

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF PENNSYLVANIA**

Takeda Pharmaceutical Company Limited,  
Takeda Pharmaceuticals North America, Inc.,  
Takeda Global Research and Development Center,  
Inc., Watson Pharmaceuticals, Inc., and Andrx Labs,  
LLC,

Plaintiffs,

v.

Mylan, Inc. and  
Mylan Pharmaceuticals, Inc.,

Defendants.

Civil Action No. \_\_\_\_\_

COMPLAINT

Plaintiffs, Takeda Pharmaceutical Company, Limited (formerly known as Takeda Chemical Industries, Ltd.) (“TPC”), Takeda Pharmaceuticals North America, Inc. (“TPNA”), and Takeda Global Research & Development Center, Inc. (“Takeda Global”) (collectively, “Takeda”); and Watson Pharmaceuticals, Inc. (“Watson”) and Andrx Labs, LLC (“Andrx”), by their undersigned counsel, for their Complaint against defendants Mylan Pharmaceuticals, Inc. (“MPI”) and Mylan, Inc. (“Mylan, Inc.”), (collectively, “Mylan”), allege as follows:

**Jurisdiction and Venue**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over the

defendants in Pennsylvania is proper under 42 P.C.S.A. §5301 and 5322 and because defendants are doing business in this jurisdiction.

**Parties**

2. TPC is a Japanese corporation having its corporate headquarters in Osaka, Japan and principal place of business in Osaka, Japan. TPNA is a wholly owned U.S. subsidiary of Takeda American Holdings, Inc., which is a wholly owned U.S. subsidiary of TPC. TPNA has its corporate headquarters and principal place of business in Deerfield, Illinois and is organized under the laws of Delaware. Takeda Global is a wholly owned subsidiary of TPNA. Takeda Global has its corporate headquarters and principal place of business in Deerfield, Illinois, and is organized under the laws of Delaware.

3. Takeda is engaged in the business of research, developing, manufacturing, and/or marketing of a broad spectrum of innovative pharmaceutical products, including ACTOPLUS MET<sup>®</sup> XR, which comprises an extended release dosage form of the combination of the active ingredients pioglitazone hydrochloride and metformin hydrochloride.

4. Watson is a Nevada corporation having corporate offices and a place of business in Parsippany, New Jersey.

5. Andrx is a Delaware limited liability company having a place of business in Davie, Florida, and is a subsidiary of Andrx Corporation, which is a subsidiary of Watson.

6. Andrx is engaged in the business of research, development, manufacturing, and/or sale of pharmaceutical products including ACTOPLUS MET<sup>®</sup> XR and/or components thereof.

7. Upon information and belief, MPI is incorporated in West Virginia having a place of business in Morgantown, West Virginia, and is a wholly owned subsidiary of Mylan, Inc. Additionally, MPI is licensed to do business in Pennsylvania as a foreign business corporation

and upon information and belief, does business in Pennsylvania. Upon information and belief, Abbreviated New Drug Application (“ANDA”) No. 203488 was filed under the name of MPI.

8. Upon information and belief, defendant Mylan, Inc. is a Pennsylvania corporation having its corporate headquarters in Canonsburg, Pennsylvania, which is in the Western District of Pennsylvania. Upon information and belief, Mylan, Inc. has actual control over the activities of MPI including MPI’s filing of ANDA No. 203488.

9. Upon information and belief, Mylan is currently transacting business in the Western District of Pennsylvania, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Upon information and belief, Mylan derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the Commonwealth of Pennsylvania and the Western District of Pennsylvania. MPI is registered with the Pennsylvania State Department, Division of Corporations, to do business as a foreign corporation in Pennsylvania. By filing its ANDA, Mylan has committed, and unless enjoined, will continue to commit a tortious act without the Commonwealth of Pennsylvania, that Mylan expects or should reasonably expect to have consequences in the Commonwealth of Pennsylvania including in this Judicial District.

**The New Drug Application**

10. TPNA sells drug products including an extended release drug product containing a combination of pioglitazone hydrochloride and metformin hydrochloride, under the trade name ACTOPLUS MET<sup>®</sup> XR in the United States pursuant to the United States Food and Drug Administration’s (“FDA”) approval of a New Drug Application (“NDA”) held by Takeda Global (NDA No. 022024).

11. ACTOPLUS MET<sup>®</sup> XR is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes (non-insulin-dependent diabetes mellitus).

12. The FDA approval letter for ACTOPLUS MET<sup>®</sup> XR is dated May 12, 2009.

**The Patents in Suit**

13. United States Patent No. 5,965,584 (“the ‘584 patent”), entitled “Pharmaceutical Composition,” a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 12, 1999 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka.

14. Plaintiff TPC has been and still is the owner through assignment of the ‘584 patent, which expires on June 19, 2016.

15. United States Patent No. 6,166,043 (“the ‘043 patent”), entitled “Pharmaceutical Composition,” a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on December 26, 2000 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka.

16. Plaintiff TPC has been and still is the owner through assignment of the ‘043 patent, which expires on June 19, 2016.

17. United States Patent No. 6,172,090 (“the ‘090 patent”), entitled “Pharmaceutical Composition,” a true and correct copy of which is appended hereto as **Exhibit C**, was duly issued on January 9, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka.

18. Plaintiff TPC has been and still is the owner through assignment of the ‘090 patent, which expires on June 19, 2016.

19. Plaintiff TPC has granted an exclusive license to plaintiff TPNA under the ‘584 patent, the ‘043 patent, and the ‘090 patent (collectively, “Takeda Patents”).

20. United States Patent No. 6,099,859 (“the ‘859 patent”), entitled “Controlled Release Oral Tablet Having a Unitary Core,” a true and correct copy of which is appended hereto

as **Exhibit D**, was duly issued on August 8, 2000 to inventors Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan and Joseph Chou.

21. Andrx has been and still is the owner through assignment of the '859 patent, which expires on March 20, 2018.

22. United States Patent No. 6,495,162 ("the '162 patent"), entitled "Controlled Release Oral Tablet Having a Unitary Core," a true and correct copy of which is appended hereto as **Exhibit E**, was duly issued on December 17, 2002 to inventors Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan and Joseph Chou.

23. Andrx has been and still is the owner through assignment of the '162 patent, which expires on March 20, 2018.

24. United States Patent No. 6,790,459 ("the '459 patent"), entitled "Methods for Treating Diabetes Via Administration of Controlled Release Metformin," a true and correct copy of which is appended hereto as **Exhibit F**, was duly issued on September 14, 2004 to inventors Xiu Xiu Cheng, Chih-Ming Chen, Steve Jan and Joseph Chou.

25. Andrx has been and still is the owner through assignment of the '459 patent, which expires on March 17, 2021.

26. United States Patent No. 6,866,866 ("the '866 patent"), entitled "Controlled Release Metformin Compositions," a true and correct copy of which is appended hereto as **Exhibit G**, was duly issued on March 15, 2005 to inventors Chih-Ming Chen, Xiu Xiu Cheng, Steve Jan and Joseph Chou.

27. Andrx has been and still is the owner through assignment of the '866 patent, which expires on March 17, 2021.

28. United States Patent No. 7,785,627 (“the ‘627 patent”), entitled “Pharmaceutical Formulation Containing a Biguanide and a Thiazolidinedione Derivative,” a true and correct copy of which is appended hereto as **Exhibit H**, was duly issued on August 31, 2010 to inventors Unchalee Kositprapa, Robert I. Goldfarb, John Cardinal and Avinash Nangia.

29. Watson has been and still is the owner through assignment of the ‘627 patent, which expires on July 31, 2026.

30. United States Patent No. 7,919,116 (“the ‘116 patent”), entitled “Controlled Release Metformin Compositions,” a true and correct copy of which is appended hereto as **Exhibit I**, was duly issued on April 5, 2011 to inventors Chih-Ming Chen, Xiu Xiu Cheng, Steve Jan and Joseph Chou.

31. Andrx has been and still is the owner through assignment of the ‘116 patent, which expires on March 20, 2018.

32. United States Patent No. 7,959,946 (“the ‘946 patent”), entitled “Pharmaceutical Formulation Containing a Biguanide and a Thiazolidinedione Derivative,” a true and correct copy of which is appended hereto as **Exhibit J**, was duly issued on June 14, 2011 to inventors Unchalee Kositprapa, Robert I. Goldfarb, John Cardinal and Avinash Nangia.

33. Watson has been and still is the owner through assignment of the ‘946 patent, which expires on July 31, 2026.

34. Plaintiff Takeda is licensed under the ‘859 patent, ‘162 patent, ‘459 patent, ‘866 patent, ‘627 patent, ‘116 patent and ‘946 patent (collectively, “Watson Patents”) in connection with ACTOPLUS MET<sup>®</sup> XR.

35. Plaintiff Watson is licensed under the ‘584 patent, ‘043 patent and ‘090 patent (collectively, “Takeda Patents”) in connection with ACTOPLUS MET<sup>®</sup> XR.

36. In accordance with its licenses, plaintiff TPNA sells extended release drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS MET<sup>®</sup> XR in the United States. Sales of TPNA's extended release drug products containing a combination of pioglitazone and metformin are made pursuant to approval by the FDA of NDA No. 022024.

37. Plaintiff Takeda Global is the holder of NDA No. 022024, under which TPNA sells ACTOPLUS MET<sup>®</sup> XR.

### **Mylan's ANDA**

38. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

39. Upon information and belief, defendant MPI, under the control of defendant Mylan, Inc., filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 203488) seeking approval to market (i) extended release tablets comprising a combination of 15 mg/1000 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) extended release tablets comprising a combination of 30 mg/1000 mg of pioglitazone hydrochloride/metformin hydrochloride (the "Mylan Products").

40. By the filing of ANDA No. 203488, Mylan has indicated that its extended release combination pioglitazone and metformin drug products are bioequivalent to Plaintiffs' extended release combination pioglitazone and metformin drug products.

41. By its filing of ANDA No. 203488 with a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Mylan seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of Plaintiffs' ACTOPLUS MET<sup>®</sup> XR

pioglitazone and metformin extended release combination drug products prior to the expiration date of the Takeda and Watson Patents.

42. By a letter (the “Notice Letter”) dated November 21, 2011, MPI informed Plaintiffs that MPI had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about November 22, 2011, NDA holder, Takeda Global, received the Notice Letter. On or about November 25, 2011, patent owner, TPC, received a copy of the Notice Letter. On or about November 22, 2011, patent owner, Watson, received a copy of the Notice Letter.

43. The Notice Letter, purporting to be MPI’s Notification of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that Mylan believes that the ‘584, ‘859, ‘043, ‘090, ‘162, ‘459, ‘866, ‘627, ‘116 and ‘946 patents are “not valid, unenforceable, or will not be infringed.”

44. Mylan’s filing of ANDA No. 203488 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of extended release drug products containing pioglitazone and metformin or salts thereof before the expiration of the Patents is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of Type 2 Diabetes.

46. Additionally, upon information and belief, Mylan’s proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Mylan and to customers of Mylan.



47. Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone and metformin extended release combination drug product, namely Mylan intends to list its generic product and refer customers to Plaintiffs' product, ACTOPLUS MET<sup>®</sup> XR. Upon information and belief, such marketing practices are substantially likely to lead to a customer of a generic combination pioglitazone and metformin extended release drug product to infer that prescribing information for ACTOPLUS MET<sup>®</sup> XR, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Mylan's generic combination pioglitazone and metformin extended release drug products.

48. Upon information and belief, the acts alleged above are, have been, and will be deliberate and willful.

49. Mylan's filing of ANDA No. 203488, and Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of at least one of the claims of the Takeda Patents and/or Watson Patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

50. Unless Mylan is enjoined from infringing, contributing to and/or inducing the infringement of the Takeda Patents and/or Watson Patents, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT I**

**(‘584 PATENT)**

51. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

52. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

53. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes.

54. Mylan's filing of ANDA No. 203488 and Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '584 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT II**  
**(THE '043 PATENT)**

55. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

56. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488 .

57. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly the use of such combinations to reduce the amount of active components administered to the diabetic patient.

58. Mylan's filing of ANDA No. 203488 and Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug

products constitute infringement of the '043 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT III**  
**(THE '090 PATENT)**

59. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

60. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

61. On information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes and particularly the use of such combinations for reducing the side effects of active components administered to a diabetic patient.

62. Mylan's filing of ANDA No. 203488 and Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '090 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT IV**  
**(THE '859 PATENT)**

63. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

64. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

65. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '859 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT V**  
**(THE '162 PATENT)**

66. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

67. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

68. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '162 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT VI**  
**(THE '459 PATENT)**

69. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

70. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

71. Mylan's filing of ANDA No. 203488, and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitutes infringement of the '459 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT VII**  
**(THE '866 PATENT)**

72. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

73. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

74. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '866 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT VIII**  
**(THE '627 PATENT)**

75. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

76. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

77. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '627 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT IX**  
**(THE '116 PATENT)**

78. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

79. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA203488 .

80. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '116 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

**COUNT X**  
**(THE '946 PATENT)**

81. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

82. On information and belief, approval of ANDA 203488 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of the Mylan Products immediately or imminently upon approval of ANDA 203488.

83. Mylan's filing of ANDA No. 203488 and/or Mylan's manufacture, use, offer for sale, and/or sale of its proposed combination pioglitazone and metformin extended release drug products constitute infringement of the '946 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (e)(2)(A).

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Mylan infringed the Takeda Patents and the Watson Patents under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA No. 203488 with the FDA seeking to market Mylan's Products;
- (b) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Mylan's Products for which it seeks FDA approval or the active ingredients pioglitazone and metformin in combination in an extended release dosage form, and/or inducing or contributing to the same, will infringe at least one claim of the Takeda Patents and/or Watson Patents;

- (c) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 203488 for Mylan to commercially make, use, sell, offer to sell or import Mylan's Products or an extended release dosage form of pioglitazone in combination with metformin or any drug product containing an extended release dosage form of pioglitazone in combination with metformin be no earlier than the date following the expiration date of the last to expire of any of the Takeda Patents and/or Watson Patents that this Court determines would be infringed through the commercial manufacture, use, sale, offer for sale or importation into the United States of said product(s);
- (d) A permanent injunction restraining and enjoining against any infringement by defendants, their officers, agents, or employees, or those acting in privity or concert with them, of any of the Takeda Patents and/or Watson Patents that this Court determines would be infringed through the commercial manufacture, use, sale, offer for sale or importation into the United States of Mylan's Products or pioglitazone or any drug product containing pioglitazone in combination with metformin in an extended release dosage form, and/or any inducement of and/or any contribution to the same;
- (e) Attorneys' fees in this action under 35 U.S.C. § 285; and
- (f) Such further and other relief as this Court may deem just and proper.



Dated: Pittsburgh, Pennsylvania  
January 6, 2012

<p>Takeda Pharmaceutical Company, Limited, Takeda Pharmaceuticals, North America, Inc., and Takeda Global Research &amp; Development Center, Inc.,</p>	<p>Watson Pharmaceuticals, Inc., and Andrx Labs, LLC,</p>
<p>By their attorneys,</p>	<p>By their attorneys,</p>
<p>s/Gary P. Hunt</p>	<p>S/Richard L. Byrne</p>
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<p>David G. Conlin (to be admitted <i>pro hac vice</i>) Kathleen B. Carr (to be admitted <i>pro hac vice</i>) Barbara L. Moore (to be admitted <i>pro hac vice</i>) Adam P. Samansky (to be admitted <i>pro hac vice</i>) EDWARDS WILDMAN PALMER LLP 111 Huntington Avenue Boston, MA 02199-7613 (617) 239-0100</p>	<p>Gary E. Hood (to be admitted <i>pro hac vice</i>) POL SINELLI SHUGHART PC 161 N. Clark Street, Suite 4200 Chicago, IL 60601 (312) 819-1900</p>
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