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

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

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I. INTRODUCTION

Late last Friday, Roche served on Amgen expert reports from 18 different experts. No less than 16 of these reports pertain to the validity and enforceability of Amgen's patents. They are chock-full of validity and enforceability-related allegations and factual bases that despite Amgen discovery requests were ***never*** before disclosed by Roche in this case.[1] And, they are voluminous — their text alone collectively totals more than 950 pages. Amgen has yet to receive all of their exhibits.[2]

Rather than honoring the pleading requirements to allow definition of the issues for trial and engagement in the discovery process to allow for a narrowing and simplification of the issues for trial, Roche has avoided and delayed discovery to produce the effect of an ever expanding litany of issues to be tried. Although the patents-in-suit have been reviewed by this Court and the Federal Circuit and repeatedly held valid, Roche's unfiltered deluge of allegations and expert reports creates an unnecessary burden on the Court and in and of itself demonstrates their lack of merit. Still, Amgen has no choice but to respond.

Roche's conduct has deprived Amgen of any reasonable opportunity to conduct discovery or prepare responses regarding these allegations. Amgen now faces the Herculean, if not impossible, task of preparing its rebuttal expert reports in a mere 14 days. Severely prejudiced by Roche's conduct, Amgen brings the present motion to strike Roche's improperly disclosed allegations and afford Amgen additional time to prepare its rebuttal expert reports.

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[1] For example, Roche belatedly disclosed more than 50 art references. Appendix A, attached hereto, sets forth a comprehensive identification of the invalidity arguments and factual bases disclosed by Roche for the first time in its April 6 expert reports.

[2] *See* Declaration of Deborah E. Fishman in Support of Amgen's Motion to Strike Belatedly Disclosed Invalidity and Unenforceability Allegations and for More Time to Respond to Roche's Expert Reports (hereafter "Fishman Decl."), Exh. 1 (4/13/07 A. Hand letter to P. Fratangelo).

II. ARGUMENT

A. THE PURPOSE OF THE FRCP AND CASE MANAGEMENT ORDER WERE UNDERMINED BY ROCHE'S CONDUCT.

Litigation by ambush is simply not part of our legal system. The Federal Rules of Civil Procedure and indeed this Court's case management schedule were designed to ensure timely and fulsome disclosure so that each party receives adequate notice to prepare its case for trial. Here, the Court's case management order reciprocally affords each party 21 days in which to prepare and serve its rebuttal expert reports.[3] The feasibility and fairness of this tight deadline were entirely dependent upon the assumption that each party fully complied with its pleading and discovery obligations. But, as shown below, that assumption did not materialize as Roche failed to comply with its obligations. And yet, the schedule as currently applied to Amgen is no longer reciprocal, fair, or feasible.

The reciprocity, fairness, and feasibility of the case management schedule have been undermined in at least two significant ways: First, the once close-ended schedule for determining and managing the issues to be tried in this case is now open-ended. Despite the closure of fact discovery and passing of the deadline for submitting opening expert reports, Roche can supplement its invalidity allegations 30 days after the Court issues its claim construction. As things currently stand, it remains uncertain precisely what validity and enforceability issues are to be tried in this case. Second, Amgen has been severely prejudiced in having been denied it the time to prepare its case and conduct fact discovery essential to rebutting Roche's invalidity allegations — whatever they turn out to be.

[3] Docket No. 143 (11/7/06 Court Order).

B. ROCHE'S DELAYS AND REFUSALS TO PROVIDE DISCOVERY ON VALIDITY ISSUES RESULTED IN PREJUDICE TO AMGEN.

Because Roche's Answer gave no clue as to the bases of its invalidity allegations, early in the discovery period, Amgen served interrogatories seeking their details.[4] But Roche effectively refused to respond.[5] Opposing Amgen's motion to compel, Roche urged the Court to allow it to answer Amgen's validity-related interrogatories after the upcoming April 17 *Markman* hearing.[6] Although Amgen's motion to compel was granted, Roche was permitted to answer the interrogatories 30 days after the Court issues its claim construction.[7] Yet, contrary to its opposition to the motion to compel, Roche's voluminous expert reports demonstrate that it was in fact fully capable of specifying its invalidity allegations and their factual bases during the fact discovery period and certainly well before the *Markman* hearing.

Amgen's diligence in attempting to prepare its validity case was not limited to its interrogatories. Amgen also served a 30(b)(6) deposition notice to discover the factual bases of Roche's invalidity defenses. Although Roche originally agreed to provide a witness, it subsequently flat out refused (without seeking a protective order) to comply with Amgen's Notice. This after Amgen made available during the fact discovery period its own witnesses on the ***same*** invalidity topics in compliance with Roche's 30(b)(6) Notice and the Court's March 27, 2007 Order.[8] Although Amgen's motion to compel is under submission, the damage has

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[4] Fishman Decl., Exh. 13 (Amgen's First Set of Interrogatories).

[5] Fishman Decl., Exh. 17 (1/19/07 D. Fishman letter to P. Carson).

[6] Docket No. 335 (Roche's Opposition to Amgen's Motion to Compel Interrogatory Responses).

[7] Docket No. 335 (Roche's Opposition to Amgen's Motion to Compel Interrogatory Responses); Fishman Decl., Exh. 2 (3/28/07 Court Order).

[8] Fishman Decl., Exh. 14 (3/27/07 Electronic Court Order).

been done. The discovery and expert reports schedule has long ceased being a level playing field.

Yet further harm to Amgen has been caused by Roche's belated disclosure of third parties allegedly having knowledge regarding the validity of Amgen's patents. On March 27, with less than a week remaining for fact discovery and 23 depositions already calendared for the remaining four days of fact discovery, Roche supplemented its Rule 26(a) statement to include ***35*** individuals purportedly having discoverable information, including Daniel Shouval, James Fisher, and Franklin Gaylis.[9] On April 6, less than a week later, each of these three individuals submitted an expert report regarding invalidity on behalf of Roche. But ***before February 7,*** Roche had engaged each of these individuals as consultants.[10] When Amgen sought to depose Dr. Gaylis during the discovery period Roche's lawyers interceded and refused to produce him, objecting "on his behalf" that Amgen's subpoena sought "information that is neither relevant to the underlying action nor reasonably calculated to lead to the discovery of admissible evidence."[11] Having refused to answer Amgen's validity-related interrogatories, failed to comply

[9] Fishman Decl., Exh. 3 (3/27/07 Defendants' Supplemental Disclosure Statement).

[10] In March, Roche provided Amgen with signed agreements by Fisher, Shouval, and Gaylis to abide by the parties' protective order. Those agreements to abide were dated and signed as of February 7. *See* Fishman Decl., Exhs. 4, 5, and 6.

[11] Fishman Decl., Exh. 15 (4/2/07 Objections of Non-Party Franklin Gaylis to Amgen Subpoena Duces Tecum) at ¶ 5. Likewise, purporting to represent Dr. Fisher, Roche's attorneys objected to Amgen's subpoena duces tecum on the ground that it sought "information that is neither relevant to the underlying action nor reasonably calculated to lead to the discovery of admissible evidence."; Fishman Decl., Exh. 16 (3/27/07 Objections of Non-Party Dr. James Fisher to Amgen's Subpoena Duces Tecum) at ¶ 5.) And yet, the very next week, Roche submitted reports from these individuals asserting that the very same information is highly relevant to this case.

with Amgen's 30(b)(6) notice, and unreasonably delayed its Rule 26(a) disclosure, Roche derailed Amgen's legitimate effort to understand the relevance of these witnesses to the case.

Obstructing Amgen's ability to respond to Roche's belated disclosure still further, Roche now presents these individuals as experts, contends their work is ***publicly available*** prior art, and yet at the same time insists upon designating their reports, underlying facts, and produced documents, as ***confidential*** under the Protective Order. In this way, Roche is misusing the Protective Order to frustrate Amgen's efforts to prepare its case by preventing Amgen from showing such "***publicly available***" information to its in-house counsel and scientists and delaying when such information can be shown to Amgen's experts and consultants.

C. ROCHE'S FAILURE TO PLEAD COMPOUNDED BY DELAYS IN PROVIDING DISCOVERY ON INEQUITABLE CONDUCT HAS RESULTED IN FURTHER PREJUDICE TO AMGEN.

In addition to the previously undisclosed invalidity allegations, Roche's April 6 expert reports contain 11 new allegations of inequitable conduct that were never pled and were withheld until the very last day of fact discovery.[12] Rule 9(b) of the Federal Rules of Civil Procedure obligated Roche to plead with particularity each of its unenforceability allegations at the time it filed its Answer.[13] Instead, Roche served a deficient Answer on November 6.[14] Amgen moved to

[12] For a comprehensive listing of the un-pled inequitable conduct allegations contained in Roche's April 6 expert report, see the attached Appendix B. Notably, a number of Roche's just-disclosed invalidity allegations are intertwined with several of its just-disclosed unenforceability allegations. For instance, in its April 6 technical expert reports, Roche disclosed for the first time in this case that it will assert invalidity on the basis of a carcinoma cell line reference. On the same day, in a 198-page report by a "legal" expert, Roche disclosed for the first time in this case that it will assert inequitable conduct on the basis of precisely the same cell line and reference.

[13] FED. R. CIV. P. 9(b): "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity…"

[14] Docket No. 140 (11/6/06 Roche's Answer and Counterclaims).

strike per Rule 9(b) on November 27, 2006.[15] Acknowledging the deficiency in its pleading, Roche moved to amend its Answer to include additional bases for its inequitable conduct defense on December 8, 2006[16] and once again on January 19, 2007,[17] and finally filed its Amended Answer on March 30, 2007.[18] Even so, Roche's April 6 expert reports contain at least 11 additional allegations of inequitable conduct that Roche has never pled — not even in its March 30 Answer, filed only a week before Roche served its expert reports.[19]

Roche cannot be heard to argue that it was unaware of the 11 additional allegations until late in discovery. Roche has been in possession of the documents underlying its additional allegations for years.[20] In fact, Roche's privilege log demonstrates that Roche has been preparing for this litigation for more than six years[21] and that it has been studying the Lin patents and file histories and prior litigation files since at least that time.[22]

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[15] Docket No. 153 (11/27/06 Amgen's Motion to Strike Roche's Defenses Nos. 2, 7, 8, 10 and 12).

[16] Docket No. 160 (12/8/06 Roche's Motion for Leave to File Amended Answer and Counterclaims).

[17] Docket No. 252 (1/19/07 Roche's Motion for Leave to File Amended Answer and Counterclaims).

[18] Docket No. 344 (3/30/07 Roche's Amended Answer).

[19] Roche's failure to include these allegations in its March 30 Amended Answer render its 6th Affirmative deficient for failure to plead with particularity as required by Rule 9(b).

[20] *See* Appendix B for a correlation of the additional allegations and date by when Roche was in possession of the underlying information.

[21] Fishman Decl., Exh. 18 (4/2/07 Roche's Fifth Supplemental Privilege Log at RNED 07535143-201 ("10/20/2000 Draft document reflecting legal advice re: CERA patent litigation. AC; WP"); RBED 07699009-010 ("02/08/2001 Confidential meeting minutes reflecting legal advice re: Amgen patent lawsuit prepared in anticipation of litigation. AC; WP"); RBED 07687678-718 ("03/30/2001 Draft document reflecting legal advice re: CERA patent litigation prepared in anticipation of litigation. AC; WP").

[22] Fishman Decl., Exh. 7 (3/23/07 Roche's Third Supplemental Privilege Log at RB00338423-25

At the same time, Roche also sought to avoid or delay discovery into its inequitable conduct allegations, waiting until the very last day of fact discovery to provide its 11 additional allegations and refusing to designate a witness in response to Amgen's 30(b)(6) Notice on Roche's unenforceability allegations and underlying facts.[23]

Roche's much-belated disclosures coming precisely when Amgen has little time to respond to Roche's voluminous expert submissions is nothing short of an ambush. Use of its expert reports to supplement its discovery responses in such a belated and tactical fashion is plainly prohibited by Rule 26(e)(2):

> 'The purpose of Rule 26(e)(2) is to prevent trial by ambush.' If a party is allowed to withhold the supplementation of its discovery responses until after fact discovery is closed, the purpose of the Rule is effectively frustrated because the opposing party is denied the opportunity to conduct discovery on the supplemented responses.[24]

This is particularly the case here, where lay-person lawyers are not on equal footing with technical experts and require the notice provided by the Rules and Court's case management schedule to have time to understand and respond to highly technical arguments.[25]

("Confidential memorandum containing and reflecting legal advice of counsel re: summary of current and future EPO litigations. AC").

[23] Fishman Decl., Exh. 8 (4/2/07 Roche's Supplemental Responses and Objections to Amgen's Third Set of Interrogatories (Interrogatory No. 26)); Fishman Decl., Exh. 9 (3/16/07 Roche's Objections to Amgen's Fourth Notice of Deposition Pursuant to F.R.C.P. 30(b)(6), Topic 27).

[24] *Heidelberg Harris, Inc. v. Mitsubishi Heavy Industries, Ltd.*, 1996 WL 680243, *6-10 (N.D. Ill. 1996) (excluding § 112 defense because factual bases of the defense were not disclosed in response to interrogatories and were disclosed for the first time in expert reports).

[25] *Licciardi v. TIG Ins. Group*, 140 F.3d 357, 363 (1st Cir. 1998)("Recognizing the importance of expert testimony in modern trial practice, the Civil Rules provide for extensive pretrial disclosure of expert testimony." *Thibeault v. Square D Co.*, 960 F.2d 239, 244 (1st Cir. 1992). Rule 26(e) of the Civil Rules requires a party to supplement its answers to interrogatories "if the party learns that the response is in some material respect incomplete or incorrect" and the other

Roche's delay and failure to respond has directly and severely prejudiced Amgen by depriving it of more than five months (or 85%) of the time in which to prepare it case before expert reports are due. Amgen now has less than 14 days in which to find and retain additional experts, educate them about Roche's contentions and asserted facts that should have and could have been disclosed earlier, and work with them to prepare responses to Roche's expert reports. Because Roche could and should have disclosed its invalidity and inequitable conduct allegations and factual bases long ago but instead chose to delay its disclosure, its previously undisclosed allegations and factual bases set forth in Appendix C hereto should be stricken.

As a separate matter, Amgen also requires additional time to respond to the sheer volume of the more than 950 pages of text in Roche's 16 expert reports regarding invalidity and inequitable conduct, many of which were not previously disclosed.[26] Roche sought and obtained a unilateral extension until 30 days after *Markman* (May 17) to supplement its invalidity interrogatory responses and repeatedly failed over the course of the past five months to disclose the invalidity and inequitable conduct allegations and bases then known to it, including utterly disregarding Amgen's 30(b)(6) deposition notice. Consequently, Amgen requests an additional 30 days (until May 28) to prepare and submit its validity and enforceability rebuttal expert reports.[27]

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party is unaware of the new or corrective information. *See* FED. R. CIV. P. 26(e)(2)).

[26] Although Roche's previously undisclosed allegations should not be part of its case at trial, until and unless they are stricken, Amgen is confronted with necessity of having to prepare a response to such issues which in turn reduces the time Amgen has to prepare its rebuttal reports as to other issues.

[27] Of course, to the extent Roche supplements its invalidity interrogatories 30 days after a *Markman* ruling to add or change the substance of its expert report, Amgen requires two weeks after any such supplementation to prepare and submit rebuttal reports responding to the additional or changed matter.

The present state of affairs is strictly of Roche's own making. Amgen therefore sees no reason why it should be penalized by an adjustment to the trial date. That should remain in place. Even still, there remains sufficient time to accomplish all of the necessary pretrial events without altering the trial date while at the same time rectifying the prejudice caused Amgen by affording it a reasonable opportunity to prepare its case.

D. ROCHE'S PREVIOUSLY UNDISCLOSED INVALIDITY ALLEGATIONS AND FACTS SHOULD BE STRICKEN FROM ITS EXPERT REPORTS AND AMGEN SHOULD RECEIVE ADDITIONAL TIME IN WHICH TO PREPARE ITS RESPONSE.

Despite Amgen's repeated requests and motions to compel fulsome discovery responses, Roche sandbagged Amgen during the fact discovery period, refusing to provide even the most basic contours of its invalidity defenses. Here are but a few examples of Roche's gamesmanship regarding its invalidity and inequitable conduct disclosures:[28]

DISCLOSURES BEFORE 4/6/07	DISCLOSURES IN 4/6/07 EXPERT REPORTS
Anticipation Only an incomplete listing of then-known prior art No correlation of prior art to claims	Multiple theories of anticipation disclosed Additional prior art references disclosed Prior art correlated with claims
Obviousness Incomplete listing of then-known prior art No correlation of prior art to claims	Multiple theories of obviousness disclosed Over 50 previously undisclosed publications, patents, and patent applications identified Combinations and motivation to combine prior art references disclosed Level of ordinary skill in the art identified

[28] This list is merely exemplary and a more comprehensive of identification of the arguments and evidence in its invalidity expert reports that were not previously disclosed in this case by Roche is set forth in the attached Appendix A.

DISCLOSURES BEFORE 4/6/07	DISCLOSURES IN 4/6/07 EXPERT REPORTS
Purported Non-Enablement Regarding Purification Nothing disclosed in prior pleadings or written discovery	Alleged insufficiency of purification technique for sufficient quantities of pure EPO alleged Alleged insufficiency of purification technique for level of purity required for pharmaceutical composition alleged Alleged '016 patent as evidence of non-enablement
Purported Non-Enablement of "Units EPO" Nothing disclosed in prior pleadings or written discovery	Multiple theories of non-enablement asserted Alleged no fixed erythropoietin standard
Purported Non-Enablement of Cell Claims Nothing disclosed in prior pleadings or written discovery	"Vertebrate cells" in '349 claim 7 alleged as overbroad

Two conclusions are immediately evident from the previously undisclosed allegations contained in Roche's April 6 expert reports:

First, there was no substantial justification for Roche to withhold its invalidity arguments and alleged prior art during fact discovery. Indeed, as discussed above, Roche's own privilege log reveals that it has been studying Dr. Lin's EPO patents and the attacks mounted against those patents.[29] Through its acquisition of Boehringer Mannheim, as well as its own involvement in foreign litigations involving Dr. Lin's EPO patents, Roche has long been aware of Dr. Lin's EPO patents for years. The multitude of just-disclosed arguments and 50+ art references demonstrate

[29] Fishman Decl., Exh. 7 (3/23/07 Roche's Third Supplemental Privilege Log at RB00220482-483 ("08/11/1996 Confidential letter reflecting legal advice of counsel regarding TKT litigation. AC"); RB00338423-425 ("10/11/2001 Confidential memorandum containing and reflecting legal advice of counsel re: summary of current and future Epo litigations. AC");
and RB00338237 ("09/19/2003 Confidential email rendering legal advice of counsel and prepared in anticipation of litigation re: TKT hearing. AC, WP").

that Roche had these facts and arguments in its possession during the fact discovery period, but simply chose not to disclose them.[30]

Second, Roche's request that the Court extend its time to respond to the entirety of Amgen's invalidity interrogatories on the pretext of needing claim construction was disingenuous. Roche's expert reports expressed a multitude of opinions and purported factual bases bases for invalidity without a claim construction. In any event, nothing in the Court's March 28 Order affording Roche the opportunity to supplement its invalidity interrogatory responses after a *Markman* ruling relieved Roche of its obligation to comply with Rule 26(e)(2) and disclose ***facts*** then known to it regarding its invalidity defense during the discovery period. Yet, this is precisely how Roche misused the Court's Order.

Under Rule 26(e), a party has a duty to supplement its disclosures and discovery responses if it learns that the information disclosed is incomplete or incorrect.[31] Rule 26(e), however, does not authorize withholding relevant and responsive discovery until the waning

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[30] Fishman Decl., Exh. 7 (3/23/07 Roche's Third Supplemental Privilege Log; RB00338423-425 ("10/11/2001 Confidential memorandum containing and reflecting legal advice of counsel re: summary of current and future Epo litigations. AC"); and RB00338237 ("09/19/2003 Confidential email rendering legal advice of counsel and prepared in anticipation of litigation re: TKT hearing. AC, WP").

[31] FED. R. CIV. P. 26(e) states: "(e) Supplementation of Disclosures and Responses. A party who has made a disclosure under subdivision (a) or responded to a request for discovery with a disclosure or response is under a duty to supplement or correct the disclosure or response to include information thereafter acquired if ordered by the court or in the following circumstances:

(1) A party is under a duty to supplement at appropriate intervals its disclosures under subdivision (a) if the party learns that in some material respect the information disclosed is incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing…(2) a party is under a duty seasonably to amend a prior response to an interrogatory, request for production, or request for admission if the party learns that the response is in some material respect incomplete or incorrect and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."

hours of fact discovery.[32] To do so would make a mockery of the purpose of discovery as well as the Court's case management deadlines requiring orderly and timely disclosures. The First Circuit has confirmed the importance of full and fair disclosure during the discovery process to avoid prejudice at trial:

> The purpose of discovery is to make a trial less a game of blindman's buff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent. Once a proper discovery request has been seasonably propounded, we will not allow a party sentiently to avoid its obligations by filing misleading or evasive responses, or by failing to examine records within its control.[33]

In *Cytyc Corp. v. Tripath Imaging, Inc.*, the Massachusetts District Court declined to exclude invalidity and unenforceability defenses where the defendant had fulfilled its Rule 26(e)(2) obligation by disclosing new information as soon as that information became available. Importantly, the court noted that the outcome would have been different had the information been purposefully withheld:

> That Cytyc determined an additional basis for its invalidity and unenforceability arguments at the very end of the fact discovery process does not render it in violation of the applicable discovery rules. ***The outcome would be different had Cytyc withheld all of the [new material] from TriPath until the waning hours of the fact discovery period and only then sprung both its expanded invalidity theory and also the materials upon which it was based***.[34]

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[32] *Thibeault v. Square D Co*., 960 F.2d 239, 244 (1st Cir. 1992) (upholding preclusive order); *see also Abbott Laboratories v. Syntron Bioresearch Inc*., 2001 WL 34082555, *1-3 (S.D. Cal. 2001)(excluding from trial § 282 prior art that had not been disclosed in discovery and for which there was no substantial justification for failure to disclose).

[33] *Anderson v. Cryovac, Inc*. 862 F.2d 910, 927-29 (1st Cir. 1988).

[34] *Cytyc Corp. v. TriPath Imagining, Inc.*, 2005 WL 1527883, *4 (D. Mass. 2005) (emphasis added).

Roche failed to provide the bases for its invalidity allegations of which it was aware and thus failed to comply with both the letter and the spirit of Rule 26(e)(2). When a party fails, without substantial justification, to amend its prior discovery responses under Rule 26 as new information becomes known, thereby causing harm to the opposing party, Rule 37 authorizes the imposition of sanctions.[35] Under ordinary circumstances, Rule 37(c)(1) acts to preclude the use of evidence not disclosed.[36]

Because Roche chose to withhold from discovery its invalidity arguments and evidence, causing direct harm to Amgen's ability to prepare its response, the Court should strike the previously undisclosed arguments and facts, as set forth in Appendix C, and preclude Roche from offering those arguments and evidence at trial.

As a separate matter, the Court should extend by four weeks Amgen's time to serve its rebuttal invalidity and inequitable conduct expert reports.[37] Given its refusal to honor Amgen's 30(b)(6) deposition notice, its belated disclosure of allegations of invalidity that Roche could and should have disclosed months ago, its request for an extension of time until at least May 17 to answer Amgen's interrogatories on invalidity, and the sheer volume of detailed information included in the 950+ pages of Roche's invalidity and inequitable conduct expert reports,

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[35] FED. R. CIV. P. 37(c)(1) states in pertinent part: "A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions."

[36] *Wilson v. Bradlees of New England, Inc.*, 250 F.3d 10, 21-22 (1st Cir. 2001) (citing *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998)).

[37] *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998) (internal citation omitted); *see Cytyc Corp. v. TriPath Imagining, Inc.*, 2005 WL 1527883, *4 (D. Mass. 2005)(stating that the Court would likely have granted a request for additional time to conduct discovery to respond to late (though substantially justified) disclosure of prior art; *see also* FED. R. CIV. P. 37(c)(1).

affording Amgen an additional four weeks to serve its expert rebuttal reports is reasonable and directly proportional to the prejudice caused by Roche's belated disclosure.

E. ROCHE'S UNPLED ALLEGATIONS OF INEQUITABLE CONDUCT SHOULD BE STRICKEN FROM ITS EXPERT REPORTS.

On April 6, Roche served the 198-page report of a "legal expert" (Michael Sophocleus). That report discloses at least 11 additional allegations of inequitable conduct not pled in this case — even to date. Just a week earlier, Roche filed its amended Answer (March 30) and omitted these additional 11 allegations of inequitable conduct. Roche's failure to plead and subsequent obstruction of Amgen's discovery into Roche's inequitable conduct allegations deprived Amgen of the notice function required both by the rules and the Court's case management schedule to prepare its case regarding enforceability for trial.

Rule 9(b) required Roche to plead each allegation of inequitable conduct with particularity, specifying the time, place, and contents of the inequitable conduct, as well as the identity of the parties responsible for the inequitable conduct.[38] Litigants are required to plead fraud-based allegations with particularity to provide an opposing party with fair notice of the substance of the claim so that the party can formulate its defense.[39] Here, Roche deficiently pled its original Answer, twice moved to amend its Answer, and even when leave was granted, failed to include all of its allegations of inequitable conduct in its Amended Answer of March 30.

Amgen's diligence in attempting to learn the basis of Roche's inequitable conduct defense was not merely limited to seeking to have Rule 9(b) enforced. Amgen served an interrogatory (Interrogatory No. 26) regarding Roche's allegations and factual bases for its

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[38] *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999).

[39] *See Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 679 (6th Cir. 1988) .

inequitable conduct defense. Roche served its response late in the discovery period and even so failed to specify certain of its allegations and failed to disclose other allegations of unenforceability altogether.[40] Amgen also served a 30(b)(6) notice for deposition on Roche to discover the bases for its allegations of inequitable conduct:[41]

> 27. All facts and circumstances known to Roche on which it may rely to support any contention by Roche that Amgen's Patents are unenforceable by reason of inequitable conduct before the U.S. Patent & Trademark Office.

Roche (without obtaining a protective order) objected and refused to designate a witness.[42] Amgen has moved to compel.

Roche has no good excuse for failing to disclose these 11 additional inequitable conduct allegations since Roche has had access to and been in possession of the facts underlying each of its 11 newly-added allegations for more than a year, in some cases for several years, and certainly before it prepared its original November 6 Answer and every pleading and discovery response thereafter. The following chart identifies each of Roche's newly-added inequitable conduct allegations and the availability of the underlying facts to Roche:

UNPLED INEQUITABLE CONDUCT ALLEGATIONS IN ROCHE'S EXPERT REPORT	ROCHE'S ACCESS TO THE FACTS
Amgen allegedly misrepresented to the PTO that a two-way non-obviousness test applied in overcoming the Lai patent.	Lin file histories are in the public record. Additionally, complete Lin file histories were produced to Roche by May 31, 2006 in the ITC proceeding.

[40] Fishman Decl., Exh. 10 (3/23/07 Letter from D. Fishman to Pat Carson).

[41] Fishman Decl., Exh. 11 (3/7/07 Amgen's Fourth Notice of Deposition to Defendants Pursuant to FRCP 30(b)(6), Topic 27).

[42] Fishman Decl., Exh. 9 (Roche's Objections to Amgen's Fourth Notice of Deposition Pursuant to FRCP 30(b)(6)).

UNPLED INEQUITABLE CONDUCT ALLEGATIONS IN ROCHE'S EXPERT REPORT	ROCHE'S ACCESS TO THE FACTS
Amgen allegedly did not disclose to the PTO EP '619's related counterpart patent U.S. 4,766,075 during the pendency of the '179 application.	EP '619 and related counterpart patent U.S. 4,766,075 are in the public record. Additionally, EP '619 is disclosed in the Lin filed histories, which were produced to Roche by May 2006 in the ITC proceeding.
Amgen allegedly failed to disclose McCormick et al., US 4,966,843, "Expression of Interferon Genes in Chinese Hamster Ovary Cells."	Patent that is publicly available.
Amgen allegedly failed to disclose the following document: Egrie, Presentation Transcript "Cloning of Human & Monkey EPO" (1984) from Hemoglobin Switching Meeting, Airlie House, Virginia, September 1984.* *Relevant to two separate allegations.	The presentation was produced to Roche by May 2006 in the ITC proceeding. (See AM-ITC 00557616, AM-ITC 00557617-23)
Amgen allegedly failed to disclose the following document: Vapnek et al., "Comparative Studies of Natural and Recombinant Erythropoietin," Banbury Reports 29: Therapeutic Peptides and Proteins, 241-56 (1988).* *Relevant to two separate allegations.	Exhibit 113 to *Amgen v. HMR/TKT* case and cited in Judge Young's Jan. 19, 2001 decision at 143. Additionally, *Amgen v. HMR/TKT* proceedings, including Trial Exhibit 113, were produced to Roche by December 2006 in this case.
Amgen allegedly failed to disclose to the PTO declarations by Dr. Thomas Heckler and Dr. Goldwasser regarding MW of u-EPO vs. r-EPO, filed as exhibits in the Cilag GmbH Opposition proceedings.	The declarations are exhibits to an Opposition proceeding that are in the public record. Additionally, those declarations were produced to Roche by May 2006 in the ITC proceeding. (See AM-ITC 00312411, AM-ITC 00311606)
Amgen allegedly concealed the standard used to measure RIA from the '349 Examiner.	Roche relies on documents produced to it by May 2006 in the ITC proceeding and by December 2006 in this case. (AM-ITC 00550777, AM-ITC 00061675-706, AM-ITC 00558618)
Amgen allegedly failed to disclose to the PTO their work with the 1411 cell line.	Trial Exhibit 2425 to *Amgen v. HMR/TKT* case. Litigation files from *Amgen v. HMR/TKT* were produced to Roche by December 2006 in this case.

UNPLED INEQUITABLE CONDUCT ALLEGATIONS IN ROCHE'S EXPERT REPORT	ROCHE'S ACCESS TO THE FACTS
Amgen failed to disclose to the PTO the Baron-Goldwasser Clinical Study.	HMR/TKT advanced the same allegation in *Amgen v. HMR/TKT* case and the argument is cited in Judge Young's Jan. 19, 2001 decision at 138.

Given its failure to plead the 11 additional inequitable conduct allegations and its obstruction of Amgen's discovery into its inequitable defense, Amgen respectfully requests that the Court strike these allegations from the Sofocleous Expert Report and preclude Roche from presenting such issues or evidence pertaining to them.

III. CONCLUSION

For the reasons stated above, Amgen respectfully requests that the Court:

- Strike the following previously undisclosed invalidity allegations and bases in the following expert reports:
  - Richard Flavell Expert Report, ¶¶ 13-18, 24-104, 109;
  - Edward Harlow Expert Report, ¶¶ 122-123;
  - Michael E. Fromm Expert Report, ¶¶ 17-18, 20-50, 59-64, 68, 74;
  - Thomas Kadesch Expert Report, ¶¶ 27-29, 45-60;
  - Jack Nunberg Expert Report, Entire Report;
  - Guenter Blobel Expert Report, ¶¶ 23-24;
  - Rodney Kellems Expert Report, ¶¶ 58-59, 62-63, 71-82, 94-95, 97-115;
  - John Lowe Expert Report, ¶¶ 65-66, 70-72, 81-94, 105-127;
  - James Fisher Expert Report, Entire Report;
  - Franklin Gaylis Expert Report, Entire Report; and
  - Daniel Shouval Expert Report, Entire Report.

- Strike the un-pled inequitable conduct allegations from the Michael Sofocleous expert report at ¶¶ 293, 309, 314-316, 324, 326, 355, 373, 378-86, 387-395, 419-433; and

- Grant Amgen an additional four weeks in which to prepare and serve its rebuttal expert reports on validity and enforceability. To the extent Roche supplements its invalidity interrogatories 30 days after a *Markman* ruling to add or change the substance of any of its expert reports, Amgen should be granted two weeks after any such supplementation to prepare and submit rebuttal reports responding to the additional or changed matter.

Respectfully Submitted,
AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

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April 13, 2007

CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I hereby certify that counsel for the Plaintiff has attempted to confer with counsel for the Defendants, F. Hoffman-LaRoche Ltd., Hoffman LaRoche Inc. and Roche Diagnostics GmbH, in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

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 April 13, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried