

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA IRELAND)
LIMITED, HZNP LIMITED and HORIZON)
PHARMA USA, INC.,)
)
Plaintiffs,)
) C.A. No. _____
v.)
)
PADDOCK LABORATORIES, LLC and)
PERRIGO COMPANY,)
)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, “Plaintiffs”), by their undersigned attorneys, bring this action against Defendants Paddock Laboratories LLC and Perrigo Company (collectively, “Defendants”), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Plaintiffs’ pharmaceutical product PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID® 2%”) prior to the expiration of United States Patent Nos. 8,217,078 (“the ’078 patent”), 8,252,838 (“the ’838 patent”), 8,546,450 (“the ’450 patent”), 8,563,613 (“the ’613 patent”), 8,618,164 (“the ’164 patent”) and 8,871,809 (“the ’809 patent”), which cover PENNSAID® 2% and its use.

THE PARTIES

2. Plaintiff Horizon Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland, with a principal place of business at Adelaide Chambers, Peter Street, Dublin 8, Ireland.

3. Plaintiff HZNP Limited is a nonresident Irish company that is a tax resident of Bermuda, with a principal place of business at 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

4. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

5. On information and belief, Defendant Paddock Laboratories, LLC (“Paddock”) is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 3940 Quebec Avenue N, Minneapolis, Minnesota 55427.

6. On information and belief, Defendant Perrigo Company (“Perrigo”) is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

7. On information and belief, Perrigo is in the business of manufacturing, distributing and selling pharmaceutical products throughout the United States, including within this judicial district. On information and belief, Perrigo derives substantial revenue from the sale of those products in Delaware, and has availed itself of the privilege of conducting business within the State of Delaware.

8. On information and belief, Paddock is a wholly-owned subsidiary of Perrigo.

9. On information and belief, according to the business records of Paddock as maintained by the Office of the Minnesota Secretary of State, Minnesota Business and Lien System, Perrigo is identified as the “Manager” of Paddock.

10. On information and belief, in letters dated December 1, 2014, and January 8, 2015, Paddock identified Andrew M. Solomon, Vice President and Assistant General Counsel of Perrigo as the agent in the U.S. authorized to accept service of process for Paddock in connection with any infringement action that may be instituted against Paddock for its filing of ANDA No. 208068 (“the Paddock ANDA”) for diclofenac sodium topical solution 2% w/w (“the Paddock Product”).

11. On information and belief, Paddock acts at the direction of, under the control of, and for the benefit of Perrigo and is controlled and/or dominated by Perrigo.

12. On information and belief, Paddock is within the control of Perrigo for purposes of responding to discovery in this action.

13. On information and belief, Paddock and Perrigo participated and collaborated in the research and development, and the preparation and filing, of the Paddock ANDA for the Paddock Product, continue to participate and collaborate in seeking FDA approval of that application, and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the Paddock Product throughout the United States, including in the State of Delaware, in the event the FDA approves Paddock’s ANDA.

14. On information and belief, Perrigo consented to the jurisdiction of this Court in *Endo Pharmaceuticals Solutions et al. v. Paddock Laboratories, LLC et al.*, Civil Action No. 14-1422, *Cadence Pharmaceuticals, Inc. et al. v. Paddock Laboratories, Inc. et al.*, Civil Action No. 11-733, *Stiefel Laboratories Inc. et al. v. Perrigo Company et al.*, Civil Action No. 10-592, and *KV Pharmaceutical Company et al. v. Perrigo Israel Pharmaceuticals Ltd. et al.*, Civil Action No. 10-641.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over Defendant Paddock Laboratories, LLC due to its organization in the state of Delaware.

17. This Court has personal jurisdiction over Defendant Perrigo Company by virtue of, *inter alia*, the fact that it regularly transacts and solicits business in Delaware and has purposefully availed itself of this forum such that it should reasonable anticipate being haled into Court here.

18. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

19. On July 10, 2012, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’078 patent entitled “Treatment of Pain with Topical Diclofenac.” At the time of its issue, the ’078 patent was assigned to Nuvo Research Inc., which later assigned the ’078 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the ’078 patent, which discloses and claims, *inter alia*, a method of applying topical agents to a knee of a patient with pain. A true and correct copy of the ’078 patent is attached hereto as Exhibit A.

20. On August 28, 2012, the USPTO duly and legally issued the ’838 patent entitled “Diclofenac Topical Formulation.” At the time of its issue, the ’838 patent was assigned to Nuvo Research Inc., which later assigned the ’838 patent to HZNP Limited. HZNP Limited

currently is the sole assignee and owner of all right, title and interest in and to the '838 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '838 patent is attached hereto as Exhibit B.

21. On October 1, 2013, the USPTO duly and legally issued the '450 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '450 patent was assigned to Nuvo Research Inc., which later assigned the '450 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '450 patent, which discloses and claims, *inter alia*, a method of treating a patient with combination therapy comprising administering a therapeutically effective amount of an oral NSAID and applying a topical diclofenac preparation to a knee. A true and correct copy of the '450 patent is attached hereto as Exhibit C.

22. On October 22, 2013, the USPTO duly and legally issued the '613 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '613 patent was assigned to Nuvo Research Inc., which later assigned the '613 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '613 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '613 patent is attached hereto as Exhibit D.

23. On December 31, 2013, the USPTO duly and legally issued the '164 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '164 patent was assigned to Nuvo Research Inc., which later assigned the '164 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '164 patent, which discloses and claims, *inter alia*, a method for applying topical

agents to a knee of a patient with pain. A true and correct copy of the '164 patent is attached hereto as Exhibit E.

24. On October 28, 2014, the USPTO duly and legally issued the '809 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '809 patent was assigned to Nuvo Research Inc., which later assigned the '809 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '809 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '809 patent is attached hereto as Exhibit F.

PENNSAID® 2%

25. Horizon Pharma Ireland Limited is the owner of FDA-approved New Drug Application No. 204623 ("the PENNSAID® 2% NDA") for diclofenac sodium topical solution 2% w/w ("PENNSAID® 2%"), which is sold in the US under the trade name PENNSAID®, and which will be sold by Horizon Pharma USA, Inc.

26. The PENNSAID® 2% solution is currently approved by the FDA for the relief of pain of osteoarthritis of the knees.

27. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '078, '838, '450, '613, '164 and '809 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

28. The '078, '838, '450, '613, '164 and '809 patents cover PENNSAID® 2% and its use.

PADDOCK'S ANDA

29. On information and belief, Paddock submitted the Paddock ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 2% w/w. On information and belief, the Paddock ANDA seeks approval to market the Paddock Product for the relief of pain of osteoarthritis of the knees.

30. On information and belief, the Paddock ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to Paddock, demonstrate the bioequivalence of the Paddock Product and PENNSAID® 2%.

31. HZNP Limited received from Paddock a letter, dated December 1, 2014 (the “Paddock December Notification”), stating that Paddock had included a certification in the Paddock ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '078, '838, '450, '613 and '164 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Paddock Product (the “December Paragraph IV Certification”).

32. The Paddock December Notification states that the Paddock ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the '078, '838, '450, '613 and '164 patents.

33. HZNP Limited received from Paddock a letter, dated January 8, 2015 (the “Paddock January Notification”), stating that Paddock had included a certification in the Paddock ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '809 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Paddock Product (the “January Paragraph IV Certification”).

34. The Paddock January Notification states that the Paddock ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the '809 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,217,078

35. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

36. Defendants have infringed the '078 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '078 patent.

37. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States, during the term of the '078 patent also would infringe the '078 patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Upon approval of the Paddock ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '078 patent.

39. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated December 1, 2014, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification filed relative to the '078 patent.

40. Upon information and belief, Defendants had actual and constructive notice of the '078 patent prior to filing Paddock's ANDA.

41. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is

not earlier than the expiration of the '078 patent, or any later expiration of any exclusivity or extension of the '078 patent to which Plaintiffs or the patent may become entitled.

42. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '078 patent.

43. Plaintiffs have no adequate remedy at law.

44. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,252,838

45. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-44 of this Complaint.

46. Defendants have infringed the '838 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '838 patent.

47. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States, during the term of the '838 patent also would infringe the '838 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Upon approval of the Paddock ANDA, and the commercial marketing of the Paddock Product, Defendants will actively induce and/or contribute to infringement of the '838 patent.

49. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated December 1, 2014, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification filed relative to the '838 patent.

50. Upon information and belief, Defendants had actual and constructive notice of the '838 patent prior to filing Paddock's ANDA.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is not earlier than the expiration of the '838 patent, or any later expiration of any exclusivity or extension of the '838 patent to which Plaintiffs or the patent may become entitled.

52. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '838 patent.

53. Plaintiffs have no adequate remedy at law.

54. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,546,450

55. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-54 of this Complaint.

56. Defendants have infringed the '450 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '450 patent.

57. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States, during the term of the '450 patent also would infringe the '450 patent under 35 U.S.C. § 271(a), (b) and/or (c).

58. Upon approval of the Paddock ANDA, and commercialization of the Paddock Product, Defendants will actively induce and/or contribute to infringement of the '450 patent.

59. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated December 1, 2014, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification filed relative to the '450 patent.

60. Upon information and belief, Defendants had actual and constructive notice of the '450 patent prior to filing Paddock's ANDA.

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is not earlier than the expiration of the '450 patent, or any later expiration of any exclusivity or extension of the '450 patent to which Plaintiffs or the patent may become entitled.

62. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '450 patent.

63. Plaintiffs have no adequate remedy at law.

64. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,563,613

65. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-64 of this Complaint.

66. Defendants have infringed the '613 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '613 patent.

67. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States, during the term of the '613 patent, would further infringe the '613 patent under 35 U.S.C. § 271(a), (b) and/or (c).

68. Upon approval of the Paddock ANDA, and commercial marketing of the Paddock Product, Defendants will actively induce and/or contribute to the infringement of the '613 patent.

69. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated December 1, 2014, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification with respect to the '613 patent.

70. Upon information and belief, Defendants had actual and constructive notice of the '613 patent prior to filing Paddock's ANDA.

71. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is not earlier than the expiration of the '613 patent, or any later expiration of any exclusivity or extension of the '613 patent to which Plaintiffs or the patent may become entitled.

72. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '613 patent.

73. Plaintiffs have no adequate remedy at law.

74. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,618,164

75. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-74 of this Complaint.

76. Defendants have infringed the '164 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '164 patent.

77. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States during the term of the '164 patent also would infringe the '164 patent under 35 U.S.C. § 271(a), (b) and/or (c).

78. Upon approval of the Paddock ANDA, and commercialization of the Paddock Product, Defendants will actively induce and/or contribute to infringement of the '164 patent.

79. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated December 1, 2014, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification filed relative to the '164 patent.

80. Upon information and belief, Defendants had actual and constructive notice of the '164 patent prior to filing Paddock's ANDA.

81. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is not earlier than the expiration of the '164 patent, or any later expiration of any exclusivity or extension of '164 patent to which Plaintiffs or the patent may become entitled.

82. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '164 patent.

83. Plaintiffs have no adequate remedy at law.

84. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,871,809

85. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-84 of this Complaint.

86. Defendants have infringed the '809 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Paddock ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Paddock Product prior to the expiration of the '809 patent.

87. Defendants' commercial manufacture, use, offer to sell, or sale of the Paddock Product within the United States, or importation of the Paddock Product into the United States during the term of the '809 patent also would infringe the '809 patent under 35 U.S.C. § 271(a), (b) and/or (c).

88. Upon approval of the Paddock ANDA, and commercialization of the Paddock Product, Defendants will actively induce and/or contribute to infringement of the '809 patent.

89. This action is being filed within 45 days of receipt by Plaintiffs of the Paddock Notification dated January 8, 2015, which purportedly advised Plaintiffs of Paddock's Paragraph IV Certification filed relative to the '809 patent.

90. Upon information and belief, Defendants had actual and constructive notice of the '809 patent prior to filing Paddock's ANDA.

91. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Paddock's ANDA be a date that is not earlier than the expiration of the '809 patent, or any later expiration of any exclusivity or extension of the '809 patent to which Plaintiffs or the patent may become entitled.

92. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '809 patent.

93. Plaintiffs have no adequate remedy at law.

94. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,217,078;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,252,838;

C. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,546,450;

D. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,563,613;

E. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,618,164;

F. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,871,809;

G. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '078 patent;

H. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '838 patent;

I. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '450 patent;

J. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '613 patent;

K. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '164 patent;

L. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using,

offering to sell, or selling the Paddock Product within the United States, or importing the Paddock Product into the United States, prior to the expiration date of the '809 patent;

M. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '078 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

N. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '838 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '450 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

P. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '613 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

Q. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '164 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

R. If Defendants commercially manufacture, use, offer to sell, or sell the Paddock Product within the United States, or import the Paddock Product into the United States, prior to the expiration of the '809 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

S. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Paddock ANDA shall be a date not earlier than the expiration date of the '078, '838, '450, '613, '164 and/or '809 patents, inclusive of any extensions;

T. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

U. Costs and expenses in this action; and

V. Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney

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