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-CV-12237WGY

ROCHE'S RESPONSE AND PARTIAL CONSENT TO AMGEN'S EMERGENCY MOTION FOR EXPEDITED CASE MANAGEMENT CONFERENCE

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") herein respond to Amgen's Emergency Motion for Expedited Case Management Conference.

Introduction

Roche agrees that a case management conference is necessary here, but not for the reasons advanced by Amgen. 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 vested in Amgen the authority of an Article III Judge, Amgen has unilaterally canceled previously scheduled expert depositions, and "re-set" the expert discovery cutoff, and announced it will proffer no less than 10 additional expert reports, necessitating rescheduling approximately 25 expert depositions, effectively precluding the parties from meeting the current scheduled expert discovery cut-off.

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 it simply destroyed the schedule. With summary judgment motions due on June 8th and trial scheduled for September, the prejudice to Roche is palpable.

As explained below, Amgen's pretextual protests for needing "supplemental" reports is unfounded and pure rhetoric. Roche has complied with this Court's directives and schedule. Having seen Roche's expert reports and taken key Roche expert depositions, Amgen now simply wants to have the last word on all issues in the case and to preclude Roche from responding. Not only is Amgen's tactic grossly unfair and prejudicial to Roche, it has subverted the calendar this Court has carefully implemented in this case.

Even more seriously, Amgen's actions will completely undermine the Court-ordered date for the submission of summary judgment motions, now due on June 8. Because of Amgen's upheaval of the schedule, depositions of experts will not be completed until the last week of June, long after the time that summary judgment motions are currently to be filed. This is also a prejudicial and unworkable outcome.

In light of Amgen's abuses, Roche proposes the following agenda for a conference on June 6 (if the Court is inclined to hear the parties on that day):

1. In light of Amgen taking upon itself the relief that the Court has otherwise denied it, and having undone the Court's calendar, Roche respectfully requests that the Court impose a schedule that is fair to *both* parties and affording Roche the ability to advance its theories in response to Amgen's;

2. Reject Amgen's proposed agenda as the issues presented: (i) are not yet ripe for adjudication -- Amgen agenda items 3 and 4 (by this Court's May 25 order answering papers are

not yet due on the motions); or (ii) are not yet presented to the Court as particular applications have not even been briefed at all by Amgen -- agenda items 2 and 5; or (iii) have already been repeatedly decided against Amgen by this Court on previous motions -- agenda items 1 and 6. In all, Amgen's proposed Agenda items are inappropriate to burden the Court with at this juncture.

I. Roche Has Complied With The Court's Orders Regarding Expert Discovery

Contrary to Amgen's assertions, Roche has made its experts available for deposition and has consistently complied with the Court's discovery and scheduling orders. Amgen's purported excuse for its emergency conference is illogical and belied by Amgen's own conduct. Amgen complains in its expedited motion that it cannot complete all the depositions of the experts. However, what Amgen did not tell the Court is that it worked with Roche to schedule virtually all of the expert depositions by June 8, 2007 without complaint. Indeed, that included **22** of Amgen's expert witnesses. Once the depositions were scheduled, and a good number (mostly Roche witnesses) already taken, Amgen announced last Thursday that it was canceling scheduled depositions of its witnesses so that it could put in sur-rebuttal reports (something not requested nor contemplated by the Court's schedule), under the pretext of the reports submitted by Roche. Amgen's allegations and protests are wrong as Roche has properly complied with the Court's rulings and the proper and orderly disclosure of information in this case. Amgen's tactics, and indeed its excuse, are part of a plan to ambush Roche.

Amgen announced for the first time last Thursday (May 24), that it intends to serve an unspecified number of additional expert reports, and proceeded to cancel previously scheduled depositions of Amgen witnesses. Amgen moved for relief from the Court on an expedited basis and the Court denied Amgen's request (Order dated May 25, 2007). Ignoring the Court's order, Amgen proceeded to give itself the relief it wanted by fiat through canceling depositions.

Amgen knew that Roche's objections would be ineffective as Roche had no control over nor recourse against Amgen. This tactic continued into the weekend as more and more depositions were canceled by Amgen, and Amgen finally presented a general list of 10 new expert reports, including from Amgen experts whose depositions had already been taken.

Most telling of Amgen's tactics was Amgen canceling the depositions of its own witnesses and proposing to go forward with the depositions of Roche's experts. It seems clear to Roche that Amgen is trying to have the benefit of all of Roche's expert opinions without giving the experts the opportunity to see Amgen's positions (even on issues where Amgen has the burden) and then to have the ability to refashion its arguments in sur-rebuttal reports on all issues before the Court.[1] The schedule of reports, based on burden, has been disregarded by Amgen totally.

Even more transparent is Amgen's *post hoc* rationale for its conduct, which rests on a distortion of reality, and comes down to nothing more than some calculated gambit by Amgen to completely disrupt Roche's right to adequately prepare for trial during the September trial calendar -- a schedule Roche understands the Court intends to preserve. It is for this reason alone that Roche agrees that the Court's intervention is necessary, not for the purported agenda advanced by Amgen.

[1] For example, Amgen cancelled the deposition of Amgen expert Dr. Catlin the day before it was scheduled and informed Roche that his deposition could not take place until June 8, the last day of expert discovery (of course no longer the last day). Similarly, after completing the depositions of Roche experts Dr. William Jorgenson and Dr. Alexander Klibanov, Amgen informed Roche on May 24, 2007 that the deposition of Amgen expert Dr. Torchilin, who addressed the issues raised by those Roche experts, already scheduled to take place on May 25, would not take place until June 8th because Amgen was going to submit a further report for Dr. Torchilin. Then, after already having Amgen experts Drs. Kolodner and Mclawhon deposed on their then limited existing reports, Amgen one week later announced (with no prior warning) that these Amgen experts would submit further reports. These are pure litigation ambush tactics, by which Amgen wrongfully tries to concoct reasons to blame the current situation on Roche.

A simple review of the actual history of expert discovery demonstrates that it has been Amgen, not Roche that has impeded discovery. Amgen's arguments about late disclosed or new theories are pure fiction. On April 6, 2007, Roche and Amgen served their opening burden-based expert reports -- rebuttal reports were then due on April 27, 2007. On April 26, 2007, the parties submitted a joint application to the Court extending the time for rebuttal expert reports (to May 11) and expert discovery and summary judgment filing (to June 8). That stipulation also provided for two additional features: (1) Amgen's pending motion objecting to certain invalidity and inequitable conduct positions advanced by Roche was withdrawn and terminated, and (2) Roche agreed to provide its supplemental responses to Amgen's invalidity interrogatories on May 1, -- 16 days earlier than required by the Court. One of the foundations of the agreement for the extension of rebuttal expert reports, was the recognition that the Court had permitted, in response to Amgen's own motion, Roche to supplement its interrogatories on invalidity by May 17, 2007 (this date was also confirmed at the Markman hearing on April 27, 2007).[2] Roche agreed to move the date of that response up to May 1 to allow Amgen time to address those issues in Amgen's rebuttal expert reports. Not surprisingly, when Roche served its supplemental interrogatories on May 1, it also served supplemental expert reports to further address the contentions in those responses, as Roche told Amgen it would do in entering into the extension of the schedule.[3] Roche has not only complied with this Court's orders on discovery and scheduling, it has worked to disclose information to Amgen. It can hardly be doubted that Roche has been more than forthcoming in discovery, producing more than 16 million pages of documents, providing all the fact witnesses requested by Amgen (from no less than three

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

[3] Both parties have been guided by and mindful of the Court's rule that the experts may only testify about matters that are set forth in their reports.

different countries), all in the shortest possible time frame, and timely and appropriately supplementing written discovery. [4]

Unlike Roche, which provided its fact witnesses during the early weeks of fact discovery, Amgen withheld its key witnesses to the last week of that period (fact discovery cut-off was April 2 -- just 4 days before opening expert reports were due). In fact, it was only during that last week of fact discovery that Amgen produced Dr. Lin, Dr. Egrie, Dr. Vapnek (all within a three-day window and some on the same day), Mr. Watt, Mr. Odre (only offered on the last day of fact discovery) and Dr. Boone. In spite of Amgen's inconvenient scheduling, Roche labored to complete these depositions. Then, at the completion of the depositions of these vital witnesses, also on April 2, Roche served supplemental interrogatory responses on its inequitable conduct allegations. Amgen omits that it too served supplemental interrogatory responses on April 2. In truth, Roche had virtually 3 days to analyze the deposition testimony of key Amgen witnesses, whereas Amgen has had more than six weeks to address Roche's inequitable conduct allegations. In response, Amgen served two rebuttal reports totaling about 300 pages to these allegations and as the agreed upon extension makes clear, when Amgen complained it needed more time, Roche assented.

[4] Amgen inconsistently argues, on the one hand, that Roche's supplemental reports allege "different contentions" which were "never disclosed" to Amgen, and, on the other hand, that Roche's expert reports are "duplicative" and "rehash" Roche's theories. *See* Docket No. 449 (Amgen's Motion) at 2, 4. Amgen cannot have it both ways.

II. The Parties Had No Trouble Scheduling Depositions Until Amgen Violated the Court's Schedule

In response to Roche's opening reports, on May 11, 2007, Amgen answered with 21 separate expert reports of its own. When added to Amgen's opening salvo of 7 expert reports, Amgen's total expert reports reached to almost 30. The reality is that this is a complex case involving novel and unique molecules and issues and contentions not previously presented to this Court concerning the patents-in-suit. There is no question but that expert witnesses will play a large role for all parties in this jury trial. Amgen knew this all along; in fact, given the disclosures each side made of experts under the protective order, both sides were girding for a significant challenge in this case.[5]

Any difficulties in covering the depositions are present for both sides, as they have comparable numbers of experts. Still, before Amgen announced its intent to proffer yet further reports, the parties were able to schedule all the necessary depositions to be completed by June 8. It is ludicrous and misleading for Amgen to tell this Court that it is Roche's plan to present all of its experts at trial, just as Amgen has no intention of presenting all of its 21 expert witnesses at trial. Amgen's argument is just plain wrong, and Amgen is aware of this.

Amgen knows that in a jury trial such as this involving a running trial calendar, it is perfectly normal and in fact advisable to have overlapping experts, because the parties need options allowing flexibility so that the Court and jury are not burdened by the variegated schedules of the parties' experts. When the trial starts the Court and the jury will have no patience for an unavailable expert. Moreover, the parties cannot predict what expert will be available to testify at the trial given normal personal issues. Roche has no intention to present

[5] Additionally, issue-narrowing motions, such as those for summary judgment, are pending before the Court and more will be filed in the near future. The Court's rulings on these motions will focus for the parties the issues for trial, and Roche will correspondingly use only the experts it finds necessary in light of these rulings.

overlapping witnesses, and does not expect the Court will allow multiple experts testifying on exactly the same topic. But the availability of witnesses is a precarious thing and in a case of this importance, back up witnesses for key expert topics are necessary.[6]

Also, many experts have discrete and limited topics in this multi-faceted case. Amgen has tactically decided that a single witness will be on the stand for many days. For example, Dr. Lodish's two reports to date combine to 354 pages and Roche is informed he will submit another report on June 4th (after all of the other Amgen reports) responding to Roche witnesses. Roche instead has confined its witnesses to limited topics, so there may be more witnesses each speaking on fewer topics. It is arbitrary for Amgen to seek to limit the number of witnesses the Court and the jury should hear at this time.

Accordingly, any demand by Amgen to limit Roche's ability to defend itself against Amgen's lawsuit through the use of expert testimony is unreasonable and without merit.

III. The Court's Four Prior Rulings Barring Disclosure of FDA Negotiations Should Stand

For now a fifth time Amgen, without even filing a motion, demands confidential information regarding ongoing negotiations between Roche and the FDA. As this Court has repeatedly held, Roche maintains its position that ongoing discussions and negotiations between Roche and the FDA, such as correspondence regarding the timing of approval of MIRCERA™, are not appropriate for discovery at this juncture (See December 29, 2006 Order) and the Court should, therefore, not entertain Amgen's attempt to circumvent this Order for yet a ***fifth*** time.

[6] While Amgen has more than 20 experts already, Amgen has had a key expert withdraw from the case for health reasons. Amgen claims that none of the other experts overlap this witness and has suggested that it will replace that expert with several others (and Amgen has not yet replaced him although they have known of this problem for several weeks). At this juncture, Amgen has simply said that it will get back to Roche by June 8th. Roche, too has withdrawn an expert (with no need for a new report as there was a second expert on the topic), and has had to deal with scheduling another who became unavailable due to a sudden death in the family.

The FDA **has not approved** Roche's MIRCERA, and Amgen knows this. Amgen also knows that the FDA has scheduled an Advisory Committee on ESA treatments in the Renal Anemia area for September 11, 2007, probably during the trial of this action. As a consequence, the expectation is that the jury trial of this action may move forward at a time even before Roche has approval from the FDA, which if the Court does not impose strict limitations of what Amgen can argue to the jury in this regard, is likely to result in significant prejudice to Roche during the trial. The reality is that nothing has changed since the Court last denied Amgen this same request to warrant the Court altering in any way its prior rulings, and Amgen has offered absolutely nothing to persuade the Court to do so.

IV. This Court Has Already Denied Amgen's Motion to Bifurcate or Phase the Jury Trial

Again, without filing a motion and without explaining what it wants, Amgen asks this Court during a case management conference to entertain an unspecified application to bifurcate or phase the jury trial scheduled for the September 2007 calendar. Amgen neglects to remind the Court that Amgen has already requested and was denied this very relief. *See* Docket 175 (Motion to Bifurcate Roche's Antitrust and Unfair Competition Counterclaims from Amgen's Patent Infringement Claims for Trial and Discovery and to Stay Discovery on those Claims). Amgen has shown no concern for the busy docket of this Court by repeatedly making the same motions and seeking the same relief time and time again, forcing the Court to continually reinforce its rulings. Amgen's disregard for the Court's orders was manifest when, after having been denied expedited briefing on its motion, Amgen employed self-help and canceled depositions and decided on its own to violate the Court's schedule.

Conclusion

Despite the fact that Amgen specifically sought from the Court the existing discovery schedule, and has more than 50 attorneys of record in this case, Amgen absurdly maintains that it faces "impossible" challenges with respect to processing and responding to Roche's expert reports. *See* Docket 449 (Emergency Motion For Expedited Case Management Conference) ("Amgen's Motion") at 2. If the burden of completing expert discovery falls more heavily on one party, then it is clearly Roche, as Amgen has litigated the patents-in-suit before and has worked with many of its experts in prior litigations.

It is Amgen who has acted inappropriately throughout expert discovery. In an effort to gain an unfair advantage, Amgen has, in particular, employed the tactic of preparing supplemental reports on behalf of its expert witnesses beyond the applicable deadline and only after deposing Roche's expert witnesses. Amgen has engaged in such behavior despite the parties' agreement that depositions would take place only after all of the experts' reports had been submitted. Amgen's actions demonstrate its attempt to provide for itself the relief it now seeks from the Court, and such tactics should not be tolerated.

Such tactics are intended by Amgen to prejudice Roche and should be considered by the Court when deciding the issues proposed to be discussed at Amgen's proposed case management conference.

Accordingly, while Roche does not object to the Court holding an expedited case management conference, Roche respectfully requests that the Court reject Amgen's agenda and employ the agenda put forth herein by Roche.

DATED: Boston, Massachusetts
June 1, 2007

Respectfully submitted,

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

By its Attorneys,

/s/ Julia Huston
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
jhuston@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*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, NY 10022
Tel: (212) 836-8000

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/s/ Julia Huston
Julia Huston

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