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

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS LTD., GLENMARK PHARMACEUTICALS SA, and GLENMARK PHARMACEUTICALS INC., USA, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Glenmark Pharmaceuticals Ltd. ("Glenmark Ltd."), Glenmark Pharmaceuticals SA ("Glenmark SA"), and Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") (collectively, "Glenmark" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. 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 in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 209495 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' NEXIUM® pharmaceutical products that are sold in the United States.

THE PARTIES

2. Plaintiff AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff Aktiebolaget Hässle ("Hässle") is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AZ LP holds an approved New Drug Application from the FDA for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

5. Plaintiff Zeneca Inc. ("Zeneca") is a Delaware corporation having its principal place of business at Wilmington, Delaware. Zeneca has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 6,369,085; 7,411,070; and 8,466,175.

6. On information and belief, Glenmark Ltd. is an Indian company having its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (East), Mumbai, India 400099. On information and belief, Glenmark Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs.

7. On information and belief, Glenmark SA is a wholly-owned subsidiary of Glenmark Ltd.

8. On information and belief, Glenmark SA is a Swiss company having its principal place of business at 2nd Floor, Swisscom Building, Rue de la Maladiere 23, Neuchâtel, 2000, Switzerland. On information and belief, Glenmark SA is in the business of researching and developing generic drugs.

9. On information and belief, Glenmark USA is a wholly-owned subsidiary of Glenmark Ltd.

10. On information and belief, Glenmark USA is a corporation organized under the laws of the State of Delaware, with its principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. On information and belief, Glenmark USA is in the business of manufacturing, marketing, distributing, and selling, in the State of New Jersey and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Glenmark.

11. On information and belief, Defendants collaborate to manufacture, import, market, distribute, and sell generic pharmaceutical products in the State of New Jersey and throughout the United States.

12. On information and belief, following any FDA approval of ANDA No. 209495, Glenmark will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209495 throughout the United States, and/or import such generic drug products into the United States.

BACKGROUND

The NDA

13. AZ LP is the holder of New Drug Application ("NDA") No. 21153 for NEXIUM® Esomeprazole Magnesium Delayed-Release Capsules, in 20 mg and 40 mg dosage forms. NEXIUM® is a prescription drug approved for use to relieve the symptoms of acid reflux disease and treat erosive esophagitis. Esomeprazole magnesium trihydrate is the active ingredient in NEXIUM®.

The Patents-in-Suit

14. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-Omeprazole," was duly and legally issued by the United States Patent and Trademark Office ("the USPTO") on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts. A true and correct copy of the '085 patent is attached as Exhibit A.

15. Plaintiff AZ AB has been and still is the owner of the ’085 patent. The ’085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’085 patent expires on November 25, 2018.

16. United States Patent No. 7,411,070 (“the ’070 patent”), entitled “Form of S-omeprazole,” was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the ’070 patent are directed to, *inter alia*, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts. A true and correct copy of the ’070 patent is attached as Exhibit B.

17. Plaintiff AZ AB has been and still is the owner of the ’070 patent. The ’070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’070 patent expires on November 25, 2018.

18. United States Patent No. 8,466, 175 (“the ’175 patent”), entitled “Form of S-omeprazole,” was duly and legally issued by the USPTO on June 18, 2013 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the ’175 patent are directed to, *inter alia*, methods of treating Heliobacter infections comprising administration of magnesium salts of esomeprazole trihydrate. A true and correct copy of the ’175 patent is attached as Exhibit C.

19. Plaintiff AZ AB has been and still is the owner of the ’175 patent. The ’175 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’175 patent expires on November 25, 2018.

The ANDA

20. On information and belief, Glenmark filed ANDA No. 209495 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of esomeprazole magnesium delayed-release capsules, 20 mg and 40 mg ("Glenmark's Esomeprazole Magnesium Delayed-Release Capsules"), which are generic versions of Plaintiffs' NEXIUM® Esomeprazole Magnesium Delayed-Release Capsules, in 20 mg and 40 mg dosage forms.

21. By letter dated September 1, 2016 (the "ANDA Notice Letter"), Glenmark notified Plaintiffs that Glenmark had filed ANDA No. 209495 seeking approval to market Glenmark's Esomeprazole Magnesium Delayed-Release Capsules and that Glenmark was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

JURISDICTION AND VENUE

22. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

23. On information and belief, Glenmark Ltd. is an Indian company having its principal place of business at Glenmark House, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri (East), Mumbai, India 400099. On information and belief, Glenmark Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs.

24. On information and belief, Glenmark Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

25. On information and belief, Glenmark Ltd. purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Glenmark's generic products. On information and belief, Glenmark USA—"the North American division of Glenmark [Ltd.]"—claims that it "has emerged as one of the leading generic organizations in the U.S." *See* http://us-glenmarkpharma.com/product-listing/. On information and belief, "Glenmark's current generic portfolio has grown at a consistent rate with over 100 products authorized for distribution and 60+ products pending approval by the FDA." *See* http://us-glenmarkpharma.com/products/pipeline/.

26. On information and belief, Glenmark SA is a Swiss company having its principal place of business at 2nd Floor, Swisscom Building, Rue de la Maladiere 23, Neuchâtel, 2000, Switzerland. On information and belief, Glenmark SA is in the business of researching and developing generic drugs.

27. On information and belief, Glenmark USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. Glenmark SA has designated Glenmark USA, located in New Jersey, to accept service of process for this matter.

28. On information and belief, Glenmark USA is in the business of manufacturing, marketing, distributing, and selling, in the State of New Jersey and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Glenmark.

29. On information and belief, Defendants acted in concert to develop Glenmark's Esomeprazole Magnesium Delayed-Release Capsules and to seek approval from the FDA to sell

Glenmark's Esomeprazole Magnesium Delayed-Release Capsules throughout the United States, including within this judicial district.

30. On information and belief, and as stated in the ANDA Notice Letter, Glenmark prepared and filed ANDA No. 209495.

31. On information and belief, and as stated in the ANDA Notice Letter, the FDA received ANDA No. 209495 from Glenmark.

32. On information and belief, by virtue of, *inter alia*, Glenmark's preparation and/or filing of ANDA No. 209495 and sales-related activities in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, and Glenmark USA's principal place of business located in New Jersey, this Court has personal jurisdiction over Glenmark Ltd., Glenmark SA, and Glenmark USA. *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where Defendant's "ANDA filings and its distribution channels establish that [the Defendant] plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing.").

33. On information and belief, Glenmark Ltd., Glenmark SA, and Glenmark USA have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., BTG International Limited, Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC v. Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals Ltd.*, Civ. Action No. 2:16-cv-03743-KM-JBC (D.N.J.); *Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi v. Glenmark Pharmaceuticals Inc., USA, and Glenmark Pharmaceutical Ltd.*, Civ. Action No. 3:15-cv-02523-

MAS-LHG (D.N.J.); and *AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd., and AstraZeneca AB v. Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd., and Glenmark Pharmaceuticals Inc., USA*, Civ. Action No. 1:15-cv-00615-RMB-KMW (D.N.J.).

34. On information and belief, Glenmark has availed itself of the jurisdiction of this court by filing a petition to confirm an arbitration award in this district. *See Glenmark Pharmaceuticals Ltd. v. Napo Pharmaceuticals, Inc.*, Civ. Action No. 2:14-cv-02592-CCC-JBC (D.N.J.).

35. On information and belief, Glenmark has further availed itself of the jurisdiction of this court by asserting counterclaims in this district. *See, e.g., Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. v. Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd.*, Civ. Action No. 3:08-cv-04355-GEB-DEA (D.N.J.).

36. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

COUNT 1: INFRINGEMENT OF THE '085 PATENT

37. Plaintiffs incorporate by reference paragraphs 1–36 of this Complaint as if fully set forth herein.

38. On information and belief, Defendants submitted ANDA No. 209495 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Glenmark's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '085 patent.

39. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial

manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's Esomeprazole Magnesium Delayed-Release Capsules.

40. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 209495 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '085 patent constitutes infringement of one or more claims of the '085 patent, either literally or under the doctrine of equivalents.

41. On information and belief, Glenmark's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed by, for example, physicians and administered by, for example, physicians to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

42. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, provides only a bare allegation of invalidity and unenforceability of the '085 patent's claims without providing any explanation or identifying any legal basis or supporting facts. Because Defendants allege that the '085 patent is invalid or unenforceable without providing any explanation or identifying any legal basis or supporting facts, Defendants effectively admit that the '085 patent is both valid and enforceable.

43. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '070 PATENT

44. Plaintiffs incorporate by reference paragraphs 1–43 of this Complaint as if fully set forth herein.

45. On information and belief, Defendants submitted ANDA No. 209495 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Glenmark's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '070 patent.

46. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's Esomeprazole Magnesium Delayed-Release Capsules.

47. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 209495 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Glenmark's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '070 patent constitutes infringement of one or more claims of the '070 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Glenmark's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed by, for example, physicians and administered by, for example, physicians to human patients in a therapeutically effective amount

to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

49. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, provides only a bare allegation of invalidity and unenforceability of the '070 patent's claims without providing any explanation or identifying any legal basis or supporting facts. Because Defendants allege that the '070 patent is invalid or unenforceable without providing any explanation or identifying any legal basis or supporting facts, Defendants effectively admit that the '070 patent is both valid and enforceable.

50. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '175 PATENT

51. Plaintiffs incorporate by reference paragraphs 1–50 of this Complaint as if fully set forth herein.

52. On information and belief, Defendants submitted ANDA No. 209495 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Glenmark's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '175 patent.

53. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 209495 to obtain approval for the commercial manufacture, use, sale, offer for sale,

or importation into the United States of Glenmark's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '175 patent constitutes infringement of one or more claims of the '175 patent, either literally or under the doctrine of equivalents.

54. On information and belief, Glenmark's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed by, for example, physicians and administered by, for example, physicians to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease, including Heliobacter infection. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '175 patent.

55. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '085, '070, and '175 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 209495 by Defendants infringes one or more claims of each of the '085, '070, and '175 patents under 35 U.S.C. § 271(e)(2);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Glenmark's ANDA No. 209495 shall be no earlier than the latest expiration date of the Patents-in-Suit and any additional periods of exclusivity;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with Defendants, from making, using, selling, offering to sell, or importing the esomeprazole magnesium product described in Defendants' ANDA No. 209495 prior to the latest expiration of the Patents-in-Suit and any additional periods of exclusivity;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: October 14, 2016

Respectfully submitted,

/s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA*, C.A. No. 3:13-cv-01669-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13-cv-04854-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. No. 3:14-cv-4782-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC.*, C.A. No. 3:14-cv-7870-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ANDRX LABS, LLC, ANDRX CORPORATION, and ACTAVIS, INC.*, C.A. No. 3:14-cv-8030-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. PERRIGO COMPANY PLC, PERRIGO COMPANY, L. PERRIGO COMPANY, and PADDOCK LABORATORIES, LLC*, C.A. No. 3:15-cv-1057-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. HEC PHARM CO., LTD., HEC PHARM GROUP, and HEC PHARM USA INC.*, C.A. No. 3:15-cv-06025-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,*, C.A. No. 3:15-cv-06092-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. 3:15-cv-07415-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.*, C.A. No. 3:15-cv-08267-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.*, C.A. No. 3:16-cv-01682-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, and ZENECA INC. v. HETERO USA INC., HETERO LABS LTD. UNIT-III, and HETERO LABS LTD.*, C.A. No. 3:16-cv-02442-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, and ZENECA INC. v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA INC.*, C.A. No. 3:16-cv-04414-MLC-TJB (District of New Jersey)

Date: October 14, 2016

By: */s/ John E. Flaherty*

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