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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, v. HETERO LABS LIMITED, HETERO USA, INC., HETERO LABS LIMITED UNIT-VI, Defendants.	)	C.A. No. 25-3945

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Hetero USA, Inc. ("Hetero USA"), Hetero Labs Limited Unit-VI ("Hetero Unit-VI"), and Hetero Labs Limited ("Hetero Ltd.") (collectively, "Hetero" or "Defendants") hereby answer the Complaint of Plaintiffs Pharmacosmos A/S, Pharmacosmos Holding A/S, and

Pharmacosmos Therapeutics Inc. (collectively, "Pharmacosmos" or "Plaintiffs") as set forth below. This pleading is based upon Hetero's knowledge as to its own activities, and upon information and belief as to the activities of others. Hetero denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

RESPONSE TO NATURE OF THE ACTION[1]

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. 220282 ("Hetero's ANDA") filed or caused to be filed by Hetero 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 Hetero's ANDA, Hetero 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") (true and correct copies of the '352 and '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: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States and that Hetero submitted ANDA No. 220282 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"). Hetero further admits that Exhibits A and B to the Complaint appear to be copies of the Patents-in-Suit. Hetero denies that Plaintiffs are entitled to any relief whatsoever against Hetero in this action. Hetero denies the remaining allegations in Paragraph 1.

RESPONSE 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,

[1] Hetero denies any allegation that may be implied or inferred from the headings of the Complaint.

Denmark.

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

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

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

5. On information and belief, Defendant Hetero Ltd. is a corporation organized and existing under the laws of India and has a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India. *See, e.g., Axsome Malta Ltd. v. Hetero USA Inc.*, No. 2:24-cv-10618 (D.N.J.), ECF No. 11, ¶ 7.

ANSWER: Hetero admits that Hetero Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

6. On information and belief, Hetero 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: Hetero admits that Hetero Ltd. is in the business of manufacturing, importing, distributing, and selling pharmaceutical drug products. Hetero denies any remaining allegations in Paragraph 6 of the Complaint.

7. On information and belief, Hetero Ltd. is a parent company of Hetero USA. *See, e.g., Sanofi-Aventis U.S. LLC v. Sandoz Inc.*, No. 1:20-cv-00804 (D. Del.), ECF No. 1 ¶ 164, ECF

No. 36 ¶ 164.

ANSWER: Hetero admits that Hetero Ltd. is the parent company of Hetero USA, Inc. Hetero denies any remaining allegations in Paragraph 7 of the Complaint.

8. On information and belief, Defendant Hetero 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 1035 Centennial Ave., Piscataway, New Jersey 08854, as indicated on page 3 of its Paragraph IV Notice Letter. *See also, e.g., Axsome Malta Ltd. v. Hetero USA Inc.*, No. 2:24-cv-10618 (D.N.J.), ECF No. 11, ¶ 5; *Sanofi-Aventis U.S. LLC v. Sandoz Inc.*, No. 1:20-cv-00804 (D. Del.), ECF No. 1 ¶ 160, ECF No. 36 ¶ 160; https://hetero.com/contact-us (last accessed April 3, 2025).

ANSWER: Hetero admits that Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Ave, Piscataway, NJ 08854.

9. On information and belief, Hetero USA is the U.S. Regulatory Agent for Defendant Hetero Unit-VI. Hetero's March 25, 2025 letter to Pharmacosmos containing notice of Hetero's ANDA filing and certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Hetero's Paragraph IV Notice Letter"), at p.1.

ANSWER: Hetero admits that Hetero USA, Inc. is the United States regulatory agent for Defendants Hetero Labs Limited and Hetero Unit-VI for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 9 of the Complaint.

10. On information and belief, Hetero USA is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826.

ANSWER: Admitted.

11. On information and belief, Hetero USA is registered with New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

ANSWER: Admitted.

12. On information and belief, Hetero 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: Hetero admits that Hetero USA is in the business of manufacturing, importing,

distributing, and selling pharmaceutical drug products. Hetero denies any remaining allegations in Paragraph 12 of the Complaint.

13. On information and belief, Hetero Unit-VI has a principal place of business in Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India. *See, e.g., Sanofi-Aventis U.S. LLC v. Sandoz Inc.*, No. 1:20-cv-00804 (D. Del.), ECF No. 1 ¶ 162, ECF No. 36 ¶ 162.

ANSWER: Denied.

14. On information and belief, Hetero Unit-VI 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: Hetero admits that Hetero Unit-VI is in the business of developing and manufacturing pharmaceutical drug products. Hetero denies any remaining allegations in Paragraph 14 of the Complaint.

15. On information and belief, Hetero prepared and submitted Hetero's ANDA and continues to collaborate in seeking FDA approval of that application. See Hetero Paragraph IV Notice Letter at pp.1-2.

ANSWER: Hetero admits that Hetero USA prepared and submitted ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 15 of the Complaint.

16. On information and belief, Hetero intends to commercially manufacture, market, offer for sale, and sell the product described in Hetero's ANDA ("Hetero's ANDA Product") throughout the United States, including in the State of New Jersey, in the event the FDA approves Hetero's ANDA.

ANSWER: Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA seeking approval to engage in commercial manufacture, use, or sale of Hetero's ANDA Product. Hetero denies any remaining allegations in Paragraph 16 of the Complaint.

RESPONSE TO JURISDICTION AND VENUE

17. 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: Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States. Hetero denies the remaining allegations in Paragraph 17 of the Complaint.

18. 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 18 states 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, Hetero does not contest subject matter jurisdiction in this District for the purposes of this action. Hetero denies any remaining allegations in Paragraph 18 of the Complaint.

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

ANSWER: Paragraph 19 states 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, Hetero Ltd. does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 19 of the Complaint.

20. In addition, this Court has personal jurisdiction over Hetero Ltd., and venue is proper as to Hetero Ltd., at least because upon information and belief Hetero Ltd.: (1) directs and/or controls Hetero USA, which has a principal place of business and business addresses in New Jersey; (2) directed Hetero Unit-VI and Hetero USA to prepare and submit Hetero's ANDA from Hetero USA's principal place of business in New Jersey and, through its agent Hetero USA, served Hetero's Paragraph IV Notice Letter on Pharmacosmos A/S; (3) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiaries, agents, and/or alter egos; (4) maintains pervasive, continuous, and systematic contacts with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (5) derives substantial revenue from the sale of its products in New Jersey; and (6) intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute Hetero's ANDA Product for which it seeks approval under Hetero's ANDA, including throughout New Jersey.

ANSWER: Paragraph 20 states 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, Hetero Ltd. does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 20 of the Complaint.

21. This Court has personal jurisdiction over Hetero 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.*, *Axsome Malta Ltd. v. Hetero USA Inc.*, No. 2:24-cv-10618 (D.N.J.); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:24-cv-09209 (D.N.J.); *Esperion Therapeutics, Inc. v. Hetero USA Inc.*, No. 2:24-cv-06389 (D.N.J.); *Abbvie Inc. v. Hetero USA Inc.*, No. 3:24-cv-04852 (D.N.J.); *Intra-Cellular Therapies, Inc. v. Hetero USA, Inc.*, No. 3:24-cv-04317 (D.N.J.); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:23-cv-20354 (D.N.J.); *Rigel Pharms., Inc. v. Annora Pharma Private Ltd.*, No. 2:22-cv-04732 (D.N.J.); *Celgene Corp. v. Hetero Labs Limited*, No. 2:20-cv-14389 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Hetero USA Inc.*, No. 3:17-cv-07923 (D.N.J.).

ANSWER: Paragraph 21 states 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, Hetero Ltd. does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 21 of the Complaint.

22. Alternatively, this Court may exercise jurisdiction over Hetero Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Pharmacosmos' claims arise under federal law; (2) Hetero Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Hetero 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 Hetero Ltd. satisfies due process.

ANSWER: Paragraph 22 states 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, Hetero Ltd. does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 22 of the Complaint.

23. Venue is proper in this Court as to Hetero USA under 28 U.S.C. § 1400(b) because Hetero 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. Hetero USA, on behalf of Hetero Ltd. and Hetero Unit-VI, served Hetero's Paragraph IV Notice Letter, which indicated that Hetero USA, Hetero Ltd. and Hetero Unit-VI submitted Hetero's ANDA. On information and belief, Hetero USA, in conjunction with Hetero Ltd. and Hetero Unit-VI, submitted Hetero's ANDA from

Hetero USA's principal place of business in New Jersey.

ANSWER: Paragraph 23 states 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, Hetero USA does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 23 of the Complaint.

24. In addition, this Court has personal jurisdiction over Hetero USA, and venue is proper as to Hetero USA, because on information and belief, Hetero USA: (1) along with Hetero Ltd. and Hetero Unit-VI, prepared and submitted Hetero's ANDA from Hetero USA's principal place of business in New Jersey and served Hetero's Paragraph IV Notice Letter on behalf of itself, Hetero Ltd., and Hetero Unit-VI, on Pharmacosmos A/S; (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 wholesale drug distributor's license (Registration No. 5004050) and a New Jersey Business Entity identification number (Registration No. 0400362826); (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) intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Hetero's ANDA Product in New Jersey.

ANSWER: Paragraph 24 states 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, Hetero USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 24 of the Complaint.

25. This Court has personal jurisdiction over Hetero 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.*, *Axsome Malta Ltd. v. Hetero USA Inc.*, No. 2:24-cv-10618 (D.N.J.); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:24- cv-09209 (D.N.J.); *Esperion Therapeutics, Inc. v. Hetero USA Inc.*, No. 2:24-cv-06389 (D.N.J.); *Abbvie Inc. v. Hetero USA Inc.*, No. 3:24-cv-04852 (D.N.J.); *Intra-Cellular Therapies, Inc. v. Hetero USA, Inc.*, No. 3:24-cv-04317 (D.N.J.); *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:23- cv-20354 (D.N.J.); *Rigel Pharms., Inc. v. Annora Pharma Private Ltd.*, No. 2:22-cv-04732 (D.N.J.); *Celgene Corp. v. Hetero Labs Limited*, No. 2:20-cv-14389 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. v. Hetero USA Inc.*, No. 3:17-cv-07923 (D.N.J.).

ANSWER: Paragraph 25 states 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, Hetero USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 25 of the Complaint.

26. Hetero USA has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g.*, *Symed Labs Limited v. Amneal Pharms. LLC*, No. 2:18-cv-13628 (D.N.J.); *Symed Labs Limited v. Amneal Pharms. LLC*, No. 2:15-cv-08307 (D.N.J.); *Symed Labs Limited v. Glenmark Pharms. Inc., USA*, No. 2:15-cv-08306 (D.N.J.); *Symed Labs Limited v. Hikma Pharms. USA Inc.*, No. 2:15-cv-08304 (D.N.J.).

ANSWER: Paragraph 26 states 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, Hetero USA does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 26 of the Complaint.

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

ANSWER: Paragraph 27 states 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, Hetero Unit VI does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 27 of the Complaint.

28. In addition, this Court has personal jurisdiction over Hetero Unit-VI, and venue is proper as to Hetero Unit-VI, at least because upon information and belief Hetero Unit-VI: (1) as a division of Hetero Ltd., directs and/or controls Hetero USA, its U.S. Regulatory Agent, which has a principal place of business and business addresses in New Jersey; (2) as a division of Hetero Ltd., directed its U.S. Regulatory Agent, Hetero USA, to prepare and submit Hetero's ANDA from Hetero USA's principal place of business in New Jersey and, through its agent Hetero USA, served Hetero's Paragraph IV Notice Letter on Pharmacosmos A/S; (3) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiaries, agents, and/or alter egos; (4) maintains pervasive, continuous, and systematic contacts with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey; (5) derives substantial revenue from the sale of its products in New Jersey; and (6) intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute

Hetero's ANDA product for which it seeks approval under Hetero's ANDA, including throughout New Jersey.

ANSWER: Paragraph 28 states 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, Hetero Unit VI does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 28 of the Complaint.

29. Alternatively, this Court may exercise jurisdiction over Hetero Unit-VI pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Pharmacosmos' claims arise under federal law; (2) Hetero Unit-VI is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Hetero Unit-VI 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 Hetero Unit-VI satisfies due process.

ANSWER: Paragraph 29 states 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, Hetero Unit VI does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 29 of the Complaint.

30. On information and belief, Hetero USA, Hetero Unit-VI, and Hetero Ltd. 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 Hetero's ANDA Product.

ANSWER: Paragraph 30 of the Complaint contains legal conclusions to which no response is required. Hetero denies any remaining allegations in Paragraph 30 of the Complaint.

31. On information and belief, Hetero USA, Hetero Unit-VI, and Hetero Ltd. 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 Hetero's ANDA Product.

ANSWER: Paragraph 31 of the Complaint contains legal conclusions to which no response is required. Hetero denies any remaining allegations in Paragraph 31 of the Complaint.

32. On information and belief, Hetero USA, Hetero Unit-VI, and Hetero Ltd. filed or

caused to be filed Hetero's ANDA with the FDA. *See* Hetero Paragraph IV Notice Letter at pp.1-2.

ANSWER: Hetero admits that Hetero USA filed ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 32 of the Complaint.

33. On information and belief, Hetero USA, Hetero Unit-VI, and Hetero Ltd. prepared and submitted Hetero's ANDA in New Jersey, based on work performed in New Jersey in support for Hetero's 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 Hetero USA, Hetero Unit-VI, and Hetero Ltd., and comprises part of Hetero's ANDA submission.

ANSWER: Hetero admits that Hetero USA prepared and submitted ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 33 of the Complaint.

34. On information and belief, Hetero Ltd. is the holder of the Drug Master File for trilaciclib dihydrochloride dihydrate which underlies Hetero's ANDA submission.

ANSWER: Hetero admits that Hetero Ltd. the holder of the Drug Master File for trilaciclib dihydrochloride dihydrate which is referenced in Hetero's ANDA. Hetero denies any remaining allegations in Paragraph 34 of the Complaint.

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

ANSWER: Hetero admits that Hetero USA filed ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 35 of the Complaint.

36. Hetero USA, on behalf of itself, Hetero Unit-VI, and Hetero Ltd., sent Pharmacosmos the Hetero Paragraph IV Notice Letter, dated March 25, 2025, providing notice that Hetero'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"), and stating that Hetero had filed Hetero's ANDA seeking approval from the FDA to commercially manufacture, use, market, or sell its Eq. 300mg Base/Vial generic trilaciclib product in the United States.

ANSWER: Hetero admits that pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Hetero sent a notice letter dated March 25, 2025. Hetero admits that Hetero USA, Inc. submitted ANDA No. 220282 to FDA seeking approval to engage in commercial manufacture, use, or sale of its ANDA Product. Hetero denies any remaining allegations in Paragraph 36 of the Complaint.

37. Pharmacosmos A/S received Hetero's Paragraph IV Notice Letter on March 27, 2025.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of the Complaint and therefore denies them.

RESPONSE TO PHARMACOSMOS' APPROVED COSELA® AND THE PATENTS-IN-SUIT

38. 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 38 contains legal conclusions to which no response is required. To the extent an answer is required, Hetero admits that the prescribing information for COSELA® states that the "Initial U.S. Approval" for "COSELA ® (trilaciclib) for injection, for intravenous use" was in 2021. Hetero also admits that, according to the Orange Book, COSELA® was granted New Chemical Exclusivity which purportedly expires on February 12, 2026. Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

39. 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 C.

ANSWER: Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, the allegations in Paragraph 39 of the Complaint appear to characterize the Prescribing Information for COSELA®, which is subject to change and speaks for itself. According to Exhibit C, the Prescribing Information states that COSELA® 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." Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

40. 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." Exhibit C at Sections 1, 2.

ANSWER: Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, the allegations in Paragraph 40 of the Complaint appear to characterize the Prescribing Information for COSELA®, which is subject to change and speaks for itself. According to Exhibit C, the Prescribing Information states, "Administer 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." Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

41. The prescribing information for COSELA® further details the platinum/etoposide-

containing regimen of Study 1 (G1T28-05), the primary study supporting FDA approval of COSELA®. Exhibit C at Sections 6, 14. For example, the prescribing information for COSELA® details that "Study 1 (G1T28-05) was a randomized (1:1), double-blind, placebo- controlled study of COSELA 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 COSELA® treatment group, "Carboplatin (AUC 5) and atezolizumab (1200 mg) were administered on Day 1 and etoposide (100 mg/m^2) and COSELA (240 mg/m^2) … 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." Exhibit C at Section 14; *see also* Exhibit C at Section 6 ("Study 1 (G1T28-05; NCT03041311) was an international, randomized (1:1), double-blind, placebo-controlled study of COSELA 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 41 contains legal conclusions to which no response is required. To the extent a response is required, the allegations in Paragraph 41 of the Complaint appear to characterize the Prescribing Information for COSELA®, which is subject to change and speaks for itself. According to Exhibit C, the Prescribing Information states "Study 1 (G1T28-05) was a randomized (1:1), double-blind, placebo- controlled study of COSELA 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," "Carboplatin (AUC 5) and atezolizumab (1200 mg) were administered on Day 1 and etoposide (100 mg/m^2) and COSELA (240 mg/m^2) … 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." Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

42. The prescribing information for COSELA® 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 COSELA compared with placebo (Table 5)." *Id.* at Section 14.

ANSWER: Paragraph 42 contains legal conclusions to which no response is required. To

the extent a response is required, the allegations in Paragraph 42 of the Complaint appear to characterize the Prescribing Information for COSELA®, which is subject to change and speaks for itself. According to Exhibit C, the Prescribing Information states 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 COSELA compared with placebo (Table 5)." Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

43. 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: Hetero lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this Paragraph of the Complaint and therefore denies them.

44. 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 COSELA®.

ANSWER: Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that the '352 and '666 Patents have been listed in the Orange Book with respect to COSELA®. Plaintiffs caused the '352 and '666 Patents to be listed in the Orange Book, and Hetero denies that the '352 and '666 Patents were properly listed. Hetero denies any remaining allegations in Paragraph 44 of the Complaint.

45. 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." The '352 patent will expire on July 23, 2039.

ANSWER: Hetero admits that Exhibit A to the Complaint appears to be a copy of the '352 Patent, which indicates on its face an issue date of December 20, 2022. Hetero further admits that

the ’352 Patent is titled “Preservation of Immune Response During Chemotherapy Regimens.” Hetero denies any remaining allegations in Paragraph 45.

46. 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.” The ’666 patent will expire on November 13, 2040.

ANSWER: Hetero admits that Exhibit B to the Complaint appears to be a copy of the ’666 Patent, which indicates on its face an issue date of December 17, 2022. Hetero further admits that the ’666 Patent is titled “Morphic Forms of Trilaciclib And Methods of Manufacture Thereof.” Hetero denies any remaining allegations in Paragraph 46.

47. Pharmacosmos Holding A/S is the assignee of the ’352 and ’666 patents.

ANSWER: Hetero admits G1 Therapeutics, Inc. is listed on the face of the Patents-in-Suit as the Assignee. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 47 of the Complaint and therefore denies them.

48. Pharmacosmos Therapeutics Inc. holds an exclusive license under the ’352 and ’666 patents to commercialize COSELA® in the United States.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint and therefore denies them.

RESPONSE TO HETERO’S ANDA AND NOTICE LETTER

49. On information and belief, Hetero 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 Hetero’s ANDA Product as a purported generic version of COSELA® prior to the expiration of the ’352 and ’666 patents. On information and belief, Hetero’s ANDA contains a Paragraph IV Certification with respect to the ’352 and ’666 patents.

ANSWER: Paragraph 49 contains legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero USA filed ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero admits that Hetero’s ANDA contains a Paragraph IV Certification with respect to the ’352 and ’666 Patents. Hetero denies any

remaining allegations in Paragraph 49 of the Complaint.

50. Pharmacosmos A/S received Hetero's Paragraph IV Notice Letter in Denmark on March 27, 2025. In its Paragraph IV Notice Letter, Hetero Inc. represented that Hetero's ANDA included Paragraph IV Certifications with respect to the '352 and '666 patents, and that Hetero 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 Hetero's Paragraph IV Notice Letter, Hetero's ANDA Product contains trilaciclib.

ANSWER: Hetero admits that on March 25, 2025 Hetero sent its Paragraph IV Notice Letter to Pharmacosmos A/S. Hetero admits that its Paragraph IV Notice Letter represented that its ANDA included Paragraph IV Certifications with respect to the '352 and '666 Patents. Hetero further admits that Hetero USA filed ANDA No. 220282, which seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 50 of the Complaint.

51. Hetero's Paragraph IV Notice Letter purported to contain a "Detailed Statement for ANDA 220282" ("Detailed Statement").

ANSWER: Hetero admits that Hetero's Paragraph IV Notice Letter contains a Detailed Statement for ANDA No. 220282. Hetero's Paragraph IV Notice Letter speaks for itself. Hetero denies any remaining allegations in Paragraph 51.

52. Hetero's Detailed Statement alleged that the '352 and '666 patents will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product and that the '352 and '666 patents are invalid.

ANSWER: Hetero admits that Hetero's Paragraph IV Notice Letter contains a Detailed Statement for ANDA No. 220282. Hetero's Paragraph IV Notice Letter speaks for itself. Hetero denies any remaining allegations in Paragraph 52.

53. Hetero's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Hetero confidential information regarding Hetero's ANDA Product. On April 2, 2025 shortly after receiving Hetero's Paragraph IV Notice Letter, Pharmacosmos requested that Hetero revise its purported OCA to provide Pharmacosmos with access to modules 1, 2, and 3 of Hetero's ANDA.

ANSWER: Hetero admits that it provided Pharmacosmos with an OCA and that on April 2, 2025, Pharmacosmos provided edits to Hetero's OCA significantly expanding access to

Hetero's confidential information including requesting access for unidentified in-house attorneys and access for an unlimited number of outside scientific consultants to modules 1, 2, and 3 of Hetero's ANDA. Hetero denies any remaining allegations in Paragraph 53 of the Complaint.

54. On April 17, 2025, without further negotiation, Hetero responded to Pharmacosmos' request by stating that Hetero would not provide Pharmacosmos with access to modules 1, 2, or 3 of Hetero's ANDA as Pharmacosmos requested unless "outside counsel would like to agree to the [original] terms proposed by Hetero for accessing the ANDA," in its purported OCA.

ANSWER: Hetero admits that it provided Pharmacosmos with an OCA and that on April 2, 2025, Pharmacosmos provided edits to Hetero's OCA significantly expanding access to Hetero's confidential information including requesting access for unidentified in-house attorneys and access for an unlimited number of outside scientific consultants to modules 1, 2, and 3 of Hetero's ANDA. To the extent the allegations in Paragraph 54 attempt to characterize Hetero's good faith attempts to negotiate the appropriate scope of the OCA, Hetero denies these allegation and denies any remaining allegations in Paragraph 54 of the Complaint.

55. Plaintiffs subsequently offered to meet and confer with Hetero in an effort to agree on reasonable terms for Hetero's purported OCA, but the parties were not able to reach an agreement as of the date of this Complaint. To date, Hetero has not provided Pharmacosmos with a copy of any portion of Hetero's ANDA.

ANSWER: Hetero admits that it provided Pharmacosmos with an OCA and that on April 2, 2025, Pharmacosmos provided edits to Hetero's OCA significantly expanding access to Hetero's confidential information including requesting access for unidentified in-house attorneys and access for an unlimited number of outside scientific consultants to modules 1, 2, and 3 of Hetero's ANDA. Hetero further admits that the parties were unable to agree on the terms of the OCA. To the extent the allegations in Paragraph 55 attempt to characterize Hetero's good faith attempts to negotiate the appropriate scope of the OCA, Hetero denies these allegation and denies any remaining allegations in Paragraph 55 of the Complaint.

56. Pharmacosmos is not aware of any other means, other than discovery in this lawsuit, to obtain information regarding Hetero's ANDA Product. In the absence of receiving such information within the 45-day statutory period, Pharmacosmos will utilize the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to support its allegations of infringement and to present the Court with evidence that Hetero's ANDA Product fall within the scope of one or more claims of the '352 and '666 patents.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint and therefore denies them.

57. On information and belief, Hetero Unit-VI is a division of Hetero Ltd. Hetero Paragraph IV Notice Letter at p.1, n.1; *see also, e.g., Sanofi-Aventis U.S. LLC v. Sandoz Inc.*, No. 1:20-cv-00804 (D. Del.), ECF No. 1 ¶ 162, ECF No. 36 ¶ 162, ECF No. 37, p.2; *Ingenus Pharms., LLC v. Hetero USA, Inc.*, No. 1:24-cv-01025 (D. Del.), ECF No. 13, p.1.

ANSWER: Hetero admits that Hetero Unit-VI is a manufacturing facility of Hetero Ltd. Hetero denies any remaining allegations in Paragraph 57.

58. On information and belief, Hetero USA, Hetero Unit-VI, and Hetero Ltd., have participated in the preparation and submission of Hetero's ANDA, have provided material support to the preparation and submission of Hetero's ANDA, and intend to support the further prosecution of Hetero's ANDA.

ANSWER: Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA. Hetero denies any remaining allegations in Paragraph 58.

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

ANSWER: Hetero admits that Hetero USA filed ANDA No. 220282 and seeks approval from the FDA for ANDA No. 220282. Hetero denies any remaining allegations in Paragraph 59.

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

ANSWER: Denied.

61. Pharmacosmos is commencing this action within 45 days of the date of receipt of Hetero'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: Paragraph 61 of the Complaint contains legal conclusions to which no response

is required. To the extent an answer is required, Hetero 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.

RESPONSE TO ACTS GIVING RISE TO THIS ACTION

COUNT I

RESPONSE TO INFRINGEMENT OF THE '352 PATENT BY HETERO

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

ANSWER: Hetero incorporates its responses to the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 61 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA and seeks approval from the FDA for ANDA No. 220282. Hetero denies the remaining allegations in Paragraph 63 of the Complaint.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Paragraph 66 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, Hetero's ANDA speaks for itself. Hetero denies any remaining allegations in Paragraph 66 of the Complaint.

67. On information and belief Hetero's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA® (Exhibit C).

ANSWER: Denied.

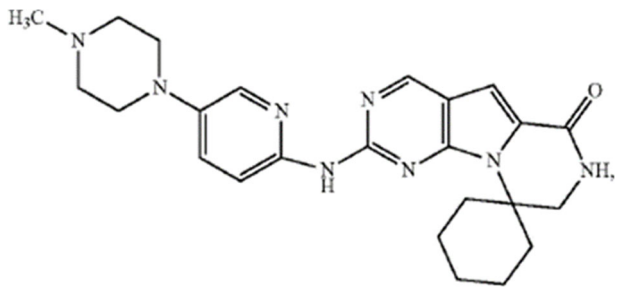
68. On information and belief, physicians will follow the instructions on Hetero's ANDA Product Labeling when administering Hetero's ANDA Product.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68 of the Complaint and therefore denies them.

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

ANSWER: Denied.

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: 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: Hetero admits that Paragraph 70 recites claim 1 of the '352 Patent. Hetero denies any remaining allegations in Paragraph 70 of the Complaint.

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

ANSWER: Paragraph 71 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, denied.

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

ANSWER: Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA and seeks approval from the FDA for ANDA No. 220282. Hetero denies the remaining allegations in Paragraph 72 of the Complaint.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

to infringe one or more claims of the '352 patent.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA and seeks approval from the FDA for ANDA No. 220282. Hetero denies the remaining allegations in Paragraph 79 of the Complaint.

80. The foregoing actions by Hetero 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: Denied.

81. On information and belief, Hetero 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: Denied.

82. Hetero's Detailed Statement in Hetero's Paragraph IV Notice Letter lacks any sufficient contention that the Hetero ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '352 patent.

ANSWER: Denied.

83. Pharmacosmos will be irreparably harmed if Hetero 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 Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

84. The submission of Hetero'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 Hetero'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: Denied.

COUNT II

RESPONSE TO INFRINGEMENT OF THE '666 PATENT BY HETERO

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

ANSWER: Hetero incorporates its responses to the preceding paragraphs as if fully set forth herein.

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

ANSWER: Hetero admits that Hetero USA submitted ANDA No. 220282 to FDA and seeks approval from FDA for ANDA No. 220282. Hetero denies the remaining allegations in Paragraph 86 of the Complaint.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

91. Unless enjoined by this Court, upon approval of Hetero's ANDA, Hetero will make, use, offer to sell, or sell Hetero's ANDA Product within the United States, or will import Hetero's ANDA Product into the United States, and will thereby infringe, contribute to the infringement and/or induce the infringement of one or more claims of the '666 patent.

ANSWER: Denied.

92. On information and belief, Hetero 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: Denied.

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

ANSWER: Denied.

94. Pharmacosmos will be irreparably harmed if Hetero 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 Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Denied.

95. The submission of Hetero's ANDA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Hetero'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: Denied.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

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

HETERO'S AFFIRMATIVE DEFENSES

Hetero asserts the following defenses to the Complaint, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hetero reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Assertion of a defense is not a concession that Hetero has the burden of proving the matter asserted.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief can be granted.

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

Hetero has not and will not infringe, literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '352 Patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the '352 Patent)

The claims of the '352 Patent are invalid for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

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

Hetero has not and will not infringe, literally or under the doctrine of equivalents, either directly or indirectly, any valid and enforceable claim of the '666 Patent.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity of the '666 Patent)

The claims of the '666 Patent are invalid for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE
(Costs)

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

SEVENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Hetero's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE
(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.

NINTH 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.

TENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiffs Pharmacosmos A/S, Pharmacosmos Holding A/S, and Pharmacosmos Therapeutics Inc. (collectively, "Pharmacosmos" or "Counter-Defendants"), other than those expressly admitted herein, and without prejudice to the right of Hetero USA, Inc. ("Hetero USA") and Hetero Labs Limited ("Hetero Limited") (collectively, Hetero USA and Hetero Limited are "Hetero") to plead additional Counterclaims as the facts of the matter warrant, Hetero hereby asserts the following Counterclaims against Pharmacosmos:

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that ANDA No. 220282 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, "Patents-in-Suit") 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. Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1035 Centennial Ave, Piscataway, NJ 08854.

3. Hetero Labs Limited is a corporation organized and existing under the laws of India, having a place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

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, 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.

6. Upon information and belief and based on the allegations in the Complaint, 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.

7. This Court has personal jurisdiction over Pharmacosmos A/S because Pharmacosmos A/S has availed itself of the legal protections of the State of New Jersey by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Pharmacosmos A/S has voluntarily submitted to the jurisdiction of the Court in this matter.

9. This Court has personal jurisdiction over Pharmacosmos Holding A/S because Pharmacosmos Holding A/S has availed itself of the legal protections of the State of New Jersey by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Pharmacosmos Holding A/S has voluntarily submitted to the jurisdiction of the Court in this matter.

11. This Court has personal jurisdiction over Pharmacosmos Therapeutics Inc. because Pharmacosmos Therapeutics Inc. has availed itself of the legal protections of the State of New Jersey by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Pharmacosmos Therapeutics Inc. has voluntarily submitted to the jurisdiction of the Court in this matter.

FACTUAL BACKGROUND

13. 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 300 mg/vial intravenous trilaciclib, marketed under the trade name COSELA®.

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

15. Upon information and belief and based on the allegations in the Complaint, Pharmacosmos Holding A/S purports to be the assignee of the Patents-in-Suit.

16. Upon information and belief, Pharmacosmos A/S caused the Patents-in-Suit to be listed in the Orange Book as patents that purport to be associated with COSELA®.

17. 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

18. Hetero has submitted ANDA No. 220282 to the FDA, seeking approval to engage in the commercial manufacture, use, or sale of 300 mg/vial Trilaciclib ("Hetero's ANDA Product") prior to the expiration of the Patents-in-Suit.

19. ANDA No. 220282 contained Paragraph IV Certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be

infringed by the commercial manufacture, use or sale of Hetero's ANDA Product.

20. On or around March 25, 2025, Hetero sent Pharmacosmos A/S a notice letter providing notice of Hetero's submission of ANDA No. 220282 to the FDA.

21. On or around May 7, 2025 Plaintiffs filed this lawsuit alleging that Hetero infringes the Patents-in-Suit.

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

22. Hetero realleges and incorporates by reference the allegations in Paragraphs 1–21 of these Counterclaims as if fully set forth herein.

23. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Pharmacosmos regarding the invalidity of the '352 Patent, based on Plaintiffs' allegations in the Complaint that Hetero has infringed or will infringe the '352 Patent.

24. 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. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

25. 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 applicant for the '352 Patent.

26. The alleged invention of the '352 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '352 Patent in the United States.

27. 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.

28. 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.

29. 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.

30. 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 without undue experimentation.

31. 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.

32. The claims of the ’352 Patent are also invalid 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.

33. Hetero is entitled to a judicial declaration that all claims of the '352 Patent are invalid.

COUNT II
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,529,352)

34. Hetero realleges and incorporates by reference the allegations in Paragraphs 1-33 of these Counterclaims as if fully set forth herein.

35. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Pharmacosmos regarding whether Hetero's submission of ANDA No. 220282 and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product, infringe, have infringed, or will infringe any valid and enforceable claim of the '352 Patent either directly or indirectly.

36. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '352 Patent and is not liable for such infringement.

37. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '352 Patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '352 Patent.

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

38. Hetero realleges and incorporates by reference the allegations in Paragraphs 1-37 of these Counterclaims as if fully set forth herein.

39. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Pharmacosmos regarding the invalidity of the '666 Patent, based on Plaintiffs' allegations in the Complaint that Hetero has infringed or will infringe the '666 Patent.

40. 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. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

41. 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 applicant for the ’666 Patent.

42. The alleged invention of the ’666 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’666 Patent in the United States.

43. 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.

44. 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.

45. 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.

46. 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 without undue experimentation.

47. 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.

48. The claims of the ’666 Patent are also invalid 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.

49. Hetero is entitled to a judicial declaration that all claims of the ’666 Patent are invalid.

COUNT IV
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 12,168,666)

50. Hetero realleges and incorporates by reference the allegations in Paragraphs 1-49 of these Counterclaims as if fully set forth herein.

51. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Pharmacosmos regarding whether Hetero’s submission of ANDA No. 220282 and/or Hetero’s manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero’s ANDA Product, infringe, have infringed, or will infringe any valid and enforceable claim of the ’666 Patent either directly or indirectly.

52. Hetero has not infringed, contributed to the infringement of, or induced the

infringement of any valid and enforceable claim of the '666 Patent and is not liable for such infringement.

53. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '666 Patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '666 Patent.

PRAYER FOR RELIEF

Wherefore, Hetero respectfully requests that this Court enter judgment against AbbVie and issue an order:

a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs/Counter-Defendants therein;

b) Declaring all claims of the Patents-in-Suit invalid;

c) Declaring that the filing of ANDA No. 220282 has not infringed and does not infringe any valid and enforceable claim, if any, of the Patents-in-Suit;

d) Declaring that Hetero has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, of the Patents-in-Suit;

e) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product, does not, and would not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the Patents-in-Suit;

f) Declaring that this case is an exceptional case in favor of Hetero pursuant to 35 U.S.C. § 285;

g) Declaring Hetero the prevailing party and awarding costs and attorney fees to

Hetero; and

h) Awarding Hetero such other and further relief as the Court deems just and equitable.

By: /s/Douglas R. Weider
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Dated: July 14, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 and 40.1

Defendants Hetero USA, Inc. ("Hetero USA"), Hetero Labs Limited Unit-VI ("Hetero Unit-VI"), and Hetero Labs Limited ("Hetero Ltd."), 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.

By: */s/Douglas R. Weider*
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Dated: July 14, 2025