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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

VALEANT PHARMACEUTICALS  
NORTH AMERICA LLC; VALEANT  
PHARMACEUTICALS IRELAND LTD.;  
DOW PHARMACEUTICAL SCIENCES, INC.;  
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.;  
MYLAN LABORATORIES LTD.; and  
MYLAN INC.,

Defendants.

Civil Action No. 18-14305

*Document Electronically Filed*

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Valeant Pharmaceuticals North America LLC (“Valeant”), Valeant Pharmaceuticals Ireland Ltd. (“Valeant Ireland”), Dow Pharmaceutical Sciences, Inc. (“Dow”), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”), Mylan Laboratories Ltd. (“Mylan Labs”), and Mylan Inc. (collectively, “Mylan”) allege as follows:

## **THE PARTIES**

1. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Labs.

6. Upon information and belief, Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Pharmaceuticals.

7. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

## **NATURE OF THE ACTION**

8. This is an action for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”) and 9,877,955 (“the ’955 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Mylan’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic efinaconazole topical solution, 10% (“Mylan’s generic efinaconazole topical solution”).

## **JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

10. Upon information and belief, this Court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan’s generic efinaconazole topical solution. Upon information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Pharmaceuticals is registered to do business in this judicial district. Upon information and belief, Mylan Pharmaceuticals has

previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Upon information and belief, Mylan Pharmaceuticals has a place of business at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Pharmaceuticals publicly touts its New Jersey presence at <https://mylanbetterhealth.com/en/us/new-jersey>.

11. Mylan Pharmaceuticals has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, New Jersey and elsewhere. Mylan Pharmaceuticals' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Mylan Pharmaceuticals intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Mylan Pharmaceuticals will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

12. Upon information and belief, this Court has jurisdiction over Mylan Labs. Upon information and belief, Mylan Labs is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Labs directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution. Upon information and belief, Mylan Labs purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Labs is registered to do business in this judicial district. Upon information and belief, Mylan Labs has previously

submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Upon information and belief, Mylan Labs has a place of business at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Labs publicly touts its New Jersey presence at <https://mylanbetterhealth.com/en/us/new-jersey>.

13. Upon information and belief, this Court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution. Upon information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Inc. is registered to do business in this judicial district. Upon information and belief, Mylan Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Upon information and belief, Mylan Inc. has a place of business at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Inc. publicly touts its New Jersey presence at <https://mylanbetterhealth.com/en/us/new-jersey>.

14. Mylan Pharmaceuticals and Mylan Inc. availed themselves of the rights, benefits, and privileges of this Court by filing at least the following complaints in the District of New Jersey: *Mylan Pharmaceuticals, Inc., et al. v. Novartis Pharmaceuticals Corporation*, Civil Action No. 2:18-cv-12022; *Mylan Pharmaceuticals, Inc. v. Celgene Corporation*, Civil Action

No. 2:14-cv-02094; and *Mylan Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 3:14-cv-04560.

15. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Valeant Pharmaceuticals International, Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 2:15-cv-8180 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB, et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

16. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB, et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P., et al. v. Lupin Limited, et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

17. Mylan knows or should know that Jublia® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that

information is included in the label and prescribing information for Jublia®.

18. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

### **THE PATENTS IN SUIT**

19. The United States Patent and Trademark Office (“PTO”) issued the ’506 patent on May 8, 2007. The ’506 patent claims, generally speaking, *inter alia*, methods for treating onychomycosis by administering efinaconazole. Plaintiffs hold all substantial rights in the ’506 patent and have the right to sue for infringement thereof. The ’506 patent is valid and enforceable. A copy of the ’506 patent is attached hereto as Exhibit A.

20. The PTO issued the ’494 patent on October 18, 2011. The ’494 patent claims, generally speaking, *inter alia*, methods for treatment of a disorder of the nail or nail bed by applying pharmaceutical compositions consisting essentially of a vehicle that is volatile and/or that rapidly penetrates a nail following application onto the surface of the nail, a triazole antifungal active pharmaceutical ingredient (encompassing efinaconazole) and a wetting agent. Plaintiffs hold all substantial rights in the ’494 patent and have the right to sue for infringement thereof. The ’494 patent is valid and enforceable. A copy of the ’494 patent is attached hereto as Exhibit B.

21. The PTO issued the ’978 patent on July 16, 2013. The ’978 patent claims, generally speaking *inter alia*, pharmaceutical compositions consisting essentially of a vehicle that is volatile and/or that rapidly penetrates a nail following application onto the surface of the nail, a triazole antifungal active pharmaceutical ingredient (encompassing efinaconazole) and a wetting agent. Plaintiffs hold all substantial rights in the ’978 patent and have the right to sue for infringement thereof. The ’978 patent is valid and enforceable. A copy of the ’978 patent is

attached hereto as Exhibit C.

22. The PTO issued the '009 patent on April 5, 2016. The '009 patent claims, generally speaking, *inter alia*, pharmaceutical compositions for the topical treatment of a disorder of the nail or nail bed including efinaconazole, ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and antioxidant. Plaintiffs hold all substantial rights in the '009 patent and have the right to sue for infringement thereof. The '009 patent is valid and enforceable. A copy of the '009 patent is attached hereto as Exhibit D.

23. The PTO issued the '272 patent on February 14, 2017. The '272 patent claims, generally speaking, *inter alia*, methods for the treatment of onychomycosis by topically applying pharmaceutical compositions including efinaconazole, ethanol, diisopropyl adipate, C12-15 alkyl lactate and cyclomethicone. Plaintiffs hold all substantial rights in the '272 patent and have the right to sue for infringement thereof. The '272 patent is valid and enforceable. A copy of the '272 patent is attached hereto as Exhibit E.

24. The PTO issued the '394 patent on May 30, 2017. The '394 patent claims, generally speaking, *inter alia*, compositions including efinaconazole, water, C12-15 alkyl lactate, diisopropyl adipate, cyclomethicone, ethanol, BHT, a salt of EDTA, and citric acid, and methods of treating a fungal infection with the same compositions. Plaintiffs hold all substantial rights in the '394 patent and have the right to sue for infringement thereof. The '394 patent is valid and enforceable. A copy of the '394 patent is attached hereto as Exhibit F.

25. The PTO issued the '698 patent on January 9, 2018. The '698 patent claims, generally speaking, *inter alia*, pharmaceutical formulations comprising ethanol, cyclomethicone, diisopropyl adipate and mixed C12-15 alkyl lactates, and methods for the treatment of a disorder of the nail or nail bed by applying the same compositions. Plaintiffs hold all substantial rights in

the '698 patent and have the right to sue for infringement thereof. The '698 patent is valid and enforceable. A copy of the '698 patent is attached hereto as Exhibit G.

26. The PTO issued the '955 patent on January 30, 2018. The '955 patent claims, generally speaking, *inter alia*, methods for the treatment of onychomycosis by applying a pharmaceutical composition including efinaconazole, ethanol, diisopropyl adipate, C12-15 alkyl lactate and cyclomethicone. Plaintiffs hold all substantial rights in the '955 patent and have the right to sue for infringement thereof. The '955 patent is valid and enforceable. A copy of the '955 patent is attached hereto as Exhibit H.

27. Dow is the holder of New Drug Application ("NDA") No. 203567 for Jublia<sup>®</sup>, which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

28. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia<sup>®</sup>.

#### **MYLAN'S INFRINGING ANDA SUBMISSION**

29. Upon information and belief, Mylan Pharmaceuticals filed or caused to be filed with the FDA ANDA No. 212064, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

30. Upon information and belief, Mylan Pharmaceuticals' ANDA No. 212064 seeks FDA approval to sell in the United States Mylan's generic efinaconazole topical solution, intended to be a generic version of Jublia<sup>®</sup>.

31. Dow received a letter dated August 13, 2018 from Mylan purporting to be a Notice of Certification for ANDA No. 212064 ("Mylan's notice letter") under Section

505(j)(2)(B)(ii) and (iv), 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

32. Mylan's notice letter alleges that Mylan Pharmaceuticals has submitted to the FDA ANDA No. 212064 seeking FDA approval to sell Mylan's generic efinaconazole topical solution, intended to be a generic version of Jublia®.

33. Upon information and belief, ANDA No. 212064 seeks approval of Mylan's generic efinaconazole topical solution that is the same, or substantially the same, as Jublia®.

### **COUNT I AGAINST MYLAN**

#### **Infringement of the '506 Patent under § 271(e)(2)**

34. Paragraphs 1-33 are incorporated herein as set forth above.

35. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '506 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '506 patent.

36. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '506 patent.

37. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '506 patent.

38. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '506 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT II AGAINST MYLAN**

### **Declaratory Judgment of Infringement of the '506 Patent**

39. Paragraphs 1-38 are incorporated herein as set forth above.
40. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
41. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
42. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '506 patent, including Mylan's filing of ANDA No. 212064.
43. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '506 patent.
44. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '506 patent.

## **COUNT III AGAINST MYLAN**

### **Infringement of the '494 Patent under § 271(e)(2)**

45. Paragraphs 1-44 are incorporated herein as set forth above.
46. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '494 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before

the expiration date of the '494 patent.

47. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '494 patent.

48. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '494 patent.

49. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '494 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT IV AGAINST MYLAN**

##### **Declaratory Judgment of Infringement of the '494 Patent**

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

53. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '494 patent, including Mylan's filing of ANDA No. 212064.

54. Upon information and belief, any commercial manufacture, use, offer for sale,

sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '494 patent.

55. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '494 patent.

### **COUNT V AGAINST MYLAN**

#### **Infringement of the '978 Patent under § 271(e)(2)**

56. Paragraphs 1-55 are incorporated herein as set forth above.

57. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '978 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '978 patent.

58. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '978 patent.

59. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '978 patent.

60. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '978 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT VI AGAINST MYLAN**

### **Declaratory Judgment of Infringement of the '978 Patent**

61. Paragraphs 1-60 are incorporated herein as set forth above.
62. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
63. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
64. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '978 patent, including Mylan's filing of ANDA No. 212064.
65. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '978 patent.
66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '978 patent.

## **COUNT VII AGAINST MYLAN**

### **Infringement of the '009 Patent under § 271(e)(2)**

67. Paragraphs 1-66 are incorporated herein as set forth above.
68. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '009 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before

the expiration date of the '009 patent.

69. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '009 patent.

70. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '009 patent.

71. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '009 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT VIII AGAINST MYLAN**

#### **Declaratory Judgment of Infringement of the '009 Patent**

72. Paragraphs 1-71 are incorporated herein as set forth above.

73. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

74. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

75. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '009 patent, including Mylan's filing of ANDA No. 212064.

76. Upon information and belief, any commercial manufacture, use, offer for sale,

sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '009 patent.

77. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '009 patent.

### **COUNT IX AGAINST MYLAN**

#### **Infringement of the '272 Patent under § 271(e)(2)**

78. Paragraphs 1-77 are incorporated herein as set forth above.

79. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '272 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '272 patent.

80. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '272 patent.

81. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '272 patent.

82. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '272 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT X AGAINST MYLAN**

### **Declaratory Judgment of Infringement of the '272 Patent**

83. Paragraphs 1-82 are incorporated herein as set forth above.
84. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
85. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.
86. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '272 patent, including Mylan's filing of ANDA No. 212064.
87. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '272 patent.

88. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '272 patent.

## **COUNT XI AGAINST MYLAN**

### **Infringement of the '394 Patent under § 271(e)(2)**

89. Paragraphs 1-88 are incorporated herein as set forth above.
90. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '394 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before

the expiration date of the '394 patent.

91. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '394 patent.

92. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '394 patent.

93. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '394 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT XII AGAINST MYLAN**

### **Declaratory Judgment of Infringement of the '394 Patent**

94. Paragraphs 1-93 are incorporated herein as set forth above.

95. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

96. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

97. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '394 patent, including Mylan's filing of ANDA No. 212064.

98. Upon information and belief, any commercial manufacture, use, offer for sale,

sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '394 patent.

99. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '394 patent.

### **COUNT XIII AGAINST MYLAN**

#### **Infringement of the '698 Patent under § 271(e)(2)**

100. Paragraphs 1-99 are incorporated herein as set forth above.

101. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '698 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '698 patent.

102. Upon information and belief, Mylan's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '698 patent.

103. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '698 patent.

104. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '698 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

### **COUNT XIV AGAINST MYLAN**

#### **Declaratory Judgment of Infringement of the '698 Patent**

105. Paragraphs 1-104 are incorporated herein as set forth above.

106. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

107. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

108. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '698 patent, including Mylan's filing of ANDA No. 212064.

109. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '698 patent.

110. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '698 patent.

#### **COUNT XV AGAINST MYLAN**

##### **Infringement of the '955 Patent under § 271(e)(2)**

111. Paragraphs 1-110 are incorporated herein as set forth above.

112. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '955 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212064 seeking approval for the commercial marketing of Mylan's generic efinaconazole topical solution before the expiration date of the '955 patent.

113. Upon information and belief, Mylan's generic efinaconazole topical solution

will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '955 patent.

114. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

115. If Mylan's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '955 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT XVI AGAINST MYLAN**

##### **Declaratory Judgment of Infringement of the '955 Patent**

116. Paragraphs 1-115 are incorporated herein as set forth above.

117. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

118. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

119. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic efinaconazole topical solution before the expiration date of the '955 patent, including Mylan's filing of ANDA No. 212064.

120. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '955 patent.

121. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic efinaconazole topical solution will constitute infringement of at least one claim of the '955 patent.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request that the Court enter judgment in their favor and against Mylan on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '506 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '506 patent;
2. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '494 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '494 patent;
3. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '978 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '978 patent;
4. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least

one claim of the '009 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '009 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '272 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '272 patent;

6. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '394 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '394 patent;

7. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '698 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of the '698 patent;

8. enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '955 patent by submitting or causing to be submitted ANDA No. 212064 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic efinaconazole topical solution before the expiration of

the '955 patent;

9. order that the effective date of any approval by the FDA of Mylan's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent, or such later date as the Court may determine;

10. enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic efinaconazole topical solution until expiration of the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent, or such later date as the Court may determine;

11. enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 212064 until expiration of the '506 patent, the '494 patent, the '978 patent, the '009 patent, the '272 patent, the '394 patent, the '698 patent, and the '955 patent;

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

13. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: September 26, 2018  
Newark, New Jersey

Respectfully submitted,

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**CERTIFICATION OF NON-ARBITRABILITY**  
**PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: September 26, 2018  
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

**GIBBONS P.C.**

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