

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS)
INCORPORATED,)
)
Plaintiff,)
)
v.) C.A. No. 20-988 (RGA) (CJB)
)
SUN PHARMACEUTICAL INDUSTRIES)
LIMITED,)
)
Defendant.)

VERTEX PHARMACEUTICALS)
INCORPORATED,)
)
Plaintiff,)
)
v.) C.A. No. 21-1019 (RGA)
)
LUPIN LIMITED and)
LUPIN PHARMACEUTICALS, INC.,)
)
Defendants.)

CONSOLIDATED SCHEDULING ORDER

WHEREAS, Plaintiff Vertex Pharmaceuticals Incorporated (“Vertex”) holds approved New Drug Application (“NDA”) No. 203188 for the drug product Kalydeco[®] (ivacaftor 150 mg tablets);

WHEREAS, on July 27, 2020, Vertex brought a patent infringement suit against Sun Pharmaceutical Industries Limited (“Sun”) arising from the submission of Sun’s ANDA No. 214027, seeking approval to commercially market a generic version of Vertex’s Kalydeco[®] prior to the expiration of United States Patent No. 10,646,481 (the “’481 patent”) (“Sun Action”);

WHEREAS, on July 13, 2021, Vertex brought a patent infringement suit against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”) arising from Lupin’s

submission of ANDA No. 216074, seeking approval to commercially market a generic version of Vertex's Kalydeco® prior to the expiration of the '481 patent ("Lupin Action");

WHEREAS, Vertex, Sun, and Lupin agree that the Sun Action and the Lupin Action may present common questions of law or fact, and that considerations of efficiency, expense, and fairness favor the consolidation of the Sun Action and the Lupin Action for all purposes including trial;

WHEREAS, subject to the Court's approval, Vertex, Sun, and Lupin have agreed to a schedule for the consolidated Sun and Lupin Actions;

WHEREAS, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED this **24th day of September, 2021** that:

1. Consolidation. These actions are consolidated for all purposes including trial, and all filings shall be made in *Vertex Pharmaceuticals Incorporated v. Sun Pharmaceutical Industries Limited* (C.A. No. 20-cv-988-RGA-CJB).

2. Rule 26(a)(1) Initial Disclosures. Vertex and Lupin shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) and Paragraph 3 of the Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI") ("Default Standard") by **September 30, 2021**.¹

3. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings in the Lupin Action, shall be filed on or before **March 25, 2022**.

¹ Vertex and Sun made their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) and Paragraph 3 of the Default Standard on October 9, 2020.

4. Fact Discovery.

a. Fact Discovery Cut Off. All fact discovery shall be initiated so that it will be completed on or before **November 18, 2022.**

b. Document Production. Document production shall be substantially complete by **April 29, 2022.**

c. Privilege Log. Privilege logs shall be substantially completed and served by each party by **July 29, 2022.** The parties agree that no documents generated after Vertex's receipt of Sun's Paragraph IV Notice Letter (i.e., June 11, 2020) shall be required to be logged by either Vertex or Sun. The parties agree that no documents generated after Vertex's receipt of Lupin's Paragraph IV Notice Letter (i.e., June 2, 2021) shall be required to be logged by Lupin. The parties further agree that privileged communications with outside litigation counsel in preparation for the Sun Action and/or Lupin Action need not be logged. The parties further agree that documents that are redacted for privilege shall be clearly labeled as "Redacted – Privileged" and need not be logged, unless a party requests that a document redacted for privilege be logged in good faith to investigate the validity of a claim for privilege.

d. Requests for Admission. Vertex may serve a maximum of **35** requests for admission on Sun and a maximum of **35** requests for admission on Lupin. Sun and Lupin may each serve a maximum of **35** requests for admission on Vertex. Any requests for admission directed to the authentication of documents are excluded from this limitation, and may be served up until 60 days prior to trial.

e. Interrogatories. Vertex may serve a maximum of **20** interrogatories, including contention interrogatories, on Sun, and a maximum of **20** interrogatories, including contention interrogatories, on Lupin. Sun and Lupin may each serve a maximum of **20** interrogatories, including contention interrogatories, on Vertex.

f. Depositions.

i. Limitation on Hours for Deposition Discovery. Vertex is limited to a total of **70** hours of taking testimony by deposition upon oral examination of Sun, and a total of **70** hours of taking testimony by deposition upon oral examination of Lupin. Sun and Lupin are limited to a total of **100** hours of taking testimony by deposition upon oral examination of Vertex, including the depositions of any former employees of Vertex.

ii. Location of Depositions. The parties agree to take depositions of the parties' witnesses who are located within the United States at a location in the United States near the place where each witness is employed or another location agreed to by the parties. The parties agree to take depositions of the parties' witnesses who are located outside the United States at a location to be agreed to by the parties on a deposition-by-deposition basis. The parties agree to present for deposition at a location in the United States or another location agreed to by the parties on a deposition-by-deposition basis witnesses designated to testify under Fed. R. Civ. P. 30(b)(6).

iii. Remote Depositions. Should it be infeasible to conduct in-person depositions of fact or expert witnesses on the schedule contemplated herein due to legal, safety, personal health and/or public health concerns (e.g., as resulting from a pandemic or another such emergency), the parties shall meet and confer regarding the possibility of conducting remote depositions via videoconference, including the procedure by which such depositions shall be conducted.

g. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order shall contact the Court's Case Manager to schedule an in-person or video conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party

seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

h. Miscellaneous Discovery Matters.

i. Other Litigations and Proceedings. Other than the above-captioned cases, there is no other pending or completed litigation, including inter partes reviews (“IPRs”), involving the asserted patent. Vertex does not currently expect to institute any further litigation in this or other Districts within the next year. Lupin does not presently expect to file any IPRs for the asserted patent, but any IPR would need to be filed by July 15, 2022.

ii. Initial Discovery in Patent Litigation. Vertex and Lupin agree to exchange initial patent disclosures as set forth below.²

A. Vertex made its initial disclosures under Paragraph 4(a) of the Default Standard in the Lupin Action on **September 3, 2021**.

² Vertex and Sun previously made their initial patent disclosures under Paragraphs 3 and 4 of the Default Standard.

B. Lupin shall produce its core technical documents under Paragraph 4(b) of the Default Standard, including a complete copy of Lupin's Abbreviated New Drug Application ("ANDA") No. 216074, no later than **October 4, 2021**.

C. Vertex shall make its initial disclosures under Paragraph 4(c) of the Default Standard in the Lupin Action no later than **November 10, 2021**.

D. Lupin shall make its initial disclosures under Paragraph 4(d) of the Default Standard no later than **December 17, 2021**.

iii. ESI. The parties agree to follow the Default Standard and will meet and confer regarding additional parameters for the production of ESI.

5. Service by Electronic Means. The parties agree to accept service of all documents, including discovery requests and responses, via electronic mail. The parties agree that service on any party via electronic mail shall be made on both Delaware and lead counsel for that party.

6. Application to Court for Protective Order. A Stipulated Protective Order was previously entered in the Sun Action on November 12, 2020 (D.I. 30). Vertex and Lupin agree that it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information in the Lupin Action, and counsel for Vertex and Lupin will confer and attempt to reach an agreement on a proposed form of order and submit it to the Court on or before September 30, 2021. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 4(g) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential

pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

7. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in paragraph 7. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

8. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

9. Claim Construction Issue Identification. Vertex and Lupin have agreed to the following schedule for claim construction issue identification in the Lupin Action.³ On or before **January 20, 2022**, Vertex and Lupin shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **February 3, 2022**. The Joint Claim Construction Chart, in Word format shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent in issue as well as those portions of the intrinsic

³ On March 16, 2021, Vertex and Sun informed the Court that neither side had raised any claim construction issues in the Sun Action, and requested that the Markman hearing be taken off the calendar in that Action (D.I. 39).

record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

10. Claim Construction Briefing.⁴ Vertex shall serve, but not file, its opening brief, not to exceed 5,000 words, on **February 24, 2022**. Lupin shall serve, but not file, its answering brief, not to exceed 7,500 words, on **March 17, 2022**. Vertex shall serve, but not file, its reply brief, not to exceed 5,000 words, on **March 31, 2022**. Lupin shall serve, but not file its sur-reply brief, not to exceed 2,500 words, on **April 14, 2022**. No later than **April 19, 2022** the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, insubstantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Representative Claims
- II. Agreed-upon Constructions
- III. Disputed Constructions
 - A. [TERM 1]⁵
 - 1. Plaintiff's Opening Position
 - 2. Defendant's Answering Position
 - 3. Plaintiff's Reply Position
 - 4. Defendant's Sur-Reply Position
 - B. [TERM 2]
 - 1. Plaintiff's Opening Position

⁴ As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. Plaintiff should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendant want to add additional representative claims, Defendant may do so. The representative claims and the agreed-upon claim constructions do not count against the word limits.

⁵ For each term in dispute, there should be a table or the like setting forth the term in dispute and the parties' competing constructions. The table does not count against the word limits.

2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

11. Hearing on Claim Construction. Beginning at **9:00 a.m.** on **May 12, 2022**, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present live testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above- scheduled claim construction hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

Disclosure of Expert Testimony.

a. Expert Reports. For the party or parties who have the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before **January 18, 2023**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party or parties is due on or before **March 17, 2023**. Reply expert reports from the party or parties with the initial burden of proof are due on or before **April 17, 2023**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any

such disputes, and, if they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived.

Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before **June 16, 2023**.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion according to the schedule in Attachment A.

13. Case Dispositive Motions. No motion for summary judgment may be filed without leave of Court.

14. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

15. Pretrial Conference. On **October 13, 2023**, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at **9:00 a.m.** The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

16. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities

relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

17. Trial. This matter is scheduled for a three (3) day bench trial beginning at 8:30 a.m. on **October 23, 2023**, with the subsequent trial days beginning at 8:30 a.m. and ending at 5:00 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

18. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

19. Case Schedule. A summary of the case schedule appears in Attachment A.

/s/ Richard G. Andrews

The Honorable Richard G. Andrews
UNITED STATES DISTRICT JUDGE

ATTACHMENT A: CASE SCHEDULE

Date/Deadline	Event
September 3, 2021	Vertex identified accused products and asserted patents under Paragraph 4(a) of the Delaware Default Standard for Discovery, Including Discovery of Electronically Stored Information (“ESI”) (“Default Standard”) in the Lupin Action (§ 4.h.ii.A)
September 30, 2021	Vertex and Lupin to submit a proposed Protective Order (§ 6)
September 30, 2021	Vertex and Lupin to serve their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) and Paragraph 3 of the Default Standard (§ 2)
October 4, 2021	Lupin to produce core technical documents for the accused products under Paragraph 4(b) of the Default Standard (§ 4.h.ii.B)
November 10, 2021	Vertex to serve its initial disclosures in the Lupin Action under Paragraph 4(c) of the Default Standard (§ 4.h.ii.C)
December 17, 2021	Lupin to serve its initial disclosures under Paragraph 4(d) of the Default Standard (§ 4.h.ii.D)
January 20, 2022	Vertex and Lupin to exchange proposed preliminary claim construction of disputed terms (§ 9)
February 3, 2022	Vertex and Lupin to submit joint claim construction chart identifying the term(s)/phrase(s) of the claim(s) in issue and each party’s proposed construction of the disputed claim language (§ 9)
February 24, 2022	Vertex to serve opening claim construction brief in Lupin Action (§ 10)
March 17, 2022	Lupin to serve answering claim construction brief (§ 10)
March 25, 2022	Motions to join other parties and to amend or supplement pleadings due (§ 3)
March 31, 2022	Vertex to serve reply claim construction brief in Lupin Action (§ 10)
April 14, 2022	Lupin to serve sur-reply claim construction brief (§ 10)
April 19, 2022	Vertex and Lupin to file joint claim construction brief (§ 10)
April 29, 2022	Parties to substantially complete document production (§ 4.b)
May 12, 2022	Hearing on claim construction in the Lupin Action (§ 11)
July 29, 2022	Parties to serve substantially complete privilege logs (§ 4.c)
November 18, 2022	Parties to complete fact discovery (§ 4.a)
January 18, 2023	Parties to serve opening expert reports on those issues for which the party bears the burden of proof (§ 12.a)

March 17, 2023	Parties to serve rebuttal expert reports (§ 12.a)
April 17, 2023	Parties to serve reply expert reports (§ 12.a)
June 16, 2023	Parties to complete expert depositions (§ 12.a)
July 14, 2023	Parties to file opening <i>Daubert</i> motions
August 4, 2023	Parties to file oppositions to <i>Daubert</i> motions
August 18, 2023	Parties to file replies to <i>Daubert</i> motions
5:00 pm four business days before final pretrial conference	Parties to file Joint Proposed Final Pretrial Order and <i>Daubert</i> motions (§§ 12.b, 14)
October 13, 2023	Final pretrial conference (§ 14)
October 23 2023	Trial (§ 16)