MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants,
Dr. Reddy's Laboratories, Inc.
and Dr. Reddy's Laboratories, Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PHARMACOSMOS A/S; PHARMACOSMOS HOLDING A/S; and PHARMACOSMOS THERAPEUTICS INC.,, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Honorable Julien X. Neals, U.S.D.J. Civil Action No. 25 CV 3967 (JXN)(AME) **DEFENDANTS DR. REDDY'S LABORATORIES, INC. & DR. REDDY'S LABORATORIES, LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "DRL"), by and through the undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiffs Pharmacosmos A/S, Pharmacosmos Holding A/S, and Pharmacosmos Therapeutics Inc. (collectively, "Pharmacosmos" or "Plaintiffs"). DRL denies all allegations in Plaintiffs' Complaint except those admitted specifically below. This pleading is based upon DRL's knowledge of its own activities, and upon information and belief as to the activities of others.

NATURE OF THE ACTION

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. 220230 ("DRL's ANDA") filed or caused to be filed by DRL Inc. and DRL Ltd. 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 DRL's ANDA, DRL seeks approval to market a generic version of the pharmaceutical product COSELA® (trilaciclib) prior to the expiration of United States Patent Nos. 8,598,186 ("the '186 patent"), 8,598,197 ("the '197 patent"), 9,957,276 ("the '276 patent"), 10,189,849 ("the '849 patent"), 10,189,850 ("the '850 patent"), 10,927,120 ("the '120 patent"), 11,040,042 ("the '042 patent"), 9,487,530 ("the '530 patent"), 10,085,992 ("the '992 patent"), 10,966,984 ("the '984 patent"), 11,717,523 ("the '523 patent"), 11,529,352 ("the '352 patent"); and 12,168,666 ("the '666 patent"). True and correct copies of the patents-in-suit are attached as Exhibits A-M. Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the Complaint purports to bring an action for infringement under the Patent Laws of the United States, Title 35 of the United States Code, Sections 100 *et seq.*, and 35 U.S.C. §§ 271(a-c, e-g). Further answering, DRL admits that DRL filed ANDA No. 220230 ("DRL's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use, or sell trilaciclib for injection, 300 mg ("DRL's ANDA Product") prior to the expiration of United States Patent Nos. 8,598,186 ("the '186 patent"), 8,598,197 ("the '197 patent"), 9,957,276 ("the '276 patent"), 10,189,849 ("the '849 patent"), 10,189,850 ("the '850 patent"), 10,927,120 ("the '120 patent"), 11,040,042 ("the '042 patent"), 9,487,530 ("the '530 patent"), 10,085,992 ("the '992 patent"), 10,966,984 ("the '984 patent"), 11,717,523 ("the '523 patent"), and 12,168,666 ("the '666 patent"). DRL also admits that purported copies of the patents-in-suit are attached to the Complaint as Exhibits A-M. DRL specifically denies that Plaintiffs are entitled to any remedy or relief, and further denies the remaining allegations in this paragraph.

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.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph 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: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph 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: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

5. On information and belief, Defendant DRL Ltd. is a corporation organized and existing under the laws of India and has a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

ANSWER: DRL admits that DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad Telangana, 500034, India.

6. On information and belief, DRL 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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it seeks regulatory approval of and sells generic products in the United States. DRL denies the remaining allegations in this paragraph.

7. DRL Ltd.'s Integrated Annual Report for 2023-24 states that its United States "revenues (excluding other operating income) … based on the location of the customers" for the year ended March 31, 2024 was 135,565 million Indian Rupees (approximately 1.59 billion U.S. dollars as of April 21, 2025), approximately 48.5% of its total global revenues. DRL Ltd. Integrated Annual Report 2023-24, p. 374 (Exhibit O); *see also*, DRL Ltd. Form 20-F for 2024, p. 151 (Exhibit P).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that the documents cited in this paragraph speak for themselves. DRL denies the remaining allegations in this paragraph.

8. On information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey and has a principal place of business in New Jersey at 600 College Road East, Princeton, New Jersey, 08540. *See, e.g.*, *In Re Selenious Acid Litig.*, No. 2:24-cv-07791 (D.N.J.), ECF No. 63 at ¶ 5; *Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:24-cv-07875 (D.N.J.), ECF No. 9 at ¶ 3.

ANSWER: DRL admits that DRL Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

9. On information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd. See, e.g., DRL Ltd. Integrated Annual Report 2023-24, pp. 94, 375; DRL Ltd. Form 20-F for 2024, pp. 40, 205.

ANSWER: DRL admits that DRL Inc. is a wholly owned subsidiary of DRL Ltd. DRL denies the remaining allegations in this paragraph.

10. On information and belief, DRL Inc. is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100518911.

ANSWER: DRL admits that DRL Inc. is registered with New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100518911. DRL denies the remaining allegations in this paragraph.

11. On information and belief, DRL Inc. is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002312.

ANSWER: DRL admits that DRL Inc. is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002312. DRL denies the remaining allegations in this paragraph.

12. On information and belief, DRL 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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it seeks regulatory approval of and sells generic products in the United States. DRL denies the remaining allegations in this paragraph.

13. On information and belief, DRL Inc. and DRL Ltd. prepared and submitted DRL's ANDA and continue to collaborate in seeking FDA approval of that application. *See* DRL Paragraph IV Notice Letter, pp. 1-2.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 220230 seeking regulatory approval for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

ANSWER: his paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 220230 seeking regulatory approval to manufacture and sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

15. This is a civil action for infringement of the '186 patent, '197 patent, '276 patent, '849 patent, '850 patent, '120 patent, '042 patent, '530 patent, '992 patent, '984 patent, '523 patent, '352 patent, and '666 patent (collectively, "the patents-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the Complaint purports to bring an action for infringement of the '186 patent, '197 patent, '276 patent, '849 patent, '850 patent, '120 patent, '042 patent, '530 patent, '992 patent, '984 patent, '523 patent, and '666 patent, as well as U.S. Patent No. 11,529,352 ("the '352 patent") (collectively, "the patents-in-suit") under 35 U.S.C. §§ 100 *et seq*. DRL denies the remaining allegations in this paragraph.

16. 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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest subject matter jurisdiction for purposes of this case only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue for purposes of this case only, and expressly reserves the right to contest personal jurisdiction or venue in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

18. In addition, this Court has personal jurisdiction over DRL Ltd., and venue is proper as to DRL Ltd., at least because upon information and belief DRL Ltd.: (1) directs and/or controls DRL Inc., which has a principal place of business and business addresses in New Jersey; (2) along with DRL Inc., submitted DRL's ANDA in New Jersey and served DRL's Paragraph IV Notice Letter; (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) on information and belief, derives substantial revenue from the sale of its products in New Jersey; and (6) on information

and belief, intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute DRL's ANDA Product for which it seeks approval under DRL's ANDA, including throughout New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue for purposes of this case only, and expressly reserves the right to contest personal jurisdiction or venue in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

19. This Court has personal jurisdiction over DRL 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.*, *Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:24-cv-07875 (D.N.J.); *In Re Selenious Acid Litig.*, No. 2:24-cv-07791 (D.N.J.); *Vifor (Int'l) AG v. Dr. Reddy's Lab'ys, Ltd.*, No. 3:24-cv-06833 (D.N.J.); *Eisai R&D Mgmt. Co., Ltd. v. Dr. Reddy's Lab'ys, Inc.*, No. 24-cv-06765 (D.N.J.); *Esperion Therapeutics, Inc. v. Dr. Reddy's Lab'ys Inc.*, No. 2:24-cv-06391 (D.N.J); *Novo Nordisk Inc. v. Dr. Reddy's Lab'ys, Ltd.*, No. 1:23-cv-22112 (D.N.J.); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:21-cv-02111 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Dr. Reddy's Lab'ys, Inc.*, No. 3:19-cv-18764 (D.N.J.); *AstraZeneca LP v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:19-cv-15739 (D.N.J.).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

20. DRL Ltd. has further availed itself to the jurisdiction of New Jersey by initiating litigation in this Judicial District. *See, e.g.*, *Dr. Reddy's Lab'ys, Inc. v. Astrazeneca AB*, No. 1:18-cv-16057 (D.N.J.); *Dr. Reddy's Lab'ys, Inc. v. Astrazeneca AB*, No. 3:15-cv-08128 (D.N.J.); *Dr. Reddy's Lab'ys, Inc. v. Purdue Pharm. Prods. L.P.*, No. 2:14-cv-03230 (D.N.J.); *Dr. Reddy's Lab'ys, Ltd. v. Eli Lilly & Co.*, No. 3:09-cv-00192 (D.N.J.); *Dr. Reddy's Lab'ys, Ltd. v. Astrazeneca AB*, No. 3:08-cv-02496 (D.N.J.).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

22. Venue is proper in this Court as to DRL Inc. under 28 U.S.C. § 1400(b) because DRL 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. DRL sent its DRL's Paragraph IV Notice Letter, which indicated that DRL Inc. and DRL Ltd. submitted DRL's ANDA in New Jersey. DRL Paragraph IV Notice Letter at pp.1-2.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, DRL does not contest venue for purposes of this case only, and expressly reserves the right to contest venue in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

23. In addition, this Court has personal jurisdiction over DRL Inc., and venue is proper as to DRL Inc., because on information and belief, DRL Inc.: (1) submitted DRL's ANDA with DRL Ltd. and served DRL's Paragraph IV Notice Letter on behalf of itself and DRL Ltd.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 wholesale drug distributor's license (Registration No. 5002312) and New Jersey Business Entity identification number (Registration No. 0100518911); (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 DRL's ANDA Product in New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction or venue for purposes of this case only, and expressly reserves the right to contest personal jurisdiction or venue in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

24. This Court has personal jurisdiction over DRL 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.*, *Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:24-cv-07875 (D.N.J.); *In Re Selenious Acid Litig.*, No. 2:24-cv-07791 (D.N.J.); *Vifor (Int'l) AG v. Dr. Reddy's Lab'ys, Ltd.*, No. 3:24-cv-06833 (D.N.J.); *Eisai R&D Mgmt. Co., Ltd. et al. v. Dr. Reddy's Lab'ys, Inc.*, No. 24-cv-06765 (D.N.J.); *Esperion Therapeutics, Inc. v. Dr. Reddy's Lab'ys Inc.*, No. 2:24-cv-06391 (D.N.J); *Novo Nordisk Inc. v. Dr. Reddy's Lab'ys, Ltd.*, No. 1:23-cv-22112 (D.N.J.); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:21-cv-02111 (D.N.J.); *Mitsubishi Tanabe Pharma Corp. v. Dr. Reddy's Lab'ys, Inc.*, No. 3:19-cv-18764 (D.N.J.); *AstraZeneca LP v. Dr. Reddy's Lab'ys, Ltd.*, No. 2:19-cv-15739 (D.N.J.).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

25. DRL Inc. has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g.*, *Dr. Reddy's Lab'ys, Inc. v. Astrazeneca AB*, No. 1:18-cv-16057 (D.N.J.); *Dr. Reddy's Lab'ys, Inc. v. Astrazeneca AB*, No. 3:15-cv-08128 (D.N.J.); *Dr. Reddy's Lab'ys, Inc. v. Purdue Pharm. Prods. L.P.*, No. 2:14-cv-03230 (D.N.J.); *Dr. Reddy's Lab'ys, Ltd. v. Eli Lilly & Co.*, No. 3:09-cv-00192 (D.N.J.); *Dr. Reddy's Lab'ys, Ltd. v. Astrazeneca AB*, No. 3:08-cv-02496 (D.N.J.).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

26. On information and belief, DRL Ltd. and DRL Inc. 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 DRL's ANDA Product.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, DRL admits that DRL Inc. is a wholly owned subsidiary of DRL Ltd. DRL denies the remaining allegations in this paragraph.

27. On information and belief, DRL Ltd. and DRL Inc. 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 DRL's ANDA Product.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it sells pharmaceutical products throughout the United States. DRL denies the remaining allegations in this paragraph.

28. On information and belief, DRL Ltd. and DRL Inc. filed or caused to be filed DRL's ANDA with the FDA. See DRL Paragraph IV Notice Letter at pp.1-2.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that it filed ANDA No. 220230 with the FDA. DRL denies the remaining allegations in this paragraph.

29. On information and belief, DRL Ltd. and DRL Inc. submitted DRL's ANDA in New Jersey, based on work performed in New Jersey in support of DRL'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 DRL Ltd. and DRL Inc., and comprises part of DRL's ANDA submission.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

30. On information and belief, DRL Ltd. and DRL Inc. taking actions which, among other things, led to the filing of DRL's ANDA and its maintaining of distribution channels,

including in New Jersey, establish that DRL will commercially manufacture, use, offer to sell, sell, and/or import DRL's ANDA Product throughout the United States, including in New Jersey, if granted approval.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL does not contest personal jurisdiction for purposes of this case only, and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Plaintiffs. DRL denies the remaining allegations in this paragraph.

31. DRL's agent, on behalf of DRL Ltd. and DRL Inc., sent Pharmacosmos a letter dated March 24, 2025 ("DRL's Paragraph IV Notice Letter") providing notice that DRL's ANDA contains a certification with respect to the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, 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 DRL had filed DRL's ANDA seeking approval from the FDA to commercially manufacture, use, market, or sell its 300 mg base/vial generic trilaciclib product in the United States.

ANSWER: DRL admits that it sent Pharmacosmos a letter dated March 24, 2025 ("DRL's Notice Letter"), providing notice that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL further admits that DRL's Notice Letter provided Pharmacosmos with information regarding DRL's ANDA No. 220230 pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

32. Pharmacosmos received DRL's Paragraph IV Notice Letter in New Jersey on March 25, 2025.

ANSWER: On information and belief, DRL admits that Pharmacosmos received DRL's Notice Letter on March 25, 2025. DRL denies the remaining any allegations in this paragraph.

PHARMACOSMOS'S APPROVED COSELA® AND THE PATENTS-IN-SUIT

33. 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: DRL admits, according to the records of the FDA, Pharmacosmos A/S is the holder of NDA No. 214200 for COSELA®, which is the tradename for trilaciclib for injection. DRL further admits that, according to the records of the FDA, the FDA approved NDA No. 214200 on February 12, 2021. DRL also admits that new chemical entity exclusivity is listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with NDA No. 214200, which expires on February 12, 2026. DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

34. 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 (ES-SCLC)." A true and correct copy of the prescribing information for COSELA® is attached as Exhibit N.

ANSWER: DRL admits that the COSELA® Prescribing Information speaks for itself. DRL further admits that a purported copy of the prescribing information for COSELA® is attached to the Complaint as Exhibit N. DRL denies the remaining allegations of this paragraph.

35. 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 N at Sections 1, 2.

ANSWER: DRL admits that the COSELA® Prescribing Information speaks for itself. DRL denies the remaining allegations of this paragraph.

36. 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 N 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/m2) and COSELA (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." Exhibit N 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 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.").

DRL admits that the COSELA® Prescribing Information speaks for itself. DRL denies the remaining allegations of this paragraph.

37. 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: DRL admits that the COSELA® Prescribing Information speaks for itself. DRL denies the remaining allegations of this paragraph.

38. Upon 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: DRL lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies them.

39. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit 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: DRL admits that the FDA's Orange Book lists the patents-in-suit in connection with COSELA®. DRL denies the remaining allegations in this paragraph.

40. The '186 patent was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on December 3, 2013 and is titled "CDK Inhibitors." A true and correct copy of the '186 patent is attached as Exhibit A. The '186 patent is currently set to expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '186 patent was issued on December 3, 2013, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '186 patent

has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '186 patent is attached to the Complaint as Exhibit A. DRL specifically denies that the '186 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

41. Pharmacosmos' application for patent term extension under 35 U.S.C. §156 for the '186 patent is currently pending and requests an extension of 1,162 days, which would set the expiration date of the '186 patent to December 30, 2034.

ANSWER: DRL admits that according to the records of the U.S. Patent and Trademark Office ("USPTO"), Pharmacosmos has requested a patent term extension under 35 U.S.C. § 156 for the '186 patent. DRL denies the remaining allegations of this paragraph.

42. The '197 patent was duly and legally issued by the USPTO on December 3, 2013 and is titled "CDK Inhibitors." A true and correct copy of the '197 patent is attached as Exhibit B. The '197 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '197 patent was issued on December 3, 2013, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '197 patent has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '197 patent is attached to the Complaint as Exhibit B. DRL specifically denies that the '197 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

43. The '276 patent was duly and legally issued by the USPTO on May 1, 2018 and is titled "CDK Inhibitors." A true and correct copy of the '276 patent is attached as Exhibit C. The '276 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '276 patent was issued on May 1, 2018, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '276 patent has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '276 patent is attached to the Complaint as Exhibit C. DRL specifically denies that the '276 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

44. The '849 patent was duly and legally issued by the USPTO on January 29, 2019 and is titled "CDK Inhibitors." A true and correct copy of the '849 patent is attached as Exhibit D. The '849 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '849 patent was issued on January 29, 2019, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '849 patent has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '849 patent is attached to the Complaint as Exhibit D. DRL specifically denies that the '849 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

45. The '850 patent was duly and legally issued by the USPTO on January 29, 2019 and is titled "CDK Inhibitors." A true and correct copy of the '850 patent is attached as Exhibit E. The '850 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '850 patent was issued on January 29, 2019, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '850 patent has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '850 patent is attached to the Complaint as Exhibit E. DRL specifically denies that the '850 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

46. The '120 patent was duly and legally issued by the USPTO on February 23, 2021 and is titled "CDK Inhibitors." A true and correct copy of the '120 patent is attached as Exhibit F. The '120 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '120 patent was issued on February 23, 2021, and is titled "CDK inhibitors." DRL further admits that according to FDA's Orange Book, the '120 patent has a listed expiration date of October 25, 2031. DRL also admits that a purported copy of the '120 patent is attached to the Complaint as Exhibit F. DRL specifically denies that the '120 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

47. The '042 patent was duly and legally issued by the USPTO on June 22, 2021 and is titled "Transient Protection of Normal Cells During Chemotherapy." A true and correct copy of the '042 patent is attached as Exhibit G The '042 patent will expire on October 25, 2031.

ANSWER: DRL admits that on its face, the '042 patent was issued on June 22, 2021, and is titled "Transient Protection of Normal Cells During Chemotherapy." DRL further admits that according to FDA's Orange Book, the '042 patent has a listed expiration date of October 25, 2031. DRL also

admits that a purported copy of the '042 patent is attached to the Complaint as Exhibit G. DRL specifically denies that the '042 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

48. The '530 patent was duly and legally issued by the USPTO on November 8, 2016 and is titled "Transient Protection of Normal Cells During Chemotherapy." A true and correct copy of the '530 patent is attached as Exhibit H. The '530 patent is currently set to expire on March 14, 2034.

ANSWER: DRL admits that on its face, the '530 patent was issued on November 8, 2016, and is titled "Transient Protection of Normal Cells During Chemotherapy." DRL further admits that according to FDA's Orange Book, the '530 patent has a listed expiration date of March 14, 2034. DRL also admits that a purported copy of the '530 patent is attached to the Complaint as Exhibit H. DRL specifically denies that the '530 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

49. The '992 patent was duly and legally issued by the USPTO on October 2, 2018 and is titled "Transient Protection of Normal Cells During Chemotherapy." A true and correct copy of the '992 patent is attached as Exhibit I. The '992 patent will expire on March 14, 2034.

ANSWER: DRL admits that on its face, the '992 patent was issued on October 2, 2016, and is titled "Transient Protection of Normal Cells During Chemotherapy." DRL further admits that according to FDA's Orange Book, the '992 patent has a listed expiration date of March 14, 2034. DRL also admits that a purported copy of the '992 patent is attached to the Complaint as Exhibit I. DRL specifically denies that the '992 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

50. The '984 patent was duly and legally issued by the USPTO on April 6, 2021 and is titled "Transient Protection of Normal Cells During Chemotherapy." A true and correct copy of the '984 patent is attached as Exhibit J. The '984 patent will expire on March 14, 2034.

ANSWER: DRL admits that on its face, the '984 patent was issued on April 6, 2021, and is titled "Transient Protection of Normal Cells During Chemotherapy." DRL further admits that according

to FDA's Orange Book, the '984 patent has a listed expiration date of March 14, 2034. DRL also admits that a purported copy of the '984 patent is attached to the Complaint as Exhibit J. DRL specifically denies that the '984 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

51. The '523 patent was duly and legally issued by the USPTO on August 8, 2023 and is titled "Transient Protection of Normal Cells During Chemotherapy." A true and correct copy of the '523 patent is attached as Exhibit K. The '523 patent will expire on March 14, 2034.

ANSWER: DRL admits that on its face, the '523 patent was issued on August 8, 2023, and is titled "Transient Protection of Normal Cells During Chemotherapy." DRL further admits that according to FDA's Orange Book, the '523 patent has a listed expiration date of March 14, 2034. DRL also admits that a purported copy of the '523 patent is attached to the Complaint as Exhibit K. DRL specifically denies that the '523 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

52. The '352 patent was duly and legally issued by the USPTO on December 20, 2022 and is titled "Preservation of Immune Response During Chemotherapy Regimens." A true and correct copy of the '352 patent is attached as Exhibit L. The '352 patent will expire on July 23, 2039.

ANSWER: DRL admits that on its face, the '352 patent was issued on December 20, 2022, and is titled "Preservation of Immune Response During Chemotherapy Regimens." DRL further admits that according to FDA's Orange Book, the '352 patent has a listed expiration date of July 23, 2039. DRL admits that a purported copy of the '352 patent is attached to the Complaint as Exhibit L. DRL specifically denies that the '352 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

53. 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." A true and correct copy of the '666 patent is attached as Exhibit M. The '666 patent will expire on November 13, 2040.

ANSWER: DRL admits that on its face, the '666 patent was issued on December 17, 2024, and is titled "Morphic Forms of Trilaciclib And Methods of Manufacture Thereof." DRL further admits that according to FDA's Orange Book, the '666 patent has a listed expiration date of November 13, 2040. DRL also admits that a purported copy of the '666 patent is attached to the Complaint as Exhibit M. DRL specifically denies that the '666 patent was duly and legally issued, and denies the remaining allegations of this paragraph.

54. Pharmacosmos Holding A/S is the assignee of the patents-in-suit.

ANSWER: DRL admits that Pharmacosmos Holding A/S is the purported assignee of the patents-in-suit according to the records of the USPTO. DRL denies the remaining allegations in this paragraph.

55. Pharmacosmos Therapeutics Inc. holds an exclusive license under the patents-in-suit to commercialize COSELA® in the United States.

ANSWER: DRL lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

DRL'S ANDA AND NOTICE LETTER

56. On information and belief, DRL submitted DRL's 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 DRL's ANDA Product as a purported generic version of COSELA® prior to the expiration of the patents-in-suit. On information and belief, DRL's ANDA contains a Paragraph IV Certification with respect to the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, and '666 patents.

ANSWER: DRL admits that it submitted ANDA No. 220230 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell DRL's ANDA Product in the United States. DRL further admits that DRL's Notice Letter provided information to Plaintiffs regarding DRL's ANDA No. 220230 pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

57. Pharmacosmos Therapeutics Inc. received DRL's Paragraph IV Notice Letter in New Jersey on March 25, 2025. In its Paragraph IV Notice Letter, DRL Inc. represented that DRL's ANDA included Paragraph IV Certifications with respect to the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, and '666 patents, and that DRL Inc. is seeking approval to engage in the commercial manufacture, use, or sale of DRL's ANDA Product prior to the expiration of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, and '666 patents. According to DRL's Paragraph IV Notice Letter, DRL's ANDA Product contains trilaciclib.

ANSWER: On information and belief, DRL admits that Pharmacosmos received DRL's Notice Letter on March 25, 2025. DRL further admits that DRL's Notice Letter provided information to Plaintiffs regarding DRL's ANDA No. 220230 pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

58. DRL's Paragraph IV Notice Letter did not provide notice of any certification required by 21 U.S.C. § 355(j)(2)(A) for the '352 patent with DRL's ANDA. However, on information and belief, in light of its PIV Certifications with respect to the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, and '666 patents, DRL is seeking approval from the FDA to commercially manufacture, use, market, or sell DRL's ANDA product prior to the expiration of the '352 patent.

ANSWER: DRL admits that DRL's Notice Letter provided information to Plaintiffs regarding DRL's ANDA No. 220230 pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

59. DRL's Paragraph IV Notice Letter purported to contain a "Detailed Statement for ANDA 220230" ("Detailed Statement").

ANSWER: DRL admits that DRL' Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

60. DRL's Detailed Statement alleged that one or more claims of each of the '186, '197, '276, '850, '120, '530, '992, '984, '523, and '666 patents will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Product and that one or more claims of each of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, and '523 patents are invalid. DRL's Detailed Statement did not allege that the '666 patent is invalid.

ANSWER: DRL admits that DRL's Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), and that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

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

ANSWER: DRL admits that DRL's Notice Letter included an "Offer of Confidential Access." DRL further admits that counsel for Plaintiffs and counsel for DRL discussed the terms of the "Offer of Confidential Access" contained in DRL's Notice Letter. DRL denies the remaining allegations in this paragraph.

62. On April 7, 2025, DRL informed Pharmacosmos that they would get back to Pharmacosmos "soon." On April 16, 2025, DRL informed Pharmacosmos that they "should be able to get back to [Pharmacosmos] early next week." On April 25, 2025, DRL refused to produce the entirety of Module 1, 2, and 3, instead offering the proposed label to DRL's ANDA product and Section 2.3.S. On April 28, 2025, Pharmacosmos informed DRL that it maintained is position that Modules 1, 2, and 3 of DRL's ANDA were necessary to evaluate DRL's position. Pharmacosmos informed DRL that it appeared the parties were at an impasse but offered to meet and confer. DRL has not responded to Pharmacosmos' offer to meet and confer, and the parties were not able to reach an agreement as of the date of this Complaint. To date, DRL has not provided Pharmacosmos with a copy of any portion of DRL's ANDA.

ANSWER: DRL admits that counsel for Plaintiffs and counsel for DRL discussed the terms of the "Offer of Confidential Access" contained in DRL's Notice Letter, and that Plaintiffs filed this Complaint on May 7, 2025. DRL denies the remaining allegations in this paragraph.

63. On information and belief, DRL Inc. and DRL Ltd. have participated in the preparation and submission of DRL's ANDA, have provided material support to the preparation and submission of DRL's ANDA, and intend to support the further prosecution of DRL's ANDA.

ANSWER: DRL admits that it submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

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

ANSWER: DRL admits that it submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

66. Pharmacosmos is commencing this action within 45 days of the date of receipt of DRL'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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that the Complaint in this Action was filed on May 7, 2025. DRL denies the remaining allegations in this paragraph.

ACTS GIVING RISE TO THIS ACTION

COUNT I
INFRINGEMENT OF THE '186 PATENT BY DRL

67. The allegations of paragraphs 1-66 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-66 as if fully set forth herein.

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

ANSWER: DRL admits that it submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

69. DRL has infringed the '186 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

70. The claims of the '186 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '186 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

71. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

72. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '186 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '186 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

73. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

74. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

75. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

76. On information and belief, DRL has acted with full knowledge of the '186 patent and without a reasonable basis for believing that it would not be liable for infringement of the '186 patent; active inducement of infringement of the '186 patent; and/or contribution to the infringement by others of the '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

77. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '186 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

78. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '186 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

79. The submission of DRL'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 DRL's ANDA Product before the expiration of the '186 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT II
INFRINGEMENT OF THE '197 PATENT BY DRL

80. The allegations of paragraphs 1-79 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-79 as if fully set forth herein.

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

ANSWER: DRL admits that it submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

82. DRL has infringed the '197 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

83. The claims of the '197 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '197 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

84. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

85. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '197 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '186 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

86. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

87. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

88. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the remaining allegations in this paragraph.

89. On information and belief, DRL has acted with full knowledge of the '197 patent and without a reasonable basis for believing that it would not be liable for infringement of the '197 patent; active inducement of infringement of the '197 patent; and/or contribution to the infringement by others of the '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

90. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '197 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

91. The claims of the '197 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '197 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

92. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '186 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

93. The submission of DRL'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 DRL's ANDA Product before the expiration of the '197 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT III
INFRINGEMENT OF THE '276 PATENT BY DRL

94. The allegations of paragraphs 1-93 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-93 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

96. DRL has infringed the '276 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

97. The claims of the '276 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '276 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

98. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

99. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '276 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '276 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

100. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

101. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

102. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

103. On information and belief, DRL has acted with full knowledge of the '276 patent and without a reasonable basis for believing that it would not be liable for infringement of the '276 patent; active inducement of infringement of the '276 patent; and/or contribution to the infringement by others of the '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

104. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '276 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

105. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '276 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between

Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

106. The submission of DRL'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 DRL's ANDA Product before the expiration of the '276 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT IV
INFRINGEMENT OF THE '849 PATENT BY DRL

107. The allegations of paragraphs 1-106 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-106 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

109. DRL has infringed the '849 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

110. The claims of the '849 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '849 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

111. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

112. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '849 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '849 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

113. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

114. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

115. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

116. On information and belief, DRL has acted with full knowledge of the '849 patent and without a reasonable basis for believing that it would not be liable for infringement of the '849 patent; active inducement of infringement of the '849 patent; and/or contribution to the infringement by others of the '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

117. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '849 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

118. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '849 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

119. The submission of DRL'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 DRL's ANDA Product before the expiration of the '849 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT V
INFRINGEMENT OF THE '850 PATENT BY DRL

120. The allegations of paragraphs 1-119 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-119 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

122. DRL has infringed the '850 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

123. The claims of the '850 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '850 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

124. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

125. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '850 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '850 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

126. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

127. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

128. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

129. On information and belief, DRL has acted with full knowledge of the '850 patent and without a reasonable basis for believing that it would not be liable for infringement of the '850 patent; active inducement of infringement of the '850 patent; and/or contribution to the infringement by others of the '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

130. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '850 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

131. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '849 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between

Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

132. The submission of DRL'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 DRL's ANDA Product before the expiration of the '850 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT VI
INFRINGEMENT OF THE '120 PATENT BY DRL

133. The allegations of paragraphs 1-132 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-132 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

135. DRL has infringed the '120 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

136. The claims of the '120 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '120 patent is titled "CDK inhibitors." DRL denies the remaining allegations in this paragraph.

137. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

138. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '120 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '120 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

139. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

140. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

141. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

142. On information and belief, DRL has acted with full knowledge of the '120 patent and without a reasonable basis for believing that it would not be liable for infringement of the '120 patent; active inducement of infringement of the '120 patent; and/or contribution to the infringement by others of the '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

143. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '120 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

144. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '120 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

145. The submission of DRL'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 DRL's ANDA Product before the expiration of the '120 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT VII
INFRINGEMENT OF THE '042 PATENT BY DRL

146. The allegations of paragraphs 1-145 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-145 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

148. DRL has infringed the '042 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

149. The claims of the '042 patent are directed to, *inter alia*, trilaciclib and salts thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that the '042 patent is titled "Transient Protection of Normal Cells During Chemotherapy." DRL denies the remaining allegations in this paragraph.

150. According to DRL's Paragraph IV Notice Letter, and on information and belief, DRL's ANDA Product contains trilaciclib dihydrochloride. DRL's Paragraph IV Notice Letter at pp. 2-3.

ANSWER: DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

151. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '042 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '042 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

152. On information and belief, if DRL's ANDA is approved, DRL and its affiliates will immediately make, use, sell, offer for sale, or otherwise distribute DRL's ANDA Product in the United States, including in New Jersey, thereby directly infringing one or more claims of the '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

153. DRL's commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of DRL's ANDA Product will actively induce and/or contribute to the infringement of the '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

154. Unless enjoined by this Court, upon approval of ANDA No. 220230, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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 '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

155. On information and belief, DRL has acted with full knowledge of the '042 patent and without a reasonable basis for believing that it would not be liable for infringement of the '042 patent; active inducement of infringement of the '042 patent; and/or contribution to the infringement by others of the '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

156. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any sufficient contention that DRL's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '042 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

157. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '042 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between

Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

158. The submission of DRL'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 DRL's ANDA Product before the expiration of the '042 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT VIII
INFRINGEMENT OF THE '530 PATENT BY DRL

159. The allegations of paragraphs 1-158 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-158 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

161. DRL has infringed the '530 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

162. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '530 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the

submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '530 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

164. On information and belief DRL's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA® (Exhibit N).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

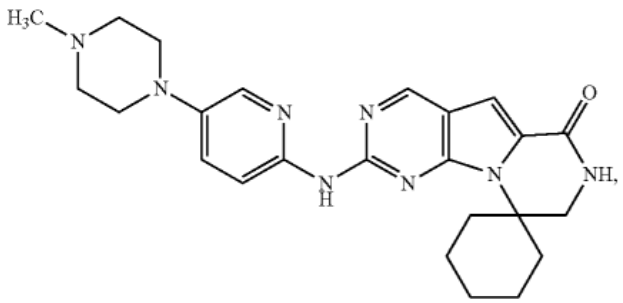
166. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

167. As an example, claim 36 of the '530 patent recites:

> A method of reducing the effect of chemotherapy on healthy cells in a subject being treated for cyclin-dependent kinase 4/6 (CDK4/6) replication independent cancer, wherein said healthy cells are hematopoietic stem cells or hematopoietic progenitor cells, the method

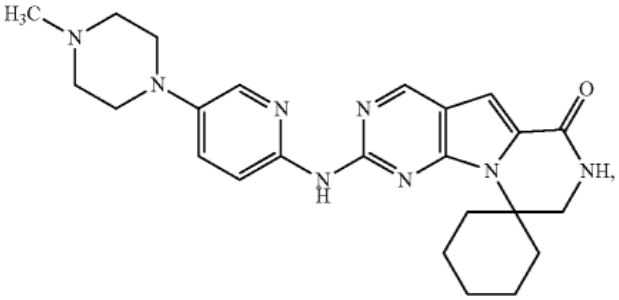
comprising administering to the subject an effective amount of at least one chemotherapeutic agent and a compound of the formula:



or a pharmaceutically acceptable salt thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that claim 36 of the '530 patent recites:

> A method of reducing the effect of chemotherapy on healthy cells in a subject being treated for cyclin-dependent kinase 4/6 (CDK4/6) replication independent cancer, wherein said healthy cells are hematopoietic stem cells or hematopoietic progenitor cells, the method comprising administering to the subject an effective amount of at least one chemotherapeutic agent and a compound of the formula:



or a pharmaceutically acceptable salt thereof.

DRL denies the remaining allegations in this paragraph.

168. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will practice the method recited in at least claim 36 of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

169. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any contention that the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will not infringe, and/or that DRL's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product will not contribute to the infringement of, or induce the infringement of certain claims of the '530 patent, including claim 36.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

171. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product will infringe one or more claims of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

172. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

173. On information and belief, DRL plans and intends to, and will, actively induce infringement of one or more claims of the '530 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '530 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

174. On information and belief, physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

175. On information and belief, DRL knows, should know, or is willfully blind to the fact that physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '530 patent, and DRL has the specific intent to actively encourage physicians to infringe one or more claims of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

176. On information and belief, DRL knows that DRL's ANDA Product and DRL's ANDA Product Labeling are especially made or adapted for use in infringing the '530 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and DRL's ANDA Product Labeling are not suitable for substantial non-infringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '530 patent immediately and imminently upon approval of DRL's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

177. Notwithstanding DRL's knowledge of the claims of the '530 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with DRL's ANDA Product Labeling following FDA approval of DRL's ANDA prior to the expiration of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

178. The foregoing actions by DRL constitute and/or will constitute infringement of the '530 patent; active inducement of infringement of the '530 patent; and/or contribution to the infringement by others of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

179. On information and belief, DRL has acted with full knowledge of the '530 patent and without a reasonable basis for believing that it would not be liable for infringement of the '530 patent; active inducement of infringement of the '530 patent; and/or contribution to the infringement by others of the '530 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

180. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '530 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

181. The submission of DRL'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 DRL's ANDA Product before the expiration of the '530 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT IX
INFRINGEMENT OF THE '992 PATENT BY DRL

182. The allegations of paragraphs 1-181 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-181 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

184. DRL has infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

185. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '992 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '992 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

186. On information and belief, DRL's ANDA product will be accompanied by DRL's ANDA Product Labeling.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

187. On information and belief DRL's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA® (Exhibit N).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

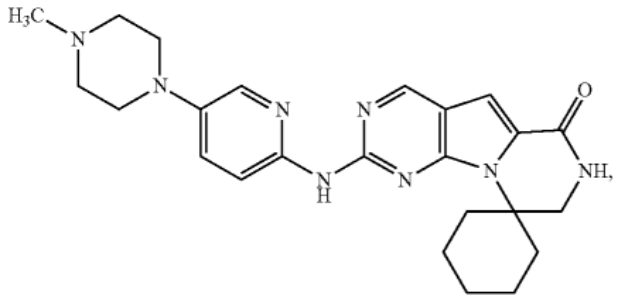
ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

189. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

190. As an example, claim 1 of the ’992 patent recites:

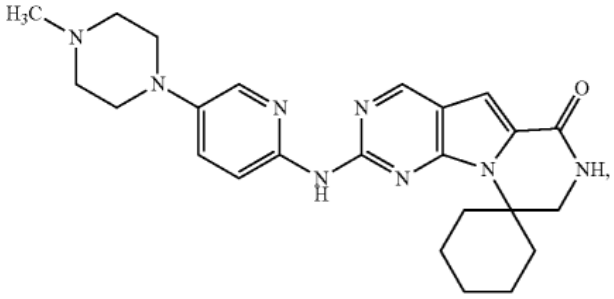
> A method of reducing the effect of chemotherapy on healthy cells in a human treated for cyclin-dependent kinase 4/6 (CDK4/6) replication independent small cell lung cancer, wherein said healthy cells are hematopoietic stem cells or hematopoietic progenitor cells, the method comprising administering to the human an effective amount of chemotherapeutic agent carboplatin, an effective amount of chemotherapeutic agent etoposide, and an effective amount of a CDK4/6 inhibitor of the formula:



> or a pharmaceutically acceptable salt thereof.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that claim 1 of the ’992 patent recites:

> A method of reducing the effect of chemotherapy on healthy cells in a human treated for cyclin-dependent kinase 4/6 (CDK4/6) replication independent small cell lung cancer, wherein said healthy cells are hematopoietic stem cells or hematopoietic progenitor cells, the method comprising administering to the human an effective amount of chemotherapeutic agent carboplatin, an effective amount of chemotherapeutic agent etoposide, and an effective amount of a CDK4/6 inhibitor of the formula:



> or a pharmaceutically acceptable salt thereof.

DRL denies the remaining allegations in this paragraph.

191. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will practice the method recited in at least claim 36 of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

192. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any contention that the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will not infringe, and/or that DRL's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product will not contribute to the infringement of, or induce the infringement of certain claims of the '992 patent, including claim 1.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

194. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product will infringe one or more claims of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

195. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

196. On information and belief, DRL plans and intends to, and will, actively induce infringement of one or more claims of the '992 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '992 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

197. On information and belief, physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

198. On information and belief, DRL knows, should know, or is willfully blind to the fact that physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '992 patent, and DRL has the specific intent to actively encourage physicians to infringe one or more claims of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

199. On information and belief, DRL knows that DRL's ANDA Product and DRL's ANDA Product Labeling are especially made or adapted for use in infringing the '992 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and DRL's ANDA Product Labeling are not suitable for substantial non-infringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '992 patent immediately and imminently upon approval of DRL's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

200. Notwithstanding DRL's knowledge of the claims of the '992 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with DRL's ANDA Product Labeling following FDA approval of DRL's ANDA prior to the expiration of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

201. The foregoing actions by DRL constitute and/or will constitute infringement of the '992 patent; active inducement of infringement of the '992 patent; and/or contribution to the infringement by others of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

202. On information and belief, DRL has acted with full knowledge of the '992 patent and without a reasonable basis for believing that it would not be liable for infringement of the '992 patent; active inducement of infringement of the '992 patent; and/or contribution to the infringement by others of the '992 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

203. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '992 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

204. The submission of DRL'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 DRL's ANDA Product before the expiration of the '992 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT X
INFRINGEMENT OF THE '984 PATENT BY DRL

205. The allegations of paragraphs 1-204 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-204 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

207. DRL has infringed the '984 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

208. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '984 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '984 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

209. On information and belief, DRL's ANDA product will be accompanied by DRL's ANDA Product Labeling.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

210. On information and belief DRL's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA® (Exhibit N).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

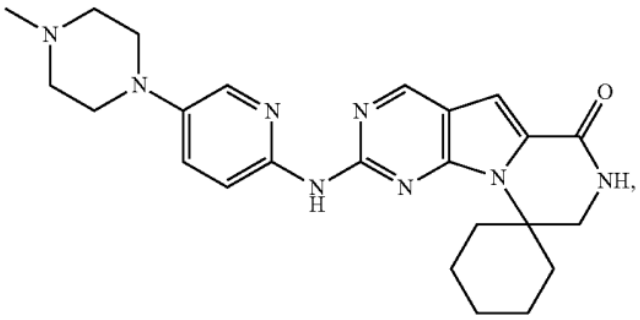
ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

212. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

213. As an example, claim 1 of the '984 patent recites:

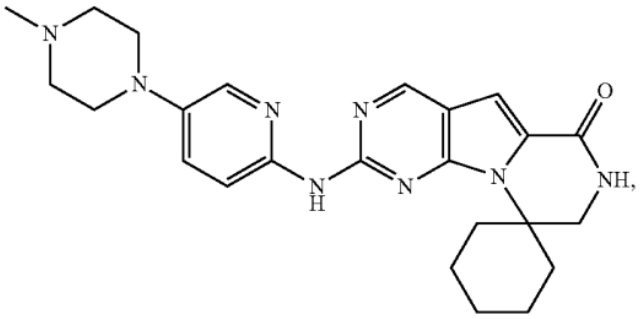
A method of treating a human with cancer comprising:
administering to the human an effective amount of a selective CDK4/6 inhibitor of structure:



or a pharmaceutically acceptable salt thereof; and,
administering to the human a chemotherapeutic agent;
wherein the selective CDK4/6 inhibitor is administered to the human about 24 hours or less prior to administration of the chemotherapeutic agent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that claim 1 of the '984 patent recites:

A method of treating a human with cancer comprising:
administering to the human an effective amount of a selective CDK4/6 inhibitor of structure:



or a pharmaceutically acceptable salt thereof; and,
administering to the human a chemotherapeutic agent;
wherein the selective CDK4/6 inhibitor is administered to the human about 24 hours or less prior to administration of the chemotherapeutic agent.

DRL denies the remaining allegations in this paragraph.

214. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will practice the method recited in at least claim 1 of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

215. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any contention that the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will not infringe, and/or that DRL's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product will not contribute to the infringement of, or induce the infringement of certain claims of the '984 patent, including claim 1.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

217. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product will infringe one or more claims of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

218. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

219. On information and belief, DRL plans and intends to, and will, actively induce infringement of one or more claims of the '984 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '984 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

220. On information and belief, physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

221. On information and belief, DRL knows, should know, or is willfully blind to the fact that physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '984 patent, and DRL has the specific intent to actively encourage physicians to infringe one or more claims of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

222. On information and belief, DRL knows that DRL's ANDA Product and DRL's ANDA Product Labeling are especially made or adapted for use in infringing the '984 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and DRL's ANDA Product Labeling are not suitable for substantial non-infringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '984 patent immediately and imminently upon approval of DRL's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

223. Notwithstanding DRL's knowledge of the claims of the '984 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with DRL's ANDA Product Labeling following FDA approval of DRL's ANDA prior to the expiration of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

224. The foregoing actions by DRL constitute and/or will constitute infringement of the '984 patent; active inducement of infringement of the '984 patent; and/or contribution to the infringement by others of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

225. On information and belief, DRL has acted with full knowledge of the '984 patent and without a reasonable basis for believing that it would not be liable for infringement of the '984 patent; active inducement of infringement of the '984 patent; and/or contribution to the infringement by others of the '984 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

226. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '984 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

227. The submission of DRL'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 DRL's ANDA Product before the expiration of the '984 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT XI
INFRINGEMENT OF THE '523 PATENT BY DRL

228. The allegations of paragraphs 1-227 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-227 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

230. DRL has infringed the '523 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with a Paragraph IV certification and seeking FDA approval of DRL's ANDA prior to the expiration of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

231. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '984 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA and its accompanying Paragraph IV Certification directed to the '984 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

232. On information and belief, DRL's ANDA product will be accompanied by DRL's ANDA Product Labeling.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

233. On information and belief DRL's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA® (Exhibit N).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

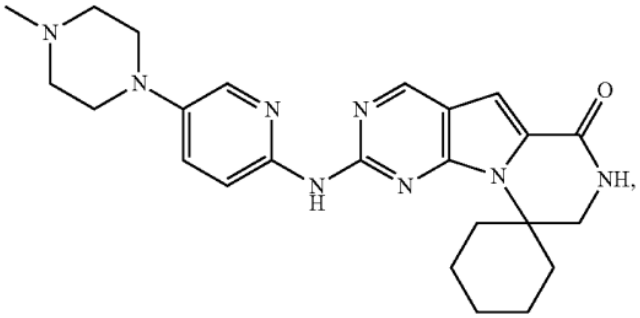
ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

235. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

236. As an example, claim 1 of the '523 patent recites:

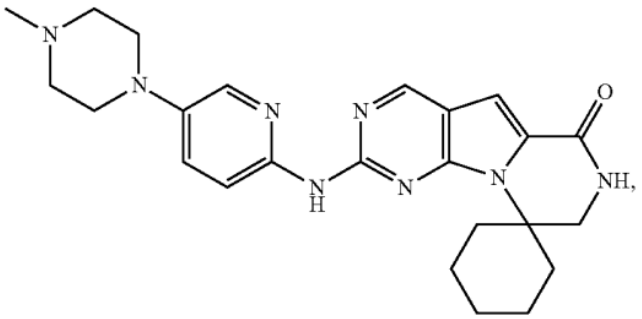
> A method of reducing chemotherapy-induced myelosuppression in a human receiving chemotherapy for the treatment of small cell lung cancer comprising administering to the human an effective amount of at least one chemotherapeutic agent and an effective amount of a CDK4/6 inhibitor of the structure:



> or a pharmaceutically acceptable salt thereof, wherein the CDK4/6 inhibitor is administered 24 hours or less prior to administration of the chemotherapeutic agent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits claim 1 of the '523 patent recites:

> A method of reducing chemotherapy-induced myelosuppression in a human receiving chemotherapy for the treatment of small cell lung cancer comprising administering to the human an effective amount of at least one chemotherapeutic agent and an effective amount of a CDK4/6 inhibitor of the structure:



> or a pharmaceutically acceptable salt thereof, wherein the CDK4/6 inhibitor is administered 24 hours or less prior to administration of the chemotherapeutic agent.

DRL denies the remaining allegations in this paragraph.

237. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will practice the method recited in at least claim 1 of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

238. DRL's Detailed Statement in DRL's Paragraph IV Notice Letter lacks any contention that the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will not infringe, and/or that DRL's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product will not contribute to the infringement of, or induce the infringement of certain claims of the '523 patent, including claim 1.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

240. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product will infringe one or more claims of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

241. On information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will infringe one or more claims of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

242. On information and belief, DRL plans and intends to, and will, actively induce infringement of one or more claims of the '523 patent when DRL's ANDA is approved, and plans

and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '523 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

243. On information and belief, physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

244. On information and belief, DRL knows, should know, or is willfully blind to the fact that physicians who act according to DRL's ANDA Product Labeling will infringe one or more claims of the '523 patent, and DRL has the specific intent to actively encourage physicians to infringe one or more claims of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

245. On information and belief, DRL knows that DRL's ANDA Product and DRL's ANDA Product Labeling are especially made or adapted for use in infringing the '523 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and DRL's ANDA Product Labeling are not suitable for substantial non-infringing use. On information and belief, DRL plans and intends to, and will, contribute to infringement of the '523 patent immediately and imminently upon approval of DRL's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

246. Notwithstanding DRL's knowledge of the claims of the '523 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with DRL's ANDA Product Labeling following FDA approval of DRL's ANDA prior to the expiration of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

247. The foregoing actions by DRL constitute and/or will constitute infringement of the '523 patent; active inducement of infringement of the '523 patent; and/or contribution to the infringement by others of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

248. On information and belief, DRL has acted with full knowledge of the '523 patent and without a reasonable basis for believing that it would not be liable for infringement of the '523 patent; active inducement of infringement of the '523 patent; and/or contribution to the infringement by others of the '523 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

249. Pharmacosmos will be irreparably harmed if DRL is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '523 patent. Pharmacosmos does not have an adequate remedy at law, and considering the balance of hardships between Pharmacosmos and DRL, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

250. The submission of DRL'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 DRL's ANDA Product before the expiration of the '523 patent also entitles Pharmacosmos to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT XII
INFRINGEMENT OF THE '352 PATENT BY DRL

251. The allegations of paragraphs 1-250 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-250 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

253. On information and belief, DRL seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of DRL's ANDA Product before the expiration of the '352 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL denies the allegations in this paragraph.

254. On information and belief, DRL did not disclose that it submitted any certifications, including a Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(A) for the '352 patent with DRL's ANDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

255. On information and belief, to the extent that DRL filed a statement under 21 U.S.C. § 505(j)(2)(A)(viii) ("section viii statement"), representing to FDA that it was not seeking approval for a method of use claimed by the '352 patent, DRL has infringed the '352 patent under 35 U.S.C. § 271(e)(2)(A) by submitting DRL's ANDA with an improper, insufficient, and/or misleading section viii statement with respect to the '352 patent and seeking FDA approval of DRL's ANDA prior to the expiration of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

256. DRL Inc. and DRL Ltd. are jointly and severally liable for any infringement of the '352 patent because, on information and belief, DRL Inc. and DRL Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of DRL's ANDA directed to the '352 patent to the FDA.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

257. On information and belief, DRL's ANDA product will be accompanied by DRL's ANDA Product Labeling.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

258. On information and belief, DRL's ANDA Product Labeling will be substantially identical to the prescribing information for COSELA®.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

259. On information and belief, like COSELA®, DRL's ANDA Product will be 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 (ES-SCLC). On information and belief, DRL's ANDA Product Labeling will contain information instructing the administration of DRL's ANDA Product prior to a platinum/etoposide-containing regimen for ES-SCLC, which includes standard of care platinum/etoposide-containing regimens for ES-SCLC.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

260. On information and belief, to the extent that DRL has filed a Section viii statement regarding the '352 patent, such statement is unfounded and/or erroneous. On information and belief, DRL has not and cannot modify the label for DRL's ANDA Product using 35 U.S.C. § 505(j)(2)(A)(viii) in a way that would avoid infringement of one or more claims of the '352 patent. Upon information and belief, DRL should have made a Paragraph IV certification to the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

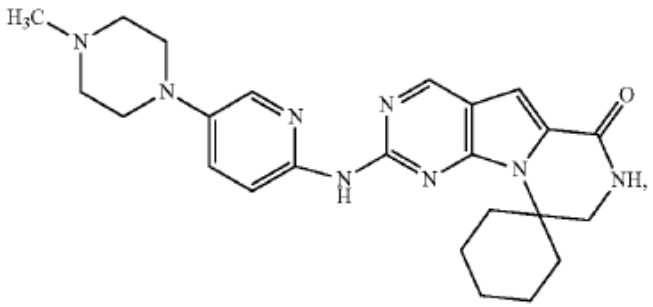
ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

262. 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,

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

iii) 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:

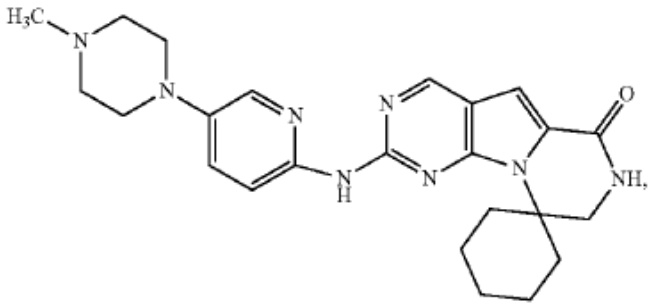
i) administering to the human at least one dose of an effective amount of the immune checkpoint inhibitor, and wherein the maintenance phase is administered following the cessation of the induction phase.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that 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,

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

iii) 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.

DRL denies the remaining allegations in this paragraph.

263. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's ANDA Product Labeling will practice the method recited in at least claim 1 of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

268. On information and belief, physicians will follow the clinical study information, prescribing information, and other instructions contained in DRL's ANDA Product Labeling when administering DRL's ANDA Product.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's ANDA includes a proposed label for DRL's ANDA Product. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

270. On information and belief, DRL knows, should know, or is willfully blind to the fact that, if DRL's ANDA Product is approved, physicians will follow the instructions contained in DRL's ANDA Product Labeling to administer DRL's ANDA Product in accordance with the standard of care. On information and belief, administration of DRL's ANDA product as instructed by DRL's ANDA Product Labeling in accordance with the standard of care will infringe one or more claims of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

271. On information and belief, DRL knows, should know, or is willfully blind to the fact that physicians who act according to DRL's ANDA Product Labeling will infringe one or

more claims of the '352 patent, and DRL has the specific intent to actively encourage physicians to infringe one or more claims of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

272. On information and belief, DRL will market DRL's ANDA Product with the specific intent and/or with the desire to actively induce, aid, and abet infringement of the '352 patent. DRL knows or reasonably should know that its proposed conduct will induce infringement of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

273. On information and belief, if DRL's ANDA is approved, DRL's marketing practices will induce physicians to administer DRL's ANDA Product in a manner that infringes one or more claims of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

276. The foregoing actions by DRL 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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

277. On information and belief, DRL 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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

278. DRL's Paragraph IV Notice Letter does not provide any contention that DRL 's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '352 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL admits that DRL's Notice Letter speaks for itself. DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

280. The submission of DRL'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 DRL'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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

COUNT XIII
INFRINGEMENT OF THE '666 PATENT BY DRL

281. The allegations of paragraphs 1-279 above are repeated and re-alleged as if set forth fully herein.

ANSWER: DRL incorporates by reference its responses to paragraphs 1-280 as if fully set forth herein.

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

ANSWER: DRL admits that DRL submitted ANDA No. 220230 to the FDA seeking approval to manufacture, use, or sell DRL's ANDA Product in the United States. DRL denies the remaining allegations in this paragraph.

283. The '666 patent is entitled "Morphic Forms of Trilaciclib and Methods of Manufacture Thereof."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that, on its face, the '666 patent is titled "Morphic Forms of Trilaciclib and Methods of Manufacture Thereof." DRL denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

288. Unless enjoined by this Court, upon approval of DRL's ANDA, DRL will make, use, offer to sell, or sell DRL's ANDA Product within the United States, or will import DRL'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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

289. On information and belief, DRL 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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

292. The submission of DRL'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 DRL'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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, DRL denies the allegations in this paragraph.

PRAYER FOR RELIEF

This section of Plaintiffs' Complaint is a prayer for relief and does not require a response. To the extent any response is required, DRL denies that Plaintiffs are entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

DRL hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. DRL reserves the right to assert additional defenses and/or otherwise supplement this Answer as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '186 patent, the '197 patent, the '276 patent, the '849 patent, the '850 patent, the '120 patent, the '042 patent, the '530 patent, the '992 patent, the '984 patent, the '523 patent, the '352 patent, or the '666 patent. either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

The filing of DRL's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, '352, and '666 patents.

Third Affirmative Defense

DRL has not, does not, and will not indirectly infringe any valid and enforceable claim of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, '352, and '666 patents.

Fourth Affirmative Defense

The claims of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, '352, and '666 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including, without limitation, sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

Fifth Affirmative Defense

The Complaint fails to state a claim upon which relief can be granted.

Sixth Affirmative Defense

DRL has not willfully infringed any claim of the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, '352, and '666 patent.

Seventh Affirmative Defense

Plaintiff is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines

Eighth Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiffs/Counterclaim-Defendants Pharmacosmos A/S, Pharmacosmos Holding A/S, and Pharmacosmos Therapeutics Inc. (collectively, "Pharmacosmos"), Defendants/Counterclaim-Plaintiffs DRL Pharmaceuticals, Inc. ("DRL Inc.") and DRL Pharmaceuticals, Ltd. ("DRL Ltd.") (collectively, "DRL") state as follows:

PARTIES

1. DRL Inc. is a corporation organized under the laws of New Jersey, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540.

2. DRL Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad Telangana, India 500034.

3. On information and belief, 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.

4. On information and belief, 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.

5. On information and belief, 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.

NATURE OF ACTION

6. DRL seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 8,598,186 ("the '186 patent"), 8,598,197 ("the '197 patent"), 9,957,276 ("the

'276 patent"), 10,189,849 ("the '849 patent"), 10,189,850 ("the '850 patent"), 10,927,120 ("the '120 patent"), 11,040,042 ("the '042 patent"), 9,487,530 ("the '530 patent"), 10,085,992 ("the '992 patent"), 10,966,984 ("the '984 patent"), 11,717,523 ("the '523 patent"), 11,529,352 ("the '352 patent"), and 12,168,666 ("the '666 patent") (collectively, the "Patents-in-Suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337, 1338, 1367, 2201, and 2202.

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants Pharmacosmos because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its Complaint here.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400 for purposes of this case, and by Pharmacosmos's choice of forum.

10. There is an actual and justiciable controversy between the parties as to the infringement the '186, '197, '276, '849, '850, '120, '042, '530, '992, '984, '523, '352, and '666 patent.

FACTUAL BACKGROUND

11. Upon information and belief, Pharmacosmos A/S is the holder of NDA No. 214200, which purportedly covers COSELA®, trilaciclib for injection, 300 mg.

12. An NDA must include, among others, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

13. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA")

publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

14. The '186 patent, titled "CDK Inhibitors," issued on December 3, 2013.

15. The '197 patent, titled "CDK Inhibitors," issued on December 3, 2013.

16. The '276 patent, titled "CDK Inhibitors," issued on May 1, 2018.

17. The '849 patent, titled "CDK Inhibitors," issued on January 29, 2019.

18. The '850 patent, titled "CDK Inhibitors," issued on January 29, 2019.

19. The '120 patent, titled "CDK Inhibitors," issued on February 23, 2021.

20. The '042 patent, titled "Transient Protection of Normal Cells During Chemotherapy," issued on June 22, 2021.

21. The '530 patent, titled "Transient Protection of Normal Cells During Chemotherapy," issued on November 8, 2016.

22. The '992 patent, titled "Transient Protection of Normal Cells During Chemotherapy," issued on October 2, 2018.

23. The '984 patent, titled "Transient Protection of Normal Cells During Chemotherapy," issued on April 6, 2021.

24. The '523 patent, titled "Transient Protection of Normal Cells During Chemotherapy," issued on August 8, 2023.

25. The '352 patent, titled "Preservation of Immune Response During Chemotherapy Regimens," issued on December 20, 2022.

26. The '666 patent, titled "Morphic Forms of Trilaciclib and Methods of Manufacture Thereof," issued on December 17, 2024.

27. Upon information and belief, Pharmacosmos Holdings A/S is the assignee of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents.

28. Upon information and belief, Pharmacosmos caused the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents to be listed in the Orange Book in connection with COSELA®.

29. By listing the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents in the Orange Book, Pharmacosmos created a reasonable apprehension that it would file a patent infringement suit against applicants seeking regulatory approval for a generic version of COSELA®.

30. DRL submitted Abbreviated New Drug Application (“ANDA”) No. 220230 (“DRL’s ANDA”) to the FDA pursuant to 21 U.S.C. § 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, and sale of trilaciclib for injection, 300 mg (“DRL’s ANDA Product”).

31. Pharmacosmos filed a complaint against DRL on May 7, 2025, alleging infringement of the’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents.

32. As a consequence of the foregoing, there is an actual and justiciable controversy between DRL, on the one hand, and Pharmacosmos, on the other hand, as to whether the claims of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents are invalid and/or unenforceable, and whether the products and/or activities described in DRL’s ANDA No. 220230 infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents.

COUNT I
(Declaration of Noninfringement of the '186 Patent)

33. DRL re-alleges and incorporates the allegations of paragraphs 1-32 as if fully set forth herein.

34. Pharmacosmos alleges ownership, title, and/or interest to the '186 patent and has brought claims against DRL alleging infringement of the '186 patent.

35. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '186 patent.

36. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '186 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

37. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '186 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

38. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '186 patent and is not liable for any alleged infringement.

39. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '186 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

40. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product

has not, does not, and will not infringe any valid or enforceable claim of the '186 patent.

41. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Invalidity of the '186 Patent)

42. DRL re-alleges and incorporates the allegations of paragraphs 1-41 as if fully set forth herein.

43. Pharmacosmos alleges ownership, title, and/or interest to the '186 patent and has brought claims against DRL alleging infringement of the '186 patent.

44. One or more of the claims of the '186 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

45. The '186 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.

46. The alleged invention of the '186 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 '186 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '186 patent and would have had a reasonable expectation of success in doing so.

47. The subject matter claimed in the '186 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

48. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '186 patent.

49. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '186 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

50. DRL is entitled to a declaration that all claims of the '186 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

51. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement of the '197 Patent)

52. DRL re-alleges and incorporates the allegations of paragraphs 1-51 as if fully set forth herein.

53. Pharmacosmos alleges ownership, title, and/or interest to the '197 patent and has brought claims against DRL alleging infringement of the '197 patent.

54. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '197 patent.

55. The filing of DRL's ANDA has not, does not, and will not infringe any valid or

enforceable claim of the '197 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

56. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '197 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

57. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '197 patent and is not liable for any alleged infringement.

58. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '197 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

59. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '197 patent.

60. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Invalidity of the '197 Patent)

61. DRL re-alleges and incorporates the allegations of paragraphs 1-60 as if fully set forth herein.

62. Pharmacosmos alleges ownership, title, and/or interest to the '197 patent and has brought claims against DRL alleging infringement of the '197 patent.

63. One or more of the claims of the '197 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

64. The '197 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.

65. The alleged invention of the '197 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 '197 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '197 patent and would have had a reasonable expectation of success in doing so.

66. The subject matter claimed in the '197 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

67. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '197 patent.

68. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '197 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

69. DRL is entitled to a declaration that all claims of the '197 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

70. This case is an exceptional one, and DRL is entitled to an award of its reasonable

attorneys' fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Noninfringement of the '276 Patent)

71. DRL re-alleges and incorporates the allegations of paragraphs 1-70 as if fully set forth herein.

72. Pharmacosmos alleges ownership, title, and/or interest to the '276 patent and has brought claims against DRL alleging infringement of the '276 patent.

73. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '276 patent.

74. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '276 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

75. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '276 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

76. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '276 patent and is not liable for any alleged infringement.

77. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '276 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

78. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '276 patent.

79. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Invalidity of the '276 Patent)

80. DRL re-alleges and incorporates the allegations of paragraphs 1-79 as if fully set forth herein.

81. Pharmacosmos alleges ownership, title, and/or interest to the '276 patent and has brought claims against DRL alleging infringement of the '276 patent.

82. One or more of the claims of the '276 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

83. The '276 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.

84. The alleged invention of the '276 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 '276 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '276 patent and would have had a reasonable expectation of success in doing so.

85. The subject matter claimed in the '276 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

86. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’276 patent.

87. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’276 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

88. DRL is entitled to a declaration that all claims of the ’276 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

89. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Noninfringement of the ’849 Patent)

90. DRL re-alleges and incorporates the allegations of paragraphs 1-89 as if fully set forth herein.

91. Pharmacosmos alleges ownership, title, and/or interest to the ’849 patent and has brought claims against DRL alleging infringement of the ’849 patent.

92. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL’s ANDA and/or the manufacture, use, or sale in the United States of DRL’s ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the ’849 patent.

93. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '849 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

94. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '849 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

95. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '849 patent and is not liable for any alleged infringement.

96. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '849 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

97. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '849 patent.

98. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Invalidity of the '849 Patent)

99. DRL re-alleges and incorporates the allegations of paragraphs 1-98 as if fully set forth herein.

100. Pharmacosmos alleges ownership, title, and/or interest to the '849 patent and has brought claims against DRL alleging infringement of the '849 patent.

101. One or more of the claims of the '849 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for

invalidity and unenforceability.

102. The ’849 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.

103. The alleged invention of the ’849 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 ’849 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’849 patent and would have had a reasonable expectation of success in doing so.

104. The subject matter claimed in the ’849 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

105. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’849 patent.

106. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’849 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

107. DRL is entitled to a declaration that all claims of the ’849 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

108. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IX
(Declaration of Noninfringement of the '850 Patent)

109. DRL re-alleges and incorporates the allegations of paragraphs 1-108 as if fully set forth herein.

110. Pharmacosmos alleges ownership, title, and/or interest to the '850 patent and has brought claims against DRL alleging infringement of the '850 patent.

111. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '850 patent.

112. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '850 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

113. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '850 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

114. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '850 patent and is not liable for any alleged infringement.

115. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '850 patent is not infringed by DRL's ANDA, or the DRL

ANDA Product and/or activities described therein.

116. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '850 patent.

117. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT X
(Declaration of Invalidity of the '850 Patent)

118. DRL re-alleges and incorporates the allegations of paragraphs 1-117 as if fully set forth herein.

119. Pharmacosmos alleges ownership, title, and/or interest to the '850 patent and has brought claims against DRL alleging infringement of the '850 patent.

120. One or more of the claims of the '850 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

121. The '850 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.

122. The alleged invention of the '850 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 '850 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '850 patent and would have had a reasonable expectation of success in doing so.

123. The subject matter claimed in the '850 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

124. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '850 patent.

125. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '850 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

126. DRL is entitled to a declaration that all claims of the '850 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

127. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XI
(Declaration of Noninfringement of the '120 Patent)

128. DRL re-alleges and incorporates the allegations of paragraphs 1-127 as if fully set forth herein.

129. Pharmacosmos alleges ownership, title, and/or interest to the '120 patent and has brought claims against DRL alleging infringement of the '120 patent.

130. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or

enforceable claim of the ’120 patent.

131. The filing of DRL’s ANDA has not, does not, and will not infringe any valid or enforceable claim of the ’120 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

132. The manufacture, use, or sale of DRL’s Product has not, does not, and will not infringe any valid or enforceable claim of the ’120 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

133. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’120 patent and is not liable for any alleged infringement.

134. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’120 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

135. DRL is entitled to a declaration that the manufacture, use, or sale of DRL’s Product has not, does not, and will not infringe any valid or enforceable claim of the ’120 patent.

136. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XII
(Declaration of Invalidity of the ’120 Patent)

137. DRL re-alleges and incorporates the allegations of paragraphs 1-136 as if fully set forth herein.

138. Pharmacosmos alleges ownership, title, and/or interest to the ’120 patent and has brought claims against DRL alleging infringement of the ’120 patent.

139. One or more of the claims of the ’120 patent are invalid under one or more

provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

140. The '120 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.

141. The alleged invention of the '120 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 '120 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '120 patent and would have had a reasonable expectation of success in doing so.

142. The subject matter claimed in the '120 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

143. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '120 patent.

144. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '120 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

145. DRL is entitled to a declaration that all claims of the '120 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and

unenforceability.

146. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIII
(Declaration of Noninfringement of the '042 Patent)

147. DRL re-alleges and incorporates the allegations of paragraphs 1-146 as if fully set forth herein.

148. Pharmacosmos alleges ownership, title, and/or interest to the '042 patent and has brought claims against DRL alleging infringement of the '042 patent.

149. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '042 patent.

150. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '042 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

151. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '042 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

152. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '042 patent and is not liable for any alleged infringement.

153. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and

nonlimiting explanations for why the '042 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

154. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '042 patent.

155. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIV
(Declaration of Invalidity of the '042 Patent)

156. DRL re-alleges and incorporates the allegations of paragraphs 1-155 as if fully set forth herein.

157. Pharmacosmos alleges ownership, title, and/or interest to the '042 patent and has brought claims against DRL alleging infringement of the '042 patent.

158. One or more of the claims of the '042 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

159. The '042 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.

160. The alleged invention of the '042 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 '042 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '042 patent and would have had a reasonable expectation of success in doing so.

161. The subject matter claimed in the '042 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

162. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '042 patent.

163. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '042 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

164. DRL is entitled to a declaration that all claims of the '042 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

165. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XV
(Declaration of Noninfringement of the '530 Patent)

166. DRL re-alleges and incorporates the allegations of paragraphs 1-165 as if fully set forth herein.

167. Pharmacosmos alleges ownership, title, and/or interest to the '530 patent and has brought claims against DRL alleging infringement of the '530 patent.

168. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United

States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '530 patent.

169. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '530 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

170. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '530 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

171. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '530 patent and is not liable for any alleged infringement.

172. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '530 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

173. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '530 patent.

174. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XVI
(Declaration of Invalidity of the '530 Patent)

175. DRL re-alleges and incorporates the allegations of paragraphs 1-174 as if fully set forth herein.

176. Pharmacosmos alleges ownership, title, and/or interest to the '530 patent and has brought claims against DRL alleging infringement of the '530 patent.

177. One or more of the claims of the ’530 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

178. The ’530 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.

179. The alleged invention of the ’530 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 ’530 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’530 patent and would have had a reasonable expectation of success in doing so.

180. The subject matter claimed in the ’530 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

181. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’530 patent.

182. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’530 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

183. DRL is entitled to a declaration that all claims of the ’530 patent are invalid under

35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

184. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XVII
(Declaration of Noninfringement of the '992 Patent)

185. DRL re-alleges and incorporates the allegations of paragraphs 1-184 as if fully set forth herein.

186. Pharmacosmos alleges ownership, title, and/or interest to the '992 patent and has brought claims against DRL alleging infringement of the '992 patent.

187. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '992 patent.

188. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '992 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

189. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '992 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

190. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '992 patent and is not liable for any alleged infringement.

191. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '992 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

192. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '992 patent.

193. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XVIII
(Declaration of Invalidity of the '992 Patent)

194. DRL re-alleges and incorporates the allegations of paragraphs 1-193 as if fully set forth herein.

195. Pharmacosmos alleges ownership, title, and/or interest to the '992 patent and has brought claims against DRL alleging infringement of the '992 patent.

196. One or more of the claims of the '992 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

197. The '992 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.

198. The alleged invention of the '992 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 '992 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '992 patent and would

have had a reasonable expectation of success in doing so.

199. The subject matter claimed in the ’992 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

200. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’992 patent.

201. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’992 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

202. DRL is entitled to a declaration that all claims of the ’992 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

203. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XIX
(Declaration of Noninfringement of the ’984 Patent)

204. DRL re-alleges and incorporates the allegations of paragraphs 1-203 as if fully set forth herein.

205. Pharmacosmos alleges ownership, title, and/or interest to the ’984 patent and has brought claims against DRL alleging infringement of the ’984 patent.

206. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the

issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '984 patent.

207. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '984 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

208. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '984 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

209. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '984 patent and is not liable for any alleged infringement.

210. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '984 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

211. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '984 patent.

212. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XX
(Declaration of Invalidity of the '984 Patent)

213. DRL re-alleges and incorporates the allegations of paragraphs 1-212 as if fully set forth herein.

214. Pharmacosmos alleges ownership, title, and/or interest to the '984 patent and has

brought claims against DRL alleging infringement of the ’984 patent.

215. One or more of the claims of the ’984 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

216. The ’984 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.

217. The alleged invention of the ’984 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 ’984 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’984 patent and would have had a reasonable expectation of success in doing so.

218. The subject matter claimed in the ’984 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

219. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’984 patent.

220. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’984 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

221. DRL is entitled to a declaration that all claims of the ’984 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

222. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XXI
(Declaration of Noninfringement of the ’523 Patent)

223. DRL re-alleges and incorporates the allegations of paragraphs 1-222 as if fully set forth herein.

224. Pharmacosmos alleges ownership, title, and/or interest to the ’523 patent and has brought claims against DRL alleging infringement of the ’523 patent.

225. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL’s ANDA and/or the manufacture, use, or sale in the United States of DRL’s ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the ’523 patent.

226. The filing of DRL’s ANDA has not, does not, and will not infringe any valid or enforceable claim of the ’523 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

227. The manufacture, use, or sale of DRL’s Product has not, does not, and will not infringe any valid or enforceable claim of the ’523 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

228. DRL has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’523 patent and is not liable for any alleged

infringement.

229. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '523 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

230. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '523 patent.

231. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXII
(Declaration of Invalidity of the '523 Patent)

232. DRL re-alleges and incorporates the allegations of paragraphs 1-231 as if fully set forth herein.

233. Pharmacosmos alleges ownership, title, and/or interest to the '523 patent and has brought claims against DRL alleging infringement of the '523 patent.

234. One or more of the claims of the '523 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

235. The '523 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.

236. The alleged invention of the '523 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 '523 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to

combine the teachings of the prior art to achieve the alleged invention of the '523 patent and would have had a reasonable expectation of success in doing so.

237. The subject matter claimed in the '523 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

238. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '523 patent.

239. DRL incorporates by reference DRL's Notice Letter, which contains exemplary and nonlimiting explanations for why the '523 patent is not infringed by DRL's ANDA, or the DRL ANDA Product and/or activities described therein.

240. DRL is entitled to a declaration that all claims of the '523 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

241. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXIII
(Declaration of Noninfringement of the '352 Patent)

242. DRL re-alleges and incorporates the allegations of paragraphs 1-241 as if fully set forth herein.

243. Pharmacosmos alleges ownership, title, and/or interest to the '352 patent and has brought claims against DRL alleging infringement of the '352 patent.

244. There is an actual, substantial, continuing, and justiciable controversy exists

between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL's ANDA and/or the manufacture, use, or sale in the United States of DRL's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '352 patent.

245. The filing of DRL's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '352 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

246. The manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '352 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

247. DRL 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 any alleged infringement.

248. DRL is entitled to a declaration that the manufacture, use, or sale of DRL's Product has not, does not, and will not infringe any valid or enforceable claim of the '352 patent.

249. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXIV
(Declaration of Invalidity of the '352 Patent)

250. DRL re-alleges and incorporates the allegations of paragraphs 1-249 as if fully set forth herein.

251. Pharmacosmos alleges ownership, title, and/or interest to the '352 patent and has brought claims against DRL alleging infringement of the '352 patent.

252. One or more of the claims of the '352 patent are invalid under one or more

provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

253. 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.

254. 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 not more than the predictable use of prior art elements according to their established functions. A person of 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.

255. The subject matter claimed in the '352 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

256. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the '352 patent.

257. DRL is entitled to a declaration that all claims of the '352 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

258. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXV
(Declaration of Noninfringement of the ’666 Patent)

259. DRL re-alleges and incorporates the allegations of paragraphs 1-258 as if fully set forth herein.

260. Pharmacosmos alleges ownership, title, and/or interest to the ’666 patent and has brought claims against DRL alleging infringement of the ’666 patent.

261. There is an actual, substantial, continuing, and justiciable controversy exists between DRL, on the one hand, and Pharmacosmos, on the other hand, regarding, *inter alia*, the issue of whether the filing of DRL’s ANDA and/or the manufacture, use, or sale in the United States of DRL’s ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the ’666 patent.

262. The filing of DRL’s ANDA has not, does not, and will not infringe any valid or enforceable claim of the ’666 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

263. The manufacture, use, or sale of DRL’s Product has not, does not, and will not infringe any valid or enforceable claim of the ’666 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

264. DRL 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 any alleged infringement.

265. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’666 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

266. DRL is entitled to a declaration that the manufacture, use, or sale of DRL’s Product

has not, does not, and will not infringe any valid or enforceable claim of the '666 patent.

267. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXVI
(Declaration of Invalidity of the '666 Patent)

268. DRL re-alleges and incorporates the allegations of paragraphs 1-267 as if fully set forth herein.

269. Pharmacosmos alleges ownership, title, and/or interest to the '666 patent and has brought claims against DRL alleging infringement of the '666 patent.

270. One or more of the claims of the '666 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

271. 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.

272. 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 not more than the predictable use of prior art elements according to their established functions. A person of 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.

273. The subject matter claimed in the '666 patent fails to comply with 35 U.S.C. § 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 would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

274. There is an actual, present, genuine, and justiciable controversy between DRL and Pharmacosmos regarding, *inter alia*, the validity of all claims of the ’666 patent.

275. DRL incorporates by reference DRL’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’666 patent is not infringed by DRL’s ANDA, or the DRL ANDA Product and/or activities described therein.

276. DRL is entitled to a declaration that all claims of the ’666 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

277. This case is an exceptional one, and DRL is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, DRL Pharmaceuticals Inc. and DRL Pharmaceuticals Ltd. (“DRL”) respectfully request that this Court enter a Judgment and Order in its favor and against Counterclaim-Defendants Pharmacosmos as follows:

(a) Declaring that the filing of DRL’s ANDA has not infringed and does not infringe any valid and enforceable claim of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents;

(b) Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of DRL’s ANDA Product does not and will not infringe any valid and enforceable claim of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents;

(c) Declaring that all claims of the ’186, ’197, ’276, ’849, ’850, ’120, ’042, ’530, ’992, ’984, ’523, ’352, and ’666 patents are invalid and/or unenforceable;

(d) Awarding DRL its costs and expenses in this action;

(e) Declaring this an exception case in favor of DRL pursuant to 35 U.S.C. § 285 and awarding DRL its reasonable attorneys' fees; and

(f) Awarding DRL any further and additional relief as the Court deems just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.

By: s/ James S. Richter
James S. Richter
jrichter@midlige-richter.com

Dated: July 14, 2025

OF COUNSEL *(Pro Hac Vice Forthcoming)*

Jovial Wong
Sharon Lin
Anna Sonju
WINSTON & STRAWN LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5000
jwong@winston.com
slin@winston.com
asonju@winston.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following actions currently pending in this District:

- PHARMACOSMOS A/S et al v. TEVA PHARMACEUTICALS, INC. et al, Civil Action No. 2:25-cv-03218-JXN-AME
- PHARMACOSMOS A/S et al v. HETERO LABS LIMITED et al Civil Action No. 2:25-cv-03945-JXN-AME

DRL is not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: July 14, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories, Ltd.., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: July 14, 2025

CERTIFICATION OF SERVICE

I certify that on July 14, 2025, a true and correct copy of the foregoing Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories, Ltd.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint for Patent Infringement was served upon all counsel of record by notice of electronic filing.

s/ James S. Richter
James S. Richter

Dated: July 14, 2025