

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB BIOPHARMA SRL,)
)
Plaintiffs,)
)
v.) C.A. No. 20-987 (CFC)
)
ANNORA PHARMA PRIVATE LIMITED,)
APOTEX INC., APOTEX CORP.,)
AUROBINDO PHARMA USA INC.,)
AUROBINDO PHARMA LTD.,)
LUPIN LTD., MICRO LABS LTD.,)
MICRO LABS USA, INC.,)
MSN PHARMACEUTICALS INC.,)
MSN LABORATORIES PRIVATE LTD. and)
ZYDUS PHARMACEUTICALS (USA) INC.,)
)
Defendants.)

UCB, INC. and UCB BIOPHARMA SRL,)
)
Plaintiffs,)
)
v.) C.A. No. 20-1343 (CFC)
)
SUNSHINE LAKE PHARMA CO., LTD.,)
)
Defendant.)

PROPOSED SCHEDULING ORDER

This 7th day of July, 2021, 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 that:

1. Consolidation. These cases are consolidated for all purposes and all papers shall be filed in C.A. No. 20-987-CFC. See D.I. 68 in C.A. No. 20-987-CFC; D.I. 19 in C.A. No. 20-1343-CFC.

2. Relevant Deadlines and Dates. All relevant deadlines and dates established by this Order are set forth in the chart attached as Exhibit A.

3. Initial Disclosures. The parties served their initial disclosures required by Federal Rule of Civil Procedure 26(a)(1) and Paragraph 3 of the District of Delaware Default Standard on **February 26, 2021.**

4. Disclosure of Asserted Claims and Infringement Contentions. Plaintiffs served their asserted claims and infringement contentions on **April 9, 2021**, which were required to contain the following information:

- (a) Each claim of each asserted patent that is allegedly infringed by each opposing party, including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted;
- (b) Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality (“Accused Instrumentality”) of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process;
- (c) A chart identifying specifically where and how each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(f),

the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;

- (d) For each claim alleged to have been indirectly infringed, an identification of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of multiple parties, the role of each such party in the direct infringement must be described;
- (e) Whether each limitation of each asserted claim is alleged to be present literally or under the doctrine of equivalents in the Accused Instrumentality;
- (f) For any patent that claims priority to an earlier application, the priority date to which each asserted claim is alleged to be entitled;
- (g) If a party claiming patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own or its licensee's apparatus, product, device, process, method, act or other instrumentality practices the claimed invention, the party shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act or other instrumentality that incorporates or reflects that particular claim; and
- (h) If a party claiming patent infringement alleges willful infringement, the basis for such allegation.

5. Document Production Accompanying Disclosure of Asserted Claims and Infringement Contentions. Plaintiffs were required to produce the following documents with their “Disclosure of Asserted Claims and Infringement Contentions”:

- (a) Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other manner of providing to a third party, or sale of or offer to sell, or any public use of, the claimed invention prior to the date of application for the asserted patent(s);
- (b) All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the asserted patent(s) or the priority date identified pursuant to paragraph 4(f) of this Order, whichever is earlier;
- (c) A copy of the file history for each asserted patent;
- (d) All documents evidencing ownership of the patent rights by the party asserting patent infringement;
- (e) If a party identifies instrumentalities pursuant to paragraph 4(g) of this Order, documents sufficient to show the operation of any aspects or elements of such instrumentalities the patent claimant relies upon as embodying any asserted claims; and
- (f) All agreements, including licenses, transferring an interest in any asserted patent.

Plaintiffs' production of a document as required by this paragraph shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102.

6. Invalidity Contentions. Defendants served their invalidity contentions on **May 28, 2021**, which were required to contain the following information:

- (a) The identity of each item of prior art that the party alleges anticipates each asserted claim or renders the claim obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication shall be identified by its title, date of publication, and where feasible, author and publisher. Each alleged sale or public use shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. For pre-AIA claims, the prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. For pre-AIA claims, prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s);
- (b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If obviousness is alleged, an explanation of why the prior art

renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness;

- (c) A chart identifying specifically where and how in each alleged item of prior art each limitation of each asserted claim is found, including for each limitation that such party contends is governed by 35 U.S.C. § 112(f), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and
- (d) Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(b), or lack of enablement or insufficient written description under 35 U.S.C. § 112(a) of any of the asserted claims.

7. Document Production Accompanying Invalidity Contentions. Defendants were required to produce the following documents with their “Invalidity Contentions”:

- (a) Specifications, schematics, flow charts, artwork, formulas, or other documentation sufficient to show the operation of any aspects or elements of an Accused Instrumentality identified by the patent claimant in its chart produced pursuant to paragraph 4(c) of this Order; and
- (b) A copy or sample of the prior art identified pursuant to paragraph 6(a) that does not appear in the file history of the patent(s) at issue. To the extent any such item is not in English, an English translation of the portion(s) relied upon shall be produced.

The producing party shall separately identify by production number the documents that correspond to each category set forth in this paragraph.

8. Amendment to Contentions. Amendments of Infringement and Invalidity Contentions may be made only by order of the Court upon a timely showing of good cause. Non-exhaustive examples of circumstances that may, absent undue prejudice to the non-moving party, support a finding of good cause include (a) recent discovery of material prior art despite earlier diligent search and (b) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contentions. The duty to supplement discovery responses does not excuse the need to obtain leave of the Court to amend Infringement and Invalidity Contentions.

9. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **November 15, 2021**.

10. Discovery. The parties are agreeing to these limitations before reviewing any disclosures in the case. The parties reserve the right to request alterations of these limitations for good cause shown.

- (a) Discovery Cut Off. All discovery in this case shall be initiated so that it will be completed on or before **December 17, 2021**.
- (b) Electronic Discovery. The parties agree to abide by the District of Delaware's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI").
- (c) Document Production. Defendants produced their respective ANDAs by **February 26, 2021**. Document production shall be substantially completed on or before **October 8, 2021**.
- (d) Requests for Admission. Defendants collectively may propound a maximum of 20 common requests for admission to Plaintiffs. In addition,

each Defendant Group¹ may propound 25 individual requests for admission to Plaintiffs. Plaintiffs may propound a maximum of 25 requests for admission to each Defendant Group. Requests for authentication shall not count against each side's limit.

(e) Interrogatories. Defendants collectively may propound a maximum of 20 common interrogatories, including contention interrogatories, to Plaintiffs. In addition, each Defendant Group may propound 5 individual interrogatories, including contention interrogatories, to Plaintiffs. Plaintiffs may propound a maximum of 20 common interrogatories, including contention interrogatories, to all Defendants collectively (to which each Defendant Group will respond individually), and Plaintiffs may propound 5 individual interrogatories, including contention interrogatories, to each Defendant Group.

(f) Depositions.

i. Limitation on Deposition Discovery. Plaintiffs are limited to a total of 15 hours of taking testimony of fact witnesses by deposition upon oral examination against each Defendant Group, *except that* should a Defendant Group designate more than 2 witnesses to address Plaintiffs' 30(b)(6) topics, Plaintiffs are entitled to an additional 2 hours for each 30(b)(6) witness (i.e., if the Defendant Group identifies four 30(b)(6) witnesses, Plaintiffs shall have a total of

¹ "Defendant Group" means the defendants who collectively submitted an ANDA(s) with the FDA. For example, one "Defendant Group" is Apotex Inc. and Apotex Corp and another "Defendant Group" is Annora Pharma Private Limited.

23 hours per Defendant Group). Defendants are collectively limited to a total of 75 hours of taking testimony of fact witnesses by deposition upon oral examination. No single deposition shall last more than 7 hours on the record except that for any deposition conducted primarily through an interpreter, 2 hours of time on the record will count for 1 hour of deposition time against this total allotment. All deposition hours are inclusive of any Fed. R. Civ. P. 30(b)(6) depositions.

- ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this District Court must ordinarily be required, upon request, to submit to a deposition at a place designated within this District. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. In particular, the parties will negotiate in good faith regarding the deposition location of foreign witnesses, and whether in-person depositions are feasible in light of the Covid-19 pandemic. The parties will approach the Court to the extent necessary to resolve any disputes. Any remote depositions that are conducted outside of the United States shall be treated as if the deposition was taken in the United States. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

The parties agree that, by **October 15, 2021**, they will meet and confer to reach an agreement on whether fact depositions will be conducted in-person or be conducted remotely, in view of the ongoing COVID-19 pandemic. Should the parties decide to proceed with fact depositions in-person, for any witness currently employed by a party and located outside of the United States, that witness shall be brought to the United States, at the sole cost and expense of the producing party, at a location to be mutually agreed upon by the parties if at all possible, and if no agreement is reached, then the depositions shall take place in the offices of the parties' respective Delaware counsel. The parties shall similarly meet and confer by **May 27, 2022** to reach agreement on whether expert depositions will be conducted in-person or be conducted remotely, in view of the ongoing COVID-19 pandemic. During the meet-and-confers, the parties will reach agreement on how to handle exhibits at any depositions that are conducted remotely.

- iii. Any witness who refuses to appear for a deposition shall not be allowed to testify at any proceeding, hearing, or trial.
- iv. If a witness testifies in a foreign language for any deposition, the party producing said witness shall use best efforts inform the party taking the deposition of that fact at least three weeks prior to the date of the deposition.

11. Pinpoint Citations. Pinpoint citations are required in all briefing, letters, and concise statements of facts. The Court will ignore any assertions of controverted facts and controverted legal principles not supported by a pinpoint citation to, as applicable: the record, an attachment or exhibit, and/or case law or appropriate legal authority. *See United States v. Dunkel*, 927 F.2d 955, 956 (“Judges are not like pigs, hunting for truffles buried in briefs.”).

12. Application to Court for Protective Order. The Court entered a protective order on **March 29, 2021.**

13. Disputes Relating to Discovery Matters and Protective Orders. Should counsel find they are unable to resolve a dispute relating to a discovery matter or protective order, the parties shall contact the Court’s Case Manager to schedule an in-person conference/argument.

(a) Unless otherwise ordered, by no later than 72 hours prior to the conference/argument, the party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and the party’s position on those issues. The party shall submit as attachments to its letter (1) an averment of counsel that the parties made a reasonable effort to resolve the dispute and that such effort included oral communication that involved Delaware counsel for the parties, and (2) a draft order for the Court’s signature that identifies with specificity the relief sought by the party. The party shall file concurrently with its letter a motion that in no more than one paragraph sets forth the relief sought.

(b) By no later than 48 hours 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 reasons for its opposition.

- (c) Two hard copies of the parties' letters and attachments must be provided to the Court within one hour of e-filing the document(s). The hard copies shall comply with paragraphs 11 and 15 of this Order.
- (d) If a motion concerning a discovery matter or protective order is filed without leave of the Court that does not comport with the procedures set forth in this paragraph, the motion will be denied without prejudice to the moving party's right to bring the dispute to the Court through the procedures set forth in this paragraph.

14. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk an original and two copies of the papers. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

15. Hard Copies. The parties shall provide to the Court two hard copies of all letters filed pursuant to paragraph 13 of this Order, all briefs, and any other documents filed in support of any such letters and briefs (i.e., the concise statement of facts filed pursuant to paragraph 21 of this Order, appendices, exhibits, declarations, affidavits, etc.). This provision also applies to papers filed under seal. Exhibits and attachments shall be separated by tabs. Each exhibit and attachment shall have page numbers of some sort such that a particular page of an exhibit or attachment can be identified by a page number. The parties shall take all practical measures to avoid filing multiple copies of the same exhibit or attachment. The parties should highlight the text of exhibits and attachments they wish the Court to read. The parties should ordinarily include in an exhibit or attachment only the pages of the document in question that (1) identify the document (e.g., the first page of a deposition transcript or the cover page of a request for discovery) and (2) are relevant to the issue(s) before the Court.

16. Claim Construction. The parties have agreed that formal claim construction is not necessary in this case.

17. Disclosure of Expert Testimony.

(a) Expert Reports. For the party with the initial burden of proof on the subject matter (including the burden of production on the objective indicia of nonobviousness), the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before **February 18, 2022**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **April 8, 2022**. Reply expert reports from the party with the initial burden of proof are due on or before **May 13, 2022**. No other expert reports will be permitted without either the consent of all the parties or leave of the Court. Along with the submissions of the expert reports, the parties shall provide the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before **July 1, 2022**.

(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 Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than **July 15, 2022**, unless otherwise ordered by the Court.

(c) Depositions. Unless extended by agreement of the parties or by order of the Court, expert depositions are limited to a maximum of 7 hours per expert, except that if an expert offers opinions related to both infringement and validity, the deposition of such expert shall be limited to 10 hours. If an expert submits a declaration in support of a party's claim construction position, that expert shall be produced for 5 hours of deposition (in addition to any depositions conducted during expert discovery).

18. Case Dispositive Motions. No case dispositive motion under Rule 56 shall be filed without leave of the Court.

19. 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.

20. Pretrial Conference. At the Court's convenience, on or after ~~October~~^{November} 1, 2022, the Court will hold a Rule 16(e) final pretrial conference in court with counsel beginning at 3:00 p m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5:00 p.m. on _____ [the date that is 21 days before 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. The joint pretrial order shall comply with paragraphs 11 and 15 of this Order.

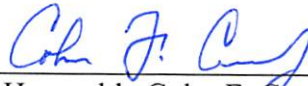
21. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each side shall be limited to three *in limine* requests, unless otherwise permitted by the Court. Each *in limine* request

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. Motions *in limine* shall comply with paragraphs 11 and 15 of this Order.

22. Compendium of Cases. A party may submit with any briefing two courtesy copies of a compendium of the selected authorities on which the party would like the Court to focus. The parties should not include in the compendium authorities for general principles or uncontested points of law (e.g., the standards for summary judgment or claim construction). An authority that is cited only once by a party generally should not be included in the compendium. An authority already provided to the Court by another party should not be included in the compendium. Compendiums of cases shall not be filed electronically with the Court, but a notice of service of a compendium of cases shall be filed electronically with the Court. Compendiums shall comply with paragraph 15 of this Order.

23. Trial. This matter is scheduled for a **five (5) day bench trial** beginning at **9:00 a.m.** at the Court's convenience **on November 14, 2022** with subsequent trial days beginning at 9:00 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

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



The Honorable Colm F. Connolly
United States District Court Judge

EXHIBIT A – PROPOSED DEADLINES

Event	Proposed Deadline
Rule 26(a)(1) Initial Disclosures and Paragraph 3 Default Standard Initial Disclosures	February 26, 2021
Defendants' ANDA Production	February 26, 2021
Protective Order	March 29, 2021
Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions & Accompanying Document Production	April 9, 2021
Defendants' Disclosure Invalidity Contentions & Accompanying Document Production	May 28, 2021
Parties Exchange Proposed Claim Terms	June 22, 2021
Deadline for Substantial Completion of Document Production	October 8, 2021
Deadline to Meet and Confer re: Fact Depositions	October 15, 2021
Deadline to Amend or Supplement the Pleadings and to Join Additional Parties	November 15, 2021
Completion of Fact Discovery	December 17, 2021
Opening Expert Reports (including Plaintiffs' objective indicia opinions)	February 18, 2022
Rebuttal Expert Reports (including Defendants' objective indicia opinions)	April 8, 2022
Reply Expert Reports	May 13, 2022
Deadline to Meet and Confer re: Expert Depositions	May 27, 2022
Close of Expert Discovery	July 1, 2022
Deadline to file <i>Daubert</i> Motions	July 15, 2022
Submission of Joint Proposed Pretrial Order	21 days before PTC
Pretrial Conference	At the Court's convenience on or after October , 2022, at — m. <u>11/1/22</u>
Trial Begins (scheduled for 5 days)	November 14, 2022
Thirty Month Stay Deadline (if applicable)	November 12, 2023