

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

DEY, L.P., and DEY, INC., )  
 )  
 )  
 Plaintiffs, )  
 )  
 v. )  
 ) C.A. No.: \_\_\_\_  
 TEVA PARENTERAL MEDICINES, INC., )  
 TEVA PHARMACEUTICALS USA, INC., )  
 and TEVA PHARMACEUTICAL )  
 INDUSTRIES, LTD., )  
 )  
 Defendants. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Dey, L.P. and Dey, Inc. (collectively “Dey”) hereby allege as follows:

**THE PARTIES**

1. Dey, L.P. is a limited partnership organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, L.P.’s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware 19801, and Dey, L.P.’s registered agent for service of process in Delaware is The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

2. Dey, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, Inc.’s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware 19801, and Dey, Inc.’s registered agent for service of process in Delaware is The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

3. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd.

(“Teva Ltd.”) is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, Israel. Upon information and belief, Teva Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs. Upon information and belief, Teva Ltd. established Defendant Teva Pharmaceuticals USA, Inc. and Defendant Teva Parenteral Medicines, Inc. for the purpose of distributing, marketing, and selling its generic drug products throughout the United States.

4. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. and is controlled and/or dominated by Teva Ltd. Upon information and belief, Teva USA, itself and through its wholly-owned subsidiary and agent Defendant Teva Parenteral Medicines, Inc., manufactures and/or distributes numerous generic drugs for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

5. Upon information and belief, Defendant Teva Parenteral Medicines, Inc. (“TPM”) is a corporation organized and existing under the laws of Delaware, with its principal place of business at 19 Hughes, Irvine, California. Upon information and belief, TPM is a wholly-owned subsidiary of Teva USA. Upon information and belief, TPM is controlled and/or dominated by Teva Ltd. and Teva USA. Upon information and belief, TPM is the United States agent for Teva Ltd. and Teva USA for purposes including, but not limited to, making regulatory submissions to the U.S. Food and Drug Administration (“FDA”) relating to generic products. Upon information and belief, TPM also is the United States marketing and sales agent for Teva Ltd. and Teva USA relating to generic products, wherein, following FDA approval of an Abbreviated New Drug

Application (“ANDA”), TPM manufacturers and supplies the approved generic drug product to Teva USA, which then markets and sells the product throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

6. Upon information and belief, TPM’s preparation and submission of ANDA No. 91-141 was done at the direction, under the control, and for the direct benefit of Teva USA and Teva Ltd. Upon information and belief, Teva Ltd. and Teva USA directed TPM to submit ANDA No. 91-141, in whole or in part, to shield Teva Ltd. and Teva USA from liability for patent infringement based upon that act.

7. Teva USA maintains a website at URL [www.tevausea.com](http://www.tevausea.com) at which it represents that it is dedicated to market generic products in the United States. Upon information and belief, based in part on representations on their website, Teva USA and TPM hold themselves out as a unitary entity by representing to the public that the activities of TPM are directed, controlled, and carried out by Teva USA.

8. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 91-141, Teva Ltd. itself and through its wholly-owned subsidiary Teva USA will sell its generic product throughout the United States.

9. TPM, Teva USA, and Teva Ltd. are collectively referred to hereafter as “Teva.”

10. Teva manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the state of Delaware.

### **NATURE OF ACTION**

11. This is an action for infringement of United States Patent Nos. 6,667,344 (“the ’344 patent”), 6,814,953 (“the ’953 patent”), 7,348,362 (“the ’362 patent”), and 7,462,645 (“the

'645 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*, including §§ 271(e)(2) and 271(b). A copy of the '344 patent is attached as Exhibit A. A copy of the '953 patent is attached as Exhibit B. A copy of the '362 patent is attached as Exhibit C. A copy of the '645 patent is attached as Exhibit D.

12. This action arises out of the filing by TPM, acting jointly with, and/or as the agent of its co-Defendants, of ANDA No. 91-141 with the FDA seeking approval to manufacture and sell a generic version of plaintiff's Perforomist® inhalation product prior to the expiration of the '344, '953, '362, and '645 patents.

### **JURISDICTION AND VENUE**

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Teva because of its continuous and systematic contacts with the state of Delaware, including its sales of prescription drugs in the state of Delaware. TPM and Teva USA are subject to personal jurisdiction in Delaware because, among other things, they are residents and citizens of the state of Delaware and have submitted themselves to the jurisdiction of courts in Delaware by virtue of their incorporation under Delaware law. Teva Ltd. is also subject to personal jurisdiction in Delaware because, among other things, Teva Ltd. directly and/or through its wholly-owned subsidiaries, manufactures, markets, and sells generic drugs throughout the United States and within the state of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the state of Delaware. In addition, this Court has personal jurisdiction over each of the Defendants because each has consented to jurisdiction in this district in previous litigations by affirmatively filing claims.

15. TPM, Teva USA, and Teva Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the drug products described in ANDA No. 91-141. More specifically, each of TPM, Teva USA, and Teva Ltd., as part of Teva USA's pharmaceutical products division, will manufacture, market, and/or sell the products described in ANDA No. 91-141, should FDA approval be granted.

16. If ANDA No. 91-141 is approved, the Teva ANDA Product would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

17. Venue is proper in this judicial district based on 28 U.S.C. § 1400 (b) and/or 28 U.S.C. § 1391 (b), (c), and (d).

### **BACKGROUND**

18. Perforomist® (formoterol fumarate inhalation solution) is indicated for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

19. Dey sells Perforomist® in the United States pursuant to a New Drug Application that has been approved by the FDA.

## FACTS COMMON TO ALL COUNTS

20. TPM, acting jointly with, and/or as the agent of its co-Defendants, submitted ANDA No. 91-141 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 344(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale throughout the United States, including Delaware, of generic Formoterol Fumarate Inhalation Solution 0.02mg/2mL (“the Teva ANDA Product”). ANDA No. 91-141 specifically seeks FDA approval to market the Teva ANDA Product prior to the expiration of the ’344, ’953, ’362 and ’645 patents.

21. By letter dated May 12, 2009 (the “Notice Letter”), TPM notified Dey that it had submitted to the FDA ANDA No. 91-141 for Teva’s ANDA product. The purpose of the submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva’s ANDA Product prior to the expiration of the ’344, ’953, ’362, and ’645 patents.

22. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

23. In the Notice Letter, TPM also notified Dey that, as a part of its ANDA, TPM had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’344, ’953, ’362, and ’645 patents. Upon information and belief, TPM submitted ANDA No. 91-141 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’344, ’953, ’362, and ’645 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Teva’s ANDA Product.

24. Following receipt of the Notice Letter, Dey requested materials from ANDA No. 91-141 and samples of the ANDA product. To date, Dey has not received any such materials and samples.

**COUNT 1**  
**(Infringement of the '344 Patent Under 35 U.S.C. § 271(e)(2))**

25. Dey repeats and realleges paragraphs 1 through 24 above as if fully set forth herein.

26. Dey is the owner of all right, title, and interest in the '344 patent.

27. The '344 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 23, 2003 for an invention entitled "Bronchodilating Compositions and Methods." The '344 patent will expire on June 22, 2021.

28. Perforomist® inhalation product is covered by one or more claims of the '344 patent, and, pursuant to 21 U.S.C. § 355(b)(1), the '344 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Dey's Perforomist® drug product.

29. TPM, acting jointly with, and/or as the agent of its co-Defendants, submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product. By submitting the application, TPM has committed an act of infringement with respect to the '344 patent under 35 U.S.C. § 271(e)(2)(A).

30. When TPM submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly

with TPM to submit the application, and/or causing their agent to submit the application, Teva USA and Teva Ltd. committed an act of infringement with respect to the '344 patent under 35 U.S.C. § 271(e)(2)(A).

31. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '344 patent.

32. Teva USA's and Teva Ltd.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 91-141 and TPM's paragraph IV certification to the FDA constitutes infringement of the '344 patent under 35 U.S.C. § 271(e)(2)(A). Further Teva USA's and Teva Ltd.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '344 patent.

33. The acts of infringement set forth above will cause Dey irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

**COUNT 2**  
**(Infringement of the '344 Patent Under 35 U.S.C. § 271(b))**

34. Dey repeats and realleges paragraphs 1 through 33 above as if fully set forth herein.

35. Teva USA and Teva Ltd., individually and collectively, actively induced TPM to submit ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product.

36. Teva USA and Teva Ltd. will be actively involved in the manufacture, marketing, and sale of the Teva ANDA product, should FDA approval be granted.



37. Any such commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '344 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Teva ANDA Product, Teva USA and Teva Ltd. committed an act of indirect infringement with respect to the '344 patent under 35 U.S.C. § 271(b).

**COUNT 3**

**(Infringement of the '953 Patent Under 35 U.S.C. § 271(e)(2))**

38. Dey repeats and realleges paragraphs 1 through 37 above as if fully set forth herein.

39. Dey is the owner of all right, title, and interest in the '953 patent.

40. The '953 patent was duly and legally issued by the PTO on November 9, 2004 for an invention entitled "Bronchodilating Compositions and Methods." The '953 patent will expire on June 22, 2021.

41. Perforomist® inhalation product is covered by one or more claims of the '953 patent, and, pursuant to 21 U.S.C. § 355(b)(1), the '953 patent is listed in the Orange Book as covering Dey's Perforomist® drug product.

42. TPM, acting jointly with, and/or as the agent of its co-Defendants, submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product. By submitting the application, TPM has committed an act of infringement with respect to the '953 patent under 35 U.S.C. § 271(e)(2)(A).

43. When TPM submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly with TPM to submit the application, and/or causing their agent to submit the application, Teva USA and Teva Ltd. committed an act of infringement with respect to the '953 patent under 35 U.S.C. § 271(e)(2)(A).

44. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '953 patent.

45. Teva USA's and Teva Ltd.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 91-141 and TPM's paragraph IV certification to the FDA constitutes infringement of the '953 patent under 35 U.S.C. § 271(e)(2)(A). Further Teva USA's and Teva Ltd.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '953 patent.

46. The acts of infringement set forth above will cause Dey irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

**COUNT 4**  
**(Infringement of the '953 Patent Under 35 U.S.C. § 271(b))**

47. Dey repeats and realleges paragraphs 1 through 46 above as if fully set forth herein.

48. Teva USA and Teva Ltd., individually and collectively, actively induced TPM to submit ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic

Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product.

49. Teva USA and Teva Ltd. will be actively involved in the manufacture, marketing, and sale of the Teva ANDA product, should FDA approval be granted.

50. Any such commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '953 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Teva ANDA Product, Teva USA and Teva Ltd. committed an act of indirect infringement with respect to the '953 patent under 35 U.S.C. § 271(b).

**COUNT 5**  
**(Infringement of the '362 Patent Under 35 U.S.C. § 271(e)(2))**

51. Dey repeats and realleges paragraphs 1 through 50 above as if fully set forth herein.

52. Dey is the owner of all right, title, and interest in the '362 patent.

53. The '362 patent was duly and legally issued by the PTO on March 25, 2008 for an invention entitled "Bronchodilating  $\beta$ -Agonist Compositions and Methods." The '362 patent will expire on June 22, 2021.

54. Perforomist® inhalation product is covered by one or more claims of the '362 patent, and, pursuant to 21 U.S.C. § 355(b)(1), the '362 patent is listed in the Orange Book as covering Dey's Perforomist® drug product.

55. TPM, acting jointly with, and/or as the agent of its co-Defendants, submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to

engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product. By submitting the application, TPM has committed an act of infringement with respect to the '362 patent under 35 U.S.C. § 271(e)(2)(A).

56. When TPM submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly with TPM to submit the application, and/or causing their agent to submit the application, Teva USA and Teva Ltd. committed an act of infringement with respect to the '362 patent under 35 U.S.C. § 271(e)(2)(A).

57. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '362 patent.

58. Teva USA's and Teva Ltd.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 91-141 and TPM's paragraph IV certification to the FDA constitutes infringement of the '362 patent under 35 U.S.C. § 271(e)(2)(A). Further Teva USA's and Teva Ltd.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '362 patent.

59. The acts of infringement set forth above will cause Dey irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

**COUNT 6**  
**(Infringement of the '362 Patent Under 35 U.S.C. § 271(b))**

60. Dey repeats and realleges paragraphs 1 through 59 above as if fully set forth herein.

61. Teva USA and Teva Ltd., individually and collectively, actively induced TPM to submit ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product.

62. Teva USA and Teva Ltd. will be actively involved in the manufacture, marketing, and sale of the Teva ANDA product, should FDA approval be granted.

63. Any such commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '362 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Teva ANDA Product, Teva USA and Teva Ltd. committed an act of indirect infringement with respect to the '362 patent under 35 U.S.C. § 271(b).

**COUNT 7**  
**(Infringement of the '645 Patent Under 35 U.S.C. § 271(e)(2))**

64. Dey repeats and realleges paragraphs 1 through 63 above as if fully set forth herein.

65. Dey is the owner of all right, title, and interest in the '645 patent.

66. The '645 patent was duly and legally issued by the PTO on December 9, 2008 for an invention entitled "Bronchodilating Beta-Agonist Compositions and Methods." The '645 patent will expire on June 22, 2021.

67. Perforomist® inhalation product is covered by one or more claims of the '645 patent, and, pursuant to 21 U.S.C. § 355(b)(1), the '645 patent is listed in the Orange Book as covering Dey's Perforomist® drug product.

68. TPM, acting jointly with, and/or as the agent of its co-Defendants, submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product. By submitting the application, TPM has committed an act of infringement with respect to the '645 patent under 35 U.S.C. § 271(e)(2)(A).

69. When TPM submitted ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product, it was acting jointly with its co-Defendants and/or acting as the agent of its co-Defendants. By acting jointly with TPM to submit the application, and/or causing their agent to submit the application, Teva USA and Teva Ltd. committed an act of infringement with respect to the '645 patent under 35 U.S.C. § 271(e)(2)(A).

70. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '645 patent.

71. Teva USA's and Teva Ltd.'s inducement, encouragement, aiding, or abetting of the submission of ANDA No. 91-141 and TPM's paragraph IV certification to the FDA constitutes infringement of the '645 patent under 35 U.S.C. § 271(e)(2)(A). Further Teva USA's

and Teva Ltd.'s commercial use, offer for sale, or sale of the ANDA products would infringe the '645 patent.

72. The acts of infringement set forth above will cause Dey irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

**COUNT 8**  
**(Infringement of the '645 Patent Under 35 U.S.C. § 271(b))**

73. Dey repeats and realleges paragraphs 1 through 72 above as if fully set forth herein.

74. Teva USA and Teva Ltd., individually and collectively, actively induced TPM to submit ANDA No. 91-141 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States including Delaware of the Teva ANDA Product.

75. Teva USA and Teva Ltd. will be actively involved in the manufacture, marketing, and sale of the Teva ANDA product, should FDA approval be granted.

76. Any such commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will infringe the '645 patent. By engaging in a cooperative venture with its co-Defendants, and each of them, to submit the ANDA to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, or sale throughout the United States, including Delaware, of the Teva ANDA Product, Teva USA and Teva Ltd. committed an act of indirect infringement with respect to the '645 patent under 35 U.S.C. § 271(b).

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for following relief:

- a. That judgment be entered that Defendants, individually and collectively, have infringed the '344 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-141 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will constitute an act of infringement of the '344 patent;
- b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 91-141 shall be a date which is not earlier than the expiration date of the '344 patent including any extensions;
- c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining TPM, Teva USA, Teva Ltd., their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '344 patent;
- d. That judgment be entered that Teva USA and Teva Ltd. have infringed the '344 patent under 35 U.S.C. § 271(b) or (c) by inducing TPM to submit ANDA No. 91-141 under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva USA and Teva Ltd. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry, which will constitute an act of infringement of the '344 patent;
- e. A declaration that the '344 patent is valid and enforceable;



f. That judgment be entered that Defendants, individually and collectively, have infringed the '953 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-141 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will constitute an act of infringement of the '953 patent;

g. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 91-141 shall be a date which is not earlier than the expiration date of the '953 patent including any extensions;

h. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining TPM, Teva USA, Teva Ltd., their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '953 patent;

i. That judgment be entered that Teva USA and Teva Ltd. have infringed the '953 patent under 35 U.S.C. § 271(b) or (c) by inducing TPM to submit ANDA No. 91-141 under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva USA and Teva Ltd. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry, which will constitute an act of infringement of the '953 patent;

j. A declaration that the '953 patent is valid and enforceable;

k. That judgment be entered that Defendants, individually and collectively, have infringed the '362 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-141

under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will constitute an act of infringement of the '362 patent;

l. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 91-141 shall be a date which is not earlier than the expiration date of the '362 patent including any extensions;

m. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining TPM, Teva USA, Teva Ltd., their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '362 patent;

n. That judgment be entered that Teva USA and Teva Ltd. have infringed the '362 patent under 35 U.S.C. § 271(b) or (c) by inducing TPM to submit ANDA No. 91-141 under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva USA and Teva Ltd. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry, which will constitute an act of infringement of the '362 patent;

o. A declaration that the '362 patent is valid and enforceable;

p. That judgment be entered that Defendants, individually and collectively, have infringed the '645 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 91-141 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use,

offer for sale, and/or importation of the Teva ANDA Product prior to patent expiry will constitute an act of infringement of the '645 patent;

q. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 91-141 shall be a date which is not earlier than the expiration date of the '645 patent including any extensions;

r. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining TPM, Teva USA, Teva Ltd., their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '645 patent;

s. That judgment be entered that Teva USA and Teva Ltd. have infringed the '645 patent under 35 U.S.C. § 271(b) or (c) by inducing TPM to submit ANDA No. 91-141 under the Federal Food Drug, and Cosmetic Act, as a joint venture in which Teva USA and Teva Ltd. will participate in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to patent expiry, which will constitute an act of infringement of the '645 patent;

t. A declaration that the '645 patent is valid and enforceable;

u. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. § 271 (e)(4)(C) as appropriate;

v. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

w. Such further and other relief as this Court deems proper and just.



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Frederick L. Cottrell, III (#2555)

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