IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TOLMAR THERAPEUTICS, INC. and TOLMAR PHARMACEUTICALS, INC., Plaintiffs, v. FORESEE PHARMACEUTICALS CO., LTD., Defendants.	Case No. 21-cv-15782-JXN-CLW Judge: Julien Xavier Neals Magistrate Judge: Cathy L. Waldor

PLAINTIFFS' FIRST AMENDED COMPLAINT

Eric I. Abraham
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08543
(609) 924-0808
eabraham@hillwallack.com

Of Counsel:
Jeffrey R. Gargano
Melissa M. Haulcomb
K&L GATES LLP
70 W. Madison St., Suite 3300
Chicago, IL 60602

Zachary D. Miller
MORGAN, LEWIS & BOCKIUS LLP
110 North Wacker Drive
Chicago, IL 60606

Attorneys for Plaintiffs

Plaintiffs Tolmar Therapeutics, Inc. ("TTI") and Tolmar Pharmaceuticals, Inc. ("TPI") (collectively "Tolmar" or "Plaintiffs"), by its attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of the submission of New Drug Application ("NDA") No. 211488 by Foresee Pharmaceuticals Co., Ltd. ("Foresee") and the current Applicant Holder, Accord BioPharma, Inc. ("Accord" collectively, "Defendants"), to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, sell, offer for sale, and/or import Defendants' proposed Camcevi® 42mg (leuprolide) injectable emulsion for the treatment of adult patients with advanced prostate cancer ("Camcevi product"), prior to the expiration of TTI's U.S. Patent No. 8,470,359.

THE PARTIES

2. Plaintiff TTI is a company organized under the laws of the State of Delaware with its principal place of business at 701 Centre Ave., Fort Collins, CO 80526.

3. TTI is the holder and owner of NDA Nos. 021379, 021488 and 021731 for Eligard® 22.5 mg, 30 mg, and 45 mg (leuprolide acetate) injectable. Tolmar's

Eligard (leuprolide acetate) injectable products are approved by the FDA for the treatment of advanced prostate cancer.

4. TTI is the owner and assignee of U.S. Patent No. 8,470,359 (the "'359 Patent"), which is listed in the FDA's publication Approved Drug Products With Therapeutic Equivalence Evaluations, also known as the "Orange Book" with respect to TTI NDA Nos. 021379, 021488 and 021731.

5. TPI is a company organized under the laws of the State of Delaware and has its principal place of business at 701 Centre Ave., Fort Collins, CO 80526. TPI is an exclusive licensee under the '359 Patent.

6. On information and belief, Defendant Foresee is a company organized under the laws of Taiwan with its principal place of business at 9F-2., No.19-3, Sanchong Rd., Nangang Dist., Taipei City 115, Taiwan.

7. On information and belief, Defendant Foresee is in the business of, among other things, developing, manufacturing, selling, marketing, and distributing drugs, including distributing, selling and marketing drugs in the United States, including within the state of New Jersey, through its own actions and the actions of its agents, subsidiaries and/or licensees, from which Foresee derives or will derive a substantial portion of its revenue.

8. On information and belief, Defendant Foresee engaged the services of third-party NDA Regulatory Development, Inc. ("NDA Regulatory") as a consultant

and US agent for the purposes of preparing and filing Foresee's NDA No. 211488. *See* Exhibit A, May 25, 2021 correspondence from FDA to Foresee c/o NDA Regulatory attention Judith Plon granting final approval of NDA No. 211488 ("FDA Approval Letter").

9. On information and belief, NDA Regulatory is in the business of providing drug and medical device consultancy services, supporting companies in their drug/device development, regulatory submissions and clinical requirements and serves as a US agent for foreign companies leading the preparation and submission of their NDAs. *See* https://ndareg.com/. On further information and belief, NDA Regulatory has a principal place of business at 209 Princeton South Corporate Center, Suite 340, Ewing, NJ 0828. Exhibit A (FDA Approval Letter); *see also* https://ndareg.com/about-nda/.

10. On information and belief, Defendant Accord is a company organized under the laws of the State of Delaware with its principal place of business at 1009 Slater Road, Suite 210, Durham, North Carolina 27703.

11. On information and belief, Defendant Accord is in the business of, among other things, developing, manufacturing, selling, marketing, and distributing pharmaceuticals in the United States, including within the state of New Jersey, through its own actions and the actions of its agents, subsidiaries and/or licensees,

from which Accord derives or will derive a substantial portion of its revenue. *See* https://www.accordhealthcare.us/company-profile.

12. On information and belief, Defendant Accord became the Applicant Holder of NDA No. 211488 in January, 2022. *See* Exhibit B, Excerpt of FDA's January 2022 *Additions/Deletions for Prescription Drug Product List*, showing Applicant Holder name change for Leuprolide mesylate (i.e., NDA No. 211488) from Foresee to Accord ("Excerpt of FDA's January 2022 Changes to Prescription Drug List"). *See also* Exhibit C, Current FDA Orange Book: Product Details for NDA No. 211488 showing Accord as current Applicant Holder as of March 30, 2022 ("Current FDA Orange Book Product Details for NDA No. 211488").

13. On information and belief, Defendant Accord is currently or will imminently be marketing, offering for sale, distributing, importing, and/or selling the Camcevi Product in the United States. *See* Exhibit D, Accord's Camcevi Website, under construction as of March 29, 2022 ("Accord's Camcevi Website – Under Construction"); *see also* Exhibit E, May 26, 2021 Press Release, *Accord BioPharma to Head the U.S. Commercialization* ("Accord Commercialization Press Release"); Exhibit F ("Accord's Camcevi Billing and Coding Guide"); *see also* https://www.camcevihcp.com.

14. On March 31, 2022, Defendant Accord announced the launch of the Camcevi Product in the United States. *See* *https://www.prnewswire.com/news-*

releases/accord-biopharma-announces-us-launch-for-camcevi-leuprolide-injection-emulsion-for-the-treatment-of-advanced-prostate-cancer-in-adults-301515068.html. Further, on information and belief, sales representatives of Defendant Accord have been actively calling on healthcare professionals throughout the United States, including in this Judicial District, to offer for sale and sell the Camcevi Product.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States of America and therefore this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

17. This Court has personal jurisdiction over Foresee because, upon information and belief, Foresee engaged third-party NDA Regulatory to prepare NDA No. 211488 and submit it to the FDA and to act as its US agent in the submission and subsequent FDA review of NDA No. 2111488. Exhibit A (FDA Approval Letter). On further information and belief, NDA No. 211488 was substantially prepared and filed with the FDA from NDA Regulatory's place of business at 200 Princeton South Corporate Center, Suite 340, Ewing, New Jersey 08628.

18. Further, this Court also has personal jurisdiction over Foresee because, among other things, on information and belief: (i) Foresee has filed NDA No. 211488 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sell, and/or importation of the product described in NDA No. 211488 in the United States, including in the state of New Jersey; (ii) Foresee will, through its wholly owned subsidiary and/or its wholly owned affiliate and/or through its licensee, market, distribute, offer for sale, sell, use, and/or import into the United States the product described in NDA No. 211488 in the United States, including the state of New Jersey, and will derive substantial revenue from such activity in the state of New Jersey. *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, the product described in NDA No. 211488 would, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located in New Jersey and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

19. On information and belief, Accord is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the Camcevi Product described in NDA No. 211488. *See* Exhibit D (Accord's Camcevi

Website – Under Construction); *see also* https://www.camcevihcp.com; *https://www.prnewswire.com/news-releases/accord-biopharma-announces-us-launch-for-camcevi-leuprolide-injection-emulsion-for-the-treatment-of-advanced-prostate-cancer-in-adults-301515068.html*.

20. On information and belief, Accord maintains extensive and systematic contacts with pharmaceutical retailers, wholesalers, and/or distributors in New Jersey providing for the distribution of Accord's products in the State of New Jersey, including in this Judicial District.

21. On information and belief, Accord regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey, including in this Judicial District. Further, on information and belief, sales representatives of Defendant Accord have been actively calling on healthcare professionals throughout the United States, including in this Judicial District, to offer for sale and sell the Camcevi Product. On information and belief, Accord derives substantial revenue from the sale of those products in New Jersey, including in this Judicial District, and will derive substantial revenue from the sale of the Camcevi Product in New Jersey, including in this Judicial District.

22. This Court has personal jurisdiction over Accord because Accord is the current Applicant Holder for NDA No. 211488 and, upon information and belief,

Accord has commenced, or will imminently engage in, the use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) in the United States, including the state of New Jersey. *See* Exhibit B (Excerpt of FDA's January 2022 Changes to Prescription Drug List); *see also* Exhibit C (Current FDA Orange Book Product Details for NDA No. 211488); Exhibit E (Accord Commercialization Press Release); https://www.camcevihcp.com; *https://www.prnewswire.com/news-releases/accord-biopharma-announces-us-launch-for-camcevi-leuprolide-injection-emulsion-for-the-treatment-of-advanced-prostate-cancer-in-adults-301515068.html*.

23. Further, this Court also has personal jurisdiction over Accord because, among other things, on information and belief: (i) Accord is the current Applicant Holder of NDA No. 211488, which has been approved for commercial manufacture, use, offer for sale, sell and/or importation of the product described in NDA No. 211488 in the United States, including in the state of New Jersey; (ii) Accord will either on its own, or through a wholly owned subsidiary and/or its wholly owned affiliate and/or through its licensee, market, distribute, offer for sale, sell, use, and/or import into the United States the product described in NDA No. 211488 in the United States, including the state of New Jersey, and will derive substantial revenue from such activity in the state of New Jersey. *See Acorda Therapeutics v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, the product

described in NDA No. 211488 will, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located in New Jersey and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey. *See* Exhibit F (Accord's Camcevi Billing and Coding Guide); *see also* Exhibit D (Accord's Camcevi Website – Under Construction); https://www.camcevihcp.com; *https://www.prnewswire.com/news-releases/accord-biopharma-announces-us-launch-for-camcevi-leuprolide-injection-emulsion-for-the-treatment-of-advanced-prostate-cancer-in-adults-301515068.html*.

24. For at least the above reasons (and additional reasons to be further developed through discovery if necessary), this Court has personal jurisdiction over Foresee and Accord.

BACKGROUND

25. TPI, through a license from its affiliate TTI, commercially markets, offers for sale and sells ELIGARD® (leuprolide acetate) for injectable suspension in the United States. ELIGARD® (leuprolide acetate) for injectable suspension is indicated for the treatment of advanced prostate cancer and is marketed and sold in four dosages: 7.5 mg (one month); 22.5 mg (three months); 30 mg (four months); and 45 mg (six months). *See* https://eligard.com/about-eligard/.

26. The ’359 Patent, entitled “Sustained Release Polymer” (Exhibit G hereto), was duly and legally issued on June 25, 2013. TTI is the owner and assignee of the ’359 Patent. TPI is an exclusive licensee under the ’359 Patent. The ’359 Patent is due to expire on October 15, 2023 and has been listed in connection with the 22.5 mg (three months), 30 mg (four months) and 45 mg (six months) ELIGARD® (leuprolide acetate) for injectable suspension products in the Orange Book.

27. The ’359 Patent discloses and claims a “novel polymer composition for use in a sustained release formulation comprising the composition being emplaced within the tissue of a patient suffering from a malcondition such as prostate cancer.” Exhibit G (’359 Patent) at col. 1, lines 15–21.

28. Claim 1 of the ’359 Patent recites:

> 1. A flowable composition for a controlled release formulation comprising
>
> an organic solvent,
>
> a medicament
>
> and a polymer of Formula
>
> HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH
>
> wherein:
>
> R^a is an alkane diradical comprising about 4 to about 8 carbons and is a residue of an alkane diol,

> P is a polymeric segment of repeating units of lactide, lactic, co(lactide-glycolide) or co(lactic-glycolic) moieties,
>
> the polymer is substantially insoluble in water and body fluid, the polymer has substantially no titratable carboxylic acid groups, and the polymer has a weight average molecular weight from about 10 kD to about 50 kD, and the polymer in neat form is a solid at ambient temperature,
>
> the organic solvent is a polar, aprotic organic solvent having at least some water solubility.

INFRINGEMENT BY DEFENDANTS

29. Foresee submitted NDA No. 211488 to the FDA on July 27, 2020. Exhibit A (FDA Approval Letter). NDA No. 211488 was submitted "pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") for CAMCEVI (leuprolide) injectable emulsion, for subcutaneous use." *Id.* NDA No. 211488 is indicated for the treatment of adult patients with advanced prostate cancer. *Id.*

30. NDA No. 211488 was approved by the FDA on May 25, 2021. A copy of the FDA Approval letter for NDA No. 211488 is attached hereto as Exhibit A (FDA Approval Letter).

31. In January 2022, Accord became the Applicant Holder of NDA No. 211488, as is now reflected in the FDA's Orange Book. *See* Exhibit B (Excerpt of FDA's January 2022 Changes to Prescription Drug List) at 2; *see also* Exhibit C (Current FDA Orange Book Product Details for NDA No. 211488).

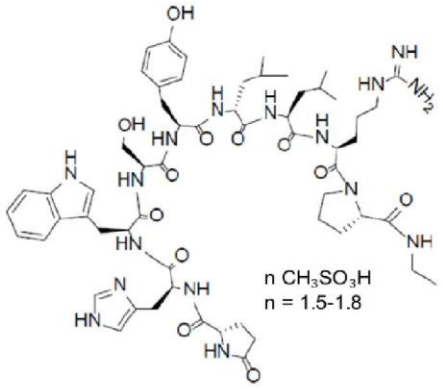
32. A copy of the Camcevi label submitted to, and approved by, the FDA in connection with NDA No. 211488 is attached hereto as Exhibit H (Camcevi Label).

33. The description of the Camcevi injectable product from the label approved by the FDA in connection with NDA No. 211488 is copied below:

11 DESCRIPTION

CAMCEVI is a sterile formulation of leuprolide mesylate for subcutaneous injection. CAMCEVI is designed to deliver approximately 42 mg of leuprolide over 6 months.

Leuprolide mesylate is a synthetic nonapeptide analog of naturally occurring GnRH and is a GnRH agonist. The analog possesses greater potency than the natural hormone. The chemical name is 5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-leucyl-L-leucyl-L-arginyl-N-ethyl-L-prolinamide mesylate (salt) with the following structural formula. The pH of 50 mg/mL solution of leuprolide mesylate in water is approximately 5.7.



CAMCEVI is supplied as a kit with a pre-filled, single-dose, sterile syringe for subcutaneous injection. Each pre-filled syringe delivers 42 mg leuprolide (equivalent to approximately 48 mg leuprolide mesylate), poly(D, L-lactide) (184 mg) polymer and *N*-methyl-2-pyrrolidone (136 mg).

Exhibit H (Camcevi Label) at Section 11.

34. The Camcevi injectable emulsion product described in NDA No. 211488 and the approved label ("Camcevi Product") is a flowable composition for a controlled release formulation and includes organic solvent (N-methyl-2-

pyrrolidone) and a medicament (leuprolide mesylate) as required by Claim 1 of the '359 Patent.

35. The Camcevi Product comprises leuprolide mesylate, which is a pharmaceutically acceptable salt of leuprolide. *Id.* at Section 3.

36. Each pre-filled syringe containing the Camcevi Product delivers 42 mg of leuprolide (equivalent to approximately 48 mg of leuprolide mesylate) over a period of six-months upon subcutaneous injection to a patient. Exhibit H (Camcevi Label). *Id.* at Sections 3, 11.

37. The Camcevi Product also includes a poly(D, L-lactide) polymer. On information and belief, the poly(D, L-lactide) polymer is synthesized from D, L-lactide monomers with a laurel alcohol initiator ($C_{12}H_{25}OH$). Thus, the poly(D, L-lactide) polymer contains a hydroxyl (–OH) end-group and an ester end-group.

38. The Camcevi Product meets the limitation of Claim 1 of the '359 Patent requiring a polymer having the formula HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH under the doctrine of equivalents. The poly(D, L-lactide) polymer used in the Camcevi Product is equivalent to the polymer in Claim 1 of the '359 Patent having the formula HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH.

39. Upon information and belief, the poly(D, L-lactide) polymer used in the Camcevi Product has the formula R^a—O(O=)C—(P)—OH, where R^a has the formula $C_{12}H_{25}$. This polymer has insubstantial differences from the polymer in

Claim 1 of the ’359 Patent which has the formula HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH.

40. The location of the R^a group—at the end of the polymer in the Camcevi Product compared to in the middle of the polymer in Claim 1—is an insubstantial difference in terms of the polymer formula. Given the number of polymeric repeating units, P, that make up both polymers, the R^a group in Claim 1 and the equivalent R^a group in the Camcevi Product both make up less than 1% of the overall polymer weight. This is an insubstantial difference.

41. The location of the R^a group has an insignificant impact, if any, on the relevant properties of the polymer, including solubility, molecular weight, solid phase, and the absence of carboxylic acid groups. Specifically, the ’359 Patent notes that “[t]he chemical neutrality of the polymer is an outstanding advantage of the invention in that no acidic groups are present in the polymer to bring about auto-catalytic degradation.” Exhibit G (’359 Patent) at col. 10, lines 3–8. The polymer in the Camcevi Product preserves the “outstanding advantage of the [’359 Patent] invention in that no acidic groups are present.” Thus, the polymer in the Camcevi Product has only insubstantial differences when compared to the polymer described in Claim 1.

42. The poly(D, L-lactide) polymer used in the Camcevi Product having the formula R^a—O(O=)C—(P)—OH, also provides the same function, in the same

way, to achieve the same result as the polymer in Claim 1 of the '359 Patent having the formula HO—(P)—C(=O)O—R^a—O(O=)C—(P)—OH.

43. Both the polymer in Claim 1 of the '359 Patent and the poly(D, L-lactide) polymer used in the Camcevi Product provide the same function—a matrix for the controlled release of a medicament—in the same way—by forming a substantially solid depot upon contact with body fluid—to achieve the same result—the long term delivery of a medicament. Indeed, the polymer in Claim 1 and that used in the Camcevi Product both degrade over time, allowing for the long-term delivery of a medicament.

44. The Camcevi Product meets the limitation of Claim 1 of the '359 Patent requiring a polymer having R^a, wherein "R^a is an alkane diradical comprising about 4 to about 8 carbons and is a residue of an alkane diol" under the doctrine of equivalents.

45. On information and belief, the poly(D, L-lactide) polymer used in the Camcevi Product is synthesized from D, L-lactide monomers using a lauryl alcohol initiator. During the synthesis, an –OH end-group from the lauryl alcohol initiator reacts with a carboxyl group of the D, L-lactide monomers. The result is a neutral polymer having a hydroxyl (–OH) end-group and an ester end-group. Accordingly, the R^a group in the polymer used in the Camcevi Product has the formula $C_{12}H_{25}$ and

is a residue of the lauryl alcohol initiator. This R^a group is equivalent to the claimed R^a group in the '359 Patent.

46. The R^a group in the polymer used in the Camcevi Product is insubstantially different that the R^a group described in Claim 1 of the '359 Patent. While the polymer used in the Camcevi Product has an R^a group containing 12 carbons, and the R^a group in Claim 1 of the '359 Patent requires about 4 to about 8 carbons, those differences are insubstantial. The R^a group makes up less than 1% of the overall polymer weight, so the addition of about 4 carbons is insubstantial to the function or structure of the R^a group in the claimed polymer formula. The R^a group in the Camcevi Product and the R^a group in Claim 1 of the '359 Patent are also similar chemically. Both R^a groups are alkyl alcohols, meaning they have fully saturated carbon atoms. As a result, both R^a groups react with the monomer to create a polymer without acidic groups.

47. The R^a group used in the Camcevi Product is derived from an alkane alcohol (i.e., lauryl alcohol having one hydroxyl group) instead of an alkane diol (having two hydroxyl groups) as described in Claim 1 of the '359 Patent. The use of an initiator having a single hydroxyl group results in the R^a group being located at the end of the polymer in the Camcevi Product compared to in the middle of the polymer in Claim 1. However, in the Camcevi Product, the end opposite the R^a group is identical to the end of the polymer described in Claim 1. Moreover, as described

above, the location of the R^a group has an insubstantial impact, if any, on the relevant properties of the polymer, including solubility, molecular weight, solid, phase, and the absence of acid groups. Specifically, the '359 Patent notes that "[t]he chemical neutrality of the polymer is an outstanding advantage of the invention in that no acidic groups are present in the polymer to bring about auto-catalytic degradation." Exhibit G ('359 Patent) at col. 10, lines 3–8. The use of an alkane alcohol (having one hydroxyl group) to initiate the polymer in the Camcevi Product preserves the "outstanding advantage of the ['359 Patent] invention in that no acidic groups are present." Thus, the R^a group in the polymer of the Camcevi Product has only insubstantial differences when compared to the R^a group in the polymer described in Claim 1 of the '359 Patent.

48. The R^a group in the polymer in the Camcevi Product also provides the same function, in the same way, to achieve the same result as the R^a group in the polymer described in Claim 1. Both R^a groups (i.e., the one in the Camcevi Product polymer and the one claimed in the '359 Patent) are the residue of the initiator for the polymerization reaction to form the polymer. The initiator in both instances initiates ring-opening polymerization by reaction of the hydroxyl group of the initiator with a carbonyl group of the monomer to form polymeric segments (P). And in both instances, the end result is a polymer with substantially no terminal carboxylic acid groups. In the case of the Camcevi Product, the resulting polymer

has an ester terminal group on one end and a hydroxyl terminal group on the other end, and substantially no terminal carboxylic acid groups.

49. The poly(D, L-lactide) polymer used in the Camcevi Product includes a polymeric segment of repeating units (P) of lactide as required by Claim 1 of the ’359 Patent.

50. The poly(D, L-lactide) polymer used in the Camcevi Product is substantially insoluble in water and body fluid as required by Claim 1 of the ’359 Patent.

51. Because the poly(D, L-lactide) polymer used in the Camcevi Product contains a hydroxyl (–OH) end-group and an ester end-group, it has substantially no titratable carboxylic acid groups as required by Claim 1 of the ’359 Patent.

52. On information and belief, the poly(D, L-lactide) polymer used in the Camcevi Product has an average molecular weight from about 10 kDa to about 50 kDa as required by Claim 1 of the ’359 Patent.

53. The poly(D, L-lactide) polymer used in the Camcevi Product in neat form is a solid at ambient temperature as required by Claim 1 of the ’359 Patent.

54. The organic solvent used in the Camcevi Product is N-methyl-2-pyrrolidone. Exhibit H (Camcevi Label) at Section 11. N-methyl-2-pyrrolidone is a polar, aprotic solvent having at least some water solubility as required by Claim 1 of the ’359 Patent.

55. The FDA approved labeling for Defendants' Camcevi Product encourages, recommends, instructs and/or actively promotes administration of the Camcevi Product via a subcutaneous injection into the body tissue of a patient suffering from advanced prostate cancer. Exhibit H (Camcevi Label) at Section 2.2; *see also* Exhibit I (Camcevi Instructions).

56. The purpose of the submission of NDA No. 211488 was to obtain approval under the FDCA for Defendants to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Camcevi Product by Defendants prior to the expiration of the '359 Patent. *See e.g.*, Exhibit D (Accord's Camcevi Website – Under Construction); Exhibit E (Accord Commercialization Press Release).

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY FORESEE UNDER 35 U.S.C. § 271(e)(2)

57. Tolmar incorporates each of the preceding paragraphs 1–56 as if fully set forth herein.

58. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and 35 U.S.C. § 271(e)(2).

59. Foresee's submission of NDA No. 211488 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Camcevi Product by Foresee prior to the expiration of the

'359 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A) and directly or indirectly infringes at least Claims 1, 4, 6, 8, and 11–16 of the '359 Patent under the doctrine of equivalents. In the event that Foresee commercially manufactures, uses, offers for sale, sells and/or imports the Camcevi Product in the United States, said actions would constitute infringement of the '359 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. The manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Foresee would directly or indirectly infringe at least Claims 1, 4, 6, 8, and 11–16 of the '359 Patent under the doctrine of equivalents.

61. On information and belief, Foresee will imminently engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488).

62. The foregoing actions by Foresee constitute and/or will constitute infringement of the '359 Patent.

63. On information and belief, Foresee has acted with full knowledge of the '359 Patent and without a reasonable basis for believing that it was not and/or would not be liable for infringing the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee).

64. Unless Foresee is enjoined from infringing the '359 Patent, Tolmar will suffer irreparable injury for which there is no adequate remedy at law.

COUNT II

DECLARATORY JUDGMENT FOR DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY FORESEE

65. Tolmar incorporates each of the preceding paragraphs 1–64 as if fully set forth herein.

66. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and 35 U.S.C. § 271(a).

67. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Foresee would directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the '359 Patent under the doctrine of equivalents.

68. On information and belief, Foresee has commenced, or will imminently engage in, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) in the United States.

69. On information and belief, Foresee has acted with full knowledge of the '359 Patent and without a reasonable basis for believing that it was not and/or

would not be liable for infringing the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee).

70. Accordingly, there is a real, substantial, and continuing case or controversy between Tolmar and Foresee regarding whether Foresee's manufacture, use, offer for sale, sale, marketing, distribution and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488) with its approved labeling will directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the '359 Patent under the doctrine of equivalents.

71. Tolmar should be granted a declaratory judgment that the making, using, sale, offer for sale, and/or importation into the United States of the Camcevi Product by Foresee with its approved labeling will directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the '359 Patent under the doctrine of equivalents.

72. Foresee should be enjoined from infringing the '359 Patent; otherwise Tolmar will suffer irreparable harm for which there is no adequate remedy at law.

COUNT III

DECLARATORY JUDGMENT FOR INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY FORESEE

73. Tolmar incorporates each of the preceding paragraphs 1–72 as if fully set forth herein.

74. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and 35 U.S.C. §§ 271(b) and (c).

75. On information and belief, the sale of the Camcevi Product by Foresee (as described and approved in NDA No. 211488) would actively induce infringement of Claims 13–15 of the '359 Patent under the doctrine of equivalents, by supplying with the Camcevi Product, approved labeling and instructions directing medical professionals and/or patients how to use the Camcevi Product, such as that recited by Claims 13–15 of the '359 Patent. *See* Exhibit H (Camcevi Label); *see also* Exhibit I (Camcevi Instructions).

76. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Foresee would contribute to the direct infringement at least Claims 13–15 of the '359 Patent under the doctrine of equivalents. Foresee has knowledge that the Camcevi Product is especially made and adapted for use by medical professionals and/or patients in a manner that would directly infringe Claims 13–15 of the '359 Patent. Foresee also has knowledge that the Camcevi Product lacks substantial non-infringing uses. *See* Exhibit H (Camcevi Label); *see also* Exhibit I (Camcevi Instructions).

77. On information and belief, Foresee has commenced, or will imminently engage in, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) in the United States.

78. On information and belief, Foresee has acted with full knowledge of (1) the existence of the '359 Patent; as well as (2) knowledge that that the induced acts would amount to patent infringement and/or would contribute to direct infringement of the '359 Patent. Foresee had this knowledge as of at least June 16, 2021 when Tolmar sent Foresee a letter notifying it of U.S. Patent No. 8,470,359 and claiming that Foresee's filing of NDA No. 211488 constituted infringement of the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee). Alternatively, Foresee had this knowledge since Tolmar filed its original Complaint in this action. *See* Dkt. No. 1. Further, Foresee knew of the existence of the '359 Patent when it listed the '359 Patent on an Information Disclosure Statement ("IDS") and submitted the IDS to the United States Patent & Trademark Office on April 5, 2019 during prosecution of Foresee's U.S. Patent No. 10,646,572 (which is listed in the FDA's Orange Book for the Camcevi Product). Exhibit K (Foresee's IDS identifying the '359 Patent).

79. Accordingly, there is a real, substantial, and continuing case or controversy between Tolmar and Foresee regarding whether Foresee's offer for sale,

sale, marketing, distribution and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488) with its approved labeling and instructions will actively induce infringement and/or will contribute to the direct infringement of Claims 13–15 of the '359 Patent under the doctrine of equivalents.

80. Tolmar should be granted a declaratory judgment that Foresee's sale, offer for sale, and/or importation of the Camcevi Product with its approved labeling and accompanying instructions for use, in the United States, will actively induce individuals such as medical professionals and/or patients to infringe Claims 13–15 of the '359 Patent under the doctrine of equivalents.

81. Tolmar should be granted a declaratory judgment that the sale, offer for sale, and/or importation into the United States of the Camcevi Product by Foresee will contribute to the direct infringement at least Claims 13–15 of the '359 Patent under the doctrine of equivalents.

82. Foresee should be enjoined from infringing the '359 Patent; otherwise Tolmar will suffer irreparable harm for which there is no adequate remedy at law.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY ACCORD UNDER 35 U.S.C. § 271(e)(2)

83. Tolmar incorporates each of the preceding paragraphs 1–82 as if fully set forth herein.

84. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and 35 U.S.C. § 271(e)(2).

85. On information and belief, Accord acquired the rights to NDA No. 211488 in January 2022 and is currently listed on the FDA's website as the Applicant Holder of NDA No. 211488. *See* Exhibit B (Excerpt of FDA's January 2022 Changes to Prescription Drug List); Exhibit C (Current FDA Orange Book Product Details for NDA No. 211488). Accord's act of becoming the current Applicant Holder of NDA No. 211488 for the purpose of the commercial manufacture, use, offer for sale, sale, and/or importation of the Camcevi Product by Accord prior to the expiration of the '359 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A) and directly or indirectly infringes at least Claims 1, 4, 6, 8, and 11–16 of the '359 Patent under the doctrine of equivalents. *See* Exhibit E (Accord Commercialization Press Release). In the event that Accord commercially manufactures, uses, offers for sale, sells and/or imports the Camcevi Product in the United States, said actions would constitute infringement of the '359 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

86. The manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Accord would directly or indirectly infringe at least Claims 1, 4, 6, 8, and 11–16 of the '359 Patent under the doctrine of equivalents.

87. On information and belief, Accord will imminently engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488). *See* Exhibit E (Accord Commercialization Press Release); Exhibit D (Accord's Camcevi Website – Under Construction).

88. The foregoing actions by Accord constitute and/or will constitute infringement of the '359 Patent.

89. On information and belief, Accord has acted with full knowledge of the '359 Patent and without a reasonable basis for believing that it was not and/or would not be liable for infringing the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee).

90. Unless Accord is enjoined from infringing the '359 Patent, Tolmar will suffer irreparable injury for which there is no adequate remedy at law.

COUNT V

DECLARATORY JUDGMENT FOR DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY ACCORD

91. Tolmar incorporates each of the preceding paragraphs 1–90 as if fully set forth herein.

92. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and 35 U.S.C. § 271(a).

93. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Accord would directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the '359 Patent under the doctrine of equivalents.

94. On information and belief, Accord has commenced, or will imminently engage in, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) in the United States. *See* Exhibit E (Accord Commercialization Press Release); *see also* Exhibit C (Current FDA Orange Book Product Details for NDA No. 211488); Exhibit F (Accord's Camcevi Billing and Coding Guide); Exhibit D (Accord's Camcevi Website – Under Construction).

95. On information and belief, Accord has acted with full knowledge of the '359 Patent and without a reasonable basis for believing that it was not and/or would not be liable for infringing the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee).

96. Accordingly, there is a real, substantial, and continuing case or controversy between Tolmar and Accord regarding whether Accord's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488) with

its approved labeling will directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the ’359 Patent under the doctrine of equivalents.

97. Tolmar should be granted a declaratory judgment that the making, using, sale, offer for sale, and/or importation into the United States of the Camcevi Product by Accord with its approved labeling will directly infringe at least Claims 1, 4, 6, 8, 11, 12, and 16 of the ’359 Patent under the doctrine of equivalents.

98. Accord should be enjoined from infringing the ’359 Patent; otherwise Tolmar will suffer irreparable harm for which there is no adequate remedy at law.

COUNT VI

DECLARATORY JUDGMENT FOR INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,470,359 BY ACCORD

99. Tolmar incorporates each of the preceding paragraphs 1–98 as if fully set forth herein.

100. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and 35 U.S.C. §§ 271(b) and (c).

101. On information and belief, the sale of the Camcevi Product by Accord (as described and approved in NDA No. 211488) would actively induce infringement of Claims 13–15 of the ’359 Patent under the doctrine of equivalents, by supplying with the Camcevi Product, approved labeling and instructions directing medical professionals and/or patients how to use the Camcevi Product, such as that

recited by Claims 13–15 of the '359 Patent. *See* Exhibit H (Camcevi Label); *see also* Exhibit I (Camcevi Instructions).

102. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) by Accord would contribute to the direct infringement at least Claims 13–15 of the '359 Patent under the doctrine of equivalents. Accord has knowledge that the Camcevi Product is especially made and adapted for use by medical professionals and/or patients in a manner that would directly infringe Claims 13–15 of the '359 Patent. Accord also has knowledge that the Camcevi Product lacks substantial non-infringing uses. *See* Exhibit H (Camcevi Label); *see also* Exhibit I (Camcevi Instructions).

103. On information and belief, Accord has commenced, or will imminently engage in, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Camcevi Product (as described and approved in NDA No. 211488) in the United States. *See* Exhibit E (Accord Commercialization Press Release); *see also* Exhibit F (Accord's Camcevi Billing and Coding Guide); Exhibit C (Current FDA Orange Book Product Details for NDA No. 211488); Exhibit D (Accord's Camcevi Website – Under Construction).

104. On information and belief, Accord has acted with full knowledge of (1) the existence of the '359 Patent; as well as (2) knowledge that that the induced acts

would amount to patent infringement and/or would contribute to direct infringement of the '359 Patent. On information and belief, Accord had this knowledge shortly after Tolmar sent Foresee a letter notifying it of U.S. Patent No. 8,470,359 and claiming that Foresee's filing of NDA No. 211488 constituted infringement of the '359 Patent. *See* Exhibit J (Tolmar's June 16, 2021 Notice Letter to Foresee). Alternatively, Accord had this knowledge since Tolmar filed its original Complaint in this action. *See* Dkt. No. 1.

105. Accordingly, there is a real, substantial, and continuing case or controversy between Tolmar and Accord regarding whether Accord's use, offer for sale, sale, marketing, distribution and/or importation into the United States of the Camcevi Product (as described and approved in NDA No. 211488) with its approved labeling and instructions will actively induce infringement and/or will contribute to the direct infringement of Claims 13–15 of the '359 Patent under the doctrine of equivalents.

106. Tolmar should be granted a declaratory judgment that Accord's use, sale, offer for sale, and/or importation of the Camcevi Product with its approved labeling and accompanying instructions for use, in the United States, will actively induce individuals such as medical professionals and/or patients to infringe Claims 13–15 of the '359 Patent under the doctrine of equivalents.

107. Tolmar should be granted a declaratory judgment that the use, sale, offer for sale, and/or importation into the United States of the Camcevi Product by Accord will contribute to the direct infringement at least Claims 13–15 of the '359 Patent under the doctrine of equivalents.

108. Accord should be enjoined from infringing the '359 Patent; otherwise Tolmar will suffer irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Tolmar requests the following relief:

(a) a judgment that Foresee has infringed and/or will infringe the '359 Patent under the doctrine of equivalents;

(b) a judgment that Accord has infringed and/or will infringe the '359 Patent under the doctrine of equivalents;

(c) a judgment that the asserted claims of the '359 Patent are valid and enforceable;

(d) a preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. §§ 271(a)–(c), (e)(4)(B), and 35 U.S.C. § 283 enjoining Defendants, its officers, agents, employees, and attorneys, and all persons working in concert with them from making, using, selling, offering for sale, marketing, distributing, and/or importing into the United States the Camcevi Product or any product of which the making, using, offering for sale, sale, marketing, distribution, and/or importation infringes the '359 Patent prior to the expiration date of the '359 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) a judgment declaring that making, using, selling, offering for sale, marketing, distributing, and/or importing the Camcevi Product, or any product the making, using, selling, offering for sale, marketing, distributing, and/or importation of which infringes the '359 Patent, prior to the expiration date of the '359 Patent;

(f) an award of Tolmar's damages or other monetary relief to compensate Tolmar in the event Defendants engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Camcevi Product, or any product the making, using, offering for sale, sale, marketing distribution, and/or importation of which infringes the '359 Patent prior to the expiration date of the '359 Patent, inclusive of any extension(s) and additional period(s) of exclusivity in accordance with 35 U.S.C. § 271(a)–(c) and (e)(4)(C);

(g) a declaration that this case against Defendants is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(h) a finding that Defendants' infringement is willful and that Tolmar is entitled to enhanced damages pursuant to 35 U.S.C. § 284;

(i) an award of Tolmar's costs and expenses in this action; and

(j) such further and other relief as this Court may deem just and proper.

Respectfully submitted,

Dated: April 4, 2022

/s/ *Eric I. Abraham*

Eric I. Abraham
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08543
Telephone: (609) 924-0808
Telecopier: (609) 452-1888
eabraham@hillwallack.com

Jeffrey R. Gargano
(admitted *pro hac vice*)
Melissa M. Haulcomb
(admitted *pro hac vice*)
K&L GATES LLP
70 W. Madison St., Suite 3300
Chicago, IL 60602
Telephone: (312) 372-1121
Fax: (312) 827-8000

jeffrey.gargano@klgates.com
melissa.haulcomb@klgates.com

Zachary D. Miller
(admitted *pro hac vice*)
Morgan, Lewis & Bockius LLP
110 North Wacker Drive
Chicago, IL 60606
(312) 324-1000
zachary.miller@ morganlewis.com

Attorneys for Plaintiffs Tolmar Therapeutics, Inc. and Tolmar Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above document was served on April 4, 2022 to all counsel of record via the Court's CM/ECF filing system.

Respectfully submitted,

By: /s/ *Eric I. Abraham*