UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO PLAINTIFF AMGEN INC.'S 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 REPORT AND MOTION FOR PROTECTIVE ORDER TO POSTPONE DEPOSITION OF CERTAIN WITNESSES

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

Counsel for

F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE INC.

I. INTRODUCTION

This case is in an entirely different posture than when Amgen filed its motion on May 24, 2007. With the stipulated and Court-ordered June 8, 2007 date for the completion of expert discovery just days away, Amgen has effectively made compliance with that date impossible. Apparently believing that the Court's denial of Amgen's motion to expedite the time for Roche to respond to its motion to strike did not apply to it, Amgen decided to give itself the relief it originally requested, and unilaterally canceled previously scheduled expert depositions, and on its own authority "re-set" the expert discovery cutoff. Amgen also announced to Roche, that it would serve no fewer than 8 additional supplemental expert reports; Amgen did that as well. Amgen's actions have necessitated rescheduling approximately 25 expert depositions, effectively precluding the parties from meeting the current scheduled expert discovery cut-off. Among Amgen's abuses is that the supplemental reports, which arrived as late as Tuesday morning, proffer opinions that go far beyond the issues raised in Amgen's original motion.

Of course Amgen could have put forth its witnesses and allowed the court to decide Amgen's motion, the appropriate relief, and its schedule, but instead Amgen simply "blew up" the schedule. With summary judgment motions due on June 8th and trial scheduled for September, the prejudice to Roche is palpable. Amgen completely disrupted the Court's schedule, and submitted reports with new issues to which Roche cannot respond; the prejudice and harm to Roche is manifest and respectfully should be addressed by the Court. Roche wants to be clear that it has timely provided Amgen with detailed information regarding its contentions and theories in this case. Amgen has had more than sufficient time to respond in expert reports to those contentions. In fact, the parties previously jointly requested the Court's permission to extend the time for serving

expert rebuttal reports and completing expert discovery. In reality, Amgen has had far more time for submitting expert reports that it deigned to afford Roche. What emerges from Amgen's tactic is that, not having requested sur-rebuttal reports in the Court's schedule, Amgen desired to serve yet another round of expert reports and inveigled the erroneous argument of late discovery to justify its actions. Amgen also wanted its experts to have the last word on all issues, leaving Roche no meaningful avenue for reply.[1]

Comparing Amgen's original expert reports to its new untimely supplemental reports, it becomes clear that Amgen has reevaluated its arguments and positions in light of Roche's initial expert reports. After realizing that its positions were untenable, Amgen decided to change its strategy. In its supplemental reports, Amgen advances new arguments and seeks to backtrack on its earlier positions. For example, in Amgen's expert Dr. Katre's report on infringement, dated April 6, 2007, she states that "[t]he change of amine to an amide reduces the positive charge on the protein at the site of pegylation. This reduction of one positive charge for the protein will alter the pI and the pKa of the protein which correlate with the charges on the protein." (*citations omitted*). (Katre Report ¶ 110). Roche's expert, Dr. Klibanov, responded that the change in charge is indeed evidence of a material change on CERA and proof of non-infringement. Recognizing that Dr. Klibanov had the better position, Amgen had to feign surprise and manufacture an excuse to submit new reports. Then waiting until just after Dr.

[1] Amgen's argument that it seeks by this motion only to limit the issues for trial is truly nonsensical. Amgen's tactic is to secure for itself every conceivable ability to respond to every point raised by Roche, while denying Roche its due process rights to advance theories to defend itself. This includes theories that this Court has not previously addressed in the prior litigations. It is Amgen, not Roche, which is bound by those rulings, and fairness dictates that Roche is entitled to its day in Court.

Klibanov's deposition on May 23, Amgen served a report from another expert, Dr. Torchilin (whose May 25 deposition was cancelled by Amgen) with the new argument that "pegylation effects no net change in charge for the amino acid residue that is pegylated." (Torchilin Third Expert Report ¶ 8). This is just one example where Amgen has taken license, in the guise of addressing Roche's experts, to raise new and different arguments knowing Roche has no means to respond.

Amgen has now served eight different supplemental reports between June 1 and June 5. Some of Amgen's recent supplemental reports read like true sur-rebuttal reports, rehashing many arguments raised in the opening reports, and sometimes contradicting them where Amgen realized the initial stretch arguments on infringement create invalidity problems for their patents. Amgen's recent supplemental reports in essence are further attempts to buttress those original arguments -- now that it had the advantage of seeing all of Roche's arguments, and several of Roche's experts' depositions. Moreover, Amgen raises new infringement arguments, although infringement is its burden. It is clear something happened regarding Amgen's strategy after April 6, when Amgen finally accepted that Roche was seriously contesting validity and when Amgen realized its frivolous suggestions that CERA is EPO were just that.

Amgen's complaint that it could not complete all the depositions of the experts was disingenuous. What Amgen did not tell the Court is that the parties had already agreed to a schedule for completing virtually all of the expert depositions by June 8, 2007. Indeed, that included over 22 of Amgen's own expert witnesses. Only after the depositions were scheduled, and a good number (mostly Roche witnesses) already taken, did Amgen announce that it was canceling scheduled depositions of its witnesses so that

it could put in sur-rebuttal reports (something neither requested by any party nor contemplated by the Court's schedule). Moreover, Amgen's protests of late disclosure are unfounded, as Roche has complied with the Court's rulings and the procedures for orderly disclosure of information. What Amgen falsely labels as "new" non-infringement arguments were in fact disclosed by Roche during the extensive discovery in this case, and were indeed in Roche's answers to interrogatories and described fully in Roche's expert reports. Likewise, the timing of Roche's supplemental invalidity reports, was contemplated by the Court's schedule and parties' agreement, or responded to testimony and opinions from Amgen's late-provided discovery. Roche's supposedly "new" arguments are nothing more than detailed explanations of contentions Roche had made throughout the course of discovery.

Characteristic of Amgen's failure to tell the whole story is its complaint about Roche's disclosure regarding inequitable conduct. First, Amgen itself served Supplemental Interrogatory Responses on April 2, 2007, and then again on April 20, 2007.

Only in the week before the April 2 close of fact discovery did Amgen finally produce for deposition key witnesses on this topic. In order to serve timely supplemental interrogatory responses, Roche analyzed the deposition testimony of these witnesses in a mere three days, whereas Amgen had more than six weeks to address Roche's inequitable conduct allegations in expert reports. Again, as the agreed upon extension makes clear, when Amgen complained it needed more time, Roche assented. Amgen withdrew its prior motion complaining of these allegations, and Amgen cannot now resurrect that

argument having withdrawn the motion and submitted rebuttal and even supplemental expert reports.

Roche has worked very hard to meet all deadlines, and to progress this case toward the scheduled September trial. Roche has made in good faith every effort to disclose any and all claims, defenses, and positions as soon as facts were discovered. As Amgen notes in its motion to strike Roche's supplemental expert reports, "Facts and law continue to evolve in any case as it progresses towards trial." During the course of fact discovery, Roche produced nearly 15 million pages of documents while 49 fact depositions were taken. By contrast to this vast production that Roche made in response to Amgen's 400+ document requests, Amgen produced about 2 million pages of documents.

For all of these reasons, as discussed in more detail below, the Court should deny Amgen's motion to strike Roche's expert reports, and address the schedule in a way fair to Roche given Amgen's last minute shower of supplemental expert reports.

II. ARGUMENT

A. ROCHE HAS WORKED DILIGENTLY TO COMPLY WITH COURT ORDERS AND TO MEET THE SCHEDULE FOR FACT AND EXPERT DISCOVERY INCLUDING INVALIDITY EXPERT REPORTS

Roche scrupulously complied with the Court's Order regarding its expert reports on invalidity. On April 6, 2007, Roche submitted numerous expert reports setting out in detail Roche's invalidity arguments.[2] Roche's production and disclosure were significant and in fact, in Amgen's now withdrawn motion, Amgen complained that it was too much disclosure. On May 1, 2007, as agreed by the parties and permitted by Court order,

[2] Roche also submitted a detailed report on inequitable conduct as Roche bears the burden on this issue.

Roche served its supplemental invalidity interrogatory responses, 16 days earlier than the Court required.[3] Roche repeatedly informed Amgen that Roche intended to supplement its expert reports to track the invalidity contentions in Roche's interrogatory responses, which Roche did for a small number of its invalidity experts.[4] Knowing this, Amgen proposed responsive reports for May 11, 2007 rather than the May 15th date Roche suggested. These supplemental reports do not prejudice Amgen in any way; not only did Amgen have notice of the issues they discuss, but Amgen had all the information that Roche collected in its supplemental responses.

In April, Amgen and Roche agreed to amend certain dates in the Court's schedule to allow for supplementation of contentions as allowed by the Court, and to permit the parties additional time to submit rebuttal expert reports. The parties also agreed to extend expert discovery from May 11 to June 8.[5] The Court adopted the parties' stipulation on May 2, 2007.[6]

That stipulation contained two additional provisions: (1) Amgen's then-pending motion objecting to certain invalidity and inequitable conduct positions advanced by Roche was withdrawn and terminated, and (2) Roche agreed to provide its responses to Amgen's invalidity interrogatories on May 1, 16 days earlier than required by the Court. A basis for the parties' agreement to extend the deadline for rebuttal expert reports was the recognition that the Court, in response to Amgen's own motion, had permitted Roche

---

3 Electronic Order re [Doc. No. 316] Motion to Compel a Complete Response to Interrogatories 9, 10, and 11 to Roche (dated March 28, 2007).

4 *See, e.g.*, letter from Tom Fleming to Deborah Fishman declining Amgen's request for Roche to withdraw its interrogatory response and expert reports (dated May 4, 2007).

5 Proposed Amended LR 16.1 (D) Joint Statement at 4, [Doc. No. 419] (dated April 20, 2007).

6 Electronic Order re [Doc. No. 419] Joint Statement of Counsel to Propose Amendments to LR 16.1(D) Scheduling Order is Allowed (dated May 2, 2007).

to supplement its interrogatories on invalidity by May 17, 2007 (this date was also confirmed at the *Markman* hearing on April 27, 2007).[7] In an effort to cooperate with Amgen, Roche agreed to serve its supplemental response on May 1, to allow Amgen time to address those issues in its rebuttal reports. Not surprisingly, when Roche timely served its supplemental interrogatories on May 1, it also served supplemental expert reports to add detail to the contentions in those responses, just as Roche told Amgen when the parties extended expert discovery. Roche complied with the Court's orders.

On May 11, 2007, Amgen answered Roche's expert reports (including the few served on May 1), with 21 separate expert reports of its own. When added to Amgen's opening salvo of 7 expert reports, Amgen's total reached 28. Amgen did not claim that it needed more time to respond, or that it would be submitting additional expert reports; it went forward and scheduled the expert depositions during the period for expert discovery.

The reality is that this is a complex case involving novel and unique molecules and issues and contentions not previously presented to this Court on the patents-in-suit. There is no question but that expert witnesses will play a prominent role at trial. Given the number of expert disclosures made under the protective order, both sides were girding for a significant expert challenge in this case. This is a complex matter on an expedited schedule, requiring significant expert discovery and, unlike Amgen, Roche has not litigated these patents before. As theories have developed, Roche has promptly disclosed them to Amgen and will continue to do so.

---

[7] See attached as Exhibit 1 letter dated May 23, 2007 from Thomas Fleming to Krista Carter .

Amgen misstates facts and mischaracterizes the nature of Dr. Lowe's supplemental reports in arguing that they should be stricken. These reports were submitted upon Roche's discovery of new facts and after a recent significant Supreme Court decision which clarifies the standards for obviousness.

Dr. Lowe's first supplemental report, dated May 1, 2007, was submitted after review of belated production (on May 17) by third party Genentech of documents related to the use of CHO cells to produce a functional recombinant human glycoprotein. Like the Sofocleous report, the information relied on was not available until well after Dr. Lowe had submitted his initial report on April 6, 2007, despite the fact that Roche timely served the subpoena during fact discovery. These documents, as Roche immediately discovered upon their production, related directly to the opinion given in Dr. Lowe's first report, specifically that it was known in 1983 that CHO cells could be utilized to express a functional recombinant human glycoprotein. Contrary to Amgen's contention, Dr. Lowe's supplemental report does not disclose a new defense or theory, but merely offers additional support for Dr. Lowe's April 6, 2007 report, specifically, for the argument that CHO cells were already known to express a functional recombinant human glycoprotein. Amgen seeks to preclude Dr. Lowe's report because it tends to challenge the enforceability of Amgen's claims.

Likewise, Dr. Lowe's second supplemental report, served May 8, 2007, considers the patents-in-suit in light of the Supreme Court's April 30 decision in *KSR Int'l Co. v. Teleflex Inc.*, which established an expanded and flexible new standard for analyzing the obviousness of a patent.[8]

[8] *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (April 30, 2007).

Roche took only a few days from *KSR*'s issuance to submit Dr. Lowe's supplemental report, still well before the May 17 deadline for supplemental responses to invalidity interrogatories. Because *KSR* is now controlling law regarding the standard for obviousness, and because obviousness is the central focus of Dr. Lowe's report, the Court should not strike any portion thereof. Amgen has had ample time to incorporate this new standard into its arguments, and has done so in its own supplemental expert reports.

Similarly, both the Flavell and Spinowitz supplemental reports were timely and appropriate in light of the parties' agreement and the Court's order. For example, Dr. Flavell's supplemental report, dated May 8, 2007, focuses on the Court's construction of the term "human erythropoietin." As support for this argument, Dr. Flavell argues that applying the Court's tentative construction, the claim term is invalid. Similarly, Dr. Spinowitz's supplemental expert report is directly related to claim construction. Specifically Dr. Spinowitz's supplemental report applied the Court's tentative construction of claim 1 of the '422 patent and claims 9, 11, 12, and 14 of the '933 patent. The fact that Dr. Spinowitz relies on prior art to make his argument is necessary and permissible. Likewise, Dr. Kadesch's supplemental report argues that claims 4 and 5 of the '698 patent are invalid for lack of a written description and are indefinite. In his argument, Dr. Kadesch highlights that Amgen proposed that the phrase "promoter DNA, other than human erythropoietin promoter DNA" should actually mean "DNA sequences that initiate transcription of a gene, which DNA is not a human genomic EPO promoter DNA;" and further, that the term "promoter DNA is viral promoter DNA" means the "promoter DNA originated from a virus."[9] Dr. Kadesch argues that under Amgen's

[9] Lodish Expert Report Exhibit V.

construction these claim terms are indefinite and lack a written description. Like Drs. Flavell and Spinowitz, Dr. Kadesch applies the Court's claim construction to make an invalidity argument which is directly relevant to the supplemental report.

Contrary to Amgen's contentions, Roche has met its burdens time and again. Amgen had--and took advantage of--every opportunity to respond to issues raised by Roche's expert reports. While Roche has attempted to accommodate Amgen's scheduling requests throughout the discovery period, to the point of acceding to Amgen's unilateral cancellation of some depositions, Amgen has no apparent intention of reciprocating.[10]

B. AMGEN CONTINUES TO WITHHOLD KEY DOCUMENTS AND PROVIDE LATE DISCOVERY

After Roche has submitted its expert reports, Amgen continues to produce late new documents and testimony that should have been produced months earlier. For example, several of Amgen's experts in their rebuttal reports served on May 11, 2007, cited to documents produced by third party Wyeth Pharmaceuticals to Amgen pursuant to subpoena. Amgen received the documents on or about April 11, 2007, but never provided a copy of these Wyeth documents to Roche despite an agreement between the parties to exchange any documents produced by third parties, and despite specific requests from Roche for the documents. These documents were only provided to Roche on May 17, 2007 after expert reports were submitted and a further request from Roche. On May 17, Amgen also provided a set of documents produced by third party Biogen

[10] Moreover, even assuming that arguments in Roche's supplemental reports and non-infringement reports are "new" (they are not) Amgen has had Roche's supplemental reports on invalidity for more than a full month now and Roche's non-infringement reports for almost the same period - yet Amgen has waited until June 1 to submit supplemental reports. Thus, Amgen has already given itself, yet again, the remedy it seeks now from the Court and cannot possibly sustain any claim of prejudice.

IDEC to Amgen on or about April 14, 2007 pursuant to subpoena, the existence of which Roche was never even informed about.

The late production from Amgen continues even now. Amgen's lawyers produced 672 pages of documents on June 2, 2007 (received June 4, 2007) from one of Amgen's experts, Dr. Joseph Eschbach. Roche subpoenaed Dr. Eschbach for documents and deposition on March 12, 2007 with a return date of March 23, 207 for documents. Amgen's counsel served objections and responses to the subpoena on March 21, 2007 and 68 pages of documents on April 13, 2007. Over a month and a half later, after Roche has submitted expert reports and while deposition scheduling is being finalized, 672 more pages of Dr. Eschbach's documents have been produced without explanation.

Still further, after filing the present motion, on May 25, Amgen produced fifty (50) new Amgen documents, many of which relate to Amgen experiments with pegylation of erythropoietin.[11] Amgen claims these documents were gathered when Amgen scientist Dr. Steven Elliot realized he failed to identify these experiments in response to direct questioning on such experiments at his deposition (ten weeks ago).

C. ROCHE CLEARLY DISCLOSED ITS NON-INFRINGEMENT POSITIONS IN ITS EXPERT REPORTS

Unquestionably, Roche's non-infringement rebuttal reports, served on May11 pursuant to the parties' agreement and the Court's order, were timely. Amgen strains to argue that certain of the theories of non-infringement in those reports were "new." To the contrary, all the theories for non-infringement had been disclosed in discovery through documents, witnesses, and in discovery responses, including non-infringement under 35

[11] This is a topic for which Amgen has already resisted discovery on the grounds of relevance as seen in Amgen's opposition to Roche's recent motion on this issue. [Doc. No. 356] (dated April 6, 2007).

U.S.C. § 271(g). And when Roche learned the specific underlying facts in discovery, those facts were disclosed.

Amgen was on notice that Roche was making the arguments which Amgen claims were newly disclosed in Roche's rebuttal expert reports, and Amgen received substantial discovery regarding all of these areas. For example, the following positions claimed to be "new" by Amgen were disclosed as indicated and relevant discovery was presented to Amgen.

- MIRCERA™ is materially changed from EPO because the intracellular signaling following EPO-R binding is different.[12] In Roche's interrogatory responses served at the end of fact discovery, Roche explicitly stated that the drug substance RO0503821 present in all MIRCERA™ formulations has been materially changed in terms of structure and properties because "it has a unique interaction with the human erythropoietin receptor . . .[and because] it has a continuous activation at the human erythropoietin receptor."[13]

- MIRCERA was not an "obligate glycoprotein." In Roche's interrogatory responses served at the end of fact discovery, Roche stated that the drug substance RO0503821 present in all MIRCERA formulations has been materially changed in terms of structure and properties because, "it does not require glycosylation to stimulate *in vivo* erythropoietic activity." An obligate protein needs to be properly glycosylated to be active.

- MIRCERA is materially changed because it has lost a single positive charge with the conversion of an amine to an amide. In Roche's interrogatory responses, Roche stated that the drug substance RO0503821 has been materially changed in terms of structure and properties because MIRCERA has "different pI (isolectric point) as measured by 2D gel electrophoresis and different overall net ionic charge distribution at blood plasma pH." Additionally, Amgen expert Dr. Katre in her April 6, 2007 opening expert report discusses this issue stating, "The change of amine to an amide reduces the positive charge on the protein at the site of pegylation. This reduction of one positive charge for the protein will alter the pI and the pKa of the protein which correlate with the charges on the protein." Amgen received substantial

---

12 Amgen Memorandum in Support of Motion to Strike Roche's Non-infringement, Invalidity, and Inequitable Conduct Allegations at Appendix A, May 24, 2007; citing Flavell Expert Report at ¶¶ 76, 113-117, 130.

13 Defendants' Third Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First set of Interrogatories to Defendants (Nos. 1-15) (dated 4/2/07).

> discovery on this loss of charge with conversion from an amine to an amide issue, including in Roche's BLA, which provides that "The production of RO0503821 includes a pegylation step of EPO with the MSBA30K PEG reagent. This pegylation is the result of the reaction of the succinimidyl ester group of the MSBA30K PEG reagent with the free amino group of the EPO forming an amide bond." ITC-R-BLA-00004235. Changes due to the chemical reaction are also extensively discussed throughout the Chemistry, Manufacture and Control section of the MIRCERA BLA.

Attached hereto as Appendix A is a non-exhaustive list of several non-infringement contentions that Amgen argues are "new," yet, in fact, have been described and identified in Roche's prior interrogatory responses, about which Amgen was on notice, and which Amgen received substantial and complete discovery. In addition, Amgen has had the entire BLA for MIRCERA for more than one year, and had a two-day deposition on Roche's Rule 30(b)(6) witness on all aspects and characteristics of MIRCERA. Amgen took depositions of at least seven Roche scientists during fact discovery. Amgen has had in depth discovery on the characteristics and material non-infringing differences of MIRCERA.

Roche submitted further supplemental interrogatory responses and objections on April 20, 2007, incorporating by reference the prior responses and again providing as much information to Amgen as possible, including reference to newly available documents.[14]

As Roche, litigating these patents for the first time, developed facts and theories supporting its claims and defenses, it diligently disclosed them in a timely manner to Amgen and it is not credible that Amgen could have been surprised, let alone prejudiced,

[14] Defendants' Fourth Supplemental Responses and Objections to Plaintiff Amgen Inc.'s First set of Interrogatories to Defendants (Nos. 1-15) (dated 4/20/07).

by any of the arguments espoused in Roche's non-infringement expert reports. In addition, the Markman hearing by the Court only occurred on April 17, 2007.

Amgen's actions contradict the arguments in its motion. Amgen prepared for and took the depositions of Roche non-infringement experts Drs. Jorgensen (May 18) and Klibanov (May 23) with no complaint, or protest about so-called "new" issues. Amgen never contended that it couldn't prepare for these depositions. These experts, through their reports, discussed many of the exact issues Amgen now claims are "new," and, yet, Amgen was evidently fully able to prepare for and proceed with those depositions.

Amgen was fully aware of Roche's non-infringement positions, as they were either explicitly stated in earlier interrogatory responses or were discussed in as much detail as was possible at the time in question, certainly sufficient to put Amgen on notice that Roche was contesting infringement of the relevant limitations. Roche is permitted to explain and clarify the bases of its theories as they develop in discovery.

Proving infringement is Amgen's burden, and it did not supply its five infringement expert reports, which included new claim construction and infringement arguments, until April 6, leaving Roche little time to respond and to prepare for the critical *Markman* hearing held on April 17. The opinions in Roche's experts' non-infringement reports address the previously undisclosed theories from Amgen's experts, but are nothing more than detailed explanations of the contentions Roche had made throughout the course of discovery.

For several reasons, the *Matsushita* decision,[15] which Amgen cites in support of the relief it seeks in its motion, is inapplicable. First, as discussed above, Roche's

[15] *Matsushita Elec. Indus. Co., Ltd. v. Cinram Intern., Inc.*, 299 F.Supp.2d 348, 365-66 (D. Del. 2004).

supplemental expert reports regarding non-infringement were timely. Roche has adhered to the Court's scheduling order throughout the discovery process, and its non-infringement rebuttal reports were served on May 11, the date set for exchange of rebuttal reports. Second, the discovery process is a fluid exercise, with new information continually coming to light. Roche has, at every turn, disclosed its theories and the facts supporting them, as they have been developed. Third, and perhaps most importantly, *Matsushita* contemplates a scenario wholly absent here: the precluded party asserted months after the close of discovery a defense that flatly *contradicted* the defenses it had maintained throughout the case.[16] By contrast, Roche informed Amgen of the basis for its defenses as soon as possible during the discovery period and is not changing its position on non-infringement. It is merely explaining in greater detail those positions of which Amgen has long had notice.[17]

D. SIMILARLY, ROCHE TIMELY AND APPROPRIATELY DISCLOSED ITS THEORIES ON INEQUITABLE CONDUCT

Amgen provides no good reason to strike the supplemental expert report of Michael Sofocleous on inequitable conduct. The theories advanced by Roche were all timely disclosed to Amgen, even those precipitated by Amgen's statements in its own

---

[16] In *Matsushita*, throughout discovery, the defendant "unambiguously claimed that its manufacturing process creates a groove on DVDs for the purpose of preventing resin from reaching the center hole." *Matsushita*, 299 F.Supp.2d at 365-66 (D. Del. 2004). However, some three months after fact discovery had ended, defendant argued that it did not infringe the asserted patents because it did not use a stopper or any equivalent thereof to prevent resin from protruding into the center hole as required by the patents at issue. Rather, defendant claimed that it applied resin far from the center hole and utilized a precisely controlled vacuum suction at the center of the disc to draw resin toward the hole and counter the centrifugal forces created by spinning the disc. *Id.* at 366. That case is completely different from, and has no bearing on, the present case.

[17] Similarly, Amgen's reliance on the *Heidelberg* decision is misplaced. *Heidelberg Harris, Inc. v. Mitsubishi Heavy Industries, Ltd.*, 1996 WL 680243, *6-10 (N.D. Ill. 1996). In that case, the defendants failed to set forth any grounds for challenging the validity of the asserted claims until the submission of their expert reports. In this case, Roche has made abundantly clear its grounds for challenging the validity of Amgen's asserted claims and has not wavered from them.

expert reports. Amgen has had no discernible problem responding to Roche's inequitable conduct allegations. Even before filing its current motion, Amgen had addressed Roche's inequitable conduct allegations in at least two written expert reports, totaling almost 300 pages. Amgen has since added a supplemental report of about 20 pages.

Roche's defense of inequitable conduct has been based both on evidence learned in discovery, including as late as the last day of fact discovery, and on statements in Amgen's own expert reports. Starting on March 14, 2007, Roche responded to Amgen's Interrogatory 26 relating to inequitable conduct with a 52-page answer providing extensive detail on Amgen's material misrepresentations and omissions before the Patent Office, committed with the intent to deceive the Patent Office and procure issuance of the asserted patents. On March 30, soon after the Court granted Roche leave to amend its answer, Roche formally filed its pleading, setting forth additional defenses and, as noted, supplementing its inequitable conduct defense. On April 2, although it was still gathering relevant information in discovery,[18] Roche further elaborated on its inequitable conduct contentions in a 70-page supplemental response to Interrogatory No. 26.

Only in the waning days of the fact discovery period was Roche first able to gather additional key facts supporting its inequitable conduct allegations. This timing resulted from Amgen's withholding key fact witnesses until the last week of depositions. These included the named inventor, Dr. Lin, contributing scientists Joan Egrie, Thomas Boone, Daniel Vapnek, and Graham Molineaux, as well as prosecuting attorneys Stuart Watt and Steven Odre.[19] Notwithstanding this chronology, Roche's expert Michael

---

[18] On April 2, the last day of fact discovery, Roche took the deposition of Amgen prosecuting attorney Steven Odre.

[19] It is further noted that at the April 17, 2007 hearing, the Court granted in part Roche's Motion to Compel the Production of Documents Improperly Withheld on Grounds of Privilege (Doc. No.

Sofocleous offered his opinion, supporting Roche's case for inequitable conduct, in a very detailed report dated April 6, 2007—just four days after the close of fact discovery.[20] Amgen is not prejudiced; it just wants to have the last word and to deny Roche any opportunity to respond.

Amgen mischaracterizes the nature of the Sofocleous supplemental report. Mr. Sofocleous's initial and supplemental reports were submitted in response to Interrogatory No. 26, which relates to Roche's claim of inequitable conduct. Mr. Sofocleous offered his opinion supporting Roche's case for inequitable conduct on April 6, 2007, just four days after the close of fact discovery. In fact, Mr. Sofocleous's supplemental report addressed many issues related to inequitable conduct which did not emerge and were not learned by Roche until *after* Roche received Amgen's April 6 and May 11 rebuttal expert reports. Roche was surprised by certain positions taken by many of Amgen's 21 experts, some of which, if accepted by the Court, constitute additional grounds for inequitable conduct. Not having any access to these opinions before receiving the reports, Roche acted as swiftly as possible in advancing its arguments.

Mr. Sofocleous's opinions were predicated on statements heard for the first time from Amgen's experts. To show prejudice from this supplemental report, Amgen must show that Roche's actions were a bad faith tactic that hampers Amgen's ability to respond.[21] Roche's previous inequitable conduct allegations and discovery responses go into detail about Amgen's non-disclosure and misrepresentations about prior art.

---

366). Specifically, the Court held that Roche is entitled to resume the deposition of Michael Borun to question him regarding certain of Roche's inequitable conduct defenses. This deposition has yet to take place.

[20] In fact, as noted above, the deposition of Mr. Steven Odre, Roche's prosecuting attorney was not available until April 2, 2007, the last day of fact discovery.

[21] *Carmona v. Toledo,* 215 F.3d 124, 136 (1st Cir. 2000).

Amgen's protests go more to its desire to have the last word on inequitable conduct than to any prejudice from "new" arguments.[22]

Roche has responded to Amgen's discovery by providing detailed information in documents, through witnesses, and through written discovery such as interrogatories with candor, meaning they are responsive, full, complete, and clear.[23] The allegedly new issues that Amgen claims subject it to prejudice have been explicitly stated in prior interrogatory responses or other discovery while others state further detail of non-infringement positions previously disclosed.

III. CONCLUSION

Roche has rigorously adhered to the Court's schedule and timely complied with its obligations for both fact and expert discovery. Roche respectfully requests that the Court deny Amgen's application to strike certain of Roche's supplemental reports. Since Amgen has awarded itself the relief it asked from this Court, Roche requests that the Court endeavor to make the schedule for summary judgment fair for both parties. For all the foregoing reasons, Roche respectfully requests that the Court deny Amgen's motion in its entirety.

---

[22] For example, Mr. Sofocleous's supplemental report addressed the non-disclosure of a Baron-Goldwasser clinical study and other related prior art, an inequitable conduct allegation that was fully disclosed in Mr. Sofocleous's April 6 report as well as Roche's April 2, 2007 Supplemental Interrogatory Response to Amgen's Interrogatory No. 26. The supplemental report merely expanded on Roche's contention with newly learned facts that Amgen long possessed.

[23] *Dollar v. Long Mfg., N.C., Inc.*, 561 F.2d 613, 616 (5th Cir. 1977) ("The candor required is a candid statement of the information sought...).; *Miller v. Doctor's General Hospital*, 76 F.R.D. 136, 140 (W.D. Okla. 1977).

Dated: June 6, 2007
Boston, Massachusetts

Respectfully submitted,
F. HOFFMANN LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANNLA ROCHE INC.

By its attorneys,

/s/ Keith E. Toms

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
ktoms@bromsun.com

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/ Keith E. Toms

3099/501 681243.1