UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' OPPOSITION TO AMGEN INC.'S RENEWED MOTION FOR AN EXTENSION OF TIME TO SERVE ITS EXPERTS' REPORTS REGARDING TESTING OF ROCHE'S LATE-PRODUCED CELL LINE

Amgen Inc.'s ("Amgen") Renewed Motion for an Extension of Time to Serve its Experts' Reports regarding Roche's cell line is just a veiled attempt to obtain reconsideration of the Court's Order refusing Amgen's prior request for the same relief. In its Order of February 27, 2007 (Docket No. 298), this Court disposed of Amgen's first request for such an extension of time. Seeking in essence reconsideration, Amgen is now (on the very day expert reports are due) asking the Court to undo its carefully crafted case schedule suggested by Amgen, and give Amgen the special privilege of an extension of over two months to submit additional expert reports and opinions to a date long after summary judgment motions are to be submitted. Amgen's current protestations of delay were all rejected by the Court in its February 27 Order, and if, in fact, Amgen cannot timely complete its expert reports, it is due entirely to Amgen's own conduct in this action.

Any alleged delay that Amgen has suffered in producing its expert's report is entirely attributable to its own actions. Following the Court's Order of January 23, 2007, which directed *both parties* to produce their cell lines, Amgen refused to acknowledge its

obligation to produce its cell lines, and instead sought to negotiate with Roche a stipulation which provided, among other things, that Roche would withdraw its request for Amgen's cell lines and stipulate to certain facts in lieu of producing its own cell lines.[1] After extraordinary efforts by Roche, the attempt to reach a stipulation eventually proved futile.[2] All during this time, Roche was prepared to exchange its cell lines for Amgen's cell lines and so informed Amgen; yet, Amgen refused to produce its cell lines or negotiate in good faith with Roche. On February 5, 2007, Roche attorney Carson wrote to Amgen's attorney, noting that:

> In fact, the day after that order issued [the January 23 Order], I immediately wrote to you offering to discuss the specifics of the exchange... As you know from that call, since receiving the Court's order we have been working with Roche to determine the applicable import restrictions and necessary permits required to import Roche's cell line from Europe. In contrast, it is clear from our discussion and your letter that Amgen has done nothing to initiate the production process.[3]

Amgen's delay was due to its own posturing. There is no doubt but that Roche fully complied with this Court's Orders and directives.

It took Roche filing a motion to compel with this Court, resulting in an Order dated February 27, 2007, <u>again directing Amgen to make a reciprocal production</u> of its cell lines, before any progress was made in this regard with Amgen. That February 27th Order

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[1] Roche determined that it would pursue this stipulation (even though is still disputes this issue) because doing so would obviate the need for Roche to produce one of its most valuable assets, its production cell line for MIRCERA™ (which is not even maintained in the United States), thus protecting that asset, while reserving its right to challenge the validity of the pertinent claim based on indefiniteness and non-enablement.

[2] Negotiations over this stipulation dragged on for weeks due to Amgen's delays, despite Roche repeatedly informing Amgen that it was ready to conclude the negotiations or alternatively ship its cell line at any time. When negotiations finally broke down, Roche immediately made arrangements to produce its cell line to Amgen from Germany. *See* Ex. 1 (2/23/07 letter from P. Carson to D. Fishman).

[3] *See* Ex. 2 (2/5/07 letter from P. Carson to D. Fishman).

directed the parties to exchange cell lines within 30 days, and did not allow Amgen's requested extension. As soon as that Order issued, Roche informed Amgen once again that it was ready to comply and arrange for shipment of its cell line to Amgen's designated expert. Again, Amgen delayed and delayed. Amgen could not or would not coordinate its activities regarding Roche's cell lines, going so far as to change the identity at the eleventh hour of the person to whom Roche's sample cell lines were to be sent for testing. Despite Amgen's delays in complying, Roche produced its cell line within the time directed by the Court. If there was any delay in Amgen's testing, it was solely the result of Amgen's own conduct.

Even after the Court's Feb. 27 Order, Roche wrote continually to Amgen seeking to arrange delivery, and its entreaties were only met with silence or further procrastination on Amgen's part. For example, on March 13, Roche attorney Pat Carson wrote to Amgen's lawyer stating:

> "It has now been two weeks since the Court ordered reciprocal production of the parties' respective cell lines. Following several discussions with you, on March 8th I sent you a proposed letter to accompany delivery of Roche's cell line to Amgen's designated expert for your review and requested a meet and confer regarding the logistics of exchange. Since I did not hear back from you, I sent a follow-up e-mail yesterday, again requesting a meet and confer. I have still not heard back in response.
>
> Roche has been ready to provide its cell line to Amgen for weeks...."[4]

Amgen's expert received Roche's cell line on March 21, 2007, which was well within the 30-day period set forth in the Court's February 27th Order. Amgen then needlessly waited over two weeks from receiving the cell line and until the day the expert reports were due to file its instant motion. At not time did Amgen give the Court nor

[4] *See* Ex. 3 (3/13/07 letter from P. Carson to D. Fishman) (emphasis added).

Roche any indication that it allegedly could not complete its expert reports by the scheduled date of April 6.

Roche, in contrast, to date, in compliance with the schedule set in place by the Court, has produced in excess of *14 million* pages of documents, has defended and taken close to 45 depositions alone in three weeks time in numerous countries, and then shortly thereafter served its several expert reports. Now, after all that Roche has strained to make happen in the schedule requested by Amgen, Amgen wants to ignore that schedule and submit its expert reports weeks after summary judgment briefing is to be completed in this case. Amgen's suggested relief for an extension would put part of the case on a different track than the rest, and require Roche to revisit and respond to new infringement arguments while it has to finalize its pretrial materials, all long after expert discovery will have closed. Fundamental fairness dictates that Amgen's request be denied. Alternatively, if the Court is inclined to grant Amgen's last minute application for a two-month extension for Amgen's expert reports, the Court should readjust the remaining schedule so that Roche is not prejudiced and the parties' further obligations are equitably adjusted. For these reasons, which are explained more fully below, Amgen's Renewed Motion should be denied in full.

I. THE COURT HAS ALREADY DENIED AMGEN'S REQUEST FOR AN EXTENSION OF TIME

The Court has already disposed of Amgen's request for an extension of time to serve its expert reports regarding Roche's cell line. Amgen explicitly asked the Court to extend the time to submit its expert report on February 23, 2007 in its Motion to Enforce the Court's January 23, 2007 Order (Docket No. 293). The Court disposed of Amgen's Motion in its Order of February 27, 2007 (Docket No. 298), in which it ordered both parties to produce a sample of each of the requested cell lines to a third party expert for testing.

The Court's Order further provided, "This order resolves the cross-motions, docket nos. 293 and 296. Such discovery shall be furnished within 30 days of the date of this order." Thus, Amgen's request has already been denied and it should not be burdening the Court with its plea for reconsideration.

Amgen offers no valid justification for this Court to reconsider its prior ruling. "A court should grant a motion for reconsideration of an interlocutory order only when the movant demonstrates (1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error of law in the first order." *Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass 2000).

Moreover, Roche complied with the Court's Order and produced its cell line well within the 30 day period prescribed by the Court. The Court's Order clearly anticipated and approved of the time allotted between compliance with the directive to produce cell lines and the deadline for expert reports. If Amgen believed that it was not possible to comply with the expert discovery schedule in light of the Court's Order, Amgen should have brought that fact to the attention of the Court immediately, and not waited until the very day of the deadline for expert reports to renew its request. It strains credulity to think that Amgen's experts waited to the last minute on the day that expert reports were due to inform Amgen about the alleged timing issue.[5]

II. ANY ALLEGED DELAY IN TESTING ROCHE'S CELL LINE IS ATTRIBUTABLE TO AMGEN

Amgen's actions alone are responsible for any alleged delays in Amgen's testing of Roche's cell line. Any alleged delay on Roche's part in producing its cell line is the direct

[5] Amgen did not seek a Rule 7.1 meet and confer on this issue until about a few hours before they filed their motion on April 6, 2007.

consequence of several weeks of negotiations between Amgen and Roche, which were directed toward the parties entering into a compromise because Amgen refused to produce its cells as the Court twice ordered. *See* Court's Order of January 23, 2007 and Court's Order of February 26, 2007.

Following receipt of the Court's January 23rd Order regarding the production of the parties' cell lines, Roche wrote to Amgen, agreeing that production "must occur quickly." Noting that "the Court ordered Amgen to produce reciprocal discovery, hopefully without the necessity of a motion to compel," Roche stated that it was ready to make a reciprocal exchange.[6] Amgen blatantly and without explanation refused.

Throughout, Roche continued to offer Amgen its cell line, or alternatively a stipulation to obviate the need for its production. In offering its stipulation, however, Roche insisted upon language reserving Roche's right to attack validity of the '349 claims on any ground, notwithstanding the stipulation. Throughout the negotiation process, Roche repeatedly informed Amgen that it was ready and willing to produce its cell line at any time, and it was Amgen that refused that offer and pursued negotiations in the hopes of avoiding its obligation to produce its own cell lines.[7]

Efforts to finalize the stipulation were stymied when it became clear that Amgen had been negotiating in bad faith and clearly wanted to use the stipulation for purposes other than originally represented.[8] Despite expressly agreeing to language precluding any argument that the stipulation waived Roche's right to attack validity of the '349 claims, it became clear that Amgen intended to use the stipulation for precisely that purpose.

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[6] *See* Ex. 4 (1/24/07 Ltr. from P. Carson to D. Fishman).

[7] *Id.*

[8] *See* Ex. 5 (2/16/07 Ltr. from P. Carson to D. Fishman).

Specifically, Amgen informed Roche that it must be able to use the stipulation as evidence that Roche had waived any argument that the '349 claim language is indefinite. Amgen understood its vulnerability on this issue.

Roche's experts have opined that Claim 7 of the '349 patent ("Claim 7") is indefinite and non-enabled because it purports to measure a level of production of erythropoietin by cells grown in culture but fails to provide any reliable way of measuring the production of erythropoietin that could be used to compare the cells to the production levels given in the '349 patent claims. Claim 7 depends from Claims 1-6 of the '349 patent and requires production of erythropoietin in excess of "100 [or 500 or 1000] U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay."[9] To one of skill in the art, "U of erythropoietin" is a measure of biological activity, yet radioimmunoassay cannot measure biological activity. Radioimmunoassay (RIA) can only measure the amount of a protein in a sample, not its biological activity. Amgen's witnesses confirm this.[10] Thus, claim 7 of the '349 patent is indefinite and not enabled in that it requires a certain biological activity production level of erythropoietin but provides for it to be measured by a test that cannot measure biological activity.

Furthermore, one cannot attempt to convert the results one obtains by radioimmunoassay, the amount of protein, to a measure of biological activity without having in essence a conversion ratio, or standard, that would tell one the units of activity

[9] The limitation of "100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay" is present in each of Claim 1-6 of the '349 patent, but the number of units (U) varies from 100 to 500 to 1000.

[10] To avoid the necessity of providing confidential documents to the Court, Roche will not detail Amgen's testimony here, but will of course provide it to the Court if the Court deems that information helpful for resolution of this motion.

per amount of protein. Roche's experts have explained that neither Claim 7, nor the specification of the '349 patent (all of the asserted patents share a common specification) provide such a standard. For this reason, Claim 7 is indefinite and not enabled, and thus invalid pursuant to 35 U.S.C. § 112. Also for this reason, Amgen's planned expert report, for which it seeks an extension of two more months to produce, cannot in any meaningful way shed light on whether Roche's cell line meets this production level limitation in Claim 7 of the '349 patent, the only purported reason given by Amgen to obtain a sample of Roche's cell line. Amgen's expert will have to arbitrarily choose a standard that provides a way to convert the amount of protein measured by radioimmunoassay to biological activity and then compare that number to the limitations of Claim 7. In addition to the fact that Amgen was responsible for the date upon which its expert received Roche's cell line, there is simply no reason to give Amgen an extra two months to produce an expert report that would be contrary to the record of Amgen's former employees.

Roche has at all times since the Court's January 23rd Order been ready and willing to import into the United States and produce to Amgen's designated expert its cell line, and repeatedly conveyed this fact to Amgen.[11] As soon as negotiations over the stipulation broke down based on Amgen's new insistence that it be allowed to use the stipulation for more than just proving infringement, Roche ensured Amgen that its best efforts would be used to produce its cell line promptly, again stating on February 26 that "[w]e fully expect that barring unforeseen circumstances, the sample will be in Amgen's expert's hands by

[11] On February 16, 2007, Roche once again wrote to Amgen regarding Amgen's sudden refusal to agree to language in the proposed stipulation:"[a]lternatively, we will need to resume discussions regarding appropriate safeguards for production of Amgen's relevant cell lines, including its Aranesp line, and importation and production of Roche's cell line." *See* Ex. 5 (2/16/07 Ltr. from P. Carson to D. Fishman).

Friday [March 2]".[12] Roche even went so far as to offer to allow an appropriate representative of Amgen to pick up the cell line in Penzberg, Germany, the location where Roche's cell line is maintained.[13] By letter of February 26, 2007, Roche confirmed that arrangements were being made to deliver the cell line by courier in an attempt to minimize delays at U.S. Customs.[14] Amgen is not deserving of any extension of time to remedy a problem (if one actually exists) that it created on its own.

III. FOLLOWING THE COURT'S FEBRUARY 27 ORDER DIRECTING AMGEN TO PRODUCE ITS CELL LINE, AMGEN HAS DRAGGED ITS FEET IN COMPLYING, CAUSING ITS OWN DELAY

Amgen's contention that Roche is responsible for unjustified delay of production is not based on reality. On March 8, Roche continued to press Amgen by email for an exchange of the ordered cell lines. Roche's proposal was met with silence. Roche continued to offer its cell line to Amgen. Roche sent Roche sent another email on March 12, which again was not responded to by Amgen. In addition, Roche attorneys were also calling Amgen's lawyers. Still faced with no response from Amgen, Roche attorney Carson again tried to elicit some response from Amgen by sending a letter on March 13, 2007. This letter clearly recounts that "Roche has been ready to provide its cell line to Amgen for weeks," and that it only sought Amgen's cooperation "regarding the logistics of the exchange."[15] Roche sent another letter to this effect to Amgen on March 14, still receiving no response from Amgen, stating "On March 8th, Pat [Carson] sent you a

[12] *See* Ex. 6 (2/26/07 letter from P. Carson to D. Fishman).

[13] *See* Ex. 1 (2/23/07 E-mail from P. Carson to D. Fishman) and Ex. 6 (2/26/07 letter from P. Carson to D. Fishman).

[14] *See* Ex. 6 (2/26/07 letter from P. Carson to D. Fishman).

[15] *See* Ex. 3 (3/13/07 letter from P. Carson to D. Fishman).

proposal for exchange of the cell lines and requested a meet and confer on the logistics of the exchange, to which you have never responded. She sent a follow-up email on March 11 and then her letter on March 12, and we still have not heard from you."[16] Amgen's choice was to ignore Roche's entreaties and persistent communications. If Amgen was in any way delayed, it has no one to blame but itself, and that is certainly no reason to do violence to this schedule.

Roche complied with the Court's February 27th Order, which refused Amgen's request for an extension of time and set forth an appropriate schedule for the production of cell lines with respect to the deadline for expert reports.

IV. CONCLUSION

For the reasons set forth above, Amgen's motion for an extension of time to submit expert reports regarding Roche's cell line should be denied. Alternatively, if the Court grants Amgen this relief, it should revisit the schedule for this matter and equitably adjust it to take into consideration the additional months Amgen wants.

[16] *See* Ex. 7 (3/14/07 letter from P. Fratangelo to D. Fishman).

Dated: April 10, 2007
Boston, Massachusetts

Respectfully submitted,
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