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

PHARMACOSMOS A/S;)
PHARMACOSMOS HOLDING A/S;)
and PHARMACOSMOS)
THERAPEUTICS INC.,)
)
Plaintiffs,) C.A. No. 2:25-cv-03218 (JXN-AME)
)
V.)
)
TEVA PHARMACEUTICALS, INC. and TEVA) <i>Electronically Filed</i>
PHARMACEUTICALS USA, INC.)
)
Defendants.)

**DEFENDANTS TEVA PHARMACEUTICALS, INC. AND
TEVA PHARMACEUTICALS USA, INC.'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendants")¹, by its attorneys, files this Answer in response to the Complaint for Patent

¹ In accordance with Dkt. No. 14, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") has been dismissed by stipulation and order and is no longer a party to this action. Accordingly, all references herein to "Teva" generally should be understood to refer to only the two remaining Defendants Teva USA and Teva Inc., and to not include Teva Ltd.

Infringement (the “Complaint”) of Plaintiffs Pharmacosmos A/S (“Pharmacosmos”), Pharmacosmos Holding A/S (“Pharmacosmos Holding”), and Pharmacosmos Therapeutics Inc. (“Pharmacosmos Therapeutics”), (collectively, “Pharmacosmos” or “Plaintiffs”). Teva denies all allegations made in the Complaint that are not specifically admitted below.

ANSWER TO “NATURE OF THE ACTION”²

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 et seq., and in particular under 35 U.S.C §§ 271 (a–c, e–g). This action relates to the Abbreviated New Drug Application No. 219413 (“Teva’s ANDA”) filed or caused to be filed by Teva with the United States Food and Drug Administration (“FDA”) for approval to market a generic version of Pharmacosmos’ COSELA® (trilaciclib) for injection, intravenous drug product. Through Teva’s ANDA, Teva seeks approval to market a generic version of the pharmaceutical product COSELA® (trilaciclib) prior to the expiration of United States Patent Nos. 11,529,352 (the “‘352 patent”) and 12,168,666 (the “‘666 patent”). A true and correct copy of the ‘352 patent and the ‘666 patent are attached as Exhibits A and B respectively. Plaintiffs seek injunctive relief precluding infringement, attorneys’ fees, and any other relief the Court deems just and proper.

ANSWER: Teva admits that this is an action purporting to arise under the laws of the United States, 35 U.S.C. § 100, *et seq.*, and that Teva submitted ANDA No. 219413 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of United States Patent Nos. 11,529,352 (the “‘352 patent”) and 12,168,666 (the “‘666 patent”) (collectively, “the Patents-in-Suit”). Teva further admits that Exhibits A and B to the Complaint appear to be copies of the Patents-in-Suit. Teva denies that Plaintiffs are entitled to any relief whatsoever against Teva in this action. Teva otherwise denies the allegations contained in Paragraph 1.

ANSWER TO “THE PARTIES”

2. Plaintiff Pharmacosmos Holding A/S is a corporation organized and existing under the laws of Denmark and has a principal place of business at Roervangsvej 30, DK-4300 Holbaek, Denmark.

² Teva denies any allegation that may be implied or inferred from the headings of the Complaint.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. Plaintiff Pharmacosmos A/S is a corporation organized and existing under the laws of Denmark and has a principal place of business at Roervangsvej 30, DK-4300 Holbaek, Denmark. Pharmacosmos A/S is a wholly-owned subsidiary of Pharmacosmos Holding A/S.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore denies the same.

4. Plaintiff Pharmacosmos Therapeutics Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 120 Headquarters Plaza, East Tower, 6th Floor, Morristown, New Jersey 07960. Pharmacosmos Therapeutics Inc. is a wholly-owned subsidiary of Pharmacosmos A/S.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint and therefore denies the same.

5. On information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel and has a principal place of business at P.O. Box 3190, 124 Deborah Hanevi'a St., Tel Aviv 6944020 Israel.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

6. On information and belief, Defendant Teva Ltd., directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, markets, distributes, imports, offers for sale, and/or sells generic versions of branded pharmaceutical products throughout the United States, including in New Jersey.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

7. Teva Ltd.'s Securities and Exchange Commission Form 10-K filing for the fiscal year ending December 31, 2024 ("Teva Ltd. 10-k") states that it is "one of the leading generic pharmaceutical companies in the United States" and "market[s] approximately 500 generic

prescription products in more than 1,400 dosage strengths, packaging sizes and forms.” A true and correct copy of Teva Ltd. 10-k is attached as Exhibit C.

ANSWER: Teva admits that Teva Ltd.’s Form 10-K filing for the fiscal year ending December 31, 2024 states that Teva Ltd. is “one of the leading generic pharmaceutical companies in the United States” and “market[s] approximately 500 generic prescription products in more than 1,400 dosage strengths, packaging sizes and forms.” Teva further admits that Exhibit C to the Complaint appears to be a copy of Teva Ltd. 10-k. In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to the remaining allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

8. On information and belief, Defendant Teva Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in New Jersey at 400 Interpace Parkway #3, Parsippany, New Jersey 07054, as indicated on page 4 of its Paragraph IV Notice Letter. *See also Catalyst Pharms., Inc., et al. v. Teva Pharms., Inc., et al.*, No. 2:23-cv-1190 (D.N.J.) at ECF No. 13 ¶¶ 4-5 (admitting the same).

ANSWER: Teva admits that Teva Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. On information and belief, Teva Inc. is a wholly-owned subsidiary of Teva Ltd.

ANSWER: Teva admits that Teva, Inc. is an indirect, wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. Teva denies any remaining allegations in Paragraph 9.

10. On information and belief, Teva Inc. is registered with New Jersey’s Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

ANSWER: Teva admits that Teva Inc. is registered with New Jersey’s Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134. Teva denies any remaining allegations in Paragraph 10.

11. On information and belief, Teva Inc. develops, manufactures, markets, distributes, imports, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States, including in New Jersey.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 11.

12. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in New Jersey at 400 Interpace Parkway #3, Parsippany, New Jersey 07054. *See also Catalyst Pharms., Inc., et al. v. Teva Pharms., Inc., et al.*, No. 2:23-cv-1190 (D.N.J.) at ECF No. 13 ¶¶ 4-5 (admitting the same).

ANSWER: Teva admits that Teva USA is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in New Jersey at 400 Interpace Parkway, Parsippany, New Jersey 07054.

13. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

ANSWER: Teva admits that Teva USA is an indirect, wholly-owned subsidiary of Teva Ltd. Teva denies any remaining allegations in Paragraph 13.

14. On information and belief, Teva USA maintains a physical place of business in this District, in at least Parsippany, New Jersey. Teva USA's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* [*https://www.tevausa.com/contact-us/*](https://www.tevausa.com/contact-us/) (last accessed March 13, 2025).

ANSWER: Teva admits that Teva USA has a principal place of business in New Jersey at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva admits that Teva USA's website states that its "US headquarters" is located in Parsippany, New Jersey. Teva denies any remaining allegations in Paragraph 14.

15. On information and belief, Teva USA is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184.

ANSWER: Teva admits that Teva USA is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184. Teva denies any remaining allegations in Paragraph 15.

16. On information and belief, Teva USA is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration Nos. 5000583 and 5003436.

ANSWER: Teva admits that Teva USA is registered with New Jersey's Department of Health as a business operating in New Jersey under Registration Nos. 5000583 and 5003436. Teva denies any remaining allegations in Paragraph 16.

17. On information and belief, Teva USA develops, manufactures, markets, distributes, imports, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States, including in New Jersey.

ANSWER: Paragraph 17 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 17.

18. On information and belief, Teva Inc., in collaboration with Teva Ltd. and Teva USA, prepared and submitted Teva's ANDA and the three Teva entities continue to collaborate in seeking FDA approval of that application.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 18 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 18.

19. On information and belief, Teva Inc., in collaboration with Teva Ltd. and Teva USA, intend to commercially manufacture, market, offer for sale, and sell the product described in Teva's ANDA ("Teva's ANDA Product") throughout the United States, including in the State of New Jersey, in the event the FDA approves Teva's ANDA.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 19.

ANSWER TO "JURISDICTION AND VENUE"

20. This is a civil action for infringement of the '352 and '666 patents (collectively, "the patents-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*

ANSWER: Teva admits that the Complaint alleges infringement of the Patents-in-Suit. Teva further admits that this is an action purporting to arise under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.* Teva denies the remaining allegations contained in Paragraph 20.

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and/or 35 U.S.C. § 271.

ANSWER: Paragraph 21 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva does not contest subject matter jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 21.

22. Venue is proper in this Court as to Teva Ltd. under 28 U.S.C. § 1391(c)(3) because Teva Ltd. is a foreign corporation and may be sued in any judicial district in the United States where Teva Ltd. is subject to the court's personal jurisdiction. For reasons set forth below, Teva Ltd is subject to personal jurisdiction in this district.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations contained in Paragraph 22.

23. In addition, this Court has personal jurisdiction over Teva Ltd., and venue is proper as to Teva Ltd., at least because upon information and belief Teva Ltd.: (1) directs and/or controls Teva Inc. and/or Teva USA, which both have principal places of business and business addresses in New Jersey; (2) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiaries, agents, and/or alter egos; (3) maintains pervasive, continuous, and systematic contacts with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (4) on information and belief, derives substantial revenue from the sale of its products in New Jersey; and (5) on information and belief, intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute Teva's ANDA Product for which it seeks approval under Teva's ANDA, including throughout New Jersey.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations contained in Paragraph 23 of the Complaint.

24. This Court has personal jurisdiction over Teva Ltd. for at least the additional reason that it has availed itself of the legal protections of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g., Boehringer Ingelheim Pharms., Inc. et al. v. Teva Pharms. USA, Inc. et al.*, No. 3:17-cv-11510 (D.N.J.).

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations contained in Paragraph 24 of the Complaint.

25. Teva Ltd. has further availed itself of the jurisdiction of New Jersey by initiating litigation in this Judicial District. *See, e.g., Teva Pharms. USA, Inc. et al. v. Sandoz Inc. et al.*, No. 3:17-cv-00275 (D.N.J.); *Teva Pharms. USA, Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, No. 3:17-cv-00517 (D.N.J.); *Teva Pharms. Indus. Ltd. et al. v. Lupin Ltd. et al.*, No. 2:07-cv-00247 (D.N.J.).

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations contained in Paragraph 25 of the Complaint.

26. Alternatively, this Court may exercise jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Pharmacosmos' claims arise under federal law; (2) Teva Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Teva Ltd. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting numerous ANDAs to the FDA and manufacturing, importing, offering to sell, or selling generic pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations contained in Paragraph 26 of the Complaint.

27. Venue is proper in this Court as to Teva Inc. under 28 U.S.C. § 1400(b) because Teva Inc. resides in New Jersey, has committed acts of infringement in New Jersey, and has a regular and established place of business in this Judicial District. Teva Inc. served Teva's Paragraph IV Notice Letter, which indicated that Teva Inc. filed Teva's ANDA in New Jersey.

ANSWER: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. does not contest venue in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 27.

28. In addition, this Court has personal jurisdiction over Teva Inc., and venue is proper as to Teva Inc., because on information and belief, Teva Inc.: (1) submitted Teva's ANDA and served Teva's Paragraph IV Notice Letter in New Jersey; (2) has a principal place of business and business addresses in New Jersey; (3) has employees in the places of business that it maintains in New Jersey; (4) has customers in the state of New Jersey; (5) has purposely availed itself of the privilege of doing business in New Jersey, including securing a New Jersey Business Entity identification number (Registration No. 0450614134); (6) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in New Jersey; (7) directly or indirectly markets, distributes, and/or sells its generic

pharmaceutical products in New Jersey; (8) directly or indirectly maintains pervasive, continuous, and systematic contacts with New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distributing, and/or selling generic pharmaceutical products in New Jersey; (9) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey; and (10) on information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Teva's ANDA Product in New Jersey.

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 28.

29. This Court has personal jurisdiction over Teva Inc. at least because it has availed itself of the legal protections of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g., GW Rsch. Ltd. v. Teva Pharm., Inc. et al.*, No. 2:23-cv-3914 (D.N.J.); *Axsome Therapeutics, Inc. et al. v. Teva Pharms., Inc.*, No. 2:23-cv-1695 (D.N.J.); *Jazz Pharm. Ireland Ltd. v. Teva Pharms., Inc.*, No. 2:23-cv-1617 (D.N.J.); *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialties Ltd., et al.*, No. 2:23-cv-0926 (D.N.J.); *GW Rsch. Ltd. v. Teva Pharm., Inc. et al.*, No. 2:23-cv-0018 (D.N.J.); *Takeda Pharms. America, Inc. et al. v. Teva Pharms., Inc. et al.*, No. 2:22-cv-07454 (D.N.J.); *Evoke Pharma, Inc. v. Teva Pharms. Inc. et al.*, No. 1:22-cv-02019 (D.N.J.); *Horizon Therapeutics U.S. Holding LLC et al. v. Teva Pharms., Inc.*, No. 1:22-cv-01382 (D.N.J.).

ANSWER: Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 29.

30. Venue is proper in this Court as to Teva USA under 28 U.S.C. § 1400(b) because Teva USA resides in New Jersey, has committed acts of infringement in New Jersey, and has a regular and established place of business in this Judicial District.

ANSWER: Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva USA does not contest venue in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 30.

31. In addition, this Court has personal jurisdiction over Teva USA, and venue is proper as to Teva USA because, on information and belief, Teva USA: (1) has a principal place of business and business addresses in New Jersey; (2) has employees in the places of business that it maintains in New Jersey; (3) has customers in the state of New Jersey; (4) has purposely availed itself of the privilege of doing business in New Jersey, including securing New Jersey wholesale drug manufacturer and distributor licenses (Registration Nos. 5000583 and 5003436) and a New Jersey Business Entity identification number (Registration No. 0100250184); (5) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in New Jersey; (6) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical products in New Jersey; (7) directly or indirectly maintains pervasive, continuous, and systematic contacts with New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distributing, and/or selling generic pharmaceutical products in New Jersey; (8) enjoys substantial income from sales of its generic pharmaceutical products in New Jersey; and (9) on information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Teva's ANDA Product in New Jersey.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 31.

32. This Court has personal jurisdiction over Teva USA at least because it has availed itself of the legal protections of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g., Catalyst Pharm., Inc. et al. v. Teva Pharms., Inc. et al.*, No. 2:23-cv-1190 (D.N.J.); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialties Ltd. et al.*, No. 2:23-cv-0926 (D.N.J.); *Takeda Pharms. Am., Inc. et al. v. Teva Pharms., Inc. et al.*, No. 2:22-cv-07454 (D.N.J.); *Evoke Pharma, Inc. v. Teva Pharms., Inc. et al.*, No. 1:22-cv-02019 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. et al. v. Teva Pharms. USA, Inc. et al.*, No. 3:17-cv-11510 (D.N.J.).

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 32.

33. Teva USA has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g., Teva Branded Pharm. Prods. R&D, Inc. et al. v. Deva Holding A.S.*, No. 2:24-cv-04404 (D.N.J.); *Teva Pharms. USA, Inc. v. Amarin Pharma, Inc. et al.*, No. 3:24-cv-04341 (D.N.J.); *Teva Pharms. USA, Inc. v. Biogen Int'l GmbH*, No.

2:23-cv-02491 (D.N.J.); *Teva Pharm. USA, Inc. et al. v. Sandoz Inc. et al.*, No. 3:17-cv-00275 (D.N.J.); *Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, No. 3:17-cv-00517 (D.N.J.); *Teva Pharm. Indus. Ltd. and Teva Pharm. USA, Inc. v. Lupin Ltd. et al.*, No. 2:07-cv-00247 (D.N.J.).

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations contained in Paragraph 33.

34. On information and belief, Teva Ltd., Teva Inc., and Teva USA are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Teva's ANDA Product.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 34 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 34.

35. On information and belief, Teva Ltd., Teva Inc., and Teva USA are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Teva's ANDA Product.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 35 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva

USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 35.

36. On information and belief, Teva Inc., in collaboration with Teva Ltd. and Teva USA, filed or caused to be filed Teva's ANDA with the FDA.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 36 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 36.

37. On information and belief, Teva Inc. submitted Teva's ANDA in New Jersey, based on work performed in New Jersey in support for its ANDA filing. On information and belief, this work, including but not limited to providing details on bioequivalence testing, manufacturing processes and quality control measures, and communicating with the FDA concerning the ANDA submission, was performed by Teva Inc., in collaboration with Teva Ltd. and Teva USA, and comprises part of Teva's ANDA submission.

ANSWER: Teva admits that it submitted ANDA No. 219413 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial. In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 37 contains legal conclusions to which no response is required. To the extent that a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Teva denies any remaining allegations in Paragraph 37.

38. On information and belief, Teva Ltd. is the holder of the Drug Master File for trilaciclib that underlies Teva's ANDA submission.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

39. On information and belief, Teva Inc. taking actions in concert with Teva Ltd. and Teva USA which, among other things, led to the filing of Teva's ANDA and its maintaining of distribution channels, including in New Jersey, establishes that Teva will commercially manufacture, use, offer to sell, sell, and/or import Teva's ANDA Product throughout the United States, including in New Jersey, if granted approval.

ANSWER: Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Inc. and Teva USA do not contest personal jurisdiction in this judicial district for the purposes of this action. Further, in accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Teva denies any remaining allegations in Paragraph 39.

40. Teva Inc. sent Pharmacosmos a letter dated March 11, 2025 ("Teva's Paragraph IV Notice Letter") providing notice that Teva's ANDA contains a certification with respect to the '352 and '666 patents under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), stating that Teva Inc. had filed Teva's ANDA seeking approval from the FDA to commercially manufacture, use, market, or sell its 300 mg/vial generic trilaciclib product in the United States.

ANSWER: Teva admits that Teva sent a letter to Plaintiffs stating that Teva had submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva denies the remaining allegations in Paragraph 40.

41. Pharmacosmos received Teva's Paragraph IV Notice Letter in New Jersey on March 12, 2025.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint and therefore denies the same.

ANSWER TO “PHARMACOSMOS’ APPROVED COSELA® AND THE PATENTS-IN-SUIT”

42. Pharmacosmos A/S holds New Drug Application (“NDA”) No. 214200, which the FDA approved on February 12, 2021. The FDA also granted five years of regulatory exclusivity for a new chemical entity pursuant to 21 C.F.R. § 314.108, which expires on February 12, 2026. Pharmacosmos markets and sells intravenous products that are the subject of NDA No. 214200 in the United States under the brand name “COSELA®.”

ANSWER: Paragraph 42 contains legal conclusions to which no response is required. To the extent an answer is required, Teva admits that the FDA’s Orange Book identifies Pharmacosmos A/S as the purported holder of NDA No. 214200 under the brand name “COSELA®.” Plaintiffs caused the Patents-in-Suit to be listed in the Orange Book, and Teva denies that the Patents-in-Suit were properly listed. Teva otherwise denies the allegations in Paragraph 42.

43. COSELA® (trilaciclib) is a kinase inhibitor indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer. A true and correct copy of the prescribing information for COSELA® is attached as Exhibit D.

ANSWER: Paragraph 43 states legal conclusions to which no response is required, and the text of the current prescribing information for COSELA®, which is subject to change in the future, speaks for itself. Otherwise, denied.

44. The prescribing information for COSELA® instructs that COSELA® should be “administer[ed] as a 30-minute intravenous infusion completed no more than 4 hours prior to the start of chemotherapy on each day chemotherapy is administered,” and that “the interval between doses of COSELA on sequential days should not be greater than 28 hours.” Ex. D at Sections 1, 2.

ANSWER: Paragraph 44 states legal conclusions to which no response is required, and the text of the current prescribing information for COSELA®, which is subject to change in the future, speaks for itself. Otherwise, denied.

45. The prescribing information for COSELÀ® further details the platinum/etoposide-containing regimen of Study 1 (G1T28-05), the primary study supporting FDA approval of COSELÀ®. Ex. D at Sections 6, 14. For example, the prescribing information for COSELÀ® details that “Study 1 (G1T28-05) was a randomized (1:1), double-blind, placebo-controlled study of COSELÀ or placebo administered prior to treatment with etoposide, carboplatin, and atezolizumab (E/P/A) for patients with newly diagnosed ES-SCLC not previously treated with chemotherapy,” and that, in the COSELÀ® treatment group, “Carboplatin (AUC 5) and atezolizumab (1200 mg) were administered on Day 1 and etoposide (100 mg/m²) and COSELÀ (240 mg/m²) ... were administered on Days 1, 2, and 3 of a 21-day cycle for a maximum of 4 cycles (induction). After induction, maintenance atezolizumab (1200 mg) monotherapy on Day 1 of a 21-day cycle continued until disease progression or unacceptable toxicity.” Ex. D at Section 14; *see also id.* at Section 6 (“Study 1 (G1T28-05; NCT03041311) was an international, randomized (1:1), double-blind, placebo-controlled study of COSELÀ or placebo administered prior to treatment with etoposide, carboplatin, and atezolizumab (E/P/A) for patients with newly diagnosed ES-SCLC not previously treated with chemotherapy.”).

ANSWER: Paragraph 45 states legal conclusions to which no response is required, and the text of the current prescribing information for COSELÀ®, which is subject to change in the future, speaks for itself. Otherwise, denied.

46. The prescribing information for COSELÀ® further discloses that Study 1 “demonstrated a statistically significantly shorter duration of severe neutropenia (DSN) in Cycle 1 (0 vs 4 days) and a lower proportion of patients with severe neutropenia (SN) (2% vs 49%) in patients receiving COSELÀ compared with placebo (Table 5).” *Id.* at Section 14.

ANSWER: Paragraph 46 states legal conclusions to which no response is required, and the text of the current prescribing information for COSELÀ®, which is subject to change in the future, speaks for itself. Otherwise, denied.

47. On information and belief, the platinum/etoposide-containing regimen of Study 1 reflects the standard of care for treating patients with ES-SCLC, which requires administration of a platinum/etoposide-containing regimen comprising platinum/etoposide chemotherapy (*e.g.*, carboplatin and etoposide) and an immune checkpoint inhibitor (*e.g.*, atezolizumab) administered in an induction phase and a maintenance phase.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint and therefore denies the same.

48. Pursuant to 21 U.S.C. § 355(b)(1), the '352 and '666 patents are listed in the FDA's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the “Orange Book”) as covering COSELÀ®.

ANSWER: Paragraph 48 contains legal conclusions to which no response is required. To the extent a response is required, Teva admits that the Patents-in-Suit are listed in the Orange Book with respect to COSELÀ®. Plaintiffs caused the Patents-in-Suit to be listed in the Orange Book, and Teva denies that the Patents-in-Suit were properly listed. Teva otherwise denies the remaining allegations in Paragraph 48.

49. The '352 patent was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on December 20, 2022 and is titled "Preservation of Immune Response During Chemotherapy Regimens." Ex. A. The '352 patent will expire on July 23, 2039.

ANSWER: Teva admits that Exhibit A to the Complaint appears to be a copy of U.S. Patent No. 11,529,352 (the "'352 patent"), which indicates on its face an issue date of December 20, 2022. Teva further admits that the '352 patent is titled "Preservation of Immune Response During Chemotherapy Regimens." Teva denies any remaining allegations in Paragraph 49.

50. The '666 patent was duly and legally issued by the USPTO on December 17, 2024 and is titled "Morphic Forms of Trilaciclib And Methods of Manufacture Thereof." Ex. B. The '666 patent will expire on November 13, 2040.

ANSWER: Teva admits that Exhibit B to the Complaint appears to be a copy of U.S. Patent No. 12,168,666 (the "'666 patent"), which indicates on its face an issue date of December 17, 2024. Teva further admits that the '666 patent is titled "Morphic Forms of Trilaciclib And Methods of Manufacture Thereof." Teva denies any remaining allegations in Paragraph 50.

51. Pharmacosmos Holding A/S is the assignee of the '352 and '666 patents.

ANSWER: Teva admits G1 Therapeutics, Inc. is listed on the face of the Patents-in-Suit as the assignee. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 51 of the Complaint and therefore denies the same.

52. Pharmacosmos Therapeutics Inc. holds an exclusive license under the '352 and '666 patents to commercialize COSELÀ® in the United States.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint and therefore denies the same.

ANSWER TO “TEVA’S ANDA AND NOTICE LETTER”

53. On information and belief, Teva submitted its ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Teva’s ANDA Product as a purported generic version of COSELAR® prior to the expiration of the ’352 and ’666 patents. On information and belief, Teva’s ANDA contains a Paragraph IV Certification with respect to the ’352 and ’666 patents.

ANSWER: Paragraph 53 contains legal conclusions to which no response is required. To the extent that a response is required, Teva admits that it submitted ANDA No. 219413 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva’s ANDA speaks for itself. Teva denies any remaining allegations in Paragraph 53.

54. Pharmacosmos Therapeutics Inc. received Teva’s Paragraph IV Notice Letter in New Jersey on March 12, 2025. In its Paragraph IV Notice Letter, Teva Inc. represented that Teva’s ANDA included Paragraph IV Certifications with respect to the ’352 and ’666 patents, and that Teva Inc. is seeking approval to engage in the commercial manufacture, use, or sale of its ANDA Product prior to the expiration of the ’352 and ’666 patents. According to Teva’s Paragraph IV Notice Letter, Teva’s ANDA Product contains trilaciclib.

ANSWER: Teva admits that Teva sent a letter to Plaintiffs stating that Teva had submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva’s letter speaks for itself. Teva denies any remaining allegations in Paragraph 54.

55. Teva’s Paragraph IV Notice Letter purported to contain a “Detailed Factual And Legal Basis For Its Paragraph IV Certification That U.S. Patent Nos. 11,529,352 and 12,168,666 Are Invalid, Unenforceable And/Or Not Infringed” (“Detailed Statement”).

ANSWER: Teva admits that Teva sent a letter to Plaintiffs stating that Teva had submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva's letter speaks for itself. Teva denies any remaining allegations in Paragraph 55.

56. Teva's Detailed Statement alleged that the '352 and '666 patents will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product. Teva's Paragraph IV Notice Letter did not allege that the '352 or '666 patent is invalid.

ANSWER: Teva admits that Teva sent a letter to Plaintiffs stating that Teva had submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva's letter speaks for itself. Teva denies any remaining allegations in Paragraph 56.

57. Teva's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Teva confidential information regarding Teva's ANDA Product. Plaintiffs requested that Teva revise its purported OCA. Pharmacosmos and Teva came to an agreement as to the terms of an OCA on March 28, 2025. Pharmacosmos requested access to Teva's ANDA on March 28, 2025. Teva provided access to Modules 1, 2, and 3 of Teva's ANDA on March 31, 2025.

ANSWER: Teva admits that Teva sent a letter to Plaintiffs stating that Teva had submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva's letter speaks for itself. Further, Teva admits that Teva provided access to Modules 1, 2, and 3 of Teva's ANDA on or about March 31, 2025. Teva denies any remaining allegations in Paragraph 57.

58. On information and belief, Teva Inc., in collaboration with Teva Ltd. and Teva USA, has participated in the preparation and submission of Teva's ANDA, has provided material support

to the preparation and submission of Teva's ANDA, and intends to support the further prosecution of Teva's ANDA.

ANSWER: In accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis. Further, Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 58.

59. On information and belief, if the FDA approves Teva's ANDA, Teva will manufacture, offer for sale, or sell its ANDA Product within the United States, including within New Jersey, or will import its ANDA Product into the United States, including New Jersey.

ANSWER: Paragraph 59 contains legal conclusions to which no response is required. To the extend an answer is required, Teva denies the allegations contained in Paragraph 59.

60. On information and belief, if the FDA approves Teva's ANDA, Teva will actively induce or contribute to the manufacture, use, offer for sale, or sale of its ANDA Product.

ANSWER: Paragraph 60 contains legal conclusions to which no response is required. To the extend an answer is required, Teva denies the allegations contained in Paragraph 60.

61. Pharmacosmos is commencing this action within 45 days of the date of receipt of Teva's Paragraph IV Notice Letter in accordance with the time frame for filing such a suit established by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 61 of the Complaint and therefore denies them.

ANSWER TO "COUNT I INFRINGEMENT OF THE '352 PATENT BY TEVA"

62. The allegations of paragraphs 1-61 above are repeated and re-alleged as if set forth fully herein.

ANSWER: Teva repeats and incorporates by reference its answers to Paragraphs 1-61 of the Complaint as fully set forth herein.

63. On information and belief, Teva has submitted or caused the submission of Teva's ANDA to FDA, and continues to seek FDA approval of Teva's ANDA.

ANSWER: Paragraph 63 contains legal conclusions to which no response is required. To the extent a response is required, Teva admits that it submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva denies any remaining allegations contained in Paragraph 63.

64. Teva has infringed the '352 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Teva's ANDA with a Paragraph IV certification and seeking FDA approval of Teva's ANDA prior to the expiration of the '352 patent.

ANSWER: Paragraph 64 contains legal conclusions to which no response is required. To the extent an answer is required, Teva denies the allegations contained in Paragraph 64.

65. Teva Ltd., Teva Inc., and Teva USA are jointly and severally liable for any infringement of the '352 patent because, on information and belief, Teva Ltd., Teva Inc., and Teva USA actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of Teva's ANDA and its accompanying Paragraph IV Certification directed to the '352 patent to the FDA.

ANSWER: Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 65. Further, in accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

66. On information and belief, Teva's ANDA Product will be accompanied by a label containing clinical study information, prescribing information, and other instructions ("Teva's ANDA Product Labeling").

ANSWER: Teva's ANDA speaks for itself. Further, Paragraph 66 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 66.

67. On information and belief Teva's ANDA Product Labeling will be substantially identical to the prescribing information for COSELAR® (Ex. D).

ANSWER: Teva's ANDA speaks for itself. Further, Paragraph 67 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 67.

68. On information and belief, physicians will follow the instructions on Teva's ANDA Product Labeling when administering Teva's ANDA Product.

ANSWER: Paragraph 68 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 68.

69. On information and belief, the use of Teva's ANDA Product in accordance with and as directed by Teva's ANDA Product Labeling will infringe one or more claims of the '352 patent.

ANSWER: Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 69.

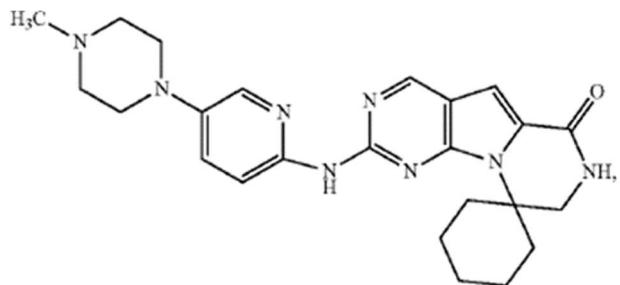
70. As an example, claim 1 of the '352 patent recites:

A method of treating a human having cancer comprising administering to the human a therapeutic regimen comprising a) an induction phase and b) a maintenance phase,

a) the induction phase comprising:

i) administering to the human an effective amount of a selective

Cyclin Dependent Kinase 4/6 (CDK4/6) inhibitor of structure:



or a pharmaceutically acceptable salt thereof,

i) administering to the human an effective amount of a chemotherapeutic agent, and

ii) administering to the human an effective amount of an immune checkpoint inhibitor, wherein, during the induction phase, the CDK4/6 inhibitor is only administered 24 hours or less prior to the administration of the chemotherapeutic agent, and wherein the chemotherapeutic agent is cytotoxic to immune effector cells;

b) the maintenance phase comprising:

i) administering to the human at least one dose of an effective amount of the immune checkpoint inhibitor, and

wherein the maintenance phase is administered following the cessation of the induction phase.

ANSWER: Teva admits that claim 1 of the '352 patent contains the quoted language.

Teva otherwise denies the allegations contained in Paragraph 70.

71. On information and belief, the use of Teva's ANDA Product in accordance with and as directed by Teva's ANDA Product Labeling will involve treating a human having cancer in accordance with the method recited in claim 1.

ANSWER: Paragraph 71 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 71.

72. On information and belief, Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product immediately and imminently upon approval of its ANDA.

ANSWER: Paragraph 72 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 72.

73. On information and belief, the manufacture, use, sale, offer for sale, or importation of Teva's ANDA Product will infringe one or more claims of the '352 patent.

ANSWER: Paragraph 73 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 73.

74. On information and belief, the manufacture, use, sale, offer for sale, or importation of Teva's ANDA Product in accordance with and as directed by Teva's ANDA Product Labeling will infringe one or more claims of the '352 patent.

ANSWER: Paragraph 74 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 74.

75. On information and belief, Teva plans and intends to, and will, actively induce infringement of one or more claims of the '352 patent when Teva's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Teva's activities will be done with knowledge of the '352 patent and specific intent to infringe that patent.

ANSWER: Paragraph 75 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 75.

76. On information and belief, physicians who act according to Teva's ANDA Product Labeling will infringe one or more claims of the '352 patent.

ANSWER: Paragraph 76 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 76.

77. On information and belief, Teva knows, should know, or is willfully blind to the fact that physicians who act according to Teva's ANDA Product Labeling will infringe one or more claims of the '352 patent, and Teva has the specific intent to actively encourage physicians to infringe one or more claims of the '352 patent as evident, *e.g.*, by Teva's ANDA Product Labeling and information submitted with Teva's ANDA.

ANSWER: Paragraph 77 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 77.

78. On information and belief, Teva knows that Teva's ANDA Product and Teva's ANDA Product Labeling are especially made or adapted for use in infringing the '352 patent, that Teva's ANDA Product is not a staple article or commodity of commerce, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Teva plans and intends to, and will, contribute to infringement of the '352 patent immediately and imminently upon approval of Teva's ANDA.

ANSWER: Paragraph 78 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 78.

79. Notwithstanding Teva's knowledge of the claims of the '352 patent, Teva has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Teva's ANDA Product with its product labeling following FDA approval of Teva's ANDA prior to the expiration of the '352 patent.

ANSWER: Teva admits that it is seeking FDA approval of its ANDA. Teva further admits it was aware of the '352 patent as of the filing of its ANDA. Teva denies the remaining allegations contained in Paragraph 79.

80. The foregoing actions by Teva constitute and/or will constitute infringement of the '352 patent, active inducement of infringement of the '352 patent, and/or contribution to the infringement by others of the '352 patent.

ANSWER: Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 80.

81. On information and belief, Teva has acted with full knowledge of the '352 patent and without a reasonable basis for believing that it would not be liable for infringement of the '352 patent, active inducement of infringement of the '352 patent, and/or contribution to the infringement by others of the '352 patent.

ANSWER: Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 81.

82. On information and belief, Teva has acted with full knowledge of the '352 patent and without a reasonable basis for believing that it would not be liable for infringement of the '352 patent, active inducement of infringement of the '352 patent, and/or contribution to the infringement by others of the '352 patent.

ANSWER: Paragraph 82 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 82.

83. Pharmacosmos will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '352 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 83.

84. The submission of Teva's ANDA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import into the United States of Teva's ANDA Product before the expiration of the '352 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Paragraph 84 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 84.

ANSWER TO "COUNT II INFRINGEMENT OF THE '666 PATENT BY TEVA"

85. The allegations of paragraphs 1-84 above are repeated and re-alleged as if set forth fully herein.

ANSWER: Teva repeats and incorporates by reference its answers to Paragraphs 1-84 of the Complaint as fully set forth herein.

86. On information and belief, Teva has submitted or caused the submission of Teva's ANDA to FDA, and continues to seek FDA approval of the Teva ANDA.

ANSWER: Paragraph 86 contains legal conclusions to which no response is required.

To the extent a response is required, Teva admits that it submitted ANDA No. 219413 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of trilaciclib for injection, 300 mg/vial before the expiration of the Patents-in-Suit. Teva denies any remaining allegations contained in Paragraph 86.

87. Teva has infringed the '666 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Teva's ANDA with a Paragraph IV certification and seeking FDA approval of Teva's ANDA prior to the expiration of the '666 patent.

ANSWER: Paragraph 87 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 87.

88. Teva Ltd., Teva Inc., and Teva USA are jointly and severally liable for any infringement of the '666 patent because, on information and belief, Teva Ltd., Teva Inc., and Teva USA actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of Teva's ANDA and its accompanying Paragraph IV Certification directed to the '666 patent to the FDA.

ANSWER: Paragraph 88 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 88. Further, in accordance with Dkt. No. 14, all claims against Teva Pharmaceutical Industries Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and they are also therefore denied on that basis.

89. On information and belief, if Teva's ANDA is approved, Teva and its affiliates will immediately make, sell, offer for sale, or otherwise distribute Teva's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '666 patent.

ANSWER: Paragraph 89 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 89.

90. Teva's commercial manufacture, use sale, or offer for sale, and/or importation into the United States of Teva's ANDA Product will actively induce and/or contribute to the infringement of the '666 patent.

ANSWER: Paragraph 90 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 90.

91. Unless enjoined by this Court, upon approval of ANDA No. 219413, Teva will make, use, offer to sell, or sell Teva's ANDA Product within the United States, or will import Teva's ANDA Product into the United States, and will thereby contribute to the infringement and/or induce the infringement of one or more claims of the '666 patent.

ANSWER: Paragraph 91 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 91.

92. On information and belief, Teva has acted with full knowledge of the '666 patent and without a reasonable basis for believing that it would not be liable for infringement of the '666 patent, active inducement of infringement of the '666 patent, and/or contribution to the infringement by others of the '666 patent.

ANSWER: Paragraph 92 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 92.

93. Teva's Detailed Statement in Teva's Paragraph IV Notice Letter lacks sufficient contention that Teva's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '666 patent.

ANSWER: Paragraph 93 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 93.

94. Pharmacosmos will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '666 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Paragraph 94 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 94.

95. The submission of Teva's ANDA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import into the United States of Teva's ANDA Product before the expiration of the '666 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Paragraph 95 contains legal conclusions to which no response is required.

To the extent a response is required, Teva denies the allegations contained in Paragraph 95.

ANSWER TO "PRAYER FOR RELIEF"

With respect to Plaintiffs' prayer for relief, Teva denies that Plaintiffs are entitled to the judgment and relief requested in Paragraphs A-G of the Prayer for Relief.

AFFIRMATIVE DEFENSES

Teva asserts the following defenses in response to the allegations in the Complaint. Teva expressly reserves the right to assert any other defenses that may now exist or in the future may be available based on the discovery and further factual investigation in this case. Assertion of a defense is not a concession that Teva has the burden of proving the matter asserted.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of the '352 Patent)

Defendants have not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '352 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity, Unenforceability of the '352 Patent)

The claims of the '352 patent are invalid and/or unenforceable for failing to comply with one or more requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement of the '666 Patent)

Defendants have not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '666 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity, Unenforceability of the '666 Patent)

The claims of the '666 patent are invalid and/or unenforceable for failing to comply with one or more requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Costs)

Upon information and belief, Plaintiffs are barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

SIXTH AFFIRMATIVE DEFENSE
(Adequate Remedy at Law, No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief at least because any alleged injury to Plaintiffs is not immediate or irreparable, Plaintiffs have an adequate remedy at law, and/or public policy concerns weigh against any injunctive relief.

SEVENTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

With respect to each purported claim for relief alleged in the Complaint, Plaintiffs fail to allege facts sufficient to state a claim against Teva upon which relief may be granted.

EIGHTH AFFIRMATIVE DEFENSE
(Equitable Defenses)

Plaintiffs' claims, in whole or in part, are barred by equitable doctrines including, but not limited to, waiver, equitable estoppel, judicial estoppel, disclaimer, acquiescence, patent misuse, and/or unclean hands.

NINTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Teva reserves the right to add to or amend this list of Affirmative Defenses with additional defenses that discovery may yield.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiffs Pharmacosmos A/S (“Pharmacosmos”), Pharmacosmos Holding A/S (“Pharmacosmos Holding”), and Pharmacosmos Therapeutics Inc. (“Pharmacosmos Therapeutics”), (collectively, “Pharmacosmos” or “Counterclaim Defendants”) other than those expressly admitted herein, and without prejudice to the right of Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”

or “Counterclaim Plaintiffs”) to plead additional Counterclaims as the facts of the matter warrant, Teva hereby asserts the following Counterclaims against Pharmacosmos.

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that Abbreviated New Drug Application (“ANDA”) No. 219413 seeking approval to engage in the commercial manufacture, use or sale of trilaciclib for injection, 300 mg/vial (“Teva’s Proposed Product”) does not infringe any valid and enforceable claim of United States Patent Nos. 11,529,352 (the “’352 patent”) and 12,168,666 (the “’666 patent”), (collectively, the “Patents-in-Suit”); that Teva’s manufacture, use, offer to sell, sale, and/or importation into the United States, of Teva’s Proposed Product, will not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents; and that each and every claim of the Patents-in-Suit is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

THE PARTIES

2. Teva Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

3. Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

4. Upon information and belief and based on the allegations in the Complaint, Pharmacosmos Holding A/S is a corporation organized and existing under the laws of Denmark and has a principal place of business at Roervangsvej 30, DK-4300 Holbaek, Denmark.

5. Upon information and belief and based on the allegations in the Complaint, Pharmacosmos A/S is a corporation organized and existing under the laws of Denmark and has a

principal place of business at Roervangsvej 30, DK-4300 Holbaek, Denmark. Pharmacosmos A/S is a wholly-owned subsidiary of Pharmacosmos Holding A/S.

6. Upon information and belief and based on the allegations in the Complaint, Pharmacosmos Therapeutics Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 120 Headquarters Plaza, East Tower, 6th Floor, Morristown, New Jersey 07960. Pharmacosmos Therapeutics Inc. is a wholly-owned subsidiary of Pharmacosmos A/S.

JURISDICTION AND VENUE

7. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Pharmacosmos Holding A/S and Pharmacosmos A/S because each Pharmacosmos Counterclaim Defendant has availed itself of the legal protections of the protections of the State of New Jersey by initiating and prosecuting this action, and by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Pharmacosmos has filed suit in this case, and has voluntarily submitted to the jurisdiction of the Court in this matter.

FACTUAL BACKGROUND

10. According to the United States Food & Drug Administration (“FDA”) publication entitled “Approved Drug Products and Therapeutic Equivalence Evaluations” (the “Orange

Book”), Pharmacosmos A/S holds approved New Drug Application (“NDA”) No. 214200 for intravenous trilaciclib under the brand name COSELA®.

11. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

12. Upon information and belief, Pharmacosmos Holding A/S purports to be the assignee of the Patents-in-Suit.

13. Upon information and belief and based on the allegations in the Complaint, Pharmacosmos Therapeutics Inc. holds an exclusive license under the '352 and '666 patents to commercialize COSELA® in the United States.

14. Upon information and belief, one or more of the Pharmacosmos Counterclaim Defendants caused the Patents-in-Suit to be listed in the Orange Book as patents that purport to cover COSELA® or methods of using COSELA®.

15. Teva submitted ANDA No. 219413 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Teva's Proposed Product prior to the expiration of the Patents-in-Suit.

16. On or around April 24, 2025, Pharmacosmos filed this lawsuit alleging that Teva infringes the Patents-in-Suit.

**COUNT 1
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,529,352)**

17. Teva realleges and incorporates by reference the allegations in Paragraphs 1-16 of these Counterclaims as fully set forth herein.

18. There is an actual, substantial, continuing, and justiciable controversy between Teva and Pharmacosmos regarding the invalidity of the '352 patent based on Pharmacosmos' allegations in its Complaint that Teva has infringed or will infringe the '352 patent.

19. Each and every claim of the '352 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

20. The alleged invention of the '352 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicants for the patent.

21. The alleged invention of the '352 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

22. The '352 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

23. The alleged invention of the '352 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '352 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '352 patent and would have had a reasonable expectation of success in doing so.

24. The subject matter claimed in the '352 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior

art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

25. The '352 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

26. The '352 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

27. The claims of the '352 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter which the named inventors regard as their invention, as required by 35 U.S.C. § 112.

28. Teva is entitled to a judicial declaration that all claims of the '352 patent are invalid.

COUNT 2
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,529,352)

29. Teva realleges and incorporates by reference the allegations in Paragraphs 1-28 of these Counterclaims as if fully set forth herein.

30. There is an actual, substantial, continuing, and justiciable controversy between Teva and Pharmacosmos regarding whether Teva's submission of ANDA No. 219413 and/or Teva's manufacture, use, offer to sell, sale, and/or importation into the United States of trilaciclib

for injection, 300 mg/vial, has infringed, or will infringe any valid and enforceable claim of the '352 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

31. Teva has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '352 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

32. Teva is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '352 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of trilaciclib for injection, 300 mg/vial, has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '352 patent.

COUNT 3
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,168,666)

33. Teva realleges and incorporates by reference Paragraphs 1-32 of these Counterclaims as if fully set forth herein.

34. There is an actual, substantial, continuing, and justiciable controversy between Teva and Pharmacosmos regarding the invalidity of the '666 patent based on Pharmacosmos' allegations in its Complaint that Teva has infringed or will infringe the '666 patent.

35. Each and every claim of the '666 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

36. The alleged invention of the '666 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicants for the patent.

37. The alleged invention of the '666 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

38. The '666 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

39. The alleged invention of the '666 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '666 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '666 patent and would have had a reasonable expectation of success in doing so.

40. The subject matter claimed in the '666 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

41. The '666 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

42. The '666 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

43. The claims of the '666 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter which the named inventors regard as their invention, as required by 35 U.S.C. § 112.

44. Teva is entitled to a judicial declaration that all claims of the '666 patent are invalid.

**COUNT 4
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,168,666)**

45. Teva realleges and incorporates by reference the allegations in Paragraphs 1-44 of these Counterclaims as if fully set forth herein.

46. There is an actual, substantial, continuing, and justiciable controversy between Teva and Pharmacosmos regarding whether Teva's submission of ANDA No. 219413 and/or Teva's manufacture, use, offer to sell, sale, and/or importation into the United States of trilaciclib for injection, 300 mg/vial, has infringed, or will infringe any valid and enforceable claim of the '666 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

47. Teva has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '666 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

48. Teva is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '666 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of trilaciclib for injection, 300 mg/vial, has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '666 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter judgment against Pharmacosmos and issue an order:

- a. Dismissing Pharmacosmos' Complaint with prejudice and denying each request for relief made by Pharmacosmos therein;
- b. Declaring all claims of the Patents-in-Suit invalid and/or unenforceable;
- c. Declaring that the filing of the ANDA No. 219413 has not infringed and does not infringe any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;
- d. Declaring that Teva has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;
- e. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's Proposed Product does not, and would not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the Patents-in-Suit, either literally or under the doctrine of equivalents;
- f. Declaring Teva the prevailing party and awarding costs and attorney fees to Teva;
- g. Declaring that this case is an exceptional case in favor of Teva pursuant to 35 U.S.C. § 285; and
- h. Awarding Teva such other and further relief as the Court deems just and proper.

Dated: July 11, 2025

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Teva Pharmaceuticals USA, Inc.*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 and 40.1

Defendants Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: July 11, 2025

/s/ Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: July 11, 2025

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