patent claims are invalid for obviousness-type double patenting over Amgen's Lai '016 patent is similar in nature to Roche's inequitable conduct allegation regarding obviousness-type double patenting over Dr. Lin's '008 patent which was disclosed in detail in Roche's first response to Amgen's Interrogatory No. 26 on March 14, 2007.[20] Roche also deposed Dr. Strickland, a co-inventor on the '016 patent, during discovery and questioned him regarding the scope of the '016 patent claims.[21] Before formally noticing Amgen of its contentions regarding the '016 patent, Roche needed to review the patent's file history which was produced during discovery to analyze the scope of the '016 claims and their overlap with those of the Lin patents. With regard to the failure to disclose the Baron/Goldwasser clinical study and Amgen's use of the 1411 cell line, Amgen has admitted that these

[18] See Heckel Decl., Exh. B at p. 60.
[19] *Id.* at p. 53.
[20] See Heckel Decl., Ex. C, Defendants' Responses and Objections to Plaintiff Amgen Inc.'s Third Set of Interrogatories to Defendants (No. 26), March 14, 2007 at pp. 5-13.
[21] Strickland Depo., 3/9/07 at pp. 134-144.

arguments were previously made in the TKT litigation. Thus, Amgen was aware of the substantive predicate facts concerning the materiality of these issues well before April 2. Moreover, as noted above, Roche gave Amgen notice early on that it was asserting the Baron/Goldwasser study as invalidating prior art.

After Roche developed its evidence through discovery, including the depositions of central Amgen scientists and prosecuting attorneys, Roche disclosed the particulars of the inequitable conduct allegations for which amendment is sought in a timely interrogatory response before the close of the discovery period. Thus, Roche has satisfied its obligations of diligent discovery and timely disclosure.

III. CONCLUSION

For all the foregoing reasons, Roche respectfully requests that its motion to amend the pleadings to conform to the evidence should be granted in full.

Dated: July 5, 2007

Boston, Massachusetts

Respectfully submitted,

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