IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORATIO WASHINGTON DEPOT TECHNOLOGIES LLC, Plaintiff, v. TOLMAR, INC., TOLMAR PHARMACEUTICALS, INC., and TOLMAR THERAPEUTICS, INC., Defendants.	C.A. No. 17-1086-LPS **DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to the Court's March 20, 2019 Order (D.I. 120) adopting the Report and Recommendation (D.I. 77), dated November 1, 2018, recommending dismissal, with prejudice, of certain patent claims and further recommending that the Court permit Plaintiff Horatio Washington Depot Technologies LLC ("Horatio") leave to amend its original complaint with respect to certain patent claims, Horatio, by its attorneys, brings this action against Tolmar, Inc., Tolmar Pharmaceuticals, Inc., and Tolmar Therapeutics, Inc. and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Tolmar, Inc., Tolmar Pharmaceuticals, Inc., and Tolmar Therapeutics, Inc. (collectively, "Tolmar" or "Defendants").

JURISDICTION AND VENUE

2. This Complaint for patent infringement arises under the United States Patent Laws, Title 35 U.S.C. § 100 et seq.

3. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Tolmar, Inc. in this District because Tolmar, Inc. is incorporated under the laws of the State of Delaware, and therefore is subject to the laws and protection of the State of Delaware. Tolmar, Inc. is subject to personal jurisdiction in this district because, *inter alia*, Tolmar, Inc. has committed, aided, abetted, actively induced, or participated in the commission of an act of patent infringement that led to foreseeable harm and injury to Plaintiff, a Delaware limited liability company.

5. This Court has personal jurisdiction over Tolmar Pharmaceuticals, Inc. in this District because Tolmar Pharmaceuticals, Inc. is incorporated under the laws of the State of Delaware, and therefore is subject to the laws and protection of the State of Delaware. Tolmar Pharmaceuticals, Inc. is subject to personal jurisdiction in this district because, *inter alia*, Tolmar Pharmaceuticals, Inc. has committed, aided, abetted, actively induced, or participated in the commission of an act of patent infringement that led to foreseeable harm and injury to Plaintiff, a Delaware limited liability company.

6. This Court has personal jurisdiction over Tolmar Therapeutics, Inc. in this District because Tolmar Therapeutics, Inc. is incorporated under the laws of the State of Delaware, and therefore is subject to the laws and protection of the State of Delaware. Tolmar Therapeutics, Inc. is subject to personal jurisdiction in this district because, *inter alia*, Tolmar Therapeutics, Inc. has committed, aided, abetted, actively induced, or participated in the commission of an act of patent infringement that led to foreseeable harm and injury to Plaintiff, a Delaware limited liability company.

7. Venue in this Court is proper under 28 U.S.C. § 1400(b). Defendants are all incorporated under the laws of the State of Delaware and have committed, aided, abetted, actively induced, or participated in the commission of an act of patent infringement that led to foreseeable

harm and injury to Plaintiff, a Delaware limited liability company. Defendants hold New Drug Application ("NDA") No. 021343 for Eligard® 7.5 mg/vial; No. 021379 for Eligard® 22.5 mg/vial; No. 021488 for Eligard® 30 mg/vial; and NDA No. 021731 for Eligard® 45 mg/vial (collectively, "Eligard"), which Tolmar commercially markets in the United States. Upon information and belief, the Eligard product is marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

PARTIES

8. Plaintiff Horatio is a Delaware limited liability company with principal place of business at 96 Horatio Street #710, New York, New York 10014.

9. Tolmar, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526.

10. Tolmar, Inc. is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of state on December 1, 2006, pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation, representing its business under file number 4258548; and (2) a statement naming "Corporation Service Company" located in 251 Little Falls Drive, Wilmington, Delaware, 19808 as its registered agent to accept service of process in the State of Delaware.

11. Tolmar Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526.

12. Tolmar Pharmaceuticals, Inc. is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of state on January 27, 2014,

pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation, representing its business under file number 5468675; and (2) a statement naming "Corporation Service Company" located in 251 Little Falls Drive, Wilmington, Delaware, 19808 as its registered agent to accept service of process in the State of Delaware.

13. Tolmar Pharmaceuticals, Inc. is also actively registered with the Delaware Board of Pharmacy, pursuant to Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License No. A4-0002129).

14. Tolmar Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526.

15. Tolmar Therapeutics, Inc. is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of state on June 9, 2004, pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation, representing its business under file number 3812699; and (2) a statement naming "Corporation Service Company" located in 251 Little Falls Drive, Wilmington, Delaware, 19808 as its registered agent to accept service of process in the State of Delaware.

16. Tolmar formulates, manufactures, packages, and markets drug products for distribution in the District of Delaware and throughout the United States. According to Tolmar's website (http://tolmar.com/), Tolmar "is a fully integrated company focused on the development, approval, and commercialization of specialty pharmaceutical products."

THE PATENTS-IN-SUIT[1]

17. On August 3, 1999, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 5,932,547 ("the '547 patent"), entitled "Non-Aqueous Polar Aprotic Peptide Formulations." A true and correct copy of the '547 patent is attached hereto as **Exhibit A**. The claims of the '547 patent are valid and enforceable. Horatio is the owner of the '547 patent by assignment and has the right to sue for past damages.

18. On September 26, 2000, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 6,124,261 ("the '261 patent"), entitled "Non-Aqueous Polar Aprotic Peptide Formulations." A true and correct copy of the '261 patent is attached hereto as **Exhibit B**. The claims of the '261 patent are valid and enforceable. Horatio is the owner of the '261 patent by assignment and has the right to sue for past damages.

19. On May 22, 2001, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 6,235,712 ("the '712 patent"), entitled "Non-Aqueous Polar Aprotic Peptide Formulations." A true and correct copy of the '712 patent is attached hereto as **Exhibit C**. The claims of the '712 patent are valid and enforceable. Horatio is the owner of the '712 patent by assignment and the right to sue for past damages.

20. Together, the '547 patent, the '261 patent, and the '712 patent are referred to as the "Asserted Patents."

[1] On March 20, 2019, the Court dismissed Counts I through VI of the Original Complaint, which asserted infringement of U.S. Patent Nos. 5,932,547 ("the '547 Patent") and 6,124,261 ("the '261 Patent"). *See* D.I. 120. Furthermore, on March 15, 2019, the parties stipulated that, given the Court's Markman Order, the accused products do not infringe claims 4, 8-10, and 12-15 of U.S. Patent No. 6,235,712 ("the '712 Patent"). Accordingly, these claims are not reasserted in this First Amended Complaint. However, Horatio preserves its rights to appeal the Court's orders regarding these claims as well as all rights to assert infringement of these claims both literally and under the doctrine of equivalents in this or any other action.

21. From 2011 to 2017, there was no product for the patentees to mark with the patent numbers in the United States.

FACTUAL BACKGROUND

22. Each of the preceding paragraphs 1 to 21 is re-alleged and re-incorporated as if fully set forth herein.

23. Tolmar Pharmaceuticals, Inc. holds approved New Drug Application ("NDA") No. 021343 for Eligard® 7.5 mg/vial; No. 021379 for Eligard® 22.5 mg/vial; No. 021488 for Eligard® 30 mg/vial; and NDA No. 021731 for Eligard® 45 mg/vial (collectively, "Eligard"), which Tolmar commercially markets in the United States. Eligard is indicated for use in the palliative treatment of advanced prostate cancer. Eligard contains leuprolide acetate, a luteinizing hormone-release hormone (LH-RH) related compound as its active pharmaceutical ingredient. Upon further information and belief, Tolmar's NDAs for Eligard were approved by the FDA on January 23, 2002; July 24, 2002; February 13, 2003; and December 14, 2004, respectively.

24. Upon information and belief, Tolmar, prepared stable non-aqueous formulations of leuprolide acetate in polar aprotic solvents by dissolving leuprolide acetate in the solvent N-methyl-2-pyrrolidone at least while developing and testing the formulation.

25. The prescribing information for Eligard states that it is an injectable suspension of leuprolide acetate containing a polymer and a polar aprotic solvent for subcutaneous administration where the formulation forms a solid drug delivery depot that provides continuous release of leuprolide acetate for up to six months. The prescribing information for Eligard contains instructions on preparing the leuprolide acetate formulation and contains instructions for the parenteral administering the leuprolide acetate formulation. A copy of the Eligard prescribing information from 2011 is attached as **Exhibit E**.

26. The prescribing information for Eligard demonstrates that the constituted 45 mg dosage form of Eligard contains 12% w/w leuprolide acetate. *See* Exhibit E at Table 5.

PRE-SUIT INDUCEMENT

27. Upon information and belief, since at least May 2010, Tolmar has had knowledge of or was willfully blind to the existence of the Asserted Patents. During the prosecution of at least Tolmar's U.S. Patent No. 8,486,455, the applicant submitted to the U.S. Patent and Trademark Office ("USPTO") in an Information Disclosure Statement ("IDS") Form SB08 a non-patent literature document FDA Orange Book – Leuprolie, [sic, Leuprolide] Acetate, (12/2009)." **Exhibit F** (U.S. Patent No. 8,486,455, Information Disclosure Statement Form SB08, submitted May 20, 2010). The Asserted Patents are listed in the December 2009 edition of the FDA Orange Book in connection with the active ingredient leuprolide acetate. **Exhibit D** (Orange Book, Dec. 2009). Tolmar also submitted information disclosure statements to the USPTO including the December 2009 FDA Orange Book listing for leuprolide acetate in at least the applications associated with U.S. Patent Nos. 8,840,916; 9,254,307; 9,283,282; and 9,539,333. To the extent that Tolmar contends that it was not aware of the Asserted Patents, it was willfully blind to, and should have known about, the Asserted Patents. From 2011 to present, the Asserted Patents were listed in the Orange Book in connection with leuprolide acetate, the same active ingredient used in Eligard. Based on its disclosures to the USPTO, Tolmar was aware of and relied on the Orange Book in assessing patents relating to leuprolide acetate.

28. Upon information and belief, after learning that Tolmar's Eligard product infringed the Asserted Patents, Tolmar took no action to cease their infringing activities.

29. Upon information and belief, Tolmar has had knowledge that at least medical professionals directly infringe the Asserted Patents.

COUNT I

Infringement of the '712 Patent by Tolmar, Inc.

30. Horatio realleges and incorporates by reference paragraphs 1-29.

31. Upon information and belief, Tolmar, Inc. has directly and/or indirectly infringed, either literally or under the doctrine of equivalents, at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, under 35 U.S.C. § 271(a) by dissolving leuprolide acetate in the polar aprotic solvent N-methyl-2-pyrrolidone to at least develop and test the formulation.

32. Upon information and belief, Tolmar, Inc. infringed at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing into the United States stable non-aqueous formulations of leuprolide acetate by dissolving leuprolide acetate in the polar aprotic solvent N-methyl-2-pyrrolidone to at least develop and test the formulation.

33. Upon information and belief, Tolmar, Inc.'s prescribing information for Eligard actively induced infringement by others pursuant to 35 U.S.C. § 271(b), such as medical professionals, of at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002.

34. Upon information and belief, Tolmar, Inc.'s Eligard product, when used as directed, was used by others such as medical professionals, in a manner that directly infringes at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents.

35. Upon information and belief, Tolmar, Inc. has had knowledge of or was willfully blind to the '712 patent at least as early as May 20, 2010.

36. Upon information and belief, Tolmar, Inc. knew of or was willfully blind to the fact that its actions with respect to its Eligard product induced the direct infringement of the ’712 patent by knowing its Eligard product and FDA-approved prescribing information infringed the ’712 patent and failing to take actions to prevent that infringement.

37. Horatio suffered injury for which it is entitled to monetary relief as a result of Tolmar, Inc.’s infringement and inducement to infringe at least claims 1, 2, and 16 of the ’712 patent.

38. Upon information and belief, Tolmar, Inc. has acted with knowledge of or was willfully blind to the high likelihood that its Eligard product infringed at least claims 1, 2, and 16 of the ’712 patent as corrected by Certificate of Correction dated October 29, 2002, and failed to take any steps to avoid infringement of the ’712 patent, and thus its past infringement is willful and deliberate.

COUNT II

Infringement of the ’712 Patent by Tolmar Pharmaceuticals, Inc.

39. Horatio realleges and incorporates by reference paragraphs 1-38.

40. Upon information and belief, Tolmar Pharmaceuticals, Inc. has directly and/or indirectly infringed, either literally or under the doctrine of equivalents, at least claims 1, 2, and 16 of the ’712 patent as corrected by Certificate of Correction dated October 29, 2002, under 35 U.S.C. § 271(a) by dissolving leuprolide acetate in the polar aprotic solvent N- methyl-2-pyrrolidone to at least develop and test the formulation.

41. Upon information and belief, Tolmar Pharmaceuticals, Inc. infringed at least claims 1, 2, and 16 of the ’712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing into the United States stable non-aqueous formulations of leuprolide acetate by

dissolving leuprolide acetate in the polar aprotic solvent N-methyl-2-pyrrolidone to at least develop and test the formulation.

42. Upon information and belief, Tolmar Pharmaceuticals, Inc.'s prescribing information for Eligard actively induced infringement by others pursuant to 35 U.S.C. § 271(b), such as medical professionals, of at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002.

43. Upon information and belief, Tolmar Pharmaceuticals, Inc.'s Eligard product, when used as directed, was used by others such as medical professionals, in a manner that directly infringes at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents.

44. Upon information and belief, Tolmar Pharmaceuticals, Inc. has had knowledge of or was willfully blind to the '712 patent at least as early as May 20, 2010.

45. Upon information and belief, Tolmar Pharmaceuticals, Inc. knew of or was willfully blind to the fact that its actions with respect to its Eligard product induced the direct infringement of the '712 patent by knowing its Eligard product and FDA-approved prescribing information infringed the '712 patent and failing to take actions to prevent that infringement.

46. Horatio suffered injury for which it is entitled to monetary relief as a result of Tolmar Pharmaceuticals, Inc.'s infringement and inducement to infringe at least claims 1, 2, and 16 of the '712 patent.

47. Upon information and belief, Tolmar Pharmaceuticals, Inc. has acted with knowledge of or was willfully blind to the high likelihood that its Eligard product infringed at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29,

2002, and failed to take any steps to avoid infringement of the '712 patent, and thus its past infringement is willful and deliberate.

COUNT III

Infringement of the '712 Patent by Tolmar Therapeutics, Inc.

48. Horatio realleges and incorporates by reference paragraphs 1-47.

49. Upon information and belief, Tolmar Therapeutics, Inc. has directly and/or indirectly infringed, either literally or under the doctrine of equivalents, at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, under 35 U.S.C. § 271(a) by dissolving leuprolide acetate in the polar aprotic solvent N- methyl-2-pyrrolidone to at least develop and test the formulation.

50. Upon information and belief, Tolmar Therapeutics, Inc. infringed at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing into the United States stable non-aqueous formulations of leuprolide acetate by dissolving leuprolide acetate in the polar aprotic solvent N-methyl-2- pyrrolidone to at least develop and test the formulation.

51. Upon information and belief, Tolmar Therapeutics, Inc.'s prescribing information for Eligard actively induced infringement by others pursuant to 35 U.S.C. § 271(b), such as medical professionals, of at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002.

52. Upon information and belief, Tolmar Therapeutics, Inc.'s Eligard product, when used as directed, was used by others such as medical professionals, in a manner that directly infringes at least claims 1, 2, and 16 of the '712 patent as corrected by Certificate of Correction dated October 29, 2002, either literally or under the doctrine of equivalents.

53. Upon information and belief, Tolmar Therapeutics, Inc. has had knowledge of or was willfully blind to the ’712 patent at least as early as May 20, 2010.

54. Upon information and belief, Tolmar Therapeutics, Inc. knew of or was willfully blind to the fact that its actions with respect to its Eligard product induced the direct infringement of the ’712 patent by knowing its Eligard product and FDA-approved prescribing information infringed the ’712 patent and failing to take actions to prevent that infringement.

55. Horatio suffered injury for which it is entitled to monetary relief as a result of Tolmar Therapeutics, Inc.’s infringement and inducement to infringe at least claims 1, 2, and 16 of the ’712 patent.

56. Upon information and belief, Tolmar Therapeutics, Inc. has acted with knowledge of or was willfully blind to the high likelihood that its Eligard product infringed at least claims 1, 2, and 16 of the ’712 patent as corrected by Certificate of Correction dated October 29, 2002, and failed to take any steps to avoid infringement of the ’712 patent, and thus its past infringement is willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter Judgement and Order in their favor and against Tolmar on the claims set forth above and respectfully request that this Court:

1. Declare that the Asserted Patent is valid and enforceable;

2. Declare that Tolmar has infringed, either literally or under the doctrine of equivalents, claims of the Asserted Patent under 35 U.S.C. § 271(a);

3. Declare that Tolmar has induced the infringement of at least one valid and enforceable claim of the ’712 patent under 35 U.S.C. § 271(b);

4. Award Plaintiff damages adequate to compensate for Tolmar's infringement, but in no event less than a reasonable royalty.

5. Declare that this case is an exceptional case under 35 U.S.C. § 285 and award to Plaintiff its fees and costs, including its attorneys' fees pursuant to 35 U.S.C. § 285, and pre-judgment interest and post-judgment interest; and

6. Any other and further relief as the Court deems just and equitable.

JURY DEMAND

Plaintiff requests trial by jury pursuant to Fed. R. Civ. P. 38(b).

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Dated: April 2, 2019

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