Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 449

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

EMERGENCY MOTION FOR EXPEDITED CASE MANAGEMENT CONFERENCE

Amgen Inc. brings this emergency motion seeking a case management conference at the Court's earliest convenience because a succession of Roche acts severely prejudice Amgen and threaten to disrupt the Court's case management schedule. Amgen's efforts to resolve these issues with Roche have been unsuccessful. With the close of expert discovery (June 8) rapidly approaching, Amgen is left with no choice but to ask the Court for expedited assistance.

Unless the Court intervenes now or by early June, Roche's tactics will impose an enormous and unwarranted burden on Amgen to depose 30 different expert witnesses by June 8, many of whom will never be called to testify at trial. Roche will continue to expand, rather than narrow, the already burgeoning issues in dispute, jeopardize the ability of the parties to adequately prepare for trial, and jeopardize the 3 week trial schedule contemplated by the Court. Amgen has continually proposed reciprocal limits on the numbers of experts and the

Dockets.Justia.com

supplementation of reports and stands ready to implement immediately whatever reciprocal limits the Court adopts.

This case is set for the Court's September running trial calendar. Amgen opposes any efforts to postpone the trial date and desires an adjudication prior to any sales of peg-EPO. During the October 2006 case management conference, both parties estimated that trial could be completed in approximately three weeks.

Since that estimate, Roche served its antitrust counterclaims in November 2006. On April 2, 2007, the last day for fact discovery, Roche served supplemental interrogatory responses disclosing for the first time 10 separate allegations of inequitable conduct. On April 6, after the close of fact discovery, Roche served 16 separate expert reports, advancing well over 30 different contentions of patent invalidity never previously disclosed in response to Amgen's interrogatories or 30(b)(6) deposition notices, and adding still more contentions of inequitable conduct never previously disclosed or pled. On May 1 and May 8, Roche unilaterally served six supplemental expert reports advancing still more theories of patent invalidity and inequitable conduct never previously disclosed or pled. Then, on May 11, Roche served rebuttal expert reports advancing at least 16 non-infringement contentions never disclosed in response to Amgen's interrogatories or fact discovery.

Confronted with overlapping reports from 30 different Roche experts,[1] Amgen faces an impossible challenge. Not only must Amgen's counsel and experts read and comprehend the totality of Roche's avalanche of paper, but Amgen must also depose all thirty of Roche's proferred experts or run the very substantial risk that Roche will choose the experts Amgen has

[1] To date, Roche has served 38 reports (opening, supplemental and rebuttal) from 30 different experts, totaling almost 2000 pages of expert opinion, excluding exhibits, graphics and experiments referenced in the reports.

not deposed to testify at trial. Clearly, some limit and restraint must be brought to all this madness. Surely, the Court does not contemplate a trial in which Roche calls 16 overlapping and duplicative experts to challenge the validity of Amgen's patents, or 10 experts to rebut Amgen's infringement case. But, as matters now stand, that is precisely what Roche insists it will do: 16 designated experts challenging the validity and enforceability of Amgen's patents, 10 experts rebutting Amgen's infringement case, and three economic experts on Amgen's injunction and Roche's antitrust claims.[2]

Because it is inconceivable that literally 52 different expert witnesses between the parties are needed or will be called to testify at trial, counsel to Amgen wrote to Roche's counsel on May 15th and proposed that each side stipulate that it would call no more than 10 experts per side at trial, and that both parties disclose now who those experts will be.[3] Roche refuses to do so, insisting that it can not agree to limit its case "at this time."

Amgen takes seriously its responsibility and the Court's repeated admonitions not to compound discovery disputes or needlessly bother the Court with contentious squabbles. That is why Amgen has worked exhaustively over the past two months to reach a workable, fair compromise with Roche to narrow the issues for trial and to stop the un-ending expansion of issues in dispute. But rather than narrow the disputes for trial, Roche is doing everything it can to expand the issues for trial notwithstanding the close of fact discovery and the dates set by the Court for submission of expert reports. Indeed, just yesterday, Roche filed a motion to add yet more contentions of inequitable conduct and to change its antitrust pleading.

---

[2] For its part, Amgen has four experts on infringement issues, and has been forced to proffer 17 experts in rebuttal to Roche's invalidity and unenforceability allegations. In addition, Amgen has one economic expert and two clinical experts on injunction issues and one additional economic expert on antitrust issues.

[3] May 15, 2006 [sic] Letter from Lloyd R. Day, Jr. to Leora Ben-Ami (attached as Exhibit A).

It appears that Roche is doing everything it can to bury Amgen in voluminous, duplicative expert reports, to sandbag Amgen with previously undisclosed defenses and contentions, and to deny Amgen the protection of the Court ordered schedule in this case by piling on supplemental reports and pleading alleging still more defenses and contentions. Roche's objectives seem clear:

- Multiply the number of witnesses and defenses Amgen must confront with no intent or ability to proffer many of them in a three-week trial.
- Force Amgen to exhaust resources and incur enormous expense to respond to all of Roche's witnesses and defenses by refusing to limit or curtail the issues for trial.
- Surprise Amgen at trial with a carefully selected subset of witnesses and defenses after it assesses which of its thirty named experts did not fare well in deposition.

Roche's tactics not only expand the number of experts for trial, but also the number and complexity of issues it seeks to dispute. In addition to rehashing every conceivable (and many inconceivable) defense to the validity and infringement of Amgen's patents, Roche advances at least 10 central theories of inequitable conduct, many of which, like Roche's ever-expanding invalidity challenges, have either been tried and rejected before, or seek to cast a new spin on those that have. Amgen currently knows of no way to corral and curtail Roche's expanding universe of allegations but through summary judgment, and it plans to file a series of motions in early June to dispose of issues that require no trial. But summary judgment is no panacea for the prejudice currently inflicted on Amgen through the close of expert discovery and up until the time the Court can intervene and establish what issues will be tried in this case, in what order, and how.

The current course not only prejudices Amgen, it will lead to a case that cannot be tried, as it must, within the schedule set by this Court. Accordingly, Amgen requests the Court's assistance in ensuring this case will not be tried by ambush, but will instead be tried in a manner

consistent with this Court's laudably high standards for professional responsibility, timely disclosure and good faith cooperation.

Finally, as the Court may know, the FDA apparently informed Roche on Friday, May 18, that its license application would not be approved prior to an FDA advisory board meeting scheduled for September 2007. According to Roche's press release disclosing the FDA action,[4] the FDA has informed Roche that its application will not be approved at this time, but may be approved at some unspecified date in the future provided Roche meets certain conditions specified by the FDA, including various undisclosed changes in the package labeling and safety warnings for peg-EPO. Roche has stated that FDA has provided Roche with a marked-up and proposed set of changes to the product labeling Roche has proposed for its product. Counsel for Amgen has repeatedly requested Roche's counsel to produce FDA's correspondence to Roche on this topic, including the "approvable" letter and draft package labeling Roche's press release states Roche received from FDA.

To date, Roche's counsel has refused to provide this information to Amgen. It is plainly unfair for Roche to trumpet its contention that peg-EPO is "approvable" and withhold the very decisions and communications of FDA that either substantiate or rebut that claim. The information Amgen seeks will indicate what FDA thinks of Roche's characterization of peg-EPO, which if any indications and dosing regimens FDA may consider approvable, and FDA's thinking regarding the warnings and safety risks entailed in using Roche's peg-EPO product, and what if anything FDA has said about the prospect and timing of any approval of peg-EPO. This information forms the basis of Roche's contention that it can and will enter the market as well as the extent to which its accused product may be used. It is not only relevant to Roche's antitrust

[4] Roche May 18, 2007 News Release entitled "Roche Receives Approvable Letter for MIRCERA® In the United States" (Exhibit B).

damages claims, but it is also relevant to rebutting the many contentions made by Roche and its experts regarding the characterization of peg-EPO, the indications and dosing regimens for which peg-EPO "will" be approved, the extent of any market exclusion to Roche caused by any act of Amgen as well as alleged safety and patient benefits of peg-EPO therapy.

Roche's refusal to provide this highly relevant information and withhold arguments is not without precedent. As the Court perhaps noticed during the April 17 *Markman* Hearing, many if not all of Roche's arguments on claims construction were raised for the first time at the hearing and were not previously disclosed in any of Roche's briefing or declaration. Amgen seeks to ensure that these tactics end and are not repeated at trial. In light of the rapidly closing window for expert depositions, Roche's continuing refusal to produce FDA's correspondence regarding its regulatory decision severely prejudices Amgen's trial preparation.

Amgen respectfully proposes that the Court schedule an emergency case management conference during the week of May 30, 2007 or for June 6, 2007, at the same time as its currently scheduled status conference in Amgen v. HMR and TKT (5/15/07 Order in Case No. 97-CV-10814-WGY). Amgen further proposes that the following issues be addressed at the case management conference or by a prompt order of the Court:

1. Immediate production of correspondence and submissions regarding FDA's decision to delay approval of Roche's MIRCERA product until sometime after the September 2007 advisory board meeting;

2. Limiting the total number of experts each side may present at trial (e.g., 10 experts) and requiring the party bearing the burden of proof to identify its experts on the issues for which it bears the burden followed immediately by the opposing party's identification of its rebuttal experts;

3. Amgen'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 Reports and Motion for Protective Order to Postpone Depositions of Certain Witnesses

4. Roche's Motion for Leave to Amend its Answer Regarding Inequitable Conduct and Relevant Market Definition for Antitrust Counterclaims;

5. The effect of FDA's decision on Roche's antitrust claims, including especially Roche's claim for antitrust damages;

6. Bifurcation, phasing, and/or order of proof at trial.

Amgen appreciates that the Court's crowded docket leaves it little time to address such requests on an expedited basis. However, Amgen believes that a case management conference is urgently required to avoid substantial prejudice to Amgen while still adhering to the trial schedule set by this Court. Given the time sensitivity of these issues under the current schedule, Amgen respectfully suggests an interim case management conference in advance of the Final Pretrial Conference is necessary for the fair and efficient administration of this case.

May 24, 2007

Respectfully Submitted,
AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BB#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-5000

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 defendants did not respond to our request.

/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 May 24, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried