UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, Plaintiff, v. DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., Defendants.	)	**CA No. _____**

COMPLAINT

Plaintiff Fresenius Kabi USA, LLC ("Fresenius Kabi"), by its undersigned attorneys, for its complaint against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the submission of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a generic version of levothyroxine sodium powder for injection prior to the expiration of U.S. Patent Nos. 9,006,289 ("the '289 Patent"), 9,168,238 ("the '238 Patent") and 9,168,239 ("the '239 Patent").

THE PARTIES

2. Plaintiff Fresenius Kabi is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the state of New Jersey, having its corporate headquarters at 107 College Road East, Princeton, NJ 08540. On information and belief, Dr. Reddy's Laboratories, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Dr. Reddy's Laboratories, Inc. also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the FDA.

4. On information and belief, Dr. Reddy's Laboratories, Ltd. is an Indian corporation organized and existing under the laws of India, having its corporate headquarters at 8-2-337, Road No. 3, Banjara Hills, Hyderabad – 500034, Andhra Pradesh, India. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of manufacturing and/or distributing numerous generic drugs for sale and use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically.

6. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. is proper because, upon information and belief, each directly, or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. has each committed, aided, abetted, induced, contributed to, and/or

participated in the commission of, a tortious act of patent infringement directly, or through its affiliates and agents, that has led to foreseeable harm and injury to Plaintiff in Delaware. Upon information and belief, Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd, through Dr. Reddy's Laboratories, Ltd., has purposefully conducted and continues to conduct business in Delaware, and, as a result, Delaware is a likely destination of Dr. Reddy's Laboratories, Inc.'s and Dr. Reddy's Laboratories, Ltd.'s generic products.

8. Upon information and belief, personal jurisdiction is also proper over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because they have purposely availed themselves of the rights and benefits of the laws of the State of Delaware, having repeatedly and purposely availed themselves of this forum by filing counterclaims in this jurisdiction for at least the past several years (*see e.g.*, Civil Action Nos. 15-1067, 15-1026, 15-988, 15-670, 14-1241, 14-1171, 14-778, 14-334, 13-2082, 13-1780, 13-1506, 13-989, 13-925), and by filing at least one complaint in this jurisdiction (s*ee e.g., Dr. Reddy's Laboratories, Inc. et al., v. Fresenius Kabi USA, LLC*, Civil Action No. 15-714).

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

THE PATENTS-IN-SUIT

10. The '289 Patent, entitled "Levothyroxine Formulations," was duly and legally issued on April 14, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '289 Patent is attached hereto as Exhibit A.

11. The '238 Patent, entitled "Levothyroxine Formulations," was duly and legally issued on October 27, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '238 Patent is attached hereto as Exhibit B.

12. The ’239 Patent, entitled “Levothyroxine Formulations,” was duly and legally issued on October 27, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the ’239 Patent is attached hereto as Exhibit C.

13. Plaintiff Fresenius Kabi is the assignee and lawfully owns all rights, title, and interest in the ’289 Patent, the ’238 Patent, and the ’239 Patent (“the patents-in-suit”), including the right to sue and to recover for past infringement thereof.

14. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”).

15. Fresenius Kabi is the holder of New Drug Application (“NDA”) No. 202231 for Levothyroxine Sodium, which the FDA approved on June 24, 2011. In accordance with 21 U.S.C. § 355(b)(1), the ’289 Patent, the ’238 Patent, and the ’239 Patent are each listed in the Orange Book in connection with approved NDA No. 202231, as patents “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale” of Fresenius Kabi’s NDA drug product.

16. Fresenius Kabi currently sells in the United States Levothyroxine Sodium. According to the Orange Book, the ’289 Patent is currently not due to expire until October 3, 2032; the ’238 Patent is currently not due to expire until August 29, 2032; and the ’239 Patent is also currently not due to expire until August 29, 2032.

DRL’S ANDA NO. 208837

17. On information and belief, DRL submitted ANDA No. 208837 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of generic 100 mcg/vial levothyroxine sodium for injection (the “ANDA Product”).

18. On information and belief, ANDA No. 208837 contains a Paragraph IV certification that the ’289 Patent, the ’238 Patent, and the ’239 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by DRL’s ANDA No. 208837.

19. On information and belief, DRL is the owner of ANDA No. 208837.

20. On information and belief, if ANDA No. 208837 is approved by the FDA before the expiration of the ’289 Patent, the ’238 Patent, and/or the ’239 Patent, DRL will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA Product, despite the patents.

21. On information and belief, if ANDA No. 208837 is approved by the FDA, DRL will begin marketing the ANDA Product for treatment of myxedema coma, and doctors and patients will use the ANDA Product for the indications marketed by DRL.

22. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, the ANDA Product’s dosage strength must have the same strength as one of the approved dosages for Fresenius Kabi’s NDA levothyroxine sodium products (“the NDA products”). In addition, the ANDA Product must be bioequivalent to the NDA products.

23. Fresenius Kabi received a letter (“the Notice Letter”), purporting to be a Notice of Certification for ANDA No. 208837 under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), and 21 CFR § 314.95(c). The Paragraph IV certifications alleged that the claims of the ’289 Patent, the ’238 Patent, and the ’239 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

24. On information and belief, ANDA No. 208837 seeks approval of a generic levothyroxine product that is the same, or substantially the same, as Fresenius Kabi's commercially marketed and approved Levothyroxine Sodium product.

25. On information and belief, DRL was aware of the '289 Patent, the '238 Patent, and the '239 Patent when ANDA No. 208837 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning the patents-in-suit.

COUNT I: INFRINGEMENT OF THE '289 PATENT – ANDA SUBMISSION

26. Fresenius Kabi incorporates and realleges paragraphs 1-25 above.

27. The submission of ANDA No. 208837, including a Paragraph IV certification regarding the '289 Patent, was an act of infringement by DRL of one or more claims of the '289 Patent under 35 U.S.C. § 271(e)(2).

28. On information and belief, the use of the ANDA Product in accordance with and as directed by the instructions contained in the proposed package insert of DRL's ANDA No. 208837 is covered by one or more claims of the '289 Patent.

29. On information and belief, DRL's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Product before the expiration of the '289 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '289 Patent.

30. On information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling will infringe one or more claims of the '289 Patent.

31. On information and belief, by seeking approval to distribute the ANDA Product with their proposed labeling, DRL intends to cause others, specifically, for example, medical professionals and patients, to perform acts that DRL knows will infringe one or more claims of the '289 Patent.

32. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, actively induce infringement of one or more claims of the ’289 Patent immediately following approval of ANDA No. 208837.

33. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, contribute to the infringement of one or more claims of the ’289 Patent immediately following approval of ANDA No. 208837.

34. On information and belief, DRL knows that its ANDA No. 208837 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’289 Patent, and that the DRL ANDA Product and their proposed labeling are not suitable for any noninfringing use.

35. On information and belief, DRL’s actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 208837 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’289 patent.

36. On information and belief, DRL has been aware of the existence of the ’289 Patent since before the submission of ANDA No. 208837.

37. On information and belief, DRL has no reasonable basis for believing that its ANDA Product will not infringe one or more valid claims of the ’289 Patent and no reasonable basis for believing that the infringed claims are invalid. DRL posited no theory of non-infringement in its Notice Letter concerning the ’289 Patent.

38. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

39. On information and belief, unless enjoined by this Court, DRL plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation

of the ANDA Product with their proposed labeling immediately following approval of ANDA No. 208837 and before the expiration of the ’289 Patent.

40. The acts of infringement by DRL set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

41. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for DRL’s ANDA No. 208837 to be a date which is not any earlier than the expiration date of the ’289 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE ’289 PATENT – DECLARATORY JUDGMENT

42. Fresenius Kabi incorporates and realleges paragraphs 1-41 above.

43. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

44. There is an actual case or controversy such that the Court may entertain Fresenius Kabi’s 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.

45. DRL has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL’s generic levothyroxine sodium product before the expiration of the ’289 patent, including DRL’s filing of ANDA No. 208837.

46. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s generic levothyroxine sodium product by DRL will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’289 patent.

47. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and DRL as to liability for the infringement of the ’289 patent claims. DRL’s actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from DRL’s threatened imminent actions.

48. Fresenius Kabi is entitled to declaratory judgment that DRL’s future commercial manufacture, use, offer for sale, sale, and/or import of DRL’s generic levothyroxine sodium product will constitute infringement of one or more claims of the ’289 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

COUNT III: INFRINGEMENT OF THE ’238 PATENT – ANDA SUBMISSION

49. Fresenius Kabi incorporates and realleges paragraphs 1-48 above.

50. The submission of ANDA No. 208837 including a Paragraph IV certification regarding the ’238 Patent was an act of infringement by DRL of one or more claims of the ’238 Patent under 35 U.S.C. § 271(e)(2).

51. On information and belief, the use of ANDA Product in accordance with and as directed by the instructions contained in the proposed package insert of DRL’s ANDA No. 208837 is covered by one or more claims of the ’238 Patent.

52. On information and belief, DRL’s commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Product before the expiration of the ’238 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’238 Patent.

53. On information and belief, the use of DRL’s ANDA Product in accordance with and as directed by DRL’s proposed labeling will infringe one or more claims of the ’238 Patent.

54. On information and belief, by seeking approval to distribute the ANDA Product with their proposed labeling, DRL intends to cause others, specifically, for example, medical

professionals and patients, to perform acts that DRL knows will infringe one or more claims of the ’238 Patent.

55. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, actively induce infringement of one or more claims of the ’238 Patent immediately following approval of ANDA No. 208837.

56. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, contribute to the infringement of one or more claims of the ’238 Patent immediately following approval of ANDA No. 208837.

57. On information and belief, DRL knows that its ANDA No. 208837 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’238 Patent, and that the DRL ANDA Product and their proposed labeling are not suitable for any noninfringing use.

58. On information and belief, DRL’s actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 208837 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’238 patent.

59. On information and belief, DRL has been aware of the existence of the’238 Patent since before the submission of ANDA No. 208837.

60. On information and belief, DRL has no reasonable basis for believing that its ANDA Product will not infringe one or more valid claims of the ’238 Patent and no reasonable basis for believing that the infringed claims are invalid. DRL posited no theory of non-infringement in its Notice Letter concerning the ’238 Patent.

61. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

62. On information and belief, unless enjoined by this Court, DRL plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product with their proposed labeling immediately following approval of ANDA No. 208837 and before the expiration of the ’238 Patent.

63. The acts of infringement by DRL set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

64. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for DRL’s ANDA No. 208837 to be a date which is not any earlier than the expiration date of the ’238 Patent, including any extensions of that date.

COUNT IV: INFRINGEMENT OF THE ’238 PATENT – DECLARATORY JUDGMENT

65. Fresenius Kabi incorporates and realleges paragraphs 1-64 above.

66. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

67. There is an actual case or controversy such that the Court may entertain Fresenius Kabi’s 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.

68. DRL has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL’s generic levothyroxine sodium product before the expiration of the ’238 patent, including DRL’s filing of ANDA No. 208837.

69. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s generic levothyroxine sodium product by DRL will directly

infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’238 patent.

70. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and DRL as to liability for the infringement of the ’238 patent claims. DRL’s actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from DRL’s threatened imminent actions.

71. Fresenius Kabi is entitled to declaratory judgment that DRL’s future commercial manufacture, use, offer for sale, sale, and/or import of DRL’s generic levothyroxine sodium product will constitute infringement of one or more claims of the ’238 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

COUNT V: INFRINGEMENT OF THE ’239 PATENT – ANDA SUBMISSION

72. Fresenius Kabi incorporates and realleges paragraphs 1-71 above.

73. The submission of ANDA No. 208837 including a Paragraph IV certification regarding the ’239 Patent was an act of infringement by DRL of one or more claims of the ’239 Patent under 35 U.S.C. § 271(e)(2).

74. On information and belief, the use of ANDA Product in accordance with and as directed by the instructions contained in the proposed package insert of DRL’s ANDA No. 208837 is covered by one or more claims of the ’239 Patent.

75. On information and belief, DRL’s commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Product before the expiration of the ’239 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’239 Patent.

76. On information and belief, the use of DRL’s ANDA Product in accordance with and as directed by DRL’s proposed labeling will infringe one or more claims of the ’239 Patent.

77. On information and belief, by seeking approval to distribute the ANDA Product with their proposed labeling, DRL intends to cause others, specifically, for example, medical professionals and patients, to perform acts that DRL knows will infringe one or more claims of the ’239 Patent.

78. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, actively induce infringement of one or more claims of the ’239 Patent immediately following approval of ANDA No. 208837.

79. On information and belief, unless enjoined by this Court, DRL plans and intends to, and will, contribute to the infringement of one or more claims of the ’239 Patent immediately following approval of ANDA No. 208837.

80. On information and belief, DRL knows that its ANDA No. 208837 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’239 Patent, and that the DRL ANDA Product and their proposed labeling are not suitable for any noninfringing use.

81. On information and belief, DRL’s actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 208837 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’239 patent.

82. On information and belief, DRL has been aware of the existence of the’239 Patent since before the submission of ANDA No. 208837.

83. On information and belief, DRL has no reasonable basis for believing that its ANDA Product will not infringe one or more valid claims of the ’239 Patent and no reasonable

basis for believing that the infringed claims are invalid. DRL posited no theory of non-infringement in its Notice Letter concerning the '239 Patent.

84. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

85. On information and belief, unless enjoined by this Court, DRL plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product with their proposed labeling immediately following approval of ANDA No. 208837 and before the expiration of the '239 Patent.

86. The acts of infringement by DRL set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

87. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for DRL's ANDA No. 208837 to be a date which is not any earlier than the expiration date of the '239 Patent, including any extensions of that date.

COUNT VI: INFRINGEMENT OF THE '239 PATENT – DECLARATORY JUDGMENT

88. Fresenius Kabi incorporates and realleges paragraphs 1-87 above.

89. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. There is an actual case or controversy such that the Court may entertain Fresenius Kabi's 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.

91. DRL has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import DRL's generic levothyroxine sodium product before the expiration of the '239 patent, including DRL's filing of ANDA No. 208837.

92. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of DRL's generic levothyroxine sodium product by DRL will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '239 patent.

93. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and DRL as to liability for the infringement of the '239 patent claims. DRL's actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from DRL's threatened imminent actions.

94. Fresenius Kabi is entitled to declaratory judgment that DRL's future commercial manufacture, use, offer for sale, sale, and/or import of DRL's generic levothyroxine sodium product will constitute infringement of one or more claims of the '239 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

RELIEF SOUGHT

WHEREFORE, Fresenius Kabi respectfully requests the following relief:

A. Judgment in favor of Fresenius Kabi and against DRL;

B. Judgment that DRL has infringed, literally or by the doctrine of equivalents, each of the '289 Patent, the '238 Patent, and the '239 Patent by the submission of ANDA No. 208837, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA Product, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of each of the '289 Patent, the '238 Patent, and the '239 Patent;

C. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A) and other provisions of 35 U.S.C. § 271, that the effective date of approval of ANDA No. 207670 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the

latest date of expiration of the ’289 Patent, the ’238 Patent, or the ’239 Patent, plus any additional periods of exclusivity;

D. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271 and 283 and Federal Rule of Civil Procedure 65, enjoining DRL, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA Product, and any product that is similar to or only colorably different from those products, before the latest date of expiration of any of the ’289 Patent, the ’238 Patent, and the ’239 Patent, and any additional periods of exclusivity;

E. A declaration that this is an exceptional case and an award to Fresenius Kabi of its reasonable attorneys’ fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

F. Damages or other monetary relief, including prejudgment interest, if DRL engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA Product, or any other products that the use of which would infringe the ’289 Patent, the ’238 Patent, and/or the ’239 Patent, or the inducement of or contribution to the foregoing, prior to the expiration of the ’289 Patent, the ’238 Patent, and the ’239 Patent;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Fresenius Kabi’s taxable costs in bringing and prosecuting this action; and

I. Such other and further relief to Fresenius Kabi as this Court may deem just and proper.

Dated: March 17, 2016

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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