IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (collectively "Plaintiffs"), file this Complaint for patent infringement against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Defendants"), under 35 U.S.C. §§ 271(e)(2), (a), (b) and (c). This patent action concerns the pharmaceutical drug product Belbuca®. Plaintiffs hereby state as follows:

JURISDICTION AND PARTIES

2. Plaintiff BioDelivery Sciences International, Inc. ("BDSI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4131 ParkLake Ave., Suite 225, Raleigh, North Carolina 27612. Plaintiff BDSI is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of prescription pharmaceuticals with a focus in the areas of pain management and addiction medicine. Plaintiff BDSI is also the holder of New Drug Application ("NDA") No. 207932 for Belbuca®.

3. Plaintiff Arius Two, Inc. ("Arius") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4131 ParkLake Ave., Suite 225, Raleigh, North Carolina 27612. Plaintiff Arius is a wholly-owned subsidiary of Plaintiff BDSI.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044. On information and belief, Defendant Teva USA maintains a registered agent in Delaware, Corporate Creations Network Inc.

5. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel.

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

7. On information and belief, the acts of Defendant Teva USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation or assistance of, or at least in part for the benefit of Defendant Teva Ltd.

8. On information and belief, Defendant Teva USA is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

9. On information and belief, Defendant Teva USA regularly conducts business in Delaware and has a state-issued license to distribute pharmaceutical drugs in Delaware.

10. On information and belief, Defendant Teva USA derives substantial revenue from the sale of its products in Delaware and throughout the United States.

11. On information and belief, Defendant Teva USA is amenable to litigating in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Teva USA has previously availed itself of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Defendant Teva USA has filed suit and sought relief in other civil actions initiated in this jurisdiction, including but not limited to: *Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, C.A. No. 1:16-cv-00278-GMS (D. Del. 2016); *Teva Pharmaceuticals USA Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 1:15-cv-00306-GMS (D. Del. 2015). Additionally, Defendant Teva USA has submitted to this Court's jurisdiction by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Millennium Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al*., C.A. No. 1:14-cv-00093-GMS (D. Del. 2014); *UCB, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 1:13-cv-01148-LPS (D. Del. 2013).

12. This Court has personal jurisdiction over Defendant Teva USA by virtue of, among other things: (1) its incorporation in Delaware; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its admission that it is subject to the Court's jurisdiction in other patent litigations.

13. On information and belief, Defendant Teva Ltd. regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Defendant Teva Ltd. has continuous and systematic contacts with Delaware.

14. On information and belief, Defendant Teva Ltd. purposefully has conducted and continues to conduct business in this judicial district by directly, or indirectly through its wholly owned subsidiaries, manufacturing, marketing, and selling generic drug products, including generic drug products manufactured by Defendant Teva Ltd., throughout the United States and in this judicial district.

15. On information and belief, Defendant Teva Ltd. is amenable to litigating in this forum based on its conduct in numerous other litigations in this District. In particular, Defendant Teva Ltd. has previously availed itself of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Defendant Teva Ltd. has filed suit and sought relief in other civil actions initiated in this jurisdiction, including but not limited to: *Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, C.A. No. 1:16-cv-00278-GMS (D. Del. 2016); *Teva Pharmaceuticals USA Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 1:15-cv-00306-GMS (D. Del. 2015). Additionally, Defendant Teva Ltd. has submitted to this Court's jurisdiction by consenting to personal jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Millennium Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 1:14-cv-00093-GMS (D. Del. 2014); *UCB, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 1:13-cv- 01148-LPS (D. Del. 2013). Additionally, on information and belief, Defendant Teva Ltd. has availed itself of this forum by filing lawsuits in this judicial district as a plaintiff.

16. This Court has personal jurisdiction over Defendant Teva Ltd. by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which are Delaware corporations; (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (4) its admission that it is subject to the Court's jurisdiction in other patent litigations.

17. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '019 Patent under 35 U.S.C. § 271(e)(2))

18. Plaintiffs reallege and incorporate by reference paragraphs 1-17.

19. The '019 patent, titled "Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces," was duly and legally issued to inventors Gilles H. Tapolsky and David W. Osborne by the United States Patent and Trademark Office ("PTO") on August 25, 2009. The '019 patent is currently assigned to Plaintiff Arius and expires on January 22, 2020. This expiration date includes a 1191 day patent term adjustment granted by the PTO in accordance with the decision in *Wyeth & Elan Pharma Int'l Ltd. v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). A true and correct copy of the '019 patent is attached as Exhibit A.

20. New Drug Application No. 207932 is directed to the use of Belbuca® in the treatment of pain by transmucosal delivery of buprenorphine. The U.S. Food and Drug Administration ("FDA") approved NDA No. 207932 on October 23, 2015. The '019 patent is

listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 207932.

21. On information and belief, Defendants filed, or caused to be filed, ANDA No. 209807 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Buprenorphine Buccal Film, 75 mcg and 150 mcg, in the United States before the expiration of the '019 patent.

22. On information and belief, ANDA No. 209807 contains a Paragraph IV certification alleging that the claims of the '019 patent are invalid.

23. Defendants sent, or caused to be sent, to Plaintiffs a letter dated December 22, 2016 ("the Notice Letter") notifying Plaintiffs that Defendants had submitted ANDA No. 209807, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity of claims 1-7 of the '019 patent. The Notice Letter does not contest infringement of the '019 patent.

24. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the '019 patent, in violation of Plaintiffs' patent rights, by submitting to the FDA ANDA No. 209807 that seeks approval to commercially market—before the expiration date of the '019 patent—Buprenorphine Buccal Film, 75 mcg and 150 mcg, (collectively, "Defendants' generic buprenorphine buccal film"), the use of which would directly infringe, literally or through the doctrine of equivalents, one or more claims of the '019 patent, and the manufacture, use, offer for sale, or sale of which would contribute to or induce the direct infringement of one or more claims of the '019 patent by prescribers and/or users of Defendants' generic buprenorphine buccal film.

25. On information and belief, Defendants have knowledge of the ’019 patent and have filed ANDA No. 209807 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 209807, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’019 patent.

26. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants, and will therefore induce infringement of one or more of the claims of the ’019 patent with the requisite intent.

27. On information and belief, if the FDA approves ANDA No. 209807, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’019 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film in practicing one or more of the methods claimed in the ’019 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’019 patent.

28. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

29. Plaintiffs have filed this complaint within 45 days of receiving the Notice Letter.

30. Defendants' statements of the factual and legal bases for their opinion regarding the validity of the '019 patent contained in the Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

31. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '019 patent, actively inducing infringement of the '019 patent, and/or contributing to the infringement by others of the '019 patent. This case is therefore "exceptional," as that term is used in 35 U.S.C. § 285.

COUNT II FOR PATENT INFRINGEMENT
(Infringement of the '866 Patent under 35 U.S.C. § 271(e)(2))

32. Plaintiffs reallege and incorporate by reference paragraphs 1-17.

33. The '866 patent, titled "Transmucosal Delivery Devices with Enhanced Uptake," was duly and legally issued to inventors Andrew Finn and Niraj Vasisht by the PTO on April 3, 2012. The '866 patent is currently assigned to Plaintiff BDSI and expires on July 23, 2027. A true and correct copy of the '866 patent is attached as Exhibit B.

34. NDA No. 207932 is directed to the use of Belbuca® in the treatment of pain by transmucosal delivery of buprenorphine. The FDA approved NDA No. 207932 on October 23, 2015. The '866 patent is listed in the Orange Book for NDA No. 207932.

35. On information and belief, Defendants filed, or caused to be filed, ANDA No. 209807 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the

commercial manufacture, use, and sale of Buprenorphine Buccal Film, 75 mcg and 150 mcg, in the United States before the expiration of the ’866 patent.

36. On information and belief, ANDA No. 209807 contains a Paragraph IV certification alleging that the claims of the ’866 patent are invalid.

37. Defendants sent, or caused to be sent, to Plaintiffs a letter dated December 22, 2016 (“the Notice Letter”) notifying Plaintiffs that Defendants had submitted ANDA No. 209807, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Notice Letter alleges invalidity of claims 1-12 of the ’866 patent. The Notice Letter does not contest infringement of claims 1-5 and 8-10 of the ’866 patent.

38. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed one or more claims of the ’866 patent, in violation of Plaintiffs’ patent rights, by submitting to the FDA ANDA No. 209807 that seeks approval to commercially market—before the expiration date of the ’866 patent—Defendants’ generic buprenorphine buccal film, the manufacture, use, offer for sale, or sale within the United States of which would directly infringe, literally or through the doctrine of equivalents, one or more claims of the ’866 patent, and the manufacture, use, offer for sale, or sale of which would contribute to or induce the direct infringement of one or more claims of the ’866 patent by prescribers and/or users of Defendants’ generic buprenorphine buccal film.

39. On information and belief, Defendants have knowledge of the ’866 patent and have filed ANDA No. 209807 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 209807, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal

film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’866 patent.

40. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants, and will therefore induce infringement of one or more of the claims of the ’866 patent with the requisite intent.

41. On information and belief, if the FDA approves ANDA No. 209807, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’866 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film in practicing one or more of the methods claimed in the ’866 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’866 patent.

42. Plaintiffs will be substantially and irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

43. Plaintiffs have filed this complaint within 45 days of receiving the Notice Letter.

44. Defendants’ statements of the factual and legal bases for their opinion regarding the validity of the ’866 patent contained in the Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

45. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’866 patent, actively inducing infringement of the ’866 patent, and/or contributing to the infringement by others of the ’866 patent. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

COUNT III FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the ’019 Patent Under 35 U.S.C. §§ 271 (b), and/or (c))

46. Plaintiffs reallege and incorporate by reference paragraphs 1-31.

47. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. The manufacture, sale, offer for sale, and/or importation of Defendants’ generic buprenorphine buccal film so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the ’019 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs’ patent rights.

49. On information and belief, Defendants have knowledge of the ’019 patent and have filed ANDA No. 209807 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants’ generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 209807, physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the ’019 patent.

50. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants’ generic buprenorphine

buccal film in accordance with the instructions and/or label provided by Defendants, and will therefore induce infringement of one or more of the claims of the ’019 patent with the requisite intent under 35 U.S.C. § 271(b).

51. On information and belief, if the FDA approves ANDA No. 209807, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’019 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed in the ’019 patent, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film for one or more of the methods claimed in the ’019 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’019 patent under 35 U.S.C. § 271(c).

52. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ’019 patent claims. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendant’s threatened imminent actions.

53. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’019 patent, actively inducing infringement of the ’019 patent, and/or contributing to the infringement by others of the ’019 patent. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the ’866 Patent Under 35 U.S.C. §§ 271 (a), (b), and/or (c))

54. Plaintiffs reallege and incorporate by reference paragraphs 1-17, 32-45.

55. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. On information and belief, and based on information provided by Defendants, if the FDA approves Defendants' generic buprenorphine buccal film for use and sale in the United States, Defendants would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '866 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights, by making, using, offering to sell, selling, and/or importing Defendants' generic buprenorphine buccal film for use and sale within the United States.

57. The manufacture, sale, offer for sale, and/or importation of Defendants' generic buprenorphine buccal film so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '866 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

58. On information and belief, Defendants have knowledge of the '866 patent and have filed ANDA No. 209807 seeking authorization to commercially manufacture, use, offer for sale, and sell Defendants' generic buprenorphine buccal film in the United States. On information and belief, if the FDA approves ANDA No. 209807, physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants and will directly infringe one or more claims of the '866 patent.

59. On information and belief, Defendants know and intend that physicians, health care providers, and/or patients will prescribe and/or use Defendants' generic buprenorphine buccal film in accordance with the instructions and/or label provided by Defendants, and will

therefore induce infringement of one or more of the claims of the ’866 patent with the requisite intent under 35 U.S.C. § 271(b).

60. On information and belief, if the FDA approves ANDA No. 209807, Defendants will sell or offer to sell their generic buprenorphine buccal film specifically labeled for use in practicing one or more of the method claims of the ’866 patent, wherein Defendants’ generic buprenorphine buccal film is a material part of the method claimed in the ’866 patent, wherein Defendants know that physicians will prescribe and patients will use Defendants’ generic buprenorphine buccal film for one or more of the methods claimed in the ’866 patent, and wherein buprenorphine buccal film is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will thus contribute to the infringement of the ’866 patent under 35 U.S.C. § 271(c).

61. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ’866 patent claims. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

62. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’866 patent, actively inducing infringement of the ’866 patent, and/or contributing to the infringement by others of the ’866 patent. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) declare that United States Patent Nos. 7,579,019 and 8,147,866 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 7,579,019 and 8,147,866 by submitting ANDA No. 209807 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Defendants' generic buprenorphine buccal film prior to the expiration of said patents;

c) declare that Defendants' commercial manufacture, use, sale, or offer for sale, or importation into the United States of Defendants' generic buprenorphine buccal film prior to the expiration of United States Patent Nos. 7,579,019 and 8,147,866 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271 (a), (b) and/or (c);

d) order that the effective date of any FDA approval of Defendants' generic buprenorphine buccal film shall be no earlier than the expiration date of United States Patent Nos. 7,579,019 and 8,147,866, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining final approval of ANDA No. 209807 until the expiration of United States Patent Nos. 7,579,019 and 8,147,866, including any exclusivities or extensions to which Plaintiffs are or become entitled, pursuant to 35 U.S.C. § 283;

f) enjoin Defendants, and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Defendants' generic buprenorphine buccal film within the United States, or importing Defendants' generic buprenorphine buccal film into the United States, until the expiration of United States Patent Nos. 7,579,019 and 8,147,866, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and/or 283;

g) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

h) grant Plaintiffs such further and additional relief that this Court deems just and proper.

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