IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED [redacted] REDACTED PUBLIC VERSION

[PROPOSED] JOINT PRETRIAL ORDER

This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. The parties are Plaintiff Almirall, LLC ("Almirall") and Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc. (collectively, "Taro"). Pursuant to Local Rule 16.3, the parties hereby submit for the Court's approval this proposed Final Pretrial Order governing the bench trial of Civ. Action No. 17-663 (JFB) (SRF), which is currently scheduled to begin on February 4, 2019.

I. NATURE OF THE CASE

A. Nature of the Action

1. Plaintiff[1] filed this Hatch-Waxman action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq. This action arises from Taro's submission of Abbreviated New Drug Application ("ANDA") No. 210191 ("Taro's ANDA") to the United States Food and Drug Administration ("FDA"). Pursuant to Taro's

[1] Almirall, LLC has replaced Allergan, Inc. as Plaintiff in this action, as stipulated in Docket No. 111.

ANDA and accompanying Paragraph IV certification, Taro seeks to market a dapsone 7.5% gel product ("Taro's ANDA Product") prior to the expiration of United States Patent No. 9,517,219 ("the '219 Patent"), listed in the FDA's Orange Book for ACZONE® (dapsone) Gel, 7.5%. Plaintiff asserts infringement of claims 1, 2, 4, and 5 of the '219 Patent.[2]

2. Taro seeks declaratory judgment of non-infringement and invalidity of the '219 Patent.

B. Plaintiff's Complaints and Asserted Claims

3. Allergan filed suit on June 1, 2017, and July 28, 2017, against Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc., respectively, for infringement of the '219 Patent based on the filing of Taro's ANDA and the accompanying Paragraph IV certification. (D.I. 1.)

4. On August 29, 2017, Case No. 17-1048, *Allergan Inc. v. Taro Pharmaceuticals, Inc.*, was consolidated with Case No. 17-663, *Allergan Inc. v. Taro Pharmaceutical Industries Ltd.*, by agreement of the parties, for all purposes including trial, and all filings were ordered to be made in the lead case C.A. No. 17-663 (VAC) (SRF) (Consol.).[3] (D.I. 15; C.A. No. 17-1048, D.I. 11.)

C. Taro's Answer, Defenses and Counterclaims

5. On July 20, 2017 and August 21, 2017, Taro filed its Answers to Plaintiff's Complaints. (D.I. 10., 17-cv-1-48 D.I. 08). Taro asserted defenses of noninfringement and invalidity for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and 112.

---

[2] Taro represents that its PIV Certification was also as to the '926 Patent. Plaintiff did not assert infringement of the '926 Patent in this litigation.

6. Taro also asserted Counterclaims for a declaratory judgment of noninfringement and invalidity under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and 112. (D.I. 10., 17-cv-1-48 D.I. 08)

D. Plaintiff's Answer to Taro's Counterclaims

7. On August 10, 2017, Plaintiff replied to Taro's July 20, 2017 Counterclaims, denying its substantive allegations and each prayer for relief. (D.I. 13.)

E. Stipulations and Dismissals

8. On October 19, 2018, the parties stipulated to the substitution of Almirall for Allergan as Plaintiff due to Taro being informed of a transfer of, *inter alia*, all right, title, and interest in the '219 Patent from Allergan to Almirall. (D.I. 111.)

F. Claim Construction

9. On August 23, 2018, the Court adopted the Report and Recommendation of Magistrate Judge Sherry R. Fallon (D.I. 87) construing the single disputed term in the '219 Patent, "polymeric viscosity builder," to mean "a polymer or polymer-based thickening agent." (D.I. 107.)

G. Pending Motions

10. The parties' respective motions *in limine* and Taro's Daubert motions are pending.

II. JURISDICTION

11. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, including 35 U.S.C. § 271, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Amendments to the Federal

[3] Additional filings made by the parties in Case No. 17-1048 are not discussed herein.

Food, Drug and Cosmetic Act, *see* 21 U.S.C. §355(j). This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Subject matter jurisdiction is not disputed. For purposes of this action, no party has contested personal jurisdiction or venue.

III. FACTS

A. Uncontested Facts

12. A joint statement of uncontested facts is attached as **Exhibit 1**. These proposed stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

B. Contested Facts

13. Almirall's statement of contested issues of fact, with a brief statement of what Almirall intends to prove, is attached as **Exhibit 2**.

14. Taro's statement of contested issues of fact, with a brief statement of what Taro intends to prove, is attached as **Exhibit 3**.

15. If this Court determines that any issue identified in the statements of issues of fact is more properly considered an issue of law, it should so be considered.

16. Any headings used in any of Exhibits 1–3 shall be for convenience only and shall not limit the character of any fact if proven as evidence to any particular claim or defense.

IV. ISSUES OF LAW

17. Almirall's statement of the issues of law that remain to be litigated is attached as **Exhibit 4**.

18. Taro's statement of the issues of law that remain to be litigated is attached as **Exhibit 5**.

19. If this Court determines that any issue identified in the statements of issues of law is more properly considered an issue of fact, it should be so considered.

V. WITNESSES

A. List of Witnesses the Parties Expect to Call

1) Expert Witnesses

20. In **Exhibit 6**, attached hereto, Almirall identifies the expert witnesses it intends to call to testify at trial. Taro's objections to any identified witness are included in Exhibit 6.

21. In **Exhibit 7**, attached hereto, Taro identifies the expert witnesses it intends to call to testify at trial. Almirall's objections to any identified witness are included in Exhibit 7.

2) Non-expert Witnesses

22. In **Exhibit 6**, attached hereto, Almirall identifies the fact witnesses it intends to call to testify at trial, and whether the witness will testify in person or by deposition. Taro's objections to any identified witness are included in Exhibit 6.

23. In **Exhibit 7**, attached hereto, Taro identifies the fact witnesses it intends to call to testify at trial and whether the witness will testify in person or by deposition. Almirall's objections to any identified witness are included in Exhibit 7.

24. Any witness not listed in Exhibits 6 and 7 will be precluded from testifying, absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary and permitted by the Court.

25. The parties agree that live fact witnesses listed on both Exhibits 6 and 7 will be called just once, and that the opposing party cross examining such witnesses will be permitted to cross examine the witness beyond the scope of the direct. For clarity, nothing herein limits a party from calling a fact witness in its rebuttal case, but such testimony will be limited to the

parties' rebuttal case. The parties agree that nothing in this paragraph pertains to expert witnesses.

3) Agreements Regarding Presentation and Identification of Witnesses

26. The parties will identify by email to the opposing parties the witnesses they intend to call, and whether those witnesses will be called live or by deposition, by 7:00 p.m. two calendar days before such witness may be called to testify. For example, if the party expects to conduct the examination of a witness on Thursday, notice of the same must be given to the opposing party by 7:00 p.m. on Tuesday. The other party shall identify any objections to testimony by such witness(es) by 7:00 p.m. the following day, and the parties shall meet and confer to resolve any objections by 9:00 p.m. that same evening. If good faith efforts to resolve the objections fail, the party objecting to the witness shall bring its objections to the Court's attention prior to the beginning of the proceedings the following day. Each party shall update its list of expected witnesses and exhibits by 7:00 p.m. at the end of each trial day.

27. Plaintiff's Position: The presentation of evidence will follow the burden of proof. For clarity, the presentation at trial will occur in the following order: (1) Plaintiffs' Opening Statement, (2) Taro's Opening Statement, (3) Plaintiff's case-in-chief on infringement, (4) Taro's rebuttal case on infringement and case-in-chief on invalidity, (4) Plaintiff's rebuttal case on infringement and case on validity, (5) Taro's rebuttal case on invalidity, (6) Plaintiff's Closing Argument (if permitted by Court), (7) Taro's Closing Argument (if permitted by Court). The parties will notify opposing counsel by 8:00 p.m. two calendar days before as to the expected day that the party intends to complete its presentation of evidence. Notwithstanding the foregoing, Plaintiff may, in stage (3) above, and Taro may in stage (4) above, call any expert witness out of order, however, if any party so elects, the expert witness called shall not be permitted to testify at

any later time during the trial under any circumstances, including during any rebuttal case of the offering party.

28. Taro's Position: The presentation of evidence will follow the burden of proof. For clarity, the presentation at trial will occur in the following order: (1) Plaintiffs' Opening Statement, (2) Taro's Opening Statement, (3) Plaintiff's case-in-chief on infringement, (4) Taro's rebuttal case on non-infringement (4) Plaintiff's rebuttal case on infringement (if permitted by Court) (5) Taro's case-in-chief on invalidity, (6) Plaintiff's rebuttal case on validity (7) Taro's rebuttal case on invalidity (if permitted by Court) (8) Plaintiff's Closing Argument (if permitted by Court), (9) Taro's Closing Argument (if permitted by Court). The parties will notify opposing counsel by 8:00 p.m. two calendar days before as to the expected day that the party intends to complete its presentation of evidence.

B. Testimony by Deposition

29. The deposition testimony that Plaintiff may offer into evidence is identified in **Exhibit 8**. The deposition testimony that Taro may offer into evidence is identified in **Exhibit 9**. This pretrial order contains the universe of deposition designations, counter-designations, rebuttal designations and objections to admission of deposition testimony; none of the foregoing shall be supplemented without consent of all parties or leave of the Court, on good cause shown.

30. With respect to those witnesses whom the parties have identified in Exhibits 6 and 7 who may be called to testify live at trial, no deposition designations or counter-designations are required. Should a fact witness identified in Exhibit 6 or 7 as testifying live at trial become unavailable (as defined in FRE 804(a)), the parties may designate specific pages and lines of transcript that they intend to read or play in lieu of the witness's appearance upon reasonable notice, subject to any objections and admissibility under the Federal Rules of Evidence.

Reasonable notice shall mean no less than 1 day for witnesses whose testimony has been designated in Exhibit 8 or 9, and no less than 3 days for all other witnesses identified in Exhibit 6 or 7.

31. A party may rely on any of the opposing party's deposition designations or counter-designations. For convenience and sake of brevity, the parties have listed counter-designations in response to specific affirmative designations by their opposing parties. To the extent an opposing party withdraws any affirmatively designated testimony or seeks to limit the manner of presentation of testimony through the designation process, a party may present its counter-designation testimony in response to other specified affirmative testimony by the opposing party, or re-designate its counter-designated testimony affirmatively. Similarly, a party may designate testimony identified as affirmative testimony in this order as a counter-designation or counter-counter designation.

32. 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. two calendar days before their anticipated use, and objections and counter-designations in accordance with Paragraph 34 will be provided no later than 7:00 p.m. the following day (one calendar day before their anticipated use). The parties will meet-and-confer by 10:00 p.m. that same night (one calendar day before their anticipated use) concerning any objections. A party may choose not to introduce deposition testimony designated in this Pretrial Order, but may not designate additional deposition testimony after the filing of this Pretrial Order.

33. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read, viewed at trial, or submitted according to the Court's instructions.

34. Unless the Court requests submission otherwise, when deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts, whether offered by videotape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. To the extent a party wishes to read or play specific portions of the deposition, and the Court approves, those portions 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 deemed admissible over any objection preserved and raised at trial, or if it is included on the joint trial exhibit list.

35. Unless a different process is requested by the Court, 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 that will be read or played. The parties will be charged for all time that elapses from the time the witness is called until the next witness is called, according to the proportions to be provided by the parties.

36. The above procedures regarding deposition designations do not apply to portions of deposition transcripts and/or video used for impeachment or cross-examination 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 and admissible for such purpose.

VI. EXHIBITS

A. Exhibits

37. The parties' joint list of trial exhibits is attached as **Exhibit 10**, identified with JTX prefixes. Plaintiff's list of trial exhibits is attached as **Exhibit 11**, identified with PTX prefixes. Taro's list of trial exhibits is attached as **Exhibit 12**, identified with DTX prefixes. Exhibit 12 contains Almirall's objections to Taro's trial exhibits and Exhibit 11 contains Taro's objections to Almirall's trial exhibits. The parties' respective Keys to their objection codes are appended at the end of each exhibit. The parties intend and agree to consider narrowing their respective exhibit lists and objections where possible and will accordingly submit any revised or joint exhibit list or objections, if any, before exhibits are due to the Court.

38. Subject to the provisions of Paragraphs 39, 40, and 47, this pretrial order contains the universe of exhibits to be used by a party at trial as well as all objections to the admission of such exhibits, neither of which shall be supplemented without consent of all parties or leave of the Court. Exhibits not listed will not be admitted into evidence unless good cause is shown.

39. 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 into evidence, may be used by any party, subject to any limitations as to its admission.

40. Exhibits to be used solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used at trial, however such exhibits will not be admitted into evidence.

41. The parties served on the opposing party electronic copies of their respective pre-marked non-demonstrative exhibits in PDF format on January 4, 2019. Plaintiff and Taro will

continue to work on finalizing a joint exhibit list before exhibits are due to the District Court, and will submit pre-marked joint (JTX) exhibits at that time. A party will provide a list of trial exhibits that may be used in connection with direct examination by 7:00 p.m. the day before their anticipated use, and objections will be provided no later than 9:00 p.m. the same night. The parties will meet-and-confer by 10:00 p.m. that same night concerning any objections. 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 beginning of proceedings 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.

42. Exhibits not objected to that are the subject of testimony by a witness at trial will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony. Nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the listed document or any other listed document.

43. 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 side. Each party reserves the right to object to the relevance 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.

44. Complete legible copies of documents may be offered and received in evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or in the circumstances it would be unfair to admit the copy in lieu of the original.

Legible copies of United States patents and the contents of the Patent and Trademark Office file histories may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections that might be made to the admissibility of certified copies.

45. 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.

46. On the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

B. Demonstrative Exhibits

47. The parties agree that the demonstrative exhibits that the parties intend to use at trial do not need to be included on their respective exhibit lists that are part of this Final Pretrial Order. Plaintiffs' demonstrative exhibits will be identified with PDX numbers, starting with PDX 1. Defendants' demonstrative exhibits will be identified with DDX numbers, starting at DDX 1. Demonstrative exhibits shall not be admitted into evidence.

48. A party will provide demonstrative exhibits to be used in connection with opening statements, direct examination, and any closing statements by 7:00 p.m. the day before their anticipated use, and objections will be provided no later than 9:00 p.m. the same night. The parties will meet-and-confer by 10:00 p.m. that same night concerning any objections. If good faith efforts to resolve the objections fail, the party objecting to the demonstrative shall bring its objections to the Court's attention at the beginning of proceedings 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 demonstrative or waiver of objection to the demonstrative. If any of

the demonstratives change after the deadline, the party intending to use the demonstrative will promptly notify the opposing party of the change(s).

49. The party seeking to use a demonstrative exhibit in connection with direct examination will provide a color representation of the exhibit to the other side in PDF or PPT form. However, for video or animations, the party seeking to use the demonstrative will provide it to the other side in an appropriate electronic format to view the video or animation. For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5" x 11" copies of the exhibits.

50. These provisions regarding demonstrative exhibits 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.

VII. DAMAGES AND INJUNCTIVE RELIEF

51. This case does not involve any claims for damages other than in each party's claim that this is an exceptional case under 35 U.S.C. § 285.

52. Plaintiff requests the following relief from the Court:

a) Ordering that the effective date of any approval of Taro's ANDA be not earlier than the expiration date of the '219 Patent, or any later date of exclusivity to which Plaintiff is or becomes entitled, if following the conclusion of trial the patent is adjudged infringed and not invalid;

b) Imposing a permanent injunction restraining and enjoining Taro and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale and/or import, of Taro's ANDA Product, until the expiration of the latest expiration date of the '219 Patent, or any later date of exclusivity to which Plaintiff is or becomes entitled, if so adjudged;

c) Declaring this case exceptional under 35 U.S.C. § 285 and granting Plaintiff its attorneys' fees;

d) Awarding Plaintiff its costs and expenses;

e) Denying each request for relief made by Defendants; and

f) Granting such other and further relief as this Court may deem just and proper.

53. Taro requests the following relief from the Court:

a) Denying each request for relief made by Plaintiff;

b) Declaring the claims of the '219 patent are not infringed and will not be infringed by the manufacture, use sale, offer for sale, marketing or importation into the United States of Taro's ANDA Products;

c) Declaring the claims of the '219 patent invalid;

d) Declaring Taro has a lawful right to obtain FDA approval for the product as described in ANDA No. 210191, and that Taro has a lawful right to manufacture, import, use, sell, or/or offer to sell the product as described in ANDA No. 210191;

e) Declaring this case exceptional under 35 U.S.C. §285 and granting Taro its attorneys' fees;

f) Awarding Taro its costs and expenses;

g) Awarding Taro such other and further relief as the Court deems just and proper.

VIII. BIFURCATED TRIAL

54. All issues will be tried without bifurcation unless otherwise ordered by the Court.

IX. MOTIONS *IN LIMINE*

55. Plaintiff's motion *in limine*, including Taro's opposition brief, is attached as **Exhibit 13**.

56. Taro's motions *in limine*, including Plaintiff's opposition briefs, are attached as **Exhibit 14**. Taro's motions *in limine* are as follows:

- Motion 1: Motion *in Limine* to Exclude Argument, Evidence or Testimony Relying on Plaintiff's Commercial Product to Prove Infringement;
- Motion 2: Daubert Motion to Exclude Dr. Majella E. Lane from Offering the Opinion Taro's Thickening Agent is Equivalent to Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer;
- Motion 3: Motion *in Limine* to Exclude Argument, Evidence or Testimony Relying on the Doctrine of Equivalence to Provide Infringement Because Plaintiff is Barred by the Doctrine of Ensnarement;
- Motion 4: Motion *in Limine* to Exclude Argument, Evidence or Testimony Relying on Plaintiff's Improper Lead Compound Obviousness Analysis; and
- Motion 5: Daubert Motion to Exclude Dr. Julie Harper From Testifying About the Obviousness of the Asserted Claims of the '219 Patent.

X. DISCOVERY

57. Discovery is complete.

XI. NUMBERS OF JURORS

58. This is a non-jury trial.

XII. NON-JURY TRIAL

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

60. Per the Scheduling Order, the parties will meet and confer at the completion of trial and submit a post-trial briefing schedule for the Court's consideration in view of the

evidence presented at trial. Per the Scheduling Order, post-trial briefing shall conclude no later than May 10, 2019.

XIII. LENGTH OF TRIAL

61. Unless otherwise ordered by the Court, 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 (including by designation), cross-examination of witnesses called by any other party (including by designation), any closing argument, and the moving/objecting parties' argument on any motions or objections a party raises to another party's exhibits and demonstrative exhibits.

62. Unless otherwise ordered by the Court, the Courtroom Deputy will keep a running total of trial time used by counsel. If any party uses all of its allotted trial time, the Court will terminate that party's trial presentation.

63. The parties note that the Court has set aside five (5) days for trial. Considering the Court's procedures for counting time, and considering the nature and extent of the parties' disputes, the parties request that the total time be equally split between Plaintiff and Defendants.

XIV. MOTIONS FOR JUDGMENT AS A MATTER OF LAW

64. The parties will address the procedure for motions pursuant to Fed. R. Civ. P. 52(c) with the Court at the Pretrial Conference.

XV. AMENDMENTS OF THE PLEADINGS

65. There are no amendments to the pleadings desired by any party.

XVI. ADDITIONAL MATTERS

66. Plaintiff intends to seek guidance and/or relief from the Court concerning whether the Taro Pharmaceutical Industries Ltd.'s Notice of Paragraph IV Certification, received by

Allergan, Inc. on or about April 17, 2017, was proper under the Hatch-Waxman Act so as to trigger the 30-month stay of approval attendant to this case.

67. Taro intends to seek guidance and/or relief from the Court relating to any and all arguments disclosed by Almirall for the first time in its contested facts on January 4, 2019, and/or in its responses to Taro's Motions *in Limine* or Daubert Motions served on January 7, 2019, for which there is no expert testimony.

XVII. SETTLEMENT

68. The parties certify that they have engaged in a good faith effort to explore the resolution of this controversy by settlement.

This order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Anthony D. Raucci

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com
araucci@mnat.com

Attorneys for Plaintiff Almirall, LLC

OF COUNSEL

James S. Trainor
Vanessa Park-Thompson
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010
(212) 921-2001
jtrainor@fenwick.com
vpark-thompson@fenwick.com

Ewa M. Davison, Ph.D.
Elizabeth B. Hagan, Ph.D.
FENWICK & WEST LLP
1191 Second Avenue, 10th Floor
Seattle, WA 98101
(206) 389-4510
edavison@fenwick.com
ehagan@fenwick.com

Rebecca A.E. Fewkes
FENWICK & WEST LLP
801 California Street
Mountain View, CA 94041
(650) 988-8500
rfewkes@fenwick.com

January 8, 2019

PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL, P.A

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc.

OF COUNSEL

Stephen P. Benson
Kimberly A. Beis

KATTEN MUCHIN ROSENMAN, LLP
525 W. Monroe Street
Chicago, IL 60661
(312) 902-5200
Stephen.benson@kattenlaw.com
Kimberly.beis@kattenlaw.com

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 1

PLAINTIFF'S AND DEFENDANTS' JOINT STATEMENT OF UNCONTESTED FACTS

EXHIBIT 1

I. BACKGROUND OF THE CASE

1. On June 1, 2017, Allergan, Inc. filed civil action 1:17-cv-00663 for patent infringement against Taro Pharmaceutical Industries Ltd. alleging infringement of United States Patent No. 9,517,219 ("the '219 Patent").

2. On July 28, 2017, Allergan, Inc. filed civil action 1:17-cv-01048 for patent infringement against Taro Pharmaceuticals, Inc. alleging infringement of the '219 Patent.

3. On August 29, 2017, Case No. 1:17-cv-01048 was consolidated with Case No. 1:17-cv-00663.

4. On July 20, 2017 and August 21, 2017, Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc. (collectively, "Taro") filed counterclaims for declaratory judgment of invalidity and non-infringement as to the '219 Patent.

5. Allergan, Inc. is no longer a party to Case No. 1:17-cv-00663 and Almirall, LLC is now Plaintiff.

6. Plaintiff Almirall, LLC ("Almirall") has represented it is a successor-in-interest to Allergan, Inc. concerning the product at issue, ACZONE® Gel, 7.5%.

7. Almirall has represented it owns the '219 Patent, which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering ACZONE® Gel, 7.5%.

8. Pursuant to Abbreviated New Drug Application ("ANDA") No. 210191, Taro seeks to market a generic dapsone 7.5% product ("Taro's ANDA Product") prior to the expiration of the '219 Patent.

9. Aqua Pharmaceuticals, LLC is listed in the Orange Book as holding approval of New Drug Application No. 207154 ("Almirall's NDA") to market ACZONE® Gel, 7.5% in the United States.

EXHIBIT 1

10. Plaintiff asserts infringement against Taro of claims 1, 2, 4, and 5 of its '219 Patent, but does not assert infringement of its '926 Patent.

11. Plaintiff Almirall has standing to maintain this civil action.

II. PARTIES

12. Plaintiff Almirall is a limited liability company organized and existing under the laws of Pennsylvania and headquartered in Exton, Pennsylvania.

13. Defendant Taro Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel and headquartered in Haifa Bay, Israel. Taro Pharmaceutical Industries Limited has a principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

14. Defendant Taro Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Canada and headquartered in Ontario, Canada. Taro Pharmaceuticals, Inc. has a principal place of business at 130 East Drive, Brampton, Ontario L6T 1C1, Canada. Taro represents that Defendant Taro Pharmaceuticals, Inc. is a wholly owned subsidiary of Taro Pharmaceuticals Ltd. through Taro Pharmaceuticals North America, Inc.

III. THE PATENT AT ISSUE

15. The '219 Patent issued on December 13, 2016 and is entitled "Topical Dapsone and Dapsone/Adapalene Compositions and Methods for Use Thereof."

16. The '219 Patent names Kevin S. Warner, Ajay P. Parashar, Vijaya Swaminathan, and Varsha Bhatt as inventors.

17. The '219 Patent issued from U.S. Patent Application No. 14/885,805 (the "805 application"), filed on October 16, 2015.

18. The '805 application was a divisional of U.S. Patent Application No. 14/082,955, filed on November 18, 2013 and issued as U.S. Patent No. 9,161,926.

19. The ’219 Patent also claims priority to two U.S. Provisional Applications: No. 61/728,403 filed on November 20, 2012 and No. 61/770,768 filed on February 28, 2013.

20. The ’219 Patent claims methods of treating acne vulgaris and rosacea with topical formulations containing the active pharmaceutical ingredient dapsone at a concentration of 7.5% w/w.

21. Claim 1 of the ’219 Patent is an independent claim. It recites:

> A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer;
>
> and water;
>
> wherein the topical pharmaceutical composition does not comprise adapalene.

22. The Court has construed the term “polymeric viscosity builder” as “a polymer or polymer-based thickening agent.”

23. Claim 2 of the ’219 Patent is a dependent claim that depends from Claim 1. It recites: “The method of claim 1, wherein the diethylene glycol monoethyl ether is present at a concentration of about 30% w/w.”

24. Claim 4 of the ’219 Patent is a dependent claim that depends from Claim 1. It recites: “The method of claim 1, wherein the topical pharmaceutical composition further comprises methyl paraben.”

25. Claim 5 of the ’219 Patent is a dependent claim that depends from Claim 1. It recites: “The method of claim 1 wherein the dermatological condition is acne vulgaris.”

EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 2

PLAINTIFF'S STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

EXHIBIT 2

TABLE OF CONTENTS

PAGE

EXHIBIT 2

EXHIBIT 2

EXHIBIT 2

EXHIBIT 2

1. Pursuant to Local Rule 16.3(c)(4), Plaintiff submits the following issues of fact that remain to be litigated.

I. TECHNICAL BACKGROUND

A. Acne

2. Acne is a dermatological condition.

3. Acne is a multifactorial disease of the pilosebaceous unit, composed of a hair follicle and sebaceous gland. It is characterized by skin blemishes of varying severity.

4. As of 2012, four underlying causes for acne had been identified:

a. Increased production of sebum by sebaceous glands in the skin creates or contributes to blockages in hair follicles and skin pores.

b. Excessive development of dead skin cells in hair follicles, known as hyperkeratinization, blocks hair follicles and results in formation of comedones (i.e., whiteheads and blackheads).

c. Colonization by the microbe *Propionibacterium acnes* causes comedones to form larger, inflamed lesions known as papules, pustules, and nodules depending on the degree of inflammation.

d. Proliferation of *P. acnes* triggers an enzyme-mediated immune response in the acne sufferer, further exacerbating inflammation of acne lesions.

5. As of 2012, there were several methods of acne treatment, targeting one or more of the four known pathogenic factors.

6. Oral acne treatments in 2012 included antibiotics and isotretinoin.

EXHIBIT 2

7. Antibiotics were understood to have antibacterial and anti-inflammatory properties, but were disfavored due to concern with development of antibiotic resistance in *P. acnes*.

8. Isotretinoin was considered unique in addressing all four underlying causes of acne, but only prescribed to patients with severe acne because it causes birth defects and other serious side effects.

9. Common topical agents used to treat acne in 2012 included retinoids, benzoyl peroxide, and antibiotics.

10. Retinoids such as adapalene were believed to have several mechanisms of action for ameliorating acne—including induction of comedone lysis, inhibition of inflammation, and reduction of hyperkeratinization—and were considered a first-line treatment.

11. Benzoyl peroxide was the oldest and most widely used agent, understood to improve comedones and to possess both antibacterial and anti-inflammatory activities.

12. Topical antibiotics reduced inflammation indirectly by reducing *P. acnes* colonization, but again their use was tempered by concern regarding antibiotic resistance.

13. Most pharmaceutical agents were not effective in targeting all four pathogenic factors underlying acne, and varied in their effectiveness as against any particular pathogenic factor.

14. The dermatologic community as of 2012 was interested in developing combination products containing two or more agents, notably, combinations of adapalene with other active ingredients. Such products were expected to be more effective in treating acne, as well as improving patient compliance by simplifying the treatment regimen.

EXHIBIT 2

15. Known combination products included Epiduo® Gel (combining adapalene and benzoyl peroxide) as well as Benzaclin and Duac (combining benzoyl peroxide and an antibiotic).

B. Rosacea

16. Rosacea is a chronic skin disease that affects the face.

17. Rosacea had been classified into four subtypes as of 2012. Subtype 1 (erythematotelangiectatic rosacea) is characterized by redness (erythema) and spider veins (telangiectasia). Subtype 2 (papulopustular rosacea) includes persistent erythema with transient papules and/or pustules. Subtype 3 (phymatous rosacea) may include thickening of the skin, nodularity, and enlargement such as rhinophyma. Subtype 4 (ocular rosacea) affects the eyes.

18. As of 2012, the pathogenesis of rosacea was not known.

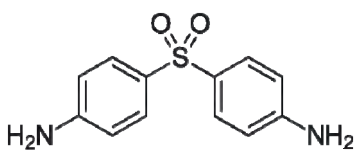
19. As of 2012, treatment was generally targeted to ameliorating symptoms rather than addressing underlying causes of the disease.

20. It was also understood that the four subtypes of rosacea responded differently to various therapies.

21. Papulopustular rosacea is the most receptive to treatment. Topical therapies for this subtype included metronidazole, sodium sulfacetamide with sulfur, and azelaic acid.

C. Dapsone

22. Dapsone, or 4,4'-diaminodiphenyl sulfone, is a sulfone compound having the chemical structure:

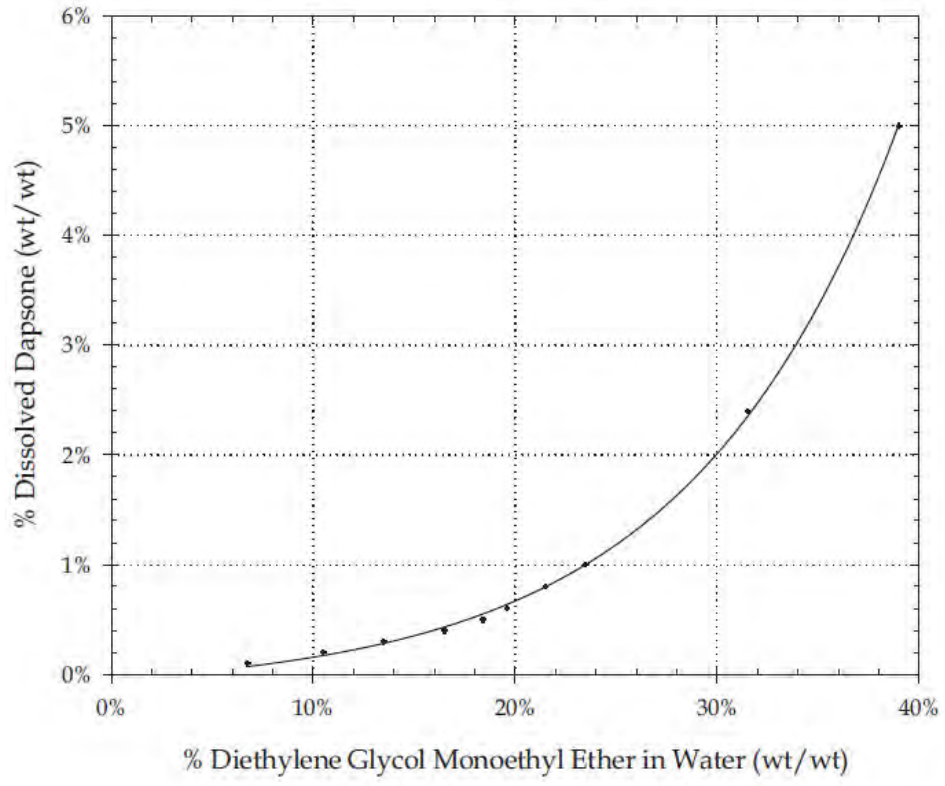


and also known by the chemical names bis-(4-aminophenyl)sulfone, 4,4'-sulfonyldianiline, and diaminodiphenylsulfone.

23. Dapsone was first used therapeutically as an oral treatment for leprosy and other diseases, but has potentially severe side effects when administered orally, including hemolysis (rupture of red blood cells).

24. Dapsone is difficult to formulate as a topical product because it is essentially insoluble in water.

25. Dapsone can be partially solubilized by the addition of the solvent diethylene glycol monoethyl ether ("DGME"), and exhibits a non-linear solubility profile in the presence of DGME in water:



26. The relationship between dapsone solubility and DGME concentration is non-linear.

27. The first topical formulation of dapsone was ACZONE® Gel, 5%, approved by the FDA in July 2005 for acne treatment through twice-daily application.

28. ACZONE® Gel, 5% contains 5% w/w dapsone (as the pharmaceutical agent), 25% w/w DGME (as the solvent), 0.85% Carbopol® 980 (as the polymer-based thickening agent), methylparaben (as the preservative), sodium hydroxide (to adjust pH), and water.

29. ACZONE® Gel, 5% was the first topical drug that used DGME approved by the FDA.

30. As of 2012, the mechanism of action of dapsone was not understood; however, it was believed to treat acne through both anti-inflammatory and antimicrobial activities. The anti-inflammatory activity is provided by dissolved dapsone that passes through the stratum corneum (the outer layer of skin), whereas the antimicrobial activity is provided by undissolved, microparticulate dapsone that remains within the stratum corneum to reduce the levels of *P. acnes* bacteria.

D. Polymeric Viscosity Builders

31. The primary role of a polymeric viscosity builder ("PVB") in a topical pharmaceutical composition is to thicken the formulation so that it holds the active ingredient and is suitable for application to the skin.

32. In thickening the formulation, the PVB creates the rheological profile of the formulation and determines the type of semisolid that is formed, such as an emulgel.

33. The rheological profile, including viscosity, of the topical formulation directly affects the quality of the formulation. Amongst other things, it influences the crystal size of the active ingredient, distribution of the active ingredient, feel on the skin, visual appearance, solubility of the active ingredient, release rate of the active ingredient, and stability of the formulation.

34. As of February 13, 2017, a POSA would have understood that a polymeric viscosity builder may include polymer only, or may include polymer and one or more additional pharmaceutically acceptable excipients.

35. As of February 13, 2017, a POSA would have understood that a polymer-based thickening agent includes one or more pharmaceutically acceptable excipients in addition to a polymer.

36. Examples of excipients that may be included in a polymer-based thickening agent in addition to the polymer include solubilizing agents, surfactants, and oils.

37. Taro's ANDA Product and ACZONE® Gel, 7.5% are bioequivalent.

38. As of 2012, Carbomer Homopolymer Type C was a known PVB. It was and is commercially available as Carbopol® 980 from Lubrizol.

39. Sepineo P 600 was another known PVB. It contains 35–40% w/w acrylamide/sodium acryloyldimethyl taurate ("A/SA") copolymer, 20–25% w/w isohexadecane, 2.5% w/w sorbitan monooleate, 5–10% w/w Polysorbate 80, and purified water q.s.

40. As of 2012, Sepineo P 600 was not used in any FDA-approved drugs and was listed as "pending" in the FDA Inactive Ingredients Database.

41. As of 2012, the specific compositions of Sepineo P 600 and Simugel were not publicly available and thus not within the general knowledge in the art.

42. By the time Taro submitted Taro's ANDA No. 210191 to the FDA on February 13, 2017, it was understood by the person of ordinary skill in the art that A/SA-based and carbomer-based PVBs were interchangeable in emulgels comprising 4,4'-diaminodiphenyl sulfone.

EXHIBIT 2

II. DEVELOPMENT OF ACZONE® GEL, 7.5%

43. ACZONE® Gel, 7.5% is approved for once-daily topical use to treat acne vulgaris.

44. ACZONE® Gel, 7.5% contains 7.5% w/w of the active ingredient dapsone. It also contains 30% w/w DGME, 4% Sepineo P 600, water and 0.2% w/w methyl paraben, and does not contain adapalene.

45. The FDA approved the marketing of the drug product ACZONE® Gel, 7.5% under Almirall's NDA on February, 24, 2016.

46. ACZONE® Gel, 7.5% is the result of Allergan's efforts to create a topical formulation with an increased dapsone concentration of 7.5% w/w.

47. As compared to ACZONE® Gel, 5%, ACZONE® Gel, 7.5% has increased concentrations of dapsone (50% increase from 5% w/w to 7.5% w/w) and of DGME (20% increase from 25% w/w/ to 30% w/w), and uses Sepineo P 600 in place of Carbopol® 980 as the polymer-based thickening agent.

48. An Allergan team led by Dr. Kevin Warner developed the ACZONE® Gel, 7.5% formulation to accommodate the 150% increase in dapsone concentration. Dr. Warner increased DGME concentration to 30% to ensure a ratio of dissolved to undissolved dapsone comparable to that of ACZONE® Gel, 5%.

49. The development of ACZONE® Gel, 7.5% required solving unexpected formulation challenges.

50. In developing a 7.5% dapsone formulation, Allergan tested five polymeric viscosity builders: Sepineo P 600, Carbopol 980, povidone/eicosene (30:70) copolymer, PPG12/SDMI copolymer, and polyvinyl alcohol.

EXHIBIT 2

51. In developing a 7.5% dapsone formulation, Allergan evaluated the five polymeric viscosity builders tested for aesthetics, compatibility with DGME, ability to mask discoloration, and feel.

52. Of the five polymeric viscosity builders tested, Allergan chose not to pursue povidone/eicosene (30:70) copolymer or PPG12/SDMI copolymer because neither formed a gel.

53. Of the five polymeric viscosity builders tested, Allergan chose not to pursue polyvinyl alcohol because it required heating the solvent phase in order to gel.

54. Of the five polymeric viscosity builders tested, Allergan chose to further evaluate Sepineo P 600 and Carbopol 980.

55. Specifically, Dr. Warner discovered that Carbopol® 980, the polymer-based thickening agent used in ACZONE® Gel, 5%, unexpectedly aggregated at DGME concentrations approaching 40% w/w.

56. Dr. Warner further discovered that Sepineo P 600, a thickening agent containing the copolymer acrylamide/sodium acryloyldimethyl taurate ("A/SA"), did not exhibit such incompatibility and resulted in smaller dapsone particle size.

57. Allergan tested three 7.5% dapsone formulations in phase 1 trials: 11078X (7.5% w/w dapsone, 25% w/w Transcutol P, 1% w/w Carbopol 980, 0.2% w/w methyl paraben, Q.S. triethanolamine pH 5.5–6.5, Q.S. hydrochloric acid pH 5.5–6.5, Q.S.100 purified water), 11079X (7.5% w/w dapsone, 30% w/w Transcutol P, 1% w/w Carbopol 980, 0.2% w/w methyl paraben, Q.S. triethanolamine pH 5.5–6.5, Q.S. hydrochloric acid pH 5.5–6.5, Q.S.100 purified water), and 11080X (7.5% w/w dapsone, 30% w/w Transcutol P, 4% w/w Sepineo P 600, 0.2% w/w methyl paraben, Q.S. hydrochloric acid pH 5.5–6.5, Q.S.100 purified water).

58. Aczone 7.5% is Formulation 11080X.

EXHIBIT 2

59. The results of pivotal phase 3 Studies 225678-006 and 225678-007, individually and pooled, demonstrate that ACZONE 7.5% applied topically once daily for 12 weeks is an effective treatment for acne vulgaris.

60. In both pivotal phase 3 Studies 225678-006 and 225678-007 and analyses of pooled data, ACZONE 7.5% was statistically superior to its vehicle, as determined by the proportion of patients with a Global Acne Assessment Score (GAAS) of 0 or 1 and change from baseline in inflammatory and noninflammatory lesion counts at week 12.

61. Holding total daily dosage constant, a patient's daily systemic exposure to a drug is expected to decrease with decreasing dosage frequency.

62. No comparable drug product competes with ACZONE® Gel, 7.5% in the market.

63. ACZONE® Gel, 7.5% is commercially successful as a once-daily product.

64. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the FDA has listed the '219 Patent in the Orange Book for Almirall's NDA.

65. The use of ACZONE® Gel, 7.5% for its prescribed purpose is an embodiment of the Asserted Claims of the '219 Patent.

III. THE '219 PATENT

A. The Specification

66. The '219 Patent provides that the claimed formulations were inventive over the prior art, as they "optimize the dermal delivery profile of dapsone to effectively treat dermatological conditions and improve the efficiency of pharmaceutical products applied to the skin." '219 Patent at 3:41–48.

67. The '219 Patent provides that the DGME of the claimed formulations "allow[s] compositions to be prepared with increased solubilized concentrations of dapsone" that are "effective in treating dermatological conditions in a subject in need thereof." *Id.* at 3:48–53.

EXHIBIT 2

68. The ’219 Patent provides that the formulations claimed were inventive over the prior art, as the PVB claimed “minimizes the intensity of yellowing of the composition caused by the increase solubility of dapsone in [DGME]” and “influences dapsone crystallization,” which “results in compositions with improved aesthetics (i.e., reduction in particle size which minimized ‘gritty’ feeling upon application).” *Id.* at 2:54–61.

69. The specification of the ’219 Patent explains that a PVB of the invention is an emulsion, i.e., involves an oil phase. For example, the specification discloses PVBs of the invention that “comprise” A/SA copolymer and that have A/SA copolymer as the polymeric base of a multi-component “emulsion” or “[A/SA-]based thickener”. *See, e.g.*, *id.* at 8:12–16, 10:49–54, Tables 1–4, 6.

70. A POSA would know that emulsions are formed when the otherwise immiscible oil phase is held in place by surfactants to form a stable composition.

71. The ’219 Patent states that in embodiments of the invention, the PVB includes A/SA copolymer, isohexadecane, sorbitan oleate and Polysorbate 80. *See, e.g.*, *id.* at 5:47–50, tbl. 7. A POSA would recognize that these four components comprise Sepineo P 600.

72. A POSA would recognize A/SA copolymer as a polymer, isohexadecane as an oil, and sorbitan monooleate and Polysorbate 80 as surfactants or emulsifiers.

73. The specification of the ’219 Patent states that the PVB of the invention influences viscosity, the concentration of DGME that can be used (and therefore the solubility to dapsone), visual appearance, dapsone crystallization, particle size, and feel on the skin. Id. at Abstract, 2:43–61, Figs. 1 & 2.

74. The specification of the ’219 Patent describes the storage stability of topical pharmaceutical compositions with the PVBs of the invention. Figure 1 of the ’219 Patent shows

the results of storage stability after 4 weeks both at 25o C and at 40o C by comparing formulations A1, which does not contain a PVB comprising A/SA, and A2, which does contain a PVB comprising A/SA.

75. The specification describes embodiments that include a "neutralizing agent" such as "ionic or amine buffer[s]" or "sodium hydroxide or triethanolamine." Id. at 6:41–45.

76. The specification describes embodiments that include a "chelating agent" such as "ethylene diamine tetraacetic acid (EDTA)." Id. at 6:47–49.

B. '219 Patent Prosecution History

77. The '805 application was filed with ten claims covering methods of treating a dermatological condition with topical dapsone compositions. Claim 1 read:

> A method for treating a dermatological condition comprising administering to a subject in need thereof a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2% w/w to about 6% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and
>
> water;
>
> wherein the topical pharmaceutical composition does not comprise adapalene.

78. When filed, each of the claims (directly or indirectly) required the use of A/SA solely as the PVB, by use of the term "consisting of".

79. None of the claims as filed—or at any point in the prosecution—referred to carbomer.

EXHIBIT 2

80. Among other things, the Examiner rejected the pending claims as obvious over WO 2009/108147 A1; 2009 ("Garrett I") in view of Hani et al. (WO 2010/105052 A1; 2010) and as taken in further view of WO 2009/061298; 2009 ("Garrett II"). The Examiner stated that Garrett I "differs from the instant claims only insofar as it does not explicitly teach (1) acrylamide/sodium acryloyldimethyl taurate copolymer in an amount of 'about 2% to about 6% w/w' (claim 1), particularly about 4% w/w (claim 7) or (2) the exact claimed amount of DGME (i.e., 'about 30% w/w'; claims 2, 7) or the exact claimed amount of dapsone ('about 7 .5% w/w'; claims 1 and 7)." The Examiner noted that "Hani et al. teaches that acrylamide/sodium acryloyldimethyl taurate copolymer is a thickener or viscosity increasing agent suitable for use in topical personal care compositions." The Examiner concluded that "substituting the cross-linked acrylic acid polymer (also known as carbomer or CARBOPOL) thickener of the dapsone formulation described in Garrett [I] as being advantageously incorporated in an amount of 0.2-4% w/w" with A/SA the substitution of A/SA (disclosed in Hani) for Carbopol 980 (disclosed in Garrett I) was prima facie obvious as "each was well known in the art to be a suitable thickening agent for topical personal care products."

81. In response, Applicants stated that "Garrett [I] teaches that a preferred composition comprises about 5% w/w dapsone wherein about 0.85% w/w Carbopol 980 is used as a thickening agent." Applicants also stated: "The new formulation of the instant claims does not include a carbomer such as Carbopol®, but instead utilizes as acrylamide/sodium acryloyldimethyl taurate copolymer, also known as 'Sepineo™ P 600,' and at a much higher concentration (about 2% to about 6% w/w) as compared to what Garrett teaches for its thickening agent."

82. Applicants stated:

EXHIBIT 2

> Therefore, there are at least three significant distinctions between the present invention and the teachings of the cited art:
>
> (i) The specific amount of dapsone recited in the instant claims; and
>
> (ii) The use of Sepineo™ P 600 as the sole thickening agent in a topical dermatological formulation comprising dapsone; and
>
> (iii) The specific amount of Sepineo™ P 600 recited in the instant claims.

83. With this Response, Applicants filed the declaration of inventor Kevin S. Warner (the "Warner Declaration").

84. The Warner Declaration stated that Dr. Warner and his team were "responsible for developing a new formulation of Allergan's Aczone (dapsone) Gel, 5% product" and that "[a]n object of this development project was to facilitate once daily dosing." During development, Dr. Warner unexpectedly found that "Carbopol 960 showed undesired polymer aggregates at 40% diethylene glycol monoethyl ether ("DGME") concentration." This incompatibility was not observed with Sepineo P 600.

85. According to the Warner Declaration, Dr. Warner also found that "Sepineo P 600 provided a smaller dapsone particle size."

86. The Warner Declaration explained that Sepineo P 600 was selected "due to Sepineo P 600's compatibility with concentrations of DGME greater than 25% and its improvement in dapsone particle size relative to Carbopol 960."

87. The Examiner accepted Applicants' arguments that the claimed formulation had unexpected properties and withdrew its obviousness rejection. However, the Examiner maintained its rejection for lack of enablement over the range of dermatological conditions claimed and issued a new rejection based on improper claim dependencies.

88. In response, Applicants amended the claims as follows (insertions underlined and bolded; deletions with strikethrough):

> A method for treating a dermatological condition **selected from the group consisting of acne vulgaris and rosacea** comprising administering to a subject having the dermatological condition **selected from the group consisting of acne vulgaris and rosacea** a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2% w/w to about 6% w/w of a polymeric viscosity builder **comprising** ~~consisting of~~ acrylamide/sodium acryloyldimethyl taurate copolymer; and
>
> water;
>
> wherein the topical pharmaceutical composition does not comprise adapalene.

89. In their Remarks, Applicants noted the change from "consisting of [A/SA]" to "comprising [A/SA]" and stated "that the pending Claims are still patentable in view of the cited prior art, and that relevant arguments made in the [prior] response and the [Warner] declaration . . . still support the patentability of the amended pending claims."

90. The Patent Office allowed the claims on September 30, 2016. In the Notice of Allowance dated September 30, 2016, the Examiner stated that the Examiner "incorporated by reference" its reasons "as to why the instantly claimed method is nonobvious over the cited prior art of record in view of the Warner Declaration."

91. At all times during the prosecution of the applications leading to the '219 Patent, statements made by Applicants concerning carbomer were made in the context of distinguishing prior art where the PVB of a topical formulation consisted only of Carbomer Homopolymer Type C.

EXHIBIT 2

92. At all times during the prosecution of the applications leading to the '219 Patent, chemical entities comprising carbomers (including Carbomer Homopolymer Type C) plus non-polymeric excipients were not known or foreseeable to persons of ordinary skill in the art for use as gelling or thickening agents, i.e., PVBs.

IV. TARO'S TOPICAL 7.5% DAPSONE ANDA AND PRODUCT

A. Taro's ANDA

93. On or around February 13, 2017, Taro submitted Taro's ANDA No. 210191 to the FDA. Through Taro's ANDA, Taro seeks approval to market a generic version of Almirall's ACZONE® Gel, 7.5% ("Taro's ANDA Product") prior to the expiration of the '219 Patent.

94. Taro's ANDA refers to and relies upon Almirall's NDA and contains data that, according to Taro, demonstrate that Taro's ANDA Product is bioequivalent to Almirall's ACZONE® Gel, 7.5%.

95. Taro prepared and submitted Taro's ANDA with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, inter alia, the '219 Patent is invalid and/or would not be infringed by the commercial manufacture, use, or sale of Taro's ANDA Product.

96. By letter dated April 17, 2017, Taro Pharmaceutical Industries Ltd. sent a Notice of Paragraph IV Certification to Plaintiff, providing asserted factual and legal bases for contentions that, *inter alia*, the '219 Patent is invalid and/or would not be infringed by the commercial manufacture, use, or sale of Taro's ANDA Product.

97. By letter dated July 7, 2017, Taro Pharmaceuticals, Inc. sent a Notice of Paragraph IV Certification to Plaintiff, providing asserted factual and legal bases for contentions that, *inter alia*, the '219 Patent is invalid and/or would not be infringed by the commercial manufacture, use, or sale of Taro's ANDA Product.

EXHIBIT 2

98. Taro Pharmaceuticals, Inc. is the owner of the Taro ANDA.

B. Taro's ANDA Product

99. Taro's ANDA Product is a topical pharmaceutical composition indicated for the treatment of acne vulgaris in patients 12 years of age or older.

100. According to clinical study results produced by Taro, Taro's ANDA Product was determined to be clinically equivalent to Almirall's ACZONE® Gel, 7.5% in the treatment of acne vulgaris, and was found to be safe and well-tolerated with a comparable adverse event profile to ACZONE® Gel, 7.5%.

1. Formulation

101. The composition of Taro's ANDA Product is as follows:

Table 1: Quantitative Formula

Strength (Label claim):	7.5% Dapsone	
Component and Quality Standard	**Quantity per unit** (mg/g)	**%** (w/w)
[redacted]		

102. Taro's ANDA Product contains [redacted]

103. Taro's ANDA Product contains [redacted]

EXHIBIT 2

[redacted]

104. Taro's ANDA Product contains [redacted]

[redacted]

105. The addition of an oil phase (such as isohexadecane) can alter the viscosity, feel, and aesthetic appearance of a topical formulation.

106. Taro's ANDA Product contains [redacted]

[redacted]

107. Emulsifiers [redacted] are necessary to stabilize the oil phase in an aqueous phase, prevent separation, and maintain the viscosity of the topical pharmaceutical composition.

108. Taro does not list A/SA copolymer as an ingredient of Taro's ANDA Product.

EXHIBIT 2

109. A comparison of the ingredients in Taro's ANDA Product and ACZONE® Gel, 7.5%, and their respective functions according to Taro, is provided below:

Table 4: Qualitative and Quantitative Comparison of Taro's Dapsone Gel, 7.5%, EBK-D72, Aczone® (dapsone) Gel 7.5% and IID Maximum Potency for Topical Route, and Including Function of Ingredients

Ingredient	Taro Gel, EBK-D72 (%w/w)	Aczone® Gel[1] (%w/w)	IID Maximum Potency for Topical Route[2] (%)	Ingredient Function
[redacted]				

110. The composition of Taro's ANDA Product [redacted]

111. Taro's selection of inactive excipients for Taro's ANDA Product was based on reverse engineering of ACZONE® Gel, 7.5%.

112. Prior to the launch of ACZONE® Gel, 7.5%, Taro had developed a prototype dapsone 7.5% gel formulation identified as EBK-D71.

EXHIBIT 2

113. EBK-D71 [redacted] A comparison of EBK-D71 and Taro's final formulation is reproduced below:

Table 51: Formulations of 180 kg Process Batches

Lot Number	S321-63499	S321-63887
Ingredient	%w/w	%w/w
[redacted]		

114. After Taro obtained samples of ACZONE® Gel, 7.5%, Taro reverse engineered ACZONE® Gel, 7.5% to determine its ingredients and their concentrations.

115. Taro's ANDA states:

3.2. Reverse Engineering of the RLD

[redacted]

116. Taro listed [redacted]

117. EBK-D71 [redacted]

118. Taro's Final Formula Review Form states, [redacted]

119. [redacted]

120. EBK-D72 was selected as the formulation for Taro's ANDA Product.

2. Physiochemical Characteristics and Bioequivalence

121. Taro's ANDA states [redacted]

122. Taro's ANDA states [redacted]

123. Taro's ANDA states [redacted]

EXHIBIT 2

124. Taro's ANDA Product and ACZONE® Gel, 7.5% [redacted]

125. In both products [redacted]

126. Taro's ANDA [redacted]

127. Taro's ANDA Product and ACZONE® Gel, 7.5% exhibit substantially similar rheological profiles.

EXHIBIT 2

128. Taro recorded the average yield stress of three lots of ACZONE® Gel, 7.5% as 114.571 Pa and the average yield stress of four exhibit batches of Taro's ANDA Product (S321-63887, 63954, 63955, 63956I) as 116.994 Pa. The measurements from Taro's ANDA are shown below:

Table 80: Yield Stress Comparison of Taro Exhibit Batches to Three Lots of RLD

Lot	Yield Stress (Pa)
[redacted]	

129. Taro's ANDA Product and ACZONE® Gel, 7.5% exhibit substantially similar yield stress.

130. Taro determined [redacted]

131. The viscosities of Taro's ANDA Product and ACZONE® Gel, 7.5% are substantially similar.

EXHIBIT 2

132. Almirall's NDA reports drug content uniformity measurements for ACZONE® Gel, 7.5%. Each measurement, after initial manufacture and on stability, was between 100–102% of the ACZONE® Gel, 7.5% label claim.

133. Taro [redacted]

Table 73: Exhibit Batches In Process Bulk Testing Results

Test and Method	Acceptance Criteria	Results			
		S321-63887	S321-63954	S321-63955	S321-63956I
[redacted]					

134. The distribution of dapsone in Taro's ANDA Product and in ACZONE® Gel, 7.5% is substantially similar.

EXHIBIT 2

135. Taro's ANDA reports dapsone particle size distribution in four Taro exhibit batches compared to ACZONE® Gel, 7.5%. The measurements from Taro's ANDA are shown below:

Table 78: Dapsone Gel, 7.5% Particle Size Distribution

	Lot #	Particle Size Distribution (µm)		
		$d_v(0.1)$	$d_v(0.5)$	$d_v(0.9)$
[redacted]				

136. Taro's ANDA Product and ACZONE® Gel, 7.5% exhibit substantially similar particle size distribution.

137. Taro's ANDA reports the amount of dapsone in solution and in suspension in three exhibit batches of Taro's ANDA product compared to ACZONE® Gel, 7.5%. The results from Taro's ANDA are shown below:

Table 79: Dapsone Gel, 7.5% Dapsone Solubility

	Lot #	Filterable Dapsone (%)	Non Filterable Dapsone (%)
[redacted]			

138. Taro's ANDA Product and ACZONE® Gel, 7.5% exhibit substantially similar percentages of dapsone in solution and in suspension.

EXHIBIT 2

139. Taro's ANDA Product and ACZONE® Gel, 7.5% have substantially similar feel on the skin.

140. Taro changed the formulation of Taro's ANDA Product to match the feel on the skin of ACZONE® Gel, 7.5%.

141. Taro ran [redacted]

142. [redacted]

Dapsone Gel 7.5% In-vitro Release Rate Comparison

[redacted]

EXHIBIT 2

143. Taro ran IVRT to compare the release rates of dapsone from ACZONE® Gel, 7.5% and Taro's ANDA Product (exhibit batch 63887). The slope ratio was 99%. A summary of those results is reproduced below:

Dapsone Gel 7.5% In-vitro Release Rate Comparison			
Dapsone	ACZONE# KDFC-2 (Exp.Apr/18)	S321-63887	S321-63890
[redacted]			

EXHIBIT 2

144. Taro's ANDA Product and ACZONE® Gel, 7.5% exhibit substantially similar dapsone release rates.

145. Taro's ANDA Product

146. Almirall's NDA provided stability data for ACZONE® Gel, 7.5%. The stability data showed no significant changes in any stability parameter over time. Specifically, ACZONE® Gel, 7.5% maintained a stable appearance, pH, viscosity, dapsone distribution, and particle size. A summary of the stability data in Almirall's NDA is reproduced below:

EXHIBIT 2

Table 9 Long-Term (25 °C/60% RH) Development Stability Data: Lot 3811-36

Product Name:	ACZONE (dapsone) Gel, 7.5%			Lot Number:	3811-36			
Storage Condition:	25 °C/60% RH			Batch Size:	8 kg			
Tests	0 Month	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Physical Appearance	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.	Formulation is opaque, white, uniform, and smooth.
Package Integrity	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.	No deformities were noted in the package.
pH (pH units)	6.6	7.1	7.0	6.7	7.1	6.9	6.8	7.3
Viscosity (cP)	396,000	405,000	371,000	421,000	390,000	384,000	415,000	442,000
Dapsone Assay Top of container Sampled Through Cap (% Label Claim, mean of n=2)	103.2	103.3	102.2	103.3	104.0	104.2	104.7	102.9
Dapsone Assay Bottom of Container (% Label Claim, mean of n=2)	102.9	100.3	101.1	104.2	NT	104.3	NT	105.7
MP top of container (% Label Claim, mean of n=2)	102.0	100.2	100.3	102.0	102.0	101.9	102.4	100.3

Table 9 Long-Term (25 °C/60% RH) Development Stability Data: Lot 3811-36 (Continued)

Product Name:	ACZONE (dapsone) Gel, 7.5%			Lot Number:	3811-36			
Tests	0 Month	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
MP Bottom of Container (% Label Claim, mean of n=2)	102.0	100.1	100.1	102.7	NT	102.1	NT	103.3
Dapsone Related Substances Top of container Sampled Through Cap (% Label Strength)	RRT 1.78* 0.07% LS RRT 1.84* 0.12% LS	RRT 1.78* 0.07% LS RRT 1.85* 0.11% LS	RRT 1.78* 0.07% LS RRT 1.86* 0.12% LS RRT 2.10 0.05% LS	RRT 1.78* 0.07% LS RRT 1.83* 0.12% LS	RRT 1.77* 0.07% LS RRT 1.84* 0.12% LS	RRT 1.63* 0.07% LS RRT 1.75* 0.12% LS	RRT 1.78* 0.07% LS RRT 1.83* 0.12% LS	RRT 1.76* 0.07% LS RRT 1.82* 0.11% LS
Dapsone Related Substances Bottom of Container (% Label Strength)	RRT 1.77* 0.07% LS RRT 1.85* 0.12% LS	RRT 1.78* 0.07% LS RRT 1.85* 0.11% LS	RRT 1.79* 0.07% LS RRT 1.87* 0.12% LS	RRT 1.77* 0.07% LS RRT 1.83* 0.12% LS	NT	RRT 1.63* 0.07% LS RRT 1.75* 0.12% LS	NT	RRT 1.76* 0.07% LS RRT 1.82* 0.11% LS
Microbial Enumeration Tests and Tests for Specified Organisms:								
Total Combined Yeasts and Molds (CFU/g)	LT 10	NT	NT	LT 10	NT	NT	NT	NT
Total Aerobic Microbial Count (CFU/g)	LT 100	NT	NT	LT 100	NT	NT	NT	NT
Absence of *S. aureus* and *P. aeruginosa*	Pass	NT	NT	Pass	NT	NT	NT	NT
Antimicrobial Preservative Effectiveness Test	Pass	NT	NT	Pass	NT	NT	NT	NT

NT = Not Tested
RRT = Relative Retention Time
LS = Label Strength
* Drug substance process impurities

EXHIBIT 2

147. Taro's ANDA tested the stability of Taro's ANDA Product. [redacted]

Table 55: Bulk Stability Study: Chemical Stability at 25°C/60%RH

		Drug Substance Assay (%)		Methylparaben Assay (%)
	Lot Number	S321-63887		S321-63887
Time Point	Initial	[redacted]		
	1 month			
	2 month			
	3 month			

Table 56: Bulk Stability Study: pH and Viscosity Stability at 25°C/60%RH

		pH		Viscosity (cP)
	Lot Number	S321-63887		S321-63887
Time Point	Initial	[redacted]		
	1 month			
	2 month			
	3 month			

148. The stabilities of Taro's ANDA Product and ACZONE® Gel, 7.5% are substantially similar.

149. ACZONE Gel, 7.5% is an off-white to yellow gel with suspended particles. Taro's ANDA describes Taro's ANDA Product as an "[o]paque, white to yellowish gel."

150. The visual appearances of Taro's ANDA Product and ACZONE Gel, 7.5% are substantially similar.

151. Taro [redacted]

V. LEVEL OF ORDINARY SKILL IN THE ART

152. A POSA to which the '219 Patent pertains would have either: (i) a bachelor- or master-level degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus at

least three years of experience in drug delivery, pharmaceutical formulations, or a related field; or (ii) a doctoral degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus some experience in drug delivery, pharmaceutical formulations, or a related field. A POSA would also have clinical experience treating acne and rosacea.

153. The level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

VI. INFRINGEMENT OF THE '219 PATENT

154. The use of Taro's ANDA Product according to the Taro ANDA would directly infringe each of Claims 1, 2, 4, and 5 of the '219 Patent.

155. Plaintiffs are entitled to a declaratory judgment that Taro's anticipated manufacture, use, sale, or offer for sale of Taro's ANDA Product along with Taro's proposed prescribing information will constitute infringement of Claims 1, 2, 4, and 5 of the '219 Patent under 35 U.S.C. §§ 271(b) and (c).

156. Upon FDA approval of Taro's ANDA, Taro intends to market and distribute Taro's ANDA Product to patients and physicians. Accompanying Taro's ANDA Product, Taro will also knowingly and intentionally include a product label and insert containing instructions for administering Taro's ANDA Product.

157. These acts by Taro will induce patients and physicians to directly infringe Claims 1, 2, 4, and 5 of the '219 Patent. Taro will encourage acts of direct infringement with knowledge of the '219 Patent and knowledge that it is encouraging infringement.

158. Taro has not sought and is not seeking authorization to sell its ANDA Product for any indication other than treatment of acne vulgaris in patients 12 years of age and older.

159. The FDA has not approved ACZONE® Gel, 7.5% for any indication other than treatment of acne vulgaris in patients 12 years of age and older.

EXHIBIT 2

160. Taro's ANDA Product is a material for use in practicing Claims 1, 2, 4, and 5 of the '219 Patent.

161. Taro's ANDA Product is a material part of the invention of Claims 1, 2, 4, and 5 of the '219 Patent.

162. Taro's ANDA Product is or will be especially made and adapted for use in infringement of Claims 1, 2, 4, and 5 of the '219 Patent.

163. Taro's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

164. Taro intends to sell its ANDA Product knowing it to be especially made and adapted for use in infringement of Claims 1, 2, 4, and 5 of the '219 Patent.

A. Treatment with Taro's ANDA Product Would Infringe Claim 1 of the '219 Patent

165. Taro's ANDA Product meets each of the limitations of Claim 1 of the '219 Patent indicated below:

Element 1a	A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea
Element 1b	a topical pharmaceutical composition comprising:
Element 1c	about 7.5% w/w dapsone;
Element 1d	about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
Element 1e	about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer; and
Element 1f	water;
Element 1g	wherein the topical pharmaceutical composition does not comprise

EXHIBIT 2

	adapalene.

1. Claim Element 1a: "A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea"

166. Taro intends that its ANDA Product will be used in "a method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea," thus meeting Element 1a of Claim 1 of the '219 Patent.

167. The proposed prescribing information for Taro's ANDA Product describes a method of '[redacted]

168. The proposed prescribing information for Taro's ANDA Product recommends that the patient[redacted]

169. Physicians and patients following Taro's proposed prescribing information will use Taro's ANDA Product in a method to treat acne vulgaris.

170. Taro does not dispute that Taro's ANDA Product meets Element 1a of Claim 1 of the '219 Patent.

2. Claim Element 1b: "a topical pharmaceutical composition comprising"

171. Taro's ANDA Product is "a topical pharmaceutical composition" and thus meets Element 1b of Claim 1 of the '219 Patent.

EXHIBIT 2

172. Taro's prescribing information for its ANDA Product states that it is [redacted] and is intended for [redacted]

173. Taro admits that its ANDA Product is [redacted]

174. Taro does not dispute that Taro's ANDA Product meets Element 1b of Claim 1 of the '219 Patent.

3. Claim Element 1c: "about 7.5% w/w dapsone"

175. Taro's ANDA Product contains about 7.5% w/w dapsone and thus meets Element 1c of Claim 1 of the '219 Patent.

176. Taro does not dispute that Taro's ANDA Product meets Element 1c of Claim 1 of the '219 Patent.

4. Claim Element 1d: "about 30% w/w to about 40% w/w diethylene glycol monoethyl ether"

177. Taro's ANDA Product contains [redacted] and thus meets Element 1d of the '219 Patent.

178. Taro does not dispute that Taro's ANDA Product meets Element 1d of Claim 1 of the '219 Patent.

5. Claim Element 1e: "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA] copolymer"

179. The term "polymeric viscosity builder" in claim element 1e can include more than one component.

180. Taro's ANDA Product comprises [redacted] of a PVB comprising Carbomer Homopolymer Type C, and thus meets claim element 1e, "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA] copolymer" under the doctrine of equivalents.

181. In developing Taro's ANDA Product, Taro began by reverse engineering ACZONE Gel, 7.5%, and specifically, the PVB in ACZONE Gel, 7.5%.

182. Taro's PVB is insubstantially different from element 1e of the asserted claims of the '219 patent.

183. Taro's PVB serves substantially the same function, acts in substantially the same way, and achieves substantially the same result as the A/SA copolymer-based PVB of the claimed invention. Thus, Taro's ANDA Product infringes Claim 1.

a. Taro's PVB Comprises Carbomer Homopolymer Type C *and* [redacted]

184. A POSA would understand from the specification that in an embodiment of the invention, the PVB is an emulsion formed by the addition of a polymer (A/SA copolymer), an oil (isohexadecane), and emulsifiers (sorbitan monooleate and Polysorbate 80). A POSA reading the disclosures in the specification would understand that in such embodiment, these components—a polymer, an oil, and emulsifiers—collectively form a "polymeric viscosity builder" of the invention.

185. A POSA would understand that in such an embodiment of claim element 1e, the oil and emulsifiers not only create an emulgel; they additionally create a system that is stable and provide for a topical formulation that would have a different appearance and feel than in their absence.

186. In assessing Taro's ANDA Product, a POSA would understand that that the use of Carbomer Homopolymer Type C, as opposed to A/SA copolymer, was inconsequential to the function of the PVB, the way it acted, and the result it achieved in the context of the invention claimed in the '219 Patent. A POSA would understand that in the context of the '219 Patent, the polymer (Carbomer Homopolymer Type C), [redacted]

[redacted]n Taro's ANDA Product, ***as a collective entity***, are the PVB in Taro's ANDA Product, because they serve substantially the same function, act in substantially the same way, and achieve substantially the same result as the PVB of the claimed invention and are insubstantially different from it.

187. In particular, a POSA would understand that the oil and surfactants in Taro's ANDA Product combine with the Carbomer Homopolymer Type C to thicken the formulation, creating the rheological profile and forming an emulgel. [redacted] provide for stability, and as viscous liquids, would also impact the thickness and rheological profile of the emulgel.

188. A POSA would know that [redacted] can facilitate functions and mechanisms of action that the '219 Patent attributes to the PVB component of the invention, including increasing viscosity, influencing dapsone crystallization, reducing particle size, allowing for compositions with increased DGME concentrations, minimizing the yellowing of the composition, and reducing its "gritty" feeling on the skin. '219 Patent, Abstract, 2:54–61.

189. ACZONE® Gel, 7.5% is an embodiment of the formulation employed in the method of the '219 Patent's claims.

190. In developing Taro's ANDA Product, Taro replicated the PVB in ACZONE® Gel, 7.5% (A/SA copolymer, isohexadecane, Polysorbate 80 and sorbitan monooleate; collectively, the "ACZONE Gel, 7.5% PVB") by adding [redacted] to Carbomer Homopolymer Type C.

191. [redacted]nd isohexadecane are both paraffins derived from petroleum.

192. For at least these reasons, a POSA would recognize as the PVB in Taro's ANDA Product the collective entity of [redacted] Carbomer Homopolymer Type C, [redacted] (collectively, "Taro's PVB"), having a combined weight of [redacted] PVB.

b. Taro's PVB Is Insubstantially Different from Claim Element 1e and Performs Substantially the Same Function, in Substantially the Same Way, to Achieve Substantially the Same Result

193. A POSA would understand that in the context of the Asserted Claims, the 2.5 wt. % of carbomer-based PVB in Taro's ANDA Product is equivalent to the claimed "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA] copolymer" and satisfies claim element 1e under the doctrine of equivalents.

194. **Taro's PVB serves substantially the same function.** A POSA would understand that the Carbomer Homopolymer Type C, [redacted] in Taro's PVB combine to serve as a polymeric based thickener in Taro's ANDA Product.

195. Taro's PVB allows Taro's ANDA Product to hold dapsone while making it suitable for application to the skin.

196. Taro's PVB and the ACZONE Gel, 7.5% PVB each form an emulgel, or oil-in-water emulsion.

197. Taro's PVB and the ACZONE Gel, 7.5% PVB each contain [redacted] to reduce the physical tension between the aqueous and oil phases.

198. Taro's PVB and the ACZONE Gel, 7.5% PVB each contain a polymer to create a three-dimensional gel-like structure.

199. A POSA would understand that the Taro's PVB serves substantially the same function as claim element 1e, which is embodied by the ACZONE Gel, 7.5% PVB.

EXHIBIT 2

200. **Taro's PVB acts in substantially the same way.** A POSA would understand the following characteristics to be relevant to whether Taro's PVB acts in substantially the same way as claim element 1e: the product's form, rheological profile, crystal size of the active ingredient, distribution of the active ingredient, feel on the skin, visual appearance of the formulation, solubility of the active ingredient, release rate of the active ingredient, and stability of the formulation. A POSA would disregard as inconsequential any minor structural and manufacturing differences.

201. Taro's testing data and submissions to the FDA demonstrate that the following properties of Taro's ANDA Product are substantially similar to those of ACZONE® Gel, 7.5%:

a. Type of formulation, i.e., stable oil-in-water pharmaceutical emulsion;

b. Rheological profile, in terms of shear rate versus viscosity, shear rate versus shear stress and yield stress;

c. Viscosity;

d. Uniform distribution of dapsone;

e. Particle size distribution;

f. Percentage of dapsone in solution and in suspension;

g. Dapsone release rates. By contrast, Taro's oil-free 63499 formulation exhibits a slower dapsone release rate;

h. Stability, in terms of uniform distribution of dapsone, pH, and viscosity of the emulgel over time;

i. Feel on the skin, because the particle size and distribution of dapsone are substantially the same. In fact, Taro changed the formulation of Taro's ANDA Product to match the feeling of ACZONE® Gel, 7.5%;

j. Appearance, i.e., a white to yellowish gel. Taro's ANDA states that an oil phase was introduced to Taro's Product to match the visual appearance of ACZONE® Gel, 7.5%.

202. A POSA reading these disclosures by Taro in the context of the '219 Patent would understand that results were all influenced by the PVB in Taro's ANDA Product and indicated that Taro's PVB acted in substantially the same way as the ACZONE® Gel, 7.5% PVB, which is an embodiment of the claims.

203. Taro did not choose to employ a carbomer-based PVB because it acted in a different way than the ACZONE Gel, 7.5% PVB; Taro obtained samples of ACZONE® Gel, 7.5% and reverse engineered them in order to match the ACZONE® Gel, 7.5% in all relevant respects, including the PVB.

204. A POSA would understand from the prosecution history that the '219 Patent's inventors recognized that a A/SA copolymer-based PVB is compatible with the other components of the formulation of the claimed method, in the compositions as claimed. However, a POSA would not conclude that Taro's PVB comprising Carbomer Homopolymer Type C was incompatible with those other components of the formulation of the claims, in those claimed compositions. Nor would a POSA conclude that Taro's PVB acts in a qualitatively or substantially different way from the claim element 1e, as demonstrated by comparison with an embodiment of the formulation of the claims where the PVB is Sepineo P 600.

205. Thus, a POSA would understand that Taro's PVB acts in substantially the same way as the invention embodied by claim element 1e.

206. **Taro's PVB achieves substantially the same result.** By creating an emulgel with the same properties, Taro's PVB achieves substantially the same result as the ACZONE

Gel, 7.5% PVB: a topical formulation that is bioequivalent to ACZONE Gel, 7.5% and thus delivers sufficient dapsone for treatment of acne.

207. A POSA would understand that the substantially similar properties described above (the emulgel form, rheological profile, viscosity, yield stress, distribution of dapsone, dapsone particle size, dapsone solubility, feel on the skin, dapsone release rate, formulation stability, and visual appearance) contribute to the ability of Taro's formulation to be used to treat acne vulgaris, just like ACZONE® Gel, 7.5%.

208. The data in Taro's ANDA indicating that Taro's ANDA Product is bioequivalent to ACZONE® Gel, 7.5% confirms that the carbomer-based PVB in Taro's ANDA Product achieves the same result as the invention embodied by claim element 1e.

209. **Taro's function-way-result test fails**. The function-way-result construct offered by Taro is based on the false premise that Taro's PVB consists of Carbomer Homopolymer Type C ***only***.

210. From Taro's ANDA Product, the Asserted Claims, the disclosure of the '219 Patent, and admissions in Taro's ANDA, a POSA would not understand Taro's PVB to consist of only Carbomer Homopolymer Type C.

6. Claim Element 1f: "water"

211. Taro's ANDA Product contains water and thus meets Element 1f of Claim 1 of the '219 Patent.

212. Taro does not dispute that Taro's ANDA Product meets Element 1f of Claim 1 of the '219 Patent.

7. Claim Element 1g: "wherein the topical pharmaceutical composition does not comprise adapalene"

213. Taro's ANDA Product does not contain adapalene and thus meets Element 1g of Claim 1 of the '219 Patent.

214. Taro does not dispute that Taro's ANDA Product meets Element 1g of Claim 1 of the '219 Patent.

B. Treatment with Taro's ANDA Product Would Infringe Dependent Claim 2 of the '219 Patent

215. Taro's ANDA Product meets all of the elements of Claim 1 and thereby meets all of the same elements of Claim 2.

216. Taro's ANDA Product contains [redacted]

217. There is no evidence that the use of a PVB containing carbomer results in polymer agglomeration at [redacted]

218. Thus, treatment with Taro's ANDA Product would infringe dependent Claim 2 of the '219 Patent.

219. Taro does not dispute that, if this Court holds that Taro's ANDA Product is a topical composition described by Claim 1, treatment with Taro's ANDA Product would infringe Claim 2 of the '219 Patent.

C. Treatment with Taro's ANDA Product Would Infringe Dependent Claim 4 of the '219 Patent

220. Taro's ANDA Product meets all of the elements of Claim 1 and thereby meets all of the same elements of Claim 4.

221. Taro's ANDA Product contains [redacted]

222. Thus, treatment with Taro's ANDA Product would infringe dependent Claim 4 of the '219 Patent.

EXHIBIT 2

223. Taro does not dispute that, if this Court holds that Taro's ANDA Product is a topical composition described by Claim 1, treatment with Taro's ANDA Product would infringe Claim 4 of the '219 Patent.

D. Treatment with Taro's ANDA Product Would Infringe Dependent Claim 5 of the '219 Patent

224. Taro's ANDA Product meets all of the elements of Claim 1 and thereby meets all of the same elements of Claim 5.

225. Taro, through its proposed label, instructs, advises, and encourages physicians and patients to use Taro's ANDA Product as a treatment for acne vulgaris. Physicians and patients will inevitably follow the instructions in the proposed prescribing information, and prescribe, or use, Taro's ANDA Product as a method for the treatment of acne vulgaris.

226. Thus, treatment with Taro's ANDA Product would infringe dependent Claim 5 of the '219 Patent.

227. Taro does not dispute that, if this Court holds that Taro's ANDA Product is a topical composition described by Claim 1, treatment with Taro's ANDA Product would infringe Claim 5 of the '219 Patent.

E. Almirall's Infringement Claims Are Not Barred

1. No Prosecution History Estoppel

228. Almirall's infringement claims are not barred by prosecution history estoppel.

229. To the extent they are relevant to the scope of the claims of the '219 Patent, the claim amendments made during prosecution of U.S. Pat. App. No. 14/082,955 do not establish an estoppel for the doctrine of equivalents because multi-component PVBs were at that time unforeseeable.

230. Applicants made no narrowing amendment to disputed claim element 1e during the prosecution of the '219 Patent.

231. To the contrary, claim element 1e was broadened, not narrowed, when Applicants replaced the closed-ended "***consisting of*** [A/SA] copolymer" language with the open-ended "***comprising*** [A/SA] copolymer" language.

232. A POSA would not understand from the prosecution history that the inventors had clearly and unmistakably surrendered the right to claim any carbomer-based PVB component as an equivalent of claim element 1e, not least a PVB including Carbomer Homopolymer Type C together with non-polymeric excipients. To the contrary, a POSA would understand from the whole of the discourse reflecting the understanding of both the applicants and the examiner that the scope of a surrendered equivalent, if any, could only have been very narrow, no more than commensurate with the precise PVBs that were known in the art and/or disclosed in a prior art reference over which the claims where rejected during prosecution.

233. A POSA reading Applicants' submissions would understand that at most, Applicants were distinguishing claim element 1e from the specific PVB employed in the formulation of the prior art asserted by the Examiner, all of which consisted of Carbomer Homopolymer Type C only (Carbopol® 980).

2. No Public Dedication or Disclosure

234. Almirall's infringement claims are not barred by the public disclosure-dedication doctrine.

235. The '219 Patent is devoid of any precise or clear disclosure that would indicate to a POSA that a formulation employing a multi-component carbomer-based PVB, such as Taro's ANDA Product, had been disclosed but not claimed.

EXHIBIT 2

236. Nor is Taro's equivalent multi-component carbomer-based PVB identified in the '219 Patent as an alternative to claim element 1e; in fact, Taro's multi-component carbomer-based PVB is not described anywhere in the '219 Patent.

3. No Ensnarement

237. Almirall's infringement claims are not barred by the doctrine of ensnarement.

238. The hypothetical claims proposed by Taro, which replace element 1e with "a polymeric viscosity builder comprising Carbomer homopolymer type C" at a concentration of either "about 1% w/w to about 6% w/w" or "about 2% w/w to about 6% w/w," are not commensurate in scope with the Asserted Claims at least because they would not necessarily cover formulations comprising A/SA copolymer.

239. Taro's hypothetical claims accordingly cannot serve to bar Almirall's infringement claims as ensnaring the prior art.

240. The proper hypothetical claim replaces disputed claim element 1e with "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer **or Carbomer homopolymer type C**." This hypothetical claim is consistent with Almirall's infringement theory.

241. As demonstrated by the facts outlined below, the hypothetical claim analysis demonstrates that Almirall's equivalents theory does not impermissibly ensnare the prior art.

F. Taro's ANDA Product Infringes Dependent Claims 2, 4, and 5 of the '219 Patent

242. Because treatment with Taro's ANDA Product meets all the elements of Claim 1 either literally or under the doctrine of equivalents, Claims 2, 4, 5 would also be infringed by treatment with Taro's ANDA Product.

VII. SCOPE AND CONTENT OF PRIOR ART

A. WO 2009/108147 ("Garrett I")

243. Garrett I is an international patent application entitled "Dapsone to Treat Rosacea." It was expressly considered and cited by the Patent Office during prosecution of the '219 Patent. Garrett I concerns treatment of rosacea with topical dapsone formulations. It is not directed to the treatment of acne.

244. Garrett I describes a clinical trial comparing the efficacy for rosacea treatment of Aczone 5% twice daily, Aczone 5% once daily, MetroGel (metronidazole gel) 1% once daily, Aczone 5% plus MetroGel once daily, and a vehicle control (i.e., placebo). The results show that 5% dapsone (4,4'-diaminodiphenyl sulfone) once or twice daily was no better than placebo in treating rosacea, and did not significantly improve the performance of MetroGel in treating rosacea.

245. Garrett I defines "dapsone" broadly to mean not only the chemical compound 4,4'-diaminodiphenyl sulfone used in Aczone 5% and Aczone 7.5%, but also "dapsone analogs" and "dapsone related compounds." As defined in Garrett I, "dapsone" includes thousands of distinct chemical compounds. Garrett I also cites two earlier references, U.S. Patent Nos. 4,829,058 and 4,912,112, that teach that certain "dapsone" derivatives are more effective antimicrobial agents, either alone or in combination with 4,4'-diaminodiphenyl sulfone, than 4,4'-diaminodiphenyl sulfone itself. Garrett I discloses a concentration range of between 0.5% and 10% for "dapsone," without teaching a concentration range for any particular "dapsone" compound.

246. Garrett I teaches that in preferred embodiments, an "optimal balance" exists between dissolved "dapsone" that is available to cross through the stratum corneum (the outer

layer of skin) to become systemically available and microparticulate "dapsone" that is retained above the stratum corneum forming a reservoir that slowly dissolves and crosses the skin.

247. Garrett I discloses hundreds of possible organic solvents, including DGME as a preferred embodiment. It discloses embodiments in which a glycol ether is present at a concentration of between about 20% and about 40% by weight, but more specifically at a concentration of about 25% by weight.

248. Garrett I discloses the use of a various thickeners, including carbomers and other polymeric thickeners, but does not disclose A/SA copolymer. Garrett I further discloses specific concentrations at which those thickeners can be used in embodiments of the described invention of Garrett I.

B. Bonacucina *et al.*, "Characterization and stability of emulsion gels based on acrylamide/sodium acryloyldimethyl taurate copolymer," *AAPS PharmaSciTech* 10(2):368–375 (2009) ("Bonacucina")

249. Bonacucina is an article disclosing the use of Sepineo P 600, a polymeric viscosity builder comprising A/SA copolymer. It characterizes the gel structure of Sepineo and of a Sepineo emulsion in almond oil, but does not teach the use of Sepineo with any API.

250. Bonacucina does not discuss acne, rosacea, or the treatment of either dermatological condition.

251. Bonacucina does not disclose dapsone.

252. Bonacucina does not disclose DGME.

C. WO 2010/072958 ("Nadau-Fourcade")

253. Nadau-Fourcade is an international patent application, identical to U.S. Patent Pub. No. 2012/0004200 entitled "Topical Pharmaceutical Composition Containing a Water-Sensitive Active Principle." It concerns topical pharmaceutical compositions including a water-

sensitive pharmaceutical agent in a solubilized form, and a method of preparing such compositions.

254. Nadau-Fourcade is directed to formulations in which the API is completely dissolved. It defines the "dissolved form of the active agent" to mean "a dispersion of the active agent in molecular form in a liquid, [with] no crystallization of the active agent being visible to the naked eye or even under a cross-polarized optical microscope."

255. Nadau-Fourcade states that its composition can be used in treating many dermatologic conditions including but not limited to acne and rosacea, as well as non-dermatologic treatments.

256. Nadau-Fourcade does not disclose dapsone.

257. Nadau-Fourcade discloses many potential solvents, including ethers and their derivatives, but does not disclose DGME specifically.

258. Nadau-Fourcade discloses several broad classes of gelling agents, and includes carbomers, polyacrylamides, and polysaccharides as preferred gelling agents. It lists Sepineo P 600 as an example of a polyacrylamide gelling agent. Nadau-Fourcade discloses a preferred 15,000-fold concentration range of 0.001% to 15% for gelling agents, with a more preferred 500-fold concentration range of 0.01% to 5%. It does not specify a concentration range for any one particular gelling agent. Examples containing A/SA copolymer use a concentration of 1.5% or less.

D. Osborne, "Diethylene glycol monoethyl ether: an emerging solvent in topical dermatology products," *J. Cosmetic Dermatology* 10:324–329 (2011) ("Osborne 2011")

259. Osborne 2011 is an article describing the then-recent first use of DGME in a pharmaceutical product, Aczone 5%. It explains that dapsone has negligible solubility in water but remarkably high solubility in DGME (abbreviated DEGEE in Osborne 2011). According to

Osborne 2011, formulating dapsone in a combination of DGME and water produces a solubility profile that exploits both its antimicrobial and anti-inflammatory properties. It notes that this formulation strategy is described, *inter alia*, in U.S. Patent No. 5,863,560 ("Osborne I").

260. Osborne 2011 observes that Aczone 5% addressed acne through a topical formulation in which some dapsone is dissolved and some is not. It explains that the dissolved portion of dapsone would help address inflammation by penetrating the corneum stratum, while the undissolved portion of dapsone would stay in the top part of the pilosebaceous unit to fight the *P. acnes* bacteria that contributes to acne. Osborne 2011 notes that "[b]y adjusting the ratio of dissolved dapsone to particulate dapsone" in the Aczone 5% formulation, "the amount of active crossing the epithelium (dissolved dapsone) to treat inflammation was optimized with regard to the amount of active agent targeted to remain within the follicle (particulate dapsone) to reduce the levels of *Propionibacterium acnes*."

E. U.S. Patent No. 5,863,560 ("Osborne I")

261. Osborne I is a U.S. patent entitled "Compositions and Methods for Topical Application of Therapeutic Agents." It is one of the patents under which Aczone 5% gel was developed.

262. Osborne I describes pharmaceutical compositions comprising both dissolved and undissolved (microparticulate) pharmaceutical agents for optimal topical drug delivery.

263. Osborne I lists a number of potential agents to treat acne, including antimicrobial agents such as dapsone, with a preferred weight percentage for antimicrobial agents of 0.5% to 10%.

264. Osborne I teaches that DGME and 1-methyl-2-pyrollidone are preferred solvents for the invention. Examples containing DGME only disclose a DGME concentration of 10% w/w.

265. Osborne I does not disclose polymeric thickeners comprising A/SA copolymer.

F. WO 2009/061298 ("Garrett II")

266. Garrett II is a 2009 international patent application entitled "Topical Treatment with Dapsone in G6PD-Deficient Patients." It was expressly considered and cited by the Patent Office during prosecution of the '219 Patent. Garrett II concerns the treatment of dermatological conditions, including acne and rosacea, with topical dapsone in patients deficient in the enzyme glucose-6-phosphate dehydrogenase (G6PD).

267. Garrett II explains that Aczone 5% raised concerns about hematological adverse effects in G6PD-deficient patients, and describes a clinical study demonstrating the absence of such effects in this population.

268. Garrett II, like Garrett I, expressly defines "dapsone" to include "dapsone analogs" and "dapsone related compounds." Garrett II discloses an embodiment containing "about 0.5% to about 10% dapsone" without reference to any specific "dapsone" compound."

269. Garrett II identifies DGME and 1-methyl-2-pyrollidone as preferred solvents.

270. Garrett II teaches multiple thickeners that can be used in the treatments described, but does not disclose A/SA copolymer.

G. WO 2010/105052 ("Hani")

271. Hani is an international patent application entitled "Topical Personal Care and Pharmaceutical Compositions and Uses Thereof." It was expressly considered and cited by the Patent Office during prosecution of the '219 Patent. Hani describes topical compositions that comprise at least one personal care or pharmaceutical acid and thickened with lightly or moderately cross-linked PVP.

272. Hani does not disclose dapsone.

273. Hani discloses the use of additional thickeners, one of which is A/SA copolymer.

H. U.S. Patent Pub. No. 2006/0204526 ("Lathrop")

274. Lathrop is a published U.S. patent application entitled "Emulsive Compositions Containing Dapsone." It describes topical, emulsive compositions comprising dapsone or a dapsone derivative, surfactants, and solubility enhancers.

275. Lathrop expressly defines "Dapsone" to include 4,4'-diaminodiphenyl sulfone as well as its derivatives. This definition encompasses many thousands of distinct chemical compounds, and Lathrop does not specify a preferred dapsone compound.

276. Lathrop discloses "Dapsone" concentration ranges of about 0.05 to about 30% (600-fold) and preferably about 0.1 to 25% (250-fold). Lathrop teaches especially preferred embodiments with "Dapsone" concentrations of 1%, 2%, 5%, and 7.5%, but does not indicate whether these concentrations are suitable for all compounds within the "Dapsone" definition or for 4,4'-diaminodiphenyl sulfone. The concentration of "Dapsone" in example formulations of Lathrop does not exceed 5%.

277. Lathrop discloses a large number of possible solvents including DGME.

278. Lathrop does not disclose the use of a polymeric viscosity builder comprising A/SA copolymer.

I. Aczone 5% Prescribing Information (2008) ("2008 Aczone 5% PI")

279. The 2008 Aczone 5% PI discloses the use of 5% dapsone in a topical gel to treat acne vulgaris by twice-daily application. It does not show an indication for treatment of rosacea.

280. The 2008 Aczone 5% PI notes that serious adverse reactions had been reported with oral use of dapsone. It further states that some subjects with G6PD deficiency using Aczone 5% developed laboratory changes suggestive of hemolysis, and warns that patients should discontinue Aczone 5% if signs and symptoms of hemolytic anemia occur.

281. Although the 2008 Aczone 5% PI teaches the use of DGME, it does not disclose any concentration of DGME.

282. The 2008 Aczone 5% PI does not disclose the use of a polymeric viscosity builder comprising A/SA copolymer.

J. Lott *et al.*, "Medication adherence among acne patients: a review," *J. Cosmetic Dermatology* 9:106–166 (2010) ("Lott")

283. Lott is a journal article that teaches that less frequent dosing of acne medication correlates to greater compliance. Lott neither discloses nor suggests the use of dapsone, DGME, or an A/SA copolymer in any concentrations.

K. U.S. Patent Pub. No. 2007/0190019 ("Guo")

284. Guo is a published U.S. patent application entitled "Compositions and Methods for Topical Administration." It describes vanishing cream compositions comprising "water, at least one alcohol[,] a polymeric thickening agent, a skin penetration enhancing compound, and an emulsifying agent."

285. Guo discloses hundreds of possible active agents, one of which is dapsone. Guo discloses use of dapsone only as an antimicrobial drug and not as an anti-acne agent. Guo does not discuss using dapsone to treat acne or rosacea, or using it at a concentration of 7.5% w/w.

286. Guo does not disclose the use of diethylene glycol ethers such as DGME.

287. Guo discloses the use of A/SA copolymer, but only among many other possible polymeric thickening agents without differentiation. Although Guo teaches the use of a polymeric thickening agent in a 100-fold concentration range from about 0.1% to about 10%, examples using Simulgel 600, the thickening agent comprising A/SA copolymer, do not exceed a 5% concentration.

L. U.S. Patent Pub. No. 2009/0022818 ("SenGupta")

288. SenGupta is a published U.S. patent application entitled "High-Foaming Viscous Cleanser Composition with a Skin Care Agent." It describes a liquid cleanser comprising a cleansing surfactant, a skin-care agent, adsorptive polymeric particles, and a polymeric thickening agent, among other components.

289. SenGupta discloses dapsone as one of nine anti-acne agents that can be used either by themselves or in combination. Specific examples of formulations in SenGupta do not include dapsone.

290. SenGupta does not disclose use of glycol ethers or DGME.

291. SenGupta discloses a broad category of "acrylamide-based polymers," but neither A/SA copolymer specifically nor copolymers generally.

M. U.S. Patent Pub. No. 2011/0003894 ("Louis")

292. Louis is a published U.S. patent application entitled "Dermatological Compositions Comprising Retinoids, Dispersed Benzoyl Peroxide and Carrageenans." It describes compositions comprising two types of APIs, at least one retinoid and benzoyl peroxide, as well as at least one gelling agent of the carrageenan family of natural polysaccharides.

293. Louis describes the combination of treatments as enhancing efficacy and reducing toxicity, but notes that application of multiple products may be burdensome for the patient.

294. Louis does not disclose the use of dapsone.

295. Among retinoids, Louis prefers adapalene and its salts.

296. Louis discloses DGME as just one of many examples of glycol compounds as a "wetting agent." It discloses concentration ranges for wetting agents of 0.01 to 10% (1,000-fold) and preferably from 0.1 to 8% (80-fold).

297. Louis discloses Sepineo and Simulgel 600 PHA as gelling agents comprising A/SA copolymer. It discloses concentration ranges for gelling agents of 0.01 to 10% (1,000-fold) and preferably from 0.05 to 6% (120-fold). No concentration within these ranges is specified for Sepineo, and no example in Louis uses Sepineo. No example in Louis uses more than 3% Simulgel 600 PHA.

N. U.S. Patent No. 7,820, 186 ("Orsoni")

298. Orsoni is a U.S. patent entitled "Gel Composition for Once-Daily Treatment of Common Acne Comprising a Combination of Benzoyl Peroxide and Adapalene and/or Adapalene Salt." It describes acne treatments comprising at least a retinoid, benzoyl peroxide, and at least one gelling agent. Orsoni describes the combination of treatments as enhancing efficacy and reducing toxicity, but notes that application of multiple products may be burdensome for the patient.

299. Orsoni does not disclose dapsone.

300. Orsoni teaches a combination product including a retinoid, and specifically prefers adapalene.

301. Orsoni discloses the use of DGME as a pro-penetrating agent. Orsoni teaches concentration ranges for pro-penetrating agents of 0% to 20%, preferably 0% to 10%, and especially 2% to 5%.

302. Orsoni discloses A/SA copolymer as a gelling agent. Orsoni teaches concentration ranges of 0.1% to 15% and more preferably 0.5% to 5% for gelling agents. It does not teach any concentration greater than 4% in its examples including A/SA copolymer.

O. WO 2011/014627 ("Ahluwalia")

303. Ahluwalia is an international patent application entitled "Combination of Dapsone with Adapalene." It was expressly considered and cited by the Patent Office during prosecution

of the ’219 Patent. Ahluwalia describes topical compositions for the treatment of acne and other dermatological conditions containing at least dapsone and another API selected from adapalene, tazarotene, and tretinoin.

304. Ahluwalia explains that “acne is a multifactorial condition,” and that a “combination acne product would provide the benefit of enhanced efficacy compared to the products containing single active agent by taking advantage of the synergistic mechanism of action of the active agents for treatment of acne.”

305. Ahluwalia includes adapalene in every example formulation disclosed.

306. Ahluwalia generally teaches a concentration range of 0.5–10% w/w for dapsone and 1–50% w/w for DGME, but all examples disclose compositions with 5% w/w dapsone and 25% w/w DGME.

307. Ahluwalia also teaches the use of solvents other than DGME, including known dapsone solvents such as dimethyl isosorbide and propylene glycol.

P. U.S. Patent Pub. No. 2011/0135584 (“Mallard”)

308. Mallard is a published U.S. patent application entitled “Pharmaceutical/Cosmetic, e.g., Anti-Acne Compositions Comprising at Least One Naphthoic Acid Compound, Benzoyl Peroxide and at Least One Film-Forming Agent.” It describes topical compositions for treatment of acne including at least one naphthoic acid compound, benzoyl peroxide, and at least one film-forming agent.

309. Mallard does not disclose dapsone.

310. Mallard prefers adapalene, and includes adapalene in all example compositions.

Q. Lubrizol, Technical Data Sheet: Viscosity of Carbopol® Polymers in Aqueous Systems (2010) ("Lubrizol Technical Data Sheet")

311. The Lubrizol Technical Data Sheet discusses the viscosity of Carbopol® polymers in aqueous systems. It does not discuss acne or its treatment, rosacea or its treatment, or dapsone.

R. Lubrizol, Pharmaceutical Bulletin 21: Formulating Semisolid Products (2011) ("Lubrizol Pharmaceutical Bulletin")

312. The Lubrizol Pharmaceutical Bulletin discusses use of Carbopol® polymers, Pemulen™ polymers, and Noveon® polycarbophil in semisolid products. It does not discuss acne or its treatment, rosacea or its treatment, or dapsone.

S. Epiduo Gel Prescribing Information (2008) ("Epiduo PI")

313. The Epiduo Prescribing Information describes a topical acne treatment combining two APIs, adapalene and benzoyl peroxide.

T. Seppic, Sepineo™ P 600 (2008) ("Sepineo Brochure")

314. Seppic's brochure for the Sepineo P600 product does not discuss acne or its treatment, rosacea or its treatment, or dapsone.

VIII. THE ASSERTED CLAIMS OF THE '219 PATENT ARE NOT INVALID UNDER 35 U.S.C. § 103

315. The obviousness of the inventions of Claims 1, 2, 4, and 5 of the '219 Patent (the "Asserted Claims") is to be evaluated as of November 20, 2012.

316. Garrett I does not render obvious any of the Asserted Claims in view of either Bonacucina or Nadau-Fourcade.

A. A POSA Would Not Have Been Motivated to Select Dapsone to Treat Acne or Rosacea

317. A POSA in 2012 seeking to make an improved topical treatment for acne or rosacea would not have been motivated to select dapsone. As of 2012, there were numerous other candidates, including drugs approved for acne or rosacea treatment, that would have been

equally or more promising starting points for an improved topical formulation for treating acne or rosacea.

318. A POSA would not have been motivated by the combination of Garrett I with Bonacucina or Nadau-Fourcade to select dapsone for an improved acne treatment.

319. Garrett I is not directed to the treatment of acne.

320. Bonacucina does not disclose dapsone or any concentration thereof.

321. Bonacucina does not disclose the treatment of acne.

322. Nadau-Fourcade does not disclose dapsone or any concentration thereof.

323. Nadau-Fourcade does not suggest the use of dapsone to treat acne.

324. A POSA in 2012 seeking to make an improved acne treatment would have had no reason to select dapsone. ACZONE® Gel, 5% was viewed with skepticism by the prior art as a whole, at least in part because it had lower response rates than other topical acne treatments.

325. A POSA in 2012 seeking to make an improved acne treatment would have understood that ACZONE® Gel, 5% was considered, at best, a backup option for use with patients who were allergic to or could not tolerate more preferred acne therapies.

326. The prior art as of 2012 did not disclose or teach any known problem with ACZONE® Gel, 5%, nor provide any suggestion of any opportunity to improve upon that drug product.

327. Even if a POSA in 2012 set out to develop a new dapsone topical formulation for the treatment of acne or rosacea, the POSA would have considered the wealth of publicly available data and clinical information corresponding to ACZONE® Gel, 5% rather than the prior art asserted by Taro, including Garrett I.

328. A POSA would not have been motivated by the combination of Garrett I with Bonacucina or Nadau-Fourcade to select dapsone for an improved rosacea treatment.

329. Bonacucina does not disclose dapsone or any concentration thereof.

330. Bonacucina does not disclose the treatment of rosacea.

331. Nadau-Fourcade does not disclose dapsone or any concentration thereof.

332. Nadau-Fourcade does not suggest the use of dapsone to treat rosacea.

333. The prior art as a whole, including Garrett I, revealed that dapsone was no more effective than placebo in treating rosacea. ACZONE® Gel, 5% lacked an indication to treat rosacea, Allergan having abandoned dapsone as a possible treatment for the condition.

334. Garrett I teaches away from using dapsone to treat rosacea, disclosing that dapsone was no more effective than placebo for this indication.

335. Even if a POSA looked to Garrett I to make an improved acne or rosacea treatment, Garrett I would not have motivated a POSA to select dapsone (i.e., 4,4'-diaminodiphenyl sulfone) as claimed in the ’219 Patent.

336. Garrett I defines “dapsone” to include “the chemical compound dapsone having the chemical formula $C_{12}H_{12}N_2O_2S$ as well as bis(4-aminophenyl)sulfone, 4,4'-diaminodiphenylsulfone and its hydrates, 4,4'-sulfonylbisbenzeneamine, 4,4'-sulfonyldianiline, dia[mino]phenylsulfone, dapsone analogs, and dapsone related compounds.” Garrett I further defines “dapsone analogs” as “chemical compounds that have similar chemical structures and thus similar therapeutic potential to dapsone such as the substituted bis(4-aminophenyl)-sulfones” and “dapsone related compounds” as “chemical compounds that have similar therapeutic potential, but are not as closely related by chemical structure to dapsone such as the substituted 2,4-diamino-5-benzylpyrimidines.”

337. Garrett I discloses a vast family of dapsone derivatives and cites prior art showing that several dapsone derivatives are more effective antimicrobial agents than dapsone itself.

338. Nothing in the art in 2012 would have taught or suggested to a POSA to select dapsone in formulating an improved acne or rosacea treatment.

B. A POSA Would Not Have Been Motivated to Select a Dapsone Concentration of About 7.5% w/w

339. A POSA would not have been motivated by the combination of Garrett I with Bonacucina or Nadau-Fourcade to select a dapsone concentration of about 7.5% w/w to treat acne or rosacea.

340. Garrett I would not have directed a POSA to choose a concentration of about 7.5% w/w dapsone. Its disclosure of a 0.5% w/w to 10% w/w concentration range applies generally to the vast family of dapsone derivatives taught therein, and Garrett I does not teach a concentration greater than 5% w/w for dapsone (i.e., 4,4'-diaminodiphenyl sulfone) specifically.

341. A POSA in 2012 would not otherwise have been motivated to increase dapsone concentration above the 5% w/w concentration of ACZONE® Gel, 5%.

342. A POSA would have understood from the prior art as a whole that the 5% w/w dapsone concentration in ACZONE® Gel, 5% had already been optimized, and that the makers of ACZONE® Gel, 5% would have developed a once-daily product with a higher dapsone concentration had it been possible to do so.

343. A POSA would have understood from the prior art as a whole that increasing dapsone concentration above 5% w/w risked exacerbating adverse effects such as hemolysis, particularly in patients suffering from G6PD deficiency, without necessarily yielding a more effective product.

344. Nothing in the art in 2012 would have taught or suggested to a POSA to improve an acne or rosacea treatment by increasing the concentration of dapsone.

345. Even assuming a POSA in 2012 was motivated to develop a once-daily dapsone topical formulation, it would not have been obvious to formulate such composition having a dapsone concentration of 7.5% wt.

C. A POSA Would Not Have Been Motivated to Increase DGME Concentration Above 25% w/w

346. A POSA would not have been motivated by the combination of Garrett I with Bonacucina or Nadau-Fourcade to select a DGME concentration approaching 40% w/w in developing an improved topical dapsone treatment for acne or rosacea.

347. Garrett I does not teach a concentration approaching 40% w/w for DGME specifically.

348. Garrett I would not have directed a POSA to choose a concentration of DGME within the range of about 30% to about 40% because its disclosure of a 20% w/w to 40% w/w concentration range applies to the family of glycol ethers which includes at least hundreds of solvents, whereas a preferred embodiment that uses DGME specifically discloses a concentration of only 25% w/w.

349. Bonacucina does not disclose DGME or any concentration thereof.

350. Nadau-Fourcade discloses many categories of solvents, of which one was the family of glycol ethers. Nadau-Fourcade does not disclose DGME specifically.

351. A POSA would not have been motivated to increase DGME concentration above the 25% w/w concentration of ACZONE® Gel, 5%.

352. Absent a motivation to raise the dapsone concentration above 5% w/w, a POSA would not have been motivated to increase DGME concentration above 25% w/w.

353. A POSA would have understood from the prior art as a whole that the 25% w/w DGME concentration in ACZONE® Gel, 5% was optimal with respect to the ratio of dissolved to undissolved dapsone.

354. Increasing DGME concentration increases the amount of dapsone dissolved, and thus disrupts the balanced ratio of dissolved to undissolved (microparticulate) dapsone in the formulation.

355. A POSA would have understood from the prior art as a whole that increasing DGME concentration above 25% w/w raised safety concerns.

356. As of 2012, the FDA had not approved DGME use at concentrations greater than 25% w/w.

357. Increasing DGME concentration increases dapsone skin permeability and thus the risk of adverse effects from dapsone.

358. A POSA who wanted to raise the concentration of dapsone would have added solvent(s) other than DGME, rather than increasing DGME concentration above 25% w/w.

D. A POSA Would Not Have Been Motivated to Select a PVB Comprising A/SA Copolymer

359. A POSA would not have been motivated by the combination of Garrett I with Bonacucina or Nadau-Fourcade to select a PVB comprising A/SA copolymer for an improved topical treatment for acne or rosacea.

360. Garrett I does not disclose a PVB comprising A/SA copolymer.

361. Garrett I teaches away from replacing the PVB of ACZONE® Gel, 5%, Carbopol® 980, in order to reduce grittiness because Garrett I discloses that the dapsone microparticles responsible for the grittiness contribute to an optimal topical dapsone formulation.

362. Bonacucina would not have motivated a POSA to make a topical dapsone formulation having a PVB comprising A/SA copolymer.

363. Bonacucina does not disclose the use of Sepineo P 600 in combination with a pharmaceutical agent to treat a medical condition generally, nor acne or rosacea specifically.

364. Bonacucina discloses that 5% w/w Sepineo P 600 "could compromise correct emulsion formulation."

365. Nadau-Fourcade discloses several large families of polymeric gelling agents, including polysaccharides, carbomers, and polyacrylamides.

366. Nadau-Fourcade provides no special emphasis on Sepineo P600 among the several large families of polymeric gelling agents disclosed therein.

367. A POSA would not have been motivated to combine Garrett I and Nadau-Fourcade because their goals are incompatible. While Garrett I teaches a topical formulation in which efficacy relies on having both dissolved and undissolved dapsone, Nadau-Fourcade teaches a topical formulation in which the pharmaceutical agent is completely solubilized.

368. A POSA would not have been motivated by Nadau-Fourcade to use A/SA copolymer at a concentration in the range of about 2% w/w to about 6% w/w given that all of Nadau-Fourcade's examples containing A/SA copolymer use a concentration of 1.5% w/w or less.

369. A POSA in 2012 considering Garrett I would not have been motivated to employ PVBs other than those disclosed in Garrett I itself as useful in embodiments of the invention described therein.

E. A POSA Seeking to Develop an Improved Acne Treatment Would Have Combined Dapsone with Adapalene

370. A POSA would not have been motivated to exclude adapalene from a topical dapsone formulation for treatment of acne.

371. Even if a POSA had sought to develop an improved acne treatment that used about 7.5% w/w dapsone, that person would have done so as part of a combination product with at least one other pharmaceutical agent.

372. As of 2012, a POSA seeking to develop an improved acne treatment would have pursued a combination product containing two or more pharmaceutical agents in order to address multiple cause of acne in a single formulation.

373. A POSA in 2012 would have combined dapsone with adapalene in a topical formulation for acne treatment. Retinoids such as adapalene were considered a first-line acne treatment and were understood to address a cause of acne, hyperkeratinization, that dapsone does not. Adapalene was known to be the best tolerated topical retinoid. Other prior art references suggested combining dapsone with adapalene to treat acne.

374. Garrett I provides no reason to believe that using dapsone as a monotherapy would be advantageous, or that its combination with adapalene would be problematic.

375. Bonacucina does not disclose dapsone or adapalene, or suggest that their combination in a topical product would pose difficulties.

376. Nadau-Fourcade discloses adapalene, and does not disclose dapsone or suggest that combination of dapsone with adapalene would pose difficulties.

F. Objective Evidence Supports Nonobviousness of the ’219 Patent

377. Real-world evidence supports the nonobviousness of the Asserted Claims of the ’219 Patent.

EXHIBIT 2

1. Unexpected Results

378. The unexpected results associated with ACZONE® Gel, 7.5%, an embodiment of the invention, demonstrate the nonobviousness of the ’219 Patent.

379. Because Carbopol® 980 is compatible with 25% w/w DGME in the ACZONE® Gel, 5% formulation, a POSA would have expected Carbopol 980® to be compatible with DGME concentrations between about 30% w/w and about 40% w/w.

380. Given the incompatibility of Carbopol 980® with DGME concentrations approaching 40% w/w that was discovered during the development of ACZONE® Gel, 7.5%, a POSA would have expected polymer-based thickeners generally to be incompatible with DGME concentrations approaching 40% w/w.

381. That Sepineo P 600 but not Carbopol® 980 is compatible with DGME concentrations approaching 40% w/w and decreases dapsone particle size as compared to Carbopol® 980 were unexpected results demonstrating the nonobviousness of the asserted claims of the ’219 Patent.

382. That ACZONE® Gel, 7.5% is a successful product is an unexpected result.

383. A POSA would have understood that ACZONE® Gel, 5% treatment required twice-daily application despite being optimized as to the ratio of dissolved dapsone and undissolved dapsone, and thus a POSA would not have expected that increasing dapsone concentration to 7.5% w/w would yield an improvement over dapsone topical formulations existing in the art in terms of patient compliance or otherwise.

384. The success of ACZONE® Gel, 7.5% as a once-daily topical acne treatment further supports the nonobviousness of the asserted claims.

EXHIBIT 2

2. Industry Praise

385. ACZONE® Gel, 7.5%, the commercial embodiment of the invention of the '219 Patent, has been widely praised by both the medical community and patients as a safe and effective treatment for acne.

386. This praise demonstrates nonobviousness.

IX. THE ASSERTED CLAIMS OF THE '219 PATENT ARE NOT INVALID UNDER 35 U.S.C. § 112

387. Taro cannot prove by clear and convincing evidence that any of Claims 1, 2, 4, or 5 of the '219 Patent is invalid under 35 U.S.C. § 112 as lacking adequate written description support or as indefinite.

A. The Asserted Claims of the '219 Patent Are Not Invalid for Lack of Written Description

388. Taro cannot prove by clear and convincing evidence that claim limitation 1e, "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyltaurate copolymer", is not supported by adequate written description as required by 35 U.S.C. § 112.

389. The specification of the '219 Patent demonstrates to a POSA that the inventors were in possession of a composition comprising a "polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyltaurate copolymer."

390. The '219 Patent specification at 5:47–48 and Embodiment 44 states that the PVB in some embodiments of the invention "is" or "comprises" A/SA copolymer.

391. The '219 Patent specification in Tables 1–4 and 6 sets forth examples of compositions comprising A/SA copolymer, and in Table 7 sets forth an example of a composition comprising Sepineo P 600, which in turn comprises A/SA copolymer.

392. The specification of the ’219 Patent demonstrates to a POSA that the inventors were in possession of a composition comprising “about 2% w/w to about 6% w/w” of a PVB.

393. The ’219 Patent specification at 5:50–56 and Embodiment 45 states that the PVB in some embodiments of the claimed invention is present in a concentration of “about 2% w/w to about 6% w/w.”

394. The ’219 Patent specification in Tables 1–4, 6, and 7 sets forth examples of compositions in which a PVB comprising A/SA copolymer is within the concentration range of “about 2% w/w to about 6% w/w.”

B. The Asserted Claims of the ’219 Patent Are Not Invalid for Indefiniteness

395. Taro cannot prove by clear and convincing evidence that claim limitation 1e is indefinite under 35 U.S.C. § 112.

396. Examples of multi-component PVBs were known as of 2012. Sepineo P 600 comprises A/SA copolymer, Polysorbate 80 (a polymeric emulsifier/surfactant), sorbitan oleate (a non-polymeric emulsifier/surfactant), and isohexadecane (a non-polymeric oily compound). Carbopol Ultrez 10 comprises cross-linked polyacrylic acid polymer and a non-polymeric solvent mixture of ethyl acetate and cyclohexane.

397. The ’219 Patent specification provides sufficient guidance to a POSA to determine whether a given component of the claimed topical pharmaceutical composition is or is not part of the PVB.

398. The ’219 Patent specification at 2:12–24 describes dapsone as a “medicinal agent.”

399. The ’219 Patent specification at 2:48–50 and 5:36–44 describes DGME as a “solubilizer for dapsone.”

EXHIBIT 2

400. The ’219 Patent specification lists water in Tables 1–6 with the abbreviations for quantim satis (“Q.S.” “Q.S. 100”) or quantum sufficit id (“q.s.a.d.”). Such water is added to bring the composition to 100% weight.

401. The ’219 Patent specification at 6:41–45 describes an optional “neutralizing agent” such as generally an “ionic or amine buffer” and specifically “sodium hydroxide or triethanolamine.”

402. The ’219 Patent specification at 6:47–49 describes an optional “chelating agent” such as “ethylene diamine tetraacetic acid (EDTA).”

403. Methylparaben was a well-known preservative as of 2012.

404. A POSA would have understood that dapsone, DGME, water added to bring the composition to 100% weight, neutralizing agents, chelating agents, and methylparaben are not components of the claimed PVB.

X. REMEDIES

405. Taro’s ANDA Product infringes the Asserted Claims.

406. Almirall will suffer irreparable injury if Taro makes, uses, sells, offers for sale, or imports into the United States Taro’s ANDA Product prior to the expiration of the ’219 Patent.

407. Monetary damages are inadequate to compensate Almirall for that injury.

408. The balance of relative hardships as between Almirall and Taro favors Almirall.

409. The public interest is served by respecting Almirall’s property rights in the ’219 Patent.

410. The public interest would not be disserved by a permanent injunction against Taro’s infringement of the ’219 Patent.

411. This case is an exceptional case under the meaning of 35 U.S.C. § 285 such that Almirall should be awarded attorneys’ fees and costs.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 3

DEFENDANT'S STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

1. Pursuant to Local Rule 16.3(c)(4), Defendants submit the following issues of fact that remain to be litigated.

I. TARO'S ANDA PRODUCT AND MANUFACTURING METHOD

2. Taro submitted ANDA No. 210191 for Dapsone Gel 7.5% ("Taro's ANDA"). The product described in Taro's ANDA ("Taro's Product") is an [redacted] Taro's Product is a type of topical pharmaceutical product known as an "Emulgel", *i.e.* an emulsion thickened with, in this case, a polymer thickening agent. Emulgels were known at least as early as 2012.

3. Taro's ANDA describes the composition and manufacturing process to create Taro's Product. In the "Description and Composition of the Drug Product" of Taro's ANDA (Section 3.2.P.1), the Quantitative Formulation and Functions of Ingredients tables for Taro's Product are included.

4. The tables describing the composition of Taro's Product are reproduced below:

Table 2: Quantitative Formula

Strength (Label claim):	7.5% Dapsone	
Component and Quality Standard	**Quantity per unit** (mg/g)	**%** (w/w)
[redacted]		

Table 3: Functions of Ingredients

Component	Intended Functions
[redacted]	

5. Dapsone is the sole active ingredient in Taro's Product.

6. The product additionally includes [redacted]

7. [redacted]

8. [redacted]

9. These excipients in combination constitute [redacted] of Taro's Product.

10. Taro's Product additionally [redacted]

11. In addition, Taro's Product contains [redacted]

12. [redacted]

13. When combined, the aqueous phase and oil phase of Taro's Product create an oil-in-water emulsion, a well-known type of topical pharmaceutical composition. Oil-in-water emulsions containing dapsone [redacted] were known prior to the priority date of the '219 Patent.

14. Lastly, Taro's Product includes Carbomer Homopolymer Type C, also commonly referred to as Carbopol® 980 or simply "Carbomer."

15. Carbomer is a polymer thickening agent, sometimes also called a "gelling" agent. Carbomer consists of a single synthetic high-molecular-weight polymer of acrylic acid. Carbomer is sold in powder form. As described below with reference to the manufacturing protocol for Taro's Product, Carbomer must be carefully mixed with water followed by activation using some form of neutralizing agent, in this case sodium hydroxide. Addition of Carbomer to topical pharmaceutical products must be carefully controlled to prevent clumping of the polymer.

16. Carbomer acts as, and is, the polymer thickening agent in Taro's Product. When Carbomer is added to the oil-in-water emulsion it creates an Emulgel.

17. Taro's Product contains no other excipients. Taro's Product does not contain a polymer-based thickening agent that is a "multi-component PVB" as alleged by Plaintiffs. The multi-component PVB Plaintiffs allege is Taro's polymer-based thickening agent is not an "agent" at all, but at least four separate agents added at different times to the formulation in different ways and accomplish distinct results.

18. The addition of Carbomer to oil-in-water emulsions containing active ingredients, including dapsone, was known as of the priority date of the invention.

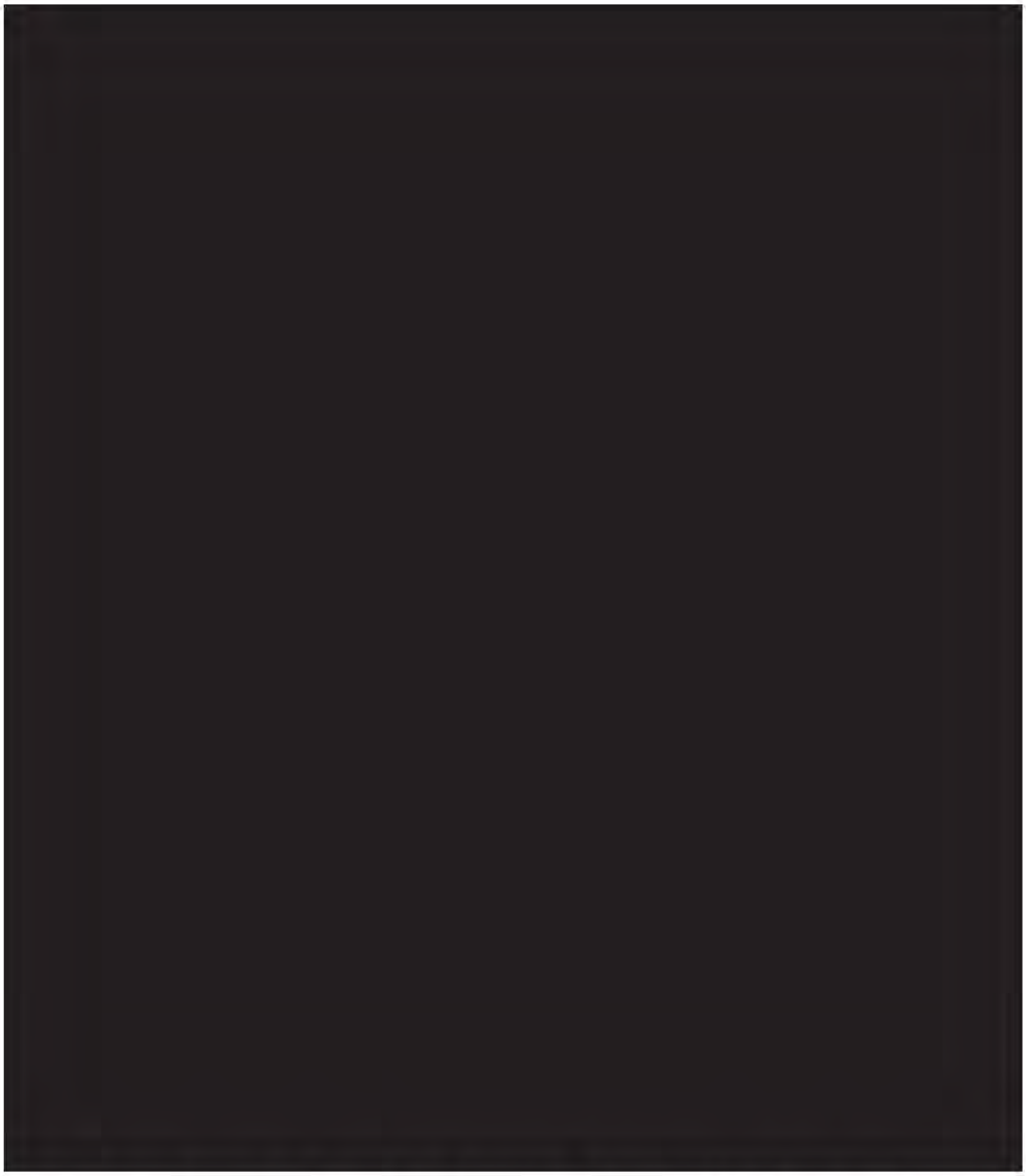
19. Taro's ANDA describes Taro's Manufacturing Process in detail.

20. The Manufacture section of Taro's ANDA (3.2.P.3) contains a subsection entitled, "Description of manufacturing process and process control" (3.2.P.3.3) which provides narrative and graphical information about the manufacturing process.

21. Section 3.2.P.3.3 contains a "Flow Diagram" that shows a graphical representation of the full manufacturing process for Taro's ANDA Product.

22. The Flow Diagram identifies preparation first of the aqueous phase of Taro's Product followed by preparation of the oil phase of the composition. The final stage of production involves the carefully controlled addition of Carbomer followed by addition of a 5% sodium hydroxide solution to activate the polymer thickening agent.

23. The Flow Diagram is reproduced in full below:



24. In addition to the graphical description, Section 3.2.P.3.3 contains a Narrative Summary of the manufacturing process.

25. The Narrative Summary describes

[redacted]

26. [redacted]

[redacted]

27. [redacted]

[redacted]

28. [redacted]

[redacted]

29. [redacted]

[redacted]

30. Thereafter, water is added to the mixture to arrive at the target weight and the product is packaged in airless pump containers of 30, 60 and 90 gram sizes.

31. As clearly stated in Flow Diagram and the Narrative Summary, Taro does not [redacted] and Carbomer to create a polymer or polymer-based thickening agent, or a multi-component PVB as Plaintiffs assert.

32. Instead, Carbomer is added separate from all other ingredients in a time consuming and carefully managed process as is typical with topical pharmaceutical formulations containing Carbomer.

33. The careful addition of Carbomer is done, in part, to prevent clumping, a problem the an inventor of the '219 Patent represented was a problem with Carbomer formulations in comparison to the A/SA formulations of the alleged invention claimed in the '219 Patent.

II. THE '219 PATENT SPECIFICATION

34. The '219 patent is directed to a method for treating the skin conditions acne vulgaris ("acne") and rosacea using a topical application of a composition comprising dapsone. (*See* '219 patent at Abstract, claim 1).

35. In general, the patent describes an embodiment of compositions including dapsone, a first solubilizing agent, which is diethylene glycol monoethyl ether, optionally at least one second solubilizing agent, a polymeric viscosity builder, and water. (*Id.* at 2:62-67; 3:1-6).

36. The abstract of the '219 patent reads:

> Dapsone and dapsone/adapalene compositions can be useful for treating a variety of dermatological conditions. The compositions of this disclosure include dapsone and/or adapalene in a polymeric viscosity builder. Subject compositions can be adjusted to optimize the dermal delivery profile of dapsone to effectively treat dermatological conditions and improve the efficiency of pharmaceutical products applied to the skin. Use of the polymeric viscosity builder provides compositions with increased concentrations of diethylene glycol monoethyl ether relative to compositions without the polymeric viscosity builder.

37. The Field and Background of the Invention begin with general reference to compositions useful for treating dermatological conditions, with a focus on acne, using dapsone and dapsone/adapalene compositions. (*Id.* at 1:19-2:8).

38. The Background generally discusses challenges associated with the treatment of acne, including the need for trial-and-error in determining the most effective treatment, efficacy being affected by patient compliance with treatment, side effects associated with available treatment and cost.

39. The Background also notes the availability of compositions with multiple-anti-acne agents having stability concerns as well as difficult with manufacture.

40. The inventors conclude the Background by stating there is a "continuing need for compositions and methods used in treatment of a variety of skin conditions, such as acne, in which topical application is potentially effective" and that the compositions and methods of the '219 patent address those needs. (*Id.* at 2:4-8).

41. A person of ordinary skill in the art would have understood from this statement that the inventors were not purporting to solve the foregoing problems, but were offering compositions that were "potentially effective." This conclusion would be confirmed by further reading of the Specification, as discussed below. For example, "treating" or "treatment" is defined in the patent as simply having some positive effect on a skin condition. (*Id.* at 5:22-34).

42. The Summary of the Invention begins with a generic discussion of dermatological issues, including acne and the prior treatments thereof.

43. The summary states a problem with prior dapsone compositions is they cause drying of skin, itching and cracking. (*Id.* at 2:25-28). It states that inclusion of skin emollients and oils in the composition causes "phase separation and precipitation of dapsone." (*Id.* at 2:29-31). It further states that improved compositions would improve treatment options and minimize problems with prior formulations and the compositions of the invention include dapsone solubilized with DGME and optionally include a PVB. Moreover, it states that the compositions can be "adjusted to optimize the dermal delivery profile of dapsone[.]" (*Id.* at 2:44-48).

44. In view of the fact the prior art described dapsone formulations with DGME and a PVB, a person of skill in the art reading this conclusion would not understand the nature of the invention.

45. More specifically, such a person would have noted the complete absence of clinical information of any kind in the patent suggesting improved treatment or reduction in side effects associated with the methods of the invention. Indeed, no clinical information or data was included in the '219 patent or presented during prosecution of the application resulting in the '219 patent.

46. At the conclusion of the Summary, the patent states that use of a PVB reduces yellowing and the particle size of dapsone in formulations, thereby reducing the feeling of grittiness. (*Id.* at 2:54-61). The specification does provide information about yellowing and grittiness, specifically at Figures 1 and 3 (yellowing) and 2 (particle size). The Figures are of very little help, however, as there is no way of discerning the "yellowing" in the images of Figures 1 and 3 and Figure 2 does not include information about the formulations at issue. As such, it is impossible to know what formulations are being compared absent reviewing the prosecution history of the '219 Patent and the parent application. One the formulations distinguished by the inventor included Carbomer and Polysorbate 80.

47. The Detailed Description and Embodiments (the "Detailed Description") begins with two columns focused on general information relating to dermatological conditions, none of which have any obvious pertinence to the invention disclosed. (*Id.* at 3-4). The conclusion of the clinical information defines the term "treating" or "treat" in the context of the invention as previously described, namely by setting a very low bar of efficacy. (*Id.* at 5:22-34).

48. The Detailed Description next generally disclose compositions of the invention, such compositions containing dapsone in the ranges of 5 to 10% w/w, DGME in the range of 10 to 40% w/w and the use of different PVBs, including A/SA and Carbomer. (*Id.* at 5-6). There is no representation that the compositions solve any of the foregoing treatment challenges or have

any particular clinical benefit beyond being dapsone formulations. Instead, a list of embodiments of the invention follows.

49. The first embodiment is extremely broad, covering a composition with dapsone between 3 and 10% w/w, a first solubilizing agent, a second optional solubilizing agent, a PVB and water. (*Id.* 6:65-7:3).

50. Many of the subsequent embodiments refer to this first embodiment, including Embodiment 20 wherein Embodiment 1 is further defined as comprising Carbomer between 0.7 and 1.5% w/w.

51. A specific formulation falling under Embodiment 20 appears in Table 5 wherein compositions contemplated for use according to the invention are disclosed. The composition includes 7.5% w/w dapsone, DGME and 1% w/w Carbomer.

52. In view of this, and other information in the patent, a person of skill in the art would have understood the Detailed Description was disclosing dapsone compositions having Carbomer as the PVB in 1% w/w concentration. The claims of the patent, however, do not encompass such compositions.

53. The patent discloses many other formulations wherein Carbomer was used in combination with dapsone and/or adapalene. A further example is found, for instance, at Example 1 comparing A/SA with 1% w/w Carbomer and noting a larger crystal size with Carbomer formulations than with A/SA. (*Id.* at 12:55). Tables 1, 2, 5, 6, and 8 also disclose Carbomer containing formulations.

54. As such, a person reading the specification and examining the claims would have understood Carbomer formulations were disclosed as being part of the invention, but not claimed.

55. The '219 Patent does not claim formulations that must have an oil phase, Emulgels, or any excipient commonly used to create an oil phase, including isohexadecane, light mineral oil, Polysorbate 80, and sorbitan monooleate.

56. Whatever role isohexadecane, Polysorbate 80 and sorbitan monooloeate play in Plaintiff's commercial product, such role cannot be attributed to any claim element, including A/SA. Further, such functions are neither required by the claims nor does Almirall have an exclusionary right tied to the use of such excipients.

III. PROSECUTION HISTORY

A. The Parent Application No. 14/082,955

57. The Parent Application was submitted with an original twenty (20) proposed claims. The original proposed claim 1 stated the following:

> A composition comprising dapsone, a first solubilizing agent which is diethylene glycol monoethyl ether, optionally at least one second solubilizing agent, a polymeric viscosity building, and water, wherein the dapsone is preset in the composition at a concentration of about 3% w/w to about 10% w/w.

58. The original proposed dependent claim 10 claimed:

> The composition of claim 1, wherein the polymeric viscosity building comprising an acrylamide/sodium acryloyldimethyl taurate copolymer.

59. And dependent claim 11 and 12 claim the PVB present at a concentration of about 2% w/w to about 6% w/w and a concentration of about 4% w/w respectively.

60. The original proposed dependent claim 14 claims:

> The composition of claim 1, further comprising Carbomer interpolymer type A, carbomer interpolymer type B or Carbomer Homopolymer Type C.

61. In a January 14, 2014 Office Action, the examiner noted the applicants claimed two separate inventions (composition and method) and required the applicant to choose which

invention the applicant wished to have examined. Further, the applicant was required to make an election of a single disclosed species for, among other things, claim 14.

62. In a February 20, 2014, Response to the Restriction Requirement and Election of Species, the applicant elected invention 1 (the composition). Further, the applicant elected carbomer homopolymer type C as the carbomer polymer listed in Claim 14.

63. In the next Office Action dated March 18, 2014, the examiner issued claim rejections as, among other references, being anticipated by both Lathrop and Ahluwalia. Lathrop teaches topical emulsive compositions of dapsone, and claims a composition containing both dapsone and Carbomer. Ahluwalia teaches topical compositions with dapsone and adapalene for the treatment of acne. Ahluwalia teaches exemplary compositions such as 5% w/w dapsone; .1% w/w or .3% w/w adapalene; 25% w/w DGME; 15% w/w propylene glycol; .01% w/w EDTA; .75% w/w Carbopol 980; sodium hydroxide and purified water. The Examiner cited Lubrizol advertising literature for the fact Carbopol 980 is a polymer thickener synonymous with carbomer homopolymer type C. The Examiner noted Ahluwalia taught ranges of dapsone, DGME and a polymeric viscosity builder and concluded the ranges clearly encompass the ranges being claimed by the applicant.

64. In response to the March Office Action, on May 20, 2014, the applicant submitted amended claims limiting, among other things, the polymeric viscosity builder in claim 1 to A/SA and cancelling multiple claims, including claim 14.

65. The applicant went on to argue against the prior rejections and specifically noted the "unexpected advantages" of the claimed composition in providing improved aesthetics and noted the particle size improvement using A/SA in comparison to Carbomer. The applicant specifically stated and included in bold "the composition comprising [A/SA] thickener has

unexpected advantages over a composition where the thickener/viscosity builder in Carbomer homopolymer type C."

66. On June 5, 2014, the Examiner again rejected multiple claims as being obvious and unpatentable over the prior art. The Examiner further discussed the applicant's claim of "unexpected advantages." The Examiner noted the tested formulations cited by the applicant were not commensurate in scope with the claims presented, and further found "a showing of unexpected results must necessarily be accompanied by a clear indication of what the skilled artisan would have expected, as well as a clear showing of how the claimed invention exceed such expectation so as to provide properties or results that were unexpected, unobvious and of statistical and practical significance" which the applicant had not done.

67. In response to another rejection, on February 2, 2015, the applicant submitted a declaration from Kevin S. Warner, one of the co-inventors of the patent application stating: "Based on the unexpected observation of Carbopol 980 incompatibility with 40% DGME, the thickener was changed from Carbopol 980 to Sepineo P 600 [i.e., A/SA] to mitigate the risk of polymer aggregation in DGME containing formulations." He further stated:

> [We] selected Sepineo P 600 as the gelling agent for our dapsone 7.5% gel formulation. We made this selection due to Sepineo P 600's compatibility with concentrations of DGME greater than 25% and its improvement in dapsone particle size relative to Carbopol 980.

68. This same declaration was submitted again in support of the '219 patent application. Dr. Warner's declaration establishes at the time of the invention a person of skill would have expected Carbopol to be compatible in the formulations of the invention.

69. After the submission of the declaration the applicant further amended and canceled certain claims and responded to the latest rejection. In focusing on unexpected results, the applicant

reiterated the "unexpected results" discussed by the co-inventor in his declaration. They noted undesirable polymer aggregates during formulations studies (using Carbomer) which lead to the utilization of A/SA.

70. The applicant went on to state Sepineo P 600 allowed for higher concentrations of DGME, which were found to be incompatible with Carbomer and that Sepineo P 600 formulations provided smaller particle size as compared to Carbomer formulations that included formulations having Carbopol and Polysorbate 80, which is why Sepineo P 600 was selected as the gelling agent. It was emphasized this result was "entirely unexpected and could not have been predicted" based on the 5% dapsone formulation, which used Carbomer or the prior art formulation.

71. After these repeated references to the unexpected superiority of A/SA over the well-known and previously utilized Carbopol 980, the Examiner issued a notice of allowability.

B. The '219 Patent

72. Originally, all of the claims were rejected as unpatentable over Garrett I in view of Hani, a rejection nearly identical to those made during prosecution of the Parent Application. By way of amendment and response to the office action dated February 18, 2016, the applicants argued the amount of dapsone, the use of Sepineo P 600 as the sole thickening agent in a topical dermatological formulation comprising dapsone and the specific amount of Sepineo P 600 recited in the claims made the claims distinct from the prior art. Applicants claimed the combination of Sepineo P 600 with dapsone was not suggested in either Garrett or Hani:

> First, Garrett teaches that a preferred composition comprises about 5% w/w dapsone wherein about 0.85% w/w carbopol 980 is used as a thickening agent. The instant claims recite new formulations of dapsone wherein the active ingredient is about 7.5% dapsone and an entirely new thickening agent is employed. The new formulation of the instant claims does not include a carbomer such as Carbopol®, but instead utilizes as [A/SA], also known as Sepineo™ P 600, and at a much higher concentration (about 2% to about 6% w/w) as compared to what Garrett teaches for its thickening agent.

73. In this response, applicants were absolutely clear: "the formulation of the instant claims does not include a carbomer such as Carbopol® . . . ." As discussed below, the examiner withdrew its rejection based on Garrett I and Hani.

74. In this response the applicant also included the declaration of Kevin Warner previously submitted in connection with prosecution of the Parent Application. In arguing the unexpected nature of the invention, the applicants argued, for example, Sepineo P 600 was found to be a more robust thickener than Carbomer, which was used in the prior 5% dapsone gel formulations. Applicant further argued Sepineo P 600 allowed for higher concentrations of DGME than with Carbomer and resulted in reduced particle size as compared to Carbomer formulations, including formulations of Carbomer and Polysorbate 80. Applicants concluded: "Sepineo P 600 was therefore selected as the gelling agent for the 7.5% w/w dapsone formulation of the instant claims."

75. The Examiner determined the Warner Application provided enough support for the unexpected results of A/SA over Carbomer formulations and the rejections for obviousness were withdrawn. It was noted by the Examiner in the prosecution of both the '926 and the '219 patents that the testing done with Sepineo and Carbopol did not use the same concentrations, but in this instance, the Examiner noted the inventor's explanation that higher concentrations of Carbopol 980 would have results in even greater aggregation. The Examiner went on to note:

> The Warner Declaration . . . provides clear evidence that the improved properties of the Applicant's claimed 7.5% w/w dapsone formulation . . . ***yields directly from the selection of the [A/SA] copolymer as the polymeric thickener of the formulation***.

IV. LEVEL OF ORDINARY SKILL IN THE ART

76. A POSA for the '219 patent would have had at least a bachelor's degree, and more likely a master's or Ph.D., in pharmaceutical sciences or a related discipline; a minimum of three

years' training or experience; and an understanding of drug-development. The more experience he or she had, the less formal education he or she would have needed. The POSA would have knowledge of topical dosage forms and formulations, including those containing dapsone, as well as thickening agents and other common excipients. He or she would have been aware of the prior art commercial and patent-protected dapsone gel formulations. Lastly, the POSA would have had at least a basic understanding of, or collaborated with others having, expertise in treating acne and/or rosacea.

V. NON-INFRINGEMENT OF THE '219 PATENT

A. Almirall's Infringement Claims Are Barred

1. Prosecution History Estoppel

77. Almirall's Infringement claims are barred by prosecution history estoppel.

78. During prosecution of Application No. 14/082,955 ("the Parent Application"), in response to a prior art rejection, the applicant amended the claims to recite "about 2% w/w to about 6% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer . . ."

79. Because the narrowing amendment limiting the PVB to A/SA was made for reasons related to patentability, a POSA would have understood that the Applicant surrendered all subject matter between the original claim limitation and the amended claim limitation.

80. A POSA would not have understood that a PVB comprising Carbomer Homopolymer Type C was unforeseeable because the prior art relied upon by the Examiner at the time of the amendment, e.g., Garrett I, taught topical dapsone compositions comprising, among other things, Carbopol 980, e.g., Carbomer Homopolymer Type C.[1]

[1] To the extent Almirall argues the amendment does not establish estoppel because multi-component PVBs were purportedly not foreseeable, that argument fails. Garrett I expressly teaches

81. Additionally, in response to the rejections, the applicant specifically noted the "unexpected advantages" of the claimed composition in providing improved aesthetics and noted the particle size improvement using A/SA in comparison to Carbomer Homopolymer Type C.

82. In response to another rejection, the applicant submitted a declaration from Kevin S. Warner, one of the co-inventors of the patent application stating that the applicant selected Sepineo P 600 due to its improvement in dapsone particle size relative to Carbopol 980. This same declaration was submitted again in support of the '219 patent application.

83. A POSA, reading the statements from the prosecution history, would have understood that the applicant had clearly and unmistakably surrendered the right to claim any carbomer-based PVB component as an equivalent to the claimed PVB comprising A/SA.

84. A POSA would not have interpreted the amendment replacing the close-ended "consisting of [A/SA] copolymer" language with the open-ended "comprising [A/SA] copolymer" language during prosecution of the '219 patent as a signal that the inventors were recapturing the surrendered carbomer or carbomer-based PVB as an equivalent to the claimed PVB.

85. For example, when the inventors replaced the "consisting of" language with the "comprising" language during prosecution of the '219 patent, the applicant stated that relevant arguments made when the claims recited "consisting of" still supported the patentability of the amended pending claims reciting "comprising."

86. Accordingly, a POSA, reading the statements from the prosecution history of the '219 patent, would have understood that the applicant had clearly and unmistakably surrendered

---

the composition described therein may be an "emulsion" containing, in addition to ***Carbomer, mineral oil, sorbitan monooleate and polysorbate 60***, e.g., a multi-component PVB under Almirall's infringement theory. (Garrett I at 5:15-26).

the right to claim any carbomer-based PVB component as an equivalent to the claimed PVB comprising A/SA.

2. Dedication To The Public

87. Almirall's Infringement claims are barred by the public dedication doctrine.

88. The compositions in multiple embodiments listed in the '219 patent include Carbomer. In some embodiments, Carbomer is present at a concentration of about 0.7% w/w to about 1.5% w/w. In other embodiments, Carbomer is present at a concentration of about 0.85% w/w to about 1.0% w/w. This disclosure alone, when read in connection with the claims, would lead a POSA to believe Carbomer, in concentrations from 0.7 w/w to 1.5% w/w or 0.85% w/w to about 1.0% w/w had been explicitly disclosed by the patentee and not claimed.

89. Specific examples of Carbomer containing embodiments include 19, 20, 21, 48, 49, 50. Further, Example 2/Table 2, Example 4/Table 5, Example 4/Table 6 and Example 6 /Table 8 all explicitly disclose Carbomer in combination with dapsone and are stated to be consistent with the scope of the invention.

90. A POSA reviewing the specification would understand Carbopol 980 was dedicated to the public through the applicant's decision to repeatedly disclose but not claim Carbopol 980.

91. Moreover, during prosecution of the Parent Application, the applicant attempted to claim Carbomer and then chose to cancel that claim in direct response to a rejection by the Examiner.

92. Based on the applicant's original attempt to claim carbomer homopolymer type C and its subsequent cancelation of that claim, a POSA would understand that Carbomer was disclosed but was not claimed in the invention and could not be claimed by the applicant.

3. Ensnarement

93. Almirall's Infringement claims are barred by the doctrine of ensnarement.

94. A hypothetical claim for purposes of an ensnarement analysis would read as follows:

> A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
> about [[2]]1% w/w to about 6% w/w of a polymeric viscosity builder comprising ~~acrylamide/sodium acryloyldimethyl taurate copolymer~~ Carbomer homopolymer type C; and
> water;
> wherein the topical pharmaceutical composition does not comprise adapalene.

95. Alternatively, under Almirall's infringement theory, a hypothetical claim for purposes of an ensnarement analysis would read as follows:

> A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
> about 2 % w/w to about 6% w/w of a polymeric viscosity builder comprising ~~acrylamide/sodium acryloyldimethyl taurate copolymer~~ Carbomer homopolymer type C; and
> water;
> wherein the topical pharmaceutical composition does not comprise adapalene.

96. As demonstrated by the facts outlined in Section III below, the hypothetical claim analysis confirms Almirall's equivalents theory impermissibly ensnares the prior art.

B. Taro's Product Does Not Infringe Claim 1 of the '219 Patent Under the Doctrine of Equivalents

1. One Percent of a PVB is Not Equivalent to Two to Six Percent of a PVB

97. Taro's ANDA Product comprises 1% w/w of a PVB comprising Carbomer Homopolymer Type C. Carbomer is the thickening agent in Taro's Product. Therefore, Taro's ANDA Product does not meet claim element i.e., "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA] copolymer."

98. A POSA would not conclude that 1% w/w is equivalent to "about 2% w/w to about 6% w/w." Indeed, during prosecution of the Parent Application, the applicant amended the claims to specifically recite "about 2% w/w to about 6% w/w."

99. Moreover, during prosecution, the applicants conceded the difference between at least 0.85% w/w and about 2% w/w and 6% w/w was significant.

2. Carbomer Is Not Equivalent to A/SA or Sepineo P 600

100. A/SA is not insubstantially different from Carbomer. A/SA has a completely different chemical structure compared to Carbomer. Additionally, A/SA is a "copolymer", meaning it consist of two different polymers cross-linked. (Carbomer is a single polymer).

101. Carbomer is a cross-linked polyacrylic acid resin. To dissolve Carbomer in water a neutralizing agent, such as a sodium hydroxide solution, must be added to adjust pH.

102. Mixing Carbomer must be carefully controlled to avoid clumping and/or precipitation of the polymer. Once the Carbomer is reconstituted, it is carefully added to the remaining excipients.

103. At the time of the invention, and now, Seppic marketed the Sepineo P 600 product as being simpler than other polymeric thickening agents because (1) it was simpler to mix; and (2) did not require neutralization.

104. Moreover, the differences in manufacturing between Taro's Product and Aczone® 7.5% Gel are significant. Unlike Taro's process, Aczone® 7.5% Gel is manufactured by

combining dapsone, methylparaben and DGME, mixing Sepineo P600 with water and then combining the two and mixing.

105. The differences in manufacturing between Taro's Product and Aczone® 7.5% Gel are not insubstantial.

106. The Warner Declaration submitted in connection with prosecution of both the Parent Application and the Divisional Application unequivocally stated the A/SA copolymer emulsion was selected over Carbomer because Carbomer was seen to precipitate at higher DGME concentrations and it was concluded the A/SA polymer was more robust.

107. In short, the inventors were issued a patent after making the argument A/SA formulations were different from Carbomer formulations, including those containing Carbomer and other excipients like Polysorbate 80, and that Carbomer formulations were unexpectedly not as robust. Both during prosecution of the Divisional Application and in the NDA, the benefits of A/SA (and Sepineo P 600) over Carbopol were repeatedly argued.

108. Carbomer is not insubstantially different from a PVB comprising A/SA, it does not function in the same way and does not render the same results.

3. The Comparisons of Clinical and Non-Clinical Attributes of Aczone® 7.5% Gel and Taro's Product Do Not Evidence an Insubstantial Difference Between Taro's Thickening Agent and A/SA or Sepineo P 600

109. Almirall seeks to show equivalency between Taro's thickening agent and Sepineo P 600 through clinical and non-clinical comparisons between Aczone® 7.5% Gel and Taro's Product characteristics. These comparisons are flawed based on Almirall's incorrect identification of the thickening agent in Taro's Product.

110. Comparison of the rheological profiles of Aczone® 7.5% Gel and Taro's Product are of little value. For example, the claims of the '219 patent do not require a specific rheological

profile. A person of skill in the art would not know the rheological profile of any of the tens of embodiments disclosed in the patent. A skilled person would have known the inventors were not claiming any specific rheological profile and therefore Almirall's reliance on this information is misplaced. The same is true of other data Almirall relies on, including solubility, particle size, and release rates.

111. The '219 patent includes absolutely no disclosure, not in the patent itself and none was submitted during prosecution, to lead a skilled artisan to believe specific characteristics of solubility, particle size and release rates were being claimed as a benefit of the invention.

112. In short, any similarity of characteristics between Taro's and Almirall's products can be achieved in any number of ways that have nothing to do with the '219 patent claims and, specifically, A/SA.

C. Taro's Does Not Infringe Dependent Claims 2, 4 and 5 of the '219 Patent

113. Taro's Product does not meet all the claim limitations of the only independent claim, either literally or under the doctrine of equivalents. For this reason, Taro does not infringe the asserted dependent claims 2, 4 and 5.

VI. THE ASSERTED CLAIMS OF THE '219 PATENT ARE INVALID UNDER 35 U.S.C. § 103

114. Garrett I renders obvious all of the Asserted Claims in view of Bonacucina and/or Nadau-Fourcade.

A. Scope and Content of the Prior Art

1. Osborne I

115. Osborne I discloses topical formulations of dapsone for the treatment of dermatological conditions such as acne. Disclosed formulations include compositions comprising 0.5% to 10% w/w of dapsone. In a preferred embodiment, the composition further comprises

DGME "which allows for an optimized ratio of microparticulate drug to dissolve drug." According to Osborne I, this ratio "determines the amount of drug delivered, compared to the amount of drug retained in or above the stratum corneum to function in the supracorneum domain." Furthermore, the "system of dapsone and [DGME] may include purified water combined with 'CARBOPOL®' gelling polymer, methylparaben, propylparaben, titanium dioxide, BHA, and a caustic material to neutralize the 'CARBOPOL®'." Osborne I also discloses polymer thickeners (i.e., PVBs, gelling agents, or thickening agents), including hydrophilic or hydroalcoholic gelling agents such as CARBOPOL®, for use in dapsone topical compositions.

2. Garrett I

116. Garrett I discloses treating rosacea patients with topical dapsone formulations with a pharmaceutically acceptable carrier. Garrett I also discloses the known use of topical dapsone formulations for acne treatment. It specifically discloses topical compositions comprising between 0.5% and 10% of dapsone. In a "preferred embodiment" the topical composition also comprises a thickening agent, water, a high-boiling, nonionic organic solvent, a preservative, dapsone in a microparticulate and dissolved state, and a base solution. In another embodiment, the topical composition comprises about 0.5% to 4.0% PVB (i.e., carbomer) and about 0.5% to 10% of dapsone that exists in both a dissolved state and a microparticulate state. Furthermore, Garrett I discloses that compositions of the invention have a glycol ether, such as DGME, present in about 20% to 40% w/w.

117. In one particular preferred embodiment, the composition comprises about 5% dapsone, about 0.85% PVB (carbomer), about 25% DGME, about 0.2% methylparaben, about 0.2% sodium hydroxide, and about 68.75% purified water. Garrett I further explains that the relative percentages for each of the reagents used in the pharmaceutical composition "may vary

depending upon the desired strength of the target formulation, gel viscosity, and the desired ratio of microparticulate to dissolved dapsone."

3. Lathrop

118. Lathrop teaches that dapsone is an anti-inflammatory agent that has been used to treat skin diseases characterized by the abnormal infiltration of neutrophils, such as dermatitis herpetiformis, linear IgA dermatosis, pustular psoriasis, pyoderma gangrenosum, acne vulgaris, and Sweet's Syndrome. Specifically, it discloses a topical emulsive composition comprising dapsone. Even more specifically, it discloses that the concentration of dapsone "may be any amount that provides effective anti-bacterial and/or anti-inflammatory properties to the emulsive composition," but that "especially preferred embodiments may be such [dapsone] percentages as 1, 2, 5 and 7.5."

119. Lathrop further teaches emulsive compositions comprising the following components in addition to dapsone: a solvation medium for dapsone, water, and a gelation or thickening agent. In particular, Lathrop teaches that organic solvents such as DGME are suitable for use as the solvation medium. The disclosed range for solvation mediums like DGME are "preferably about 5 percent to about 40 percent" and are such that the medium should "completely dissolve [d]apsone." In Example 9, Lathrop discloses the use of 25% w/w DGME with 5.0% w/w dapsone.

4. Bonacucina

120. Bonacucina specifically studied the rheological properties of Sepineo P 600 ("Sepineo"), the PVB referenced in the '219 patent that comprises acrylamide/sodium acryloyldimethyl taurate (A/SA). Sepineo is a concentrated droplet dispersion of A/SA (a viscous liquid at room temperature) in isohexadecane and polysorbate 80.

121. At the time of Bonacucina, there was interest in the use of novel polymers with complex functions as emulsifiers and thickeners. The gelling capacity of those compounds allows for formulation of stable emulsions and creams by decreasing the surface and interfacial tension while at the same time increasing the viscosity of the aqueous phase.

Bonacucina studied the self-gelling properties of Sepineo, both alone and as dispersing phase for the preparation of oil/water emulsion gels. When water is added to Sepineo, the polymer droplets disappear because the polymer molecules interact with it strongly to instantly form a stable semisolid system. The possibility of obtaining stiff and stable gelled phases with this polymer makes it a good candidate for the formulation of emulsion gels and thus Bonacucina went on to study the rheological properties of Sepineo.

Bonacucina teaches that Sepineo thickens and gels well, a property that depends strongly on polymer concentration. Concentration increases from 0.5% to 5% w/w of Sepineo modified the viscoelastic properties of the samples, changing the typical behavior of a concentrated non-entangled solution to that of a "gel-like" sample. Bonacucina concludes that Sepineo is a "prime candidate for use in the formulation of gels and emulsion gels" suitable for topical administration.

5. Nadau-Fourcade

122. Nadau-Fourcade discloses topical pharmaceutical compositions containing a water-sensitive active ingredient dissolved in a physiologically acceptable medium for use in treating, *inter alia*, common acne and acne rosacea. It recognizes that "[m]any active agents have the difficulty of being very sparingly soluble in the cosmetic or pharmaceutical solvents commonly used, especially water, and/or of being sensitive to an aqueous, oxidizing environment." This was a known problem in formulating dapsone into topical compositions. Nadau-Fourcade further notes "[t]his water sensitivity may lead to . . . crystallization of the initially dissolved active agent. . . . [and] thus limits their formulation in topically applied cosmetic or dermatological compositions."

Thus, the problem that must be solved, according to Nadau-Fourcade is "that of stabilizing the water-sensitive active agent and the composition despite the presence of water in the composition." To address this problem, Nadau-Fourcade discloses "preferred embodiment[s]" of dermatological formulations that contain hydrophilic-phase gelling agents such as Carbopol 980 and Sepineo P 600 in concentrations of ranging from 0.01% w/w to 5% w/w.

6. Guo

123. Guo discloses compositions comprising active agents for topical administration. More specifically, it discloses the use of dapsone as an active ingredient in the disclosed formulations. It also teaches the use of about 4% w/w to about 6% w/w of a PVB comprising A/SA in these same topical formulations. It also recognizes that the amount of PVB used "will depend upon the hydrophobic and hydrophilic phases, intended use, intended storage and use conditions, and other optional ingredients which may be used within the composition . . . ."

7. Louis

124. Louis discloses topical compositions for treating acne comprising active agents and at least one gelling agent. Louis specifically discloses PVBs comprising A/SA in an amount "preferably ranging from 0.05 to 6% by weight" in topical compositions for use in treating acne.

8. Mallard

125. Mallard discloses that PVBs comprising A/SA are suitable as gelling agents in topical formulations used to treat acne. More specifically, it discloses topical anti-acne compositions comprising PVBs in an amount "preferentially ranging from 0.15% to 5%" w/w. In one particular embodiment for acne treatment, the amount of the PVB comprising A/SA is 4.0% w/w.

9. SenGupta

126. SenGupta teaches the use of PVBs comprising acrylamide-based polymers in amounts ranging from .05% to 5% w/w in topical cleansers that contain dapsone as an anti-acne agent.

10. Hani

127. Hani discloses that A/SA is a suitable thickener for use in topical personal care compositions.

11. Aczone PI

128. The Aczone PI discloses that Aczone (dapsone) gel 5% w/w was approved by the FDA for use in the topical treatment of acne vulgaris. It also discloses twice daily topical use of the 5% w/w dapsone formulation for use in acne patients. *Id.* at Indications and Usage, Dosage and Administration.

129. Furthermore, the 5% w/w dapsone topical formulation comprises a gel of the PVB carbomer 980, DGME, methylparaben, sodium hydroxide, and purified water. *Id.* at Description.

12. Ahlualia

130. Ahluwalia teaches that acne was known as the most common skin disease affecting adolescents and young adults, with patient populations often exhibiting permanent scarring and seriously psychological repercussions. It further teaches that dapsone was known in the art as a treatment for acne and that compositions comprising dapsone in topical form could be used to treat patients with acne vulgaris or rosacea. Ahluwalia also references the "gritty texture," limited bioavailability, and required twice daily dosing of topical gel dapsone formulations.

13. Lott

131. Lott is a review article synthesizing several studies for patient adherence to acne medication. Lott describes acne as a chronic disease often requiring the use of medications for

extended period of time. In general, adherence to treatment decreases over time in patients with chronic diseases and adherence to topical medications is poor compared to adherence to oral medications. Lott concludes that patients taking medications requiring less frequent dosing had better adherence, and medication adherence correlated with better health status among acne patients.

14. Lubrizol Technical Data Sheet

132. The Lubrizol Technical Data Sheet teaches that Carbopol® polymers can be used to develop semisolid and oral liquid formulations with a wide range of flow and rheological properties. It further discloses that Carbopol® polymers must first be dispersed in water and neutralized with a base to form a gel.

15. Lubrizol Pharmaceutical Bulletin

133. The Lubrizol Pharmaceutical Bulletin teaches that Carbopol® exhibit excellent efficiency at low concentrations of 0.1-3 wt. %.

16. Epiduo™ Label

134. Epiduo™ (adapalene and benzoyl peroxide) Gel 0.1%/2.5% was approved in 2008 for the treatment of acne vulgaris. Epiduo™ gel contains the following inactive ingredients: A/SA copolymer, docusate sodium, edetate disodium, glycerin, isohexadecane, poloxamer 124, polysorbate 80, propylene glycol, purified water, and sorbitan oleate.

17. Osborne IV

135. Osborne IV discloses that DGME is used in hundreds of cosmetic products, as well as Allergan's FDA-approved 5% dapsone topical gel.

18. Orsoni

136. Orsoni teaches that the use of acrylamide copolymer in a topical composition will reduce the particle size of the active ingredients. Specifically, Orsoni teaches adapalene/benzoyl

peroxide compositions using carbomers as thickening agents exhibited "sedimentation" and "heterogeneity of the dispersion" due to the depolymerization of the thickening agent. When A/SA copolymer was used as the thickening agent, Orsoni found "it possible to obtain an optimum particle size and uniform dispersion . . . while at the same time ensuring the physical stability of the product." In particular, Orsoni teaches that using the A/SA copolymer results in a "better dispersion of the particles" where preferably 90%, in numerical terms, have a particle size less than 25 μm and 99%, in numerical terms, have a diameter of less than 100 μm." A preferred copolymer according to Orsoni is 4% w/w Simulgel 600®, which is equivalent to Sepineo P 600®.

19. Sepineo™ P 600 Brochure

137. The Sepineo™ P 600 Brochure states that Sepineo™ P 600 as "thickening-emulsifying polymer for topical applications" and describes its numerous benefits. Specifically, it describes how Sepineo™ P600 is provided in a "[r]eady to use fluid form" and is [v]ery easy to handle at room temperature." It requires "[n]o neutralization [or] rehydration." In the presence of water, "SEPINEO™ P 600 reverses and the polymer network deploys instantly, forming a perfectly stable gel in a few seconds." Sepineo™ P 600 Brochure. It further describes that Sepineo™ P600 gels are "stable," "have a perfectly uniform appearance" and are "very pleasant for the touch and spread on the skin." The brochure states that Sepineo™ P600 is compatible with a wide variety of solvents, including water, ethanol, acetone, glycerin, glycols, polar and non-polar oils, vegetable oils, silicone oils, and esters; and can tolerate a wide pH and temperature ranges.

B. It Would Have Been Obvious to a POSA That Dapsone Was Effective to Treat Acne or Rosacea

138. By 2012, dapsone was well known as an effective antibiotic and anti-inflammatory, as well an effective treatment for acne vulgaris and rosacea.

139. Garrett I discloses that in a clinical trial, twice-daily dapsone was more effective than vehicle in treating rosacea. Garrett also discloses that ACZONE® Gel, 5% is an effective acne treatment.

140. Accordingly, it would have been obvious to a POSA to use dapsone in a composition for use in a method of treating acne or rosacea in view of Garrett I.

C. It Would Have Been Obvious to a POSA to That Dapsone Concentrations of About 7.5% Would be Effective to Treat Acne Vulgaris

141. Garrett I discloses topical compositions comprising between 0.5% and 10% of dapsone. In one particular preferred embodiment, Garrett I teaches the composition comprises about 5% dapsone. Thus, Garrett discloses ranges that overlap with the claimed dapsone concentration.

142. Nothing in the specification or prosecution history provides evidence that a concentration of 7.5% dapsone is critical. For example, the '219 patent's specification asserts a formulation will be effective if dapsone is present at a concentrations, among others, ranging from 1% w/w to 10% w/w. Despite the fact that concentrations of dapsone vary greatly across embodiments, all embodiments are stated to be "effective in treating dermatological conditions in a subject in need thereof."

143. The prosecution history is similarly devoid of any evidence of criticality. For example, Allergan never argued during prosecution that a formulation containing 7.5% dapsone performed surprisingly better than the prior art. Commercial embodiments containing 7.5% dapsone have not been shown to be more efficacious thatn 5% dapsone formulations.

144. Moreover, there is no disclosure in the '219 patent's specification or prosecution history that once-daily dosing was achieved, attempted or even contemplated as of the alleged priority date.

145. Thus, since Garrett I discloses dapsone concentrations that overlap with the claimed dapsone concentration, and nothing in the specification or prosecution history shows that the claimed concentration is critical, it would have been obvious to a POSA that 7.5% dapsone could be used in a composition for use in a method of treating acne or rosacea.

D. It Would Have Been Obvous to a POSA to Increase DGME Concentration Above 25% w/w

146. The prior art disclosed dispone solubility increased with increased DGME concentrations. It would have been understood by persons of skill in the art the solubilized portion of dapsone in a formulation would substantially contribute to any beneficial effect on acne vulgaris.

147. Garrett I discloses that compositions of the invention have a glycol ether, such as DGME, present in about 20% to 40% w/w. Thus, Garrett discloses ranges that overlap with the claimed DGME concentration.

148. Nothing in the specification or prosecution history indicates that a concentration of DGME ranging from 30% w/w to 40% w/w or 30% w/w is critical. For example, the '219 patent's specification asserts a formulation will be effective if "[DGME] is present at a concentration of about 10% w/w to about 40% w/w, about 20% w/w to about 30% w/w, or about 25%." Despite the fact that the concentration of DGME in multiple embodiments fall outside the claimed range, all embodiments are stated to be "effective in treating dermatological conditions in a subject in need thereof."

149. Moreover, at the time of the alleged priority date of the '219 patent, DGME was a well-known solvent for poorly soluble compounds, such as dapsone. Using higher than 25% w/w DGME was part of a routine formulation optimization. It would have been obvious to the POSA to increase the DGME concentration above 25% when dapsone concentration is increased from

5% to 7.5% w/w. Indeed, DGME has been used at concentrations up to 50% in a topical gel. Thus, a POSA would not have been dissuaded from selecting and using concentrations of DGME above 25% w/w.

150. Thus, since Garrett I discloses DGME concentrations that overlap with the claimed DGME concentration, and nothing in the specification or prosecution history shows that the claimed concentration is critical, it would have been obvious to a POSA to select a concentration of DGME of about 30% to about 40% in a dapsone composition for use in a method of treating acne or rosacea.

E. It Would Have Been Obvious to a POSA to Select a Concentration of About 2% to About 6% of a Polymeric Viscosity Builder Comprising A/SA

151. At the time of the alleged priority date, existing Carbopol-based dapsone gel formulations were known to be "gritty with visible drug substance particles present." Therefore, a POSA looking to formulate a dapsone gel with improved aesthetics would have been motivated to look for alternative thickening agents.

1. Bonacucina

152. At the time of Bonacucina, there was interest in the use of novel polymers with complex functions as emulsifiers and thickeners.

153. Bonacucina studied the self-gelling properties of Sepineo™ P 600, both alone and as dispersing phase for the preparation of oil/water emulsion gels. When water is added to Sepineo™ P 600, the polymer droplets disappear because the polymer molecules interact with it strongly to instantly form a stable semisolid system.

154. A POSA would have known from Bonacucina that Sepineo™ P 600 has "self-gelling and thickening properties and the ability to emulsify oily phases, which make it easy to use in the formulation of gels and o/w emulsion gels."

155. A POSA would have understood that Sepineo™ P 600, unlike Carbopol, does not require neutralization to form a gel.

156. A POSA would have further realized the benefit of reducing the number of steps in the manufacturing process by not having to neutralize the formulation.

157. Thus, based on the teachings of Bonacucina, a POSA would have been motivated to substitute Carbopol® 980 taught by Garrett I for the A/SA copolymer taught in Bonacucina.

158. Bonacucina prepared A/SA copolymer gels with polymer concentrations from 0.5% to 5% w/w, and gels made with 3% to 5% w/w A/SA copolymer were characterized by "weak polymer-polymer interactions, an advantageous characteristic for topical administration, as the sample is thus easier to rub into the skin."

159. Thus, a POSA would have been motivated to use gels with 3 to 5% w/w of A/SA copolymer. Because this concentration overlaps with the claimed range, a POSA would have found the claimed range of about 2% w/w to about 6% w/w of a PVB comprising A/SA obvious.[2]

2. Nadau-Fourcade

160. Nadau-Fourcade discloses topical pharmaceutical compositions containing a water-sensitive active ingredient dissolved in a physiologically acceptable medium for use in treating, inter alia, common acne and acne rosacea.

161. It recognizes that "[m]any active agents have the difficulty of being very sparingly soluble in the cosmetic or pharmaceutical solvents commonly used, especially water, and/or of being sensitive to an aqueous, oxidizing environment."

[2] Additionally, Sepineo™ P 600, was listed in the FDA's Inactive Ingredients database as early as 2011, with a maximum potency of 4%. Moreover, Simulgel™ PHA 600, an equivalent product to Sepineo™ P 600 was used in Epiduo® Gel (adapalene 0.1%/benzoyl peroxide 2.5%) for treatment of acne vulgaris.

162. This was a known problem in formulating dapsone into topical compositions. Nadau-Fourcade further notes "[t]his water sensitivity may lead to . . . crystallization of the initially dissolved active agent. . . . [and] thus limits their formulation in topically applied cosmetic or dermatological compositions." Thus, the problem that must be solved, according to Nadau-Fourcade is "that of stabilizing the water-sensitive active agent and the composition despite the presence of water in the c omposition."

163. To address this problem, Nadau-Fourcade discloses "preferred embodiment[s]" of dermatological formulations that contain hydrophilic-phase gelling agents such as Carbopol 980 and Sepineo P 600 in concentrations of ranging from 0.01% w/w to 5% w/w.

164. A POSA would have had a reason to substitute Sepineo P 600 (i.e., A/SA copolymer), as taught in Nadau-Fourcade, for Carbopol®, the preferred thickening agent taught in Garrett I.

165. Both Garrett I and Nadau-Fourcade disclose topical compositions containing water insoluble APIs. Garrett I states that "[p]olymer thickeners that may be used include those known to one skilled in the art, such as hydrophilic and hydroalcoholic gelling agents frequently used in the cosmetic and pharmaceutical industries."

166. Nadau-Fourcade discloses preferable hydrophilic-phase gelling agents such as Carbopol® 980 or 981, and Sepineo P 600 (or Simulgel 600 PHA). Thus, a POSA would have been motivated to look to Nadau-Fourcade for additional thickening agents for water-insoluble drugs like dapsone.

167. Nadau-Fourcade discloses that the gelling agent is preferably in an amount of 0.01% to 5%. Moreover, a POSA would have understood that the concentration of A/SA copolymer could be adjusted with predictability.

168. Thus, a POSA would have been motivated to use gels with 0.01% to 5% w/w of A/SA copolymer. Because this concentration overlaps with the claimed range, a POSA would have found the claimed range of about 2% w/w to about 6% w/w of a PVB comprising A/SA obvious.[3]

F. It Would Have Been Obvious to a POSA to Have Sought to Use Dapsone in the Absence of Adapalene

169. As of 2012, Dapsone was known to be an effective treatment for skin conditions as a monotherapy. In fact, dapsone was said to be an established acne treatment.

170. The prior art, including Garrett I, taught that topical dapsone compositions did not require the presence of adapalene. And the prior art FDA-approved Aczone Gel 5% is a dapsone monotherapy and had been determined by FDA to be safe and effective as a monotherapy. Thus, a POSA would have been motivated, with a reasonable expectation of success, to prepare a topical dapsone composition that does not contain adapalene.

171. As of 2012, a POSA seeking to develop an improved acne treatment would not have pursued a combination product containing two or more pharmaceutical agents in order to address multiple cause of acne in a single formulation.

172. In seeking to develop an improved dapsone formulation, a POSA would not have been motivated to develop a combination drug product by combining dapsone with another agent (adapalene), but instead would have sought to increase the concentration of the dapsone in the gel.

173. Moreover, nothing in the claimed method prevents the combined use of dapsone with adapalene. The method simply states that the "the topical pharmaceutical ***composition*** does not comprise adapalene," and leaves open the possibility of topically applying a topical

[3] Additionally, Sepineo™ P 600, was listed in the FDA's Inactive Ingredients database as early as 2011, with a maximum potency of 4%. Moreover, Simulgel™ PHA 600, an equivalent product to Sepineo™ P 600 was used in Epiduo® Gel (adapalene 0.1%/benzoyl peroxide 2.5%) for treatment of acne vulgaris.

pharmaceutical containing dapsone in combination with another topical pharmaceutical composition containing adapalene.

G. There Are No Objective Indicia that Support the Non-Obviousness of the Asserted Claims

1. The Statements and Evidence in the Warner Declaration Do Not Show Unexpected Results of the Claimed Formulation

174. The only unexpected observation Dr. Warner claims in his declaration is the incompatibility of Carbopol® 980 with 40% w/w DGME. Dr. Warner did not argue that Sepineo™ P 600's compatibility with 40% w/w DGME was unexpected. Carbopol is not recited in any of the claims of the '219 patent. Thus, Dr. Warner's unexpected incompatibility of Carbopol with DGME is not an unexpected result of the composition claimed in the '219 patent.

175. Moreover, U.S. Provisional Application No. 61/728,403 ("the '403 application"), to which the '219 patent claims priority to states that Carbopol 980 with 30-35% Transcutol, e.g., 30-35% DGME, forms a "clear viscous gel," similar to the "white viscous gel" formed with Sepineo P 600 and 30-40% Transcutol. Therefore, a POSA reading the '403 application, which is incorporated by reference in the '219 patent's specification in its entirety would have understood that Carbopol 980 is compatible with 30-35% DGME.

2. Achievement of a Once-Daily Treatment Using 7.5% Dapsone Is Not Commensurate in Scope with the Asserted Claims

176. As of 2012, it was known that increasing concentrations of active ingredients could lead to other effective treatments. Therefore, it is not surprising that increasing the concentration of dapsone from 5% to 7.5% yielded a once-daily product.

177. Even assuming it would have been surprising to a POSA, such evidence of unexpected results is not commensurate in scope with and/or lacks a nexus to the claims because the claims are not limited to once-daily treatment.

3. Any Industry Praise Lacks Nexus to Any Element of the Asserted Claims

178. Once-daily dosing is not an element of the claims. Therefore, any industry praise associated with ACZONE® Gel, 7.5%'s once-daily treatment lacks nexus to any element of the Asserted Claims.

VII. THE ASSERTED CLAIMS LACK WRITTEN DESCRIPTION SUPPORT

A. There Is No Written Description Support for a Polymeric Viscosity Builder Containing A/SA Copolymer by Itself

179. The specification teaches that "[i]n some embodiments, the polymeric viscosity builder is an acrylamide/sodium acryloyldimethyltaurate copolymer, and further includes isohexadecane, sorbitan oleate, water, and Polysorbate 80."

180. The specification further describes Sepineo™ P600 as an exemplary embodiment of the claimed PVB.

181. The specification, however, does not disclose any embodiment of a PVB containing only A/SA as the PVB.

182. Thus, nothing in the '219 patent specification or its priority applications would signal to the POSA that the inventors were in possession of a composition, in which A/SA, alone, is the PVB.

B. There is No Written Description Support for a Concentration Range of About 2% to About 6% of a Polymeric Viscosity Builder

183. While the specification provides *ipsis verbis* support for the claim phrase "about 2% w/w to about 6% w/w" of a PVB, that alone is insufficient to convey to the POSA that the inventors were in possession of the claimed range.

184. Here, each and every one of the disclosed compositions encompassed by the claims comprises 4% of a PVB. Since none of the disclosed compositions support the outer boundaries

of the claimed range or species within that range other than 4% of a PVB, the specification of the '219 patent fails to provide adequate written description support for a composition comprising "about 2% w/w to about 6% w/w" of a PVB.

185. In other words, the specification lacks guidance or a legitimate blaze mark toward the claimed range of "about 2% w/w to about 6% w/w."

VIII. THE ASSERTED CLAIMS ARE INDEFINITE

186. The specification fails to provide sufficient guidance to a POSA to determine whether a given component of a given topical pharmaceutical composition is or is not part of the claimed PVB.

187. For example, the '219 patent specification states "[i]n some embodiments, the polymeric viscosity builder is an acrylamide/sodium acryloyldimethyltaurate copolymer, and further includes isohexadecane, sorbitan oleate, water, and Polysorbate 80."

188. By stating "in some embodiments," a POSA would recognize that "isohexadecane, sorbitan oleate, water, and Polysorbate 80" are some but not all of the possible "additional components" that may be part of the PVB.

189. Without more guidance, a POSA is left guessing what components, in addition to A/SA, and possibly isohexadecane, sorbitan oleate, water, and Polysorbate 80, may or may not be part of the PVB.

190. Accordingly, a POSA cannot determine with reasonable certainty the scope of the claims.

IX. REMEDIES

191. Taro's ANDA Product does not infringe the Asserted Claims.

192. Almirall will not suffer irreparable injury if Taro makes, uses, sells, offers for sale, or imports into the United States Taro's ANDA Product prior to the expiration of the '219 Patent.

193. To the extent the Court finds that Taro's ANDA Product infringes any of the Asserted Claims, monetary damages are adequate to compensate Almirall for any injury.

194. The balance of relative hardships as between Almirall and Taro favors Taro.

195. The public interest is not served by preventing Taro from making, using, selling, offering for sale, or importing into the United States Taro's ANDA Product prior to the expiration of the '219 Patent.

196. The public interest would be disserved by a permanent injunction against Taro.

197. This case is an exceptional case under the meaning of 35 U.S.C. § 285 such that Defendants should be awarded attorneys' fees and costs.

EXHIBIT 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 4

PLAINTIFF'S STATEMENT OF ISSUES OF LAW THAT REMAIN TO BE LITIGATED

EXHIBIT 4

TABLE OF CONTENTS

Page

EXHIBIT 4

1. Pursuant to Local Rule 16.3(c)(5), Plaintiff submits the following issues of law that remain to be litigated.

I. PERSON OF ORDINARY SKILL IN THE ART

2. A patent and its prior art are viewed through the eyes of a person of ordinary skill in the art (or "POSA") at the time the invention was made. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The person of ordinary skill in the art is a legal construct—a hypothetical person who is presumed to know all of the relevant prior art. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

3. "Factors that may be considered in determining the ordinary level of skill in the art may include: 1) the types of problems encountered in the art; 2) the prior art solutions to those problems; 3) the rapidity with which innovations are made; 4) the sophistication of the technology; and 5) the educational level of active workers in the field." *See Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666–67 (Fed. Cir. 2000).

4. Where an issue calls for consideration of evidence from the perspective of one of ordinary skill in the art, a witness may not testify on the issue unless qualified as a technical expert in that art. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008); *see also generally Sloan Valve Co. v. Zurn Indus., Inc.*, No. 10-cv-00204, 2013 WL 6068790, at *7 (N.D. Ill. Nov. 18, 2013) ("The majority of Dr. Magee's opinions regarding obviousness are based on the perspective of a POSITA. Because he is not a POSITA, he is not qualified to give these opinions.").

5. Claims not construed by the Court are given their plain and ordinary meaning as understood at the time of the invention by an ordinarily skilled artisan after reading the entire

patent. *See Eon Corp. IP Holdings v. Silver Springs Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016); *Phillips*, 415 F.3d at 1312–13.

II. INFRINGEMENT

A. The Infringement Analysis

6. A patent is directly infringed by anyone who "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a).

7. The patent infringement analysis consists of two steps: (1) construing the claims, and (2) comparing the accused product to the properly construed claims "to determine whether each of the claim limitations is met, either literally or equivalently." *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003). When a commercial product meets all of the claim limitations, comparison to that commercial product is appropriate and may support a finding of infringement. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1288 (Fed. Cir. 2010); *Glaxo Group Ltd. v. Torpharm*, 153 F.3d 1366, 1373 (Fed. Cir. 1998); *WCM Indus., Inc. v. IPS Corp.*, 721 F. App'x 959, 968–69 (Fed. Cir. 2018) (nonprecedential).

8. To prove infringement, the patentee must establish by a preponderance of evidence that an accused product embodies all limitations of the asserted claim(s) either literally or under the doctrine of equivalents. *See Creative Compounds, LLC v. Starmark Labs.*, 651 F.3d 1303, 1314 (Fed. Cir. 2011) (quoting *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985)). A preponderance of evidence establishes the belief in the trier of fact that what is sought to be proved is more likely true than not. *See Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005).

EXHIBIT 4

9. Under 35 U.S.C. § 271(e)(2)(A), it is an act of infringement to submit an Abbreviated New Drug Application ("ANDA") for "a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in the patent or the use of which is claimed in a patent before the expiration of such patent."

10. In Hatch-Waxman cases, the infringement inquiry is a hypothetical assessment of the product that the alleged infringer is likely to market. *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346 (Fed. Cir. 2002); *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760–61 (Fed. Cir. 2016). The focus under § 271(e)(2)(A) is on "what the ANDA applicant will likely market if its application is approved." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000).

11. The infringement inquiry is "properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Bayer*, 212 F.3d at 1248*; Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 580 (D.N.J. 2001). "Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279 (Fed. Cir. 2013) (quoting *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002)).

12. If the product that the ANDA applicant is likely to market would infringe a valid patent claim, then "the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires." *See Bristol-*

Myers Squibb Co. v. Royce Labs., 69 F.3d 1130, 1135 (Fed. Cir. 1995); 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

B. Direct and Contributory Infringement

13. Even if a defendant does not directly infringe a patent, it may still be liable for infringement if it actively induces infringement of a patent under 35 U.S.C. § 271(b) or acts as a contributory infringer under 35 U.S.C. § 271(c).

14. A person with knowledge of a patented method may induce infringement of the claimed method by actively encouraging another person to practice one or more steps of the patented method with the intent to cause performance of the whole method. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011) ("induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement"); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920–21 (2014) (inducement liability predicated on direct infringement); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961) (a patent is not infringed unless all the steps are carried out).

15. In addition to constituting inducement to infringe a patent, the sale of a product specifically labeled for use in a patented method usually is also contributory infringement. *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 926–27 (Fed. Cir. 2011).

16. As codified by U.S.C. § 271(c), contributory infringement occurs if a party sells or offers to sell: (i) "a material or apparatus for use in practicing a patented process"; (ii) "constituting a material part of the invention"; (iii) "knowing the same to be especially made or especially adapted for use in an infringement of such patent"; and (iv) "not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c); *see also In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012).

17. Contributory infringement requires that the accused infringer have knowledge of the relevant patent. *Global-Tech*, 563 U.S. at 765; *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1356–57 (Fed. Cir. 2018) ("[C]ontributory infringement requires 'only proof of a defendant's *knowledge*, not *intent*, that his activity cause[s] infringement.'" (quoting *Lifetime Indus., Inc. v. Trim-Lok, Inc*., 869 F.3d 1372, 1381 (Fed. Cir. 2017) (emphasis in original)).

C. The Doctrine of Equivalents

18. An accused device or process that does not meet each and every claim element literally may nevertheless be found to infringe the claim if "the difference between the claimed invention and the accused product [is] insubstantial.'" *Stumbo v. Eastman Outdoors*, 508 F.3d 1358, 1364 (Fed. Cir. 2007) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co*., 339 U.S. 605, 608 (1950)). "The doctrine of equivalents prohibits one from avoiding infringement liability by making only 'insubstantial changes and substitutions . . . which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.'" *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc*., 637 F.3d 1269, 1279 (Fed. Cir. 2011) (quoting *Graver Tank*, 339 U.S. at 607); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 34–35 (1997).

19. Infringement under the doctrine of equivalents is a question of fact. *Retractable Techs., Inc. v. Beckton Dickinson & Co*., 653 F.3d 1296, 1307 (Fed. Cir. 2011) (citing *Graver Tank*, 339 U.S. at 609–10). It "must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Graver Tank*, 339 U.S. at 609. It is to be evaluated at the time of infringement. *See Warner-Jenkinson*, 520 U.S. at 37.

20. "There is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents. It has long been clear that known interchangeability weighs in favor of finding infringement under the doctrine of equivalents." *Ring & Pinion Serv.*

Inc. v. ARB Corp. Ltd., 743 F.3d 831, 834 (Fed. Cir. 2014). Therefore, "foreseeability does not create a bar to the application of the doctrine of equivalents." *Id.* at 835.

21. "[T]he substitution of an ingredient known to be an equivalent to that required by the claim presents a classic example for a finding of infringement under the doctrine of equivalents." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1261 (Fed. Cir. 1989) (citing *Graver Tank*, 339 U.S. at 609). For example, in *Graver Tank*, the Supreme Court found infringement under the doctrine of equivalents when an infringer substituted non-alkaline manganese for the claimed alkaline magnesium where persons of ordinary skill in the art "understood that manganese was equivalent to and could be substituted for magnesium." *Graver Tank*, 339 U.S. at 612; *see also Recro Gainesville LLC v. Actavis Labs. FL, Inc.*, Civil Action No. 14-1118-GMS, 2017 WL 1064883, at *4, 5–6 (D. Del. Feb. 24, 2017) (finding Actavis's "ethylcellulose-based coating" equivalent to the claimed "permeable or semi-permeable coating selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof"); *Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1213 (Fed. Cir. 2007) (finding a non-polymer equivalent to a claim element requiring a "pharmaceutically acceptable polymer").

22. "Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with other ingredients, and the function which it is intended to perform." *Graver Tank*, 339 U.S. at 609. Additionally, when assessing whether a claimed element and accused equivalent are insubstantially different, the Court considers whether the equivalent "was developed as the result of independent research or experiments". *Id.* at 611.

23. An accused product that "performs substantially the same function in substantially the same way to obtain the same result" as the patented invention may infringe under [the doctrine of equivalents]." *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379 (Fed. Cir. 2006) (quoting *Graver Tank*, 339 U.S. at 608); *Stumbo,* 508 F.3d at 1364. The so called "function-way-result test" "focuses on 'an examination of the claim and the explanation of it found in the written description of the patent.'" *Stumbo*, 508 F.3d at 1364 (quotation omitted); *see also Zenith Labs. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1425 (Fed. Cir. 1994) ("A necessary part of the function/way/result equivalency analysis is the function of the substituted element as seen in the context of the patent, the prosecution history, and the prior art.") (citing *Graver Tank*, 339 U.S. at 609). The perspective of the ordinary skilled artisan must also be considered. *Intendis GmbH v. Glenmark Pharms., Inc.*, 822 F.3d 1355, 1362 (Fed. Cir. 2016) (quoting *Stumbo v. Eastman Outdoors, Inc*., 508 F.3d 1358, 1365 (Fed. Cir. 2007)). "Each prong of the function-way-result test is a factual determination." *Intendis*, 822 F.3d at 1361.

1) Prosecution History Estoppel

24. Prosecution history estoppel may bar the patentee from asserting infringement under the doctrine of equivalents if the scope of the claims has been narrowed by amendment or argument during prosecution in a way that would exclude the alleged equivalent. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd*., 535 U.S. 722, 733–34 (2002) ("*Festo II*"); *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324–25 (Fed. Cir. 2003).

25. To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1340 (Fed. Cir. 2011). The prosecution history as a whole must be examined in determining whether, based on a particular argument, a particular estoppel applies. *Martek*

Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1377 (Fed. Cir. 2009). "An objective standard is applied when looking at the prosecution history, the proper inquiry being 'whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.'" *Bayer AG*, 212 F.3d at 1252 (quoting *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998) (en banc), *abrogated on other grounds by Teva Pharm. USA, Inc. v. Sandoz, Inc.,* 789 F.3d 1335 (Fed. Cir. 2015)).

26. "Whether estoppel arises based on arguments made in a related application depends on the circumstances, and is not a matter of rote." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1141 (Fed. Cir. 2003). "[S]tatements in the parent application must be confined to their proper context and properly acknowledge the distinctions between ... [the] claims." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 976 (Fed. Cir. 2018) (quoting *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997)). Estoppel generally does not apply where the claims were amended after the impugned arguments were made. *See, e.g., U.S. v. Telectronics, Inc.*, 857 F.2d 778, 783 (Fed. Cir. 1988). Similarly, estoppel generally does not arise from the prosecution of a parent application where the impugned arguments were directed to specific claim terms that were omitted or materially altered in subsequent applications. *See, e.g., Biogen*, 318 F.3d at 1141; *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007).

27. Amendment-based estoppel, and the accompanying presumption of surrender of subject matter, only "arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo II*, 535 U.S. at 736. The inquiry is whether the amendment ***narrows*** the overall scope of the claimed subject matter. *Festo II*, 535 U.S. at 736–37. The

burden is on the accused infringer to prove a narrowing amendment. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F. 3d 1359, 1366 (Fed. Cir. 2003) ("*Festo III*").

28. The scope of the patentee's surrender is determined on a limitation-by-limitation basis. *See Festo III*, 344 F.3d at 1367. Moreover, "the scope of the estoppel must fit the nature of the narrowing amendment. A district court must look to the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made." *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010); *see also Festo II*, 535 U.S. at 738 ("There is no reason why a narrowing amendment should be deemed to relinquish equivalents . . . beyond a fair interpretation of what was surrendered.").

29. A patentee may overcome a presumption of surrender via narrowing amendment by, *inter alia*, demonstrating that the accused equivalent would have been unforeseeable at the time of amendment. *Festo III*, 344 F.3d at 1365 (citing *Festo II*, 535 U.S. at 740–41).

2) Disclosure-Dedication Rule

30. A patent applicant who discloses but does not claim subject matter has dedicated that matter to the public and cannot reclaim the disclosed matter under the doctrine of equivalents. *PSC Computer Prods. v. Foxconn Int'l*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

31. This so-called "disclosure-dedication" rule is governed by the objective understanding of a POSA. *CSP Techs., Inc. v. Sud-Chemie AG*, 643 F. App'x 953, 959 (Fed. Cir. 2016). For this rule to apply, the disclosure must be precise and clear and of such specificity that a POSA could identify the subject matter that had been disclosed and not claimed. *PSC Computer*, 355 F.3d at 1358, 1360.

32. Additionally, the unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation. *Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d

1364, 1379 (Fed. Cir. 2005). Whether a POSA ultimately could employ the disclosures of the patent to implement a purported equivalent does not amount to actually disclosing to a POSA that equivalent as an alternative to a claim limitation. *SanDisk Corp. v. Kingston Tech. Co*., 695 F.3d 1348, 1364 (Fed. Cir. 2012).

33. The disclosure-dedication rule is not without restrictions. It "does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public." *Id.* at 1363–64 (quoting *PSC Computer*, 355 F.3d at 1360). Rather, "the disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id.*

3) Ensnarement

34. A patentee cannot assert a doctrine of equivalents theory if it will encompass or "ensnare" the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*., 567 F.3d 1314, 1322 (Fed. Cir. 2009).

35. A hypothetical claim analysis is a practical method to determine whether an equivalent would impermissibly ensnare the prior art. *Intendis,* 822 F.3d at1363. Under this analysis, a patentee proposes a hypothetical claim that is sufficiently broad in scope to literally encompass the accused product or process. *Id*. If the hypothetical claim would have been allowed by the Patent and Trademark Office ("PTO") over the prior art, then the prior art does not bar the application of the doctrine of equivalents. *Id.* at 1363.

36. In crafting the appropriate hypothetical claim, although slight broadening of the claim scope is permitted, a patentee may not add any narrowing limitations. *Id*. at 1363. The proper hypothetical claim extends the actual claim to literally recite the accused product. *Id.* at 1364.

III. TARO BEARS THE BURDEN OF PROVING INVALIDITY BY CLEAR AND CONVINCING EVIDENCE

37. All issued patents are presumed valid. "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282(a).

38. A party challenging the validity of a patent claim must prove invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2240, 2245 (2011). "Clear and convincing evidence is evidence that places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" *In re Rosuvastatin Calcium Patent Litig.*, 719 F. Supp. 2d 388, 406 (D. Del. 2010) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)). Evidence meets the clear and convincing standard only if it "instantly tilt[s] the evidentiary scales in the affirmative" when weighed against the evidence offered by plaintiffs in opposition. *Colorado*, 467 U.S. at 316. Evidence that would require the Court to draw extensive inferences does not satisfy the clear and convincing standard. *See Intel Corp. v. U.S. Int'l Trade Comm'n,* 946 F.2d 821, 829–30 (Fed. Cir. 1991).

39. The burden of proof on invalidity always remains with the patent challenger and is never shifted to the patent holder. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291–92 (Fed. Cir. 1985).

40. The patent challenger faces an "added burden of overcoming the deference" afforded to the PTO when the challenger relies upon prior art that the PTO considered during prosecution. *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1560 (Fed. Cir. 1986); *see also Microsoft Corp.*, 131 S. Ct. at 2243 (a government agency is presumed to have done its job); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569

(Fed. Cir. 1996) ("The presumption of validity is based on the presumption of administrative correctness of actions of the agency charged with examination of patentability."). Thus, when prior art was before the Examiner during prosecution, a party's "burden of proving invalidity at trial [is] 'especially difficult.'" *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2006) (quoting *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004)).

IV. OBVIOUSNESS UNDER 35 U.S.C. § 103

41. 35 U.S.C. § 103(a) (pre-America Invents Act) provides that: "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

42. The "subject matter as a whole" in the case of a chemical compound is the compound's chemical structure and its properties, which are considered inseparable aspects of the invention. *See In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007).

43. Whether a claim is invalid for obviousness is determined from the perspective of a POSA. *See, e.g.*, *Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013); *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) ("A person of ordinary skill at the time of the invention interprets the prior art using common sense and appropriate perspective.").

44. Obviousness is a question of law based on an underlying factual inquiry into the "Graham factors": (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) the differences between the claimed subject matter and the prior art, and (4) any objective evidence of nonobviousness. *KSR*, 550 U.S. 398 at 406; *Eisai Co. Ltd. v. Dr. Reddy's Labs.,*

Ltd., 533 F.3d 1353, 1356 (Fed. Cir. 2008) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966)).

45. As with all bases of alleged invalidity, an accused infringer must prove obviousness by clear and convincing evidence. *Par Pharm., Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 993–94 (Fed. Cir. 2009). The burden of proof on obviousness is always with the challenger and "never shifts." *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1329 (Fed. Cir. 2008).

46. The patent challenger must demonstrate "by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Procter & Gamble*, 566 F.3d at 994.

47. "An inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements." *DePuy*, 567 F.3d at 1326–27. In fact, as a general rule, "references that teach away cannot serve to create a *prima facie* case of obviousness." *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1308 (Fed. Cir. 2006).

48. Furthermore, the decision maker must avoid "fall[ing] victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983); *KSR*, 550

U.S. at 421; *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("[T]he very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.") (internal quotations omitted).

A. Objective Indicia of Nonobviousness

49. An obviousness determination requires consideration of the objective indicia of nonobviousness (or secondary considerations) such as unexpected results, commercial success, copying, skepticism, failure of others, and long-felt but unresolved need. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075–83 (Fed. Cir. 2012); *In re Sullivan*, 498 F.3d at 1351; *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285–86 (Fed. Cir. 2000); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368 (Fed. Cir. 2004); *Ruiz*, 234 F.3d at 662–63. Even if the challenger does establish a *prima facie* case of obviousness, the patentee may rebut it with evidence of "some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *Procter & Gamble*, 566 F.3d at 994.

50. Objective factors are often the most probative and cogent evidence in the record, and must always be considered as part of the original determination of obviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983) (citations omitted). They "guard as a check against hindsight bias." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d at 1079 (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36 (1966)).

1) Unexpected Results

51. The Federal Circuit has "repeatedly emphasized" that evidence of unexpected results "constitutes independent evidence of nonobviousness." *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009) (internal quotation omitted). The "basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

52. Thus, a showing that the claimed invention exhibits some superior property or advantage that a POSA would have found surprising or unexpected supports a finding of non-obviousness. *Id.* at 750. Evidence of unexpected results may "include[] test data showing . . . unexpectedly improved properties" or properties not found in the prior art. *Procter & Gamble*, 566 F.3d at 997 (quotation omitted).

53. "[E]vidence of unexpected results may be [considered] … even if that evidence was obtained after the patent's filing or issue date." *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307 (Fed. Cir. 2011) (citation omitted); *see also Knoll Pharm. Co., Inc. v. Teva Pharm. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("There is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in studying the invention, in order for that work to be introduced into evidence in response to litigation attack. Nor is it improper to conduct additional experiments and provide later-obtained data in support of patent validity."). "[P]atentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest." *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc.*, 748 F.3d 1354, 1360 (Fed. Cir. 2014).

54. When "unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991)).

55. Although unexpected results must be commensurate in scope with the claims, there is no requirement of absolute identity of scope; rather, evidence of unexpected results has only been rejected "where the evidence was plainly disproportionate to the scope of the claim." *Genetics Inst.*, 655 F.3d at 1308. "[A] rigid requirement of absolute identity that ignores relevant properties of claimed compounds would defy the mandate of § 103 requiring consideration of the claimed 'subject matter as a whole.'" *Id*. at 1309.

2) Praise

56. Praise for the patented invention in the relevant industry is another strong indication of non-obviousness. *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008). Industry praise must be linked to the invention versus what is common between the invention and the prior art. *Id.*

57. Relevant evidence of industry praise can include industry journals and publications. *See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1351 (Fed. Cir. 2012) (finding industry praise sufficient to support non-obviousness in the form of industry press linking benefits in the industry to the claimed invention).

V. WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112

58. Sufficient written description under 35 U.S.C. § 112 requires that "the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly &*

Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). Written description is judged based on the disclosure in the specification, as of the filing date. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–64 (Fed. Cir. 1991).

59. The level of detail required to satisfy the written description requirement depends on the nature of the claims and the complexity of the technology. *Ariad*, 598 F.3d at 1351.

60. Sufficient written description does not require that the specification disclose all possible embodiments, nor even every embodiment within a claimed range. *See Bilstad v. Wakalopulos*, 386 F.3d 1116, 1123–24 (Fed. Cir. 2004); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575–77 (Fed. Cir. 1985); *see also Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) ("As our case law makes clear, however, '[a]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.'" (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001))).

VI. INDEFINITENESS UNDER 35 U.S.C. § 112

61. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. BioSig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

62. 35 U.S.C. § 112 "require[s] that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Id.* at 910 (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916) ("[T]he certainty which the law requires in patents is not greater than is reasonable, having regard to their subject matter.")).

VII. INJUNCTIVE RELIEF

63. Courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283.

64. A permanent injunction may be granted upon showing: "(1) that [the plaintiff] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *see also Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, Civ. Nos. 09-184-LPS & 10-892-LPS, 2012 WL 1901267, at *2–3 (D. Del. May 25, 2012) (citing *eBay*, 547 U.S. at 391).

65. In Hatch-Waxman cases, upon a judgment of infringement "the court shall order the effective date of any approval of the [generic] drug . . . to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). Additionally, "injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug." 35 U.S.C. § 271(e)(4)(B).

VIII. ATTORNEY'S FEES

66. In exceptional cases, 35 U.S.C. § 285 authorizes the court to award "reasonable attorney fees to the prevailing party." An "exceptional" case is "one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014).

67. When considering whether a case is exceptional, district courts are to exercise their discretion on a case-by-case basis, considering the totality of the circumstances. *Id.* Relevant factors for consideration include "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." *Id.* at 554 n.6 (quotation omitted). The party moving for attorney's fees must demonstrate exceptionality by a preponderance of the evidence. *Id.* at 557–58.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 5

DEFENDANT'S STATEMENT OF ISSUES OF LAW THAT REMAIN TO BE LITIGATED

TABLE OF CONTENTS

1. Pursuant to Local Rule 16.3(c)(5), Defendants submit the following issues of law that remain

I. PERSON OF ORDINARY SKILL IN THE ART

2. Section 103 requires that a claim be declared invalid when the invention set forth in the claim would have been obvious to one of ordinary skill in the art to which the patent pertains. 35 U.S.C. § 103(a); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). The person of ordinary skill in the art is a hypothetical person presumed to know all of the teachings of the prior art references at the time the invention was made. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984) (describing the person of ordinary skill in the art as "the inventor working in his shop with the prior art references—which he is presumed to know—hanging on the walls around him").

3. In determining the level of ordinary skill in the art, a court should consider the following factors: (1) the types of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology involved; and (5) the educational level of active workers in the field. *Daiichi Sankyo Co., Ltd. v. Apotex Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007); *see also U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1564 (Fed. Cir. 1997). "Not all such factors may be present in every case, and one or more . . . may predominate." *Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983).

II. NON-INFRINGEMENT

A. Generally

4. The patentee bears the sole burden of proving direct infringement by a preponderance of the evidence. Siemens Med. *Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011). Infringement, both literal and under the

doctrine of equivalents, is a question of fact. *TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1133 (Fed. Cir. 2004). Determining whether an accused infringer infringes the asserted patent(s) requires a two-step analysis. *Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1381 (Fed. Cir. 2005).

5. First, the asserted claim must be properly determined as to its scope and meaning. Claims must be construed the same for purposes of infringement and invalidity. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575-76 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

6. Claim limitations must be construed such that all explicit requirements of the claim, including claimed ranges, are given meaning. *See Elekta Instrument SA v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000). Where there are two possible constructions, with a narrow construction enabled by the patent's specification, the court must construe the claim narrowly in consideration of the notice function of the patent. *See Zelinski v. Brunswick Corp.*, 996 F. Supp. 757, 762 (N.D. Ill. 1997) ("Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrow meaning, we consider the notice function of the claim to be best served by adopting the narrower reading.") (quoting *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d. 1573, 1581 (Fed. Cir. 1996).

7. Second, the properly construed claim is compared to the accused device or process. *Carroll Touch, Inc. v. Electro Mech. Sys.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993).

B. Literal Infringement

8. To prove literal infringement, the patentee must show that the accused product contains every limitation in the asserted claims. *Alcohol Monitoring Sys., Inc. v. Actsoft, Inc.*, 414 Fed. Appx. 294, 300 (Fed. Cir. 2011). Therefore, if the Court finds that the accused product fails to meet even one claim limitation, there can be no infringement. *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1381 (Fed. Cir. 1998).

9. A dependent claim contains all of the limitations of the claim from which it depends. *See Cognex Corp. v. Int'l Trade Comm'n*, 550 Fed. Appx. 876, 881 (Fed. Cir. 2013). Accordingly, if a product does not infringe an independent claim, the product does not infringe any dependent claim. Id

10. In the ANDA context, the proper infringement inquiry focuses on what "is likely to be sold following FDA approval." *Novartis Pharms. Corp. v. Watson Labs.*, Inc., 611 F. App'x 988, 997 (Fed. Cir. 2015). Where the ANDA specification itself does not resolve the question of infringement, the court should look to actual samples of the generic composition to resolve the question of infringement. *E.g.*, *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1250 (Fed. Cir. 2000). In order to find infringement, a representative ANDA batch must meet all limitations of each asserted claim, including limitations pertaining to numerical limits or ranges. *See Meds. Co. v. Hospira, Inc.*, No. 09-750-RGA, 2014 WL 1292802, at *5 (D. Del. Mar. 31, 2014) (reversed on other grounds).

11. The appropriate test method to show infringement is a question of fact. *See ADC Telecomm., Inc. v. Switchcraft, Inc.*, 281 F. App'x 989, 991 (Fed. Cir. 2008). To show infringement, a plaintiff may only apply methods of testing that would have been employed by a

person of ordinary skill in the art at the time the patent was filed. *Raybestos-Manhattan, Inc. v. Texon, Inc.*, 268 F.2d 839, 842 (1st Cir. 1959). The method of testing employed by a person of ordinary skill in the art is "an objective standard and does not depend on the subjective intent of the inventor." *Id.* This is critical in ensuring the patent does not "mean one thing at the time of its issuance and another at some later date upon the discovery of a more accurate test." *Id.*

12. There can be no literal infringement of subject matter that has been disclaimed by the patent and therefore falls outside the scope of the properly construed claims. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *Id.* Disclaimer can arise from "repeated derogatory statements" in the specification about the subject matter disclaimed. *Honeywell Int'l, Inc. v. ITT Indus.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006).

C. Doctrine of Equivalents

13. Infringement under the doctrine of equivalents requires evidence that an accused product will "perform substantially the same function in substantially the same way with substantially the same results." *Ring & Pinion Serv. Inc. v. ARB Corp.*, 743 F.3d 831, 835 (Fed. Cir. 2014). The patentee must prove, for each claim asserted, the presence in the accused product of each and every claim element or its substantial equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 40 (1997*); see also DePuy Spine, Inc. v. Medtronic Sofamor*

Danek, Inc., 469 F.3d 1005, 1016-17 (Fed. Cir. 2006); and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732-33 (2002) ("Festo II").

14. An equivalent of a missing claim element or limitation is found only if "insubstantial differences distinguish the missing claim element from the corresponding aspects of the accused [product]." *Abbott Labs. v. Novopharm, Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003) (*quoting Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997)) (internal quotation marks omitted); *see also Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001) (asking "whether the element in the accused device does substantially the same thing in substantially the same way to get substantially the same result as the claim limitation"); *see also Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (*citing Warner-Jenkinson*, 520 U.S. at 40).

15. The comparison must be between the accused product and the patent claims, and not between the accused product and the patentee's commercial embodiment:

> Equivalency to limitations of the claim must be the focus of the inquiry. . . . Otherwise, laymen may be led to comparison of devices, rather than between the accused device and the claim, and to rely on generalities in the overall purpose of the devices. For example, a pen and a pencil may for many purposes or uses be generally equivalent, but claim limitations drawn to a pen would not under the doctrine of equivalents cover a pencil and vice versa.

Read Corp. v. Portec, Inc., 970 F.2d 816, 822 n.2 (Fed. Cir. 1992), *superseded on other grounds as recognized by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

1. All Element Rule

16. Finding infringement under the doctrine of equivalents is impermissible if it would vitiate a claimed element. *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1361 (Fed. Cir. 2005); *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1321 (Fed. Cir. 2003); *see also Warner-Jenkinson*, 520 U.S. at 29; *Deere & Co.*, 703 F.3d at 1356. A "subject matter is

'specifically excluded' from coverage under the doctrine of equivalents if its inclusion is somehow 'inconsistent with the language of the claim.'" *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 955 (Fed. Cir. 2006) (*quoting Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1317 (Fed. Cir. 1998)); *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346 (Fed. Cir. 2001) ("[B]y defining the claim in a way that clearly excluded certain subject matter, the patent implicitly disclaimed the subject matter that was excluded and thereby barred the patentee from asserting infringement under the doctrine of equivalents.").

17. Under this "all elements rule, there can be no infringement under the doctrine of equivalents if even one limitation of a claim or its equivalent is not present in the accused device." *Lockheed Martin*, 324 F.3d at 1321. Moreover, "[t]he 'all elements' rule attempts to balance the doctrine of equivalents with the basic patent law principle that claim language defines the scope of an invention and every limitation is material. . . . Thus, as a practical matter, the 'all elements' rule informs a doctrine of equivalents analysis by requiring that equivalence be assessed on a limitation-by-limitation basis, rather than from the perspective of the invention as a whole, and that no limitation be read completely out of the claim." *DePuy*, 469 F.3d 1016-17.

2. Prosecution History Estoppel

18. The doctrine of "prosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution." *Conoco, Inc. v. Energy & Env't Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006); *see also Festo II*, 535 U.S. at 733-34. Prosecution history estoppel is triggered by amending an original claim to narrow the literal scope of the element at issue, *Festo II*, 535 U.S. at 732, for reasons substantially related to satisfying any requirement of the Patent

Act. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003).

19. Arguments or concessions made by the patentee during prosecution may affirmatively establish that a narrowing amendment was made to overcome patentability rejections or secure allowance of a claim. *See Warner-Jenkinson*, 520 U.S. at 33 (placing "the burden on the patent holder to establish the reason for an amendment"); *see also Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1364-65 (Fed. Cir. 2015) (c*iting Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003)). Alternatively, "[w]hen the prosecution history record reveals no reason for the narrowing amendment [it is presumed under Warner-Jenkinson] that the patentee had a substantial reason relating to patentability." *Festo Corp.*, 344 F.3d at 1366-67. This presumption can only be rebutted by evidence in the prosecution history record demonstrating that the reason for the amendment was not related to patentability. *Id.* at 1367 ("[O]nly the prosecution history record may be considered in determining whether a patentee has overcome the Warner-Jenkinson presumption.") (*citing Pioneer Magnetics Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003)).

20. Once prosecution history estoppel is triggered, the patentee is presumed to have "surrendered all territory between the original claim limitation and the amended claim limitation." *Id.* at 1367.

21. Prosecution history estoppel can also occur by surrendering claim scope through argument to the patent examiner during prosecution. *Conoco*, 460 F.3d at 1363. "To invoke argument-based estoppel, the prosecution history must evince a 'clear an unmistakable surrender of subject matter.'" *Eagle Comtronics, Inc. v. Arrow Commc'n Labs., Inc.*, 305 F.3d 1303, 1316 (Fed. Cir. 2002) (internal citations omitted). "In determining whether there has been a clear and

unmistakable surrender of subject matter, the prosecution history must be examined as a whole." *Bayer*, 212 F.3d at 1252. "Any argument-based estoppel affecting a limitation in one claim extends to all claims in which that limitation appears." *Eagle*, 305 F.3d at 1316. Even if an assertion in support of patentability is not necessary to secure allowance of a claim, "a statement may operate to preclude the patentee from claiming otherwise in an infringement suit." *Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1301, 1314 (Fed. Cir. 2001). "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Conoco*, 460 F.3d at 1364.

3. Disclosure-Dedication Rule

22. Similarly, the disclosure-dedication rule prohibits assertion of infringement under the doctrine of equivalents where the accused equivalent was disclosed as an unclaimed alternative to a literally missing claim limitation. *See Johnson & Johnston Associates Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). This is because, if a patentee could "reclaim some specifically-disclosed-but-unclaimed matter under the doctrine of equivalents, the public would have no way of knowing which disclosed matter infringed and which did not," which "would eviscerate the public notice function of patents and create uncertainty in the law." *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

23. It is a "well-established rule" that "subject matter disclosed but not claimed in a patent application is dedicated to the public." *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1106 (Fed. Cir. 1996) (*quoting Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562-63 (Fed.Cir.1991)). The disclosure-dedication rule prohibits assertion of infringement under the doctrine of equivalents where the accused equivalent was disclosed as an unclaimed alternative to a literally missing claim limitation. *See Johnson*, 285 F.3d at 1054 ("When a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public.

Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would 'conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.'") (*quoting Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed.Cir.1997)). "The patentee's subjective intent is irrelevant to determining whether unclaimed subject matter has been disclosed and therefore dedicated to the public." *Johnson*, 285 F.3d at 1053, n.1.

24. The disclosure-dedication rule prohibits the patentee from re-capturing disclosed but unclaimed alternatives under the doctrine of equivalents because if a patentee could "reclaim some specifically-disclosed-but-unclaimed matter under the doctrine of equivalents, the public would have no way of knowing which disclosed matter infringed and which did not," which "would eviscerate the public notice function of patents and create uncertainty in the law." *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

25. To allow a claim of infringement based on elements disclosed in the specification but not included in the patent claims would be "contrary to our system of patent examination, in which a patent is granted following careful examination of that which an applicant claims as her invention." *Id.* at 1107; *see also id.* at 1108 ("Here, Maxwell limited her claims to fastening tabs attached between the inner and outer soles. She disclosed in the specification, without claiming them, alternatives in which the fastening tabs could be 'stitched into the lining seam of the shoes.' . . . By failing to claim these alternatives, the Patent and Trademark Office was deprived of the opportunity to consider whether these alternatives were patentable.").

26. When the patent specification discloses an alternative to one element of a claim that includes multiple elements, the disclosed alternative is dedicated to the public, and the patentee cannot use the doctrine of equivalents to try to capture that disclosed alternative as an infringement of the patent claims. *See Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991).

27. Thus, subject matter in a patent has been dedicated to the public when a POSA "can understand the unclaimed disclosed teaching upon reading the written description" with enough "specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1334 (Fed. Cir. 2004).

28. Where the patent sets forth a list of acceptable alternative components in the specification but claims only one, this amounts to a self-evident disclosure of the unclaimed alternatives in the list, which are dedicated to the public. *See In re Bendamustine Consol. Cases*, No. CV 13-2046-GMS, 2015 WL 1951399, at *2 (D. Del. Apr. 29, 2015) (disclosure-dedication rule applied where asserted patents "include[d] a list of possible organic solvents" but "only claim[ed] compositions or preparations containing" one of the enumerated solvents, noting that the specification thus "identifie[d] precise alternatives to [the claimed solvent]," making it "unnecessary to inquire into whether 'one of ordinary skill in the art could identify the subject matter that had been disclosed [but] not claimed'" as the list was a "self-explanatory" disclosure of precise alternatives to the claimed element).

29. In order for a disclosure to trigger the disclosure-dedication rule, it need not describe a complete embodiment such as would be required to satisfy the enablement or written description requirements for patentability. *See Toro Co.*, 383 F.3d at 1334 ("[T]he disclosure-dedication rule does not impose a § 112 requirement on the disclosed but unclaimed subject matter."). Thus, the "disclosures implicating the disclosure-dedication rule need not directly relate to the description of the claimed invention or be contained in the 'Detailed Description of the Invention' section of the patent, but may appear merely in the portion of the patent describing the 'Background of the Invention.'" *Id.*

30. Thus, subject matter in a patent has been dedicated to the public when a POSA "can understand the unclaimed disclosed teaching upon reading the written description" with enough "specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id.*

4. Ensnarement

31. "A doctrine of equivalents theory cannot be asserted if it will encompass or 'ensnare' the prior art." *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). This is because the doctrine of equivalents does not exist "to give a patentee something which he could not lawfully have obtained from the PTO had he tried." *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683-686 (Fed. Cir. 1990).

32. The "burden of persuasion is on the patentee to establish…that the asserted scope of equivalency would not ensnare the prior art." *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1323-24 (Fed. Cir. 2009) (*citing Wilson Sporting Goods*, 904 F.2d at 685).

33. The ensnarement doctrine is a "legal limitation[] on the application of the doctrine of equivalents," one that is to "be determined by the court," that is decided "as a matter of law," and that may be disposed of "on a pretrial motion for partial summary judgment." *Depuy Spine*, 567 F.3d at 1323.

34. Determining "whether an equivalent would impermissibly ensnare the prior art" is typically resolved through a "hypothetical claim analysis." *Jang*, 872 F.3d at 1285. There are two steps: the first is to "construct a hypothetical claim that literally covers the accused device"; the second is to determine whether the Patent Office would have found the hypothetical claim to be "patentable over the prior art." *Id.* (*quoting Intendis GmbH v. Glenmark Pharms. Inc.*, USA, 822 F.3d 1355, 1363 (Fed. Cir. 2016)). In constructing the hypothetical claim, the patentee "may not add any narrowing limitations" to try to avoid the prior art. *Id.* at 1286. "Ultimately, if such a

[hypothetical] claim would be unpatentable under 35 U.S.C. §§ 102 [i.e., anticipation] or 103 [i.e., obviousness], then the patentee has overreached, and the accused device is noninfringing as a matter of law." *Depuy Spine*, 567 F.3d at 1325.

D. Failure of Proof

35. Almirall has not provided evidence that would allow a reasonable fact finder to conclude that Taro's Proposed ANDA Products comprise "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" and therefore would infringe claims 1, 2, 4 and 5 of the '219 patent, either literally or under the doctrine of equivalents.

III. INVALIDITY

A. Obviousness

36. The determination of obviousness under § 103(a) is a question of law based on underlying facts. *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1346 (Fed. Cir. 2009).

37. "A patent may not be obtained … if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) ("the results of ordinary innovation are not the subject of exclusive rights under the patent laws").

38. "Obviousness under 35 U.S.C. § 103(a) is ultimately a legal question, based on underlying factual determinations." *Eisai Co. v. Dr. Reddy's Labs.*, Ltd., 533 F.3d 1353, 1356 (Fed. Cir. 2008). "The factual determinations underpinning the legal conclusion of obviousness include 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the

differences between the claimed invention and the prior art, and 4) evidence of secondary factors, also known as objective indicia of non-obviousness." *Id.* (*citing Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

39. The fact that a reference was previously considered by the PTO merely goes to the weight of that reference's evidence and does not increase the burden of proof or preclude a finding of invalidity. *See Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259-1260 (Fed. Cir. 2012); *see also Surface Tech., Inc. v. U.S.I.T.C.*, 801 F.2d 1336, 1340-41 (Fed. Cir. 1986). A finding of invalidity may be appropriate where the reference was considered by the PTO, but the Examiner failed to give proper consideration to the teachings of that reference. *See Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1366 (Fed. Cir. 2007).

40. In fact, "[w]hether a reference was previously considered by the PTO, the burden of proof is the same: clear and convincing evidence." *Sciele Pharma*, 684 F.3d at 1260 (*citing Microsoft Corp. v. I4I Ltd. P'ship*, 131 S. Ct. 2238, 2245-46 (2011)). "The burden does not suddenly change to something higher – 'extremely clear and convincing evidence' or 'crystal clear and convincing evidence' – simply because the prior art references were considered by the PTO." *Sciele Pharma, Inc.*, 684 F.3d at 1260. "In short, there is no heightened or added burden that applies to invalidity defenses that are based upon references that were before the Patent Office." *Id.*

1. The Scope and Content of the Prior Art

41. The scope of the prior art includes art which is "reasonably pertinent to the particular problem with which the inventor was involved." *In re GPAC Inc.*, 57 F.3d 1573, 1577 (Fed. Cir. 1995) (citation omitted). In determining whether the claimed invention falls within the scope of the relevant prior art, a court first examines, "the field of the inventor's endeavor" and "the particular problem with which the inventor was involved" at the time the invention was made.

Princeton Biochemicals, Inc. v. Beckman Coulter, Inc., 411 F.3d 1332, 1339 (Fed. Cir. 2005). "A reference is reasonably pertinent if, even though it may be in a different field of endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *Id.* (citation omitted).

42. In determining obviousness, printed publications, patents, and patent applications all constitute prior art under 35 U.S.C. § 102. Specifically, art is prior art under 102(a) if it was "patented" or "described in a printed publication … before the effective filing date of the claimed invention." 35 U.S.C. § 102(a); *see also Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) ("under section 102(a), a document is prior art only when published before the invention date."). Art is prior art under 102(b) if it was "patented or described in a printed publication … one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). A published patent application is prior art under § 102(e) if it was filed by another before the invention by the applicant for the patent. A patent granted on an application for patent by another filed in the United States before the invention by the applicant for the patent is also prior art under § 102(e).

43. With regards to 102(a), the date of invention is determined by either the date the invention was reduced to practice or the date the inventor conceived of the invention in the United States, and then exercised reasonable diligence in attempting to reduce the invention to practice. *Mahurkar*, 79 F.3d at 1577.

44. Prior art references in an obviousness evaluation must be considered as a whole and not limited to the particular invention it describes. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1076 (Fed. Cir. 2015) (*citing EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it teaches by way of technology and is not

limited to the particular invention it is describing and attempting to protect."). This is true even if a particular embodiment of the invention is not disclosed, or is not the preferred embodiment. *In re Arora*, 2010 WL 816569, at *2 (Fed. Cir. 2010) ("Dr. Arora argues that Andersson should be understood as limited to the narrow teaching that a smaller amount of a drug is needed when delivered via Andersson's inventive dry powder inhaler instead of a metered dose inhaler. It is well-settled, however, that a prior art reference must be considered for all that it teaches to those of ordinary skill in the art, not just the embodiments disclosed therein. Andersson teaches the broad principle that different drugs are equipotent at different dosages, and even provides an example of that principle."); *Purdue Pharma Prods., L.P. v. Par Pharm., Inc.*, Nos. 2009-1553, 2009-1592, 2010 WL 2203101, at *3 (Fed. Cir. 2010) ("[Prior art reference] renders the selection of tramadol obvious regardless of whether or not the patent lists tramadol as a preferred embodiment.").

45. Prior art references need not provide enabling disclosure. *See ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1360 n.2 (Fed. Cir. 2015); *Geo M. Martin, Co. v. Alliance Mach. Sys. Int'l*, LLC, 618 F.3d 1294, 1302–03 (Fed. Cir. 2010); *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289, 1297 (Fed. Cir. 2010) (vacated for en banc rehearing on inequitable conduct) ("In order to render a claimed apparatus or method obvious, the cited prior art as a whole must enable one skilled in the art to make and use the apparatus or method. An individual prior art reference, on the other hand, 'need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein.'").

46. Additionally, prior art references may be combined with the knowledge and/or experience of a person of ordinary skill in the art to "fill in the gap when limitations of the claimed invention are not specifically found in the prior art." *Belden Techs., Inc. v. Superior Essex Commc'ns LP*, 802 F. Supp. 2d 555, 563 (D. Del. 2011) (*citing Purdue Pharma Prods., L.P. v.*

Par Pharms., Inc., 642 F. Supp. 2d 329, 360 (D. Del. 2009); *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362-63 (Fed. Cir. 2013) ("[T]he knowledge of such an artisan is part of the store of public knowledge that must be consulted when considering whether a claimed invention would have been obvious."). A determination that a claimed invention would be obvious, therefore "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418.

2. The Differences Between the Claimed Invention and the Prior Art

47. In determining the differences between the claimed invention and the prior art, obviousness is judged under "an expansive and flexible approach" driven by "common sense." *KSR*, 550 U.S. at 401, 403; *see also Senju Pharm. Co. Ltd. v. Apotex Inc.*, 836 F. Supp. 2d 196, 208 (D. Del. 2011) ("[t]he Supreme Court has emphasized the need for courts to value common sense over rigid preventative rules ….") (citation omitted). In making this determination, the court must consider both the claimed invention and the prior art as a whole in light of the court's construction of the claims at issue. *See Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1479-80 (Fed. Cir. 1998) ("In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety.").

48. "While it may be easier to prove obviousness if each limitation of the claimed invention is found in the prior art, the level of skill of one of ordinary skill in the art can, at times, fill in the gap when limitations of the claimed invention are not specifically found in the prior art." *Belden Techs.*, 802 F. Supp. 2d at 563.

49. A conclusion of obviousness may be based on a single reference or a combination of prior art references. *See Senju Pharm.*, 836 F. Supp. 2d at 208 ("[A] defendant asserting obviousness in view of a combination of references has the burden to show that a person of

ordinary skill in the relevant field had a reason to combine the elements in the manner claimed."); *see also In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("We see no clear error in the Board's determination as to the teachings of the prior art references, in combination."). Where the issue of obviousness is based on a combination of elements, a patent challenger must demonstrate "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

50. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 550 U.S. at 416 (emphasis added); *see also Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1379 (Fed. Cir. 2014) (same). This is because "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." *KSR*, 550 U.S. at 402.

51. "Obviousness exists when 'a finite, and in the context of the art, small or easily traversed, number of options … would convince an ordinarily skilled artisan of obviousness.'" *Purdue Pharma*, 642 F. Supp. 2d at 368 (*quoting Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)); *see also C.W. Zumbiel Co., Inc. v. Kappos*, 702 F.3d 1371, 1387 (Fed. Cir. 2012) (finding obviousness where the invention involved "no more than the exercise of common sense in selecting one out of a finite—indeed very small—number of options"). In such a case, an invention is considered "obvious to try." *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1332 (Fed. Cir. 2014) (finding claimed dosage obvious to try). Further, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious

unless its actual application is beyond that person's skill." *KSR*, 550 U.S. at 401. "When the prior art provides the means of making the invention and predicts the results, and the patentee merely verifies the expectation through 'routine testing,' the claims are obvious." *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 642 F. Supp. 2d 329, 368 (D. Del. 2009) (*citing Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367 (Fed. Cir. 2007)).

52. "Obviousness does not require absolute predictability of success"; rather, "[a]ll that is required is a reasonable expectation of success" in making the invention via the combination. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted); *see also Duramed Pharms., Inc. v. Watson Labs., Inc.*, 413 Fed. Appx. 289, 294 (Fed. Cir. 2011) ("there is no requirement that a teaching in the prior art be scientifically tested or even guarantee success before providing a reason to combine. Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success.") (citations omitted).

53. Prior to *KSR*, the Federal Circuit imposed a rigid "teaching-suggestion-motivation" test for obviousness. Under this test, the patent challenger was required to prove that "some motivation or suggestion to combine the prior art teachings" could be found "in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *KSR*, 550 U.S. at 407. The Supreme Court in *KSR* rejected the Federal Circuit's test in favor of a more flexible obviousness standard, stating that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

54. This more flexible standard expands the obviousness analysis beyond just "published articles and the explicit content of issued patents." *Id.* at 419. In broad terms, "any need

or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420.

55. "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *Id.* "[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute." *Life Techs., Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000); *see also Std. Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) ("[O]ne should not go about determining obviousness under § 103 by inquiring into what patentees . . . would have known or would likely have done"). The inquiry into whether prior art teachings would have rendered the claimed invention obvious to one of ordinary skill in the art, is, as a matter of law, "independent of the motivations that led the inventors to the claimed invention." *Life Techs.*, 224 F.3d at 1325.

56. "One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claim." *KSR*, 550 U.S. at 419-20; *see also Norgren Inc. v. ITC*, 699 F.3d 1317, 1324-26 (Fed. Cir. 2012) (affirming invalidity of claims under § 103 where the claimed invention solved known problems by the use of an obvious solution). Even more, the discovery of a problem does not always result in a patentable invention. *Norgren*, 699 F.3d at 1327. For instance, an alleged invention is obvious in view of "evidence of known problems and an obvious solution." *Id.*

57. "Where a variable is known to affect a particular desirable result, i.e., is what has been called a 'result-effective' variable, the 'overlap itself provides sufficient motivation to optimize the ranges,' and 'it is not inventive to discover the optimum or workable ranges by routine

experimentation,' because the desire to improve results would motivate skilled artisans to experiment with, and improve upon, known conditions in the prior art." *In re Haase*, 542 Fed. Appx. 962, 967 (Fed. Cir. 2013) (*citing In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012)). "[R]anges that are not especially broad invite routine experimentation to discover optimum values, rather than require nonobvious invention." *In re Peterson*, 315 F.3d 1325, 1330 n.1 (Fed. Cir. 2003).

58. None of "the length, expense, [or] difficulty of the techniques used are dispositive since many techniques that require extensive time, money, and effort to carry out may nevertheless be arguably 'routine' to one of ordinary skill in the art." *Pfizer*, 480 F.3d at 1367.

59. A "claim to a product does not become nonobvious simply because the patent specification provides a more comprehensive explication of the known relationships between the variables and the affected properties." *In re Applied Materials, Inc.*, 692 F.3d at 1297.

60. Even if a reference does not rise to the level of prior art, a court may consider it as motivation to combine. *Lucent Techs., Inc. v. Gateway, Inc.*, 2008 WL 200303, at *6 (S.D. Cal. 2008) (*citing Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1337-38 (Fed. Cir. 2004)).

3. Objective Indicia of Non-Obviousness

61. A court also considers in its obviousness analysis secondary considerations of nonobviousness that may bear on the issue of whether the claimed invention would have been obvious. *KSR*, 550 U.S. at 406.

62. The purpose of secondary considerations of nonobviousness is to "check against hindsight bias." *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014); *accord Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) ("the role of secondary considerations" is "guarding against hindsight").

63. To weigh against a finding of obviousness, "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008); *see also In re Dill*, 604 F.2d 1356, 1361 (C.C.P.A. 1979) ("The evidence presented to rebut a prima facie case of obviousness must be commensurate in scope with the claims to which it pertains.")

64. Secondary considerations, moreover, cannot override a strong prima facie showing of obviousness. *See, e.g.*, *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008) ("objective evidence of nonobviousness simply cannot overcome … a strong prima facie case of obviousness"); *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013) ("[W]here a claimed invention represents no more than the predictable use of prior art elements according to established functions, … evidence of secondary indicia are frequently deemed inadequate to establish non-obviousness."); *Stone Strong, LLC v. Del Zotto Prods. of Fla., Inc.*, 455 F. App'x 964, 971 (Fed. Cir. 2011) ("secondary considerations are inadequate to establish nonobviousness as a matter of law," where a strong prima facie case of obviousness is shown); *Stamps.com Inc. v. Endicia, Inc.*, 437 F. App'x 897, 905 (Fed. Cir. 2011) (evidence of secondary considerations is inadequate to overcome a "strong showing of obviousness"); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) ("given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious."); *DyStar*, 464 F.3d at 1371 ("secondary considerations of nonobviousness are insufficient as a matter of law to overcome our conclusion that the … claim [at issue] would have been obvious."); *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997).

65. Objective evidence of nonobviousness can include "evidence of commercial success, long felt but unsolved needs, and failure of others, as well as unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention." *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 344 (D. Del. 2010) (citation omitted). "[T]he rationale for considering evidence of 'secondary considerations' is to provide the Court with objective evidence of how the patented invention is viewed in the marketplace, by those interested in the invention." *Imperial Chemical*, 777 F. Supp. at 372 n.91.

66. However, even if evidence of objective indicia is established, this is not necessarily sufficient to overcome a strong case of obviousness. *See Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 923 F. Supp. 2d 602, 686 (D. Del. 2013) (stating that despite finding the objective indicia of nonobviousness, "[t]he totality of that evidence did not strongly persuade the Court as to [the invention's] nonobviousness.").

a) Nexus

67. "For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention. Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quotations omitted); *see also GPAC*, 57 F.3d at 1580 ("[F]or objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention."). Even "impressive" evidence of secondary considerations is not "entitled to weight" unless "it is relevant to the claims at issue." *Paulsen*, 30 F.3d at 1482. Nexus requires a direct connection to

the claimed features of the invention as recited in the language of the patent claims. *B.E. Meyers & Co. v. U.S.*, 47 Fed. Cl. 375, 378-79 (Fed. Cl. 2000).

68. To fulfill the nexus requirement, the proffered evidence of secondary considerations must also be commensurate in scope with the asserted claims. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010); *Muniauction*, 532 F.3d at 1328 ("[S]econdary considerations may presumptively be attributed to the patented invention only where 'the marketed product embodies the claimed features, and is coextensive with them.'") (citations omitted). Thus, if evidence of secondary considerations relates to a narrow aspect of a much broader claim, such evidence is not commensurate with the scope of the claims and fails to establish the non-obviousness of the asserted claims. *See Therasense*, 593 F.3d at 1336 ("Because the claims are broad enough to cover devices that either do or do not solve the 'short fill' problem, Abbott's objective evidence of non-obviousness fails because it is not 'commensurate in scope with the claims which the evidence is offered to support.'") (*quoting In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983)); *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1264-65 (Fed. Cir. 2013) (holding that district court erred where its "analysis of the secondary considerations of nonobviousness involved only fragrance-specific uses, but the [asserted claims] are not fragrance-specific").

69. Nexus must be established through specific evidence. *See In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (party asserting secondary considerations "must submit some factual evidence that demonstrates the nexus"); *see also In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

70. Courts have routinely excluded evidence of secondary considerations absent a showing of nexus. *See, e.g.*, *Cot'n Wash, Inc. v. Henkel Corp.*, 56 F. Supp. 3d 626, 651 (D. Del.

2014) (excluding expert testimony regarding industry praise where no nexus existed), *aff'd sub nom. Cot'n Wash Inc. v. Sun Prods. Corp.*, 606 F. App'x 1009 (Fed. Cir. 2015); *Inventio AG v. Thyssenkrupp Elevator Corp.*, C.A. No. 08-00874, 2014 WL 5786668, at *8 (D. Del. Nov. 6, 2014) (evidence of secondary considerations properly excluded where plaintiff failed to show nexus to claimed invention), *aff'd*, 622 F. App'x 906 (Fed. Cir. 2015).

b) Unexpected Results

71. Whether there are unexpected results is a question of fact. *In re Peterson*, 315 F.3d at 1331. The relevant time-period for this inquiry is whether the results would have been unexpected by one of ordinary skill in the art at the time of the patentee's application and based on knowledge available at that time. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). To support a finding of unexpected results, a patentee must "show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the art would have found surprising or unexpected" compared to the closest prior art. *Id.* at 1469; *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) ("To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention."); *Alcon, Inc. v. Teva Pharm. USA, Inc.*, 664 F. Supp. 2d 443, 464 (D. Del. 2009) ("When 'unexpected' and 'significant' differences exist between the properties of the claimed invention and those of the prior art, a finding of nonobviousness may be warranted."). This showing requires "factual evidence," not merely the unsupported assertions of counsel. *In re Youngblood*, 215 F.3d 1342, at *7 (Fed. Cir. 1999) (deeming unsupported assertions "insufficient"). And any evidence that is in fact provided should be "weighed against contrary evidence indicating that the results were not unexpected or not a

substantial improvement over the prior art." *See Santarus Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 457 (D. Del. 2010) (*rev'd* on other grounds, 694 F.3d 1344 (Fed. Cir. 2012)).

72. To assert that results were unexpected, "the patent owner must first show what properties were expected." *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 348 (D. Del. 2010) (citation omitted); *see also Pfizer*, 480 F.3d at 1371 ("in order to properly evaluate whether a superior property was unexpected, the court should have considered what properties were expected."). Any unexpected property must prove to be a significant benefit in comparison to the prior art. *See Bristol-Myers*, 752 F.3d at 977 ("Unexpected properties, however, do not necessarily guarantee that a new compound is nonobvious. While a 'marked superiority' in an expected property may be enough in some circumstances to render a compound patentable, a 'mere difference in degree' is insufficient."); *Santarus Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 457 (D. Del. 2010) (*rev'd* on other grounds, 694 F.3d 1344 (Fed. Cir. 2012)) (stating that a party claiming unexpected results must "produce evidence demonstrating substantially improved results that are unexpected in light of the prior art") (citation omitted); *In re Aller*, 220 F.2d 454, 457-59 (CCPA 1955) (finding no evidence of unexpected results where claimed conditions allegedly contributed to roughly 20 percentage point improvement in yield). Further, in order to assert unexpected results, a patentee must present evidence that the results claimed to be unexpected actually occurred. *See In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) ("[i]t is well settled that unexpected results must be established by factual evidence.") Speculation or unproven hypotheses about what might become an unexpected result are simply not enough. *See In re Geisler*, 116 F.3d at 1470 (finding a statement that it was "common sense" that an effect was unexpected unpersuasive).

73. Any evidence of an unexpected result must be commensurate with the scope of the claimed invention. *In re Grasseli*, 713 F.2d 731, 743 (Fed. Cir. 1983); *see also In re Peterson*, 315 F.3d at 1331 (affirming finding by the Board that unexpected results commensurate in scope with claimed range of 1–3% were not shown where unexpected results were only associated with 2%). The patentee must compare the results achieved by the claimed invention with the results achieved by the closest prior art to determine whether they are unexpected. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). And any evidence that is in fact provided should be "weighed against contrary evidence indicating that the results were not unexpected or not a substantial improvement over the prior art." *See Santarus*, 720 F. Supp. at 457. In order for a claimed invention to have "unexpected results," there needs to be a nexus between the evidence of the unexpected properties and the claimed invention. *See, e.g.*, *In re Kao*, 639 F.3d at 1068-69; *Ex Parte Jella*, App. No. 2008-1619, 2008 WL 5693899, at *9 (B.P.A.I. Nov. 3, 2008).

c) Teaching Away

74. A reference may be said to teach away "when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Gator Tail, LLC. v. Mud Buddy, LLC*, 618 Fed.Appx. 992, 998-99 (Fed. Cir. 2015) (*quoting In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Absent evidence that the prior art "invariably" led to a different path, the prior art does not teach away. *See Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1199 (Fed. Cir. 2014).

75. "A reference does not teach away … if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed." *Id.* (*quoting DePuy Spine*, 567 F.3d at 1327).

d) Industry Praise

76. In order to support a finding of nonobviousness, "industry praise must [] be linked to the patented invention." *Geo. M. Martin*, 618 F.3d at 1305; *see also Paulsen*, 30 F.3d at 1482 (noting that the evidence of praise, while impressive, was not shown to be "relevant to the claims at issue and thus entitled to weight"). Specifically, a patentee must show that any industry praise, if such praise exists, is "attributable to … material difference[s] between [the prior art] and the invention" as opposed to features held in common between the prior art and claimed invention. *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (finding that the patentee failed to show evidence that the commercial embodiment of the patent drew praise due to the difference between the commercial embodiment and the prior art).

77. A statement that is intended to generate interest in a product is not evidence of industry praise. *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 n.3 (Fed. Cir. 1997) ("[t]his advertisement, according to RVI, represents 'industry acclaim' of the patented invention that constitutes 'strong objective evidence of nonobviousness.' We fail to appreciate the significance of this statement which is intended to generate interest in the product, not prove its superiority."). Further, reliance on journal articles that reference findings from a patentee's efficacy studies "fall[s] well short of demonstrating true industry praise." *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013).

78. To be properly considered as objective indicia of nonobviousness, evidence of industry praise must have a nexus to the claimed subject matter of the patent-in-suit. *See Muniauction*, 532 F.3d at 1328; Pharm*aStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1365 (Fed. Cir. 2007) ("The problem with that evidence is that there was no indication that the praise for the inventors' work was based on any inventive contribution they made, as opposed to their proof, through laboratory work, that fetal blood contains large numbers of stem cells. As

noted, the former is a basis for patentability; the latter is not."); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) ("While the evidence shows that the overall system drew praise as a solution to a felt need, there was no evidence that the success of the commercial embodiment of the '421 patent was attributable to the substitution of a multiplexer for a bus, which was the only material difference between [prior art] and the patented invention."); *Geo. M. Martin*, 618 F.3d at 1305 ("Industry praise must also be linked to the patented invention.").

79. "[B]are journal citations and self-referential commendation fall well short of demonstrating true industry praise." *Bayer*, 713 F.3d at 1377. "Furthermore, industry praise of what was clearly rendered obvious by published references is not a persuasive secondary consideration." *Id.*

e) Skepticism

80. In order to assert skepticism as a secondary consideration of nonobviousness, a party must provide actual evidence of skepticism through direct testimony or written or published statements; mere testimony to alleged out-of-court statements is not sufficient. *See Allergan, Inc. v. Watson Labs., Inc.-Florida*, 869 F. Supp. 2d 456, 490-91 (D. Del. 2012) ("[T]his testimony refers only to out-of-court statements of unnamed Bayer employees, no Bayer employees testified at trial, and no written or published statements of skepticism from Bayer were introduced into evidence to support Bayer's alleged rationale."). Further, evidence that one person was skeptical is insufficient to support a finding of nonobviousness. Rather, a patentee must show that "those of skill in the art were generally skeptical as to whether [the invention] was possible." *Id.* at 491. And more than "slight evidence" of skepticism must be shown to overcome strong teachings in the prior art. *B.F. Goodrich*, 72 F.3d at 1583.

81. Even if reliable evidence of skepticism is provided, a party must "demonstrate [that] the requisite nexus between the merits of the claimed invention and the evidence" of skepticism

exists. *Stamps.com Inc. v. Endicia, Inc.*, 437 Fed.Appx. 897, 905 (Fed. Cir. 2011) (citation omitted). Skepticism that is not directed at the solution provided by the patented invention "is not the type of skepticism that amounts to evidence of non-obviousness." *In re Youngblood*, 215 F.3d at *11; *see also Dow Jones & Co., Inc. v. Ablaise Ltd.*, 606 F.3d 1338, 1352 (Fed. Cir. 2010 (rejecting skepticism evidence that did "not directly address whether there was actual skepticism concerning the invention"); *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 642 F.3d 1370, 1377 (Fed. Cir. 2011) (finding skepticism that the invention would be effective for transient insomnia to be "of little relevance" where "the products disclosed by the claims at issue are not limited to treatment for transient insomnia").

B. Lack of Written Description

82. The determination that a patent is invalid for failure to meet the written description requirement is a question of fact. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002). A patent's specification must "contain a written description of the invention." 35 U.S.C. § 112.

83. To comply with the written description requirement of § 112, a patentee must describe "the invention, with all its claimed limitations." *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1379 (Fed. Cir. 2009) (citation omitted). A specification provides adequate written description if it reasonably conveys to a person of ordinary skill in the art that "the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

84. Merely describing one embodiment of a claimed invention does not necessarily satisfy the written description requirement; rather, description of a "single embodiment would support [] a generic claim only if the specification would reasonably convey to a person skilled in the art that [the inventor] had possession of the claimed subject matter at the time of filing."

LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1346 (Fed. Cir. 2005) (citation and internal quotation marks omitted). Further, a patentee "cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed." *Id.* The specification itself must demonstrate that the inventor was in possession of the entirety of the claimed invention. *Ariad*, 598 F.3d at 1352. Therefore, the written description requirement is not necessarily met because the claim language appears in the patent specification. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968-969 (Fed. Cir. 2002).

85. The Federal Circuit has articulated a variety of factors to evaluate the adequacy of the disclosure supporting generic claims, including (1) the existing knowledge in the particular field, (2) the extent and content of the prior art, (3) the maturity of the science or technology, and (4) the predictability of the aspect at issue. *Ariad*, 598 F.3d at 1351 (*citing Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). "A 'mere wish or plan' for obtaining the claimed invention is not adequate written description." *Centocor Ortho Biotech, Inc. v, Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011). The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Ariad*, 598 F.3d at 1351.

C. Non-Enablement

86. Enablement is a question of law based on underlying factual inquiries. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). A patent's specification must describe the invention and "the manner and process of making and using it, in such full, clear, concise, and

exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a).

87. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n), 1983), *aff'd. sub nom.*, *Massachusetts Inst. of Tech. v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

88. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). The doctrine "serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *Id.* at 1380-81; *see also Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991); *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

89. A claimed invention having an inoperable or impossible claim limitation lacks an enabling disclosure under 35 U.S.C. § 112. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983). If the number of inoperative combinations becomes significant, and thereby forces one of ordinary skill in the art to experiment unduly to be able to practice the claimed invention, the claims are invalid. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984).

D. Indefiniteness

90. A patent's claims must "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). Whether a claim is invalid for indefiniteness is a question of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015).

91. There are several aspects to the indefiniteness inquiry. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014). First, "definiteness is to be evaluated from the perspective of someone skilled in the relevant art." *Id.* Second, "in assessing definiteness, claims are to be read in light of the patent's specification and prosecution history." *Id.* Lastly, "'[d]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed.'" *Id.* (emphasis omitted).

92. While "the definiteness requirement must take into account the inherent limitations of language," "[a]t the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them. Otherwise, there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id.* at 2129 (internal citations and quotation marks omitted).

Where multiple known approaches exist, "the patent and prosecution history must disclose a single known approach or establish that … a person having ordinary skill in the art would know which approach to select." *Dow Chem. Co. v. Nova Chems. Corp. (Can.)*, 803 F.3d 620, 630 (Fed. Cir. 2015) (citations omitted). Thus, "[t]he claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (*citing Nautilus*, 134 S. Ct. at 2130 & n.8).

IV. ATTORNEYS' FEES

93. In exceptional cases, a court may award reasonable attorneys' fees to the prevailing party. 35 U.S.C. § 285. In deciding whether to award attorneys' fees, the court must undertake a two-step inquiry. *TruePosition, Inc. v. Andrew Corp.*, 611 F. Supp. 2d 400, 413 (D. Del. 2009) (*citing Interspiro USA, Inc. v. Figgie Int'l Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994)). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *TruePosition, Inc.*, 611 F. Supp. 2d at 413 (citation and quotation marks omitted).

94. In deciding whether a case is exceptional, the court must evaluate whether it "stands out from others with respect to the substantive strength of a party's litigation position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane*, 134 S. Ct. at 1756. This determination is a "case-by-case exercise" to be made "considering the totality of the circumstances." *Id.* The burden of proof rests with the prevailing party. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, No. CV 07-1000 (MLC), 2015 WL 5921035, at *8 (D.N.J. Oct. 9, 2015).

95. Second, the court must determine whether an award of attorneys' fees to the prevailing party is warranted. Id. Absent serious misconduct, courts have been reluctant to award fees to a prevailing party. *Otsuka*, 2015 WL 5921035, at *6-7. Examples of such serious misconduct include misleading statements "coupled with affirmative, false declarations submitted to the PTO in order to procure patents," filing of frivolous lawsuits, and re-litigation of issues already decided by the court. *E.g.*, *Intellect Wireless, Inc. v. Sharp Corp.*, 45 F. Supp. 3d 839, 853 (N.D. Ill. 2014); *Chalumeau Power Sys. LLC v. Alcatel–Lucent*, No. 11–1175-RGA, 2014 WL 4675002, at *3 (D. Del. Sept. 12, 2014), *aff'd*, 611 F. App'x 1008 (Fed. Cir. 2015); *Cognex Corp. v. Microscan Sys., Inc.*, No. 13–2027, 2014 WL 2989975, at *4 (S.D.N.Y. June 30, 2014). Such conduct is akin to the "'pattern of deceit' recognized by the Federal Circuit" in determining

whether a case is exceptional under Section 285. *Intellect Wireless, Inc.*, 45 F. Supp. 3d at 853; *see also Wedgetail, Ltd. v. Huddleston Deluxe, Inc.*, 576 F.3d 1302, 1304 (Fed. Cir. 2009); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1548 (Fed. Cir. 1984); *Hoffmann–La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989); *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1346-47 (Fed. Cir. 2000).

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 6

PLAINTIFF'S WITNESS LIST

EXHIBIT 6

WITNESS LIST

Plaintiff identifies the following witnesses whom it may call live or by deposition at trial with the following summaries. This list is not a commitment that Plaintiff will call any particular witness at trial, or a representation that any of the witnesses listed are available or will appear for trial. By identifying these witnesses, Plaintiff is not required to call them at trial, nor is Plaintiff limited in the manner in which such testimony is presented at trial.

With respect to Defendants' witnesses, Plaintiff reserves the right to introduce testimony through deposition or live examination, as appropriate. Plaintiff also reserves the right to call any witnesses called by Defendants or anyone appearing on Defendants' witness list, and to revise this list in light of further rulings by the Court or any other changed circumstances. Plaintiff further reserves the right to call one or more additional witnesses whose testimony is necessary to establish the authenticity or admissibility of any trial exhibit if the admissibility of the exhibit is challenged by Defendants. Plaintiff also reserves the right to call any witness for impeachment purposes.

I. EXPERT WITNESSES

Below are the expert witnesses Plaintiff proposes to call at trial live or by deposition. Plaintiff reserves the right to further modify, supplement, and/or amend the Final Pretrial Order and attachments in light of issues that remain open and until entry of the Final Pretrial Order.

1. Julie C. Harper, MD.
   Dermatology & Skin Care Center
   2470 Rocky Ridge Road
   Birmingham, Alabama 35243

Background and Qualifications: Dr. Harper is the head of the Dermatology and Skin Care Center of Birmingham, Alabama, as well as a Clinical Associate Professor in the Department of Dermatology at the University of Alabama-Birmingham. Dr. Harper earned her

M.D. from the University of Missouri-Columbia in 1996, and then completed an internship in internal medicine and a residence in dermatology at the University of Missouri-Columbia. She has been certified by the American Board of Dermatology since October 2000. Before opening her own dermatology practice in 2007, Dr. Harper was a full-time member of the faculty—first as Assistant Professor and Assistant Residency Program Director and later as Associate Professor and Residency Program Director—of the Department of Dermatology at the University of Alabama-Birmingham from 2000 to 2007, where in addition to seeing patients she also taught residents and medical students. As a practicing dermatologist for eighteen years, Dr. Harper has treated tens of thousands of patients for various skin conditions, including acne and rosacea. In addition, Dr. Harper is a founding director and the current president of the American Acne and Rosacea Society. She was also previously a member of the American Academy of Dermatology's Acne Work Group, and served as the President and Treasurer/Secretary of the Alabama Dermatological Society. In 2016, Dr. Harper was awarded the American Academy of Dermatology Presidential Citation Award. She has authored or co-authored over 40 publications or posters in the field of dermatology, of which most pertain to acne and/or rosacea, has given nearly 100 presentations nationally about acne and/or rosacea, and has been an Investigator or Principal Investigator on several clinical trials relating to acne and rosacea treatments.

Expected Testimony: At trial, Dr. Harper is expected to provide testimony regarding: (1) the technical background related to acne, rosacea, and prior art treatments for these dermatological conditions; (2) the level of ordinary skill in the art as of the priority date of the '219 patent; (3) the '219 patent; (4) the scope and content of the relevant prior art pertaining to the '219 patent; (5) that the asserted claims of the '219 patent are not invalid as obvious over the combinations asserted by Defendants; (6) objective evidence of the non-obviousness of the

asserted claims of the '219 patent; and (7) that Almirall's infringement position under the doctrine of equivalents does not impermissibly ensnare the prior art.

Defendants' Objections:

Taro objects to any testimony by Dr. Harper outside the scope of her 26(a)(2)(B) expert reports or deposition, outside her purported area of expertise, and/or objectionable under the Federal Rules of Evidence. Taro further objects to the extent Dr. Harper attempts to opine or testify on legal issues. Dr. Harper is a practicing dermatologist and readily admits she is neither a POSA nor a person capable of viewing the claims at issue from the perspective of a POSA. As such, Dr. Harper should be precluded from providing testimony about the obviousness of the claims at issue pursuant to Federal Rule of Evidence 702. Taro objects to Dr. Harper providing any opinions or testimony regarding obviousness and has included with the pretrial order, a Daubert motion to exclude Dr. Harper from testifying about the same. Taro refers to the Court to that motion for a more thorough analysis of Taro's objections to the testimony of Dr. Harper. *See*, Ex. 14 at Motion #5. *See* also, Ex. 14 at Motion #4.

2. Alexander M. Klibanov, Ph.D.
Massachusetts Institute of Technology
Building 56, Room 579
Cambridge, Massachusetts 02139

Background and Qualifications: Dr. Klibanov is a Professor of Chemistry and Bioengineering at M.I.T., where he has been teaching and conducting research for over 39 years. He currently holds the Novartis Endowed Chair Professorship. Dr. Klibanov obtained an M.S. degree in chemistry and a Ph.D. in chemical enzymology from Moscow University in Russia, after which he served as a Research Chemist at Moscow University's Department of Chemistry for three years. From 1977–1979, Dr. Klibanov was a Post-Doctoral Associate in the Department of Chemistry at the University of California in San Diego. Over the last 45+ years as a practicing

chemist, Dr. Klibanov has extensively researched, published, taught, and lectured in many areas of biological, medicinal, organic, pharmaceutical formulation, and polymer chemistry. Dr. Klibanov has earned numerous prestigious professional awards and honors for his work. For example, he was elected to the U.S. National Academy of Sciences (considered among the highest honors that can be given to an American scientist) and also to the U.S. National Academy of Engineering (considered among the highest honors that can be given to an American engineer). Dr. Klibanov is also a Founding Fellow of the American Institute for Medical and Biological Engineering and a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters). In addition, Dr. Klibanov received the Arthur C. Cope Scholar Award, the Marvin J. Johnson Award, the Ipatieff Prize, and the Leo Friend Award, all from the American Chemical Society, as well as the International Enzyme Engineering Prize. Dr. Klinabov currently serves on the Editorial Boards of 14 scientific journals. He has also published over 315 scientific papers in various disciplines, including several in the pharmaceutical area, and is the named inventor of 25 U.S. issued patents and many foreign patents. In addition to his research and teaching activities at M.I.T., Dr. Klibanov has consulted widely for pharmaceutical, medical device, chemical, and biotechnology companies, including both innovator and generic pharmaceutical companies. Dr. Klibanov has also founded six pharmaceutical companies and has been on the scientific advisory boards and/or boards of directors of those companies and of many others. A number of these entrepreneurial, consulting, advisory, and directorship activities have dealt with the formulation, stability, delivery, and biological evaluation of pharmaceutically active compounds.

Expected Testimony: At trial, Dr. Klibanov is expected to provide testimony regarding: (1) the technical background related to topical drug development and formulation, dapsone,

solvents, polymeric viscosity builders, and treatments for acne and rosacea; (2) the level of ordinary skill in the art as of the priority date of the '219 patent; (3) the '219 patent, its prosecution, its priority date, and how a person of ordinary skill would understand certain terms therein; (4) the scope and content of the relevant prior art pertaining to the '219 patent; (5) that the asserted claims of the '219 patent are not invalid; (6) objective evidence of the non-obviousness of the asserted claims of the '219 patent; and (7) that Almirall's infringement position under the doctrine of equivalents does not impermissibly ensnare the prior art.

Defendants' Objections:

Taro objects to any testimony by Dr. Klibanov outside the scope of his 26(a)(2)(B) expert reports or deposition, outside his purported area of expertise, and/or objectionable under the Federal Rules of Evidence. Taro further objects to the extent Dr. Klibanov attempts to opine or testify on legal issues.

3. Majella E. Lane, Ph.D.
University College London, School of Pharmacy
29-39 Brunswick Square
London
WC1N 1AX

Background and Qualifications: Dr. Lane is a Senior Lecturer and the Director of the Skin Research Group at the University College London School of Pharmacy, United Kingdom. She received a B.Sc. in Pharmaceutics in 1992 and a Ph.D. in Pharmaceutics in 1997 from Trinity College in Dublin, Ireland. After obtaining her Ph.D., Dr. Lane became Director of the Masters of Science Program in Pharmaceutical Technology at Trinity College, Dublin, from 1997 to 2005, and then joined the faculty at University College London. Among other roles, she teaches courses in the MPharm. and MSc. programmes, including courses concerning topical and transdermal preparations; skin structure and common skin disease; drug delivery across

biological barriers; and the symptoms and treatment of acne, eczema, and psoriasis. She has also supervised the theses of over fifty Ph.D. and M.S. students. Dr. Lane has published more than 130 scientific papers and co-authored fourteen book chapters in the field of pharmaceutics, and has given over 60 invited lectures at professional conferences, universities, and corporations worldwide. Many of these publications and lectures are directly relevant to the '219 patent, relating to topics such as polymers, crystallization, solubility, and stability of pharmaceutical formulations. Throughout her career, Dr. Lane has received numerous grants and awards, and has been intimately involved with industrial research in the area. She has been a consultant to numerous multinational companies such as GlaxoSmithKline, Pfizer, Procter & Gamble, and Reckitt Benckiser, including for the design of topical and transdermal formulations. Dr. Lane serves as an editor or referee for several additional scientific journals in her field, and is a member of numerous professional societies. Dr. Lane is also the Chair of Skin Forum, an interdisciplinary network of international scientists who share a common interest in the structure and characterization of human skin. Skin Forum is recognized as one of the most influential networks in dermal and cosmetic research today. Dr. Lane is currently the topical and transdermal expert for the Chemistry, Pharmacy and Standards committee of the Commission on Human Medicines for the UK Medicines Health and Regulatory Agency, which is the British equivalent of the FDA. In addition, she is a member of the European Medicines Agency working group on topical bioequivalence, and is specifically responsible for drafting new guidelines for the evaluation of topical formulations applied to the skin

Expected Testimony: At trial, Dr. Lane is expected to provide testimony regarding: (1) the level of ordinary skill in the art as of the priority date of the '219 patent; (2) technical background relevant to the topical pharmaceutical formulations of the '219 patent, including

emulsions and emulgels; the function, mechanism of action, and composition of components such as polymeric viscosity builders; and relevant characteristics such as rheological profile; (3) the '219 patent, its prosecution, and its priority date; (4) the '926 patent and its prosecution; (5) the development and formulation of Taro's ANDA Product; (6) the development and formulation of Almirall's ACZONE®, 7.5% Product; (7) infringement of the asserted claims of the '219 patent by the Taro ANDA Product; and (8) that Almirall's infringement claims are not barred, including by prosecution history estoppel, public disclosure-dedication, or ensnarement.

Defendants' Objections: Taro objects to testimony from Dr. Lane. Dr. Lane fails to analyze equivalence of any element of Taro's product to acrylamide/sodium acryloyldimethyl taurate copolymer (A/SA); instead she focuses on bioequivalence of Taro's product to Almirall's commercial product Aczone® 7.5% gel ("Aczone®"). Further, Dr. Lane's conclusions are based on conclusory analysis that fails to apply established scientific principles. Thus, Dr. Lane should be excluded from presenting her opinions at trial pursuant to Federal Rule of Evidence 702. Taro notes it has included, with the pretrial order, a Daubert motion to exclude Dr. Lane from offering the opinion Taro's thickening agent is equivalent to A/SA. Taro refers to the Court to that motion for a more thorough analysis of Taro's objections. *See*, Ex. 14 at Motion #2; *see also* Ex. 14 at Motion #1.

4. Panayiotis P. Constantinides, Ph.D.
95 Berkshire Court
Gurnee, IL 60031

Background and Qualifications: Dr. Constantinides is an independent consultant in the development of pharmaceutical products. He obtained a B.Sc. in Chemistry from the National and Kapodistrian University of Greece in 1977, and a Ph.D. in Biochemistry from Brown University in 1983. After serving as a postdoctoral fellow and then associate research scientist at

Yale University, Dr. Constantinides worked in the biotechnology and pharmaceutical industry from 1987 through 2004, at which time he founded Biopharmaceutical & Drug Delivery Consulting LLC. He currently serves as the latter's President.

Expected Testimony: At trial, Dr. Constantinides is expected to provide testimony regarding infringement of the asserted claims of the '219 patent under the doctrine of equivalents by the Taro ANDA Product, and specifically equivalence of a polymeric viscosity builder comprising A/SA copolymer and a polymeric viscosity builder comprising carbomer.

Defendants' Objections: Dr. Panayiotis Constantinides ("Constantinides") has been retained by Taro as its invalidity expert. During the course of his engagement on this matter, Constantinides has spent considerable time reviewing Almirall's patent, along with prior art and other scholarly sources, in order to arrive at an expert opinion on the question of whether Almirall's patent is valid. Constantinides was not asked, and has not undertaken, to study either Taro or Almirall's products, to examine their composition, or to form an opinion as to whether Taro's product infringes on the '219 patent. Almirall cannot rely on Constantinides' expert testimony because it failed to meet any of the various requirements set out in Fed. R. Civ. P. 26 that are intended to alert opposing parties to proposed experts, along with their qualifications, opinions and methods, in order to prevent trial by ambush. Almirall was required to disclose any expert it intended to rely on at trial no later than the date set for opening expert reports, which were scheduled for service last September. *See* Scheduling Order, D.I. 26. Almirall did not designate Constantinides at that time. Taro first learned of Almirall's intention to designate Constantinides the evening of January 4, 2019. Pursuant to Rule 26 and this Court's scheduling order, Almirall's attempted reliance is improper and too late. Second, even if Almirall's disclosure of Constantinides had been timely, it still fails to satisfy the substantive disclosure

requirements of Rule 26. Parties must submit a written and signed report for every expert they expect to offer. Fed. R. Civ. P. 26(a)(2)(B). Almirall has not even tried to meet this obligation.

Notably, Almirall has only briefly disclosed (for the first time in the Pretrial Order) the substance of Constantinides' "opinions" that it is planning to use at trial and has not disclosed the materials he considered in reaching those opinions nor the infringement issues his opinions are intended to support. Almirall simply has no right to call Taro's expert. Where a party has the ability to obtain expert testimony without subpoenaing its adversary's expert, courts overwhelmingly refuse to allow that testimony. *See, e.g. Dudley Flying Serv., Inc. v. Ag Air Maint. Servs., Inc.,* No. 3:13-CV-00156-KGB, 2015 WL 1757886 (E.D. Ark. Apr. 17, 2015) (denying permission to examine adversary's expert at trial under "special circumstances" test); In re Homestore.com, Inc., No. CV 01-11115 RSWL CWX, 2011 WL 291176 (C.D. Cal. Jan. 25, 2011) (refusing to admit testimony under "exceptional circumstances" test upon finding that proposed testimony was not unique and the party proposing testimony could find another expert). Since Almirall has its own infringement expert, there are no "exceptional circumstances" justifying its use of Constantinides' testimony.

Constantinides has not studied Taro's product, nor compared it to Almirall's, to determine if the ANDA production described in Taro's ANDA infringes the patents-at-issue. Ultimately, Constantinides' work in this case has not exposed him to "sufficient facts or data" relevant to the infringement controversy to form a reliable opinion as required by the Federal Rules of Evidence. Because Constantinides' expertise is not accompanied by sufficient facts or data on the question of whether Taro's dapsone gel 7.5% product infringes upon Almirall's patent, his testimony on that topic is inadmissible non-expert opinion testimony.

II. FACT WITNESSES

Below are the fact witnesses Plaintiff proposes to call at trial live or by deposition. Plaintiff reserves the right to further modify, supplement, and/or amend the Final Pretrial Order and attachments in light of issues that remain open and until entry of the Final Pretrial Order.

1. Kevin Warner, Ph.D.[1] (live if present at trial, and/or by deposition)
2. Alexandre Kaoukhov, M.D.
3. Avi Avramoff[2] (live if present at trial, and/or by deposition)

Defendants' Objections to Plaintiff's Fact Witnesses:

Kevin Warner, Ph.D.: Taro objects to Almirall's designation of testimony from Dr. Warner. Dr. Warner was presented as Almirall's fact witness, and as is clear from his testimony, particularly the testimony designated by Almirall, Dr. Warner was testifying in his individual capacity and not in a capacity as a 30(b)(6) witness for Almirall. Should Almirall wish to present testimony from Dr. Warner at trial, whether in his individual or corporate capacity, such testimony should be presented live at trial, wherein Dr. Warner would be subjected to cross examination.

Alexandre Kaoukhov, MD: Taro objects to Almirall calling Dr. Kaoukhov as a witness in this matter. Plaintiff and Taro came to an agreement during fact discovery regarding depositions and the calling of additional fact witnesses. Taro previously noticed the deposition of Dr. Kaoukhov and he was not deposed due to the agreement between the parties. To the extent Dr. Kaoukhov is allowed to testify, Taro should be allowed a full seven (7) hour deposition, no later than 10 days before the beginning of trial, to take place at the offices of Taro's counsel in Chicago.

---

[1] Individually and as a corporate representative of Allergan, Inc. under Fed. R. Civ. P. 30(b)(6).
[2] Individually and as a corporate representative of Taro under Fed. R. Civ. P. 30(b)(6).

Avi Avramoff: Taro objects to Dr. Avramoff being called as a witness or designated by Almirall in his individual capacity. Dr. Avramoff served as Taro's 30(b)(6) witness and was not noticed for deposition in his individual capacity.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 7

DEFENDANTS' WITNESS LIST

WITNESS LIST

Defendants identify the following witnesses whom it may call live or by deposition at trial with the following summaries. This list is not a commitment that Defendants will call any particular witness at trial, or a representation that any of the witnesses listed are available or will appear for trial. By identifying these witnesses, Defendants are not required to call them at trial, nor are Defendants limited in the manner in which such testimony is presented at trial.

With respect to Plaintiff's witnesses, Defendants reserve the right to introduce testimony through deposition or live examination, as appropriate. Defendants also reserve the right to call any witnesses called by Plaintiff or anyone appearing on Plaintiff's witness list, and to revise this list in light of further rulings by the Court or any other changed circumstances. Defendants further reserve the right to call one or more additional witnesses whose testimony is necessary to establish the authenticity or admissibility of any trial exhibit if the admissibility of the exhibit is challenged by Plaintiff. Defendants also reserve the right to call any witness for impeachment purposes.

I. EXPERT WITNESSES

Below are the experts Defendants propose to call at trial live or by deposition. Defendants reserve the right to further modify, supplement and/or amend the Final Pretrial Order and attachments in light of issues that remain open and until entry of the Final Pretrial Order.

PANAYIOTIS P. CONSTANTINIDES, PH.D.

Taro intends to offer Dr. Panayiotis Constantinides, who will testify as to his opinion that the '219 patent is invalid, ensnarement of the prior art, and to rebut opinions offered on behalf of Plaintiff by Dr. Julie Harper and Dr, Alexandre Klibanov.

Dr. Constantinides is an independent consultant, who has expertise in the development of pharmaceutical products, including topical drug products and topical drug delivery. He has thirty-one years of experience in the development of pharmaceutical products. Several drug products have been marketed and sold based on his work and contribution.

Dr. Constantinides holds a B.Sc. in Chemistry from the National and Kapodistrian University of Greece in Athens. He completed a Ph.D. in Biochemistry (physical) from Brown University in 1983. He completed a Postdoctoral Fellowship in Pharmacology and Cancer Research at Yale University in 1985, followed by two additional years at Yale University as an Associate Research Scientist.

Dr. Constantinides' professional experience includes experience in all aspects of developing formulations of oral, parenteral and topical compositions of New Molecular Entities, both small molecule and peptide therapeutics, whereby Dr. Constantinides has been heavily involved in excipient selection while formulating, including with respect to topical drug compositions.

In terms of the specific formulation technologies and dosage forms (immediate, sustained, extended and controlled release), Dr. Constantinides' drug product development experience includes all forms of pharmaceutical dosage forms, such as topical solutions, ointments, creams, foams and gels. He has extensive experience with surfactants, viscosity modifying or building agents (commonly known as thickening or gelling agents), as well as functional excipient development and qualification, including novel excipients for pharmaceutical development, new and non-traditional uses of existing pharmaceutical excipients.

For example, Dr. Constantinides has worked with lipid and lipid-based excipients, polymer and polymer-based excipients, acrylic polymers/copolymers (Carbomer/Carbopol®), polyethylene–polypropylene glycol copolymers (Poloxamers), starches, cellulosic polymers as well as mineral clays and silicates.

Dr. Constantinides received numerous awards and honors, including the Browne-Coxe Postdoctoral Fellowship at Yale University School of Medicine. He is inventor/co-inventor of 12 U.S. Patents, 4 European Patents, 17 WO (World Intellectual Property Patents) and the inventor/co-inventor on several additional Patent Applications. He has also been an editorial board member and referee for peer reviewed journals, including recently with respect to Drug Delivery & Formulation, a well-respected journal in the pharmaceutical industry and academics.

In 2004, Dr. Constantinides founded Biopharmaceutical & Drug Delivery Consulting, LLC in Gurnee, Illinois and he is currently serving as its President.

At trial, Dr. Constantinides is expected to provide testimony regarding, *inter alia*,:

1. The '219 patent and its prosecution, including any prosecution of related applications, such as the parent application;
2. The invalidity of the '219 patent;

3. The level of ordinary skill in the art as of the priority date of the '219 patent;
4. The scope and the content of the relevant prior art pertaining to the '219 patent;
5. Ensnarement of the prior art based on Plaintiff's doctrine of equivalents positions.

MANSOOR M. AMIJI, PH.D., R.PH.

Taro intends to offer Dr. Mansoor Amiji, who will testify as to his opinion that the product described in Taro's Abbreviated New Drug Application will not infringe the claims of the '219 patent, including, but not limited to, a rebutting testimony offered by Plaintiffs at trial on the issue of infringement.

Dr. Amiji is a University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. He has over 25 years of experience in teaching drug formulations to both graduate and undergraduate students, extensively covering the manufacturing and composition of pharmaceutical formulations. He also serves as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

Dr. Amiji graduated in 1988 with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, he received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmacal Sciences at Purdue University, under the supervision of Professor Kinam Park. His dissertation focused on biomaterials and water-soluble polymers.

Dr. Amiji has published extensively and is ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. He has coauthored over 60 book chapters and more than 300 peer reviewed scientific articles. Furthermore Dr. Amiji is an inventor on several

issued United States patents covering pharmaceutical devices, materials and methods and he has taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics. He has received a number of professional awards and honors.

At trial, Dr. Amiji is expected to provide testimony regarding, *inter alia*,:

1. The '219 patent and its prosecution;
2. The '926 patent and its prosecution;
3. Non-infringement of the '219 patent by Taro's ANDA product;
4. A hypothetical claim to be used for an analysis of ensnarement of the prior art based Plaintiff's doctrine of equivalents arguments.

Plaintiff's Objections: Plaintiff object to any testimony offered by Dr. Amiji in so far as such testimony was not properly noticed pursuant to Rule 26.

II. FACT WITNESS

Below is the fact witness Defendants propose to call at trial live or by deposition. Defendants reserve the right to call anyone appearing on Plaintiff's witness list besides the fact witness as defined below. Defendants also reserve the right to further modify, supplement, and/or amend the Final Pretrial Order and attachments in light of issues that remain open and until entry of the Final Pretrial Order.

1. Kevin Warner, Ph.D. (Individually and as a corporate representative of Allergan, Inc. under Fed. R. Civ. P. 30(b)(6));
2. Avi Avramoff, Ph.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 8

PLAINTIFF'S DEPOSITION DESIGNATIONS

DEPOSITION DESIGNATION OBJECTION CODES

Objection Code	Description
AA	Asked and answered; Fed. R. Evid. 611(a)
BE	Best evidence; Fed. R. Evid. 1002
BTS	Beyond the scope of examination or of 30(b)(6) topic; Fed. R. Evid. 611, Fed. R. Civ. P. 30(b)(6)
CP	Compound question
CU	Cumulative/Waste of time; Fed. R. Evid. 403
F	No foundation or assumes facts not in evidence; Fed. R. Evid. 602, 703, 901
H	Hearsay if offered for the truth of the matter asserted; Fed. R. Evid. 801, 803, 805
I	Incomplete designation; Fed. R. Evid. 106, 403
L	Leading; Fed. R. Evid. 611(c)
LAW	Lawyer argument or colloquy
LC	Legal conclusion; Fed. R. Evid. 701
MIS	Mischaracterization of testimony or evidence
O	Unqualified opinion; Fed. R. Evid. 701, 702
OB	Attorney objection improperly designated
P	Privileged; Fed. R. Evid. 501, Fed. R. Civ. P. 26(b)(3), (4)
PK	Lack of personal knowledge; Fed. R. Evid. 602
R	Not relevant; Fed. R. Evid. 401, 402
SPEC	Speculation; Fed. R. Evid. 602, 701, 702
U	Unfairly prejudicial, cumulative, or wasteful; Fed. R. Evid. 403
V	Vague or ambiguous; Fed. R. Evid. 611(a)
IC	Improper counter-designation

1. Warner, Kevin FRCP 30(b)(6) – July 18, 2018

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
10:4–18	General Objection 1[1] and 2[2]			
16:3–18:10	General Objection 1 and 2			
18:17–19:15	General Objection 1 and 2			
23:2–24:8	General Objection 1 and 2			
26:3–12	General Objection 1 and 2			
27:6–28:22	General Objection 1 and 2			
29:18–32:3	General Objection 1 and 2			
32:6–20	General Objection 1 and 2, I	32:5; 32:21-33:6;	R F, PK	
33:8–34:14	General Objection			

[1] **General Objection 1:** Taro objects to Almirall's designation of testimony from K. Warner. Dr. Warner was presented as Almirall's fact witness, and as is clear from his testimony, particularly the testimony designated by Almirall, Dr. Warner was testifying in his individual capacity and not in a capacity as a 30(b)(6) witness for Almirall. Should Almirall wish to present individual testimony from Dr. Warner at trial, whether in his individual or corporate capacity, such testimony should be presented live at trial, wherein Dr. Warner would be subjected to cross examination.

Almirall's Response: Taro's objection lacks merit given that Dr. Warner was deposed pursuant to Fed. R. Civ. P. 30(b)(6), is not an Almirall employee, and furthermore is not subject to the court's subpoena power under Fed. R. Civ. P. 45.

[2] **General Objection 2:** Taro objects to Almirall's designations of both Warner and Avramoff to the extent they are not properly grouped to identify questions/answers and or topics and are therefore incomplete and improper. In view of Almirall's failure to properly group testimony it intends to utilize at trial in its deposition designation chart, Taro reserves the right to use any and all designations (affirmative, counter or counter-counter) with respect to deposition testimony Almirall presents at trial.

Almirall's Response: There is no requirement for "grouping" of deposition designations.

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	1 and 2, I,	34:15-19;		
35:6–14	General Objection 1 and 2, I	35:16;	I, CU	
		39:12-20;	IC	
36:10–16	General Objection 1 and 2, I	40:5-10	IC	
36:20–37:5	General Objection 1 and 2, I			
37:9–15	General Objection 1 and 2, I			
37:17–38:3	General Objection 1 and 2, I			
38:7–11	General Objection 1 and 2, I			
40:11–14	General Objection 1 and 2, I	41:17-42:9;	IC, BTS, O, PK, SPEC	
40:18–41:16	General Objection 1 and 2, I, SPEC	42:14-21;	IC, BTS, O, PK, SPEC	
		43:2-43:17;	IC, BTS, O, PK, SPEC	
		43:21-44:5;	IC, BTS, O, PK, SPEC	
		44:7-10;	IC, BTS, O, PK, SPEC	
		44:13-17;	IC, O, PK, SPEC	
		44:21-45:17	IC, O, PK, SPEC	
48:6–15	General Objection 1 and 2, I	48:21-49:5;	CU	
		49:18-22;	IC, O, PK, SPEC	
49:6–17	General Objection 1 and 2, I	50:4-8;	IC, O, PK, SPEC	

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
		50:13-16; 50:20-51:2; 51:21-52:12; 52:15-52:20	IC, O, SPEC IC, O, SPEC IC IC	
55:14–56:1	General Objection 1 and 2, I	57:21-58:1; 58:4-58:13; 58:16-58:22; 61:19-62:1; 62:3-9	MIS, U MIS, U, CU MIS, U, CU IC, R IC, R	
56:12–57:6	General Objection 1 and 2, I			
57:10–20	General Objection 1 and 2			
59:1–20	General Objection 1 and 2, I, SPEC			
63:9–64:14	General Objections 1 and 2, I	64:15-65:1; 66:3-6; 66:9-13; 66:19-67:1; 67:5-67:10;	IC IC, MIS, O IC IC	66:16–18
65:2–8	General Objections 1 and 2, I			
65:12–66:2	General Objections 1 and 2, I			
68:1–14	General Objections 1 and 2, I	69:16-19; 70:1-4; 71:19-72:2; 72:9-15; 73:8-15	IC IC	72:3–8
70:22–71:18	General Objections 1 and 2, I			
72:16–21	General Objections 1 and			

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	2, I			
73:2–7	General Objections 1 and 2, I			
73:16–75:3	General Objections 1 and 2, I			
77:17–78:6	General Objections 1 and 2, I	76:11-77:16	IC	
78:13–80:20	General Objections 1 and 2, I	83:8-15; 83:17-20; 84:16-85:6;	MIS MIS	83:21–84:3
84:8–15	General Objections 1 and 2, I	85:10-86:7; 86:10-87:3;	O O	
96:19–97:8	General Objections 1 and 2, I	97:9-98:1; 98:5-8; 98:10-11; 98:21-99:16; 99:18-20; 101:1-101:6; 101:10-15; 102:14-103:9; 103:13-104:7	IC, R, V IC, R, V IC, R, V IC, R, V IC, O, PK, SPEC IC, O, PK, SPEC IC, O IC, O	
98:2–4	General Objections 1 and 2, I			
100:9–18	General Objections 1 and 2, I			
104:15–19	General Objections 1 and 2, I	104:20-105:1; 105:4-21;	IC, F IC, F, O	

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
106:22–107:2	General Objections 1 and 2, I	106:3-7; 107:3-5; 107:12-19; 108:11-20; 109:2-8	IC, F, O	
108:8–10	General Objections 1 and 2, I			
108:21–109:1	General Objections 1 and 2, I			
109:10–13	General Objections 1 and 2, I			
109:15–113:1	General Objections 1 and 2, I			
124:5–125:1	General Objections 1 and 2, I	127:17-21; 128:1-5; 131:11-132:11	IC, BTS, O, PK, SPEC IC, BTS, O, PK, SPEC IC, R	130:15–20
128:6–9	General Objections 1 and 2, I			
128:11–129:21	General Objections 1 and 2, I			
132:17–134:7	General Objections 1 and 2, I, SPEC	145:1-145:18; 145:22-146:10; 149:7-149:18;	IC, I IC IC	
139:22–140:4	General Objections 1 and 2, I			
140:8–21	General			

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	Objections 1 and 2, I			
141:10–142:13	General Objections 1 and 2, I			
146:12–147:18	General Objections 1 and 2, I			
147:20–149:6	General Objections 1 and 2, I			
158:8–159:15	General Objections 1, and 2, I	158:2-6; 162:1-8;	IC	
160:20–161:22	General Objections 1, and 2, I			
162:12–163:15	General Objections 1, and 2, I			
169:5–12	General Objections 1 and 2, I	169:13-17; 170:5-171:5	IC, H	
171:10–19	General Objections 1 and 2, I			
172:5–173:6	General Objections 1 and 2, I, SPEC	171:20-172:3		
175:8–10	General Objections 1 and 2			

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
179:15–18	General Objections 1 and 2, I			
179:22–180:18	General Objections 1 and 2, I			
182:3–185:22	General Objections 1 and 2, I	186:1-7; 186:9-10; 187:17-22;	CP CP IC, R	
186:12–187:16	General Objections 1 and 2, I			
199:22–200:3	General Objections 1 and 2, I	199:13-21;	IC, AA, F, MIS	
200:6–18	General Objections 1 and 2, I			
200:21–201:4	General Objections 1 and 2, I			
229:13–232:7	General Objections 1 and 2, I	228:16-229:4; 229:6-229:12; 232:8-17	IC, CU	
232:18–233:4				
234:15–235:5				
237:9–14	General Objections 1 and 2; I	237:1-3; 238:1-9; 246:3-13;	LAW	
238:10–240:1	General			

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	Objections 1 and 2; I	247:20-248:17	IC	
241:11–242:3	General Objections 1 and 2; I			
245:2–246:2	General Objections 1 and 2; I			
247:11–19	General Objections 1 and 2; I			
248:18–249:7	General Objections 1 and 2; I			
250:11–254:2	General Objections 1 and 2; I	254:13-255:1; 258:6-14; 258:16-259:8; 262:19-263:9; 265:1-268:1; 268:3-14	IC IC IC CU IC IC	268:15–269:1
259:9–260:7	General Objections 1 and 2; I			
261:6–22	General Objections 1 and 2; I			
269:2–6	General Objections 1 and 2; I			
279:12–280:7	General Objections 1 and 2; I	280:8-14; 280:16-18;		280:20–281:1

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
281:2–284:22	General Objections 1 and 2; I	285:1-4; 285:8-286:3; 287:5-7	O O CU	287:8–16
286:4–287:4	General Objections 1 and 2; I			
289:2–290:22	General Objections 1 and 2; I	293:6-294:1; 294:22-295:9; 295:12-296:20	IC IC IC	297:1–15
291:2–292:18	General Objections 1 and 2; I			
292:20–293:5	General Objections 1 and 2; I			
306:14–307:2	General Objections 1 and 2; I	306:10-12; 314:1-13;		
308:10–309:22	General Objections 1 and 2; I			
311:10–312:19	General Objections 1 and 2; I			
314:14–315:6	General Objections 1 and 2; I			
315:8–17	General Objections 1 and 2; I			

Kevin Warner FRCP 30(b)(6) July 18, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
318:18–319:13	General Objections 1 and 2; I	319:14-18; 321:9-322:3; 322:6-323:18	 IC IC, LAW	
332:10–19	General Objections 1 and 2; I	332:1-8;		
337:7–338:21	General Objections 1 and 2; I			
339:11–15	General Objections 1 and 2; I	338:22-339:10;		
339:17–340:17	General Objections 1 and 2, I			
342:17–344:20	General Objections 1 and 2			

2. Avramoff, Avi – July 17, 2018

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
7:23–8:12				
11:13–11:23				
12:4–12:6	See General Objection 2,[3] I	12:7-12:13; 12:22-13:4	LAW	
12:14–12:21	See General Objection 2, I			
13:5–14:5	F	14:25-15:2; 15:5-7	R R	
14:6–14:24	General Objection 2, I			
15:9–15:16	General Objection 2, I			
16:10–16:19	General Objection 2, I	16:20-18:18; 18:25-19:3; 19:6-19:12	IC, R, H IC, R, H IC, R, H	
19:25–20:17	General Objection 2, I, F			
21:2–21:13	General Objection 2, I, V, F			

[3] **General Objection 2:** Taro objects to Almirall's designations of both Warner and Avramoff to the extent they are not properly grouped to identify questions/answers and or topics and are therefore incomplete and improper. In view of Almirall's failure to properly group testimony it intends to utilize at trial in its deposition designation chart, Taro reserves the right to use any and all designations (affirmative, counter or counter-counter) with respect to deposition testimony Almirall presents at trial.

Almirall's Response: There is no requirement for "grouping" of deposition designations.

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
22:19–23:15	General Objection 2, V, I	23:16-25:18; 26:2-27:1	IC, F, SPEC, R IC, R	
30:12–30:24	General Objection 2, V, I, SPEC	31:11-15; 31:22-33:1	IC, CU IC, SPEC, O, PK	
31:16–31:21	General Objection 2, V, I, SPEC			
33:12–34:21	General Objection 2, V, I, MIS	35:8-10; 35:13-17	SPEC, O, PK, V SPEC, O, PK, V	
34:24–35:6	General Objection 2, V, I, SPEC			
36:18–38:20	General Objection 2, V, F, MIS; R; OB; I, SPEC			
41:3–43:20	General Objection 2, MIS, I, SPEC	43:21-44:13; 47:19-23; 48:1-2	IC, I	44:14–45:7; 45:10-46:8; 46:11-46:14
51:14–51:25	General Objection 2, R, F			
57:2–57:20	General Objection 2, F, MIS, I	57:21-25; 62:1-12	IC, R, V, F, PK, SPEC, O	

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
58:1–60:1	General Objection 2, F, MIS, I, V, OB, SPEC	62:11-12	IC, I, R, V, F, PK, SPEC, O	
62:13–63:25	General Objection 2, F, I			
64:5–64:13[4]	General Objection 2, F, I	64:13		
68:3–68:17	General Objection 2, F, I	68-18-68:23; 69:1-69:5	IC, PK, R IC, PK, R	
69:7–70:24	General Objection 2, F, MIS, I, V, OB	70:25-71:16; 72:14-25; 73:3-17	R, V, PK IC, R IC, R	
83:6–85:17	General Objection 2, F, I, R			
85:20–87:2	General Objection 2, F, I, R, SPEC	87:11-14; 87:17-24; 94:9-15; 96:9-97:14	V, PK, SPEC, O V, PK, SPEC, O IC IC	
87:5–87:9	General Objection 2, F, I, R			
98:8–99:3	General Objection 2			
100:11–101:4	General Objection 2, F, I, Compound	101:5-18; 101:21-102:13;	CU, U CU, U	

[4] Almirall's initial designation of 64:5–64:12 contained a typographical error; the designation was intended to read 64:5–64:13.

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
102:14–103:8	General Objection 2, F, MIS, I, V	103:9-104:24; 107:17-108:2; 108:5-108:11; 108:14-24	V, PK, SPEC, O CU, PK CU PK, SPEC, O	
104:25–106:24	General Objection 2, I, F, MIS, V			
107:2–107:11	General Objection 2, I, F, MIS, V			
107:13–107:15	General Objection 2, I, F, SPEC			
109:2–109:11	General Objection 2, I, F	110:2-110:5; 110:8-9; 110:11-15	IC IC IC, V	
109:20–110:1	General Objection 2, I, F			
110:16–110:22	General Objection 2, I, F, SPEC			
111:6–111:21	General Objection 2, I			
111:25–112:16	General Objection 2, F, I	113:9-113:15; 113:18-114:1; 114:14-23; 115:1-13; 117:6-12; 119:5-7;	PK, O, SPEC PK, O, SPEC PK, O, SPEC PK, O, SPEC PK, O, SPEC	
114:3–114:14[5]	General Objection 2, I, F, V, R			
117:13–117:21	General Objection 2, F, I,			

[5] Almirall's initial designation of 114:3–114:13 contained a typographical error; the designation was intended to read 114:3–114:14.

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	MIS, V, R	119:10-12; 122:17-24	IC	
117:22–118:13	General Objection 2, F, I, MIS, A			
118:21–119:4	General Objection 2, I, R			
120:9–120:20	General Objection 2, F, I, R			
120:24–121:19	General Objection 2, F, I, R			
121:22–122:16	General Objection 2, F, I, R			
122:25–123:10	General Objection 2, F, I			
123:13–124:9	General Objection 2, I, F, A			
124:10–125:12	General Objection 2, I	126:22-24; 127:2-129:6	IC, F, PK, O, SPEC IC, F, PK, O, SPEC	
129:10–129:21	General Objection 2, I			
140:17–141:1	General Objection 2, V, R			
145:5–145:12	General Objection 2, I	145:13-146:13	PK, O, SPEC	

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
146:14–146:22	General Objection 2, I, F, MIS			
146:25–147:12	General Objection 2, I			
147:23–148:5	General Objection 2, I	152:6-18; 152:21-153:6; 162:14-165:24; 167:6-168:9; 168:12	IC, R IC, R IC, PK, O IC, R, PK, H IC, R	
154:20–155:20	General Objection 2, I			
156:12–156:21	General Objection 2, I			
157:14–157:21	General Objection 2, F, I			
159:5–159:11	General Objection 2, I, MIS, V, F			
159:16–162:13	General Objection 2, I, F, A, V, R			
165:25–166:4	General Objection 2, I, A, F, MIS, R			
166:7–166:20	General Objection 2, I, R			
168:22–170:20	General Objection 2, I, F, MIS, R	174:1-20; 174:23-10	CU CU (assuming Taro intended to designate 174:23-175:10)	
170:23–172:12	General Objection 2, I, F, MIS, A, R			

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
172:15–173:6	General Objection 2, I, F, MIS, A, R			
175:17–176:1	General Objection 2, I, F			
176:4–176:5	General Objection 2, I			
176:15–176:18	General Objection 2, I, F	176:7-8; 176:19-22; 179:6-16		
177:11–177:25	General Objection 2, I			
178:18–179:5	General Objection 2, I, F			
179:24–180:4	General Objection 2, I, F			
183:4–184:12	General Objection 2, I, LAW, OB			
184:20–185:25	General Objection 2, I			
186:1–186:21	General Objection 2, I, LAW			
187:22–188:2	General Objection 2, I			
188:4–189:12	General Objection 2, I, F, R	189:24-190:6; 192:6-193:15	R OB, R, F, PK, SPEC	
190:7–190:14	General			

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
	Objection 2, I, F, R			
191:12–192:5	General Objection 2, I, F, SPEC			
193:25–194:8	General Objection 2, I, F	194:9-14		
194:20–196:5	General Objection 2, I, F			
196:22–197:7	General Objection 2, I, F, R			
197:10–198:8	General Objection 2, I, MIS, F, R			
198:15–198:19	General Objection 2, I, R, V			
199:2–199:21	General Objection 2, I, F			
201:10–202:1	General Objection 2, I, F, MIS			
202:15–203:10	General Objection 2			
209:19–210:4	General Objection 2, I, F			
210:12–211:11	General Objection 2, I, F, SPEC			

Avi Avramoff FRCP 30(b)(6) July 17, 2018				
Plaintiff's Designations	**Defendants' Objections**	**Defendants' Counter-Designations**	**Plaintiff's Counter-Objections**	**Plaintiff's Rebuttal Designations**
211:14–212:1	General Objection 2, I, F, MIS			
212:4–212:15	General Objection 2, I, F, MIS			
216:8–216:22	General Objection 2, I, R			
217:10–218:3	General Objection 2, I, R			
218:14–219:16	General Objection 2, I, R			
219:19–220:6	General Objection 2, I, R			

Exhibit 9

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 9

TARO'S DEPOSITION DESIGNATIONS

Exhibit 9

DEPOSITION DESIGNATION OBJECTION CODES

Objection Code	Description
AA	Asked and answered; Fed. R. Evid. 611(a)
BE	Best evidence; Fed. R. Evid. 1002
BTS	Beyond the scope of examination or of 30(b)(6) topic; Fed. R. Evid. 611, Fed. R. Civ. P. 30(b)(6)
CP	Compound question
CU	Cumulative/Waste of time; Fed. R. Evid. 403
F	No foundation or assumes facts not in evidence; Fed. R. Evid. 602, 703, 901
H	Hearsay if offered for the truth of the matter asserted; Fed. R. Evid. 801, 803, 805
I	Incomplete designation; Fed. R. Evid. 106, 403
L	Leading; Fed. R. Evid. 611(c)
LAW	Lawyer argument or colloquy
LC	Legal conclusion; Fed. R. Evid. 701
MIS	Mischaracterization of testimony or evidence
O	Unqualified opinion; Fed. R. Evid. 701, 702
OB	Attorney objection improperly designated
P	Privileged; Fed. R. Evid. 501, Fed. R. Civ. P. 26(b)(3), (4)
PK	Lack of personal knowledge; Fed. R. Evid. 602
R	Not relevant; Fed. R. Evid. 401, 402
SPEC	Speculation; Fed. R. Evid. 602, 701, 702
U	Unfairly prejudicial, cumulative, or wasteful; Fed. R. Evid. 403
V	Vague or ambiguous; Fed. R. Evid. 611(a)
IC	Improper counter-designation

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
1	10:4	10:18		17:12 18:17	18:10 19:15	R		
2	14:16	15:3						
3	16:3	17:11		17:12 18:17	18:10 19:15	R		
4	23:2	23:9						
5	23:11	23:22						
6	28:10 29:18 30:20	28:22 30:8 32:3						
7	32:5 33:8 34:2	32:11 33:14 34:14		32:12	32:20	R		
8	34:15 35:6 36:10 36:20 37:1 37:9 37:17 37:20 38:7 38:17	34:19 35:16 36:16 36:22 37:5 37:15 37:19 38:3 38:14 39:2						
9	39:12 40:5	39:20 40:10						
10	40:11	40:14						

[1] Almirall's counter-designations apply to all designations made by Taro within a Group. Should Taro offer into evidence only portions of its designated testimony at trial, Almirall reserves the right to counter designate any of Taro's remaining designated testimony. Almirall also reserves the right to offer into evidence in its own case any testimony designated by Taro.

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	40:18	41:1						
11	41:2	42:5						
12	42:6 42:14 42:17 43:2	42:9 42:16 42:21 43:11	BTS, O, PK, SPEC BTS, O, PK, SPEC BTS, O, PK, SPEC BTS, O, PK, SPEC					
13	43:12 43:21 44:7	43:17 44:5 44:10	BTS, O, PK, SPEC BTS, O, PK, SPEC BTS, O, PK, SPEC					
14	44:13 44:21	44:17 45:17	O, PK, SPEC O, PK, SPEC					
15	48:6 48:21 50:4	48:15 49:22 50:8	 O, PK, SPEC O, PK, SPEC					
16	50:13 50:20	50:16 51:2	O, SPEC O, SPEC					
17	51:21 52:15	52:12 52:20						
18	55:14 56:12 57:10	56:1 57:6 57:12		57:14 59:1	57:20 59:20	SPEC SPEC, ID	57:21 58:4 58:16	58:1 58:13 58:22
19	60:16 61:5 61:19 62:3	61:2 61:7 62:1 62:9	 R R					
20	63:9 65:2 65:12 66:9	65:1 65:8 66:6 66:13	 MIS, O	66:16	66:18			

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	66:19 67:5	67:1 67:10						
21	68:1 69:16 70:1	68:14 69:19 70:4						
22	70:22 72:9	72:2 72:15						
23	72:16 73:2	72:21 73:15						
24	73:16	74:19						
25	76:11	77:16						
26	77:17	78:6						
27	78:13	80:20						
28	83:8 83:18 84:8 85:7 86:4 86:10	83:15 83:20 85:6 86:3 86:7 87:3	MIS MIS O O	83:21	84:3	I	84:4	84:7
29	87:19 89:8 89:17 90:16 91:1 91:4	88:13 89:14 90:12 90:22 91:2 91:5	 O, SPEC O, SPEC O, SPEC V V					
30	91:7 92:3 92:8 92:18	91:22 92:4 92:16 93:10	O, SPEC O, SPEC O, SPEC O, SPEC					
31	93:15	94:6	O, SPEC					

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	94:10	94:19	O, SPEC					
32	96:21	98:1		96:19	96:20			
33	98:2 98:10 98:21 99:18	98:8 98:11 99:16 99:20	R, V R, V R, V					
34	101:1 101:10 101:16 102:9	101:6 101:15 102:4 102:13	O, PK, SPEC O, PK, SPEC O, PK, SPEC, V O, PK, SPEC, V					
35	102:14 103:13	103:9 104:7	O O	104:8	104:15	IC, I		
36	104:15 105:4	105:1 105:6	F F					
37	105:7	105:16						
38	105:18 106:3	105:21 106:7	O O					
39	106:22 107:12	107:5 107:19		108:8 108:21	108:10 109:1	I	108:11 109:2	108:20 109:8
40	110:9	111:2		109:10 109:15	109:13 110:8			
41	111:3	112:1	I	112:2	113:1			
42	113:21 116:22 117:22	116:19 117:20 118:11	H					
43	118:20 119:6 119:18	119:1 119:16 119:20	LC LC, V V					
44	119:22 120:19	120:15 121:14	O O, MIS					

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	121:17	121:22	MIS					
45	122:7 122:16	122:14 122:20						
46	127:17 128:2 128:11 129:9 131:11	127:21 128:9 128:17 129:21 132:11	BTS, O, PK, SPEC BTS, O, PK, SPEC R	124:5 128:18 130:15	125:1 129:8 130:20		131:20-131:10	
47	132:17	133:6		133:7	134:7			
48	139:22 140:8 141:10 145:9	140:4 140:21 142:13 145:18						
49	145:22	146:10						
50	146:11	147:7						
51	147:16 147:20	147:18 148:4		148:5	149:6	I	149:7	149:18
52	150:3 152:19	150:13 153:5	R F, R					
53	153:11	154:7	R					
54	156:14	157:4	R					
55	158:3 160:20	158:18 162:8		158:19	159:15			
56	169:5	169:17						
57	170:5	171:5	H					
58	171:20 175:8	172:20 175:10		172:21	173:6			
59	178:3 178:10	178:7 178:13						
60	179:15	179:18		179:22	180:18			

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
61	184:11	185:16		183:20	184:6			
62	187:17	187:22	R					
63	189:16 190:10	190:7 191:1	R R					
64	195:12 195:19	195:17 196:2	R R					
65	196:20 198:12	198:8 198:17	AA, F, MIS AA, F, MIS	182:3 196:15	183:19 196:16	IC IC, I		
66	199:13	199:21	AA, F, MIS					
67	203:5 206:10	204:18 206:19	H, R H, R					
68	208:19 211:11 213:18 216:20 219:22 220:8	209:10 213:14 216:17 217:2 220:5 220:13	R O, R, SPEC O, R, SPEC R R R	209:11	209:19			
69	221:7 221:14 222:4	221:10 222:1 222:7	O, R O, R O, R					
70	222:8 223:21 226:20	223:8 224:7 227:6						
71	228:16 230:4 234:15	229:4 231:1 235:5		229:13 231:2	230:3 232:7	I	229:6 232:8	229:12 232:17
72	237:1 237:9 238:1 245:12	237:3 237:14 238:9 246:13	LAW	238:10 248:18 250:19	239:9 249:7 251:22			

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	247:11 250:11 252:1	248:17 250:18 252:10						
73	253:11 254:13	254:2 255:4		252:11 259:9	253:10 260:7			
74	258:6 258:16	258:14 259:8		257:5	258:5			
75	261:4 262:19	261:22 263:9	H					
76	265:2 268:3	268:1 268:14		268:15	269:6			
77	270:4 270:15 271:8	270:8 271:5 272:5	F, PK, R, U F, PK, R, U F, PK, R, U					
78	274:7 274:18	274:14 274:20	BTS, SPEC BTS, SPEC	273:19 274:21	274:6 275:4		275:5 275:10 275:21	275:8 275:18 276:2
79	277:12	278:7		276:4 276:19 278:8 278:15	276:10 277:11 278:12 279:2	I	276:14 279:3	276:16 279:11
80	291:19 292:20	292:18 294:2		289:2 291:2	290:22 291:18			
81	294:22 295:12	295:9 296:20						
82	299:11 299:21	299:19 300:6						
83	301:5 303:8	301:13 303:14						
84	306:10	307:2						

Exhibit 9

	Kevin Warner, July 18, 2018							
	Taro's Designations		Almirall's Objections	Almirall's Counter-Designations[1]		Taro's Objections to Almirall's Counter-Designations	Taro's Counter-Counter Designations	
Group	Line Start	Line End		Line Start	Line End		Line Start	Line End
	308:10	309:22						
85	314:1 315:8 318:18	315:6 315:14 319:18		315:15	315:17			
86	321:9 322:6	322:3 323:18	LAW					
87	324:1	324:15						
88	329:8	330:4	F					
89	332:1 337:6	332:19 338:21						
90	338:22 339:17 340:5	339:15 339:18 340:17		339:20	340:4			
91	342:17	343:14						

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 10

JOINT LIST OF TRIAL EXHIBITS

Parties Have Agreed to Meet and Confer on Joint Exhibit List

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 11

ALMIRALL's LIST OF TRIAL EXHIBITS

Almirall's Trial Exhibit List

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 001	Harper 01; Klibanov 01; Lane 01	Warner 01	ALG_ACZ0000565-ALG_ACZ0000577	U S Patent No 9,517,219 (Warner)	none
PTX 002	Klibanov 02		ALG_ACZ0000001-ALG_ACZ0000564	U S Patent No 9,517,219 File History	none
PTX 003				Defendants' Objections and Responses to Plaintiff's First Set of Requests for Admission (Nos 1-40)	H, R, U
PTX 004				Defendants' Objections and Responses to Plaintiff's First Set of Interrogatories (Nos 1-4)	H, R, U
PTX 005				Defendants' First Supplemental Response to Plaintiff's Interrogatory No 4	H, R, U
PTX 006				Defendants' Objections and Responses to Plaintiff's Second Set of Interrogatories (Nos 5-10)	H, R, U
PTX 007				Defendants' Objections and Responses to Plaintiff's Third Set of Interrogatories (Nos 11-25)	H, R, U
PTX 008				Defendants' Objections and Responses to Plaintiff's First Set of Requests for Production (Nos 1-54)	H, R, U
PTX 009				Defendants' Objections and Responses to Plaintiff's Second Set of Requests for Production (Nos 55-58)	H, R, U
PTX 029	Lane 15			30(b)(6) Deposition of Avi Avramoff, taken July 17, 2018 (excerpts)	H, R, U
PTX 030		Avramoff 01		Taro Objections and Responses to Allergan's Notice of Deposition	H, R, U
PTX 031	Lane 12	Avramoff 02	TARO-DG-00000254-TARO-DG-00000256	Module 2 3: Quality Overall Summary (ANDA 210191)	H, U
PTX 032		Avramoff 03	TARO-DG-00000260-TARO-DG-00000286	Module 2 3: Quality Overall Summary (ANDA 210191)	H, U
PTX 033		Avramoff 04	TARO-DG-00133808-TARO-DG-00133809	Email from Shen Gao to Avi Avramoff re Dapsone 7 5% EB	H, R, U
PTX 034		Avramoff 05	TARO-DG-00132598-TARO-DG-00132599	Email from Ara Aprahamian to Genadi Mostovoy	H, R, U
PTX 035		Avramoff 06	TARO-DG-00113959-TARO-DG-00113959	Meeting Summary	H, R, U
PTX 036	Lane 11	Avramoff 07	TARO-DG-00000655-TARO-DG-00000742	Research Report	H, R, U
PTX 037		Avramoff 08	TARO-DG-00128450-TARO-DG-00128450	Project Approval Form	H, R, U
PTX 038		Avramoff 09	TARO-DG-00111078-TARO-DG-00111079	Prototype Formulation Review Form	H, R, U
PTX 039	Lane 14	Avramoff 10	TARO-DG-00111046-TARO-DG-00111047	Final Formula Review Form	H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 040		Avramoff 11	TARO-DG-00132635-TARO-DG-00132644	Email from Avi Avramoff to Kal Sundaram re Aczone (Dapsone) 7 5% Gel	H, R, U
PTX 041		Avramoff 12	TARO-DG-00131216-TARO-DG-00131217	Email from Thomas Callaghan to Kavita Srivastava re Dapsone Gel 7 5% - Advise	H, R, U
PTX 042		Avramoff 13	TARO-DG-00129736-TARO-DG-00129742	Email from Brenden Hadjikezian to Osnat Bar-Peled; Kavita Srivastava et al re Dapsone Gel 7 5% Final Review Form	H, R, U
PTX 043		Avramoff 14	TARO-DG-00134001-TARO-DG-00134003	Email from Shen Gao to Avi Avramoff re Dapsone 7 5 with attachment RFA_0887 Figures xlsx	H, R, U
PTX 044	Lane 08	Avramoff 15	TARO-DG-00000158-TARO-DG-00000172	Annotated Side-by-Side Comparison of Allergan, Inc ACZONE (dapsone) Gel, 7 5% vs Taro's - Dapsone Gel, 7 5% Prescribing Information/Patient Information	H, R, U
PTX 045		Avramoff 16	TARO-DG-00135692-TARO-DG-00135694	Email from Shen Gao to Kavita Srivastava re Dapsone Gel 7 5% Advise	H, R, U
PTX 046		Avramoff 17	TARO-DG-00133480-TARO-DG-00133491	Email from Natalie Yantovskiy to Shen Gao et al re Fw: Additional Ebs for Dapsone 7 5% EB Campaign	H, R, U
PTX 047		Avramoff 18	TARO-DG-00141861-TARO-DG-00141904	Email from Brady Brainard to Shen Gao et al re Product Slides with attachment	H, R, U
PTX 048		Avramoff 19	TARO-DG-00128664-TARO-DG-00128665	Email from Miriam Getsis to Crystal Spinks re ANDA 2109 Dapsone Gel, 7 5% - Update	H, R, U
PTX 049		Avramoff 20	TARO-DG-00143053-TARO-DG-00143094	Email from Xiaopin Jin to Kayode Famewo, et al re Fw: Project Slides with attachment	H, R, U
PTX 050		Avramoff 21	TARO-DG-00137409-TARO-DG-00137412	Email from Jerzy Zadykowicz@taro ca to Avi Avramoff@taro co il re Dapsone 7 5% Clinical Batch Dilemma	H, R, U
PTX 051		Avramoff 22	TARO-DG-00128794-TARO-DG-00128796	Email from Shen Gao to Avi Avramoff re Fw: Dapsone 7 5 with attachment	H, R, U
PTX 052		Warner 02	ALG_ACZ0264301-ALG_ACZ0264338	3 2 P 2 2 Drug Product Information	H, U
PTX 053		Warner 03	ALG_ACZ0319637-ALG_ACZ0319655	Aczone NDA Storyline: Regulatory Summary	H, R, U
PTX 054		Warner 04	ALG_ACZ0226268-ALG_ACZ0226271	Email from K Warner to Vijaya Swaminathan, et al	H, R, U
PTX 055		Warner 05	ALG_ACZ0236790-ALG_ACZ0236798	Allergan Individual Project Agreement	H, R, U
PTX 056		Warner 06	ALG_ACZ0375158-ALG_ACZ0375165	Research Article - Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloydimethyl Taurate Copolymer	H, R, U
PTX 057		Warner 08	ALG_ACZ0316758-ALG_ACZ0316760	Email from Kevin Warner to Vitarella Dom re Dapsone, Change in formulation	H, R, U
PTX 058		Warner 09	ALG_ACZ0247034-ALG_ACZ0247042	Aczone Reformulation CQAs and Risk Mitigation Update	H, R, U
PTX 059		Warner 10	ALG_ACZO174113-ALG_ACZO174116	Dapsone/Adapalene Topical Gel Formulation Summary	H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 060		Warner 11	ALG_ACZ0222016-ALG_ACZ0222021	Dapsone Suspension Product Update	H, R, U
PTX 061		Warner 12	ALG_ACZ0246068-ALG_ACZ0246085	Aczone Reformulation Development	H, R, U
PTX 062		Warner 13	ALG_ACZ0313682-ALG_ACZ0313683	E-Mail from Ajay Parashar to Varsha Bhatt, et al re Allergan reformulation development plan with attachment	H, R, U
PTX 063		Warner 14	ALG_ACZ0313684-ALG_ACZ0313689	Product Evaluation	H, R, U
PTX 064		Warner 15	ALG_ACZ0249690-ALG_ACZ0249751	Pharmaceutical Development Technical Review Aczone Reformulation (Project #1679)	H, R, U
PTX 065		Warner 16	ALG_ACZ0314425-ALG_ACZ0314441	Memorandum PD-TMEMO-00561 to K Warner to A Parashar re Dapsone Opinion	H, R, U
PTX 066		Warner 17	ALG_ACZ0385496-ALG_ACZ0385496	Aczone Reformulation CMC Sub-Team - Team Meeting Minutes	H, R, U
PTX 067		Warner 18	ALG_ACZ0248334-ALG_ACZ0248374	Development Report: FPD 137 Reformulation: Development of 7 5% Dapsone Gel	H, R, U
PTX 068		Warner 19	ALG_ACZ0200675-ALG_ACZ0200676	Email from Joan-En Lin to Kevin Warner re Aczone Reform	H, R, U
PTX 069		Warner 20	ALG_ACZ0249762-ALG_ACZ0249813	Dapsone Gel and Dapsone/ Adapalene Fixed Dose Combination Gel Formulation Development Report	H, R, U
PTX 070	Lane 36	Warner 21	ALG_ACZ0382881-ALG_ACZ0382932	Dapsone Gel and Dapsone/ Adapalene Fixed Dose Combination Gel Formulation Development Report	H, R, U
PTX 071		Warner 22	ALG_ACZ0000290-ALG_ACZ0000294	Declaration of Kevin S Warner Ph D under 37 C F R 4 1 132	H, R, U, I
PTX 074	Harper 02; Klibanov 03		TARO-DG-00065185-TARO-DG-00065248	WO 2009/108147 (“Garrett I")	A, H
PTX 075	Harper 03; Klibanov 24; Lane A		TARO-DG-00063824-TARO-DG-00063831	Giulia Bonacucina et al , *Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer* , 2(10) AAPS Pharm Sci Tech J , 368- 375 (2009) ("Bonacucina")	A, H
PTX 076	Harper 04; Klibanov 22		TARO-DG-00148447-TARO-DG-00148459	International Publ No WO 2010/072958 A2 (“Nadau-Fourcade”)	A, H
PTX 078	Harper 06		ALM-ACZ0000001-ALM-ACZ0000004	AZC ROS 01 Web Results Summary, A Phase II, Randomized, Partial-Blind, Parallel-Group, Active- and Vehicle-Controlled, Multicenter Study of the Safety and Efficacy of Aczone™ (dapsone) Gel, 5% in Subjects with Papulopustular Rosacea, available at http://www allerganclinicaltrials com/pdfs/medical_aesthetics/ Results_Web_PostingACZ-ROS-01 pdf	A, H, R, U
PTX 079	Harper 07; Klibanov 14		TARO-DG-00063817-TARO-DG-00063823	Aczone Gel 5% Prescribing Information	A, H, R, U
PTX 080	Harper 08		ALM-ACZ0000005-ALM-ACZ0000014	Aczone 7 5% Prescribing information	A, H, R, U
PTX 081	Harper 09; Klibanov 08; Lane 09		ALG _ACZ0004100-ALG _ACZ0004100	Aczone Gel 7 5% Description and Composition of Drug Product (NDA)	A, H, R, U
PTX 082	Harper 10; Klibanov 06		TARO-DG-00065298-TARO-DG-00065331	WO 2011/014627 (“Ahluwalia”)	A, H

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 083	Harper 11		ALM-ACZ0000015-ALM-ACZ0000021	Zaina T Al-Salama & Emma D Deeks, *Dapsone 7.5% Gel: A Review in Acne Vulgaris* , 22 Am J Clinical Dermatology (2016)	A, H, R, U
PTX 084	Harper 12		ALM-ACZ0000022-ALM-ACZ0000024	John V Ashurst et al , *Pathophysiological Mechanisms, Diagnosis, and Management of Dapsone-Induced Methemoglobinemia* , 110 J Am Osteopathic Assoc 16–20 (2010)	A, H, R, U
PTX 085	Harper 13		ALM-ACZ0000025-ALM-ACZ0000028	J S Chun et al , *Dapsone hypersensitivity syndrome with circulating 190-kDA and 230-kDA autoantibodies* , 34 Clinical and Experimental Dermatology e798–e801 (2009)	A, H, R, U
PTX 086	Harper 14		ALM-ACZ0000029-ALM-ACZ0000111	A Phase II, Randomized, Partial-Blind, Parallel-Group, Active- and Vehicle-Controlled, Multicenter Study of the Safety and Efficacy of Aczone™ (Dapsone) Gel, 5% in Subjects with Papulopustular Rosacea (QLT Inc publ , Feb 5, 2007)	A, H, R, U
PTX 087	Harper 15; Klibanov 19		ALM-ACZ0000112-ALM-ACZ0000113	Barry Coutinho, *Dapsone (Aczone) 5% Gel for the Treatment of Acne* , Am Family Physician (2010)	A, H, R, U
PTX 088	Harper 16		ALM-ACZ0000114-ALM-ACZ0000117	James Q Del Rosso, *The Use of Sodium Sulfacetamide 10%-Sulfur 5% Emollient Foam in the Treatment of Acne Vulgaris* , 2 J Clinical and Aesthetic Dermatology 26–29 (2009)	A, H, R, U
PTX 089	Harper 17		ALM-ACZ0000118-ALM-ACZ0000120	Meghan I Dubina & Alan B Fleisher Jr , *Interaction of Topical Sulfacetamide and Topical Dapsone with Benzoyl Peroxide* , 145 JAMA Dermatology 1027–1029 (2009)	A, H, R, U
PTX 090	Harper 18; Klibanov 20		TARO-DG-00147498-TARO-DG-00147507	Epiduo Prescribing Information (2008)	A, H
PTX 091	Harper 19		ALM-ACZ0000121-ALM-ACZ0000129	Gabriella Fabbrocini et al , *Resveratrol-Containing Gel for the Treatment of Acne Vulgaris* , 12 Am J of Clinical Dermatology 133–141 (2011)	A, H, R, U
PTX 092	Harper 20; Klibanov 05		TARO-DG-00065130-TARO-DG-00065184	WO 2009/061298 ("Garrett II")	A, H
PTX 093	Harper 21; Klibanov 28		TARO-DG-00064906-TARO-DG-00064931	U S Patent Publ No 2007/0190019 ("Guo")	A, H
PTX 094	Harper 22; Klibanov 04		TARO-DG-00065249-TARO-DG-00065297	WO 2010/105052 ("Hani")	A, H
PTX 095	Harper 23		ALM-ACZ0000130-ALM-ACZ0000139	William D James, Acne, 352 New Eng J Medicine 1463–1472 (2005)	A, H, R, U
PTX 096	Harper 24; Klibanov 18		ALM-ACZ0000140-ALM-ACZ0000150	Kirk A James et al , *Emerging Drugs for Acne* , 14 Expert Opinions on Emerging Drugs 649–659 (2009) ("James I")	A, H, R, U
PTX 097	Harper 25		ALM-ACZ0000151-ALM-ACZ0000160	Michael T Jarratt et al , *Safety and Pharmacokinetics of Once-Daily Dapsone Gel, 7.5% in Patients with Moderate Acne Vulgaris* , 15 J Drugs in Dermatology 1250–1259 (2016)	A, H, R, U
PTX 098	Harper 26		ALM-ACZ0000161-ALM-ACZ0000169	N Kellett et al , *Conjoint analysis: a novel, rigorous tool for determining patient preferences for topical antibiotic treatment for acne. A randomized controlled trial* , 154 British Journal of Dermatology 524–532 (2006)	A, H, R, U
PTX 099	Harper 27		ALM-ACZ0000170-ALM-ACZ0000173	Devon Kelley, Kate Bosworth on Adult Acne: It Sucks, Yahoo Beauty (June 3, 2016), *available at* https://www yahoo com/lifestyle/kate-bosworth-on-adult-acne-1443085524475958 html	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 100	Harper 28; Klibanov 21		ALM-ACZ0000174-ALM-ACZ0000180	H C Korting & C Schöllmann, *Current topical and systemic approaches to treatment of rosacea* , Journal of the European Academy of and Venereology No 23, 876–882 (2009)	A, H, R, U
PTX 101	Harper 29		ALM-ACZ0000181-ALM-ACZ0000186	John Kraft & Anatoli Freiman, *Management of acne* , 183 Canadian Med Assoc J E430–E435 (2011)	A, H, R, U
PTX 102	Harper 31; Klibanov 16		TARO-DG-00063832-TARO-DG-00063838	Robert Lott et al , *Medication adherence among acne patients: a review* , 9 J Cosmetic Dermatology 160–166 (2010) ("Lott")	A, H
PTX 103	Harper 32; Klibanov 30		TARO-DG-00064966-TARO-DG-00064979	U S Patent Publ No 2011/0003894 ("Louis")	A, H
PTX 104	Harper 33; Klibanov 35		TARO-DG-00148425-TARO-DG-00148431	Lubrizol Pharmaceutical Bulletin No 21: Formulating Semisolid Products (2011)	A, H
PTX 105	Harper 34		TARO-DG-00148532-TARO-DG-00148541	Lubrizol Technical Data Sheet: Viscosity of Carbopol® Polymers in Aqueous Systems (2010)	A, H
PTX 106	Harper 35		TARO-DG-00064980-TARO-DG-00064999	U S Patent Publ No 2011/0135584 ("Mallard")	A, H
PTX 107	Harper 36		ALM-ACZ0000187-ALM-ACZ0000194	P Marazzi et al , *Clinical evaluation of Double Strength Isotrexin ™ versus Benzamycin ® in the topical treatment of mild to moderate acne vulgaris* , 13 Journal of Dermatological Treatment 111–117 (2002)	A, H, R, U
PTX 108	Harper 37		ALM-ACZ0000195-ALM-ACZ0000201	Janusz Marcinkiewicz et al , *Topical taurine bromamine, a new candidate in the treatment of moderate inflammatory acne vulgaris—A pilot study* , 18 Eur J Dermatology 433–439 (2008)	A, H, R, U
PTX 109	Harper 38		ALM-ACZ0000202-ALM-ACZ0000206	Otto H Mills et al , Comparing 2 5%, 5%, and 10% Benzoyl Peroxide on Inflammatory Acne Vulgaris, 25 Int'l J Dermatology 664–667 (1986)	A, H, R, U
PTX 110	Harper 39		ALM-ACZ0001043-ALM-ACZ0001048	Shelley Moench-Kelly, *Banishing Blemishes* , Medestheticsmag com (October 29, 2018)	A, H, R, U
PTX 111	Harper 40		ALM-ACZ0000211-ALM-ACZ0000213	Victoria Moorhouse, *I've Only Had One Pimple Since Starting This Acne Treatment, InStyle* , (Apr 23, 2018), *available at* https://www instyle com/beauty/common-acne-treatment	A, H, R, U
PTX 112	Harper 41		ALM-ACZ0000214-ALM-ACZ0000226	Ayumi Naito et al , *Topical retinoids for acne vulgaris (Protocol)* , 3 The Cochrane Library 3–4 (John Wiley & Sons 2008)	A, H, R, U
PTX 113	Harper 42		ALM-ACZ0000227-ALM-ACZ0000233	Rebecca Nguyen & John Su, *Treatment of acne vulgaris* , 21 J of Pediatrics and Child Health 119–125 (2011)	A, H, R, U
PTX 114	Harper 43; Klibanov 09		ALM-ACZ0000234-ALM-ACZ0000235	Orange Book Listing for Aczone 7 5%	A, H, R, U
PTX 115	Harper 44; Klibanov 31		TARO-DG-00148438-TARO-DG-00148446	U S Patent No 7,820,186 ("Orsoni")	A, H

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 116	Harper 45; Klibanov 15		TARO-DG-00148432-TARO-DG-00148437	David W Osborne, *Diethylene glycol monoethyl ether: an emerging solvent in topical dermatology products* , 10 J Cosmetic Dermatology 324–329 (2011) ("Osborne 2011")	A, H
PTX 117	Harper 46; Klibanov 17		TARO-DG-00065000-TARO-DG-00065008	U S Patent No 5,863,560 ("Osborne I")	A, H
PTX 118	Harper 47		ALM-ACZ0000236-ALM-ACZ0000239	David Pascoe, *Aczone Fails to Impress for Rosacea, Rosacea Support Group* (July 23, 2012), *available at* https://rosacea-support org/aczone-fails-to-impress-for-rosacea html	A, H, R, U
PTX 119	Harper 48		ALM-ACZ0000240-ALM-ACZ0000243	Physicians' Desk Reference 2967 (2011) (Benzaclin)	A, H, R, U
PTX 120	Harper 49		ALM-ACZ0000244-ALM-ACZ0000247	Physicians' Desk Reference 2765 (2012) (Duac)	A, H, R, U
PTX 121	Harper 50		ALM-ACZ0000248-ALM-ACZ0000258	Frank C Powell, *Rosacea* , 352 New Eng J Med 793–803 (2005)	A, H, R, U
PTX 122	Harper 51; Klibanov 29		TARO-DG-00064932-TARO-DG-00064939	U S Patent Publ No 2009/0022818 ("SenGupta")	A, H
PTX 123	Harper 52	Warner 07	ALG_ACZ0375156-ALG_ACZ0375157	Seppic Sepineo™ P 600 Brochure	H, R, U
PTX 124	Harper 53		ALM-ACZ0000259-ALM-ACZ0000267	Linda Stein Gold et al , *Efficacy and Safety of Once-Daily Dapsone Gel, 7.5% for Treatment of Adolescents and Adults with Acne Vulgaris: First of Two Identically Designed, Large, Multicenter, Randomized, Vehicle-controlled Trials* , 15 J Drugs in Dermatology 553–561 (2016)	A, H, R, U
PTX 125	Harper 54; Klibanov 12		ALM-ACZ0000268-ALM-ACZ0000273	MaryAnn Steiner, *Dapsone Topical Gel for Acne* , Journal of the Pharmarmacy Society of Wisconsin Vol 12, Issue 6, 67–71 (2009)	A, H, R, U
PTX 126	Harper 55		ALM-ACZ0000274-ALM-ACZ0000280	Toni C Stockton et al , *Clinical Experience With Once-Daily Dapsone Gel, 7.5% Monotherapy in Patients With Acne Vulgaris* , 17 J Drugs in Dermatology 602–608 (2018)	A, H, R, U
PTX 127	Harper 56		ALM-ACZ0000281-ALM-ACZ0000298	John S Strauss, *Biology of the Sebaceous Gland and the Pathophysiology of Acne Vulgaris* , Chapter 13 in Pathophysiology of Dermatologic Diseases, Second Edition, N A Soter and H Baden eds , McGraw-Hill, New York, pp 195-210 (1991)	A, H, R, U
PTX 128	Harper 57		ALM-ACZ0000299-ALM-ACZ0000303	Yuko Takenaka et al , *Glycolic acid chemical peeling improves inflammatory acne eruptions through its inhibitory and bactericidal effects on Propionibacterium acnes* , 39 J Dermatology 350–354 (2012)	A, H, R, U
PTX 129	Harper 58		ALM-ACZ0000304-ALM-ACZ0000311	Susan C Taylor et al , *Efficacy, Safety, and Tolerability of Topical Dapsone Gel, 7.5% for Treatment of Acne Vulgaris by Fitzpatrick Skin Phototype* , 17 J Drugs in Dermatology 160–167 (2018)	A, H, R, U
PTX 130	Harper 59		ALM-ACZ0000312-ALM-ACZ0000321	Diane M Thiboutot et al , *Efficacy, Safety, and Dermal Tolerability of Dapsone Gel, 7.5% in Patients with Moderate Acne Vulgaris: A Pooled Analysis of Two Phase 3 Trials* , 9 J Clinical and Aesthetic Dermatology 18–27 (2016)	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 131	Harper 60		ALM-ACZ0000322-ALM-ACZ0000328	Stephen Titus & Joshua Hodge, *Diagnosis and Treatment of Acne* , 86 Am Family Physician 734–740 (2012)	A, H, R, U
PTX 132	Harper 61		ALM-ACZ0000329-ALM-ACZ0000334	Wayback Machine Results for David Pascoe, *Aczone Fails to Impress for Rosacea* , Rosacea Support Group (July 23, 2012), *available at* https://web archive org/web/ 20120801225046/http:/rosacea-support org: 80/aczone-fails-to-impress-for-rosacea html	A, H, R, U
PTX 133	Harper 62		ALM-ACZ0000335-ALM-ACZ0000346	Hywel C Williams et al , *Acne vulgaris* , 379 Lancet 361–372 (2012)	A, H, R, U
PTX 134	Harper 63		ALM-ACZ0000347-ALM-ACZ0000348	Dina Anderson, *Finding a Place for Topical Anti-inflammatory Acne Therapy* , Practical Dermatology 17–18 (July 2009)	A, H, R, U
PTX 135	Harper 64		ALM-ACZ0000349-ALM-ACZ0000352	Michael Ghods et al , *The Role of Dapsone Gel in the Acne Armamentarium* , The Dermatologist (June 10, 2010), *available at* https://www the-dermatologist com/content/role-dapsone-gel-acne-armamentarium	A, H, R, U
PTX 136	Klibanov 07; Lane 07		ALG_ACZ0397186-ALG_ACZ0397195	Aczone Gel 7 5% Prescribing Information, Rev May, 2018	A, H, R, U
PTX 137	Klibanov 10		ALM-ACZ0000997-ALM-ACZ0001005	Puavilai et al , *Incidence of Anemia in Leprosy Patients Treated with Dapsone* , The Journal of the Medical Association of Thailand Vol 67, No 7, 404-408 (1984)	A, H, R, U
PTX 138	Klibanov 11		ALM-ACZ0001013-ALM-ACZ0001014	World Health Organization Information Exchange System, Alert No 117,*Antimalarial Chrorproquanil-Dapsone (LapDap™) Withdrawn Following Demonstration of Post-Treatment Haemolytic Anaemia in G6PD Deficient Patients in a Phase III Trial of Chlorproquanil-Dapsone-Artesunate (Dacart™) Versus Artemether-Lumefantrine (Coartem®) and Confirmation of Findings in a Comparative Trial of LapDap™ Versus Dacart™* (March 4, 2008)	A, H, R, U
PTX 139	Klibanov 13		ALM-ACZ0000398-ALM-ACZ0000413	Aczone Gel 5% Package Insert and Label	A, H, R, U
PTX 140	Klibanov 23		ALM-ACZ0000733-ALM-ACZ0000996	Food and Drug Administration Inactive Ingredient Database (September, 2012)	A, H, R, U
PTX 141	Klibanov 25		ALM-ACZ0001015-ALM-ACZ0001029	U S Patent 4,829,058 (Seydel)	A, H, R, U
PTX 142	Klibanov 26		ALM-ACZ0001030-ALM-ACZ0001042	U S Patent 4,912,112 (Seydel)	A, H, R, U
PTX 143	Klibanov 32		ALM-ACZ0000414-ALM-ACZ0000466	European Commission Scientific Committee on Consumer Safety (SCCS), Opinion on Diethylene Glycol Monoethyl Ether (DEGEE), Eighth Plenary Meeting (2010)	A, H, R, U
PTX 144	Klibanov 33		ALM-ACZ0000467-ALM-ACZ0000732	Food and Drug Administration Inactive Ingredient Database (December, 2012)	A, H, R, U
PTX 145	Klibanov 36		ALM-ACZ0001006-ALM-ACZ0001012	*Handbook of Pharmaceutical Excipients* , 441-445 (Rowe et al , eds , 6th ed , 2009)	A, H, R, U
PTX 151	Lane 04		ALG_ACZ0000590-ALG_ACZ0000634	U S Provisional Application No 61/728,403	none
PTX 152	Lane 05		ALG_ACZ0000635-ALG_ACZ0000668	U S Provisional Application No 61/770,768	none

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 153	Lane 10		ALG_ACZ0382867-ALG_ACZ0382880	Allergan Report PD-TMEMO-00750	A, H, R, U
PTX 154	Lane 13		TARO-DG-00000609-TARO-DG-00000611	Taro's ANDA, Section 3 2 P 1	A, H, U
PTX 155	Lane 16		TARO-DG-00111048-TARO-DG-00111050	Final Formula Review Form, dated June 8, 2016	A, H, R, U
PTX 156	Lane 17		TARO-DG-00000042-TARO-DG-00000043	Proposed Label for Dapsone Gel, 7 5%	A, H, R, U
PTX 157	Lane 18		ALG_ACZ0397196-ALG_ACZ0397543	Alexander T Florence & David Attwood, Physicochemical Principles of Pharmacy (4th ed 2006)	A, H, R, U
PTX 158	Lane 20		ALG_ACZ0398626-ALG_ACZ0398674	Pratap Chandra Acharya et al , Rheology and Its Implications on Performance of Liquid Dosage Forms, in Dosage Form Design Considerations (Rakesh K Tekade ed , 2018)	A, H, R, U
PTX 159	Lane 21		ALG_ACZ0398675-ALG_ACZ0398791	Laurier L Schramm, Emulsions, Foams, and Suspensions: Fundamentals and Applications (2005)	A, H, R, U
PTX 160	Lane 22		ALG_ACZ0399140-ALG_ACZ0399150	Ajazuddin et al , Recent Expansions in an Emergent Novel Drug Delivery Technology: Emulgel, 171 J of Controlled Release 122 (2013)	A, H, R, U
PTX 161	Lane 23		TARO-DG-00000287-TARO-DG-00000313	Taro's ANDA, Section 2 3 P 2	A, H, U
PTX 162	Lane 24		ALG_ACZ0001177-ALG_ACZ0001224	Robert A Nash, Pharmaceutical Suspensions, in Pharmaceutical Dosage Forms: Disperse Systems (Lieberman et al eds , 1988)	A, H, R, U
PTX 163	Lane 25		ALG_ACZ0016215-ALG_ACZ0016252	NDA No 207154 Section 3 2 P 2 2	A, H, U
PTX 164	Lane 26		ALG_ACZ0399151-ALG_ACZ0399165	Jonathan Hadgraft & Majella E Lane, Drug Crystallization—Implications for Topical and Transdermal Delivery, 13(6) Expert Op on Drug Delivery 817 (2016)	A, H, R, U
PTX 165	Lane 28		ALG_ACZ0399166-ALG_ACZ0399167	Dapsone, Clarke's Analysis of Drugs and Poisons (Pharmaceutical Press 2005)	A, H, R, U
PTX 166	Lane 29		ALG_ACZ0399168-ALG_ACZ0399178	Katrin I Tiffner et al , A comprehensive approach to qualify and validate the essential parameters of an in vitro release test (IVRT) method of acyclovir cream, 5%, 535 Int'l J of Pharms 217 (2018)	A, H, R, U
PTX 167	Lane 32		TARO-DG-00113972-TARO-DG-00113972	Taro Document Comparing S321-63887 and S321-63890	A, H, R, U
PTX 168	Lane 33		ALG_ACZ0004105-ALG_ACZ0004112	NDA No 207154, Section 2 3 P 2	A, H, U
PTX 169	Lane 34		TARO-DG-00056374-TARO-DG-00056516	Taro's Clinical Study Report	A, H, R, U
PTX 170	Lane 35		ALG_ACZ0371058-ALG_ACZ0371080	NDA No 207154 Approval Letter, dated Feb 24, 2016	A, H, R, U
PTX 171	Lane B			Handbook of Pharmaceutical Excipients, 441-445 (Rowe et al , eds , 6th ed , 2009)	A, H, R, U, N

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 172	Lane 30		TARO-DG-00110264-TARO-DG-00110264	Results for May 25, 2016 In Vitro Release Test	A, H, R, U
PTX 173	Lane 31		TARO-DG-00110254-TARO-DG-00110254	Results for June 17, 2016 In Vitro Release Test	A, H, R, U
PTX 174	Lane 19		ALG_ACZ0397709-ALG_ACZ0397736 ALG_ACZ0398184-ALG_ACZ0398186	Excerpt from Raymond C Rowe et al , Handbook of Pharmaceutical Excipients (6th ed 2009)	A, H, R, U
PTX 175	Harper 30; Klibanov 27; Lane 27		TARO-DG-00064894-TARO-DG-00064905	U S Patent Publ No 2006/0204526 ("Lathrop")	A, H
PTX 176			TARO-DG-00110239-TARO-DG-00110239	Taro Stability Testing Report	A, H, R, U
PTX 177			TARO-DG-00110255-TARO-DG-00110255	Results for Sept 15, 2016 In Vitro Release Test	A, H, R, U
PTX 178	Klibanov 34			30(b)(6) Deposition of Kevin Warner, taken July 18, 2018 (excerpts)	H, R, U, I
PTX 179			ALG_ACZ0399179-ALG_ACZ0399199	Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics, Final Report, May 24, 2017, Cosmetic Ingredient Review	A, H, R, U
PTX 180			ALG_ACZ0399200-ALG_ACZ0399221	Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics, Tentative Report for Public Comment, Oct 7, 2016, Cosmetic Ingredient Review	A, H, R, U
PTX 181			ALG_ACZ0399222-ALG_ACZ0399232	Avraham Yacobi et al , Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies for Topical Products, 31 Pharm Research 837 (2014)	A, H, R, U
PTX 182			ALG_ACZ0399233-ALG_ACZ0399269	Suman Dandamudi, In Vitro Bioequivalence Data for a Topical Product: Bioequivalence Review Perspective, FDA Public Workshop, Oct 20, 2017	A, H, R, U
PTX 183			ALG_ACZ0399270-ALG_ACZ0399272	David R Kryscio, Spreadability Measurements to Assess Structural Equivalence (Q3) of Topical Formulations—A Technical Note, 9(1) AAPS PharmSciTech 84 (2007)	A, H, R, U
PTX 184			ALG_ACZ0399273-ALG_ACZ0399277	PQRI Workshop on the Evaluation of New and Generic Topical Drug Products—Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies, March 11–13, 2013, Product Quality Research Institute	A, H, R, U
PTX 185			TARO-DG-00000139-TARO-DG-00000141	Taro's ANDA, Section 1 12 15	A, H, U
PTX 186			TARO-DG-00000314-TARO-DG-00000328	Taro's ANDA, Section 2 3 P 3	A, H, U
PTX 187			TARO-DG-00133541-TARO-DG-00133542	Dapsone Gel 7 5% Microscopic Evaluation of Thermal Stress Studies	A, H, R, U
PTX 188				Taro Pharmaceutical Industries Ltd and Taro Pharmaceuticals, Inc 's Appendix A (Claim Chart) to Initial Invalidity Contentions, dated December 15, 2017	H, R, U
PTX 189			ALG_ACZ0000999-ALG_ACZ0001012	Lubrizol, Pharmaceutical Bulletin: Flow and Suspension Properties (2008) (ALG_ACZ0000999–1012)	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 190			TARO-DG-00147322-TARO-DG-00147330	Letter to Dara Nardini (Center for Drug Evaluation and Research) from Taro Re: ANDA #210191 / Sequence 0010 Dapsone Gel, 7 5%	A, H, R, U
PTX 191			TARO-DG-00147331-TARO-DG-00147335	Letter Response to Taro from FDA	A, H, R, U
PTX 192			TARO-DG-00000005-TARO-DG-00000039 TARO-DG-00000042-TARO-DG-00000043 TARO-DG-00000055-TARO-DG-00000056 TARO-DG-00000058-TARO-DG-00000061 TARO-DG-00000065-TARO-DG-00000066 TARO-DG-00000069-TARO-DG-00000072 TARO-DG-00000077-TARO-DG-00000087 TARO-DG-00000109-TARO-DG-00000117 TARO-DG-00000139-TARO-DG-00000141 TARO-DG-00000158-TARO-DG-00000172 TARO-DG-00000175-TARO-DG-00000185 TARO-DG-00000250 TARO-DG-00000254-TARO-DG-00000347 TARO-DG-00000396-TARO-DG-00000429 TARO-DG-00000636-TARO-DG-00000646 TARO-DG-00000655-TARO-DG-00000743 TARO-DG-00000762-TARO-DG-00000772 TARO-DG-00000774-TARO-DG-00000778 TARO-DG-00000780-TARO-DG-00000783 TARO-DG-00000798-TARO-DG-00000821 TARO-DG-00000824-TARO-DG-00000838 TARO-DG-00000842-TARO-DG-00000877 TARO-DG-00000928-TARO-DG-00000934 TARO-DG-00000965-TARO-DG-00001042 TARO-DG-00001107-TARO-DG-00001128 TARO-DG-00001179-TARO-DG-00001226 TARO-DG-00002769 TARO-DG-00056374-TARO-DG-00056516	Taro ANDA Composite	A, H, U, I
PTX 193			TARO-DG-00112143-TARO-DG-00112143	Project: Dapsone Gel 7 5%	A, H, R, U
PTX 194			TARO-DG-00141561-TARO-DG-00141561	Canada MMR	A, H, R, U
PTX 195			TARO-DG-00143250-TARO-DG-00143250	Lab requests	A, H, R, U
PTX 196			TARO-DG-00110988-TARO-DG-00110990	Here is the quantitative formula of SEPINEO P 600	A, H, R, U
PTX 197			TARO-DG-00128774--TARO-DG-00128777	Email from Brady Brainard to Shen Gao et al re Dapsone 7 5	A, H, R, U
PTX 198			TARO-DG-00143249-TARO-DG-00143251	Email from Brenden Hadjikezian to Haydar Abdalghafor, Nandor Rehak et al re Dapsone Gel 7 5% RLD has arrived	A, H, R, U
PTX 199			TARO-DG-00129995-TARO-DG-00129995	Email from Mike Teiler to Bob Whalen re Search results for SEARCH) - ICH GCP - Clinical Trials Registry	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 200			TARO-DG-00131073-TARO-DG-00131082	Email from Ara Aprahamian to Avi Avramoff	A, H, R, U
PTX 201			TARO-DG-00128822-TARO-DG-00128827	Email from Shen Gao to Shen Gao et al re Dapsone Gel 7 5% Clinical Batch Dilemma	A, H, R, U
PTX 202			TARO-DG-00135398-TARO-DG-00135399	Email from Mike Teiler to Genadi Mostovoy re Fw: Dapsone 7 5% RLD samples	A, H, R, U
PTX 203			TARO-DG-00129111-TARO-DG-00129111	Email from Shen Gao to Avi Avramoff re Fw: Dapsone 7 5% EB campaign	A, H, R, U
PTX 204			TARO-DG-00134153-TARO-DG-00134158	Email from Avi Avramoff to Xiaopin Jin re Dapsone 7 5	A, H, R, U
PTX 205			TARO-DG-00129623-TARO-DG-00129627	Email from Shen Gao to Avi Avramoff re Fw: Dapsone Gel 7 5% Initial Assessment	A, H, R, U
PTX 206			TARO-DG-00133543-TARO-DG-00133554	Email from Xiaopin Jin to Avi Avramoff et al re Dapsone 7 5% EB campaign	A, H, R, U
PTX 207			TARO-DG-00133799-TARO-DG-00133801	Email from Shen Gao to Kavita Srivastava re Fw: Dapsone Gel 7 5% Advise	A, H, R, U
PTX 208			TARO-DG-00134201-TARO-DG-00134204	Email from Xiaopin Jin to Kavita Srivastava re Fw: Dapsone Gel 7 5% Advise	A, H, R, U
PTX 209			TARO-DG-00133535-TARO-DG-00133542	Email from Xiaopin Jin to Avi Avramoff et al re Dapsone 7 5% EB campaign	A, H, R, U
PTX 210			TARO-DG-00135456-TARO-DG-00135461	Email from Avi Avramoff to Xiaopin Jin et al re Dapsone 7 5% EB campaign	A, H, R, U
PTX 211			TARO-DG-00133435-TARO-DG-00133437	Email from Shen Gao to Natalie Yantovskiy re Fw: Dapsone 7 5% clinical samples shipped	A, H, R, U
PTX 212			TARO-DG-00129602-TARO-DG-00129604	Email from Jerzy Zadykowicz to Xiaopin Jin et al re Fw: Dapsone Gel 7 5% Crystal Variance	A, H, R, U
PTX 213			TARO-DG-00131036-TARO-DG-00131045	Email from Thomas Callaghan to Jerzy Zadykowicz re Genotoxic Impurities Dapsone API from Taro Israel	A, H, R, U
PTX 214			TARO-DG-00128480-TARO-DG-00128482	Letter from Alexander Ober to Crystal Spinks, Ph D re ANDA 210191 Information Request	A, H, R, U
PTX 215			TARO-DG-00147322-TARO-DG-00147330	Letter from Crystal Spinks, Ph D to Dara Nardini re ANDA #210191/Sequence 0010 Dapsone Gel, 7 5% COMPLETE RESPONSE AMENDMENT	A, H, R, U
PTX 216			ALG_ACZ0001618-ALG_ACZ0001645	NDA No 207154, Section 2 5 (Clinical Overview)	A, H, R, U
PTX 217			TARO-DG-00000257–TARO-DG-00000259	Taro's ANDA Module 2 3: Quality Overall Summary	A, H, U
PTX 218			~	Letter from Stephen P Benson to Allergan, Inc re Notice of Certification Under 21 U S C § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C F R § 314 95	A, H

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 219			~	Letter from Stephen P Benson to Allergan, Inc re Duplicate Notice of Certification Under 21 U S C § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C F R § 314 96	A, H
PTX 220			TARO-DG-00129147-TARO-DG-00129148	Email from Hoc Quach to Shen Gao re Dapsone 7 5% QQ	A, H, R, U
PTX 221			TARO-DG-00132807-TARO-DG-00132808	Email from Natalie Yantovskiy to Shen Gao re Dapsone 7 5% Clinical Batch Dilemma	A, H, R, U
PTX 222			TARO-DG-00113954-TARO-DG-00113958	Dapsone Gel 7 5%, RLD v Exhibit Batch Evaluation - Microscopic Evaluation	A, H, R, U
PTX 223			ALG_ACZ0001603-ALG_ACZ0001603	NDA No 207154 Section 2 2 - Introduction	A, H, R, U
PTX 224			ALG_ACZ0001605-ALG_ACZ0001607	NDA No 207154 Section 2 3 - Intro & list of abbreviations	A, H, R, U
PTX 225			ALG_ACZ0001608-ALG_ACZ0001617	NDA No 207154 Section 2 4 - Nonclinical Overview	A, H, R, U
PTX 226			ALG_ACZ0001646-ALG_ACZ0001647	NDA No 207154 Section 2 6 1 - Introduction	A, H, R, U
PTX 227			ALG_ACZ0001648-ALG_ACZ0001648	NDA No 207154 Section 2 6 3 - Pharamacology Tabulated Summary	A, H, R, U
PTX 228			ALG_ACZ0001649-ALG_ACZ0001654	NDA No 207154 Section 2 6 2 - Pharmacology Written Summary	A, H, R, U
PTX 229			ALG_ACZ0001655-ALG_ACZ0001676	NDA No 207154 Section 2 6 5 - Pharmacokinetics Tabulated Summary	A, H, R, U
PTX 230			ALG_ACZ0001677-ALG_ACZ0001690	NDA No 207154 Section 2 6 4 - Pharmacokinetics Written Summary	A, H, R, U
PTX 231			ALG_ACZ0001691-ALG_ACZ0001737	NDA No 207154 Section 2 6 7 - Toxicology Tabulated Summary	A, H, R, U
PTX 232			ALG_ACZ0001738-ALG_ACZ0001761	NDA No 207154 Section 2 6 6 - Toxicology Written Summary	A, H, R, U
PTX 233			ALG_ACZ0001766-ALG_ACZ0001767	NDA No 207154 Section 2 7 1 - Summary of Biopharmaceutic Studies and Assocaited Analytical Method	A, H, R, U
PTX 234			ALG_ACZ0001768-ALG_ACZ0001826	NDA No 207154 Section 2 7 3 - Summary of Clinical Efficacy	A, H, R, U
PTX 235			ALG_ACZ0001827-ALG_ACZ0001837	NDA No 207154 Section 2 7 2 - Summary of Clincial Pharmacology Studies	A, H, R, U
PTX 236			ALG_ACZ0001838-ALG_ACZ0001912	NDA No 207154 Section 2 7 4 - Summary of Clinical Safety	A, H, R, U
PTX 237			ALG_ACZ0001913-ALG_ACZ0001913	NDA No 207154 Section 2 7 6 - Synopses of Individual Studies	A, H, R, U
PTX 238			ALG_ACZ0001914-ALG_ACZ0001917	NDA No 207154 Section 3 2 - Introduction & List of Abbreviations	A, H, R, U
PTX 239			ALG_ACZ0016207-ALG_ACZ0016207	NDA No 207154 Section 3 2 P 1 - Description and Composition of the Drug Product	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 240			ALG_ACZ0016209-ALG_ACZ0016211	NDA No 207154 Section 3 2 P 2 1 - Components for Drug Product	A, H, R, U
PTX 241			ALG_ACZ0016476-ALG_ACZ0016477	NDA No 207154 Section 3 2 S 1 3 - General Properties	A, H, R, U
PTX 242			ALG_ACZ0016478-ALG_ACZ0016478	NDA No 207154 Section 3 2 S 1 1 - Nomenclature	A, H, R, U
PTX 243			ALG_ACZ0016479-ALG_ACZ0016479	NDA No 207154 Section 3 2 S 1 2 - Structure	A, H, R, U
PTX 244			ALG_ACZ0024400-ALG_ACZ0025735	NDA No 207154 CSR 225678-004 - Clinical Study Report	A, H, R, U
PTX 245			ALG_ACZ0026112-ALG_ACZ0026113	NDA No 207154 CSR 225678-004 - Section 16 1 5 - Signature of Coordinating Investigator or Sponsor's Responsible Medical Officer	A, H, R, U
PTX 246			ALG_ACZ0026154-ALG_ACZ0026160	NDA No 207154 CSR 225678-004 - Synopsis	A, H, R, U
PTX 247			ALG_ACZ0079562-ALG_ACZ0080416	NDA No 207154 CSR 225678-006 - Clinical Study Report	A, H, R, U
PTX 248			ALG_ACZ0080518-ALG_ACZ0080519	NDA No 207154 CSR 225678-006 - Signature of Coordinating Investigator or Sponsor's Responsible Medical Officer	A, H, R, U
PTX 249			ALG_ACZ0135462-ALG_ACZ0136280	NDA No 207154 CSR 225678-007 - Clinical Study Report	A, H, R, U
PTX 250			ALG_ACZ0136382-ALG_ACZ0136383	NDA No 207154 CSR 225678-007 - Signature of Coordinating Investigator or Sponsor's Responsible Medical Officer	A, H, R, U
PTX 251			ALG_ACZ0136414-ALG_ACZ0136420	NDA No 207154 CSR 225678-007 - Synopsis	A, H, R, U
PTX 252			ALG_ACZ0163571-ALG_ACZ0163576	NDA No 207154 CSR 225678-009 - Synopsis	A, H, R, U
PTX 253			ALG_ACZ0163577-ALG_ACZ0163579	NDA No 207154 CSR 225678-010 - Synopsis	A, H, R, U
PTX 254			ALG_ACZ0164883-ALG_ACZ0164887	NDA No 207154 CSR 225567-011 - Synopsis	A, H, R, U
PTX 255			ALM_ACZ0001049-ALM_ACZ0001229	FDA NDA No 021794 Drug Approval Package: Administrative Document(s) & Correspondence	A, H, R, U
PTX 256			ALM_ACZ0001230-ALM_ACZ0001234	FDA NDA No 021794 Drug Approval Package: Approval Letter(s)	A, H, R, U
PTX 257			ALM_ACZ0001235-ALM_ACZ0001247	FDA NDA No 021794 Drug Approval Package: Chemistry Review(s)	A, H, R, U
PTX 258			ALM_ACZ0001248-ALM_ACZ0001297	FDA NDA No 021794 Drug Approval Package: Clinical Pharmacology Biopharmaceutics Review(s)	A, H, R, U
PTX 259			ALM_ACZ0001298-ALM_ACZ0001411	FDA NDA No 021794 Drug Approval Package: Medical Review(s)	A, H, R, U
PTX 260			ALM_ACZ0001412-ALM_ACZ0001444	FDA NDA No 021794 Drug Approval Package: Microbiology Review(s)	A, H, R, U

Trial Ex No	Expert Report Exhibit No	Deposition Exhibit No	Bates Nos	Description	Objections
PTX 261			ALM_ACZ0001445-ALM_ACZ0001518	FDA NDA No 021794 Drug Approval Package: Pharmacology Review(s)	A, H, R, U
PTX 262			ALM_ACZ0001519-ALM_ACZ0001535	FDA NDA No 021794 Drug Approval Package: Printed Labeling	A, H, R, U
PTX 263			ALM_ACZ0001536-ALM_ACZ0001618	FDA NDA No 021794 Drug Approval Package: Statistical Review(s)	A, H, R, U

Abbreviation and Federal Rule of Evidence Key to Taro's Objections to Plaintiff's Exhibits

LETTER	OBJECTION	APPLICABLE RULE(S)
A	Requires authentication or identification	FRE 901
B	Best evidence rules prohibit introduction	FRE 1001-1002
C	Improper compilation of separate documents	FRE 403, 901
D	Improper designation (designation is neither a question or testimony)	FRE 401, 402
E	Improper examination (vague, ambiguous, loaded, leading, etc.)	FRE 402, 403, 602, 611
F	Lack of foundation/personal knowledge (incl. calls for speculation)	FRE 402, 403, 602, 611
H	Hearsay if offered for the truth of the matter asserted	FRE 801, 802
I	Incomplete document or testimony	FRE 106, 403
M	Offer or discussion for settlement or compromise	FRE 408
N	Exhibit not produced in discovery	FRE 403
O	Improper opinion testimony	FRE 701-704
P	Privileged or attorney work product	FRE 501, 502
R	Lack of relevance	FRE 401, 402
S	Summary requiring underlying data or information	FRE 1006
T	Beyond the scope of the Rule 30(b)(6) topic for which a witness has been designated	FRE 602, FRCP 30(b)(6)
U	Unduly prejudicial, wasteful, confusing, misleading or cumulative	FRE 403

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT 12

TARO'S EXHIBIT LIST

Almirall, LLC v. Taro Pharms. Industries LTD. and Taro Pharms. C.A. No. 17-663 (JFB) (SRF)
Taro Pharmaceuticals Trial Exhibit List

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 001	U.S. Patent 9,517,219	TARO-DG-00065118 – TARO-DG-00065129	12/13/2016			Constantinides materials considered	
DTX 002	U.S. Patent Application 9,517,219 File History	ALM_ACZ0000001 - ALM_ACZ0000564	12/13/2016		Klibanov Exhibit 02	Amiji and Constantinides materials considered	
DTX 003	U.S. Patent 9,161,926 B2	TARO-DG-00065106 – TARO-DG-00065117; ALG_ACZ0000578 - ALG_ACZ0000589	10/20/2015		Lane Exhibit 06	Amiji materials considered	R, U
DTX 004	Certified U.S. Patent File History 9,161,926	TARO-DG-00148663 - TARO-DG-00149247	9/27/2018			Amiji and Constantinides materials considered	R, U
DTX 005	US Patent Provisional Application No. 61/728,40.	ALG_ACZ0000590 - ALG_ACZ0000634	1/23/2013		Lane 04	Constantinides materials considered	R, U
DTX 006	US Patent Provision Application No. 61/770,768	ALG_ACZ0000635 - ALG_ACZ0000668; TARO-DG-00065063 - TARO-DG-00065096	2/28/2013		Lane 05	Amiji and Constantinides materials considered	R, U
DTX 007	Docket Entry 59 US Patent 9,517,219 Issued December 13, 20(*(Ex. 1)* Alexander Klibanov CV *(Ex. 2)* , Expert list *(Ex. 3)* , Pharmaceutical Suspensions article by Robert Nash *(Ex. 4)* , Materials Considered *(Ex. 5)* , Physicochemical Principles of Pharmacy by A. Florence and D. Atwood *(Ex. 6)* , Lubrizol Excipients for Liquid and Semisolid Dosage Forms *(Ex. 7)* and The Chemistry and Manufacture of Cosmetics vol 2 - Formulating *(Ex. 8)*	ALG_ACZ0000565 - ALG_ACZ0000992	3/1/2018	Warner 001	Harper 001	Harper, Constantinides, Klibanov, and Lane materials considered	Inappropriate Description
DTX 008	3.2.P.2.2 Drug Product	ALG_ACZ0264301 - ALG_ACZ0264338	00/00/0000	Warner 002	Lane Exhibit 25	Amiji and Constantinides materials considered	
DTX 009	Allergan presentation Aczone (dapsone) Gel, 7.5% NDA 207154 - NDA Storyline Regulatory Summary	ALG_ACZ0319637 - ALG_ACZ0319655	1/16/2015	Warner 003		Amiji and Constantinides materials considered	F, H, R
DTX 010	Email from Kevin Warner to Vijaya Swaminathan RE Allergan reformulation development plan 01 30 2012	ALG_ACZ0226268 - ALG_ACZ0226271	2/3/2012	Warner 004		Amiji and Constantinides materials considered	F, H
DTX 011	Allergan Individual Project Agreement	ALG_ACZ0236790 - ALG_ACZ0236798	00/00/0000	Warner 005		Amiji and Constantinides materials considered	H, R
DTX 012	Giulia Bonacucina et al., "Characterization and stability of emulsion gels based on acrylamide/sodium acryloyldimethyl taurate copolymer," AAPS PharmSciTech 10 (2) 368-375	ALG_ACZ0375158 - ALG_ACZ0375165	06/00/2009	Warner 006	Harper Exhibit 3	Amiji and Constantinides materials considered	H
DTX 013	Sepineo P 600 The 3 in 1 Polymer for pharmacy	ALG_ACZ0375156 - ALG_ACZ0375157	00/00/0000	Warner 007	Harper 052	Amiji, Constantinides, and Harper materials considered	H, R, U
DTX 014	Email from Kevin Warner to Dom Vitarella RE Dapsone, Change in formulation	ALG_ACZ0316758 - ALG_ACZ0316760	1/25/2012	Warner 008		Amiji and Constantinides materials considered	H, R
DTX 015	Presentation Aczone Reformulation CQAs and Risk Mitigation Update	ALG_ACZ0247034 - ALG_ACZ0247042	1/16/2012	Warner 009		Amiji and Constantinides materials considered	H, R, U
DTX 016	Dapsone/Adapalene Topical Gel Formulation Summary	ALG_ACZ0174113 - ALG_ACZ0174116	00/00/0000	Warner 010		Amiji and Constantinides materials considered	H
DTX 017	Dow Pharmaceutical Sciences Inc. Dapsone Suspension Product Update	ALG_ACZ0222016 - ALG_ACZ0222021	12/2/2009	Warner 011		Amiji and Constantinides materials considered	F, H, R
DTX 018	Presentation Aczone Reformulation Development	ALG_ACZ0246068 - ALG_ACZ0246085	1/4/2010	Warner 012		Amiji and Constantinides materials considered	H, R, U
DTX 019	Email from Ajay Parashar to Varsha Bhatt RE Allergan reformulation development pla 01 30 2012 doc	ALG_ACZ0313682 - ALG_ACZ0313683	2/3/2012	Warner 013		Amiji and Constantinides materials considered	H, R
DTX 020	Drug product information	ALG_ACZ0313684 - ALG_ACZ0313689	00/00/0000	Warner 014		Amiji and Constantinides materials considered	F, H
DTX 021	Pharmaceutical Development Technical Review Aczone Reformulation (Project #1679)	ALG_ACZ0249690 - ALG_ACZ0249751	00/00/0000	Warner 015		Amiji and Constantinides materials considered	F, H, R
DTX 022	Memo PD-TMEMO-00561 Polymer evaluation for Aczone Reformulation 7.5% Single Agent Dapsone Optior	ALG_ACZ0314425 - ALG_ACZ0314441	3/29/2012	Warner 016		Amiji and Constantinides materials considered	F, H
DTX 023	Allergan Aczone Reformulation CMC Sub-Team Team Meeting Minutes	ALG_ACZ0385496 - ALG_ACZ0385496	4/13/2012	Warner 017		Amiji and Constantinides materials considered	H
DTX 024	Dow Pharmaceutical Sciences Development Report FPD137 Reformulation Development of 7 5% Dapsone Ge	ALG_ACZ0248334 - ALG_ACZ0248374	00/00/0000	Warner 018		Amiji and Constantinides materials considered	F, H
DTX 025	Email from Lin Joan-En to Kevin Warner RE Aczone Reform	ALG_ACZ0200675 - ALG_ACZ0200676	11/7/2012	Warner 019		Amiji and Constantinides materials considered	H, R
DTX 026	Allergan Dapsone Gel and Dapsone/ Adapalene Fixed Dose Combination Gel Formulation Development Repor	ALG_ACZ0249762 - ALG_ACZ0249813	2/8/2013	Warner 020		Amiji and Constantinides materials considered	H
DTX 027	Allergan Dapsone Gel and Dapsone/ Adapalene Fixed Dose Combination Gel Formulation Development Repor	ALG_ACZ0382881 - ALG_ACZ0382932	2/8/2013	Warner 021		Amiji and Constantinides materials considered	F, H
DTX 028	Declaration of Kevin Warner under 37 C.F.R. Section 1.132	ALG_ACZ0000290 - ALG_ACZ0000294	2/5/2015	Warner 022		Amiji, Constantinides, Klibanov materials considered	I, Duplicative of DTX 002
DTX 029	Defendants Taro Pharmaceutical Industries, Ltd. and Taro Pharmaceuticals, Inc.' Objections and Responses to Plaintiff Allergan, Inc.'s Notice of Deposition Pursuant to Fed R Civ P 30(b)(6)		6/19/2018	Avramoff 001			H, R, U
DTX 030	Module 2.3 Quality Overall Summary [2.3P Drug Product - Dapsone Gel, 7.5%	TARO-DG-00000254 - TARO-DG-00000256	00/00/0000	Avramoff 002		Lane materials considered	
DTX 031	Module 2.3 Quality Overall Summary 2.3.P.2 Pharmaceutical Development (Dapsone Gel 7.5%)	TARO-DG-00000260 - TARO-DG-00000286	00/00/0000	Avramoff 003			
DTX 032	Email from Shen Geo to Avi Avramoff Fw Dapsone 7 5% El	TARO-DG-00133606 - TARO-DG-00133607	6/10/2016	Avramoff 004			
DTX 033	Email from Ara Aphrahamian to Genadi Mostovoy Re Dapsone gel 7.5% pack size	TARO-DG-00132598 - TARO-DG-00132599	5/10/2016	Avramoff 005			
DTX 034	Overview to prepare for the RLD and understand the vitro directio	TARO-DG-00113959	5/5/2016	Avramoff 006		Amiji materials considered	
DTX 035	Research report Research & Development Canada - Dapsone Gel, 7.5% Product Development Summary	TARO-DG-00000655 - TARO-DG-00000742	1/24/2017	Avramoff 007		Amiji and Lane materials considered	
DTX 036	Project Approval Form for Dapsone gel 7.5% (Aczone X, Allergan) Head Start 60	TARO-DG-00128450	10/30/2014	Avramoff 008		Amiji materials considered	
DTX 037	Prototype Formulation Review Forn	TARO-DG-00111078 - TARO-DG-00111079	2/13/2015	Avramoff 009		Amiji materials considered	
DTX 038	Final Formula Review Form (Dapsone gel, 7.5%	TARO-DG-00111046	11/23/2015	Avramoff 010		Amiji and Lane materials considered	
DTX 039	Email from Avi Avramoff to Kal Sundaram Re Aczone (Dapsone) 7 5% Ge	TARO-DG-00132635 - TARO-DG-00132644	5/5/2016	Avramoff 011		Amiji materials considered	
DTX 040	Email from Thomas Callaghan to Kavita Snvastava Fw Dapsone gel 7.5% - Advis	TARO-DG-00131216 - TARO-DG-00131217	5/27/2016	Avramoff 012		Amiji materials considered	

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 041	Email from Brenden Hadjikezian to Osnat Bar-Peled re Fw Dapsone Gel 7.5% Final Review Form	TARO-DG-00129736 - TARO-DG-00129742	6/10/2016	Avramoff 013		Amiji materials considered	
DTX 042	Email from Shen Geo to Avi Avramoff Fw RFA 887 Dapsone 7.	TARO-DG-00134001 - TARO-DG-00134003	6/20/2016	Avramoff 014		Amiji materials considered	
DTX 043	Annotated Side by Side Comparison of Allergan, Inc. Aczone vs. Taro's Dapsone Gel, 7 5% Prescribing Information/Patient Informatio	TARO-DG-00000158 - TARO-DG-00000172	00/00/0000	Avramoff 015		Amiji and Lane materials considered	
DTX 044	Email from Sehn Gao to Kavita Srivastava Re Fw Dapsone Gel 7.5% Advis	TARO-DG-00135692 - TARO-DG-00135694	6/23/2016	Avramoff 016		Amiji materials considered	
DTX 045	Email from Natalie Yantovskiy to Shen Gao Re Fw Additional EBs for Dapsone 7.5% EB campaign	TARO-DG-00133480 - TARO-DG-00133491	6/30/2016	Avramoff 017		Amiji materials considered	
DTX 046	Email from Brady Brainard to Shen Geo Re Product Slide	TARO-DG-00141861 - TARO-DG-00141904	7/28/2016	Avramoff 018		Amiji materials considered	
DTX 047	Email from Miriam Getsis to Crystal Spinks Re ANDA 210191 Dapsone Gel, 7.5%- Update	TARO-DG-00128664	12/13/2017	Avramoff 019		Amiji materials considered	
DTX 048	Email from Jin Xiaopin to Wang Xiaoli et. al Fw Project Slide	TARO-DG-00143053 - TARO-DG-00143094	6/2/2015	Avramoff 020		Amiji materials considered	
DTX 049	Email from Jerzy Kadykowicz to Aci Avramoff Re Dapsone 7.5% Clinical Batch Dilemma	TARO-DG-00137409 - TARO-DG-00137412	5/27/2016	Avramoff 021		Amiji materials considered	
DTX 050	Email from Shen Gao to Avi Avramoff Fw Dapsone 7.	TARO-DG-00128794 - TARO-DG-00128796	6/20/2016	Avramoff 022		Amiji materials considered	
DTX 051	Transcript of Hearing before Judge Fallon		6/5/2018			Amiji materials considered	H R U
DTX 052	SEALED Taro s Opening Claim Construction Brief and Exhibits (Docket Entry No. 56)		3/1/2018			Amiji materials considered	B, H, R, U, ARG, CSL, LGL
DTX 053	Declaration of Professor Alexander M. Klibanov and Exhibits in support of Plaintiff's Proposed Claim Construction		3/1/2018		Harper 005	Amiji and Constantinides materials considered	B, H, R, U
DTX 054	Lubrizol Technical Data Sheet Viscosity of Carbopol Polymers in Aqueous Systems	TARO-DG-00148532 - TARO-DG-00148541	8/13/2010		Harper 034	Amiji and Constantinides materials considered	H
DTX 055	Deposition Transcripts of Kevin Warner		7/18/2018		Klibanov Exhibit 34	Amiji and Constantinides materials considered	B, H, R, U
DTX 056	E. Tanghetti et al., *The Efficacy and Tolerability of Dapsone 5% Gel in Female vs Male Patients with Facial Acne Vulgaris Gender as a Clinically Relevant Outcome Variable*, 1417 Journal of Dermatology JO1212 (2012)		12/00/2012	Harper 005		Amiji and Constantinides materials considered	H, R26
DTX 057	E. Tanghetti et al., Once-Daily Topical Dapsone Gel, 7.5% Effective for Acne Vulgaris Regardless of Baseline Lesion Count, With Superior Efficacy in Females, Journal of Drugs in Dermatology 1192-1198 (2018)		11/00/2018	Harper 006		Amiji and Constantinides materials considered	H, R26
DTX 058	Plaintiff's Initial Infringement Contentions		11/16/2017			Amiji and Constantinides materials considered	B, H, R, U, ARG, CSL, LGL
DTX 059	SEALED Report and Recommendations (Docket Entry No. 87)		6/6/2018			Amiji and Constantinides materials considered	H, R, U
DTX 060	September 11, 2018 CONFIDENTIAL Opening Expert Report of Dr. Panayiotis Constantinides		9/11/2018			Amiji and Constantinides materials considered	B, H, R, U
DTX 061	Curriculum Vitae of Panayiotis Constantinides				Exhibit A		H, R, U
DTX 062	Prior Expert Experience of Panayiotis Constantinide				Exhibit B		H, R, U
DTX 063	Materials Considered				Exhibit C		H R U
DTX 064	CONFIDENTIAL Rebuttal Expert Report of Mansoor M. Amiji, P.H.D, in Support of Ensnarement by Dr Panayiotis Constantinide		11/6/2018			Amiji and Constantinides materials considered	B, H, R, U
DTX 065	Curriculum Vitae of Mansoor M. Amiji, Phd, Rp		00/00/0000		Exhibit A		H, R, U
DTX 066	Prior Expert Witness Experience Mansoor M Amiji Phd Rp		00/00/0000		Exhibit B		H R U
DTX 067	Amiji List of Materials Considered		00/00/0000		Exhibit C		H, R, U
DTX 068	Reply Expert Report of Majella E Lane Ph D		11/20/2018				B H R U
DTX 069	November 6, 2018 CONFIDENTIAL Expert Report in Support of Ensnarement by Dr Panayiotis Constantinides		11/6/2018			Amiji and Constantinides materials considered	B, H, R, U
DTX 070	Provisional Application No. 61728403	TARO-DG-00065018 - TARO-DG-00065062	11/20/2012			Amiji and Constantinides materials considered	Duplicative of DTX 005
DTX 071	Attachments A-E to September 9, 2017 letter to John Phillips SEALED Letter Requesting Leave to File Early Summary Judgment (Docket Entry No 24		9/29/2017		Attachment A	Amiji materials considered	C, I
DTX 072	Module 3 3.2.P.1 Description and Composition of the Drug Produ	TARO-DG-00000609 - TARO-DG-00000611	00/00/0000		Lane Exhibit 13	Amiji materials considered	
DTX 073	Deposition Transcript of Avi Avramoff Ph.D.		7/17/2018		Lane Exhibit 15	Amiji materials considered	B, H, R, U
DTX 074	*Letter to Allergan Inc. from Stephen Benson Re Paragraph IV Certification Letter*		4/17/2017			Amiji materials considered	F, H, CSL
DTX 075	Letter from John Phillips to the Honorable Sherry R. Fallon Re Allergan, Inc. v. Taro Pharm Indus. Ltd., No. 17-663-VAC-SRF (Consolidated) (Docket Entry No. 22)		9/29/2017			Amiji materials considered	H, R, U, ARG, CSL, LGL
DTX 076	Letter from Jack Blumenfeld to the Honorable Sherry R. Fallon Re Jack's Blumenfeld's SEALED Letter to Judge Fallon and exhibits A-P (Docket Entry No. 27)		10/13/2017			Amiji materials considered	H, R, U, ARG, CSL, LGL
DTX 077	Defendant s Objections and Responses to Plaintiff s First Set of Interrogatories (1-4		10/23/2017			Amiji materials considered	H, R, U
DTX 078	Memorandum Order regarding Docket Entry No. 22 and Docket Entry No. 27 (Docket Entry No 39)		11/28/2017			Amiji materials considered	
DTX 079	Defendant s First Supplemental Response to Plaintiff s Interrogatory No.		1/26/2018			Amiji materials considered	H, R, U
DTX 080	Plaintiff Claim Construction Opening Brief filed by Allergan (Docket Entry No 58		3/1/2018			Amiji materials considered	H R U ARG CSL LGL
DTX 081	Plaintiff's Responsive-Claim Construction Brief (Docket Entry No. 62		4/5/2018			Amiji materials considered	H, R, U, ARG, CSL, LGL
DTX 082	Defendant s Responsive Claim Construction Brief (Docket Entry No 64		4/5/2018			Amiji materials considered	H R U ARG CSL LGL
DTX 083	Defendant s Objections and Responses to Plaintiff s Second Set of Interrogatories (NOS 5-10)		5/10/2018			Amiji materials considered	H, R, U
DTX 084	Defendant s Objections and Responses to Plaintiff s Third Set of Interrogatories (NOS. 11-25)		6/29/2018			Amiji materials considered	H, R, U
DTX 085	Plaintiff's Final Infringement Contention		9/11/2018			Amiji materials considered	B, H, R, U, ARG, CSL, LGL
DTX 086	Opening Expert Report of Majella E Lane Ph D		9/11/2018			Amiji materials considered	B H R U
DTX 087	Cirriculum Vitae of Majella E. Lane		00/00/2008		Lane Exhibit 2		H, R, U

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 088	Lane List of Materials Considered		00/00/0000		Lane Exhibit 03		H R U
DTX 089	Remington's Pharmaceutical Sciences					Amiji materials considered	Exhibit Not Sufficiently Identified
DTX 090	Aczone s NDA, Module 2.3	ALG ACZ0004101 - ALG ACZ0004104	00/00/0000			Amiji materials considered	
DTX 091	Module 2.3 Quality Overall Summary (TARO-DG-00000250-533	TARO-DG-00000250 - TARO-DG-00000533	00/00/0000			Amiji materials considered	
DTX 092	Gottfried Wozel, Dapsone in Dermatology and Beyond, Arch Dermatol Res (2014) 306 103-124	TARO-DG-00149258 - TARO-DG-00149279	00/00/0000			Amiji materials considered	H, R26, 282
DTX 093	Vivek Sharma, Suraj K. Nayak, et al, Polymeric Gels, Characterization, Properties and Biomedical Applications, Chapter 9, Emulgels,, pp. 251 – 264 (2018	TARO-DG-00149286 - TARO-DG-00149299	00/00/0000			Amiji materials considered	H, R26, 282
DTX 094	Veeran Gowda Kadajii, Water Soluble Polymers for Pharmaceutical Applications, www.mdpi.com/journal/polymers, 1972 - 200	TARO-DG-00149928 - TARO-DG-00149965	00/00/0000			Amiji materials considered	H, R26, 282
DTX 095	Michael Ghods, The Role of Dapsone Gel in the Acne Armamentarium, https //www.the dermatologist.com/content/role-dapsone-gel-acne-armamentariur	ALM_ACZ0000349 - ALM_ACZ0000352	00/00/0000			Harper, Constantinides materials considered /	A, H
DTX 096	WO 2009108147 A1	TARO-DG-00065185 - TARO-DG-00065248	9/3/2009		Harper 002	Constantinides and Klibanov materials considered	A, H
DTX 097	AAPS Pahm SciTech Vol. 10 No. 2 Research Article Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolym	TARO-DG-00063824 - TARO-DG-00063831	06/00/2009		Harper 003	Constantinides and Klibanov materials considered	A, H
DTX 098	US Patent Application 2012/0004200	TARO-DG-00148447 - TARO-DG-00148459	1/5/2012		Harper 004	Constantinides and Klibanov materials considered	A, H
DTX 099	WO 2011014627	TARO-DG-00065298 - TARO-DG-00065331	2/3/2011		Harper 010	Constantinides and Klibanov materials considered	A, H
DTX 100	Epiduo Gel label	TARO-DG-00147498 - TARO-DG-00147507	12/00/2008		Harper 018	Constantinides and Klibanov materials considered	A, H
DTX 101	Garrett II - International Publ No WO 2009061298	TARO-DG-00065130 - TARO-DG-00065184	5/14/2009		Harper 020	Constantinides and Klibanov materials considered	A, H
DTX 102	Hani - International Publ No 2010105052	TARO-DG-00065249 - TARO-DG-00065297	9/16/2010		Harper 022	Constantinides and Klibanov materials considered	A, H
DTX 103	Louis - US Patent Publ No 20110003894	TARO-DG-00064966 - TARO-DG-00064979	1/6/2011		Harper 032	Constantinides and Klibanov materials considered	A, H
DTX 104	Lubrizol, Pharmaceutical Bulletin Formulating Semisolid Products (2011)	TARO-DG-00148425 - TARO-DG-00148431	5/31/2011		Harper 033	Constantinides and Klibanov materials considered	A, H
DTX 105	Orsoni - US Patent No 7820186	TARO-DG-00148438 - TARO-DG-00148446	10/26/2010		Harper 044	Constantinides and Klibanov materials considered	A, H
DTX 106	US Patent No 5,863,560 - Osborne	TARO-DG-00065000 - TARO-DG-00065008	1/26/1999		Harper 046	Constantinides and Klibanov materials considered	A, H
DTX 107	Michael Ghods et al., *The Role of Dapsone Gel in the Acne Armamentarium* The Dermatologist (June 10, 2010)	ALM-ACZ0000349 - ALM-ACZ0000352	10/29/2018		Harper 064	Constantinides and Klibanov materials considered	A, H, Duplicate of DTX 95
DTX 108	U.S. Patent No. 2017/0266138 A1 - Warner	TARO-DG-00148460 - TARO-DG-00148478	9/21/2017			Constantinides and Klibanov materials considered	H, R, U
DTX 109	Jessica R. Walter, Topical Drug Innovation From 2000-2014, JAMA Dermatology 2015	TARO-DG-00149423 - TARO-DG-00149425	00/00/0000			Constantinides and Klibanov materials considered	H, R, R26, 282
DTX 110	Responsive Expert Report of Julie Harper, MD		11/2/2018		Harper	Constantinides materials considered	B, H, R, U
DTX 111	Curriculum Vitae of Julie C Harper MD		00/00/0000		Exhibit A		B H R U
DTX 112	Materials Considered by Julie Harper MD in connection with her Responsive Expert Report		00/00/0000		Exhibit B		B, H, R, U
DTX 113	Responsive Expert Report of Julie Harper, MD regarding Ensnaremer		11/15/2018				B, H, R, U
DTX 114	Robert Lott et al., "Medication adherence among acne patients a review." J. Cosmeti Dermatology 9 160-166 (2010)	TARO-DG-00063832 - TARO-DG-00063838	00/00/2010		Harper 031	Constantinides materials considered	A, H
DTX 115	Mallard - US Patent Publ No 20110135584	TARO-DG-00064980 - TARO-DG-00064999	6/9/2011		Harper 035	Constantinides materials considered	A H
DTX 116	Aczone 7.5 Percent Prescribing Informatio	ALG ACZ0397186 - ALG ACZ0397195	05/00/2008		Lane Exhibit 07	Constantinides materials considered	
DTX 117	Taro Pharmaceuticals Inc s Initial Invalidity Contentions		12/15/2017			Constantinides materials considered	B H R U ARG CSL LGL
DTX 118	Appendix A to December 15, 2017 Taro Pharmaceuticals, Inc. s Initial Invalidity Contentions (Obviousness of the '219 Patent)		12/15/2017			Constantinides materials considered	B, H, R, U, ARG, CSL, LGL
DTX 119	Responsive Expert Report of Professor Alexander M. Klibanov served November 11, 2018 and materials cited therein		11/11/2018			Constantinides materials considered	B, H, R, U
DTX 120	Curriculum Vitae of Alexander M. Klibanov		00/00/0000		Klibanov Exhibit A		B, H, R, U
DTX 121	List of Expert Testimony of Alexander M. Klibanov, Ph.I		00/00/0000		Klibanov Exhibit B		B, H, R, U
DTX 122	Materials Considered by Alexander M. Klibanov, Ph.I		00/00/0000		Klibanov Exhibit C		B, H, R, U
DTX 123	https //www.youtube.com/watch?v=SHiwvwnx1tA					Constantinides materials considered	A, F, H, N
DTX 124	https //www.accessdata.fda.gov/scripts/cder/ob/					Constantinides materials considered	N, R
DTX 125	http //wayback.archive-it.org/7993/20170112022245/http /www.fda.gov/Drugs/InformationOnDrugs/ucm113978.htm					Constantinides materials considered	N, R
DTX 126	Allergan End of Phase 2 Meeting Briefing Package	ALG ACZ0237709 - ALG ACZ0237755	00/00/0000			Constantinides materials considered	A F H R U
DTX 127	January 25, 2012 Email from Kevin Warner to Jacqueline Brassard re Dapsone, Change Information	ALG_ACZ0317136 - ALG_ACZ0317137	1/25/2012			Constantinides materials considered	A, F, H, R, U
DTX 128	Email from Jacqui Dombroksi to Alexandre Kaoukhov Re Dapsone 7.5% topical gel SEPINEO P600 & SIMULGEL 600 PHA gb	ALG_ACZ0320295 - ALG_ACZ0320297	7/26/2013			Constantinides materials considered	A, F, H, R, U
DTX 129	U.S. Patent 2010/0310480 A1- Garrett	TARO-DG-00064940 - TARO-DG-00064965	12/9/2010			Constantinides materials considered	Improper Description, H, R, U, R26, 282
DTX 130	U.S. Patent 6,060,085	TARO-DG-00065009 – TARO-DG-00065017	5/9/2000			Constantinides materials considered	H R U R26
DTX 131	U.S. Patent 6,620,435 B1- Osborne	TARO-DG-00065097 - TARO-DG-00065105	9/16/2003			Constantinides materials considered	H, R, U, R26
DTX 132	WO 2010/072958 A2	TARO-DG-00148558 - TARO-DG-00148593	00/00/0000			Constantinides materials considered	H U
DTX 133	US Patent Application No. 15/611,551 File History	TARO-DG-00149426 - TARO-DG-00149927	6/1/2017			Constantinides materials considered	F, H, R, U

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 134	David W. Osborne, "Diethylene glycol monoethyl ether an emerging solvent in topical dermatology products." J. Cosmetic Dermatology 10 324-329 (2011) ("Osborn 2011")	TARO-DG-00148432 - TARO-DG-00148437	00/00/2011		Harper 045	Constantinides materials considered	A, H
DTX 135	Response to Final Office Action dated January 4, 201	TARO-DG-00147459 - TARO-DG-00147480	3/5/2018			Constantinides materials considered	I, F, H, R, U
DTX 136	Pre-Appeal Brief Request for Review	TARO-DG-00147481 - TARO-DG-00147487	5/4/2018			Constantinides materials considered	I, F, H, R, U
DTX 137	Marie-Alexandrine Bolzinger, Penetration of Drugs Through Skin, a Complex Rat controlling Membrane, Current Opinion in Colloid & Interface Science, June 2012, at 156 - 165	TARO-DG-00147488 - TARO-DG-00147497	00/00/0000			Constantinides materials considered	H, R, U
DTX 138	Raymond C. Rowe, Handbook of Pharmaceutical Excipients, 6th Edition, 200	TARO-DG-00147508 - TARO-DG-00148424	00/00/0000			Constantinides materials considered	H, R, U
DTX 139	Vinod P. Shah, Principles and Criteria in the Development and Optimization of Topical Therapeutic Products, Meeting Report, Skin Pharmacol 199	TARO-DG-00148479 - TARO-DG-00148487	00/00/0000			Constantinides materials considered	H, R, U
DTX 140	Gregory E. Amidon, Proposed New USP General Information Chapter, Excipier Performance (1059), Pharmacopieal Forum, Vol. 33(6), Nov. – Dec. 2007, at 1311 – 1323	TARO-DG-00148488 - TARO-DG-00148500	00/00/0000			Constantinides materials considered	H, R, U
DTX 141	Clarence T. Ueda, Topical and Transdermal Drug Products, Pharmacopeial Forum, Vol. 35(3) May – June 2009 at 750 – 764	TARO-DG-00148501 - TARO-DG-00148515	00/00/0000			Constantinides materials considered	H, R, U
DTX 142	Dow Pharmaceutical Sciences, Inc., Topical Dermatological Formulation Development "Things You Should Know" 2009	TARO-DG-00148516 - TARO-DG-00148531	00/00/0000			Constantinides materials considered	H, R, U
DTX 143	Adrian C. Williams, Penetration Enhancers, Advanced Drug Delivery Reviews, 56 (2004) at 603 – 618	TARO-DG-00148542 - TARO-DG-00148557	00/00/0000			Constantinides materials considered	H, R, U
DTX 144	Gattefosse Dermacare and Dermasol formulations (Version 2014)	TARO-DG-00148594 - TARO-DG-00148613	00/00/0000			Constantinides materials considered	H, R, U, R26, 282
DTX 145	Sangram K. Samal, Catatonic Polymers and Their Therapeutic Potential, Chem. Soc. Rev., 2012,41	TARO-DG-00148614 - TARO-DG-00148662	00/00/0000			Constantinides materials considered	H, R, U, R26, 282
DTX 146	Rong-Kun Chang, Generic Development of Topical Dermatologic Products Formulatic Development, Process Development, and Testing of Topical Dermatoligic Products, AAPS PharmSciTech Vol 15 No 1 January 2013	TARO-DG-00149248 - TARO-DG-00149257	00/00/0000			Constantinides materials considered	H, R, U
DTX 147	David C. Calabrese, Dose-Optimization Intervention Yields significant Drug Cos Savings, Journal of Managed Care Pharmacy, March/April 2002 Vol. 8, No. 2, at 146 - 151	TARO-DG-00149280 - TARO-DG-00149285	00/00/0000			Constantinides materials considered	H, R, U, R26, 282
DTX 148	Gattefosse' Topical Solubilizers with Different Gelling Agnet	TARO-DG-00149300	00/00/0000			Constantinides materials considered	H, R, U, R26, 282
DTX 149	Gattefosse Transcutol Regulatory, Tox and Safety Overview (Last Updated September 15 2010)	TARO-DG-00149301 - TARO-DG-00149379	00/00/0000			Constantinides materials considered	H, R, U
DTX 150	Gattefosse, Efficient Skin Delivery No Compromise with Transcuto	TARO-DG-00149380 - TARO-DG-00149395	00/00/0000			Constantinides materials considered	H, R, U
DTX 151	Gattefosse Web Page, Gel Formulation Technologies	TARO-DG-00149396	00/00/0000			Constantinides materials considered	A, H, R, U, R26, 282
DTX 152	Orange Book, Alphagan 0.2%	TARO-DG-00149397 - TARO-DG-00149398	00/00/0000			Constantinides materials considered	H, R, U
DTX 153	Orange Book, Alphagan 0.5%	TARO-DG-00149399	00/00/0000			Constantinides materials considered	H, R, U
DTX 154	Orange Book, Alphagan 0.1%	TARO-DG-00149400	00/00/0000			Constantinides materials considered	H, R, U
DTX 155	Orange Book, Alphagan 0.3%	TARO-DG-00149401	00/00/0000			Constantinides materials considered	H, R, U
DTX 156	Jack Cook, Quality-by-Design Are We There Yet?, AAPS PharmSciTech, Vol. 15, No. 1, February 2014	TARO-DG-00149402 - TARO-DG-00149410	00/00/0000			Constantinides materials considered	H, R, U
DTX 157	Juan G. Rosas et al; Quality by design approach of a pharmaceutical gel manufacturin process, part 1 determination of the design space. J. Pharm. Sci. (2011) 100 4432-4441	TARO-DG-00149411 - TARO-DG-00149420	00/00/0000			Constantinides materials considered	H, R, U
DTX 158	Annabelle C. Fowler, Pharmaceutical Line Extensions in the United States, A Primer o Definitions and Incentives, NBER-IFS International Network on the Value of Medical Research, October 6, 2016	TARO-DG-00149966 - TARO-DG-00149990	10/6/2016			Constantinides materials considered	H, R, U
DTX 159	Guo - US Patent Publ No WO 20070190019	TARO-DG-00064906 - TARO-DG-00064931	8/16/2007		Harper 021	Constantinides, Klibanov & Lane materials considered	A, H
DTX 160	Lathrop - US Patent Publ No 20060204526	TARO-DG-00064894 - TARO-DG-00064905	9/14/2006		Harper 030	Constantinides, Klibanov & Lane materials considered	A, H
DTX 161	SenGupta - US Patent Publ No 20090022818	TARO-DG-00064932 - TARO-DG-00064939	1/22/2009		Harper 051	Constantinides, Klibanov & Lane materials considered	A, H
DTX 162	Formulation Recommendation 7.5% Dapsone Formulations for Phase I	ALG_ACZ0382867 - ALG_ACZ0382880	10/17/2012		Lane Exhibit 10		
DTX 163	Final Formula Review Form	TARO-DG-00111048 - TARO-DG-00111050	6/8/2016		Lane Exhibit 16		
DTX 164	Prescription - Dapsone Gel 7.5%	TARO-DG-00000042 - TARO-DG-00000043	00/00/0000		Lane Exhibit 17		
DTX 165	Physicochemical Principles of Pharmacy Fourth Editio	ALG_ACZ0397196 - ALG_ACZ0397543	00/00/0000		Lane Exhibit 18		H
DTX 166	Handbook of Pharmaceutical Excipients Sixth Editio	ALG_ACZ0397709 - ALG_ACZ0398186	00/00/0000		Lane Exhibit 19		H
DTX 167	Rheology and Its Implications on Performance of Liquid Dosage Form	ALG_ACZ0398626 - ALG_ACZ0398674	00/00/2008		Lane Exhibit 20		H
DTX 168	Emulsions Foams and Suspension	ALG_ACZ0398675 - ALG_ACZ0398791	00/00/2005		Lane Exhibit 21		H
DTX 169	Journal of Controlled Release Recent expansions in an emergent novel drug delivery technology Emulge	ALG_ACZ0399140 - ALG_ACZ0399150	00/00/2013		Lane Exhibit 22		H
DTX 170	Module 2.3 Quality Overall Summary	TARO-DG-00000287 - TARO-DG-00000313	00/00/0000		Lane Exhibit 23		
DTX 171	Pharmaceutical Suspensions - Robert Nasl	ALG_ACZ0001177 - ALG_ACZ0001224	12/13/2017		Lane Exhibit 24		H
DTX 172	Jonathan Hadgraft Drug crystallization - implications for topical and transdermal delivery	ALG_ACZ0399151 - ALG_ACZ0399165	00/00/2016		Lane Exhibit 26		H
DTX 173	Clark's Analysis of Drugs and Poisons, London Pharmaccutical Press Electronic version 2005	ALG_ACZ0399166 - ALG_ACZ0399167	00/00/2005		Lane Exhibit 28		H
DTX 174	Katrin Tiffiner Research Paper - A comprehensive approach to qualify and validate the essential parameters	ALG_ACZ0399168 - ALG_ACZ0399178	00/00/0000		Lane Exhibit 29		H
DTX 175	Calibration Block Report Linear Regression Curv	TARO-DG-00110264	5/26/2016		Lane Exhibit 30		Improper Description, H
DTX 176	Calibration Report Linear Regression Curv	TARO-DG-00110254	6/17/2016		Lane Exhibit 31		Improper Description, H
DTX 177	Dapsone 7.5% EBK-D72 AND EBK-D73	TARO-DG-00113972	00/00/0000		Lane Exhibit 32		Improper Description, H
DTX 178	2.3.P.2 Pharmaceutical Development	ALG_ACZ0004105 - ALG_ACZ0004112	00/00/0000		Lane Exhibit 33		
DTX 179	Protocol DPSG 1517	TARO_DG-00056374 - TARO_DG-00056516	1/16/2017		Lane Exhibit 34		Improper Description, H

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 180	Letter from the Department of Health and Human Services to Allergan, Inc.Attn Jeremy McCumber, MS	ALG_ACZ0371058 - ALG_ACZ0371080	00/00/0000		Lane Exhibit 35		
DTX 181	Aczone 7.5 Percent Prescribing Information	ALM-ACZ0000005 - ALM-ACZ0000014	02/00/2016		Harper Exhibit 8; Klibanov Exhibit 7; Lane Exhibit 7		
DTX 182	S. Puavilai et al., "Incidence of Anemia in Leprosy Patients Treated with Dapsone, Journal of the Medical Association of Thailand	ALM-ACZ0000997 - ALM-ACZ0001005	00/00/0000		Klibanov 10		H, R26
DTX 183	World Health Organization Information Exchange System, Alert No. 117*Antimalarial Chrorproquanil-Dapsone (LapDap) Withdrawn Folloing Demonstration of Post-TreatmentHaemolytic Anaemia in G6PD Deficient Patients in a Phase III Trial of Chlorproquanil-Dapson-Artesunate* (March 4, 2008)	ALM-ACZ0001013 - ALM-ACZ0001014	3/4/2008		Klibanov 11		H, R26
DTX 184	Aczone Gel 5% Package Insert	ALM-ACZ0000398 - ALM-ACZ0000413	00/00/0000		Klibanov 13		
DTX 185	Aczone 5 Percent Prescribing Informatio	TARO-DG-00063817 - TARO-DG-00063823	03/00/2008		Klibanov Exhibit 14	Klibanov Materials Considered	
DTX 186	IIGQInternetZIP	ALM_ACZ0000733 - ALM_ACZ000099(	00/00/0000		Klibanov Exhibit 23		Improper Description, H, R26
DTX 187	US Patent 4 829 058- Seydel	ALM-ACZ0001015 - ALM-ACZ0001029	5/9/1989		Klibanov Exhibit 25		H R26
DTX 188	US Patent 4,912,112- Seydel	ALM-ACZ0001030 - ALM-ACZ0001042	3/27/1990		Klibanov Exhibit 26		H, R26
DTX 189	European Commission Scientific Committee on Consumer Safety (SCCS*Opinion on Diethylene Glycol Monoethyl Ether (DEGEE)* Eighth Plenary Meeting (2010)	ALM_ACZ0000414 - ALM_ACZ0000466	9/21/2010		Klibanov Exhibit 32		H, R26
DTX 190	IIGQInternetZIP	ALM_ACZ0000467 - ALM_ACZ0000732	00/00/0000		Klibanov Exhibit 33		Improper Description H R26
DTX 191	Handbook of Pharmaceutical Excipients Sixth Edition	ALM_ACZ0001006 - ALM_ACZ0001012	00/00/0000		Klibanov Exhibit 36		H, R26
DTX 192	Aczone 7.5 Percent New Dug Application	ALG_ACZ0004100	00/00/0000		Harper 009; Klibanov Exhibit 08	Lane materials considered	
DTX 193	Web results Posting ACZ-ROS-01	ALM-ACZ0000001 - ALM-ACZ0000004	00/00/0000		Harper 006		H R26
DTX 194	Zaina T. Al-Salama & Emma D. Deeks,*Dapsone 7.5% Gel A Review in Acne Vulgaris* 22 Am J Clinical Dermatology (2016	ALM-ACZ0000015 - ALM-ACZ0000021	00/00/0000		Harper 011		H, R26
DTX 195	John V. Ashurst et al., *Pathophsiological Mechanisms Diagnosis and Management of Dapsone-Induced Methemoglobinemia* 110 J. Am. Osteopathic Assoc. 16-20 (2010)	ALM-ACZ0000022 - ALM-ACZ0000024	01/00/2010		Harper 012		H, R26
DTX 196	J.S. Chun et al., *Dapsone hypersensitivity syndrome with circulating 190-kDA and 230-kDA autoantibodies* 34 Clinical and Experimental Dermatology e798-e801 (2009	ALM-ACZ0000025 - ALM-ACZ0000028	00/00/2009		Harper 013		H, R26
DTX 197	QLT Inc. Clinical Study Report ACZ ROS 01 Aczone (dapsone) Gel, 5%	ALM-ACZ0000029 - ALM-ACZ0000111	2/5/2007		Harper 014		H, R26
DTX 198	Barry Coutinho, "Dapsone (Aczone) 5% Gel for the Treatment of Acne," American Family Physician (December 2010)	ALM-ACZ0000112 - ALM-ACZ0000113	2/15/2010		Harper 015	Klibanov materials considered	H, R26
DTX 199	James Q. Del Rosso, *the Use of Sodium Sulfacetamide 10%-Sulfur 5% Emollient Foam in the Treatment of Acne Vulgaris* 2 J. Clinical and Aesthetic Dermatology 26-29 (2009)	ALM-ACZ0000114 - ALM-ACZ0000117	08/00/2009		Harper 016		H, R26
DTX 200	Meghan I. Dubina & Alan B. Fleisher Jr.,*Interaction of Topical Sufacetamide and Topical Dapsone with Benzoyl Peroxide* 145 JAMA Dermatology 1027-1029 (2009)	ALM-ACZ0000118 - ALM-ACZ0000120	09/00/2009		Harper 017		H, R26
DTX 201	Gabriella Fabbrocini et al., *Resvertrol-Containing Gel for the Treatment of Acne Vulgaris* 12 Am J of Clinical Dermatology 133-141 (2011)	ALM-ACZ0000121 - ALM-ACZ0000129	00/00/0000		Harper 019		H, R26
DTX 202	James D. Williams, *Acne* , 1463-1472 The New England Journal of Medicine (2005)	ALM-ACZ0000130 - ALM-ACZ0000139	00/00/2005		Harper 023		H, R26
DTX 203	Kirk A. James et al., "Emerging Drugs for Acne," Expert Opinion Emerging Drugs 14(4) 649-659 (2009)	ALM-ACZ0000140 - ALM-ACZ0000150	00/00/2009		Harper 024	Klibanov materials considered	H, R26
DTX 204	Michael T. Jarratt et al., *Safety and Pharmacokinetics of Once-Daily Dapsone Gel 7.5%* in Patients with Moderate Acne Vulgaris, 15 J. Drugs in Dermatology 1250-1259 (2016)	ALM-ACZ0000151 - ALM-ACZ0000160	10/00/2016		Harper 025		H, R26
DTX 205	N. Kellett et al., *Conjoint analysis a novel rigorous tool for determining patient preferences for topical antibiotic treatment for acne. A randomized controlled trial* 154 British Journal of Dermatology 524-532 (2006)	ALM-ACZ0000161 - ALM-ACZ0000169	00/00/2006		Harper 026		H, R26
DTX 206	Devon Kelley, *Kate Bosworth on Adult Acne It Sucks* Yahoo Beauty (June 3, 2016)	ALM-ACZ0000170 - ALM-ACZ0000173	00/00/0000		Harper 027		H, R26
DTX 207	H.C. Korting & C. Schollmann, "Current Topical and Systemic Approaches to Treatment of Rosacea," JEADV 23 876-882 (2209)	ALM-ACZ0000174 - ALM-ACZ0000180	00/00/2009		Harper 028	Klibanov materials considered	H, R26
DTX 208	John Kraft & Anatoli Freiman,*Management of acne* 183 Canadian Med. Assoc. J. E430-E435 (2011)	ALM-ACZ0000181 - ALM-ACZ0000186	4/19/2011		Harper 029		H, R26
DTX 209	P. Marazzi et al., *Clinical evaluation of Double Strength Isotrexin versus Benzamycin in the topical treatment of mild to moderate acne vulgaris* 13 Journal of Dermatological Treatment 111-117 (2002)	ALM-ACZ0000187 - ALM-ACZ0000194	7/12/2009		Harper 036		H, R26
DTX 210	Janusz Marcinkiewicz et al., *Topical taurine bromamine a new candidate in the treatment of moderate inflammatory acne vulgaris – A pilot study* 18 Eur J. Dermatology 433-439 (2008)	ALM-ACZ0000195 - ALM-ACZ0000201	00/00/2008		Harper 037		H, R26
DTX 211	Otto H. Mills et al., *Comparing 2.5% 5% and 10% Benzoyl Peroxide on Inflammatory Acne Vulgaris* 25 Int 1J Dermatology 664-667 (1986)	ALM-ACZ0000202 - ALM-ACZ0000206	00/00/0000		Harper 038		H, R26
DTX 212	Shelley Moench-Kelly,*Banishing Blemishes* Medesthesticsmag.com	ALM-ACZ0001043 - ALM-ACZ0001048	00/00/2017		Harper 039		H, R26
DTX 213	Victoria Moorhouse,*I ve Only Had One Pimple Since Starting This Acne Treatment* InStyle	ALM-ACZ0000211 - ALM-ACZ0000213	4/23/2018		Harper 040		H, R26
DTX 214	Ayumi Naito et al.,*Topical retinoids for acne vulgaris (Protocol)* 3 The Cochrane Library (John Wiley & Sons 2008)	ALM-ACZ0000214 - ALM-ACZ0000226	00/00/2008		Harper 041		H, R26
DTX 215	Rebecca Nguyen & John Su,*Treatment of acne vulgaris* 21 J. of Pediatrics and Child Health 119-125	ALM-ACZ0000227 - ALM-ACZ0000233	00/00/2010		Harper 042		H, R26
DTX 216	Food and Drug Administration,*Patent and Exclusivity for N207154* , Orange Book Approved Drug Products with Therapeutic Equivalence Evaluations	ALM-ACZ0000234 - ALM-ACZ0000235	10/6/2018		Harper 043	Klibanov materials considered	H, R26

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 217	David Pascoe, *Aczone Fails to Impress for Rosacea* Rosacea Support Group (July 23, 2012)	ALM-ACZ0000236 - ALM-ACZ0000239	7/23/2012		Harper 047		H, R26
DTX 218	Physicians Desk Reference 2967 (2011) (Benzactin	ALM-ACZ0000240 - ALM-ACZ0000243	00/00/2011		Harper 048		H, R26
DTX 219	Physicians Desk Reference 2765 (2012) (Duac)	ALM-ACZ0000244 - ALM-ACZ0000247	00/00/2012		Harper 049		H, R26
DTX 220	Frank C. Powell, *Rosacea* 352 New England Journal of Medicine 793-803 (2005)	ALM-ACZ0000248 - ALM-ACZ0000258	2/24/2005		Harper 050		H, R26
DTX 221	Linda Stein gold et al., *Efficacy and Safety of Once-Daily Dapsone Gel 7.5% for Treatment of Adolescents and Adults with Acne Vulgaris First of Two Identically Deigned Large Multicenter Randomized Vehicle-Controlled Trials* 15 J. Drugs in Dermatology 553-561 (2016)	ALM-ACZ0000259 - ALM-ACZ0000267	05/00/2006		Harper 053		H, R26
DTX 222	Mary Ann Steiner, "Dapsone Topical Gel for Acne," J. Pharm. Soc. Wisc. 12(6) 67-71 (2009)	ALM-ACZ0000268 - ALM-ACZ0000273	00/00/2009		Harper 054	Klibanov materials considered	H, R26
DTX 223	Toni C. Stockton et al.,*Clinical Experience With Once-Daily Dapsone Gel 7.5% Monotherapy in Patients with Acne Vulgaris* 17 J. Drugs in Dermatology 602-608 (2018)	ALM-ACZ0000274 - ALM-ACZ0000280	06/00/2018		Harper 055		H, R26
DTX 224	John S. Strauss, *Biology of the Sebaceous Gland and the Pathophysiology of Acne Vulgaris* Chapter 13 in Pathophysiology of Dermatologic Diseases, Second Edition, N.A. Soter and H. Baden eds., McGraw-Hill, New York 195-210 (1991)	ALM-ACZ0000281 - ALM-ACZ0000298	00/00/0000		Harper 056		H, R26
DTX 225	Yuko Takenaka et al, *Glycolic acid chemical peeling improves inflammatory acne eruptions through its inhibitory and bactericidal effects on Propionibacterium acnes* 39 J Dermatology 350-354 (2012)	ALM-ACZ0000299 - ALM-ACZ0000303	00/00/2011		Harper 057		H, R26
DTX 226	Susan C. Taylor et al., *Efficacy Safety and Tolerability of Topical Dapsone Gel 7.5% for Treatment of Acne Vulgaris by Fitzpatrick Skin Phototype* 17 J. Drugs in Dermatology 160-167 (2018)	ALM-ACZ0000304 - ALM-ACZ0000311	02/00/2018		Harper 058		H, R26
DTX 227	Diane M. Thiboutot et al., *Efficacy Safety and Dermal Tolerability of Dapsone Gel 7.5% in Patients with Moderate Acne Vulgaris A Pooled Analysis of Two Phase 3 Trials* 9 J Clinical and Aesthetic Dermatology 18-27 (2016)	ALM-ACZ0000312 - ALM-ACZ0000321	10/00/2016		Harper 059		H, R26
DTX 228	Stephen Titus & Joshua Hodge,*Diagnosis and Treatment of Acne* 86 American Family Physician 734-740 (2012)	ALM-ACZ0000322 - ALM-ACZ0000328	00/00/2012		Harper 060		H, R26
DTX 229	Wayback Machine Results for David Pascoe,*Aczone Fails to Impress for Rosacea* Rosacea Support Group (July 23 2012)	ALM-ACZ0000329 - ALM-ACZ0000334	7/23/2012		Harper 061		H, R26
DTX 230	Hywel C. Williams et al., *Acne Vulgaris* 379 Lancet 361-372 (2012)	ALM-ACZ0000335 - ALM-ACZ0000346	1/28/2012		Harper 062		H, R26
DTX 231	Dina Anderson, *Finding a Place for Topical Anti-inflammatory Acne Therapy* Practical Dermatology 17-18 (July 2009)	ALM-ACZ0000347 - ALM-ACZ0000348	07/00/2009		Harper 063		H, R26
DTX 232	Responsive Expert Report of Professor Alexander M. Klibanov Regarding Ensnarement		11/20/2018				B, H, R, U
DTX 233	November 20, 2018 CONFIDENTIAL Reply Expert Report of Dr. Panayiotis Constantinides		11/20/2018				B, H, R, U
DTX 234	Taro's ANDA Section 1.12.15 Request for Waiver of In Vivo BA/BE Studies	TARO-DG-00000139 - TARO-DG-00000141	00/00/0000			Interrogatory Responses	
DTX 235	Taro's ANDA Section 2 3 P Drug Product	TARO-DG-00000257 - TARO-DG-00000259	00/00/0000			Interrogatory Responses	
DTX 236	Report on Compatibility Study for Taro's Dapsone Gel 5% and Title Dapsone Gel 7 5%	TARO-DG-00000636 - TARO-DG-00000644	00/00/0000			Interrogatory Responses	
DTX 237	Evaluation and Verification of Residual Solvents in Raw Material, Material Name Carbomer Homopolymer Type C NF ERK/RK Code RK-0104	TARO-DG-00000826 - TARO-DG-00000834	10/16/2014			Interrogatory Responses	
DTX 238	Dapsone A4212 MV Data Spreadsheet	TARO-DG-00110231 - TARO-DG-00110231	00/00/0000			Interrogatory Responses	F, H, R
DTX 239	RSD calculation Dec 09 2016	TARO-DG-00110233 - TARO-DG-00110233	12/9/2016			Interrogatory Responses	F H R
DTX 240	Summary for Obscuration vs Sample Weight and Dispersant	TARO-DG-00110234 - TARO-DG-00110234	00/00/0000			Interrogatory Responses	F, H, R
DTX 241	In-vitro D71 NR Nov 15 - Jan 16	TARO-DG-00110246 - TARO-DG-00110246	00/00/0000			Interrogatory Responses	F H R
DTX 242	D71 Specs Draft Nov 2015	TARO-DG-00110841 - TARO-DG-00110841	11/00/2015			Interrogatory Responses	F, H, R
DTX 243	Packaged Product Certificate of Analysis EBK-D71 Dapsone Gel, 7.5%	TARO-DG-00110862 - TARO-DG-00110881	5/11/2016			Interrogatory Responses	F H R U
DTX 244	In-Process Certificate of Analysis EBK-D71 Dapsone Gel, 7.5%	TARO-DG-00110882 - TARO-DG-00110887	5/11/2016			Interrogatory Responses	F, H, R, U
DTX 245	EB-Sample-List D71 2016-Jan	TARO-DG-00110888 - TARO-DG-00110888	01/00/2016			Interrogatory Responses	F H R U
DTX 246	EB-Sample-List D71 2016-Jun	TARO-DG-00110895 - TARO-DG-00110895	06/00/2016			Interrogatory Responses	F, H, R, U
DTX 247	Antimicrobial Effectiveness Test, USP<51> Certificate of Analysis	TARO-DG-00112119 - TARO-DG-00112119	5/11/2016			Interrogatory Responses	F, H, R, U
DTX 248	Microbiological Test Method Suitability Study For EBK-D71, Dapsone Gel 7.5%	TARO-DG-00112132 - TARO-DG-00112138	5/12/2016			Interrogatory Responses	F, H, R, U
DTX 249	Taro Pharma Inc. Laboratory Notebook PD 294	TARO-DG-00113703 - TARO-DG-00113743	3/16/2015			Interrogatory Responses	F, H, R, U
DTX 250	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00113954 - TARO-DG-00113958	00/00/0000			Interrogatory Responses	F, H
DTX 251	Taro Pharmaceuticals Canada Inc. Laboratory Notebook PD255	TARO-DG-00126173 - TARO-DG-00126184	4/13/2011			Interrogatory Responses	F, H, I, R, U
DTX 252	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00128811 - TARO-DG-00128815	00/00/0000			Interrogatory Responses	F, H, I, R, U
DTX 253	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00128817 - TARO-DG-00128821	00/00/0000			Interrogatory Responses	F, H, U
DTX 254	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00128824 - TARO-DG-00128827	00/00/0000			Interrogatory Responses	F, H, U
DTX 255	Email from Hoc Quach to Shen Gao et al. re Dapsone 7.5% QQ	TARO-DG-00129147 - TARO-DG-00129148	5/27/2016			Interrogatory Responses	F, H
DTX 256	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00129152 - TARO-DG-00129155	00/00/0000			Interrogatory Responses	F, H, U
DTX 257	Email from Tracey Tweedlie-Yuill to Sandeep Kale et al. re Dapsone Gel 7.5% (In Vitro Results) (RFA-0896)	TARO-DG-00129732 - TARO-DG-00129733	6/20/2016			Interrogatory Responses	F, H, R
DTX 258	Dapsone Gel 7.5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00131639 - TARO-DG-00131642	00/00/0000			Interrogatory Responses	F, H, U
DTX 259	Email from Natalie Yantovskiy to Shen Goa et al. re Dapsone Gel 7.5% Clinical Batch Dilemma	TARO-DG-00132807 - TARO-DG-00132808	5/27/2016			Interrogatory Responses	F, H
DTX 260	Dapsone Gel 7 5% EB Lot S321-63499 Microscopic Evaluation	TARO-DG-00134815 - TARO-DG-00134818	00/00/0000			Interrogatory Responses	F H U
DTX 261	Email from Parminder Bhimbh to Jerry Zadykowicz re D71 (RLD) Initial Clinical Screening	TARO-DG-00135403 - TARO-DG-00135403	5/26/2016			Interrogatory Responses	F, H, R
DTX 262	Email from Nandor Rehak to Tracey Tweedlie-Yuill et al. re Dapsone 7.5% Work	TARO-DG-00139166 - TARO-DG-00139168	7/13/2017			Interrogatory Responses	F, H, R, U
DTX 263	Module 3.2.P.2.1. Components of the Drug Product	ALG ACZ0016209 - ALG ACZ0016211	00/00/0000			Interrogatory Responses	
DTX 264	Allegan Report Number AN11045 BM-A1 Long Term Freezer Stability of Dapsone Hydroxylamine in Human Plasma (-20C)	ALG ACZ00174439 - ALG ACZ00174439	00/00/0000			Interrogatory Responses	Incorrect Bates Nos., F H I R
DTX 265	Aczone Reformulation CMC Sub-Team / Team meeting Minutes	ALG ACZ0217973 - ALG ACZ0217974	6/13/2012			Interrogatory Responses	F, H, R

TX NO	DESCRIPTION	PRODUCTION NOS.	DOCDATE	DEPONENT	EXPERT REPORT EXHIBIT NO.	ALSO MENTIONED	OBJECTIONS
DTX 266	Aczone Reformulation CMC Sub-Team / Team Meeting Minutes	ALG_ACZ0234577 - ALG_ACZ0234578	3/13/2012			Interrogatory Responses	F H R
DTX 267	PFD Update Aczone Reformulation	ALG_ACZ0247228 - ALG_ACZ0247236	2/14/2012			Interrogatory Responses	F, H, R
DTX 268	Formulation Recommendation 7.5% Dapsone Formulations for Phase I	ALG_ACZ0249035 - ALG_ACZ0249048	10/17/2012			Interrogatory Responses	F, H, R
DTX 269	Aczone Reformulation Pharm Dev Tech Review / Team meeting Minutes	ALG_ACZ0249687 - ALG_ACZ0249689	9/14/2012			Interrogatory Responses	F, H, R
DTX 270	Proposed plan for 7.5% Dapsone Gel Prototype formulations	ALG_ACZ0250088 - ALG_ACZ0250090	1/30/2012			Interrogatory Responses	F, H, R
DTX 271	Aczone Reformulation GMC PFD Update	ALG_ACZ0252742 - ALG_ACZ0252752	00/00/0000			Interrogatory Responses	F, H, R
DTX 272	Micro Update - 14 May 2012	ALG_ACZ0253936 - ALG_ACZ0253936	5/14/2012			Interrogatory Responses	F, H, R
DTX 273	Rheology of Sepineo Solutions	ALG_ACZ0379403 - ALG_ACZ0379420	3/13/2015			Interrogatory Responses	F, H, R
DTX 274	Evaluation of Polymeric Thickeners for Aczone Reformulation	ALG_ACZ0382851 - ALG_ACZ0382861	12/10/2012			Interrogatory Responses	F, H, R
DTX 275	Summary of Manufacturing Process for R&D Stability Supplies Manufactured by Do Pharmaceutical Sciences	ALG_ACZ0382862 - ALG_ACZ0382866	9/14/2012			Interrogatory Responses	F, H, R
DTX 276	Aczone Reformulation (Project #1679)	ALG_ACZ0383748 - ALG_ACZ0383809	00/00/0000			Interrogatory Responses	F, H, R
DTX 277	PFD Update - CMC Sub team - Aczone Reformulation	ALG_ACZ0385470 - ALG_ACZ0385495	3/13/2012			Interrogatory Responses	F, H, R
DTX 278	PFD Update - CMC Sub team - Aczone Reformulation	ALG_ACZ0385497 - ALG_ACZ0385499	4/20/2012			Interrogatory Responses	F, H, R
DTX 279	CMC Team Meeting Project 1679 Aczone Reformulation	ALG_ACZ0385501 - ALG_ACZ0385524	6/13/2012			Interrogatory Responses	F H R
DTX 280	CMC Formulation Development Update	ALG_ACZ0385525 - ALG_ACZ0385533	00/00/0000			Interrogatory Responses	F, H, R
DTX 281	CMC Team Meeting - Project 1679 Aczone Reformulation	ALG_ACZ0385535 - ALG_ACZ0385558	7/16/2012			Interrogatory Responses	F H R
DTX 282	Analytical Updates - Rangan Mallik Xiaoli Liang Nov 2012	ALG_ACZ0385559 - ALG_ACZ0385576	11/20/2012			Interrogatory Responses	F, H, R
DTX 283	CMC Team Meeting - Project 1679 Aczone Reformulation	ALG_ACZ0385577 - ALG_ACZ0385591	12/12/2012			Interrogatory Responses	F H R
DTX 284	Global Pharmaceutical Sciences Pharmaceutical Development - Technical Report (PI TRPT-00315) Techonology Transfer Report for Dapsone 7.5% Topical Gel Manufacturing Process Project 1679	ALG_ACZ0396842 - ALG_ACZ0396903	00/00/0000			Interrogatory Responses	F, H, R

Key to Almirall's Objections to Taro's Exhibits

ABBREVIATION	OBJECTION	APPLICABLE RULE(S)
A	Requires authentication or identification	FRE 901
ARG	Argumentative	FRE 611(a)
B	Best evidence rules prohibit introduction	FRE 1002, 1003
C	Improper compilation of separate documents	FRE 403, 901
CSL	Counsel testifying	FRE 103, 602
D	Improper designation (designation is neither a question or testimony)	FRE 401, 402
E	Improper examination (vague, ambiguous, loaded, leading, etc.)	FRE 402, 403, 602, 611
F	Lack of foundation/personal knowledge (incl. calls for speculation)	FRE 402, 403, 602, 611
H	Hearsay if offered for the truth of the matter asserted	FRE 801, 802
I	Incomplete document or testimony	FRE 106, 403
LGL	Calls for legal conclusion	FRE 103, 602
M	Offer or discussion for settlement or compromise	FRE 408
N	Exhibit not produced in discovery	FRE 403
O	Improper opinion testimony	FRE 701-704
P	Privileged or attorney work product	FRE 501, 502
R	Lack of relevance	FRE 401, 402
S	Summary requiring underlying data or information	FRE 1006
T	Beyond the scope of Rule 30(b)(6) topic for which a witness has been designated	FRE 602, FRCP 30(b)(6)
U	Unduly prejudicial, wasteful, confusing, misleading or cumulative	FRE 403
R26	Lack of notice of how expert witness intends to rely on document	FRCP 26(a)(2)(B)
282	Failure to identify publication in 35 U.S.C. § 282 notice	35 U.S.C. § 282(c)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED [redacted]

EXHIBIT 13

AMIRALL'S MOTION IN LIMINE AND TARO'S OPPOSITION

Plaintiff's Motion *in Limine* No. 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED

PLAINTIFF'S MOTION *IN LIMINE* NO. 1 TO PRECLUDE TESTIMONY OF DR. AMIJI OUTSIDE THE SCOPE OF HIS EXPERT REPORT

OF COUNSEL:

James S. Trainor
Vanessa Park-Thompson
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010
(212) 921-2001
jtrainor@fenwick.com
vpark-thompson@fenwick.com

Ewa M. Davison, Ph.D.
Elizabeth B. Hagan, Ph.D.
FENWICK & WEST LLP
1191 Second Avenue, 10th Floor
Seattle, WA 98101
(206) 389-4510
edavison@fenwick.com
ehagan@fenwick.com

Rebecca A.E. Fewkes
FENWICK & WEST LLP
801 California Street
Mountain View, CA 94041
(650) 988-8500
rfewkes@fenwick.com

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com
araucci@mnat.com

Attorneys for Plaintiff Almirall, LLC

Defendants should be precluded from eliciting expert opinion testimony from Dr. Amiji outside the scope of his expert report. Specifically, Dr. Amiji should not be allowed to testify regarding the amendment of claim 1 of U.S. Patent Application No. 14/082,955 ("the '955 application") in support of his prosecution history estoppel opinion.

I. BACKGROUND

Dr. Mansoor Amiji, on behalf of Taro, provided a single expert report rebutting application of the doctrine of equivalents in this case. Ex. 1. Among his arguments, Dr. Amiji asserted that prosecution history estoppel here serves as a bar to Almirall's doctrine of equivalents infringement theory. Ex. 1 at 31–33 (¶¶ 79–83). With respect to the '955 application—the "Parent Application" to which the asserted '219 patent claims priority—Dr. Amiji focused entirely on prosecution of original ***claim 14*** of the '955 application, observing that: (1) original claim 14 recited "multiple types of carbomer"; (2) applicant elected to proceed with carbomer homopolymer type C in response to a restriction requirement for claim 14; and (3) applicant canceled claim 14. *Id.* ¶ 80; *see also id.* ¶¶ 62–63. Referring to this prosecution history for original claim 14 of the '955 application, Dr. Amiji concluded: "Based on the applicant's original attempt to claim carbomer homopolymer type C and its subsequent cancelation of that claim a POSA would understand that Carbomer was not claimed in the invention and could not be claimed by the applicant." *Id.* ¶ 80. The remainder of Dr. Amiji's opinion regarding prosecution history estoppel relied only on the arguments made by the applicant in prosecuting the '219 patent itself. *See id.* ¶¶ 81–83.

Despite the narrow focus of Dr. Ajimi's argument, however, Taro in its statement of uncontested facts now points to the amendment of original ***claim 1*** of the '955 application. Although Dr. Amiji recited the prosecution history of the '955 application in a background section of his report titled "Patents-in-Suit," including events related to original claim 1, his opinion that prosecution of the '955 application estops Almirall's doctrine of equivalents theory relies exclusively on prosecution events relating to original ***claim 14***. *Compare id.* ¶¶ 60–70 *with id.* ¶¶ 79–83. Dr. Amiji had opportunity to provide an opinion related to claim 1 of the '955

application, as Taro's early summary judgment motion asserted estoppel arising from amendment of that claim. *See* D.I. 22 at 4–5. Despite this opportunity, for the '955 application Dr. Amiji's report asserted only estoppel arising from modifications to claim 14. Ex. 1 ¶¶ 79–83. Given that Dr. Amiji chose not to rely on prosecution events relating to amendment of ***claim 1*** of the '955 application when providing his prosecution history estoppel opinion in his expert report, he should not be allowed to do so at trial.

II. PRECLUSION IS THE APPROPRIATE REMEDY

This Court has explained that it "will, as it must, limit the expert testimony at trial to that disclosed in the expert reports." *Stored Value Solutions, Inc. v. Card Activation Techs., Inc.*, C.A. No. 09-495-LPS, 2010 WL 3834457, at *2 n.1 (D. Del. Sept. 27, 2010); *accord Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, C.A. No. 12-540-LPS, 2015 WL 10457176, at *4 (D. Del. Apr. 23, 2015) ("Absent approval of the Court, all experts for all parties are PRECLUDED from testifying beyond the scope of their reports . . . ."). Such limitation is appropriate here.

Federal Rule of Civil Procedure 26(a)(2)(B) requires an expert to disclose in his report "a complete statement of all opinions the witness will express *and the basis and reasons for them*." *Id.* (emphasis added). Dr. Amiji did not disclose amendment of claim 1 of the '955 application as a basis or reason for his prosecution history estoppel opinion. Such testimony regarding claim 1 is not consistent with his report, nor is it a "reasonable synthesis and/or elaboration of the opinions contained in [his] report." *Cf. Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 585 F. Supp. 2d 568, 581 (D. Del. 2008). Rather, it is an entirely separate basis for prosecution history estoppel.

Moreover, Almirall has not had opportunity to respond to Dr. Amiji's opinions for this basis of prosecution history estoppel, nor to probe those opinions in deposition. Almirall would be prejudiced by presentation of his opinion as to claim 1 for the first time at trial. Cure of this prejudice would require supplemental reports and depositions, which would not be possible without disrupting the approaching trial date. Dr. Amiji's testimony on this previously

undisclosed prosecution history estoppel opinion should accordingly be precluded. *See Hurley v. Atlantic City Police Dept.*, 174 F.3d 95, 113 (3d Cir. 1999) (factors in determining whether allowing testimony beyond the scope of expert reports is abuse of discretion include prejudice to opposing party, ability to cure the prejudice, disruption of trial, and bad faith or willfulness of non-compliance), *abrogated on other grounds by Potente v. Cty. of Hudson*, 187 N.J. 103, 114, 900 A.2d 787, 794 (2006) (applying state law); *see also Forest Labs., Inc. v. Ivax Pharm., Inc.*, 237 F.R.D. 106, 113–14 (D. Del. 2006) (sustaining objections to expert's trial testimony as beyond the scope of his expert reports).

III. CONCLUSION

For the reasons stated above, Almirall respectfully requests that the Court preclude Defendants from eliciting testimony from Dr. Amiji regarding prosecution history estoppel due to the amendment of claim 1 of the '955 application as beyond the scope of his expert report.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Anthony D. Raucci

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com
araucci@mnat.com

Attorneys for Plaintiff Almirall, LLC

OF COUNSEL:

James S. Trainor
Vanessa Park-Thompson
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010
(212) 921-2001
jtrainor@fenwick.com
vpark-thompson@fenwick.com

Ewa M. Davison, Ph.D.
Elizabeth B. Hagan, Ph.D.
FENWICK & WEST LLP
1191 Second Avenue, 10th Floor
Seattle, WA 98101
(206) 389-4510
edavison@fenwick.com
ehagan@fenwick.com

Rebecca A.E. Fewkes
FENWICK & WEST LLP
801 California Street
Mountain View, CA 94041
(650) 988-8500
rfewkes@fenwick.com

December 31, 2018

EXHIBIT 1

CONFIDENTIAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED

[CONFIDENTIAL]

REBUTTAL EXPERT REPORT OF MANSOOR M. AMIJI, PH.D, R.PH.

I. INTRODUCTION

1. I, Mansoor M. Amiji, Ph.D., R.Ph. submit my expert report in the above-captioned case on behalf of Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals Inc. (collectively, "Taro").

2. I have been asked to respond to the report submitted on behalf of Plaintiff[1] by Majella E. Lane, Ph.D. alleging that the product described in Taro's ANDA No. 21-0191, if sold and used according to its label, would induce infringement of certain claims of U.S. Patent No. 9,517,219 ("the '219 patent"). In particular, I have been asked for my opinions regarding alleged infringement of claims 1, 2, 4 and 5 of the '219 patent (collectively the "asserted claims") pursuant to the Doctrine of Equivalents ("DOE").

II. QUALIFICATIONS

3. In 1988, I graduated with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, I received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmacal Sciences at Purdue University, under the supervision of Professor Kinam Park. My dissertation focused on biomaterials and water-soluble polymers. During my graduate studies at Purdue University, I took several industrial pharmaceutics courses and had hands-on training pharmaceutical formulations.

4. I am currently a University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. I am also jointly appointed as a Professor of Chemical Engineering in the College of Engineering at Northeastern University. I am also

[1] I understand Almirall has been substituted for Allergan as the Plaintiff in this action. I also understand I am to respond to Dr. Lane's report and refer to any prior submissions, opinions, statements, etc. as if they were provided by Almirall as opposed to Allergan.

currently an Affiliate Faculty Member in the Department of Biomedical Engineering at Northeastern University. I have taught and carried out research in pharmaceutical sciences at Northeastern University since 1993, and from 2010 to 2016, I served as the Chairman of the Department of Pharmaceutical Sciences. In 2000, I was a Visiting Research Scholar in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT) in Cambridge, Massachusetts in the laboratory of Professor Robert Langer.

5. As a tenured faculty member at Northeastern University, I have over 25 years of experience in teaching drug formulations to both graduate and undergraduate students. In theory and laboratory courses that I have taught and continue to teach, I extensively cover the manufacturing and composition of pharmaceutical formulations. I also serve as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

6. Over the course of my career I have published extensively and am ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. I have coauthored over 60 book chapters and more than 300 peer reviewed scientific articles. I am also an inventor on several issued United States patents covering pharmaceutical devices, materials and methods. I have taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics.

7. I have served as a grant reviewer for the National Institutes of Health, the Department of Defense, the United States Department of Agriculture, and the American Chemical Society. I am a member of several professional and industrial societies, including the American Association of Pharmaceutical Scientists (AAPS) and the Controlled Release Society (CRS), and have participated as a reviewer for more than 50 scientific journals. I have also

received a number of professional awards and honors, including the Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology in 2006; a Fellowship and Meritorious Manuscript Award from the AAPS in 2007; the Tsuneji Nagai Award from the CRS in 2012; and the Northeastern University School of Pharmacy Distinguished Alumni Award in 2016. Over the course of my career, I have advised numerous post-doctoral associates, doctoral students, master's students, visiting scientists, and research fellows.

8. A true and correct copy of my curriculum vitae, which includes a list of the published papers that I have written, professional honors and memberships, and presentations that I have given, is attached to this report as Exhibit A. The matters in which I have testified in the past four years are included in Exhibit B.

9. I am being compensated at a rate of $850 per hour for testimony.

III. OVERVIEW OF OPINION

10. In formulating and providing my opinions herein, I reviewed relevant portions of Taro's ANDA, the expert reports of Dr. Lane and Dr. Panayiotis P. Constantinides, the '219 patent and prosecution history, the patent and prosecution history of U.S. Patent No. 9,161,926, as well as background literature and other documents cited throughout this report, including the documents set forth in Exhibit C. The bases for my opinions include the references and observations cited in this report, my education, and my many years of experience in industry and academia, including the development of formulations of pharmaceutical products.

11. The product described in Taro's ANDA will not infringe any of the asserted claims of the '219 patent. Taro's ANDA describes a product that does not include "about 2% w/w to 6% w/w of a polymeric viscosity agent comprising A/SA". Because each asserted claim

of the ’219 patent requires treatment with a formulation containing A/SA, Taro’s Product if sold doctrine of equivalents.

IV. LEGAL STANDARDS

12. I am not a patent attorney, nor have I independently researched the law of patent validity. I have been informed of certain legal standards below that I have relied on in forming my opinions in my report.

13. I understand that for a claim to be found to be infringed, Plaintiff bears the burden of establishing by a preponderance of the evidence that each and every claim limitation is present in the accused product or method. I understand that each claim is to be evaluated individually.

14. I understand that patent claims can be independent or dependent. Dependent claims incorporate all the limitations of an identified independent claim, and then further narrow the claim through additional limitations. I understand that if an independent claim is not infringed by an accused product, then all claims that depend from that claim are also not infringed because each would be missing a shared limitation.

15. I understand that the process for determining infringement requires two steps. First, I have been instructed to apply the Court’s claim construction to those identified terms, then, for the remaining terms, use the plain and ordinary meaning to a person of ordinary skill in the art (“POSA”) at the time of the invention. Second, I have been informed that I should compare the construed claims to the identified accused product or method to determine if all elements are present. I understand that if any claim element is not present in the accused product or method, then the overall product or method does not infringe the claim.

16. I understand that a claim element that is not literally present in the accused product or method may still infringe under the legal doctrine of equivalents. I understand the doctrine of equivalents exists so that an accused infringer may not avoid infringement because of

minor or insubstantial changes that take a product or method outside the literal scope of the claims. I understand that the doctrine of equivalents applies when there are insubstantial differences between the claim element that is not literally present and the accused equivalent structure or method step in the accused device or process.

17. I understand that one test to determine whether an accused equivalent element is insubstantially different from a claim limitation is the "function-way-result" test. I understand that under that test, an accused equivalent infringes if it performs substantially the same function in substantially the same way to achieve substantially the same result as the claim element in question. I also understand that this is only one way of determining equivalence, and that it may not be appropriate in all situations.

18. I understand that the doctrine of equivalents is applied on a claim element-by-element basis. In other words, I understand that I am not to consider the claim as a whole when analyzing whether a claim element is present under the doctrine of equivalents.

19. I also understand that there are situations where the doctrine of equivalents is not allowed to be applied at all.

20. I have been informed and understand there is a doctrine referred to as prosecution history estoppel. It is my understanding prosecution history estoppel prevents a patentee from recapturing subject matter is surrendered during the prosecution of the patent. I understand the surrender of the subject matter does not need to be explicit, but that it must be clear and unequivocal.

21. I have also been informed and understand there is a doctrine referred to as the "dedication to the public" or the "dedication-disclosure" rule, which generally means if a patent

drafter discloses but declines to or does not claim certain subject matter, that unclaimed subject matter is dedicated to the public and its use will not infringe the patent.

22. I also understand under the doctrine of ensnarement a patentee is barred from asserting a scope of equivalents that would encompass or "ensnare" the prior art to find an accused product infringes.

V. TECHNOLOGY BACKGROUND

23. The '219 patent generally claims methods of treating acne with a formulation containing 7.5% dapsone, a solubilizing agent and a polymeric viscosity builder ("PVB" or "thickening agent"). The '219 patent was distinguishing from the prior art during prosecution because the formulation used a polymeric thickening agent called acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA") instead of the prior used carbomer homopolymer type C ("Carbomer"). Carbomer is commercially available as Carbopol 980.

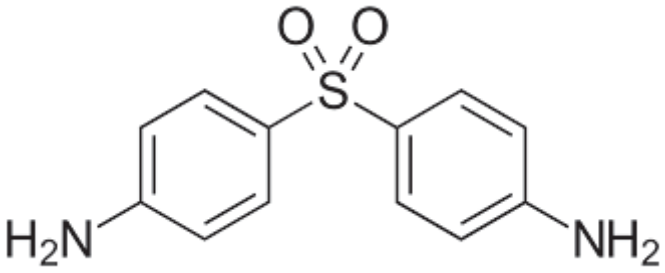
24. The '219 patent, along with the prosecution history of the patent inclusive of the references cited in those documents, include descriptions and evidence of background relevant to the technology claimed in the patents-in-issue. The background information relates, for example, to dapsone, formulations of dapsone at varying concentrations, including formulations containing Carbomer as the thickening agent. If asked, I am prepared to discuss the background of the invention claimed in the '219 patent, in particular with reference to the patent-in-suit, prosecution histories of the patent, and art cited within that document. I will also reference the parent application to the '219 patent, including its prosecution history. Finally, I will also rely on my own personal knowledge and experience.

25. Basic topical drug formulation relevant to the '219 patent can be found in established references such as Remington's Pharmaceutical Sciences. Basic information on pharmaceutical excipients can be found in the references such as the Handbook for

Pharmaceutical Excipients. In describing the basic background of the patent-in-suit, I may additionally rely on these texts along with my own knowledge gained from a career designing pharmaceutical dosage forms, including topical formulations utilizing thickening agents.

A. Dapsone as a Topical Anti-inflammatory Agent

26. Dapsone, whose chemical name is diaminodiphenyl sulfone (chemical structure shown below) was first synthesized in 1908 and was available as an antibacterial and antiprotozoal antibiotic in 1937 and was commonly used in combination with other drugs, such as rifampicin and clofazimine, for the treatment of leprosy. Additionally, it is a second-line medication for the treatment and prevention of Pneumocystis carinii pneumonia and for the prevention of toxoplasmosis in HIV positive patients and those who have poor immune function.



27. Dapsone has intrinsic anti-inflammatory properties and has been indicated topically for treatment of many different types of skin conditions such as for acne, dermatitis herpetiformis and others. The anti-inflammatory effects of dapsone resemble those seen with non-steroidal anti-inflammatory agents such as ibuprofen or meloxicam. Dapsone is poorly soluble in water (solubility = 0.2 mg/mL), but can dissolve readily in organic solvents such as methanol (solubility = 50 mg/mL).

28. The first animal tests for the anti-inflammatory effects of dapsone were carried out in 1970's using various rodent models of inflammatory diseases. Although the exact mechanisms of anti-inflammatory effects of dapsone has not been well understood, the drug

tends to inhibit inflammatory conditions through multiple biological processes including decrease in reactive oxygen species generation, inhibition of specific enzymes, as well as lowering pro-inflammatory cytokine levels.

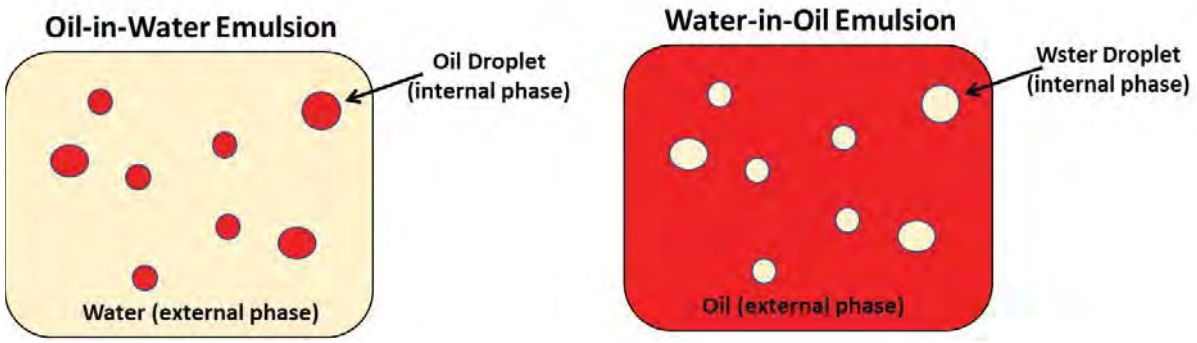
29. When ingested for antimicrobial effects, dapsone has significant issues with toxicity in the liver and other organs in the body. As such, dapsone use as an anti-inflammatory agent is generally restricted to topical administration, such as on the skin, in order to decrease systemic availability and side effects.

B. Topical Drug Products

30. As opposed to systemic administration where the drug products are given by oral or injectable route of administration, a drug product is administered topically for local treatment of diseases of the skin and mucosal surfaces that are accessible. The main advantage of topical drug administration is achievement of maximum benefits of treating the disease condition locally without systemic side effects. Many different diseases of the skin, such as dry skin, eczema, hives, acne, etc., benefit from topical products that confine the medication to the affected area.

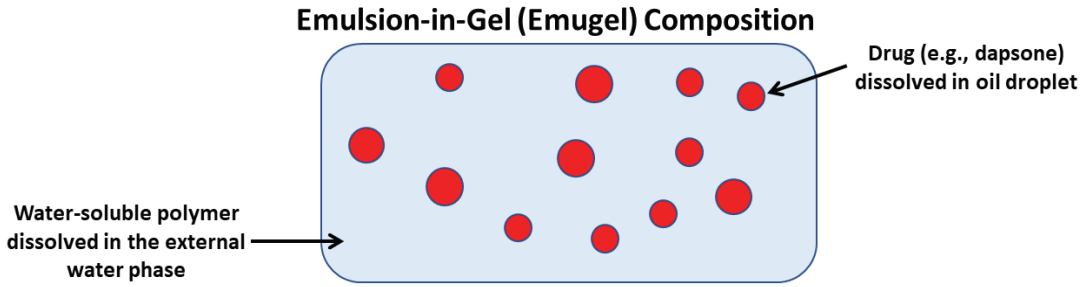
31. Skin is the largest organ in the body and provides the greatest surface area for topical drug administration. In order to achieve maximum benefit for local treatment of skin diseases, a topical drug product needs to have desired attributes that can provide therapeutic benefits in a safe and effective manner. For example, the drug product should be formulated to give the required dose of the active agent in an amount sufficient to cover the affected area and remain at the site for a reasonable period of time. Additionally, the product consistency should be such that it is easy to spread on the skin surface, but not too thin to have poor residence. The formulation should also maintain drug stability over the course of the shelf-life of the product.

32. For these formulation attributes to be met, a person of skill in the art ("POSA") would develop a topical drug product in an ointment, cream, lotions, foams or gel composition. An ointment is a lipid product intended for application on the skin that is usually prepared with petrolatum base. Creams and lotions are prepared by mixing oil and water to form emulsions. These simple emulsions can be either oil-in-water (O/W) or water-in-oil (W/O) depending on the relative percentage by weight of the oil and water phases and the choice of the emulsifier or surfactant used (see figure below). Common household examples of O/W and W/O emulsions are salad dressings and margarine, respectively. Foams are prepared by incorporation of a propellant that aerosolizes upon release, such as in shaving cream. Lastly, gels are made using water-soluble polymers that at a specific concentration will create a product with gel-like consistency that is required to have a product spread easily on the skin. In contrast to ointment, which generally do not absorb or dissolve in water, emulsions and gel products would be able to either imbibe water or completely dissolve in water.



33. Emulsion-gel hybrid or "emugels" are topical drug products that combine the properties of O/W emulsion with a water-soluble polymer gel incorporated to increase the viscosity of the final product (Vivek Sharma, et al, Polymeric Gels, Characterization, Properties and Biomedical Applications, Chapter 9, Emulgels,, pp. 251 – 264 (2018)). The water-soluble polymers used to prepare emugels are also referred to as "polymeric viscosity builders" (PVB).

As shown in the figure below, an emugel will consist of oil droplets (internal phase) surrounded by water (external phase) of an emulsion. A water-soluble polymer is dissolved in the external water phase to create a hydrogel, such that the final product is useful for topical drug administration. Based on the properties of the active drug, it could be dissolved either in the internal oil phase or the external water phase. Dapsone, for example, is water-insoluble and would preferentially dissolve in the oil phase of the emulsion. Additionally, water-soluble and oil-soluble excipients can be incorporated in the respective phases of the emulsion.



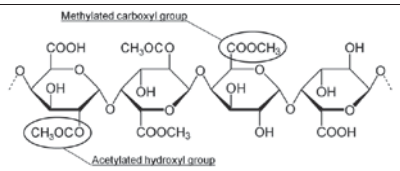
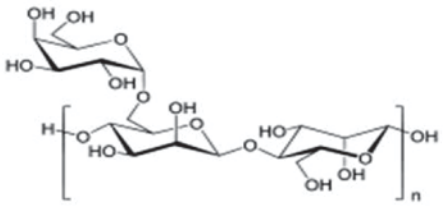
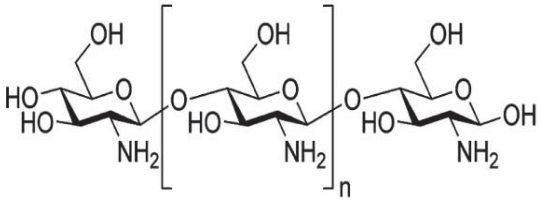
C. Viscosity Enhancement in Topical Emugels

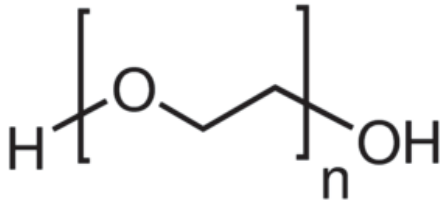
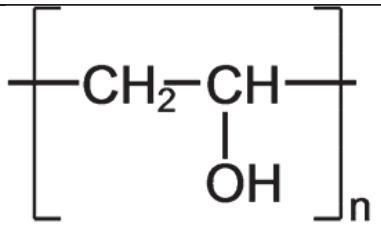
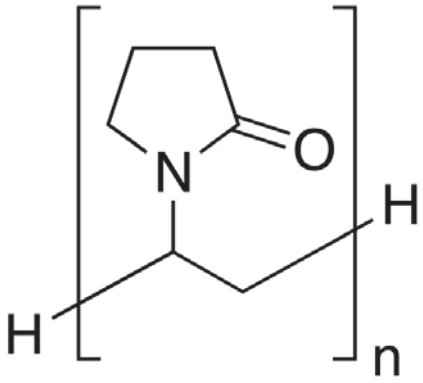
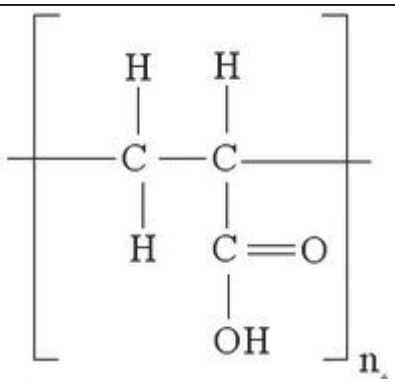
34. There are many benefits of emulsions, gels, and emugels as a topical drug product, including aesthetic appeal, ease of incorporation of diverse types of water-soluble and oil-soluble drugs and excipients, as well as the possibility of washing the product off of the skin when needed. However, since emulsions are heterogenous formulations with oil and water, they are also susceptible to stability issues such as phase separation and creaming as well as stability and homogeneity of drug dispersion within the formulation. Increasing the viscosity of the water phase in an O/W emulsion ensures that the final product will be dispensed as a semi-solid composition that will be easier to spread, will remain on the skin, and will have other desired properties as opposed to liquid emulsions.

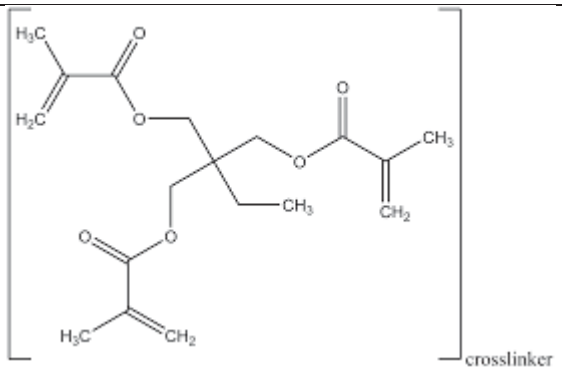
D. Polymeric Viscosity Builders

35. To increase the viscosity of the external water phase in an O/W emulsion of an emugel, water-soluble polymers can be added to induce gelation. In the context of pharmaceutical products, these polymeric viscosity builders (PVB) or gelators are pharmaceutical excipients that can create interconnecting networks in solution to imbibe water and increase viscosity of the final product. Both natural and synthetic water-soluble polymers are used to increase viscosity of the emugels.

36. The Table below shows some illustrative examples and structures of natural and synthetic water-soluble polymers used in pharmaceutical products to increase viscosity. The final viscosity of the formulation is determined by the type of polymer, the molecular weight, and the concentration in the final composition.

Polymer Type	**Name**	**Chemical Structure**
Natural	Pectin	
	Guar gum	
	Chitosan	

Synthetic		
	Poly(ethylene glycol) (PEG) or poly(ethylene oxide) (PEO	
	Poly(vinyl alcohol) (PVA)	
	Poly(N-vinylpyrrolidone) (PVP)	
	Crosslinked polyacrylic acid resins (Carbopol, Carbomer)	

	Acrylamide/sodium acryloyldimethyl taurate copolymer (e.g., Sepineo P600)	

37. Neutral polymers such as PEG or PVA dissolve in water by hydrogen bonding. However, charged polymers, such as Carbopol will dissolve through ion-dipole interactions especially when the pH is increased to above 5.0 when the carboxylic acid group is ionized. Since the ion-dipole interaction is stronger than hydrogen bonding, Carbopol tends to provide greater increase in viscosity when the pH is raised to between 5.0 to 7.0.

VI. TARO'S ANDA PRODUCT AND MANUFACTURING METHOD

38. Taro has submitted ANDA No. 210191 for Dapsone Gel 7.5% ("Taro's ANDA"). I have reviewed relevant portions of Taro's ANDA to analyze whether the product described therein ("Taro's Product") if used according to its labeling would cause infringement of any of the Asserted Claims.

39. Taro's ANDA describes the composition and manufacturing process to create Taro's Product. In the "Description and Composition of the Drug Product" of Taro's ANDA (Section 3.2.P.1), the Quantitative Formulation and Functions of Ingredients tables for Taro's Product are included. TARO-DG-00000610. These tables describing the composition of Taro's Product are reproduced below:

Table 2: Quantitative Formula

Strength (Label claim):	7.5% Dapsone	
Component and Quality Standard	**Quantity per unit** (mg/g)	**%** (w/w)
Dapsone, USP	75.00	7.50
Purified Water, USP	596.5	Calculated 59.65[1]
[redacted]		

Table 3: Functions of Ingredients

Component	**Intended Functions**
Dapsone, USP	Active Pharmaceutical Ingredient (API)
Purified Water, USP	Vehicle/anti-solvent
[redacted]	

40. Dapsone is the sole active ingredient in Taro's Product.[2] The product additionally includes water, [redacted]

[2] The excipients of Taro's Product, including commonly known uses of the same are indicated at TARO-DG-00000679-80.

[redacted] These excipients in combination constitute an aqueous phase of Taro's Product.[3]

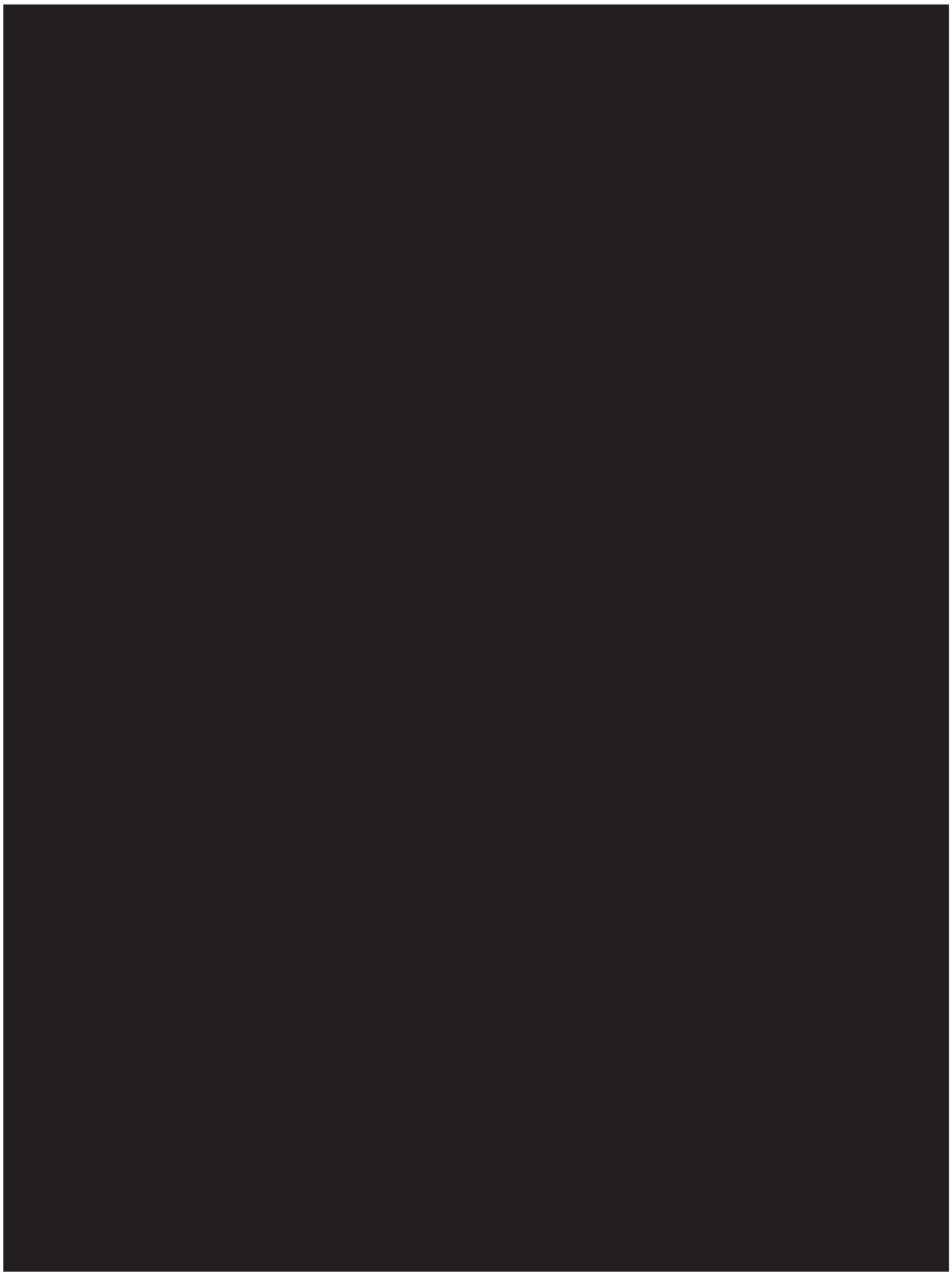
41. Taro's Product additionally includes [redacted]

42. Lastly, Taro's Product includes Carbomer Homopolymer Type C, also commonly referred to as Carbopol 980 or simply "Carbomer." *See* Lubrizol, Viscosity of Carbopol Polymers in Aqueous Systems (2010). Carbomer is a polymeric thickening (or "gelling") agent consisting of a single synthetic high-molecular-weight polymer of acrylic acid. Carbomer is used in Taro's Product to increase the viscosity of the gel and it is the sole thickening agent in Taro's formulation. As described below with reference to the manufacturing protocol for Taro's Product, Carbomer must be carefully mixed with water followed by activation using some form of neutralizing agent, in this case sodium hydroxide. Addition of Carbomer to topical pharmaceutical products must be carefully controlled to prevent clumping of the polymer.

43. Taro's ANDA describes Taro's Manufacturing Process in detail. The Manufacture section of Taro's ANDA (3.2.P.3) contains a subsection entitled, "Description of manufacturing process and process control" (3.2.P.3.3) which provides narrative and graphical information about the manufacturing process. This section also describes what controls are implemented by Taro to ensure adherence to the product and manufacturing specifications.

[3] As described below, Taro's Product additionally includes an oil phase. Topical formulations having an aqueous and oil phase are common.

Section 3.2.P.3.3 contains a "Flow Diagram" that shows a graphical representation of the full manufacturing process for Taro's ANDA Product. TARO-DG-00000769. The Flow Diagram identifies [redacted] *Id.* The Flow Diagram is reproduced in full below:



44. In addition to the graphical description, Section 3.2.P.3.3 contains a Narrative Summary of the manufacturing process. TARO-DG-00000770-71. This narrative provides more detail about each step of the manufacturing process shown in the Flow Diagram.[4]

45. The Narrative Summary describes [redacted]

46. At this point, [redacted] Thereafter, water is added to the mixture to arrive at the target weight and the product is packaged in airless pump containers of 30, 60 and 90 gram sizes. *Id.*

47. As clearly stated in Flow Diagram and the Narrative Summary, Taro does not [redacted] and Carbomer to create a polymeric thickening agent. Instead, Carbomer is added separate from all other ingredients in a

[4] Batch Records for Taro's Product are also a good source for learning the manufacturing protocol. *See* TARO-DG-00000798-821.

time consuming and carefully managed process as is typical with topical pharmaceutical formulations containing Carbomer.

VII. PATENTS-IN-SUIT

A. Disclosures of the '219 and '926 Patents

a. The '219 Patent

48. For the purposes of my report, I separately refer to the Abstract, Specification and Claims of the '219 patent as issued.

49. The Abstract is presented on the face of the '219 patent. It is my understanding the purpose of an abstract is to enable the public to determine quickly from a cursory inspection the nature and gist of the technical disclosure in the specification. *See* 37 CFR § 1.72(b). The abstract reads:

> Dapsone and dapsone/adapalene compositions can be useful for treating a variety of dermatological conditions. The compositions of this disclosure include dapsone and/or adapalene in a polymeric viscosity builder. Subject compositions can be adjusted to optimize the dermal delivery profile of dapsone to effectively treat dermatological conditions and improve the efficiency of pharmaceutical products applied to the skin. Use of the polymeric viscosity builder provides compositions with increased concentrations of diethylene glycol monoethyl ether relative to compositions without the polymeric viscosity builder.

50. In my opinion, the Abstract of the '219 patent provides very little to apprise the public the nature of the invention. At most, the abstract describes dapsone and/or adapalene compositions with a PVB and that the use of the PVB somehow allows for higher concentrations of DGME. It is important to note the abstract does not specifically identify A/SA and also describes adapalene compositions that are explicitly excluded from the claims. See Claims 1 and 6. In my opinion, a person reading the abstract in combination with the claims (described in more detail below) would understand the patent disclosed subject matter that was not claimed and

therefore could be practiced without infringing the issued claims. This understanding would be reinforced by further examination of the Specification and Claims, as described below.

51. It is my understanding the specification of a patent is a written description of the invention and of the manner and process of making and using the invention. *See* 37 CFR § 1.71. It is my further understanding the specification must be in such full, clear, concise, and exact terms as to enable any person skilled in the relevant art to make and use the same. *Id.* It is also my understanding the specification must set out the precise invention in a manner to distinguish it from other inventions and from what is old. *Id.* In my report I refer to the "Field and Background of the Invention", the "Summary of the Invention" and the "Description of the Preferred Embodiments" as the specification of the '219 patent.[5]

52. The Field and Background of the Invention (the "Background") begin with general reference to compositions useful for treating dermatological conditions, with a focus on acne, using dapsone and dapsone/adapalene compositions. Col. 1, ln. 19- Col. 2, ln. 8. The Background generally discusses challenges associated with the treatment of acne, including the need for trial-and-error in determining the most effective treatment, efficacy being affected by patient compliance with treatment, side effects associated with available treatment and cost. The Background also notes the availability of compositions with multiple-anti-acne agents having stability concerns as well as difficult with manufacture.

53. The inventors conclude the Background by stating there is a "continuing need for compositions and methods used in treatment of a variety of skin conditions, such as acne, in which topical application is potentially effective" and that the compositions and methods of the '219 patent address those needs. Col. 2, ln. 4-8. In my opinion, the concluding statement makes

[5] It is my understanding original claims as filed with the patent application are part of the invention disclosure.

clear the inventors were not purporting to solve the foregoing problems, but were offering compositions that were "potentially effective." *Id.* This conclusion would be confirmed by further reading of the Specification, as discussed below. In example, "treating" or "treatment" is defined in the patent as simply having some positive effect on a skin condition. *See* Col. 5:22-34. That is an extremely low bar for compositions comprising active ingredients well-known to provide benefits to patients having acne.

54. The Summary of the Invention begins with a somewhat generic discussion of dermatological issues, including acne and the prior treatments thereof. It is my understanding the Summary of the Invention should be "commensurate with the invention as claimed and any object recited should be that of the invention as claimed." *See* 37 CFR 1.73. The summary states a problem with prior dapsone compositions is they cause drying of skin, itching and cracking. Col 2:25-28. It is stated inclusion of skin emollients and oils in the composition causes "phase separation and precipitation of dapsone." Col 2:29-31. It is further stated improved compositions would improve treatment options and minimize problems with prior formulations and the compositions of the invention include dapsone solubilized with DGME and optionally include a PVB. It is further stated the compositions can be "adjusted to optimize the dermal delivery profile of dapsone[.]" Col 2:44-48. In view of the fact the prior art described dapsone formulations with DGME and a PVB, a person of skill in the art reading this conclusion would not understand the nature of the invention. More specifically, such a person would have noted the complete absence of clinical information of any kind in the patent suggesting improved treatment or reduction in side effects associated with the methods of the invention. (Clinical information or data also was not included during prosecution of the application resulting in the '219 patent.)

55. At the conclusion of the Summary the patent stated that use of a PVB reduces yellowing and the particle size of dapsone in formulations, thereby reducing the feeling of grittiness. Col 2:54-61. The specification does provide information about yellowing and grittiness, specifically at Figures 1 and 3 (yellowing) and 2 (particle size). The Figures are of very little help, however, as there is no way of discerning the "yellowing" in the images of Figures 1 and 3 and Figure 2 does not include information about the formulations at issue. As such, it is impossible to know what formulations are being compared. In conclusion, a POSA would understand the inventors were alleging some benefit of compositions with respect to yellowing and particle size, but the support for those benefits is of almost no value.

56. The Detailed Description and Embodiments (the "Detailed Description") begins with two columns focused on general information relating to dermatological conditions, none of which have any obvious pertinence to the invention disclosed. Cols. 3-4. The conclusion of the clinical information defines the term "treating" or "treat" in the context of the invention as previously described, namely by setting a very low bar of efficacy. Col 5:22-34.

57. The Detailed Description next generally disclose compositions of the invention, such compositions containing dapsone in the ranges of 5 to 10% w/w, DGME in the range of 10 to 40% w/w and the use of different PVBs, including A/SA and Carbomer. Cols. 5-6. There is no representation that the compositions solve any of the foregoing treatment challenges or have any particular clinical benefit beyond being dapsone formulations. Instead, a list of embodiments of the invention follows. The first embodiment is extremely broad, covering a composition with dapsone between 3 and 10% w/w, a first solubilizing agent, a second optional solubilizing agent, a PVB and water. Col 6:65-Col 7:3. Many of the subsequent embodiments refer to this first embodiment, including Embodiment 20 wherein Embodiment 1 is further defined as including

Carbomer between 0.7 and 1.5% w/w. A specific formulation falling under Embodiment 20 appears in Table 5 wherein compositions contemplated for use according to the invention are disclosed. The composition includes 7.5% w/w dapsone, DGME and 1% w/w Carbomer. In view of this, and other information in the patent, a person of skill in the art would have understood the Detailed Description was disclosing dapsone compositions having Carbomer as the PVB in 1% w/w concentration. The claims of the patent, however, do not encompass such compositions.

58. The patent disclosed many other formulations wherein Carbomer was used in combination with dapsone and/or adapalene. A further example is found, for instance, at Example 1 comparing A/SA with 1% w/w Carbomer and noting a larger crystal size with Carbomer formulations than with A/SA (Col. 12, l. 55). Tables 1, 2, 5, 6, and 8 also disclose Carbomer containing formulations. As such, a person reading the specification and examining the claims would have understood Carbomer formulations were disclosed as being part of the invention, but not subsequently claimed. As described below, the reason those formulations were not claimed is due to the applicant specifically disavowing formulations wherein the thickening agent was Carbomer in response to a rejection by the patent office.[6] Similarly, adapalene formulations are described as being part of the invention, but those formulations are expressly precluded by the claims. The only polymeric viscosity builder or thickener referenced in the claims themselves is A/SA.[7]

[6] I have reviewed the deposition of inventor Kevin Warner and understand Carbomer formulations were proposed for Phase I clinical studies along with the formulation that eventually became Aczone® 7.5% gel. Warner Dep. 245:15-248:19. The eventual formulation was selected, but Dr. Warner does not know if the Carbomer formulations would have succeeded if pursued. 266:13-270:3.

[7] It is interesting the applicant claimed A/SA as opposed to Sepineo P 600, as that is what they claim to be the PVB in its Aczone 7.5% Gel product and the only form of A/SA that was ever considered.

59. If asked, I am prepared to talk about the '219 patent, including the Background, Summary and Detailed Description. I am also prepared to discuss how a person of ordinary skill in the art would have understood the disclosure of the '219 patent alone and in view of the prosecution history (described in detail below). Finally, I am prepared to talk about the claims and claim scope.

B. The Parent Application No. 14/082,955

60. It is my understanding the application that resulted in the '219 patent was a division of Application No. 14/082,955. I refer to Application No. 14/082,955 as the "Parent Application" as I understand that to be the proper designation to indicate its relation to the application that resulted in the '219 patent (the "Divisional Application"). The Parent Application issued as U.S. Patent No. 9,161,926 ("the '926 Patent"). It is my understanding the '926 Patent has not been asserted against Taro. Nevertheless, I have been informed the prosecution of the Parent Application can be relevant to an understanding of the subject matter of a divisional application and the claims of a patent issuing from such a divisional application. For this reason, I have reviewed the prosecution history of the '926 patent and, if asked, am prepared to describe the prosecution history for the Court.

61. The Parent Application was submitted with an original twenty (20) proposed claims. The original proposed claim 1 stated the following:

> A composition comprising dapsone, a first solubilizing agent which is diethylene glycol monoethyl ether, optionally at least one second solubilizing agent, a polymeric viscosity building, and water, wherein the dapsone is preset in the composition at a concentration of about 3% w/w to about 10% w/w. TARO-DG-00063859

The original proposed dependent claim 10 claimed:

> The composition of claim 1, wherein the polymeric viscosity building comprising an acrylamide/sodium acryloyldimethyl taurate copolymer. *Id*.

And dependent claim 11 and 12 claim the PVB present at a concentration of about 2% w/w to about 6% w/w and a concentration of about 4% w/w respectively. *Id.* These claims are consistent with embodiments in the specification of the '219 patent, as previously discussed.

62. The original proposed dependent claim 14 claims:

> The composition of claim 1, further comprising Carbomer interpolymer type A, carbomer interpolymer type B or Carbomer Homopolymer Type C. TARO-DG-00063860.

Claim 14 is a claim covering a composition with 7.5% dapsone, 30% DGME, 1% Carbomer and water. It would also cover the same composition additionally including Polysorbate 80, sorbitan monooleate, light mineral oil and a neutralizing agent. That claim was withdrawn based on an examiner's patentability rejection.

63. In a January 14, 2014 Office Action, the patent examiner noted the applicants claimed two separate inventions (composition and method) and required the applicant to choose which invention the applicant wished to have examined. TARO-DG-00063901-63902. Further, the applicant was required to make an election of a single disclosed species for, among other things, claim 14. TARO-DG-00063902-63904. In a February 20, 2014, Response to the Restriction Requirement and Election of Species, the applicant elected invention 1 (the composition). Further, the applicant elected carbomer homopolymer type C as the carbomer polymer listed in Claim 14. TARO-DG-00063911.

64. In the next Office Action dated March 18, 2014, the Examiner issued claim rejections as, among other references, being anticipated by both Lathrop and Ahluwalia. TARO-DG-00063918-63923. I understand Lathrop teaches topical emulsive compositions of dapsone, and claims a composition containing both dapsone and Carbomer. TARO-DG-00063918-919. Ahluwalia teaches topical compositions with dapsone and adapalene for the treatment of acne.

Ahluwalia teaches exemplary compositions such as 5% w/w dapsone; .1% w/w or .3% w/w adapalene; 25% w/w DGME; 15% w/w propylene glycol; .01% w/w EDTA; .75% w/w Carbopol 980; sodium hydroxide and purified water. TARO-DG-00063919. The Examiner cited Lubrizol advertising literature for the fact Carbopol 980 is a polymeric thickener synonymous with carbomer homopolymer type C. TARO-DG-00063919. The Examiner noted Ahluwalia taught ranges of dapsone, DGME and a polymeric viscosity builder and concluded the ranges clearly encompass the ranges being claimed by the applicant. TARO-DG-00063921-922.

65. In response to the March Office Action, on May 20, 2014, the applicant submitted amended claims limiting, among other things, the polymeric viscosity builder in claim 1 to A/SA and cancelling multiple claims, including claim 14. TARO-DG-00064079.

66. The applicant went on to argue against the prior rejections and specifically noted the "unexpected advantages" of the claimed composition in providing improved aesthetics and noted the particle size improvement using A/SA in comparison to Carbomer. TARO-DG-00064088-64089. The applicant specifically stated and included in bold "the composition comprising [A/SA] thickener has unexpected advantages over a composition where the thickener/viscosity builder in Carbomer homopolymer type C." TARO-DG-00064089.

67. On June 5, 2014, the Examiner again rejected multiple claims as being obvious and unpatentable over the prior art. TARO-DG-00064097-64102. The Examiner further discussed the applicant's claim of "unexpected advantages." The Examiner noted the tested formulations cited by the applicant were not commensurate in scope with the claims presented, and further found "a showing of unexpected results must necessarily be accompanied by a clear indication of what the skilled artisan would have expected, as well as a clear showing of how the claimed invention exceed such expectation so as to provide properties or results that were

unexpected, unobvious and of statistical and practical significance" which the applicant had not done. TARO-DG-00064105-64108.

68. In response to another rejection, on February 2, 2015, the applicant submitted a declaration from Kevin S. Warner, one of the co-inventors of the patent application stating: "Based on the unexpected observation of Carbopol 980 incompatibility with 40% DGME, the thickener was changed from Carbopol 980 to Sepineo P 600 [i.e., A/SA] to mitigate the risk of polymer aggregation in DGME containing formulations." ALG-ACZ0000292. He further stated: [We] selected Sepineo P 600 as the gelling agent for our dapsone 7.5% gel formulation. We made this selection due to Sepineo P 600's compatibility with concentrations of DGME greater than 25% and its improvement in dapsone particle size relative to Carbopol 980." *Id*. This same declaration was submitted again in support of the '219 patent application.

69. After the submission of the declaration the applicant further amended and canceled certain claims and responded to the latest rejection. TARO-DG-00064182-64184. In focusing on unexpected results, the applicant reiterated the "unexpected results" discussed by the co-inventor in his declaration. TARO-DG-00064188. They noted undesirable polymer aggregates during formulations studies (using Carbomer) which lead to the utilization of A/SA. TARO-DG-00064188-64189. The applicant went on to state Sepineo P 600 allowed for higher concentrations of DGME, which were found to be incompatible with Carbomer and that Sepineo P 600 formulations provided smaller particle size as compared to Carbomer formulations, which is why Sepineo P 600 was selected as the gelling agent. TARO-DG-00064189. It was emphasized this result was "entirely unexpected and could not have been predicted" based on the 5% dapsone formulation, which used Carbomer or the prior art formulation. *Id*.

70. After these repeated references to the unexpected superiority of A/SA over the well-known and previously utilized Carbopol 980, the Examiner issued a notice of allowability. TARO-DG-00064344.

C. Prosecution of the '219 Patent

71. I have reviewed the prosecution history of the '219 patent and, if asked, I am prepared to describe the prosecution history for the Court. As explained below, and throughout my report, the applicants' responses and representations made to the patent examiner, both about the basic and novel characteristics of the invention being claimed in the application that led to the '219 patent and the nature of the prior art, are relevant to my non-infringement analysis. As explained in detail below, a full review of the prosecution history makes clear the applicants were focused on the novelty of using A/SA as the thickening agent and expressly disclaimed Carbomer formulations.

72. Originally, all of the claims were rejected as unpatentable over Garrett in view of Hani, a rejection nearly identical to those made during prosecution of the Parent Application. (The claims were also rejected on the ground on nonstatutory double patenting, as being unpatentable over claims 1-6 of the '926 patent.). ALG_ACZ0000052-72. By way of amendment and response to the office action dated February 18, 2016, the applicants argued the amount of dapsone, the use of Sepineo P 600 as the sole thickening agent in a topical dermatological formulation comprising dapsone and the specific amount of Sepineo P 600 recited in the claims made the claims distinct from the prior art.[8] ALG_ACZ0000284. Applicants claimed the combination of Sepineo P 600 with dapsone was not suggested in either Garrett or Hani:

[8] This argument is interesting in that the applicant did not claim Sepineo P 600, but a PVB comprising A/SA. As previously mentioned, the claim is broad enough to cover the use of A/SA *alone* as the PVB.

> First, Garrett teaches that a preferred composition comprises about 5% w/w dapsone wherein about 0.85% w/w carbopol 980 is used as a thickening agent. The instant claims recite new formulations of dapsone wherein the active ingredient is about 7.5% dapsone and an entirely new thickening agent is employed. The new formulation of the instant claims does not include a carbomer such as Carbopol®, but instead utilizes as [A/SA], also known as Sepineo™ P 600, and at a much higher concentration (about 2% to about 6% w/w) as compared to what Garrett teaches for its thickening agent.

ALG_ACZ00000284. In this response, applicants were absolutely clear: "the formulation of the instant claims does not include a carbomer such as Carbopol® …" ALG_ACZ0000283-284. As discussed below, the examiner withdrew its rejection based on Garrett and Hani.

73. In this response the applicant also included the declaration of Kevin Warner previously submitted in connection with prosecution of the Parent Application. Warner Declaration, ALG_ACZ0000290-294. In arguing the unexpected nature of the invention, the applicants argued, for example, Sepineo P 600 was found to be a more robust thickener than Carbomer, which was used in the prior 5% dapsone gel formulations. ALG_ACZ0000292. Applicant further argued Sepineo P 600 allowed for higher concentrations of DGME than with Carbomer and resulted in reduced particle size as compared to Carbomer. *Id*. Applicants concluded: "Sepineo P 600 was therefore selected as the gelling agent for the 7.5% w/w dapsone formulation of the instant claims." Response to Office Action, ALG_ACZ000286.

74. The Examiner determined the Warner Application provided enough support for the unexpected results of A/SA over Carbomer and the rejections for obviousness were withdrawn. ALG_ACZ0000503-505. It was noted by the Examiner in the prosecution of both the '926 and the '219 patents that the testing done with Sepineo and Carbopol did not use the same concentrations, but in this instance, the Examiner noted the inventor's explanation that higher concentrations of Carbopol 980 would have results in even greater aggregation. ALG_ACZ0000504. The Examiner went on to note "The Warner Declaration … provides clear

evidence that the improved properties of the Applicant's claimed 7.5% w/w dapsone formulation … yields directly from the selection of the [A/SA] copolymer as the polymeric thickener of the formulation. ALG-ACZ0000504.

75. I note throughout the prosecution of both the '926 and '219 patents, the applicants noted the superiority of A/SA to Carbomer and the incompatibility of Carbomer with their invention. Such consistent efforts to distinguish the alleged invention from the prior art utilizing, claiming and describing the use of Carbomer put the public and a person of skill in the art on notice that only products containing A/SA could be covered by the claims of the '926 and '219 patents and more specifically the thickening agent Carbomer was not covered by the claims.

VIII. CLAIM CONSTRUCTION

76. I understand the Court has construed the term "polymeric viscosity builder" ("PVB") and that the construction is applicable to my analysis of the '219 patent (Markman Order dated June 6, 2018, C.A. No. 17-663, Docket No. 87). The Parties' proposed constructions and the Court's construction are reproduced below:

Allergan	Taro	Court
"polymer-based system with one or more components that contributes to creating or maintaining the viscosity of the topical pharmaceutical composition"	"a polymer or polymer-based thickening agent"	"a polymer or polymer-based thickening agent"

77. My opinions set forth below apply the Court's claim construction. For all terms that have not been construed by the Court, I apply the plain and ordinary meaning to a POSA as of November 20, 2012.[9]

IX. DR. LANE'S INFRINGEMENT THEORIES ARE BARRED

78. Dr. Lane's infringement analysis requires a finding the 1% Carbomer used as a thickening agent in Taro's Product is equivalent to "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA]". *See* Lane Report at ¶ 67. As explained in more detail below, I disagree with Dr. Lane's opinion regarding the identity of the thickening agent in Taro's Product or that the thickening agent in Taro's Product is equivalent to the missing claim elements. (Furthermore, I disagree with Dr. Lane's attempt to show equivalence between excipients in Taro's Product and unclaimed elements.) Nevertheless, *even if* one were to accept Dr. Lane's construction of the PVB in Taro's Product, numerous limitations on the DOE preclude a finding of infringement. Specifically, Dr. Lane's DOE opinions are precluded under the doctrines of 1) prosecution history estoppel; 2) commitment to the public; and 3) ensnarement. Additionally, it appears Dr. Lane is utilizing a "whole claim" analysis instead of analyzing the specific element at issue. For these reasons alone, it is my opinion Dr. Lane has not demonstrated Taro infringes the '219 patent.

A. Prosecution History Estoppel

79. I have been informed there is a doctrine called prosecution history estoppel which essentially bars a patentee from making narrowing amendments and/or narrowing the scope of the claims during the prosecution of the patent and then broadening the scope of the claims to invoke the doctrine of equivalents.

[9] I understand from Counsel Almirall is asserting a priority date of November 20, 2012. By using this date I am giving no opinion as to whether to this an appropriate priority date for the '219 patent.

80. During prosecution of the Parent Application, the applicant attempted to claim Carbomer and then chose to cancel that claim in direct response to a rejection by the Examiner. Specifically, as noted above in Section VII. B. the original proposed claims in the Parent Application included a claim for multiples types of carbomer, which in response to an Office Action the applicant limited to carbomer homopolymer type C (referred to herein as, Carbomer). The applicant then in response to yet another rejection, canceled the claim in its entirety, thus no longer claiming Carbomer. Based on the applicant's original attempt to claim carbomer homopolymer type C and its subsequent cancelation of that claim a POSA would understand that Carbomer was not claimed in the invention and could not be claimed by the applicant.

81. The claim to Carbomer did not reappear in the Divisional Application that resulted in the '219 patent. However, the patent examiner found the claims obvious in view of Garrett and Hani. As described above, the applicants specifically overcame the objections by arguing the claims did not include Carbomer.

> First, Garrett teaches that a preferred composition comprises about 5% w/w dapsone wherein about 0.85% w/w carbopol 980 is used as a thickening agent. The instant claims recite new formulations of dapsone wherein the active ingredient is about 7.5% dapsone and an entirely new thickening agent is employed. The new formulation of the instant claims does not include a carbomer such as Carbopol®, but instead utilizes as [A/SA], also known as Sepineo™ P 600, and at a much higher concentration (about 2% to about 6% w/w) as compared to what Garrett teaches for its thickening agent.

ALG_ACZ00000284. It bears repeating, applicants were absolutely clear: "the formulation of the instant claims does not include a carbomer such as Carbopol® …" ALG_ACZ0000283-284.

82. In further response to obviousness objections, one of the co-inventors submitted a declaration explaining that Carbomer was unexpectedly not compatible with higher percentages of DGME. The Warner Declaration went on to state the inventors chose A/SA over Carbomer because A/SA was a more robust thickener. These arguments were successful in convincing the

patent examiner to withdraw its objections and allow the patent claims drawn to formulations having thickening agents comprised of A/SA.

83. It is clear to me, as it would be to any skilled person in the pharmaceutical arts, the patentee narrowed the scope of the claims, removing any reference to and claiming superiority over Carbomer during the prosecution of the patent. A person of skill in the art would understand formulations comprising 7.5% dapsone, DGME and Carbomer would not be covered by the claims. It is my opinion Almirall is estopped from bringing its doctrine of equivalents argument to encapsulate Taro's Product.

B. Dedication To The Public

84. I understand there is a rule referred to as the "dedication-disclosure rule" or "dedication to the public." I understand this rule applies when an applicant discloses subject matter but does not then claim the subject matter, thus dedicating it to the public. As discussed above, there are multiple Carbomer formulations disclosed as being consistent with the invention. None of these formulations are claimed, as evidenced by Dr. Lane's opinion Taro's Product does not fall within the literal scope of the patent.

85. For example, the compositions in multiple embodiments listed in the '219 patent include Carbomer. In some embodiments, Carbomer is present at a concentration of about 0.7% w/w to about 1.5% w/w. In other embodiments, Carbomer is present at a concentration of about 0.85% w/w to about 1.0% w/w. This disclosure alone, when read in connection with the claims, would lead a POSA to believe Carbomer, in concentrations from .7 w/w to 1.5% w/w or .85% w/w to about 1.0% w/w had been explicitly disclosed by the patentee and not claimed, and therefore the use thereof would not be considered practicing the patent.

86. Specific examples of Carbomer containing embodiments include 19, 20, 21, 48, 49, 50. Further, Example 2/Table 2, Example 4/Table 5, Example 4/Table 6 and Example 6

/Table 8 all explicitly disclose Carbomer in combination with dapsone and are stated to be consistent with the scope of the invention.

87. The '219 patent also makes clear the inventors believed Carbomer formulations to be inferior to those containing A/SA. In Example 1, the patentee specifically differentiates its invention utilizing A/SA to a composition containing Carbopol, claiming a clear difference in the particle size of the dapsone. The Specification notes larger crystals were observed with Carbomer formulations. So, while the examples include Carbomer as an option, it is not claimed and the examples specifically tout the superiority of A/SA over Carbomer in the invention. This comparison, extolling a purported benefit of A/SA over the well-known and previously utilized Carbomer would lead a POSA to understand Carbomer was disclosed by the patentee, not the preferred thickening agent described by the patentees and, not claimed.

88. A POSA reviewing the specification would understand Carbopol 980 was dedicated to the public through the applicant's decision to repeatedly disclose but not claim Carbopol 980. A POSA would have therefore concluded the use of Carbopol 980 (among other PVBs) would be appropriate to use in a topical pharmaceutical formulation and would not be covered by the claims or inventions of the '926 or '219 patents.

89. Additionally, the applicant repeatedly used A/SA and Sepineo interchangeably in the prosecution of the patent, but in the actual claims the patentee claimed A/SA, not Sepineo. While it appears the, based on the label of ACZONE 7.5%, excipients like polysorbate 80, sorbitan monolete and isohexadecane are utilized in Sepineo P 600, the applicant did not claim Sepineo P 600 – it claimed A/SA. Applicants disclosed some of the additional excipients utilized in Taro's ANDA product [redacted] in the Detailed Description and the Examples but neither those excipients nor Sepineo P 600 not appear

anywhere in the claims. [redacted]

C. The Ensnarement Doctrine Bars Almirall's DOE Theory

90. I have been informed that determining whether an equivalent would impermissibly ensnare the prior art is typically resolved through a hypothetical claim analysis. I understand there are two steps to this analysis. The first step is to construct a hypothetical claim that literally covers the accused product. I understand that while the scope of the hypothetical claim may be broader, it may not add any narrowing limitation.

91. In this case, a hypothetical claim for purposes of an ensnarement analysis would expand the claimed PVB amount to cover [redacted] of a PVB and replace A/SA with Carbomer. That claim would read as follows[10]:

> A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about [[2]] [redacted] w/w to about 6% w/w of a polymeric viscosity builder comprising ~~acrylamide/sodium acryloyldimethyl taurate copolymer~~ Carbomer homopolymer type C; and
>
> water;

[10] Insertions appear as underlined text (e.g., insertions) while deletions appear as strikethrough or surrounded by double brackets (e.g., ~~deletions~~ or [[deletions]]).

wherein the topical pharmaceutical composition does not comprise adapalene.

92. Almirall disputes Taro's ANDA Product contains [redacted]

Thus, under Almirall's infringement theory, a hypothetical claim for purposes of an ensnarement analysis would simply replace A/SA with Carbomer. That claim would read as follows:

> A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising ~~acrylamide/sodium acryloyldimethyl taurate copolymer~~ Carbomer homopolymer type C; and
>
> water;
>
> wherein the topical pharmaceutical composition does not comprise adapalene.

93. The second step to an ensnarement analysis is to determine whether the PTO would have found the hypothetical claim patentable over the prior art. If such a hypothetical claim would not have been patentable under either 35 U.S.C. §§ 102 (i.e., anticipation) or 103 (i.e., obviousness), then the patentee has overreached and the accused product does not infringe.

94. I have reviewed the Expert Report of Dr. Panayiotis P. Constantinides, Ph.D. in Support of Defendants' Ensnarement Defense served concurrently herewith ("Constantinides Ensnarement Report"), in which he opines that the hypothetical claims I constructed above (including the dependent claims) would have been obvious to a POSA at the time of the alleged

invention. (Constantinides Ensnarement Report ¶¶ 5-22). I agree with Dr. Constantinides' obviousness analysis and ultimate conclusion.

95. Because the hypothetical claim analysis confirms Almirall's equivalents theory impermissibly ensnares the prior art, Almirall should be barred from asserting Taro's ANDA Product infringes under the doctrine of equivalents.

X. THE USE OF TARO'S PRODUCT WILL NOT INDUCE INFRINGEMENT OF ANY ASSERTED CLAIM OF THE '219 PATENT

96. Dr. Lane offers the opinion use of Taro's Product will induce infringement of independent claim 1 and dependent claims 2, 4 and 5 of the '219 patent. Claim 1 of the '219 patent is the sole independent claim being asserted against Taro. As described below, Claim 1 describes a method of treating a dermatological condition with a described topical pharmaceutical formulation. In the event Taro's Product does not meet each element of the topical pharmaceutical formulation set out in Claim 1, either directly or through the doctrine of equivalents, it is my understanding Taro cannot induce infringement of the '219 patent, irrespective of the labeling described in Taro's ANDA. *See* Lane Report at ¶¶ 50-53. Furthermore, it is my understanding if Taro does not infringe, either directly or indirectly, the only asserted independent claim it also cannot infringe any other claim depending on the independent claim.

97. Claim 1 of the '219 patent is reproduced below:

> 1. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/v dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;

about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide sodium acryloyldimethyl taurate copolymer; and

water

wherein the topical pharmaceutical composition does not comprise adapalene.

98. Dr. Lane separates claim 1 into seven different limitations, the fifth being "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA]." Lane Report at ¶ 67.[11] Taro's Product neither includes "about 2% w/w to about 6% w/w of a polymeric viscosity builder" nor a PVB "comprising [A/SA]."[12] Therefore, Taro's Product when used according to its label does not literally infringe independent claim 1 of the '219 patent. Further, as described in detail below, Taro's Product does not infringe independent claim 1 under the doctrine of equivalents, because the [redacted] Carbomer used in Taro's Product is not equivalent to "about 2% w/w to about 6% w/w of a [PVB] comprising [A/SA]."[13] (As described above, Dr. Lane's DOE arguments are also barred.)

A. Dr. Lane Improperly Interprets the Claims

99. Dr. Lane's entire analysis treats the missing claim element as being Sepineo P 600, instead of A/SA. The '219 patent claims a thickening agent "comprising A/SA." It does not claim a thickening agent consisting of Sepineo P 600. The fact Almirall chose to formulate the Aczone® 7.5% gel product by using a purchased product (one that was created by someone other than Almirall) containing Polysorbate 80, sodium monooleate and isohexadecane in addition to

[11] Throughout my report, when responding to Dr. Lane's infringement claims, unless otherwise noted I respond to the limitation conventions she has chosen. By doing so I am in no way conceding she has properly separated the various elements of the claims in the patent-in-suit.
[12] My opinion focuses on the fact Taro's Product is not a topical pharmaceutical composition described in the Asserted Claims. It is not necessary for me to offer an opinion on whether Taro's proposed labeling would induce others to practice the methods of the Asserted Claims *if* Taro's Product was a topical composition described by the claims. *See* Lane Report at ¶¶ 50-53.
[13] For the same reason, Taro's Product, if sold and used according to its label, does not infringe the Asserted Claims depending, either directly or indirectly, on claim 1, namely claims 2, 4 and 5 of the '219 patent.

A/SA does not convert the claim to one reciting those excipients. Dr. Lane repeatedly states Taro's Product is equivalent to "the claimed polymeric viscosity builder, as embodied by Sepineo P 600", but never once shows the polymeric thickening agent in Taro's product, Carbomer, is equivalent to A/SA.[14]

100. At Section 5(a) of Dr. Lane's report, it is clear her understanding of the claims is incorrect. Dr. Lane begins by listing the ingredients of Sepineo P 600 and arguing the Sepineo P 600 product is "an embodiment" of the claims. The remaining portion of her analysis set out in Section 5 is to show equivalency between Sepineo P 600 and Taro's Product. [redacted] *See* Lane Report at ¶¶ 44, 73 and 86. It is my understanding comparing unclaimed features of an embodiment of a claim to an accused product for the purpose of establishing equivalency is improper as it is not comparing a missing claim feature to a corresponding feature in the accused product.

101. Dr. Lane also appears to be taking the position that all thickening agents pursuant to the claims must result in emulgels. *See* Lane Report at ¶¶ 74, 81-88. As an initial matter, I agree the role of a PVB is to thicken a formulation. Lane Report at ¶ 74. I disagree "the polymeric viscosity builder … determines the type of semisolid that is formed – e.g., an emulsion gel (emulgel)." *Id.* As Dr. Lane herself admits in her report, [redacted] *See* Lane Report ¶ 47.[15] The thickening agent

[14] The closest Dr. Lane comes to comparing the two polymers are the basic observations that both Carbomer and A/SA are polymers that serve to thicken formulations. *See* Lane Report at ¶ 87.

[15] The Aczone® 5% gel also was not an emulgel. That formulation is set out at Table 8 in the '219 patent as a "useful composition." It is not an emulgel and uses Carbomer as the thickening agent at 0.85% w/w.

used in that formulation (as in its final formulation) was Carbomer.[16] As Dr. Lane further concedes, [redacted]

102. Nothing in the claims mandates the topical pharmaceutical formulation need be an emulgel. As exemplified by the Garrett reference that was a basis of the patent examiner's obviousness rejections discussed above, it was well understood in the art in 2012 that a topical formulation could be formulated with dapsone, DGME and Carbomer (as the thickening agent) and that such formulations could optionally be formulated as an emulsion by addition of oil and surfactants. TARO-DG-00065190. This is similarly set out in the '219 patent wherein the inventors state: "Compositions described herein are typically in the form of a gel, an emulsion, a cream, a liquid, a paste, a lotion, a nanoemulsion, a reverse emulsion, or a liposomal cream." '219 patent at Col. 6:53-56. I also disagree with Dr. Lane's surprising statement that the Aczone® 7.5% gel and Taro's Product formulations not included an oil-phase those products would be "simple liquid formulations not suitable for treatment of acne because they would not stay on the skin." Lane Report at ¶ 84. Dr. Lane seems to forget the Aczone® 5% Gel product

[16] It is telling that Dr. Lane's theory appears to be Taro's thickening agent was Carbomer in the first formulation and then Carbomer and the added excipients in the second formulation, all the while conceding the other formulation excipients were not added to thicken Taro's Product, but to create an oil-phase in the product. *See e.g.* Lane Report at Section 5(b)(1). It is worth noting the persons responsible for developing Aczone® 7.5% gel knew Carbomer was the thickening agent in Carbomer formulations. *See e.g.* ALG_ACZ0264306.

[17] I have reviewed the expert declaration of Dr. Klibanov. Dr. Klibanov also appears to concede A/SA in the Aczone® formulation and Carbomer in Taro's Product are the thickening agents in the products. March 1, 2018, Declaration of A. Klibanov, Docket No. 59, at ¶¶ 38 and 43. I agree.

only had an aqueous phase, was deemed suitable for treatment of acne and is currently marketed and sold by Almirall. The formulation is *not* a "simple liquid", but a gel.

103. The problem, inevitably, with Dr. Lane's analysis is she attributes advantages of unclaimed excipients to the missing term "A/SA." Dr. Lane knows the function of Polysorbate 80, sodium monooleate and isohexadecane is creating an emulsion, or emulgel in the formulation. That has nothing to do with the claim element reciting a polymeric thickening agent. Imagine a car company has a patent on a car seat comprising leather and a competitor sells a car seat with vinyl. Now imagine a doctrine of equivalents arguments wherein the patentee seeks to claim equivalence based on the fact its cars have heated seats and the accused product also has heated seats and both are warm in the winter. The fact they both have seat heaters and are warm in the winter would be irrelevant to the claims of the patent. Dr. Lane's argument is no different.

104. In summary, the fact that Almirall purchased a product containing both a polymeric thickening agent and common excipients used to create an emulsion and used that product in its formulation does not transform the missing claim element reciting a thickening agent comprising A/SA into one reciting a thickening agent comprising a polymer and excipients capable of creating an oil-phase in the topical pharmaceutical formulation.[18] The inventors, for whatever reason, chose to claim the polymer A/SA alone and my understanding is they cannot now transform that broad claim into a narrower claim so as to capture Taro's Product.[19] The

[18] It is clear Taro understood A/SA in the Aczone® 7.5% gel was the gelling agent in the product and the other excipients served to create the oil phase. TARO-DG-00000682. Dr. Lane does not disagree.

[19] 3. My understanding is the inventors never tested a formulation with A/SA alone and I have not seen any testing done with Sepineo P 600 at a concentration other than 4% w/w. It appears 4% Sepineo P 600 was chosen because that percentage had previously been approved in the IIG. Warner Dep. 294:22-297:5. The claims are much broader.

claims allow for formulations that are gels and do not contain an oil-phase, as such Dr. Lane is incorrect to attempt to show equivalency of the oil-phase of Taro's Product to the oil-phase of Aczone® 7.5% Gel.

B. Dr. Lane Incorrectly Identifies the Thickening Agent Used in Taro's Product

105. The Court has construed "polymeric viscosity builder" to mean "a polymer or polymer-based thickening agent." *See* Section VIII, *supra*. As explained previously, thickening agents are commonly used in topical pharmaceutical applications. Although not all thickening agents are polymeric, the most common types of polymeric thickeners are acrylamide thickeners. A well-known example of this type thickener is Carbomer Homopolymer Type C, commercially available as Carbopol® 980 from Lubrizol. In this report, for ease of reference I have referred to Carbomer Homopolymer Type C as "Carbomer."

106. Taro's product contains [redacted] Carbomer. *See* Section VI, *supra*. It is the only thickening agent in Taro's Product, which also includes a solubilizer, a preservative, emulsifiers and oil. The fact Carbomer is a thickening agent cannot be argued. *See* Lubrizol, Viscosity of Carbopol Polymers in Aqueous Systems, 2010. Plaintiff's NDA clearly states its own development work included looking at both Carbomer and Sepineo P 600 as thickening agents in developing Aczone® 7.5% Gel. [redacted]

107. Dr. Lane incorrectly identifies other pharmaceutical excipients as being part of Taro's thickening agent so as to arrive at her opinion that Taro's thickening agent is not just Carbomer, but Carbomer in combination [redacted] By combining these other excipients [redacted]

[redacted] Dr. Lane arrives at a "thickening agent" that falls within the concentration range of Claim 1. However, Dr. Lane seems to concede Taro added the Oil-Phase Excipients *not* to act as a "thickening agent", but to create an emulgel that more closely mimicked the reference listed drug.[20] Lane Report at ¶¶ 17-18. Dr. Lane is correct, Taro's addition of the Oil-Phase Excipients function to create an emulsion (it is also correct Taro's product prior to addition of the Oil-Phase Excipients appeared to be an acceptable topical pharmaceutical composition.) Avramoff Dep. 143:17-24 and Ex. 10.[21] That does not transform the thickening agent in Taro's Product from Carbomer to Carbomer plus the Oil-Phase Excipients.

108. In my long career, I have never heard anyone calling Carbomer, oil and surfactants in a formulation a "thickening agent." Dr. Lane has given no justification for the combination other than to say she does so based on her understanding of the ingredients in the Sepineo P600 product used as a thickening agent used in Aczone® 7.5% Gel and its being a "[polymer-based thickening agent] comprising [A/SA]." I do not agree with Dr. Lane's reasoning. A POSA would understand based on the prosecution history that Sepineo P 600 was an example of a polymer-based thickening agent comprising A/SA as recited in the claims. (Moreover, it would have been understood Sepineo P 600 was simply a product marketed as a thickening agent that did not have the drawbacks of more traditional thickening agents like Carbomer. *See e.g.* ALG_ACZ0264309 (explaining selection of Sepineo P 600 was based, in

[20] There is nothing unusual about a pharmaceutical company attempting to match the reference listed drug as closely as possible. Not only does FDA encourage use of the same excipients in the same concentrations, but it is more helpful to patients who may be switching from a brand to generic to be familiar with the form and feel of the medication. It is well documented that patients have become confused when the form of generic pills differ from the brand, especially where patients receive tablets from different manufacturers at different times. [redacted]

[21] Neither formulation contained A/SA, and that is the claim element at issue.

part, on the ease of processing relative to Carbomer).) However, as stated above, the claims are not drawn to Sepineo P600. Instead, they are drawn to any polymer or polymer-based thickening agent comprising A/SA. Given the breadth of the claim, A/SA alone would be a polymer thickening agent pursuant to the claims, a fact Almirall does not appear to dispute. *See* Markman Hearing Transcript at 9:14-21. Furthermore, not a single ingredient other than A/SA in the Sepineo P 600 product is claimed in the patent. The only reference to any of these excipients is in a reference at column 5 wherein it is stated a PVB that is A/SA can *optionally* include other excipients. As such, whether Taro's Product has one or more of these excipients or does not, it has no relevance to any claim limitation.

109. During prosecution, the applicants conceded Carbomer alone was the thickening agent used in other dapsone formulations and distinguished Sepineo P 600 as being a better thickener. The Garrett reference the applicants distinguished during prosecution described Carbomer formulations that additional could include other excipients, like sodium monooleate, mineral oil and other emulsifiers. It is well-known by those skilled in the art that Carbomer is a thickening agent and that oil and emulsifiers in combination create an oil-phase in topical gel products.[22]

110. The Inactive Ingredient Database ("IID") is a database maintained by FDA to identify inactive ingredients used in approved drug products. The IID identifies Carbomer use in many approved topical formulations, including gels and ointments. In each of those cases, based on the concentrations used, I am confident Carbomer is being used as a polymer thickening agent, just as Taro has done. Similarly, the IID identifies a single use of Sepineo P 600 in an

[22] For clarity, in my report I have applied the definition of a person of skill in the art articulated by Dr. Constantinides. Opening Expert Report of Panayiotis P. Constantinides, Sept. 11, 2018, at Section IV. My opinions would not change were I to use the definition offered by Dr. Lane. *See* Lane Report at ¶¶ 32-35.

approved gel product. Based on the concentration it is my full expectation the gel product identified is Aczone® 7.5% Gel.

111. The IID database confirms what any person of ordinary skill in the art would understand, namely that Carbomer *alone* is the polymer thickening agent in Taro's Product and Sepineo P 600 alone is the polymer-based thickening agent in Aczone® 7.5% Gel. Thickening agents are just that, agents. They are polymer or polymer based products used to thicken topical pharmaceutical formulations. There is absolutely no justification in the patent or otherwise to look at other excipients in a formulation and label them a thickening agent. The fact Sepineo P 600 is a commercial product sold to thicken formulations is irrelevant. Almirall's NDA makes absolutely clear it is a single agent added to its formulation, unlike the Taro Product. *See* ALG_ACZ0004101-2.

112. In summary, I fundamentally disagree with Dr. Lane's opinion that the Oil-Phase Excipients in Taro's Product combine with Carbomer to create a polymeric thickening agent. Carbomer serves that function alone. The Oil-Phase Excipients are present purely to create an oil-phase in the gel, *i.e.* to create an emulgel. The claims don't require the topical formulations of the claims be emulgels and the term PVB in the patents doesn't incorporate that requirement, as discussed in detail above.

C. Taro's Product Does Not Literally Meet The Claim Limitations of Claim 1 of the '219 Patent And Therefore Taro Cannot Induce Literal Direct Infringement of Claim 1

113. It is my understanding Almirall is not alleging Taro induces direct literal infringement of claim 1 of the '219 patent, and Dr. Lane does not offer an opinion on direct literal infringement in her report.[23] Nevertheless, for completeness I note Taro's Product does

[23] *See also*, Nov. 16, 2017, Initial Infringement Contentions and Sept. 11, 2018, Final Infringement Contentions, wherein Almirall relies solely upon the doctrine of equivalents.

not meet each element of the topical pharmaceutical composition described in claim 1. Specifically, Taro's Product does not contain A/SA in any amount. Therefore, it is my opinion Taro will not induce direct literal infringement of claim 1 of the '219 patent irrespective of the labeling indicated in Taro's ANDA.

D. Taro's Product Does Not Infringe Claim 1 of the '219 Patent Under the Doctrine of Equivalents

114. As has been explained in detail above, Dr. Lane claims Carbomer and the Oil-Phase Excipients in Taro's Product are equivalent to Sepineo P 600. Dr. Lane's framing of the analysis is incorrect, both because it is inconsistent with the express language of Claim 1 and improperly identifies the thickening agent in Taro's Product. Dr. Lane's argument is also barred pursuant to the doctrines of prosecution history estoppel, commitment to the public and ensnarement. As discussed below, the thickening agent and concentrations in Taro's Product are not equivalent to "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA]."

1. One Percent of a PVB is Not Equivalent to Two to Six Percent of a PVB

115. The claims require "about 2% w/w to about 6% w/w of a polymeric viscosity builder." Taro's Product contains [redacted] w/w of Carbomer, the sole thickening agent in the formulation. The difference between [redacted] and about 2% w/w is not an insubstantial difference. The amount of thickening agent included in a product impact viscosity, drug dissolution, bioavailability and other clinical drug attributes. The '219 patent includes numerous examples of various thickening agents being used across a range of concentrations, demonstrating small incremental differences in the amount of a thickening agent matter. This is consistent with my own experience. Further, I do not believe a formulation containing Carbomer at about 6% w/w would be viable due to the potential for Carbomer to precipitate out of the formulation.

116. During prosecution, the applicants conceded the difference between at least 0.85% w/w and about 2% w/w and 6% w/w was significant. As explained, the patent office rejected the proposed claims in the Divisional Application as being obvious over Garrett, which taught the use of Carbomer as a thickening agent. *See* Section XX, *supra.* In response, applicants argued:

> Garrett teaches that a preferred composition comprises … about 0.85% w/w/ carbopol 980 is used as a thickening agent. … The new formulation of the instant claims does not include carbomer such as Carbopol®, but instead utilizes as [A/SA] … and *at a much higher concentration* (about 2% to about 6% w/w) as compared to what Garrett teaches for its thickening agent.

ALG_ACZ0000284 (Emphasis added). This argument is consistent with my own opinion, namely that the difference between [redacted] and "about 2% w/w to 6% w/w" of a polymer or polymer-based thickening agent is not insubstantial, and therefore not equivalent.

117. Taro's Product does not have an equivalent concentration of a thickening agent to the claimed ranges, and therefore does not meet all limitations of the '219 patent, either literally or under the doctrine of equivalents. As such, Taro's Product, if sold pursuant to its labeling cannot infringe Claim 1 of the '219 patent.

a. Carbomer Is Not Equivalent to A/SA or Sepineo P 600

118. Carbomer is a cross-linked polyacrylic acid resin. To dissolve Carbomer in water a neutralizing agent, such as a sodium hydroxide solution, must be added to adjust pH. Neutralizing a Carbomer solution above pH 5 resulted in ionization of the carboxylic acid groups in the polymers, the creation of ion-dipole interactions within the dissolution medium and dissolution of the polymer.

119. Mixing Carbomer must be carefully controlled to avoid clumping and/or precipitation of the polymer. Once the Carbomer is reconstituted, it is carefully added to the remaining excipients. At each step, the temperature, rate of addition of the polymer and mixing

rate must be monitored and controlled. An example of this manufacturing process is described above, at Section XX describing the manufacturing of Taro's Product.

120. A/SA is not insubstantially different from Carbomer. As described above, A/SA has a completely different chemical structure compared to Carbomer. Additionally, A/SA is a "copolymer", meaning it consist of two different polymers cross-linked. (Carbomer is a single polymer.) The fact A/SA is a copolymer is important because the ratio of one polymer to other can change the characteristics of the product. The inventors controlled this aspect by purchasing the Sepineo P 600 product from Seppic. At the time of the invention, and now, Seppic marketed the Sepineo P 600 product as being simpler than other polymeric thickening agents because (1) it was simpler to mix; and (2) did not require neutralization. (Seppic Sepineo™ P 600 Brochure (2008) (ALG_ACZ0375156-57)). These advantages were similarly important to Almirall, as stated in its NDA: "Sepineo P 600 was chosen as a gelling agent for … ease of processing relative to Carbopol 980." ALG_ACZ0264309.

121. The difference in manufacturing between Taro's Product and Aczone® 7.5% Gel is stark. Unlike Taro's process, Aczone® 7.5% Gel is manufactured by combining dapsone, methylparaben and DGME, mixing Sepineo P600 with water and then combining the two and mixing. *See* ALG_ACZ0004101-103. The differences between these two processes are not insubstantial. It is clear Carbomer is neither performing the same function as A/SA (or Sepineo P 600) nor is it performing its function in the same way.

122. The Warner Declaration submitted in connection with prosecution of both the Parent Application and the Divisional Application unequivocally stated the A/SA copolymer emulsion was selected over Carbomer because Carbomer was seen to precipitate at higher DGME concentrations and it was concluded the A/SA polymer was more robust.

ALG_ACZ_0000291-292. This is repeated in the NDA describing thickener selection. *See* ALG_ACZ-264306. Dr. Warner also explained in his deposition why he believed, and continues to believe presumably, Carbomer is not as robust a thickening agent. Warner Dep, 76:6-77:16 and 114:15-119:20.

123. Dr. Lane does not address how, if at all, Carbomer in Taro's Product is as "robust" as either A/SA or Sepineo P 600. To the extent it is more "robust", clearly that would constitute a solution to problem the inventors were not able to solve. In any event, it demonstrates an additional reason why the use of Carbomer in Taro's Product is not an insubstantial difference from the use of a thickening agent comprising A/SA. (Certainly, the more difficult manufacturing associated with the use of Carbopol relative to Sepineo P 600 remains.)

124. The only evidence Dr. Lane purports to offer supporting an argument that Carbomer and A/SA are similar is to state: "[Carbomer] and A/SA are both polymers that act in the same way to create a three-dimensional gel-like structure." Lane Report at ¶ 87. She goes on to state both "swell to increase the viscosity of the formulation in the same way." *Id.* Her arguments are not convincing for a number of reasons. First, if the fact both are polymers creating a three-dimensional gel like structure is the standard, it makes little sense the inventors claimed A/SA, argued A/SA was superior to the prior art and received a patent covering the use of A/SA as the "sole thickening agent." *See*, TARO-DG-00064186. Furthermore, although both act to increase viscosity, as discussed above, they do not do so in the same way. Carbomer is pH dependent whereas the A/SA product used by Almirall is not. As such, Dr. Lane's brief attempt to argue equivalence of Carbomer to A/SA is not convincing and I disagree with her opinion.

125. In short, the inventors were issued a patent based on the argument their PVB was different from Carbomer and that Carbomer was unexpectedly not as robust. Both during prosecution of the Divisional Application and in the NDA, the benefits of A/SA (and Sepineo P 600) over Carbopol were repeatedly argued. I see nothing in Taro's Product, formulation or manufacturing suggesting Taro somehow overcame these differences. Carbomer is not insubstantially different from a PVB comprising A/SA, it does not function in the same way and does not render the same results.

b. The Comparisons of Clinical and Non-Clinical Attributes of Aczone® 7.5% Gel and Taro's Product Do Not Evidence an Insubstantial Difference Between Taro's Thickening Agent and A/SA or Sepineo P 600

126. Dr. Lane seeks to show equivalency between Taro's thickening agent and Sepineo P 600 through clinical and non-clinical comparisons between Aczone® 7.5% Gel and Taro's Product characteristics. These comparisons are flawed based on Dr. Lane's incorrect identification of the thickening agent in Taro's Product. Furthermore, the comparisons she makes draw no connection between Carbomer on the one hand and A/SA on the other. Because she never demonstrates any attribute is attributable to a claimed feature in the '219 patent, *i.e.* A/SA, her comparisons are of little value.

127. The first comparison Dr. Lane seeks to make, at Section 5(b)(2) of her report, relates to the rheological profiles of the two products. Many of the properties tested are impacted by Taro's thickening agent, Carbomer (i.e. the viscosity and shear stress). However, it is not surprising two different products can have similar rheological profiles, even achieving them in different ways. Based on my review of Almirall's development documents and the deposition of Kevin Warner, the goals in formulating a 7.5% dapsone product at Almirall was that the product would have similar characteristics to the Aczone® 5% Product.

128. However, the claims do not require a specific rheological profile in any event. A person of skill in the art would not know the rheological profile of *any* of the tens of embodiments disclosed in the patent. Furthermore, the patent explicitly states the compositions can be modified in different ways to achieve different composition characteristics. A skilled person would have known the inventors were not claiming any specific rheological profile and therefore Dr. Lane's reliance on this information is misplaced.

129. The same is true of other data Dr. Lane relies on, including solubility, particle size, and release rates. The '219 patent includes absolutely no disclosure, not in the patent itself and none was submitted during prosecution, to lead a skilled artisan to believe specific characteristics of solubility, particle size and release rates were being claimed as a benefit of the invention. All of these characteristics can be influenced in innumerable ways by the addition and removal of excipients and also by controlling the concentrations of excipients. The claims of the '219 patent simply do not speak to any of these results. Furthermore, Dr. Lane has made no showing that specific characteristics of Aczone® 7.5% Gel are attributable to the only thickening agent claimed, namely A/SA. In fact, it is clear from her report she attributes many, if not all, the product characteristics to unclaimed elements of the Aczone® product. In short, any similarity of characteristics between Taro's and Almirall's products can be achieved in any number of ways that have nothing to do with the '219 patent claims and, specifically, A/SA.

130. An additional reason Dr. Lane's comparisons are unconvincing relates to studies Almirall performed with Carbomer formulations containing Polysorbate 80. It my understanding, based on information I have reviewed, Almirall studies the impact of Polysorbate 80 in Carbomer formulations to determine the impact on particle size. The results were interpreted by Almirall to mean addition of Polysorbate 80 did not result in a formulation with particle size seen

with the Sepineo P 600 formulations tested. (The comparisons are problematic in that too many of the excipients and concentrations differ between formulations making it near impossible to determine how characteristics of the formulations are impacted by the multiple formulation factors). [redacted] This further supports my opinion Taro's thickening agent is not equivalent to a PVB comprising A/SA.

131. The '219 patent, in any event, is not convincing in its attempt to evidence particle size differences between Carbomer versus A/SA formulations. Figure 2 is not labeled to identify A1 through A4. However, it is my understanding A1 and A4 are Carbomer formulations and A3 and A2 are A/SA formulations. (A4 appears to be the formulation containing 1.25% Carbomer and .2% Polysorbate 80.) Looking at the images, it appears the particle size of one of the Carbomer formulations, namely A1, may be smaller than one of the A/SA formulations, namely A3. As such, I do not find particle size comparisons to the product convincing as they have not been demonstrated to be attributable to the Carbomer and/or A/SA.

E. Taro's Does Not Infringe Dependent Claims 2, 4 and 5 of the '219 Patent

132. The only independent claim asserted against Taro is Claim 1. As explained in detail above, it is my opinion Taro's Product does not meet all the claim limitations of the only independent claim, either literally or under the doctrine of equivalents. As such, it would be impossible for Taro's Product, if sold according to its label, to induce infringement of any claim depending on Claim 1. For this reason, it is my opinion Taro does not infringe the asserted dependent claims 2, 4 and 5.

XI. CONCLUSION

133. In my opinion, Taro's Product, if sold, would not infringe claims 1, 2, 4 or 5 of the '219 patent.

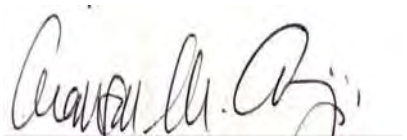
X. RESERVATION OF RIGHTS

134. I have based my opinions and analysis on documents and information available to me at the time I signed this report. If and when any new evidence arises, I reserve the right to supplement or modify my opinions to reflect that evidence.

135. In the event Plaintiff submits any reply to this expert report, I reserve the right to respond to any issues raised by such a reply.

136. If called to testify, my testimony may include an explanation of the scientific principles that underlie the opinions expressed in this report.

137. I reserve the right to make and use demonstratives to help explain my opinions.



November 6th, 2018 Mansoor M. Amiji, Ph.D., R.Ph.

Defendant's Opposition to Plaintiff's Motion *in Limine* No. 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED **HIGHLY CONFIDENTIAL – FILED UNDER SEAL OUTSIDE COUNSEL ONLY – SUBJECT TO PROTECTIVE ORDER**

EXHIBIT __

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE TESTIMONY FROM DR. AMIJI REGARDING ORIGINAL CLAIM 1 OF U.S. PATENT APPLICATION NO. 14/082,955

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: January 7, 2019

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Almirall seeks to preclude testimony from Taro's expert Dr. Mansoor Amiji regarding the amendment to original claim 1 of Application No. 14/082,955 ("'955 application") in support of Taro's defense that Almirall's equivalents theory is barred by the doctrine of prosecution history estoppel. According to Almirall, "Dr. Amiji's report asserted only estoppel arising from modification to claim 14," and accordingly, "he should not be allowed to [rely on the amendment to original claim 1] at trial." (Motion at 2). Almirall's Motion lacks merit and should be denied.

As Almirall itself admits, Dr. Amiji included in his report a discussion of the prosecution history of the '955 application, "*including events related to original claim 1*." (Motion at 1 (emphasis added)). Specifically, in discussing the prosecution history of the '955 application, Dr. Amiji noted:

> 65. In response to the March Office Action, on May 20, 2014, the applicant submitted amended claims limiting, among other things, the polymeric viscosity builder in claim 1 to A/SA and cancelling multiple claims, including claim 14. TARO-DG-00064079.

(Ex. 1, Excerpt of Amiji Rebuttal Rpt. ¶ 65 (emphasis added)). Dr. Amiji further noted:

> 66. The applicant went on to argue against the prior rejections and specifically noted the "unexpected advantages" of the claimed composition in providing improved aesthetics and noted the particle size improvement using A/SA in comparison to Carbomer. TARO-DG-00064088-64089. The applicant specifically stated and included in bold "the composition comprising [A/SA] thickener has unexpected advantages over a composition where the thickener/viscosity builder in Carbomer homopolymer type C." TARO-DG-00064089.

(*Id.* ¶ 66 (emphasis added)). Therefore, Dr. Amiji *explicitly* indicated in his report that: (i) Almirall

amended original claim 1 of the '955 application to narrow the literal scope of the claimed polymeric viscosity builder, limiting it to A/SA, and (ii) the narrowing amendment was made to overcome a patentability rejection over prior art compositions containing Carbomer.

Almirall's sole argument appears to be that Dr. Amiji did not reach the ultimate legal conclusion that the narrowing amendment to original claim 1 created a presumption of prosecution history estoppel. *See, e,g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739-40 (2002) (holding that any *narrowing amendment* made to *overcome a patentability rejection* creates a *presumption* of prosecution history estoppel as to the added limitation). But an expert's opinion on a *legal conclusion* "is neither necessary nor controlling." *See High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1313 (Fed. Cir. 2013). Regardless, this Court has permitted expert trial testimony that is a reasonable elaboration of the expert's report. *Lab. Skin Care, Inc. v. Ltd. Brands, Inc.*, 2011 WL 4005444, at *7 (D. Del. Sept. 8, 2011), *aff'd*, 478 F. App'x 672 (Fed. Cir. 2012); *see also Forest Labs., Inc. v. Ivax Pharm., Inc.*, 237 F.R.D. 106, 113 (D. Del. 2006) (recognizing experts should be "permitted a certain degree of latitude," may "explain the opinions and conclusions" in their reports, and may provide "reasonable explanations"). Here, even if the Court were to find Dr. Amiji did not expressly rely on the amendment to claim 1 in reaching his conclusion that Almirall's equivalents theory is barred by prosecution history estoppel, his anticipated testimony regarding the narrowing amendment to original claim 1 would be a permissible elaboration on the opinions set out in his expert report.

Moreover, in determining whether an expert's testimony has exceeded the scope of his or her report, "the Court examines whether the objecting party had *sufficient notice* of the testimony based upon the contents of the report and the elaborations made during expert discovery and deposition." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 585 F. Supp. 2d 568,

581 (D. Del. 2008) (emphasis added). Here, there can be no dispute that Almirall had sufficient notice of Dr. Amiji's anticipated testimony regarding the amendment to original claim 1 and its presumptive impact on Almirall's doctrine of equivalents theory. (*See* Ex. 1, Excerpt of Amiji Rebuttal Rpt. ¶¶ 65-66; *see also* D.I. 22 at 4-5; Ex. 2, Taro's First Suppl. Resp. to Rog. No. 4).

Finally, Almirall argues that it "would be prejudiced by presentation of [Dr. Amiji's] opinion as to claim 1" at trial. (Motion at 2). According to Almirall, "[c]ure of this prejudice would require supplemental reports and depositions, which would not be possible without disrupting the approaching trial date." (*Id.*) But Almirall's expert Dr. Majella Lane had an opportunity to attempt to rebut the presumption of prosecution history estoppel in her Reply Report by, *inter alia*, demonstrating that the alleged equivalent was unforeseeable at the time of the amendment (it was not)[1] or that it was only tangentially related to the amendment (it was not)[2]. *See Rhodia Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1382 (Fed. Cir. 2005). Despite this opportunity, Dr. Lane ignored the prosecution history of the '955 application entirely and limited her analysis to the '219 patent's prosecution history. Almirall also had an opportunity to seek deposition testimony from Dr. Amiji regarding the amendment but chose not to do so. Almirall's failure to address the amendment in its expert reports or at deposition should not preclude Taro from eliciting expert opinion testimony from Dr. Amiji regarding the same.

For at least the foregoing reasons, the Court should deny Almirall's Motion *in Limine* and allow expert testimony from Dr. Amiji regarding the amendment to original claim 1 of the '955 application in support of Taro's prosecution history estoppel defense at trial.

---

[1] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1382 (Fed. Cir. 2007) (equivalent is foreseeable if skilled artisan "would have known that the alternative existed in the field of art as defined by the original claim scope").

[2] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) ("amendment made to avoid prior art that contains the equivalent in question is not tangential.").

Respectfully submitted,

/s/ John C. Phillips, Jr.
John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: January 7, 2019

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED

[CONFIDENTIAL]

REBUTTAL EXPERT REPORT OF MANSOOR M. AMIJI, PH.D, R.PH.

59. If asked, I am prepared to talk about the '219 patent, including the Background, Summary and Detailed Description. I am also prepared to discuss how a person of ordinary skill in the art would have understood the disclosure of the '219 patent alone and in view of the prosecution history (described in detail below). Finally, I am prepared to talk about the claims and claim scope.

B. The Parent Application No. 14/082,955

60. It is my understanding the application that resulted in the '219 patent was a division of Application No. 14/082,955. I refer to Application No. 14/082,955 as the "Parent Application" as I understand that to be the proper designation to indicate its relation to the application that resulted in the '219 patent (the "Divisional Application"). The Parent Application issued as U.S. Patent No. 9,161,926 ("the '926 Patent"). It is my understanding the '926 Patent has not been asserted against Taro. Nevertheless, I have been informed the prosecution of the Parent Application can be relevant to an understanding of the subject matter of a divisional application and the claims of a patent issuing from such a divisional application. For this reason, I have reviewed the prosecution history of the '926 patent and, if asked, am prepared to describe the prosecution history for the Court.

61. The Parent Application was submitted with an original twenty (20) proposed claims. The original proposed claim 1 stated the following:

> A composition comprising dapsone, a first solubilizing agent which is diethylene glycol monoethyl ether, optionally at least one second solubilizing agent, a polymeric viscosity building, and water, wherein the dapsone is preset in the composition at a concentration of about 3% w/w to about 10% w/w. TARO-DG-00063859

The original proposed dependent claim 10 claimed:

> The composition of claim 1, wherein the polymeric viscosity building comprising an acrylamide/sodium acryloyldimethyl taurate copolymer. *Id*.

And dependent claim 11 and 12 claim the PVB present at a concentration of about 2% w/w to about 6% w/w and a concentration of about 4% w/w respectively. *Id.* These claims are consistent with embodiments in the specification of the '219 patent, as previously discussed.

62. The original proposed dependent claim 14 claims:

> The composition of claim 1, further comprising Carbomer interpolymer type A, carbomer interpolymer type B or Carbomer Homopolymer Type C. TARO-DG-00063860.

Claim 14 is a claim covering a composition with 7.5% dapsone, 30% DGME, 1% Carbomer and water. It would also cover the same composition additionally [redacted] That claim was withdrawn based on an examiner's patentability rejection.

63. In a January 14, 2014 Office Action, the patent examiner noted the applicants claimed two separate inventions (composition and method) and required the applicant to choose which invention the applicant wished to have examined. TARO-DG-00063901-63902. Further, the applicant was required to make an election of a single disclosed species for, among other things, claim 14. TARO-DG-00063902-63904. In a February 20, 2014, Response to the Restriction Requirement and Election of Species, the applicant elected invention 1 (the composition). Further, the applicant elected carbomer homopolymer type C as the carbomer polymer listed in Claim 14. TARO-DG-00063911.

64. In the next Office Action dated March 18, 2014, the Examiner issued claim rejections as, among other references, being anticipated by both Lathrop and Ahluwalia. TARO-DG-00063918-63923. I understand Lathrop teaches topical emulsive compositions of dapsone, and claims a composition containing both dapsone and Carbomer. TARO-DG-00063918-919. Ahluwalia teaches topical compositions with dapsone and adapalene for the treatment of acne.

Ahluwalia teaches exemplary compositions such as 5% w/w dapsone; .1% w/w or .3% w/w adapalene; 25% w/w DGME; 15% w/w propylene glycol; .01% w/w EDTA; .75% w/w Carbopol 980; sodium hydroxide and purified water. TARO-DG-00063919. The Examiner cited Lubrizol advertising literature for the fact Carbopol 980 is a polymeric thickener synonymous with carbomer homopolymer type C. TARO-DG-00063919. The Examiner noted Ahluwalia taught ranges of dapsone, DGME and a polymeric viscosity builder and concluded the ranges clearly encompass the ranges being claimed by the applicant. TARO-DG-00063921-922.

65. In response to the March Office Action, on May 20, 2014, the applicant submitted amended claims limiting, among other things, the polymeric viscosity builder in claim 1 to A/SA and cancelling multiple claims, including claim 14. TARO-DG-00064079.

66. The applicant went on to argue against the prior rejections and specifically noted the "unexpected advantages" of the claimed composition in providing improved aesthetics and noted the particle size improvement using A/SA in comparison to Carbomer. TARO-DG-00064088-64089. The applicant specifically stated and included in bold "the composition comprising [A/SA] thickener has unexpected advantages over a composition where the thickener/viscosity builder in Carbomer homopolymer type C." TARO-DG-00064089.

67. On June 5, 2014, the Examiner again rejected multiple claims as being obvious and unpatentable over the prior art. TARO-DG-00064097-64102. The Examiner further discussed the applicant's claim of "unexpected advantages." The Examiner noted the tested formulations cited by the applicant were not commensurate in scope with the claims presented, and further found "a showing of unexpected results must necessarily be accompanied by a clear indication of what the skilled artisan would have expected, as well as a clear showing of how the claimed invention exceed such expectation so as to provide properties or results that were

unexpected, unobvious and of statistical and practical significance" which the applicant had not done. TARO-DG-00064105-64108.

68. In response to another rejection, on February 2, 2015, the applicant submitted a declaration from Kevin S. Warner, one of the co-inventors of the patent application stating: "Based on the unexpected observation of Carbopol 980 incompatibility with 40% DGME, the thickener was changed from Carbopol 980 to Sepineo P 600 [i.e., A/SA] to mitigate the risk of polymer aggregation in DGME containing formulations." ALG-ACZ0000292. He further stated: [We] selected Sepineo P 600 as the gelling agent for our dapsone 7.5% gel formulation. We made this selection due to Sepineo P 600's compatibility with concentrations of DGME greater than 25% and its improvement in dapsone particle size relative to Carbopol 980." *Id*. This same declaration was submitted again in support of the '219 patent application.

69. After the submission of the declaration the applicant further amended and canceled certain claims and responded to the latest rejection. TARO-DG-00064182-64184. In focusing on unexpected results, the applicant reiterated the "unexpected results" discussed by the co-inventor in his declaration. TARO-DG-00064188. They noted undesirable polymer aggregates during formulations studies (using Carbomer) which lead to the utilization of A/SA. TARO-DG-00064188-64189. The applicant went on to state Sepineo P 600 allowed for higher concentrations of DGME, which were found to be incompatible with Carbomer and that Sepineo P 600 formulations provided smaller particle size as compared to Carbomer formulations, which is why Sepineo P 600 was selected as the gelling agent. TARO-DG-00064189. It was emphasized this result was "entirely unexpected and could not have been predicted" based on the 5% dapsone formulation, which used Carbomer or the prior art formulation. *Id*.

70. After these repeated references to the unexpected superiority of A/SA over the well-known and previously utilized Carbopol 980, the Examiner issued a notice of allowability. TARO-DG-00064344.

C. Prosecution of the '219 Patent

71. I have reviewed the prosecution history of the '219 patent and, if asked, I am prepared to describe the prosecution history for the Court. As explained below, and throughout my report, the applicants' responses and representations made to the patent examiner, both about the basic and novel characteristics of the invention being claimed in the application that led to the '219 patent and the nature of the prior art, are relevant to my non-infringement analysis. As explained in detail below, a full review of the prosecution history makes clear the applicants were focused on the novelty of using A/SA as the thickening agent and expressly disclaimed Carbomer formulations.

72. Originally, all of the claims were rejected as unpatentable over Garrett in view of Hani, a rejection nearly identical to those made during prosecution of the Parent Application. (The claims were also rejected on the ground on nonstatutory double patenting, as being unpatentable over claims 1-6 of the '926 patent.). ALG_ACZ0000052-72. By way of amendment and response to the office action dated February 18, 2016, the applicants argued the amount of dapsone, the use of Sepineo P 600 as the sole thickening agent in a topical dermatological formulation comprising dapsone and the specific amount of Sepineo P 600 recited in the claims made the claims distinct from the prior art.[8] ALG_ACZ0000284. Applicants claimed the combination of Sepineo P 600 with dapsone was not suggested in either Garrett or Hani:

[8] This argument is interesting in that the applicant did not claim Sepineo P 600, but a PVB comprising A/SA. As previously mentioned, the claim is broad enough to cover the use of A/SA *alone* as the PVB.

XI. CONCLUSION

133. In my opinion, Taro's Product, if sold, would not infringe claims 1, 2, 4 or 5 of the '219 patent.

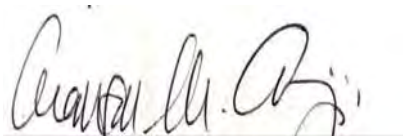
X. RESERVATION OF RIGHTS

134. I have based my opinions and analysis on documents and information available to me at the time I signed this report. If and when any new evidence arises, I reserve the right to supplement or modify my opinions to reflect that evidence.

135. In the event Plaintiff submits any reply to this expert report, I reserve the right to respond to any issues raised by such a reply.

136. If called to testify, my testimony may include an explanation of the scientific principles that underlie the opinions expressed in this report.

137. I reserve the right to make and use demonstratives to help explain my opinions.



November 6th, 2018 Mansoor M. Amiji, Ph.D., R.Ph.

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (VAC) (SRF) CONSOLIDATED

DEFENDANTS' FIRST SUPPLEMENTAL
RESPONSE TO PLAINTIFF'S INTERROGATORY NO. 4

Defendants, Taro Pharmaceutical Industries Ltd. ("TPIL") and Taro Pharmaceuticals, Inc. ("TPI"), (collectively "Taro") hereby supplement their answers, objections and responses to Plaintiff Allergan, Inc.'s ("Plaintiff" or "Allergan") Interrogatory No. 4 pursuant to Federal Rules of Civil Procedure 26 and 33. Taro hereby incorporates by reference the General Objections set forth in its Objections and Responses to Plaintiff's First Set of Interrogatories, served on October 23, 2017.

OBJECTIONS AND RESPONSE

INTERROGATORY NO. 1

If You contend that You do not infringe any Asserted Claim, separately as to each Asserted Claim that You contend that You do not infringe either literally or under the doctrine of equivalents, identify and describe all factual and legal bases for Your contention, including identifying every limitation of the Asserted Claim purportedly not met by the Taro ANDA Product, describing why You contend the Taro ANDA Product does not meet that limitation, describing why that limitation is not met under the doctrine of equivalents, identifying all documents relating to each such contention, and identifying the individuals at Taro with knowledge of the facts supporting those contentions.

RESPONSE TO INTERROGATORY NO. 1

An answer to this contention interrogatory is not required at this time because the Court's Scheduling Order states "contention interrogatories, if filed, shall first be addressed by the party with the burden of proof no later than the date established for completion of document production, with responsive answers due within thirty (30) days thereof." Allergan has the burden of proof regarding infringement and Taro has not yet received Allergan's infringement contentions. Provided Allergan serves its infringement contentions as required by the Court's Scheduling Order, Taro will respond to Allergan's infringement contentions accordingly. Taro further objects to this Interrogatory to the extent it seeks information protected by the attorney-client or work product privilege or is the subject of expert discovery. Taro will provide expert discovery in accordance with the Court's Scheduling Order. Taro further objects to this interrogatory as containing multiple discrete subparts, each of which is a separate interrogatory for the purposes of Fed. R. Civ. P. 33.

Subject to and without waiving the foregoing objections or General Objections, Taro directs Allergan to Taro's Motion for Leave to File Summary Judgment (D.I. 24 and corresponding exhibits), Taro's April 17, 2017 Notice Letter, Taro's July 7, 2017 duplicate notice letter, and Taro's ANDA No. 210191, which was produced to Allergan on August 1, 2017, pursuant to D. Del. Local Rule 26.2 *See* Fed. R. Civ. P. 33(d)(1) ("Where the answer to an interrogatory may be derived or ascertained from the business records of the party upon whom the interrogatory has been served . . . and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained."). Taro expressly reserves the right to supplement its response to this Interrogatory after Taro has received and reviewed Allergan's infringement contentions.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 4:

Taro incorporates its October 23, 2017 objections to Interrogatory No. 4 as if fully set forth herein. Taro further objects to the extent a response depends on the construction of claim terms that have yet to be construed by the Court. Taro objects to the extent a response requires information that is the subject of further discovery. Taro reserves the right to amend or supplement this response as additional relevant information is revealed through further discovery.

Taro further objects to responding to this contention interrogatory at this time because Taro has not yet received Allergan's final infringement contentions. Provided Allergan serves its final infringement contentions as required by the Court's Scheduling Order, Taro will respond to Allergan's infringement contentions accordingly. Taro objects to this contention interrogatory as premature to the extent it requests Taro "identify and describe all factual and legal bases for [its] contention" and "identify[] all documents relating to each such contention." Discovery is ongoing, and Taro will supplement its response in accordance with the Federal Rules and Local Rules at an appropriate time.

Taro further objects to this contention interrogatory as overly broad, unduly burdensome, not proportional to the needs of this case, and requesting information protected by the attorney-client privilege and/or work-product doctrine as it requires "all" factual and legal bases and the identity of "all" documents relating to each contention.

Subject to and without waiving the foregoing objections or General Objections, Taro supplements its response as follows:

Plaintiff's requests are premature because at least two claim terms are currently in dispute. Until the parties resolve the dispute and/or the Court rules on claim construction, Taro cannot fully respond to Plaintiff's requests.

However, Taro will not infringe any claim of the '219 patent at least because all of the asserted claims 1-8 are invalid under at least 35 U.S.C. § 103. *See* Taro's Initial Invalidity Contentions and accompanying document production (Dec. 15, 2017), incorporated by reference as if fully set forth herein. Therefore, Taro will not infringe any claim of the '219 patent. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573 (Fed. Cir. 1983).

Taro will not infringe any claim of the '219 patent at least because Taro's ANDA Product will not contain any amount of a "polymeric viscosity builder ["PVB"] comprising acrylamide/sodium acryloyldimethyl taurate copolymer ["A/SA"]." *See, e.g.*, TARO-DG-00000140; *see also* Plaintiff's Initial Infringement Contentions at 2 (Nov. 16, 2017) (Plaintiff admitting "Taro does not list acrylamide/sodium acryloyldimethyl taurate . . . as an ingredient of its ANDA Product") (internal citation omitted). Therefore, Taro will not infringe any claim of the '219 patent.

Taro denies Plaintiff's contention that Taro's ANDA Product contains an equivalent to a "polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer." In support, Taro incorporates D.I. 22 (and corresponding redacted D.I. 24) as if fully set forth herein. Taro further states that Plaintiff publically dedicated the use of Carbomer Homopolymer Type C in topical dapsone formulations by disclosing it in the prosecution history and the specification while declining to claim it. *See, e.g.*, the '219 patent at Example 1, Table 1. Plaintiff is also estopped from claiming any PVB other than one containing A/SA because (1) the '219 patent applicants narrowed their claims during prosecution to require A/SA and (2) argued

A/SA was superior to Carbopol 980. *See, e.g.*, the U.S. Patent Application 14/885,805, Feb. 18, 2016 Response, Warner Decl., at 3; *id.*, Feb. 18, 2016 Response at 8; U.S. Patent Application 14/082,955, May 20, 2014 Response at 2, 10-12. Therefore, Taro will not infringe any claim of the '219 patent.

Plaintiff's statements that Carbomer Homopolymer Type C [redacted] Plaintiff has not provided specific evidence or testing as to why particular unidentified combinations of excipients from Taro's ANDA Product perform substantially the same function, in substantially the same way, to achieve substantially the same result and/or are insubstantially different from a PVB comprising A/SA.

Citations to Taro's ANDA are insufficient bases to prove that any excipient, alone or in combination with other excipients, is equivalent to the claimed PVB comprising A/SA. Plaintiff's contentions focus on alleged interchangeability of Taro's excipients to the unclaimed product Sepineo, rather than the functionality of the claimed PVB specifically comprising A/SA. Plaintiff also circumvents the importance of A/SA by focusing on unclaimed elements, and therefore fails to provide any basis that Taro's excipients perform the same function, the same way, to achieve the same result as the claimed A/SA. In fact, Plaintiff cannot do so, as it previously averred to the PTO during prosecution of the '219 patent that a PVB specifically comprising A/SA performs a fundamentally different function from Carbomer Homopolymer Type C. *See, e.g.*, ALG_ACZ0000284-286. Therefore, Plaintiff's requests are premature at least until Plaintiff provides further foundation.

Individuals with knowledge of the facts supporting these responses are identified in Taro's Initial Disclosures made pursuant to Fed. R. Civ. P. 26(a)(1), incorporated by reference as if fully set forth herein.

Taro expressly reserves the right to supplement its response to this interrogatory after Taro has received and reviewed Allergan's final infringement contentions, conducted further discovery, and the Court makes its ruling on claim construction.

DATED: January 26, 2018

PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL, P.A.

/s/ David A. Bilson

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants

Of Counsel:
Stephen P. Benson
Matthew M. Holub
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe St.
Chicago, IL 60661
(312) 902-5200
stephen.benson@kattenlaw.com
matthew.holub@kattenlaw.com
kimberly.beis@kattenlaw.com

CERTIFICATE OF SERVICE

I, David A. Bilson, Esquire, hereby certify that on January 26, 2018, a copy of **DEFENDANTS' FIRST SUPPLEMENTAL RESPONSE TO PLAINTIFF'S INTERROGATORY NO. 4** was caused to be served upon the following counsel via electronic means:

Jack B. Blumenfeld
Maryellen Noreika
Morris, Nichols, Arsht & Tunnell LLP
1201 N. Market Street
Wilmington, DE 19899
jblumenfeld@mnat.com
mnoreika@mnat.com

Jeffrey B. Elikan
Chanson Chang
Jihong Lou
Michelle L. Wallace
Erica N. Andersen
Covington & Burling LLP
One City Center
850 Tenth Street, N.W.
Washington, DC 20001
jelikan@cov.com
cchang@cov.com
jlou@cov.com
mwallace@cov.com
eandersen@cov.com

/s/ David A. Bilson
David A. Bilson (#4986)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	)	C.A. No. 17-663 (JFB) (SRF) CONSOLIDATED [redacted]

EXHIBIT 14

TARO'S MOTIONS IN LIMINE AND ALMIRALL'S OPPOSITIONS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

MOTION #1

DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE ARGUMENT, EVIDENCE OR TESTIMONY RELYING ON PLAINTIFF'S COMMERCIAL PRODUCT TO PROVE INFRINGEMENT

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Taro moves to preclude Almirall from relying on or presenting arguments, evidence, or opinions that compare the accused Taro ANDA Product to Almirall's New Drug Application ("NDA") No. 207154 and/or commercial ACZONE Gel, 7.5% to prove infringement. Such comparison is contrary to controlling precedent—the language of the asserted patent claims, and not the patent holder's commercial product, define the inquiry for infringement. Thus, any such argument, evidence, or testimony presented by Almirall should be excluded under Federal Rules of Evidence 402 and 403.

The Federal Circuit has long held that the patent infringement inquiry requires a comparison of the accused product to the claims at issue, not the patent holder's commercial product. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1577 (Fed. Cir. 1992) ("Determining patent infringement requires examination of the patent claims and a comparison of those claims to the alleged infringing product, not a comparison of the accused product and the patentee's product."); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481-82 (Fed. Cir. 1984) ("Infringement is not determined . . . by comparison between commercial products sold by the parties."). This prohibition extends equally to resolving determinations under the doctrine of equivalents. *See, e.g., AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1327-28 (Fed. Cir. 2007) ("Infringement, either literally or under the doctrine of equivalents, does not arise by comparing the accused product . . . with a commercialized embodiment of the patentee." (citation and internal quotation marks omitted)). Indeed, this Court has excluded evidence comparing an accused product to a purported commercial embodiment. *See, e.g., ICU Medical, Inc. v. Rymed Techs, Inc.*, 752 F. Supp. 2d 486, 495-96 (D. Del. Nov. 23, 2010) (Stark, J.) (excluding evidence of infringement under the doctrine of equivalents based on comparison of accused product to plaintiffs' commercial embodiment).

Almirall, however, ignores such precedent, seeking instead to advance infringement arguments at trial that not only rely, but depend, on Almirall's own NDA No. 207154 and/or commercial ACZONE Gel, 7.5%. For example, Almirall alleges [redacted] (App., Ex. A, Lane Opening Rpt. ¶ 73). But [redacted] are ***not claimed*** in the '219 patent. Almirall further asserts that the [redacted] yet another ***unclaimed*** ingredient. As the Federal Circuit has explained, "[i]t is the limitations and functions of the invention ***described in the claims***, not the elements or functions of the accused device, which establish the reference point for the doctrine of equivalents analysis." *AquaTex Indus.*, 479 F.3d at 1327-28 (district court erred in relying on unclaimed features to find a lack of equivalents).

Almirall takes it one step further by relying on data generated with its own ACZONE Gel, 7.5% product in an attempt to prove its infringement claim under the doctrine of equivalents. That is, based on its improper comparison of Taro's ANDA Product to ACZONE Gel, 7.5%, Almirall states Sepineo P 600 is a commercial embodiment of the asserted claims, and then points to data comparing ACZONE Gel, 7.5% to Taro's ANDA Product as evidence that the polymeric viscosity builder in Taro's ANDA Product "creates an emulgel with a similar rheological profile, viscosity, yield stress, distribution of the active ingredient, particle size of the active ingredient, solubility of the active ingredient, feel on the skin, release rate of the active ingredient, formulation stability, and visual appearance to ACZONE Gel, 7.5%." (App., Ex. A, ¶ 130; *see also* ¶¶ 96-100 (comparing distribution of dapsone), ¶¶ 122-127 (comparing stability); *see also id.* ¶¶ 89-95 (comparing rheological profiles); ¶¶ 101-104 (comparing particle size); ¶¶105-107 (comparing

dapsone solubility); ¶¶ 108-110 (comparing "feel"); ¶¶ 111-121 (comparing dapsone release rates); ¶ 128 (comparing "visual appearance")). According to Almirall, "[t]hese properties contribute to the ability of Taro's formulation to be administered once daily for the treatment of acne vulgaris, just like ACZONE Gel, 7.5%" and "is supported by Taro's ANDA No. 210191, which presents data indicating its product is bioequivalent to ACZONE Gel, 7.5%." (*Id.* ¶ 130). [1]

But "bioequivalency of an accused product with a product falling within the scope of the claims of the patent at issue is not sufficient to establish infringement by equivalents." *See, e.g.*, *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009) (upholding grant of summary judgment of noninfringement). Even assuming Plaintiff's ACZONE Gel, 7.5% is an "embodiment" of the patent, the claims themselves do not require any of the aforementioned properties, e.g., rheological profile, solubility, stability, particle size, release rates, etc. "It is the limitations and functions of the invention described in the claims, not the elements or functions of the accused device, which establish the reference point for the doctrine of equivalents analysis." *Insta–Foam Prod., Inc. v. Universal Foam Sys., Inc.*, 906 F.2d 698, 702 (Fed. Cir. 1990).

Simply put, Almirall should not be permitted to rely on NDA No. 207154 and/or ACZONE Gel, 7.5% as evidence of infringement under the doctrine of equivalents. *See, e.g.*, *ICU Medical, Inc.*, 752 F. Supp. at 495-96. For at least the foregoing reasons, any testimony, evidence, or opinion presented by Almirall or its expert(s) comparing Taro's ANDA Product to Almirall's NDA No. 207154 and/or ACZONE Gel, 7.5% in support of Almirall's infringement claims should be excluded.

[1] Almirall's infringement expert, Dr. Lane, testified she did not conduct her function-way-result analysis with reference to the missing claim element, acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA"), because she was not asked to do that analysis. App., Ex. B, Lane Dep. 239:5-11.

Respectfully submitted,

/s/ John C. Phillips, Jr.
John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

MOTION #2

DEFENDANTS' DAUBERT MOTION TO EXCLUDE DR. MAJELLA E. LANE FROM OFFERING THE OPINION TARO'S THICKENING AGENT IS EQUIVALENT TO ACRYLAMIDE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Taro moves to exclude Dr. Majella E. Lane from offering opinions that the thickening agent in Taro's proposed product is equivalent to the missing claim element, acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA"). The claims at issue each recite treatment of acne vulgaris with a topical pharmaceutical composition comprising A/SA. U.S Patent No. 9,517,219 ("the '219 Patent") at Claims 1-2 and 4-5. The parties do not dispute that Taro's product does not contain A/SA and Almirall's infringement claims rely on Dr. Lane's doctrine of equivalents analysis. However, Dr. Lane fails to analyze equivalence of any element of Taro's product to A/SA; instead she focuses on bioequivalence of Taro's product to Almirall's commercial product Aczone® 7.5% gel ("Aczone®"). Further, Dr. Lane's conclusions are based on conclusory analysis that fails to apply established scientific principles. Thus, Dr. Lane should be excluded from presenting her opinions at trial pursuant to Federal Rule of Evidence 702.

Under Rule 702, an expert witness may testify if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The requirements of Rule 702 have been said to embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.,* 233 F.3d 734, 741 (3d Cir. 2000) (citing *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d 717, 741–43 (3d Cir.1994)); *Daubert v. Merrell Dow Pharm, Inc.,* 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993); *Schneider ex rel. Estate of Schneider v. Fried,* 320 F.3d 396, 404 (3d Cir. 2003).

The law requires Almirall to establish an element of Taro's product is equivalent to A/SA. *Abbott Labs. v. Novopharm, Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003) (an equivalent of a missing

claim element or limitation is found only if "insubstantial differences distinguish the missing claim element from the corresponding aspects of the accused [product]." (internal quotations omitted); *see also Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001) (asking "whether the element in the accused device does substantially the same thing in substantially the same way to get substantially the same result as the claim limitation"); *see also Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (*citing Warner-Jenkinson*, 520 U.S. at 40). However, Dr. Lane was not asked to and did not compare any element of Taro's product to the missing claim element. App., Ex. B, Lane Dep. Tr. 239:5-11; *see also* App. Ex. A, Lane Opening ¶ 69 (the thickening agent in Taro's product "is insubstantially different from the claimed polymeric viscosity builder, as embodied by Sepineo P 600, the [thickening agent in Aczone®] (which is itself an embodiment of the 'topical pharmaceutical formulation' recited in claim 1.") Instead, she conclusively states Taro's product is equivalent to the claims at issue because it is bioequivalent to Aczone®. In giving her opinion, she improperly seeks to show equivalence of excipients in Taro's product to *unclaimed* elements of the '219 patent. *See* Defendants' Motion *In Limine* to Exclude Argument, Evidence or Testimony Relying on Plaintiff's Commercial Product to Prove Infringement. Dr. Lane's analysis is contrary to the law and must be excluded.

Dr. Lane's opinions, *even if* legally sound (they are not), are unsubstantiated conclusions devoid of any expert analysis. For example, Dr. Lane asserts Taro's product has a uniform dapsone distribution similar to Aczone® and concludes the "data demonstrates that the [thickening agent] used in Taro's ANDA Product and [Aczone®] resulted in substantially similar distribution of dapsone." App., Ex. A, Lane Opening at ¶100. Dr. Lane's conclusion is devoid of any analysis seeking to demonstrate the similarity she identifies is attributable to Taro's thickening agent acting in a substantially similar way to A/SA. *See id*. ¶¶ 96-100. In another example, Dr. Lane seeks to

demonstrate the similarity in particle size of dapsone in Taro's product to the particle size of dapsone in Aczone®. *See id.* ¶¶ 101-104. Dr. Lane concludes, without evidence, "Taro's particle size distribution data establishes that the polymeric viscosity builder used in Taro's ANDA Product … and Sepineo P 600, the polymeric viscosity builder in [Aczone®] …, act in the same way by producing a substantially similar particle size distribution." *Id.* ¶ 104. Dr. Lane provides the same conclusory, empty analysis with respect to dapsone solubility, *id.* ¶¶ 107-100, dapsone release rate, *id.* ¶¶ 111-127, and visual appearance, *id.* ¶¶ 128. Dr. Lane was unable to provide any details at her deposition to explain how these similarities were attributable to what she asserts is Taro's thickening agent, or how any corresponding attributes in the Aczone® product were attributable to A/SA.

Dr. Lane's opinions fail to apply the correct legal standard and are conclusory in nature. As such, they fail to satisfy the standards of expert testimony required by Rule 702. Dr. Lane should therefore be precluded from offering testimony that the thickening agent in Taro's product is equivalent to the missing claims element, A/SA.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

MOTION #3

DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE ARGUMENT, EVIDENCE OR TESTIMONY RELYING ON THE DOCTRINE OF EQUIVALENCE TO PROVE INFRINGEMENT BECAUSE PLAINTIFF IS BARRED BY THE DOCTRINE OF ENSNAREMENT

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Taro moves to preclude Almirall from offering evidence or argument that Taro infringes the '219 patent under the doctrine of equivalents because Almirall's equivalents theory is barred by the doctrine of ensnarement, "the longstanding principle that the prior art restricts the scope of equivalency that the party alleging infringement under the doctrine of equivalents can assert." *Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1576 (Fed. Cir. 1994).

A doctrine of equivalents theory cannot be asserted if it will encompass or "ensnare" the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009). "This limitation is imposed even if a jury has found equivalence as to each claim element." *Id.* at 1323. Ensnarement is typically resolved through a "hypothetical claim analysis." *Jang v. Boston Sci. Corp.*, 872 F.3d 1275, 1285 (Fed. Cir. 2017). There are two steps to this analysis: the first is to construct a hypothetical claim that literally covers the accused device; the second is to determine whether the PTO would have allowed the hypothetical claim over the prior art. *Id.* While "[t]he burden of producing evidence of prior art to challenge a hypothetical claim rests with an accused infringer, []the burden of proving patentability of the hypothetical claim rests with the patentee." *Id.* When an equivalents theory encompasses or ensnares the prior art, it "cannot be asserted." *Id.*

Almirall proposes the following hypothetical claim for evaluating ensnarement[1]:

> A method . . . comprising administering . . . a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2 % w/w to about 6% w/w of a polymeric viscosity builder comprising [A/SA][2] copolymer **or Carbomer homopolymer type C[3]**; and

[1] Additions underlined and bolded.
[2] "A/SA" refers to acrylamide/sodium acryloyldimethyl taurate.
[3] Referred to herein as "carbomer."

water;
wherein the topical pharmaceutical composition does not comprise adapalene.

(App., Ex. C, Lane Reply Rpt. ¶ 55). As discussed below, this hypothetical claim would not have been allowed by the PTO over the prior art.

For example, during prosecution, the examiner rejected the claims of the '219 patent as obvious over Garrett I[4]. In rejecting the claims, the examiner asserted Garrett I discloses a method for treating rosacea with topical dapsone compositions, wherein dapsone may be present in an amount of about 0.5-10% w/w. (App., Ex. D, '219 patent PH[5], 11-18-15 Office Action at 9). The examiner further noted Garrett I teaches that the composition may include carbomer as a thickener and "the thickener generally comprises 0.2-4% w/w of the composition." (*Id.* at 9). The examiner additionally stated Garrett teaches the "composition includes an organic solvent system, preferably diethylene glycol monoethyl ether (DGME) . . . which is generally incorporated in an amount of about 25-35% w/w." (*Id.*)

The only difference between the claims and Garrett I, according to the examiner, is Garrett I "does not explicitly teach (1) [A/SA] copolymer in an amount of 'about 2% to about 6% w/w' (claim 1), particularly about 4% (claim 7) or (2) the exact amount of DGME (i.e., 'about 30% w/w'; claims, 7) or the exact claimed amount of dapsone ("about 7.5% w/w'; claims 1 and 7)." (*Id.*) The examiner nevertheless found the claims obvious over Garrett I because "[a] person of ordinary skill in the art before the effective filing date of the claimed invention would have had a reasonable expectation of success in varying the amounts of the components of the composition described in Garrett within the desired range therein." (*Id.* at 11).

[4] "Garrett I" refers to International Publication Number WO 2009/108147.
[5] "PH" refers to prosecution history.

In response, the applicant submitted a declaration by inventor Dr. Kevin Warner stating, for example, that Sepineo P 600 (which comprises A/SA copolymer) was a more robust thickener than carbomer. (App, Ex. E, '219 patent PH, Warner Decl. at 3). Dr. Warner further argued Sepineo P 600 allowed for higher concentrations of DGME than with carbomer and resulted in reduced particle size as compared to carbomer. *Id.* Based on the Warner Declaration, the applicant concluded: "Sepineo P 600 was therefore selected as the gelling agent for the 7.5% w/w dapsone formulation of the instant claims." (App., Ex. F, '219 patent PH, 02-18-16 Response at 8).

The examiner determined the Warner Declaration provided enough support for the unexpected results of A/SA over carbomer and withdrew the obviousness rejections. (App., Ex. G., '219 patent PH, 03-07-16 Office Action at 2-4). In particular, the examiner noted: "The Warner Declaration . . . provides clear evidence that ***the improved properties of the Applicant's claimed 7.5% w/w dapsone formulation . . . yields directly from the selection of the [A/SA] copolymer as the polymeric thickener of the formulation***." (*Id.* at 3).

In view of the above, it is clear that the PTO would not have allowed the claims of the '219 patent ***but for*** the purported unexpected superiority of A/SA copolymer over carbomer. Thus, a hypothetical claim requiring carbomer as an alternative to A/SA, as Almirall proposes, would not have been found to be patentable by the PTO over the prior art.

For at least the foregoing, Almirall should be precluded from offering evidence or argument that Taro infringes the '219 patent under the doctrine of equivalents because Almirall's equivalents theory encompasses or ensnares the prior art and thus "cannot be asserted." *Jang*, 872 F.3d at 1285.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

MOTION #4

DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE ARGUMENT, EVIDENCE OR TESTIMONY RELYING ON PLAINTIFF'S IMPROPER LEAD COMPOUND OBVIOUSNESS ANALYSIS

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Taro moves to preclude Almirall, under Federal Rules 402 and 403, from relying on or presenting arguments, evidence, or opinions of an improper obviousness analysis requiring the identification of a "lead compound" a POSA would have used as a starting point. Plaintiff misapplies the law. This is not a chemical compound case—this case involves a method of treating acne with a pharmaceutical composition containing dapsone.

It is black letter law that courts must take "an expansive and flexible approach" in determining obviousness, and must consider: (1) the level of ordinary skill; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07, 415 (2007). This analysis must be viewed through the perspective of a hypothetical POSA. *Id.* at 415-22.

The Federal Circuit has condoned a "lead compound" analysis when assessing the obviousness of chemical compounds. *See, e.g.*, *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed.Cir.2012). The analysis involves the identification of a compound a POSA would select to modify to arrive at the claimed compound(s). *Id.* The "lead compound" analysis, however, does not necessarily apply to cases involving pharmaceutical formulations of known compounds. *See, e.g.*, *Galderma Labs, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 137 (Fed. Cir. 2013). This is especially true where, as here, the known compound has already been used to effectively treat the same condition claimed in the patent-at-issue.

Despite this well-established precedent, Almirall argues a POSA would not have selected dapsone, a known chemical compound marketed to treat acne, to formulate an "improved" acne medication. In essence, Almirall asserts that in assessing the obviousness of the claims at issue, the analysis must begin with a lead compound, e.g., a compound that a POSA would have favored over other compounds. (*See e.g.*, App., Ex. H, Klibanov Rebuttal Rpt. §§ XIII (A) & XIV (A);

App., Ex. I, Harper Rebuttal Rpt. ¶ 3 and §§ XV (A)-(C)). Alternatively, Almirall asserts a POSA would have to start with a "reference composition" to modify to arrive at the claims at issue. The lead compound frameworks Almirall attempts are neither appropriate nor legally sanctioned.

Almirall will no doubt rely on *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352 (Fed. Cir. 2011), where the Federal Circuit applied the "reference composition" analysis to a mixture. (There is no precedent for requiring the identification of a lead chemical compound in a formulation case.) However, the court limited the "lead compound" test to factual circumstances not present here.[1] In *Unigene*, the court considered whether a claimed formulation was obvious over a "previously FDA-approved formulation," or "reference composition," it was designed to imitate. *Id.* at 1361. The Federal Circuit affirmed the district court's use of the lead compound analysis, comparing its use of a "reference composition" to the use of a "lead compound." *Id.* It stated:

> *In the context of a composition or formulation patent where the patented formulation was made to mimic a previously FDA-approved formulation*, the functional and pharmaceutical properties of the "lead compound" can be more relevant than the actual chemical structure . . . Thus, the term "reference composition" is more appropriate than "lead compound" when considering obviousness for a chemical composition that the [inventor] deliberately imitate[d].

Id. (emphasis added). Therefore, *Unigene* held the lead compound framework *may be* appropriate in analyzing formulations when there is a clear "reference formulation" the inventor sought to imitate, not that it must be applied to compositions in fields where development proceeds from a particular starting point. In this case, the patented composition was not made to mimic the FDA-approved ACZONE Gel, 5% (a point Almirall has gone to great lengths to demonstrate). In short, the "lead compound" or "reference composition" framework does not fit the facts of this case.

[1] In addition, the court stated "[w]here the patent at issue claims a chemical compound, a lead compound is *often* used in analyzing obviousness. *Id.* at 1361 (emphasis added)." Thus, the Federal Circuit in *Unigene* recognized that the lead compound framework *is not* always required or most appropriate, even in chemical compound cases.

After *Uniqene*, the Federal Circuit clarified that in cases involving compositions, "[n]othing in the statute or our case law requires [a challenger] to prove obviousness by starting with a prior art commercial embodiment and then providing motivation to alter that commercial embodiment." *Galderma* 737 F.3d at 137. In *Galderma*, the patented composition was a topical gel to treat acne, containing 0.3% of the active ingredient adapalene. *Id.* at 734. The prior art included an earlier FDA-approved acne product containing only 0.1% adapalene. *Id.* at 735. The Federal Circuit rejected the broad application of a "reference composition" standard, and found the claims invalid as obvious. *Id.* at 737-41. Thus, the Federal Circuit expressly rejected the very analysis Almirall demands in this case.[2]

There is absolutely no precedent for Almirall's proposition dapsone would not have been a "lead compound" to formulate into an "improved" acne medication. Dapsone had been known to be effective to treat acne for decades prior to the filing of the '219 patent and was already being sold in a commercially successful topical gel. Nothing in the law requires Taro to show a POSA would have selected dapsone *over any other* known active ingredient known to treat acne. The fact is dapsone had been an effective chemical compound used topically to treat acne for years prior to the filing of the patent-in-suit and the obviousness question is simply whether the methods of using the claimed composition with dapsone would have been obvious.

For at least the foregoing, the Court should exclude any testimony, evidence, or opinion presented by Almirall or their expert(s) relying on an improper "lead compound" or "reference composition" analysis to show the non-obviousness of the Asserted Claims.

---

[2] *Accord Ex Parte Abdul Gaffar*, 2015 WL 7720188, at *3 (P.T.A.B. June 13, 2016); *Auxilium Pharms., Inc. v. Watson Labs., Inc.*, 2014 WL 9859224, at *13 (D.N.J. 2014) (rejecting argument that "the obviousness inquiry in this [pharmaceutical composition] case should begin with the identification of a 'reference composition' (or commercial embodiment) that a POSA would have used as a starting point during the relevant time period").

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

IN UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

MOTION #5

DEFENDANTS' DAUBERT MOTION TO EXCLUDE DR. JULIE HARPER FROM TESTIFYING ABOUT THE OBVIOUSNESS OF THE ASSERTED CLAIMS OF THE '219 PATENT

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Taro moves to exclude Dr. Julie Harper from testifying about the obviousness of the asserted claims of the '219 patent. The parties do not dispute a POSA with respect to the claims at issue would have been a scientist with training and experience in formulating pharmaceutical dosage forms. Dr. Harper is a practicing dermatologist and readily admits she is neither a POSA nor a person capable of viewing the claims at issue from the perspective of a POSA. As such, Dr. Harper should be precluded from providing testimony about the obviousness of the claims at issue pursuant to Federal Rule of Evidence 702.

Under Rule 702, an expert witness may testify if: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. The requirements of Rule 702 have been said to embody "three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit." *Elcock v. Kmart Corp.,* 233 F.3d 734, 741 (3d Cir. 2000) (citing *In re Paoli R.R. Yard PCB Litig.,* 35 F.3d 717, 741–43 (3d Cir.1994)); *Daubert v. Merrell Dow Pharm, Inc.,* 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993); *Schneider ex rel. Estate of Schneider v. Fried,* 320 F.3d 396, 404 (3d Cir. 2003).

Almirall is asking Dr. Harper to testify that: (1) a POSA would not have selected dapsone for an improved treatment for acne; (2) a POSA selecting dapsone would not have chosen 7.5% w/w of dapsone in an "improved formulation"; (3) a POSA would have combined 5% w/w dapsone with another active ingredient, adapalene; and (4) secondary considerations support the

patentability of the claims at issue. Dr. Harper is not qualified to give the opinions she has been asked to provide.[1]

Dr. Harper was deposed in this matter on December 10, 2018. Dr. Harper candidly testified she is not a POSA pursuant to the definition she provided in her expert report. *See*, *e.g.,* App., Ex. J, Harper Dep. 47:20-48:3. Furthermore, she honestly admits her expertise is limited to her experience as a practicing physician prescribing commercially-available acne medications. *See*, *e.g., id.* at 71:6-19. Dr. Harper stated she could not testify from the perspective of a POSA and would have to leave any testimony relating to the formulations of the claims at issue to the formulation experts. *See, e.g.*, *id.* at 51:1-52:5.

Notwithstanding Dr. Harper's frank admissions, her expert report is replete with the very testimony she affirms she is not qualified to give. *See*, *e.g.*, App., Ex. I, Harper Rebuttal Report, Section XV.A, XV.B, XV.C and XV. D ("But a person or ordinary skill in the art would have selected a first-line agent for addressing inflammation, not one that had been marginalized as a second-line treatment at best. (¶150); "Garrett I would have provided no motivation or expectation of success, and would in fact have taught away from dapsone." (¶161); "A person or ordinary skill in 2012 would have believed that the makers of Aczone *had already* optimized the dapsone concentration in the original 5% formulation, and therefore would have seen no benefit in increasing the dapsone concentration to 7.5%." (¶164)). Dr. Harper presents as a physician doing good things for her patients; however, she should not be allowed to offer opinions on the

[1] Even if Dr. Harper were qualified to give these opinions, they are objectionable at least for the reasons addressed in Taro's motions in limine relating to Almirall's flawed "lead compound" arguments.

obviousness of the claims at issue relating to the formulations of topical compositions containing dapsone, DGME and a polymeric viscosity builder.[2]

Almirall should not be permitted to present the proposed testimony of Dr. Harper. To the extent Dr. Harper seeks to testify generally about her experience prescribing topical dapsone formulations, Taro does not dispute she is qualified to do so; the problem with any such testimony would be it lacks relevance to the claims at issue and therefore is objectionable. For at least the foregoing reasons, Dr. Harper should be precluded from testifying, at a minimum, as to the obviousness of the claims at issue at trial.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendants Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals, Inc.

Of Counsel:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, IL 60661-3693
(312) 902.5200
stephen.benson@kattenlaw.com
kimberly.beis@kattenlaw.com

Dated: December 31, 2018

[2] Highlighting the fact the '219 patent is purely a formulation patent and not a patent disclosing an "improved" once-a-day Aczone 7.5% gel with a specific efficacy and toxicity profile, there is nothing in the '219 patent discussing a once-a-day treatment, disclosing efficacy of any proposed formulation or addressing the toxicity of the broad formulations of the claims.

IN UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, LLC, Plaintiff, v. TARO PHARMACEUTICALS INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17 663 (JFB) (SRF) CONSOLIDATED

EXHIBIT 14

APPENDIX

1. **Exhibit A** is a true and correct copy of excerpts of the Opening Expert Report of Dr. Majella Lane, dated September 6, 2018.
2. **Exhibit B** is a true and correct copy of excerpts from the Transcript of the Deposition of Dr. Majella Lane held on December 21, 2018.
3. **Exhibit C** is a true and correct copy of excerpts from the Reply Expert Report of Dr. Majella Lane, dated November 20, 2018.
4. **Exhibit D** is a true and correct copy of the November 18, 2015 Office Action from the prosecution history of the ‘219 patent.
5. **Exhibit E** is a true and correct copy of the Declaration of Kevin Warner, from the prosecution history of the ‘219 patent.
6. **Exhibit F** is a true and correct copy of the February 18, 2016 Response to Office Action from the prosecution history of the ‘219 patent.
7. **Exhibit G** is a true and correct copy of the March 7, 2016 Office Action from the

prosecution history of the ‘219 patent.

8. **Exhibit H** is a true and correct copy of excerpts from the Rebuttal Expert Report of Dr. Alexandre Klibanov, dated November 6, 2018.
9. **Exhibit I** is a true and correct copy of excerpts from the Rebuttal Expert Report of Dr. Julie Harper, dated November 6, 2018.
10. **Exhibit J** is a true and correct copy of excerpts from the Transcript of the Deposition of Dr. Julie Harper held on December 10, 2018.

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-664 (JFB) (SRF) (Consolidated) **CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**

OPENING EXPERT REPORT OF MAJELLA E. LANE, Ph.D.

I declare under penalty of perjury of the laws of the United States of America that the following is, to the best of my knowledge and belief, true and correct.

Dated: September 11, 2018

Majella E. Lane

Majella E. Lane

TABLE OF CONTENTS

Page