

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and)
SCR PHARMATOP,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
PADDOCK LABORATORIES, INC.;)
PERRIGO COMPANY; PADDOCK)
LABORATORIES, LLC; EXELA PHARMA)
SCIENCES, LLC; EXELA PHARMSCI, INC.;)
and EXELA HOLDINGS, INC.;)
)
Defendants.)

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, “Plaintiffs”) for their Complaint against defendants Paddock Laboratories, Inc.; Perrigo Company; and Paddock Laboratories, LLC (collectively, the “Paddock Defendants”) and defendants Exela Pharma Sciences, LLC; Exela PharmSci, Inc.; and Exela Holdings, Inc. (collectively, the “Exela Defendants”) (the Paddock Defendants and the Exela Defendants collectively, the “Defendants”), allege as follows:

PARTIES

1. Plaintiff Cadence Pharmaceuticals, Inc. (“Cadence”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12481 High Bluff Drive, Suite 200, San Diego, California, 92130.

2. Plaintiff SCR Pharmatop (“Pharmatop”) is a civil law partnership organized and existing under the laws of France, having its headquarters at 10, Square St. Florentin, 78150 Le Chesnay, France.

3. Upon information and belief, defendant Paddock Laboratories, Inc. (“Paddock”) is a corporation organized and existing under the laws of the State of Minnesota, with headquarters at 3940 Quebec Avenue North, Minneapolis, MN 55427. Upon information and belief, Paddock is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

4. Upon information and belief, defendant Perrigo Company is a Michigan corporation, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and belief, Perrigo Company acquired substantially all of the assets of Paddock on or about July 26, 2011. Upon information and belief, Perrigo Company is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

5. Upon information and belief, defendant Paddock Laboratories, LLC (“Paddock LLC,” and collectively with Perrigo Company, “Perrigo”) is a Delaware corporation, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and belief, Paddock LLC is a subsidiary of Perrigo Company organized to integrate Paddock’s business portfolio with Perrigo Company’s business portfolio. Upon information and belief, Paddock LLC is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

6. Upon information and belief, defendant Exela Pharma Sciences, LLC (“Exela Pharma Sciences”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1325 William White Place, Lenoir, North Carolina, 28645. Upon information and belief, Exela Pharma Sciences is in the business of

manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

7. Upon information and belief, defendant Exela PharmSci, Inc. (“Exela PharmSci”) is a corporation organized and existing under the laws of the State of Virginia, with its headquarters at 19978 Palmer Classic Parkway, Reston, Virginia, 20147. Upon information and belief, Exela PharmSci is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Exela Pharma Sciences is a wholly owned subsidiary of Exela PharmSci.

8. Upon information and belief, defendant Exela Holdings, Inc. (“Exela Holdings”) is an entity organized under the laws of the State of Delaware, with its headquarters at 19978 Palmer Classic Parkway, Ashburn, Virginia, 20147. Upon information and belief, Exela Holdings is the parent company of Defendants Exela Pharma Sciences and Exela PharmSci.

NATURE OF THE ACTION

9. This is a civil action for infringement of United States Patent No. 6,028,222 and U.S. Patent No. 6,992,218 (collectively, the “Patents-in-Suit”). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over the Paddock Defendants because, *inter alia*, the Paddock Defendants have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has

led to foreseeable harm and injury to Cadence, a Delaware corporation. This Court has personal jurisdiction over the Paddock Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

12. This Court has personal jurisdiction over Paddock because, *inter alia*, Paddock has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

13. Upon information and belief, defendant Paddock regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Paddock 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.

14. In addition, Paddock has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes, and has purposely availed itself of Delaware Courts by asserting counterclaims, in at least the following actions:

- *Allergan, Inc. et al. v. Paddock Laboratories, Inc.*, No. 1:2010-cv-00851 (D. Del.); and related case No. 1:2010-cv-00501 (D. Del.) ;
- *In re Tramadol Hydrochloride Extended-Release Tablets Patent Litigation*, No. 1:2010-md-02126 (D. Del.); related case *Purdue Pharma Products, L.P., et al. v. Paddock Laboratories, Inc.*, No. 1:2010-cv-00129 (D. Del.); and related case No. 1:2009-cv-00666 (D. Del.); and
- *In re Brimonidine Patent Litigation*, No. 1:2007-md-01866 (D. Del.); and related case *Allergan, Inc., et al. v. Exela Pharmsci, Inc., et al.*, No. 1:2007-cv-00516 (D. Del.).

15. This Court has personal jurisdiction over Perrigo Company because, *inter alia*, Perrigo Company has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

16. Upon information and belief, defendant Perrigo Company regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Perrigo Company 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.

17. In addition, Perrigo Company has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes, and has purposely availed itself of Delaware Courts by asserting counterclaims, in at least the following actions:

- *Stiefel Laboratories Inc. and Stiefel Research Australia PTY. Ltd., v. Perrigo Company and Perrigo Israel Pharmaceuticals Ltd.*, No. 1:10-cv-00592 (D.Del.); related case No. 1:09-cv-00758 (D.Del.); and related case No. 1:09-cv-00167 (D.Del.);
- *KV Pharmaceutical Company, et al., v. Perrigo Israel Pharmaceuticals Ltd., Perrigo Company, et al.*, No. 1:10-cv-00641 (D.Del.); and
- *Smithkline Beecham Corporation, et al., v. Perrigo Company*, No. 1:04-cv-00107 (D.Del.).

18. This Court has personal jurisdiction over Paddock LLC by virtue of, *inter alia*, Paddock LLC's incorporation in the State of Delaware.

19. This Court has personal jurisdiction over Exela Pharma Sciences by virtue of, *inter alia*, Exela Pharma Sciences' incorporation in the State of Delaware.

20. This Court has personal jurisdiction over Exela Holdings by virtue of, *inter alia*, Exela Holdings' incorporation in the State of Delaware.

21. This Court has personal jurisdiction over Exela PharmSci because, *inter alia*, together with Exela Pharma Sciences and Exela Holdings, Exela PharmSci has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Cadence, a Delaware

corporation. This Court has personal jurisdiction over Exela PharmSci for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

22. This Court has personal jurisdiction over Exela PharmSci because, *inter alia*, together with Exela Pharma Sciences and Exela Holdings, Exela PharmSci has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

23. Upon information and belief, Exela PharmSci regularly and continuously transacts business within the state of Delaware, including by distributing or selling pharmaceutical products in Delaware.

24. In addition, Exela PharmSci has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes, and has purposely availed itself of Delaware Courts by asserting counterclaims, in at least the following action: *Allergan Inc. v. Exela PharmSci, Inc., et al.*, No. 1:2007-cv-00516 (D.Del.); *In re Brimonidine Patent Litigation*, No. 1:2007-md-01866 (D.Del.).

25. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

26. United States Patent No. 6,028,222 (“the ’222 patent”), titled “Stable Liquid Paracetamol Compositions, and Method for Preparing the Same,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on February 22, 2000, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the ’222 patent.

27. Pharmatop granted an exclusive license to the '222 patent to Bristol-Myers Squibb Company ("BMS"), with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '222 patent with regard to all rights pertinent hereto. A true and correct copy of the '222 patent is attached as Exhibit A.

28. United States Patent No. 6,992,218 ("the '218 patent"), titled "Method for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles," was duly and legally issued by the PTO on January 31, 2006, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the '218 patent.

29. Pharmatop granted an exclusive license to the '218 patent to BMS, with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '218 patent with regard to all rights pertinent hereto. A true and correct copy of the '218 patent is attached as Exhibit B.

OFIRMEV®

30. Cadence holds approved New Drug Application ("NDA") No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. OFIRMEV® was approved by the Food and Drug Administration (the "FDA") on November 2, 2010. OFIRMEV® is indicated for the treatment of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

31. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21

U.S.C. § 355(b)(1) and attendant FDA regulations, the '222 patent and the '218 patent were listed in the Orange Book with respect to OFIRMEV®.

THE PADDOCK DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

32. Upon information and belief, Paddock submitted Abbreviated New Drug Application (“ANDA”) No. 202605 to the FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials (“Paddock’s Generic Product”), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

33. By a letter dated July 7, 2011 (the “Paddock Letter”), Paddock stated that it had submitted ANDA No. 202605 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Paddock’s Generic Product prior to the expiration of the Patents-in-Suit.

34. The Paddock Letter also stated that ANDA No. 202605 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that alleges the '222 patent and '218 patent are invalid and that Paddock’s Generic Product will not infringe any of the claims of the '218 patent. The Paddock Letter does not state that Paddock’s Generic Product will not infringe any of the claims of the '222 patent.

35. Cadence received notice of ANDA No. 202605 and its section 355(j)(2)(A)(vii)(IV) allegations on or about July 8, 2011. However, neither Pharmatop nor Pharmatop’s representative have received notice from Paddock as required under 21 USC § 355(j)(2)(B)(iii) and 21 CFR 314.52(a).

36. By filing ANDA No. 202605, Paddock has necessarily represented to the FDA that the components of Paddock's Generic Product have the same active ingredient as that of the corresponding components of OFIRMEV[®], have the same route of administration, dosage form, and strengths as the corresponding components of OFIRMEV[®], and are bioequivalent to the corresponding components of OFIRMEV[®].

37. Paddock's submission of ANDA No. 202605 to the FDA, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the Patents-in-Suit under 35 USC § 271(e)(2)(A). Moreover, in the event that the Paddock Defendants commercially manufacture, import, use, offer for sale, or sell Paddock's Generic Product or induce or contribute to such conduct, said actions would constitute infringement of the Patents-in-Suit under 35 USC § 271(a), (b) and/or (c).

38. Perrigo is jointly and severally liable for infringement of the Patents-in-Suit. Upon information and belief, Perrigo participated in, contributed to, aided, abetted and/or induced Paddock's submission of ANDA No. 202605 and its section 355(j)(2)(A)(vii)(IV) allegations to the FDA.

39. Upon information and belief, Perrigo has acquired substantially all of Paddock's assets, and as a result of the acquisition by Perrigo, Perrigo is jointly and severally liable for the infringement of the Patents-in-Suit.

40. The Paddock Defendants were aware of the Patents-in-Suit prior to filing ANDA No. 202605, and its actions render this an exceptional case under 35 U.S.C. § 285.

41. The acts of infringement by the Paddock Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

THE EXELA DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

42. Upon information and belief, Exela Pharma Sciences submitted Abbreviated New Drug Application (“ANDA”) No. 20-3092 to the FDA, under Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials (“Exela’s Generic Product”), as a generic version of the OFIRMEV[®] product, prior to the expiration of the Patents-in-Suit.

43. By a letter dated July 12, 2011 (the “Exela Letter”), Exela Pharma Sciences stated that it had submitted ANDA No. 20-3092 seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of Exela’s Generic Product prior to the expiration of the Patents-in-Suit.

44. The Exela Letter also stated that ANDA No. 20-3092 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that alleges the ’222 patent and ’218 patent are invalid and that Exela’s Generic Product will not infringe any of the claims of the Patents-in-Suit.

45. Cadence received notice of ANDA No. 30-3092 and the section 355(j)(2)(A)(vii)(IV) allegations on or about July 13, 2011. However, neither Pharmatop nor Pharmatop’s representative have received notice from Exela Pharma Sciences, as required under 21 USC § 355(j)(2)(B)(iii) and 21 CFR 314.52(a).

46. By filing ANDA No. 20-3092, Exela Pharma Sciences necessarily represented to the FDA that the components of Exela’s Generic Product have the same active ingredient as that of the corresponding components of OFIRMEV[®], have the same route of

administration, dosage form, and strengths as the corresponding components of OFIRMEV[®], and are bioequivalent to the corresponding components of OFIRMEV[®].

47. Exela Pharma Sciences' submission of ANDA No. 20-3092 to the FDA, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the Patents-in-Suit under 35 USC § 271(e)(2)(A). Moreover, in the event that the Exela Defendants commercially manufacture, import, use, offer for sale, or sell Exela's Generic Product or induce or contribute to such conduct, said actions would constitute infringement of the Patents-in-Suit under 35 USC § 271(a), (b) and/or (c).

48. Exela Holdings and Exela PharmSci are jointly and severally liable for infringement of the Patents-in Suit. Upon information and belief, Exela Holdings and Exela PharmSci participated in, contributed to, aided, abetted and/or induced Exela Pharma Sciences' submission of ANDA No. 20-3092 and its section 355(j)(2)(A)(vii)(IV) allegations to the FDA.

49. The Exela Defendants were aware of the Patents-in-Suit prior to filing ANDA No. 20-3092, and their actions render this an exceptional case under 35 U.S.C. § 285.

50. The acts of infringement by the Exela Defendants set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I

(Infringement of the '222 Patent by the Paddock Defendants)

51. Plaintiffs incorporate each of the preceding paragraphs 1 to 50 as if fully set forth herein.

52. Paddock's submission of ANDA No. 202605, including its § 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by the Paddock Defendants.

53. Upon FDA approval of ANDA No. 202605, the Paddock Defendants will infringe the '222 patent by making, using, offering to sell, or selling Paddock's Generic Product in the United States and/or importing Paddock's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

54. Upon information and belief, the Paddock Defendants had actual and constructive knowledge of the '222 patent prior to filing ANDA No. 202605 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '222 patent.

COUNT II

(Declaratory Judgment of Infringement of the '222 Patent by the Paddock Defendants)

55. Plaintiffs incorporate each of the preceding paragraphs 1 to 54 as if fully set forth herein.

56. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. Plaintiffs are further entitled to a declaration that, if the Paddock Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Paddock's Generic Product within the United States, import Paddock's Generic Product into the United States, or induce or contribute to such conduct, the Paddock Defendants would infringe the '222 patent under 35 U.S.C. § 271(a), (b) and/or (c).

58. Plaintiffs will be irreparably harmed by the Paddock Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III

(Infringement of the '218 Patent by the Paddock Defendants)

59. Plaintiffs incorporate each of the preceding paragraphs 1 to 58 as if fully set forth herein.

60. Paddock's submission of ANDA No. 202605, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by the Paddock Defendants.

61. Upon FDA approval of ANDA No. 202605, the Paddock Defendants will infringe the '218 patent by making, using, offering to sell, or selling Paddock's Generic Product in the United States and/or importing Paddock's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

62. Upon information and belief, the Paddock Defendants had actual and constructive knowledge of the '218 patent prior to filing ANDA No. 202605 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT IV

(Declaratory Judgment of Infringement of the '218 Patent by the Paddock Defendants)

63. Plaintiffs incorporate each of the preceding paragraphs 1 to 62 as if fully set forth herein.

64. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. Plaintiffs are further entitled to a declaration that, if the Paddock Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Paddock's Generic Product within the United States, import Paddock's Generic Product into the

United States, or induce or contribute to such conduct, the Paddock Defendants would infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

66. Plaintiffs will be irreparably harmed by the Paddock Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT V
(Infringement of the '222 Patent by the Exela Defendants)

67. Plaintiffs incorporate each of the preceding paragraphs 1 to 66 as if fully set forth herein.

68. Exela Pharma Sciences' submission of ANDA No. 20-3092, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by the Exela Defendants.

69. Upon FDA approval of ANDA No. 20-3092, the Exela Defendants will infringe the '222 patent by making, using, offering to sell, or selling Exela's Generic Product in the United States and/or importing Exela's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

70. Upon information and belief, the Exela Defendants had actual and constructive knowledge of the '222 patent prior to filing ANDA No. 20-3092 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '222 patent.

COUNT VI

(Declaratory Judgment of Infringement of the '222 Patent by the Exela Defendants)

71. Plaintiffs incorporate each of the preceding paragraphs 1 to 70 as if fully set forth herein.

72. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. Plaintiffs are further entitled to a declaration that, if the Exela Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Exela's Generic Product within the United States, import Exela's Generic Product into the United States, or induce or contribute to such conduct, the Exela Defendants would infringe the '222 patent under 35 U.S.C. § 271(a), (b) and/or (c).

74. Plaintiffs will be irreparably harmed by the Exela Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT VII

(Infringement of the '218 Patent by the Exela Defendants)

75. Plaintiffs incorporate each of the preceding paragraphs 1 to 74 as if fully set forth herein.

76. Exela Pharma Sciences' submission of ANDA No. 20-3092, including the section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by the Exela Defendants.

77. Upon FDA approval of ANDA No. 20-3092, the Exela Defendants will infringe the '218 patent by making, using, offering to sell, or selling Exela's Generic Product in the United States and/or importing Exela's Generic Product into the United States, and by

actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

78. Upon information and belief, the Exela Defendants had actual and constructive knowledge of the '218 patent prior to filing ANDA No. 20-3092 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '218 patent.

COUNT VIII

(Declaratory Judgment Of Infringement of the '218 Patent by the Exela Defendants)

79. Plaintiffs incorporate each of the preceding paragraphs 1 to 78 as if fully set forth herein.

80. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

81. Plaintiffs are further entitled to a declaration that, if the Exela Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Exela's Generic Product within the United States, import Exela's Generic Product into the United States, or induce or contribute to such conduct, the Exela Defendants would infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

82. Plaintiffs will be irreparably harmed by the Exela Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that all Defendants have infringed each of the Patents-In-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of the Paddock Defendants' ANDA No. 202605 and/or the Exela Defendants' ANDA No. 20-3092 shall not be earlier than the expiration dates of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

C. A preliminary and permanent injunction restraining and enjoining the Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of any of Paddock's Generic Product or Exela's Generic Product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

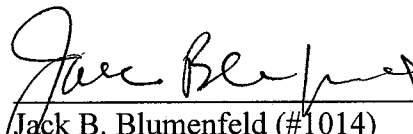
D. That Plaintiffs be awarded monetary relief if the Defendants commercially manufacture, use, offer for sale, or sell their respective generic versions of Cadence's OFIRMEV[®] brand product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the United States before the latest expiration date of any of the Patents-In-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

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