IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC. Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. 09-189-GMS

JOINT STATUS REPORT

Pursuant to Rule 16 of the Federal Rules of Civil Procedure, D. Del. L.R. 16.2(b), and the Court's October 28, 2009 Order (D.I. 24) and October 29, 2009 Oral Order Rescheduling Rule 16 Teleconference, the parties, by and through their undersigned counsel, jointly submit this Status Report. Counsel for the parties conferred in preparation for the status and scheduling telephone conference before the Court on November 24, 2009 at 9:30 am. Attached for the Court's consideration as Exhibit A is a chart summarizing the parties' proposed schedule for this action.

I. Jurisdiction and Service

The parties agree that the Court has subject-matter jurisdiction over Plaintiff's claims against Teva Parenteral Medicines, Inc. pursuant to 28 U.S.C. §§ 1331 and 1338(a). No party will move to dismiss for lack of personal jurisdiction of this Court or seek a change of venue. All parties have been served.

II. Substance of the Action

This is a Hatch-Waxman patent infringement action. Plaintiff Cubist Pharmaceuticals, Inc. ("Cubist") sells daptomycin for injection under the trademark CUBICIN® pursuant to

approved New Drug Application No. 21-572. CUBICIN® is an intravenous bactericidal antibiotic indicated for the treatment of complicated skin and skin structure infections caused by certain gram-positive microorganisms, such as *Staphylococcus aureus*, including methicillin-resistant strains, also know as MRSA. CUBICIN® is also indicated for the treatment of *S. aureus* bloodstream infections (bacteremia), including right-sided infective endocarditis caused by MRSA.

United States Patent Nos. 6,468,967 ("the '967 patent"), 6,852,689 ("the '689 patent"), and RE39,071 ("the RE'071 patent") are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to CUBICIN®.

Defendant Teva Parenteral Medicines, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 91-039 to the FDA, seeking approval for a generic version of daptomycin for injection ("TPM's ANDA Product") before the expiration of the '967, '689, and RE'071 patents. By letter dated February 6, 2009, Cubist was notified that the ANDA had been submitted.

On March 23, 2009, Plaintiff filed this action against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (jointly "TPM") alleging that submission of TPM's ANDA was an act of infringement of the '967, '689, and RE'071 patents under 35 U.S.C. § 271(e)(2). TPM has denied Plaintiff's allegations of infringement of the '967, '689, and RE'071 patents.

III. Identification of Issues

1. Whether TPM has infringed under 35 U.S.C. § 271(e)(2), which involves the issue of whether the commercial manufacture, use or sale of TPM's ANDA products would infringe the patents-in-suit.

2. The validity of the ‘967, ‘689, and RE’071 patents and whether the certificate of correction of the RE’071 patent was proper.

IV. Narrowing of Issues

The parties expect that, as discovery proceeds and the case progresses, they may be able to narrow the issues by way of stipulation or agreement. TPM believes that an early summary judgment motion regarding whether the certificate of correction for the RE’071 patent was proper could significantly narrow the issues in the case because the TPM ANDA Product would not infringe the claims of the RE’071 patent as they read before the certificate of correction was issued. Therefore TPM respectfully requests that it be permitted to file on December 14, 2009 a letter brief seeking permission to file such a motion, that plaintiff’s answering letter brief be filed on December 21, 2009 and TPM’s reply letter brief be filed on December 23, 2009. Plaintiff does not believe that summary judgment motions should be permitted in this case since it will be tried to the Court.

V. Relief

a. Plaintiff

Plaintiff seeks at least the following relief:

1. A determination that TPM has infringed the ‘967, ‘689, and RE’071 patents;
2. A determination that the commercial use, sale, offer for sale, manufacture, and/or importation by TPM of the TPM ANDA Products would infringe the ‘967, ‘689, and RE’071 patents;
3. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of TPM’s ANDA, under § 505(j) of the Federal Food, Drug, Cosmetic Act (21 U.S.C. § 355(j)), be no earlier than the expiration date

of the ‘967, ‘689, and/or RE’071 patents, including any applicable patent or regulatory extensions.

4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining TPM, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its proposed generic version of Plaintiff’s CUBICIN® brand drug product prior to the expiration of the ‘967, ‘689, and/or RE’071 patents, including any extensions thereto; and

5. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285 and an award of attorneys’ fees and costs.

b. Defendants

TPM seeks at least the following relief:

1. A determination that the certificate of correction issued for the RE’071 patent was improper and an order that TPM does not infringe, induce infringement or contribute to infringement of any uncorrected asserted claim of the RE’071 patent;

2. An order that all claims of the RE’071 patent are invalid as an improper reissue;

3. An order that TPM has not infringed, induced infringement or contributed to the infringement of any valid claim, if any, of the ’967, ’689, and/or RE’071 patents, either literally or under the doctrine of equivalents;

4. An order that Cubist take nothing by their Complaint, denying Cubist's request for injunctive relief and dismissing Cubist's Complaint with prejudice; and

5. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285 and an award of attorneys' fees and costs to TPM.

VI. Amendment of the Pleadings

The parties propose a May 21, 2010 deadline for amendment of pleadings to include inequitable conduct defenses, and a February 23, 2010 deadline for any other amendments.

VII. Joinder of Parties

At present, the parties are not aware of any additional parties who should be joined in this action. The parties propose a February 23, 2010 deadline to add such parties.

VIII. Discovery

a. Issues

1. Plaintiff

Plaintiff requires, at a minimum, the following discovery to prepare for trial: (i) written discovery to, and responses and documents from, Defendants relating to facts and the parties' contentions; (ii) fact depositions of Defendants and their key employees relating to Defendants' infringement; (iii) fact depositions relating to validity issues, including the scope and content of the prior art being asserted by the Defendant and objective evidence of nonobviousness; (iv) discovery relating to Defendant's contentions in this case; and (v) expert discovery, including but not limited to expert reports and depositions.

2. Defendants

TPM requires, at a minimum, the following discovery to prepare for trial: (i) written discovery to, and responses and documents from, Cubist relating to facts and their contentions;

(ii) fact depositions of Cubist and their key employees relating to the alleged inventions and the development of daptomycin; (iii) fact depositions relating to validity issues, including the scope and content of the prior art, including the inherent characteristics of the daptomycin products disclosed in the prior art, and alleged secondary considerations of nonobviousness; (iv) document and deposition discovery from third parties including Eli Lilly and Company and its current and former employees and agents, regarding the development of daptomycin and the circumstances surrounding the prosecution of the reissue that led to the RE'071 patent and its correction; and (v) expert discovery, including but not limited to expert reports and depositions.

b. Limitations on Discovery

The parties agree that discovery should be conducted in accordance with the parameters set forth in the Federal Rules of Civil Procedure and the Local Rules of this Court, except as follows:

1. Depositions

The parties agree to limit third party, party Rule 30(b)(6), and party employee depositions to 80 hours of testimony per side.

c. Protective Order

The parties' Stipulated Protective Order was entered by the Court on June 25, 2009.

d. Electronic Discovery

The parties have been working in good faith and anticipate reaching agreement prior to the scheduling conference regarding the scope of electronic discovery so as to minimize the burden and expense on all parties. The parties will be prepared to discuss the scheduling impacts, if any, resulting from these discussions regarding electronic discovery with the Court at the scheduling conference.

IX. Estimated trial length

The parties believe at this time that they will require eight (8) days to resolve the issues set forth in the parties' respective pleadings. The parties will cooperate in an attempt to reduce the length of trial through the use of stipulations and other means for expediting the presentation of evidence.

X. Jury trial

The parties agree that because no money damages are currently being sought, there is no present need for a jury trial.

XI. Settlement

The parties intend to open a dialogue to discuss settlement. The parties are open to referral to a Magistrate Judge for informal mediation or settlement discussion at an appropriate time.

XII. Other matters conducive to just, speedy, and inexpensive determination of this action

The parties' proposed schedule, including the request for a mid-April 2011 trial date, reflects their joint belief that justice can best be served if a final decision on the merits is rendered before the expiration of the thirty-month stay on August 6, 2011.

Date: November 17, 2009

Respectfully submitted,

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EXHIBIT A – PROPOSED CASE SCHEDULE

Event	Proposed Date
Fact Discovery	
Initial Disclosures	Complete
Deadline to Amend the Pleadings Other Than Inequitable Conduct	February 23, 2010
Deadline to Amend the Pleadings To Include Inequitable Conduct	May 21, 2010
Deadline to Join Additional Parties	February 23, 2010
Completion of Fact Discovery	August 20, 2010
Claim Construction	
Plaintiff advises Defendants of the asserted claims of each patent-in-suit	December 4, 2009
Parties exchange proposed claim terms in need of construction	December 18, 2009
Deadline for parties to meet and confer regarding narrowing and reducing the number of claim construction issues	January 6, 2010
Final Joint Claim Chart	January 30, 2010
Opening Claim Construction Briefs	February 16, 2010
Responsive Claim Construction Briefs	March 4, 2010
Claim Construction Hearing—Three hours (one and a half hours per side)	April 2010 proposed; date to be determined by the Court
Expert Discovery	
Opening Expert Reports on issues for which a party bears the burden of proof	September 17, 2010
Rebuttal Expert Reports	October 29, 2010
Reply Expert Reports	November 24, 2010
Close of Expert Discovery	January 14, 2010

Trial Phase	
Plaintiff Provides Draft Joint Pretrial Order	January 26, 2011
Defendants Provide Response to Plaintiff's Draft Pretrial Order	February 10, 2011
Motions *in limine* (fully briefed)	February 25, 2011
Submission of Joint Proposed Pretrial Order	February 25, 2011
Pretrial Conference	Late March 2011; date to be determined by the Court
Trial Begins	Mid April 2011; date to be determined by the Court[1]

[1] If the Court's calendar does not accommodate this trial date, the parties respectfully request the opportunity to revise those dates in this schedule that are not set by the Court in light of the available trial date.