Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

Attorneys for Plaintiff
American Regent, Inc.

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett (*pro hac vice* to be filed)
Adam LaRock (*pro hac vice* to be filed)
Alex Alfano (*pro hac vice* to be filed)
Ryan Conkin (*pro hac vice* to be filed)
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

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

AMERICAN REGENT, INC., *Plaintiff*, v. ENDO OPERATIONS LIMITED, *Defendant.*	Civil Action No. 25-11945 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Endo Operations Limited ("Endo") alleges as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Endo's submission to the United States Food and Drug

Administration ("FDA") of Abbreviated New Drug Application No. 219680 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic version of ARI's Tralement® (trace elements injection 4*, USP) in 1 mL single-dose vials and 5 mL Pharmacy Bulk Package vials and Multrys® (trace elements injection 4*, USP) drug products ("the ANDA Products") prior to the expiration of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

3. On information and belief, Defendant Endo Operations Limited is a company organized and existing under the laws of Ireland, having a principal place of business at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland. On further information and belief, and as indicated in Endo's letter dated May 14, 2025 ("the Notice Letter"), Endo maintains a regular and established place of business at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. On information and belief, this Court has personal jurisdiction over Endo under the New Jersey state long arm statute and consistent with due process of law because Endo has

extensive contacts with the State of New Jersey and regularly does business in this Judicial District. Further, Endo plans to sell the ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

6. This Court has personal jurisdiction over Endo because it has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, and as indicated in the Notice Letter, Endo maintains a regular and established place of business at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677. On further information and belief, Endo regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Endo derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

7. This Court has personal jurisdiction over Endo because, on information and belief, Endo derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

8. On information and belief, Endo is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district.

9. This Court has personal jurisdiction over Endo because, on information and belief, Endo derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

10. This Court has personal jurisdiction over Endo because, *inter alia,* Endo has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Endo will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

11. In the alternative, this Court has personal jurisdiction over Endo because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Endo is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Endo has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting the ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Endo satisfies due process.

12. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

13. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Endo has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677. In the alternative, Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) at least because, on information and belief, Endo is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

14. On information and belief, Endo has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

15. On information and belief, as set forth above, on information and belief, Endo maintains regular and established places of business in New Jersey, including its offices and/or facilities at 300 Tice Blvd., Suite 230, Woodcliff Lake, New Jersey 07677.

16. On information and belief, Endo has taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate its intent to market the ANDA Products. As set forth above, on information and belief, if the ANDA is approved, Endo intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Products.

BACKGROUND

17. ARI holds New Drug Application ("NDA") No. 209376 for Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), which were approved by the FDA on July 2, 2020 and which ARI manufactures and sells in this judicial district and throughout the United States.

18. Tralement® is the first and only FDA-approved multi-trace element injection for patients weighing at least 10 kg. The FDA has approved both 1 mL and 5 mL forms of Tralement®; ARI markets a 1 mL Tralement® product.

19. Tralement® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

20. Multrys® is the first and only FDA-approved multi-trace element injection for neonatal and pediatric patients weighing less than 10 kg.

21. Multrys® is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

22. Tralement® and Multrys®, as well as the use of Tralement® and Multrys® in accordance with their labels, are covered by one or more claims of the Patents-in-Suit.

23. ARI is the owner of the ’548 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on October 17, 2023. A copy of the ’548 patent is attached as Exhibit 1.

24. The ’548 patent has been listed in connection with Tralement® and Multrys® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

25. As indicated in the Orange Book, the patent expiration date for the ’548 patent is July 1, 2041.

26. ARI is the owner of the ’022 patent, which is entitled “Trace element compositions, methods of making and use” and was duly and legally issued on May 7, 2024. A copy of the ’022 patent is attached as Exhibit 2.

27. As indicated in the Orange Book, the patent expiration date for the ’022 patent is July 1, 2041.

28. ARI is the owner of the '565 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on June 4, 2024. A copy of the '565 patent is attached as Exhibit 3.

29. As indicated in the Orange Book, the patent expiration date for the '565 patent is July 1, 2041.

30. ARI is the owner of the '956 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '956 patent is attached as Exhibit 4.

31. As indicated in the Orange Book, the patent expiration date for the '956 patent is July 1, 2041.

32. ARI is the owner of the '957 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit 5.

33. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

34. Through the Notice Letter, Endo notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that Endo had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the Patents-in-Suit.

35. On information and belief, Endo was responsible for preparing and submitting the ANDA with a Paragraph IV Certification.

36. On information and belief, Endo submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the

manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

37. On information and belief, the ANDA Products are generic versions of Tralement® (trace elements injection 4*, USP) and Multrys® (trace elements injection 4*, USP), as their reference listed drugs, containing the same or equivalent ingredients in the same or equivalent amounts.

38. In the Notice Letter, Endo disclosed that the ANDA Products are (1) Trace Elements Injection 4* USP (1000 mcg Zn/mL, 60 mcg Cu/mL, 3 mcg Mn/mL, and 6 mcg Se/mL) single-dose vials and (2) Trace Elements Injection 4* USP (3 mg Zn/mL, 0.3 mg Cu/mL, 55 mcg Mn/mL, and 60 mcg Se/mL) single-dose vials..

39. On information and belief, the ANDA Products contain zinc, copper, manganese, and selenium in the same or equivalent amounts as Tralement® and Multrys®, respectively.

40. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as Tralement® and Multrys®.

COUNT I: INFRINGEMENT OF THE ’548 PATENT

41. ARI realleges paragraphs 1–40 as if fully set forth herein.

42. Endo’s submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the ’548 patent, constitutes direct and indirect infringement of the ’548 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

43. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Endo or on its behalf, and will be administered by patients and/or medical practitioners in the United States

according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '548 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Endo's specific intent and encouragement, and will be conduct that Endo knows or should know will occur. On information and belief, Endo will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '548 patent.

44. On information and belief, Endo's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '548 patent, either literally or under the doctrine of equivalents. On information and belief, Endo intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Endo knows that the ANDA Products are especially made or adapted for use in infringing the '548 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

45. ARI will be irreparably harmed if Endo is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '548 patent, or any later expiration of exclusivity for the '548 patent to which

ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

46. Endo has had knowledge of the '548 patent since at least the date Endo submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

47. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '022 PATENT

48. ARI realleges paragraphs 1–47 as if fully set forth herein.

49. Endo's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '022 patent, constitutes infringement of the '022 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

50. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Endo or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '022 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Endo's specific intent and encouragement, and will be conduct that Endo knows or should know will occur. On information and belief, Endo will actively induce, encourage, aid, and abet that conduct by patients

and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '022 patent.

51. On information and belief, Endo's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '022 patent, either literally or under the doctrine of equivalents. On information and belief, Endo intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Endo knows that the ANDA Products are especially made or adapted for use in infringing the '022 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

52. ARI will be irreparably harmed if Endo is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '022 patent, or any later expiration of exclusivity for the '022 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

53. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '565 PATENT

54. ARI realleges paragraphs 1–53 as if fully set forth herein.

55. Endo's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '565 patent,

constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

56. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Endo or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Endo's specific intent and encouragement, and will be conduct that Endo knows or should know will occur. On information and belief, Endo will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

57. On information and belief, Endo's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Endo intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Endo knows that the ANDA Products are especially made or adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

58. ARI will be irreparably harmed if Endo is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

59. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '956 PATENT

60. ARI realleges paragraphs 1–59 as if fully set forth herein.

61. Endo's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '956 patent, constitutes direct and indirect infringement of the '956 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

62. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Endo or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '956 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Endo's specific intent and encouragement, and will be conduct that Endo knows or should know

will occur. On information and belief, Endo will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '956 patent.

63. On information and belief, Endo's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '956 patent, either literally or under the doctrine of equivalents. On information and belief, Endo intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Endo knows that the ANDA Products are especially made or adapted for use in infringing the '956 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

64. ARI will be irreparably harmed if Endo is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '956 patent, or any later expiration of exclusivity for the '956 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

65. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE '957 PATENT

66. ARI realleges paragraphs 1–65 as if fully set forth herein.

67. Endo's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

68. On information and belief, the ANDA Product, if the ANDA is approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Endo or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Endo's specific intent and encouragement, and will be conduct that Endo knows or should know will occur. On information and belief, Endo will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

69. On information and belief, Endo's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Endo intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Endo knows that the ANDA Products are especially made or adapted

for use in infringing the '957 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

70. ARI will be irreparably harmed if Endo is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

71. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, ARI prays that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Endo has infringed at least one claim of the Patents-in-Suit through Endo's submission of the ANDA with a Paragraph IV Certification to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States the ANDA Products before the expiration of the Patents-in-Suit;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Endo's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of the ANDA Products before the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the Patents-in-Suit;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective

date of any FDA approval of the ANDA, shall not be earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(d) The entry of a permanent and/or preliminary injunction enjoining Endo, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States the ANDA Products, or any products that infringes any of the Patents-in-Suit, or inducing or contributing to the infringement of any of the Patents-in-Suit until after the expiration date of the Patents-in-Suit, including any extension and/or additional periods of exclusivity to which ARI is or becomes entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(e) The entry of a permanent and/or preliminary injunction enjoining Endo, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(f) Damages or other monetary relief to ARI if Endo engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the ANDA Products prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which ARI is or becomes entitled;

(g) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding ARI its attorney's fees incurred in this action; and

(h) Such further relief as this Court deems proper and just.

Dated: June 18, 2025

By: */s/ Charles H. Chevalier*

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
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Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

Attorneys for Plaintiff
American Regent, Inc.