

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

EXELA PHARMA SCIENCES, LLC,

Plaintiff,

v.

ETON PHARMACEUTICALS, INC.,

Defendant.

C.A. No. 20-365-MN

REDACTED VERSION

[PROPOSED] JOINT PRETRIAL ORDER

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Dated: February 22, 2022

**LIST OF EXHIBITS IN
JOINT PRETRIAL ORDER**

STATEMENT OF FACTS WHICH ARE ADMITTED AND REQUIRE NO PROOF

Joint	--	Exhibit 1
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ISSUES OF FACT THAT REMAIN TO BE LITIGATED

Plaintiff	--	Exhibit 2
Defendant	--	Exhibit 3

ISSUES OF LAW THAT REMAIN TO BE LITIGATED

Plaintiff	--	Exhibit 4
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BRIEF STATEMENTS OF INTENDED PROOFS

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Defendant	--	Exhibit 12

MOTIONS *IN LIMINE*

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Defendant	--	

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This matter comes before the Court at a final pretrial conference held on February 28, 2022 pursuant to Rule 16 of the Federal Rules of Civil Procedure.

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I. NATURE OF THE CASE

1. This is a patent infringement action brought by Plaintiff Exela Pharma Sciences, LLC (“Plaintiff” or “Exela”) against Defendant Eton Pharmaceuticals, Inc. (“Defendant” or “Eton”) for infringement of U.S. Patent Nos. 10,478,453 (the “’453 patent”); 10,583,155 (the “’155 patent”); 10,905,713 (the “’713 patent”); 10,912,795 (the “’795 patent”); and 10,933,089 (the “’089 patent”) (collectively, the “Patents-in-Suit”)¹ under 35 U.S.C. §§ 271(a-c, e). Plaintiff’s infringement claims arise out of the filing by Defendant with FDA of an Abbreviated New Drug Application (“ANDA”), seeking approval for a generic version of Plaintiff’s ELCYS® brand L-cysteine injection product before the expiration of the Patents-in-Suit.

2. The Second Amended Complaint, filed by Exela on April 14, 2021 (D.I. 70), is Plaintiff’s operative pleading. The Answer to Second Amended Complaint, filed by Eton on August 12, 2021 (D.I. 149), is Defendant’s operative pleading.

3. In the Second Amended Complaint, Plaintiff has alleged that Defendant’s effort to seek FDA approval to market a generic version of ELCYS® prior to the expiration of the Patents-in-Suit constitutes an act of infringement pursuant to 35 U.S.C. §271(e)(2).

4. Plaintiff has further alleged that immediately upon approval of ANDA No. 214082, Defendant will infringe the ’453 patent, the ’713 patent, the ’795 patent, and the ’089 patent under 35 U.S.C. § 271(a) by the manufacture, use, offer for sell, sell, and/or import of Defendant’s Cysteine Hydrochloride Injection, USP 500 mg/50 mL (50 mg/mL), 10 mL Fill (“Eton’s ANDA Product”), which is a generic version of ELCYS®.

¹ Plaintiff additionally asserted U.S. Patent No. 10,653,719 but, to simplify the issues for trial, agreed to dismiss it. (D.I. 152, Stipulation of Dismissal of Plaintiff’s Counts VIII and IX with Respect to U.S. Patent No. 10,653,719.)

5. Plaintiff has further alleged that Defendant will induce infringement and/or contribute to the infringement of the '453 patent, the '155 patent, and the '795 patent under 35 U.S.C. § 271 (b) and/or (c) if the FDA approves Defendant's ANDA and Defendant was to sell Eton's ANDA Product with its proposed labeling.

6. The claims presently asserted against Defendant ("asserted claims") are set forth below:

'453 Patent	'155 Patent	'713 Patent	'795 Patent	'089 Patent
1-7, 9, 10, 14, 22	1-8, 10-21, 23-25, 27-29	1, 8-11, 15-16	1, 11, 19, 27	1, 2, 7, 8, 14, 15

7. Plaintiff contends that each of the patents-in-suit covers Plaintiff's ELCYS® (L-cysteine hydrochloride injection) product, which is approved by the U.S. Food and Drug Administration ("FDA"). It is an injectable L-cysteine hydrochloride product that has low aluminum levels and maintains those low levels throughout its shelf life. All Patents-in-Suit patent are listed in the FDA Approved Drug Products and Therapeutic Equivalents publication ("the Orange Book") as covering ELCYS®.

8. Eton contends that Eton's ANDA product will not infringe any of the asserted claims, and that Exela has failed to show that Eton's ANDA product will infringe any of the asserted claims.

9. Eton also contends that the asserted claims are invalid as being anticipated or rendered obvious at least since Allergy Laboratories, Inc. manufactured the same product using the same method since at least the earlier 2010's.

10. On July 21, 2021, the parties filed the Joint Claim Construction Brief. D.I. 134.

11. The parties dispute the construction of the terms “about” and “a pharmaceutically acceptable amount of cystine.” The parties’ positions on these terms are set forth in the chart below:

Claim Term	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“about”	Plain and ordinary meaning, i.e., “approximately”	Indefinite
“a pharmaceutically acceptable amount of cystine”	Plain and ordinary meaning, i.e., an amount of cystine that is compatible chemically and/or toxicologically with the other ingredients comprising a formulation and/or the mammal being treated therewith	Indefinite

12. The Court vacated the *Markman* hearing, reasoning that: “[I]t seems to me that given that—there are a few terms at issue, and the issue on indefiniteness, it doesn’t make sense for me to address these issues now. I might as well do them in the context of trial.” July 29, 2021 Hearing Transcript at 9:13-20.

13. In the Second Amended Complaint, Plaintiff has requested that the Court:

- enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendant has infringed at least one claim of the Patents-in-Suit by submitting ANDA No. 214082 to FDA to seek approval to manufacture, use, import, offer to sell, and/or sell Eton’s ANDA Product in the United States before the expiration of the Patents-in-Suit;
- enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Defendant’s commercial manufacture, use, importation, offer to sell, and or sell of Eton’s ANDA Product in the United States before the expiration of the Patents-in-Suit

constituted infringement of one or more claims of the Patent-in-Suit under 35 U.S.C. § 271 (a), (b), and/or (c);

- order that the effective date of any approval by the FDA of Eton's ANDA Product be a date that is not earlier than the expiration dates of the Patents-in-Suit, as extended by any applicable period of exclusivity;
- permanently enjoin Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose is covered by the Patents-in-Suit;
- preliminarily and permanently enjoin Defendant and its affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert and or participation with any of them, or acting on their behalf, from infringing the Patents-in-Suit;
- declare that this case is exceptional under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys' fees and costs;
- perform an accounting of Defendant's infringing activities not presented at trial and an award by the Court of additional damages for any such infringing sales;
- award other further relief as the Court may deem just and proper.

14. In its answer to the Second Amended Complaint, Eton has asserted a number of Affirmative Defenses.

15. The Pretrial Conference is currently scheduled for February 28, 2022 at 1:00 PM.

16. The trial is currently scheduled to begin on March 14, 2022.

II. JURISDICTION

17. This action arises under the patent laws of the United States, Title 35, United States Code. Jurisdiction over the parties' claims and counterclaims lies under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and is not disputed.

18. Venue over this case is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) and is not disputed.

III. FACTS

A. Uncontested Facts

19. A joint statement of uncontested facts is set forth in **Exhibit 1**. These proposed uncontested facts require no proof at trial and will become part of the evidentiary record in this case. Any party, with prior notice to all other parties, may read any or all of the uncontested facts to the Court, and will be charged for the time used to do so. However, a party need not read these facts into the record for them to be considered by the Court in reaching its ultimate judgment as they are considered part of the record as of the issuance of this Order.

B. Contested Facts

20. Plaintiff's statement of issues of fact that remain to be litigated is attached as **Exhibit 1**.

21. Defendant's statement of issues of fact that remain to be litigated is attached as **Exhibit 2**.

IV. ISSUES OF LAW

22. Plaintiff's statement of issues of law that remain to be litigated is attached as **Exhibit 3**.

23. Defendant's statement of issues of law that remain to be litigated is attached as **Exhibit 4**.

V. WITNESSES TO BE CALLED IN PERSON OR BY DEPOSITION

A. List of Witnesses Plaintiff Expects to Call

24. Plaintiff's list of the names of the fact and expert witnesses Plaintiff currently intends to call live or by deposition at trial is attached as **Exhibit 6**. Plaintiff further identifies any witness listed on Defendant's witness disclosure. Plaintiff currently expects that the witnesses that Plaintiff intends to call live will testify in-person at trial.

B. List of Witnesses Defendant Expects to Call

25. Defendant's list of the names of the fact and expert witnesses Defendant currently intends to call live or by deposition at trial is attached as **Exhibit 7**.

C. Agreed Upon Procedures

26. Any witness not listed in **Exhibits 6-7** will be precluded from testifying, whether in-person or by deposition, absent good cause shown.

27. With the exception of expert witnesses, or unless otherwise agreed to by the parties, each witness will testify only once, either live or by deposition.

28. By **6:00 p.m.** (all times are Eastern time) on March 1, 2022, the parties will exchange in good faith final witness lists. For planning purposes, the parties will identify which of those witnesses they expect to testify live and which they expect to testify by deposition at that time.

29. The listing of a witness on a party's witness list does not require that the party call that witness to testify, either in person or by deposition.

30. Each party will provide the other party with a list, in order of presentation, of witnesses it intends to call live on direct examination by **7:00 p.m.** two nights before those witnesses are intended to testify in Court. (For example, if a party intends to call a witness on Wednesday, that party shall disclose that witness's name to the opposing party no later than **7:00 p.m.** on Monday.) This list must also include those witnesses who are to be called by designation (whose designations will have been previously disclosed pursuant to the procedures described below), so as to disclose the order in which any witnesses called by designation shall appear.

31. The other party shall identify any objections to such witness(es) by **7:00 p.m.** the following day, and the parties shall meet and confer to resolve any objections by **10:00 p.m.** that same evening. If good faith efforts to resolve the objections are unsuccessful, the party objecting to the witness shall bring its objections to the Court's attention at the beginning of the following day. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

32. With the exception of expert witnesses and a corporate representative for each party, the parties agree that witnesses should be prevented from hearing the testimony of other witnesses pursuant to Federal Rules of Evidence 615. Counsel for the parties shall notify one another by e-mail of their corporate representative no less than three days before the first day of trial—i.e., by March 11, 2022.

D. Testimony by Designation

33. A chart of Plaintiff's deposition designations, Defendant's objections to Plaintiff's deposition designations, Defendant's counter-designations, and Plaintiff's objections to

Defendant's counter-designations are set forth in **Exhibit 8** hereto. Plaintiff's deposition designations are subject to revision. Exela reserves the right to supplement its deposition designations for any witness Defendant fails to present live who Defendant has listed in Exhibit 7 as a witness it intends to present live. Given the volume of testimony Eton has designated, Exela also reserves the right to affirmatively rely on its counter and counter-counter-designations as well as any testimony Eton has designated.

34. A chart of Defendant's deposition designations, Plaintiff's objections to Defendant's deposition designations, Plaintiff's counter-designations, and Defendant's objections to Plaintiff's counter-designations are set forth in **Exhibit 9** hereto. Eton reserves the right to supplement its deposition designations for any witness Plaintiff fails to present live who Plaintiff has listed as being present live pursuant to Exhibit 6.

35. Unless otherwise agreed between the parties, the party offering deposition testimony (other than for the purpose of impeachment) shall identify the deposition testimony to be offered from previously-exchanged designations by **7:00 p.m.** at least two calendar days prior to the testimony being offered into the record. The party receiving the designations shall inform the opposing party of any objections and counter-designations by **7:00 p.m.** at least one calendar day prior to the testimony being offered into the record. Any objections to counter-designations shall be provided by **9:00 p.m.** that same day. The parties shall meet-and-confer by **10:00 p.m.** to resolve any objections that same day. If good faith efforts to resolve the objections are unsuccessful, the party objecting to the designations shall bring its objections to the Court's attention at the beginning of the following day.

36. The party who initially proposes the use of the deposition testimony will provide the Court with an accounting of the time for each party's designations based on the parties'

proportional share of lines of testimony for read-in testimony and by actual time for video testimony so that the Court may accurately charge time to the designating parties.

37. All irrelevant and redundant material, including colloquy between counsel and objections, or pauses between questions, will be eliminated when the designations are read or played at trial. The eliminated material will not be included in the accounting of time charged to the designating parties.

38. When deposition designation excerpts are introduced, all admissible deposition designation, and counter-designation excerpts, whether offered by videotape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. The specific portions of the deposition shall be read or played in page order. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on the offering party's trial exhibit list and is not otherwise objected to, or is included on the joint trial exhibit list.

39. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and counter-designations.

40. For those witnesses whose deposition will be played or read to the Court, the parties shall be permitted to make brief transition statements to introduce the witnesses and their role in the litigation. However, counsel shall not be permitted to argue or comment on the evidence during transition statements.

E. Impeachment with Prior Inconsistent Testimony

41. The above procedures regarding deposition designations do not apply to portions of deposition transcripts and/or video used for impeachment of a witness. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party

specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

42. The Court may allow objections to efforts to impeach a witness with prior testimony, including objections based on lack of completeness and/or lack of consistency.

F. Objections to Expert Testimony

43. The parties agree that the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections. Thus, the time taken by the Court to hear and consider the objection shall be charged to the party that does not prevail. For example, if a party raises an objection that expert testimony is beyond the scope and the objection is overruled, the time to consider the objection will be charged to the objecting party.

VI. EXHIBITS

A. Exhibits

44. **Exhibit 10** contains a listing of the parties' exhibits, which includes:

- (a) the uncontested joint exhibits, identified by the prefix JTX;
- (b) Plaintiff's contested exhibits, identified by the prefix PTX; and
- (c) Defendant's contested exhibits, identified by the prefix DTX.

45. **Exhibit 10** contains a list of exhibits that may be introduced into evidence, as well as all objections to the admission of such objections, neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. A party may offer any exhibit appearing on either party's exhibit list. Exhibits not listed will not be admitted unless good cause is shown.

46. Absent an agreement of the parties or a directive from the Court adopting an alternative procedure, the following rules govern the admission of exhibits:

47. Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission.

48. Exhibits to be used solely for impeachment need not be included on the trial exhibit lists or disclosed in advance of being used at trial.

49. The listing of a document on a party's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing party for the purpose that the opposing party wishes to admit the document. Each party reserves the right to object to the relevancy or admissibility of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.

50. Any document that on its face appears to have been authored by an employee, officer, or agent of a party shall be deemed *prima facie* authentic, subject to the right of any party against whom such document is offered to adduce evidence to the contrary or to require that the offering party provide authenticating evidence if the opposing party has a reasonable basis to believe the document is not authentic.

51. The parties stipulate that the parties' ANDA and NDA submissions to FDA are authentic and are records of regularly conducted activity (i.e., business records) pursuant to Fed. R. Evid. 803(6).

52. Absent an agreement by the parties or an Order of the Court, no exhibit will be admitted unless offered into evidence through a witness, testifying live or by deposition, who

must at least be shown and give testimony about the exhibit. At some point before the completion of the trial, any party that has used an exhibit with a witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence.

53. Unless otherwise agreed to by the parties during the trial, the parties will each provide to each other's counsel of record via e-mail containing a written list of exhibits, by exhibit number, for each witness that it intends to call in Court by **7:00 p.m.** two calendar days before the day the witness will testify. Objections to any of the disclosed exhibits shall be made by no later than **7:00 p.m.** the following day, and the parties will meet and confer regarding any objections by **10:00 p.m.** that same evening. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention prior to the witness being called to the stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

54. Subject to resolution to Miscellaneous Issue No.1 (*see infra* Section XIV), the parties will exchange a list of exhibits they plan to use in opening statements by **6:00 p.m.** two days before the start of trial. The parties will provide any objections to such exhibits by **12:00 p.m.** (noon) on the day before the start of trial. The parties agree to meet and confer no later than **4:00 p.m.** on the day before the start of trial to attempt to resolve any such objections so that exhibits may be used during opening statements or objections can be resolved by the Court. If good faith efforts to resolve objections to exhibits fail, the objecting party shall bring its objections to the Court's attention before commencement of any opening statements.

55. Legible photocopies of United States patents and the content of PTO file histories may be offered and received in evidence in lieu of certified copies thereof.

56. Legible photocopies of printed publications (with agreed upon English translations thereof) may be offered and received in evidence in lieu of originals thereof.

57. The parties stipulate that a duplicate of any document or photograph may be marked for identification, and, if otherwise admissible, offered and received into evidence with the same force and effect as the original, subject to any and all objections as could be made to the original, and on condition that the original of any such duplicate, if within the custody or control of a party, be available for inspection at the trial upon reasonable notice.

58. If closing argument is allowed, the parties agree that any exhibit that has been admitted into evidence during the course of trial can be used in closing argument and that the parties need not disclose the intent to use any admitted exhibit prior to closing arguments.

59. The exhibit lists indicate whether each trial exhibit has previously been marked as a deposition exhibit. To remove duplicates and improve legibility of the exhibits used at trial, the parties agree that the trial exhibit shall be treated as identical to the indicated deposition exhibit regardless of whether it bears a deposition exhibit sticker.

60. On or before the first day of trial, each party will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list corresponding to their respective final exhibit lists.

B. Demonstratives

61. The parties agree that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. Plaintiff's demonstratives will be identified with PDX numbers. Defendant's demonstratives will be identified with DDX numbers.

62. Demonstratives to be used on direct examination will be exchanged pursuant to the procedures set forth below. These provisions do not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be

provided to the other side in advance of their use. In addition, blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

63. Subject to the resolution of Miscellaneous Issue No. 1 (*see infra* Section XIV), the parties will exchange demonstratives to be used in opening statements, by **6:00 p.m.** two days before the start of trial. The parties will provide any objections to such demonstratives no later than **12:00 p.m.** (noon) on the day before the start of trial. The parties agree to meet and confer no later than **4:00 p.m.** on the day before the start of trial to attempt to resolve any such objections.

64. A party will provide demonstrative exhibits to be used in connection with direct examination by **7:00 p.m.** the night before their intended use, and objections will be provided not later than **9:00 p.m.** the night before their intended use. The parties will then meet and confer in an attempt to resolve any objections to the demonstratives that are expected to be used during direct examinations no later than **10:00 p.m.** that same evening.

65. The party seeking to use a demonstrative will provide to the other side a color representation of the demonstrative to the other side in PDF form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side on a DVD, CD, or other electronic means (e.g., file transfer). For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as an 8.5 x 11 PDF.

66. If good faith efforts to resolve objections to demonstratives fail, the objecting party shall bring its objections to the Court's attention before its intended use. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of a demonstrative or waiver of objection to the demonstrative.

VII. STATEMENTS OF INTENDED PROOF

67. Plaintiff's statement of what Plaintiff intends to prove at trial is attached as

Exhibit 11.

68. Defendant's statement of what Defendant intends to prove at trial is attached as

Exhibit 12.

VIII. DAMAGES

69. There currently are no damages claims in the case.

IX. MOTIONS IN LIMINE

70. Plaintiff's motions *in limine*, Defendant's oppositions, and Plaintiffs' replies are attached as **Exhibit 13.**

71. Defendant has not presented any motions *in limine*.

X. NON-JURY TRIAL

A. Presentation of Evidence and Argument

72. The trial shall proceed based on the customary orders of proof. Subject to the resolution of Miscellaneous Issue No. 1 (*see infra* Section XIV), Plaintiff shall present its opening statement on all issues, followed by Defendant's opening statement on all issues. Plaintiff shall present its affirmative case on infringement, followed by Defendant's rebuttal on infringement and affirmative case on invalidity. Plaintiff shall then present its rebuttal on invalidity. If the Court allows closing arguments, Plaintiff shall then present its closing argument on all issues followed by Defendant's closing argument on all issues, followed by Plaintiff's rebuttal closing argument.

B. Process for Post-Trial Briefing

73. Pursuant to the Preferences & Procedures for Civil Cases for the Honorable Maryellen Noreika, along with their post-trial briefs, Plaintiff and Defendant shall provide

proposed Findings of Fact and Conclusions of Law, separately stated in numbered paragraphs, constituting a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form, along with citations to the record.

74. The parties propose the following post-trial briefing schedule:

- a. The parties shall simultaneously file their respective opening post-trial briefs and proposed findings of fact and conclusions of law by April 22, 2022, or on a date chosen after trial based on the Court's preferences and instructions. Plaintiff's opening brief shall address infringement. Defendant's opening brief shall address invalidity, including objective indicia of nonobviousness.
- b. The parties shall simultaneously file their respective responsive briefs by May 20, 2022, or on a date chosen after trial based on the Court's preferences and instructions. Plaintiff's responsive brief shall address invalidity, including objective indicia of nonobviousness. Defendant's responsive brief shall address infringement.

75. The parties propose the following page limits:

- a. Opening post-trial briefs shall be limited to 40 pages.
- b. Responsive post-trial briefs shall be limited to 40 pages.
- c. The proposed Findings of Fact shall be limited to 100 pages.
- d. The proposed Conclusions of Law shall be limited to 100 pages.

XI. LENGTH OF TRIAL

76. The trial will be timed. Unless otherwise ordered, time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, closing arguments, its arguments on any

motions for judgment as a matter of law, and all sides' arguments on objections a party raises to another party's exhibits and demonstrative exhibits.

77. The Courtroom Deputy will keep a running total of trial time used by counsel.

78. The Court has allocated 5 court days for this trial. The time will be split equally between the two sides as determined by the Court.

XII. AMENDMENTS OF THE PLEADINGS

79. Neither party intends to seek an amendment to the pleadings at this time.

XIII. ADDITIONAL MATTERS

A. Handling of Confidential Information at Trial

80. The parties anticipate that the majority of the trial will be open to the public and not sealed unless a party specifically requests that a particularly sensitive portion be sealed. If a party makes such a request, subject to the Court's approval, and for good cause shown, the courtroom shall be cleared of those individuals not qualified under the Protective Order entered in this case, except that each party's corporate representative may remain in the courtroom throughout the entirety of trial.

XIV. MISCELLENEOUS ISSUES

A. Issue No. 1: Opening Statements

81. **Plaintiff's Position:** Plaintiff respectfully requests that the Court permit opening statements.

82. **Defendant's Position:** Eton defers to the Court's preference.

B. Issue No. 2: Prior Use Defense Under 35 U.S.C. § 273 ("Defense to infringement based on prior commercial use")

83. **Plaintiff's Position:** Plaintiff respectfully asks the Court to find that Defendant has waived any defense under 35 U.S.C. § 273 because it was not timely disclosed. *See*

Allfasteners USA, LLC v. Acme Operations Pty., Ltd., No. LA CV18-06929 JAK (RAOx), 2021 WL 4027738, at *15 (C.D. Cal. May 25, 2021) (finding the defense must be plead in answer pursuant to 35 U.S.C. § 282(b) and that defendant had waived the defense because the cutoff date for amending pleadings had passed). Eton did not plead this defense in any of its three answers. *See* D.I. 8 (Answer to Complaint); D.I. 20 (Answer to Amended Complaint); D.I. 149 (Answer to Second Amended Complaint).

84. In addition, Plaintiff would be unduly prejudiced if Defendant was permitted to present this undisclosed defense at trial, since Plaintiff had no notice of it, and had no opportunity to investigate and respond to it during fact and expert discovery. In preparing this Pretrial Order, Defendant for the first time has asserted a prior commercial use defense to infringement under 35 U.S.C. § 273. (*See* Exhibit 5 at 5.) That defense was never raised in Defendant's non-infringement contentions or interrogatory responses. Defendant's expert did not raise or address the defense in his expert report on non-infringement.

85. **Defendant's Position:** As presented this is an issue to exclude Eton from presenting testimony. Thus, it should have been addressed as a Motion *In Limine*. Since Plaintiff failed to present this as a Motion *In Limine*, on that basis alone Plaintiff's request should be denied.

86. Plaintiff's claim that this is a new defense belies the facts in this case. Plaintiff knew at the outset that Eton's proposed ANDA product uses the same formulation as that used for the Sandoz product. In fact, Eton stated as much in its Answer to the Second Amended Complaint. (*See* Answer to Second Amended Complaint (Dkt. No. 149) at 114 ("Eton admits that the manufacturing instructions and specifications in the ANDA are identical to the manufacturing instructions and specifications used by Allergy Laboratories to manufacture the

same Cysteine Hydrochloride Injectable product since at least 2013.”) Second Affirmative Defenses (“Eton’s proposed ANDA product is identical to the product marketed and sold by Sandoz Inc. in the United States by at least 2010.”)

87. This was also clearly disclosed in Eton’s Preliminary Invalidity Contentions. Plaintiff also elicited testimony about this from a number of fact witnesses . Thus, Plaintiff was well aware that Eton’s proposed ANDA product was commercially sold as the Sandoz product well before the patents-in-suit were filed.

88. Far from an “undisclosed defense” this has been the cornerstone of Eton’s defenses from the beginning of this litigation. As such, Plaintiff was well aware of these facts and, in fact, questioned multiple witnesses about this. Therefore, there is no prejudice to Plaintiff requiring the Court to resolve.

C. Issue No. 3: Identification of Obviousness Combinations

89. **Plaintiff’s Position:** As of the time of this Pretrial Order, Defendant has not identified the specific obviousness combinations it intends to assert at trial against each asserted claim. Defendant has represented it will identify those combinations in conjunction with the requirements of 35 U.S.C. § 282(c). Should Defendant’s identification be deficient, Plaintiff respectfully requests that the Court require Defendant to disclose its obviousness combinations for each asserted claims forthwith.

90. **Defendant’s Position:** Here again, Plaintiff is attempting to preclude relevant testimony claiming it is a “Miscellaneous Issue” rather than a Motion *In Limine*. On that basis alone, the Court should deny Plaintiff’s request.

91. As Plaintiff acknowledges its request is premature. On February 10, 2022, Eton filed its Notice Pursuant to 35 U.S.C. § 282(c), which contains the obviousness combinations Plaintiff claims are not forthcoming. But long before the 282 statement was filed, Plaintiff was

well aware of the obviousness combinations which are all set forth in Eton's Invalidity Contentions.

XV. SETTLEMENT

92. Plaintiff and Defendant certify that the parties have engaged in good faith efforts to explore the resolution of the case by settlement.

IT IS HEREBY ORDERED that this order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

FISH & RICHARDSON P.C.

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**ATTORNEYS FOR DEFENDANT
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SO ORDERED, this _____ day of _____, 2022.

The Honorable Maryellen Noreika