UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,

Plaintiff,

v.

F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation,

Defendants.

Civil Action No.: 05-12237 WGY

October 17, 2006 as modified
YOUNG, D.J.
So ordered as the case management scheduling order.
Discovery due April 30, 2007
Dispositive Motions due April 9, 2007
William G. Young
U.S. District Judge

LR 16.1(D) JOINT STATEMENT

Pursuant to the Court's September 11, 2006 Order, the parties, having satisfied their obligations under Fed. R. Civ. P. 26(f) and LR 16.1(B), submit this Joint Statement:

I. PROPOSED AGENDA FOR OCTOBER 23, 2006 SCHEDULING CONFERENCE.

While the parties have not reached agreement on the agenda for the Scheduling Conference, they mutually request the Court to address the following issues at the conference:

1. Status of pending motion to dismiss.
2. Whether to set a trial date on Amgen's claims for declaratory judgment and/or hearing for preliminary injunction (should one be filed).
3. Whether to enter a scheduling order and discovery plan at this stage, and, if so, how to calculate the dates.
4. Whether to address the parties' disagreements as to discovery limitations at this stage, and, if so, how to resolve them.
5. Whether to enter a Protective Order governing confidential information at this stage.

Each party separately states its respective position on these issues below.

Amgen's Position: As more fully explained in Plaintiff Amgen's September 8, 2006 Motion to set a scheduling conference, Amgen respectfully submits that it is both appropriate and necessary for the Court to address the date and schedule by which a trial on the merits of Amgen's claims for declaratory relief will be held.

The ITC's summary determination last July does not affect this Court's jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Unlike the ITC, which has no jurisdiction to enter declaratory judgments, this Article III Court may now decide whether Defendants' announced plans to manufacture, import and sell peg-EPO in the United States in the first quarter of next year will infringe Amgen's Lin patents. *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997). Indeed, the fact that the ITC has decided that it cannot currently provide the relief Amgen seeks until sometime after Defendants' have imported infringing product for non-exempt purposes, makes the prompt declaration of rights in this Court all the more urgent and important.

Since Amgen's September 8 Motion, Defendants have publicly announced that their peg-EPO sales force is "up and running," that their "marketing plan is in place," that they anticipate FDA action on their pending license application on February 20, 2007, and that they intend to launch peg-EPO for commercial sale in the United States notwithstanding this lawsuit. Amgen's existing customers report that Roche is aggressively courting them, telling them that commercial sales of peg-EPO in the United States will begin in the First Quarter of 2007. They also report that Roche's sales representatives are telling them that Roche will price peg-EPO more favorably than Amgen's products, and that customers will make more profit using peg-EPO than Amgen's products. And Roche is also telling customers that it will hire their favorite Amgen sales representatives to service their peg-EPO accounts for Roche. Indeed, Roche has stepped up its

efforts to recruit and hire members of Amgen's sales force, soliciting key Amgen employees with offers to join Roche to promote and sell peg-EPO throughout the United States.

While Defendants would predictably prefer to postpone adjudication of their infringing conduct until a year ***after*** FDA approval, and propose a pre-trial schedule that will do just that, Amgen respectfully submits that equity requires an earlier adjudication of the parties' respective rights. Amgen respectfully proposes that the Scheduling Conference address:

(a) setting a May 2007 date for trial on Amgen's claims for declaratory judgment and/or an earlier hearing for preliminary injunction;

(b) the pretrial schedule set out below, including a discovery plan; and

(c) entry of an appropriate Protective Order governing information produced during discovery in this case.

By contrast, the schedule and discovery plan Defendants propose would delay any trial on Amgen's declaratory judgment claims until twelve (12) months ***after*** Defendants enter the U.S. market selling their infringing product. Plainly, a schedule that would allow Defendants to enter the market by infringing Amgen's patents for this length of time with no adjudication of Amgen's claims for declaratory judgment is prejudicial to Amgen's interests.[1]

Defendants' contention that immediate discovery will prove inefficient and duplicative because the pricing and labeling of peg-EPO are not yet certain is a red-herring. The relief

[1] Defendants make reference to Amgen's October 13, 2006 press release regarding its Aranesp® product. Defendants' reference states that Amgen did not receive an "unconditional approvable letter." Amgen in fact did receive a complete response letter, commonly referred to as an "approvable" letter, for the additional labeling it sought on its Aranesp® product, subject to certain conditions. While Defendants seek to use these circumstances as somehow emblematic of "delay" and "uncertainty," there was no delay by FDA in meeting its PDUFA date and no level of uncertainty that has any bearing on this case. Notwithstanding Defendants statements that they intend to launch their peg-EPO product at risk in Spring 2007, if Defendants have received any communication from FDA as to whether FDA intends to miss its February 2007 PDUFA date, or otherwise intends to issue a "not approved" letter to their BLA, it should so indicate.

Amgen seeks is a declaration of rights prior to or shortly after FDA approval, precisely to obviate the need for protracted and complex damages-related discovery. If, however, Amgen is required to seek preliminary injunctive relief in lieu of prompt declaratory relief, discovery on Defendant's anticipated pricing and labeling are clearly probative and proper now.

The other principal differences between Amgen's proposed schedule and discovery plan and those proposed by Defendants are:

- Amgen proposes immediate commencement of discovery whereas Defendants propose no discovery until after Defendants have entered the market selling their accused product;
- Amgen proposes the use in this proceeding of the discovery previously provided in the ITC proceeding whereas Defendants propose to quarantine certain highly sensitive information from the ITC proceeding until discovery in this litigation begins, or, at a minimum, subject it to the highest level of confidentiality in this proceeding;
- Amgen proposes scheduling a hearing on claim construction for a date prior to the exchange of expert reports whereas Defendants propose scheduling the exchange of expert reports to occur before the Court's claim construction; and
- Defendants propose a jury trial whereas Amgen respectfully submits that none of the claims in suit are subject to trial by jury.

Roche's Position: Defendants dispute Amgen's arguments and hyperbole, and respectfully suggest that it is premature to schedule any firm dates because the accused product has not been approved for marketing or use in the United States, and since the International Trade Commission has recently determined that based on the very same arguments raised in Amgen's rhetoric above, no act of infringement for which Defendants could be liable outside of 35 U.S.C. § 271(e)(1) has yet occurred in the United States. As Defendants pointed out in their pending motion to dismiss, FDA approval is fraught with uncertainty and delay. Just last week Amgen experienced FDA delay first-hand with respect to its pending application for extended dosing of Aranesp for patients with chronic kidney disease and anemia. As stated in Amgen's

press release dated October 13, 2006, rather than issuing an unconditional "approvable" letter the FDA requested additional clinical data for the once-monthly dosing regime, including an additional clinical study.

Defendants' position is that the parties need not burden the Court at this time with further submissions or interruptions until the Court has had the opportunity to consider the matters already *sub judice*, and in particular, Defendants' pending Rule 12(b)(1) and 12(b)(6) motion to dismiss for lack of subject matter jurisdiction and failure to state a claim, dated April 11, 2006. After resolution of Defendants' motion to dismiss, at the Court's convenience, the parties can quickly attend a Rule 16 Conference with the Court and propose an appropriate schedule.

Plaintiff's proposal is similarly premature as it presumes that the Court has decided the pending motion to dismiss, as well as having denied the motion of Ortho Biotech Products, L.P. ("Ortho") to intervene. Defendants' proposal takes no position as to the decision of those motions other than to note that they are still pending, and that should the Court grant Ortho's motion to intervene, then Plaintiff's proposal is completely inapplicable and an entirely new and different proposal will need be prepared. Amgen's insistence on immediate discovery will lead to inefficiency and duplicative efforts. Amgen does not even acknowledge that while MIRCERA is still before the FDA, and its label still under consideration, issues relating to pricing and labeling are not certain. Giving Amgen this extraordinarily sensitive and unresolved information at this time is not only prejudicial to Defendants but will require the entire process be redone at such time as approval is granted.

If, however, the Court is inclined to have a schedule in place at this time, Defendants submit that the dates should be keyed off the date that the United States Defendant receives written notice from the FDA giving final approval of the accused product so that it is finally

cleared for marketing in the United States ("FDA Approval"). At such time, Defendants will so advise the Court, even though Defendants may not even then have committed any act which could allegedly constitute infringement.

Putting aside Amgen's hyperbole, the simple fact is that Amgen rushed to the ITC in an attempt to disrupt Defendants' clinical trials and to obtain wrongfully highly sensitive information from Defendants. After the dismissal in the ITC, Amgen immediately exhorted this Court to expedite litigation which Amgen will again use to damage Defendants to the public. Not satisfied with its over 20-year monopoly, it is inequitable for Amgen to wrongly deny Defendants due process. Amgen does not possess equitable rights greater than those due to Defendants.

Defendants' proposed schedule is designed to adhere to the Court's practices of scheduling trial within one year of the date of the Scheduling Order, yet appropriately defers the burden of litigation until FDA Approval is actually granted.

II. PROPOSED PRETRIAL AND TRIAL SCHEDULE

[illegible]	[illegible]	[illegible]
INITIAL DISCLOSURES AND PLEADINGS		
Initial disclosures and information required by Fed. R. Civ. P. 26(a)(1) shall be exchanged by:	November 6, 2006	10 days after FDA Approval
All motions to join other parties (other than entities related to the current parties) shall be filed on or before:	November 6, 2006	45 days after FDA Approval

Roche shall file its Answer and Counterclaims on or before:	November 6, 2006	Not appropriate for inclusion in a scheduling order, as a fixed date would be contrary to the rules. Answer and counterclaims are due 10 days after Court decides motions to dismiss pursuant to Fed. R. Civ. P. 12(a)(4)(A).
All motions to amend the pleadings under Fed. R. Civ. P. 15(a) shall be filed on or before:	November 17, 2006	60 days after FDA Approval
DISCOVERY		
Discovery may commence on:	October 24, 2006	21 days after Defendants serve their Answer to the Complaint.
ITC Discovery	To expedite discovery and eliminate duplication of effort, Amgen proposes that all discovery responses and documents produced in the related ITC Investigation (Inv. No. 337-TA-568) shall be considered to have been served and/or produced in this action.	This is not appropriately addressed at a Local Rule 16.1 conference. To the extent the Courts elects to address it, because FDA Approval has not yet occurred, documents and information adduced in the ITC proceeding should be quarantined until this action goes forward, and then, due to its extremely sensitive nature, be subject to the highest level of confidentiality possible and the most restrictive terms possible (*e.g.* disclosure limited to outside counsel of record and the Court) as was done in the ITC.
Interrogatories:	A maximum of 40 unique interrogatories, including contention interrogatories,	A maximum of 40 unique interrogatories shall be permitted for each side. For

[illegible]	[illegible]	[illegible]
	shall be permitted for each side. Contention interrogatories may be served at any time before the fact discovery cutoff.	example, Amgen (collectively with Ortho Biotech Products, L.P., if it is permitted to intervene) may serve the same 40 interrogatories on each of the Defendants, but may not serve 120 unique interrogatories by propounding different interrogatories to the different Defendants. No one interrogatory may require that a party explain its response to more than one request for admission. Contention interrogatories may be served at any time during the discovery period, provided that they are served in sufficient time to permit responses to be timely served in accordance with the Federal Rules before the fact discovery cutoff.
Requests for Admission:	40 unique Requests for Admission	40 unique Requests for Admission
Document Production:	Each party shall: (1) propound their initial requests for production of documents no later than October 30, 2006; (2) propound any additional requests for production of documents no later than December 15, 2006; (3) respond and produce documents according to applicable Federal Rules;	Not appropriate for inclusion in scheduling order, as the Federal Rules of Civil Procedures govern these activities.

	and (4) complete production of all responsive documents by January 12, 2007.	
All motions to compel must be filed:	Before the close of the applicable discovery period.	Before the close of the applicable discovery period.
Fact discovery shall be completed by:	March 9, 2007 (137 days after the commencement of discovery).	180 days after FDA Approval
Initial reports of experts on issues for which a party bears the burden of proof are due on:	April 2, 2007 (24 days after completion of fact discovery).	30 days after the deadline for completion of fact discovery.
Rebuttal reports of responding experts are due on:	April 20, 2007 (18 days after serving opening expert reports).	18 days after the deadline for serving opening expert reports.
Any party desiring to depose an expert witness shall notice and complete said deposition no later than:	April 30, 2007 (10 days after serving rebuttal expert reports).	10 days after the deadline for serving rebuttal reports.
CLAIMS CONSTRUCTION		
Both parties' opening briefs setting forth their respective claims construction positions shall be filed and served no later than:	March 5, 2007 (before service of expert reports).	14 days after the deadline for completion of expert discovery.
Both parties' responsive briefs shall be filed and served no later than:	March 19, 2007 (14 days after opening *Markman* briefs).	14 days after opening *Markman* briefs.

[illegible]	[illegible]	[illegible]
Subject to the Court's schedule, a *Markman* hearing on construction of disputed claim terms shall be held:	Before April 2, 2007 (14 days after last *Markman* briefs.	21 days after the deadline for filing of last summary judgment brief.
DISPOSITIVE MOTIONS		
Any case dispositive motion pursuant to the Federal Rules of Civil Procedure shall be filed and served with an opening brief on or before:	April 9, 2007 (21 days after last *Markman* briefs).	21 days after the deadline for filing responsive *Markman* briefs
Any opposition to a case dispositive motion shall be filed and served within:	14 days after service of the motion	14 days after service of the motion.
Any reply in support of a case dispositive motion shall be filed and served within:	7 days after service of any opposition to such motion.	7 days after service of any opposition to such motion.
Hearing on case-dispositive motions shall be held before:	At such time before the Trial Date that is convenient to the Court.	At such time before the Trial Date that is convenient to the Court.
PRE-TRIAL AND TRIAL		
A Final Pretrial Conference will be held on:	May 11, 2007 (10 days before the Trial Date set by the Court).	14 days before the Trial Date set by the Court.
Trial should commence in Courtroom No. 18, United States Courthouse, One Courthouse Way, Boston, Massachusetts, at 9:00 a.m. EDT on:	May 21, 2007 or as soon thereafter as the Court's schedule permits.	At such time convenient to the Court based on the foregoing schedule.

Defendants respectfully request a trial by jury on all issues in this action that are properly

tried to a jury either by right or as an advisory jury. Plaintiff Amgen does not believe that Defendants are entitled to a trial by jury of Amgen's claims for declaratory and injunctive relief.

III. MAGISTRATE JUDGE

The parties do not consent to trial by a Magistrate Judge.

Respectfully submitted,

AMGEN INC., Plaintiff
By its attorneys,

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

LLOYD R. DAY, JR.
DAVID M. MADRID
LINDA A. SASAKI-BAXLEY
DEBORAH E. FISHMAN
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
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Of Counsel:

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

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

F. HOFFMANN-LAROCHE, LTD., ROCHE DIAGNOSTICS GmbH, and HOFFMANN LAROCHE, INC., Defendants

By their attorneys,

/s/ Julia Huston

LEE CARL BROMBERG (BBO#058480)
JULIA HUSTON (BBO#562160)
KEITH E. TOMS (BBO#663369)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02210
Telephone: (617) 443-9292

LEORA BEN-AMI
PATRICIA A. CARSON
THOMAS F. FLEMING
HOWARD SUH
PETER FRATANGELO (BBO#639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Telephone: (212) 836-8000

October 16, 2006

CERTIFICATION PURSUANT TO LOCAL RULE 16.1(d)(3)

Pursuant to Local Rule 16.1(d)(3), the undersigned affirm that they have conferred:

(a) with a view to establishing a budget for the cost of conducting the full course -- and various alternative courses -- of the litigation; and

(b) to consider the resolution of the litigation through the use of alternative dispute resolution programs such as those outlined in Local Rule 16.4.

/s/ Michael R. Gottfried
Michael R. Gottfried, counsel for Amgen

/s/ Stuart Watt
Stuart Watt, Amgen representative

CERTIFICATION PURSUANT TO LOCAL RULE 16.1(d)(3)

Pursuant to Local Rule 16.1(d)(3), the undersigned affirm that they have conferred:

(a) with a view to establishing a budget for the cost of conducting the full course -- and various alternative courses -- of the litigation; and

(b) to consider the resolution of the litigation through the use of alternative dispute resolution programs such as those outlined in Local Rule 16.4.

/s/ Thomas M. Fleming
Thomas M. Fleming
Counsel for Defendants

/s/ George W. Johnston
George W. Johnston
Representative of Defendants

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 October 16, 2006.

/s/ Michael R. Gottfried
Michael R. Gottfried