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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BIOMARIN PHARMACEUTICAL INC. and MERCK & CIE,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs BioMarin Pharmaceutical Inc. ("BioMarin") and Merck & Cie ("Merck") (collectively, "Plaintiffs"), by their undersigned attorneys, for their complaint against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from DRL's filing of a purported Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market a generic version of the pharmaceutical drug product Kuvan® prior to the expiration of U.S. Patent Nos. 7,566,462 ("the '462 patent"), 7,566,714 ("the '714 patent"), 7,612,073 ("the '073 patent"), 8,003,126 ("the '126 patent"), 8,067,416 ("the '416 patent"), RE43,797 ("the '797 patent"), and 8,318,745 ("the '745 patent") (collectively, the "patents-in-suit").

THE PARTIES

2. Plaintiff BioMarin is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 770 Lindaro Street, San Rafael, California 94901.

3. Plaintiff Merck is a Swiss corporation having a principal place of business at Weisshausmatte, 6469 Altdorf, Switzerland.

4. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a corporation incorporated under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products, which it distributes in New Jersey and throughout the United States.

5. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is a company organized under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India. Upon information and belief, Dr. Reddy's

Laboratories, Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in New Jersey and throughout the United States through at least Dr. Reddy's Laboratories, Inc.

6. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

7. Upon information and belief, Dr. Reddy's Laboratories, Inc. is the exclusive agent in North America for Dr. Reddy's Laboratories, Ltd.

JURISDICTION AND VENUE

8. Subject matter jurisdiction over this action is premised on 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over DRL by virtue of, *inter alia*, DRL having a presence in New Jersey, DRL having conducted business in New Jersey, DRL having availed itself of the rights and benefits of New Jersey law, DRL purposefully availing itself of the privilege of conducting business in New Jersey, DRL having previously consented to personal jurisdiction in this Court, and DRL having engaged in systematic and continuous contacts with the State of New Jersey.

10. DRL has stipulated and/or consented to personal jurisdiction before this Court in other patent cases including: *Janssen Pharmaceutica N.V. v. Dr. Reddy's Labs., Ltd.*, 03-6185 D.N.J. (JWB); *Teva Pharm. Indus. v. Dr. Reddy's Labs., Ltd.*, 07-2894 D.N.J. (GEB) (JJH); *Hoffmann La Roche Inc. v. Dr. Reddy's Labs., Ltd.*, 07-4516 D.N.J. (SRC) (CCC); *Astrazeneca UK Ltd. v. Dr. Reddy's Labs., Ltd.*, 08-3237 D.N.J. (MLC) (TJB); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, 09-4638 D.N.J. (JAG) (MCA); *The Meds. Co. v. Dr. Reddy's Labs., Ltd.*, 11-2456 D.N.J. (PGS) (DEA); *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, 12-2867 D.N.J. (MLC) (DEA); and *Astrazeneca AB v. Dr. Reddy's Labs., Ltd.*, 13-91 D.N.J.

(JAP) (TJB). Furthermore, DRL asserted counterclaims in a majority of these cases, thus availing itself of the benefits and protections of the laws of New Jersey and its court system.

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

THE PATENTS-IN-SUIT

12. On July 28, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '462 patent, entitled "Stable Tablet Formulation," to BioMarin as assignee of the inventors Steven Jungles, Mark A. Henderson, Victoria Sluzky, and Robert Baffi. A copy of the '462 patent is attached hereto as Exhibit A.

13. BioMarin is the owner of all right, title, and interest in the '462 patent.

14. On July 28, 2009, the USPTO duly and lawfully issued the '714 patent, entitled "Methods and Compositions for the Treatment of Metabolic Disorders," to BioMarin and Merck Eprova AG as assignees of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Merck Eprova AG subsequently assigned all of its interest in the '714 patent to BioMarin. A copy of the '714 patent is attached hereto as Exhibit B.

15. BioMarin is the owner of all right, title, and interest in the '714 patent.

16. On November 3, 2009, the USPTO duly and lawfully issued the '073 patent, entitled "Methods of Administering Tetrahydrobiopterin, Associated Compositions, and Methods of Measuring," to BioMarin as assignee of inventors Daniel I. Oppenheimer and Alejandro Dorenbaum. A copy of the '073 patent is attached hereto as Exhibit C.

17. BioMarin is the owner of all right, title, and interest in the '073 patent.

18. On August 23, 2011, the USPTO duly and lawfully issued the '126 patent, entitled "Stable Table Formulation," to BioMarin as assignee of inventors Steven Jungles, Mark

Henderson, Victoria Sluzky, and Robert Baffi. A copy of the '126 patent is attached hereto as Exhibit D.

19. BioMarin is the owner of all right, title, and interest in the '126 patent.

20. On November 29, 2011, the USPTO duly and lawfully issued the '416 patent, entitled "Methods and Compositions for the Treatment of Metabolic Disorders," to BioMarin and Merck Eprova AG as assignees of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Merck Eprova AG subsequently assigned all of its interest in the '416 patent to BioMarin. A copy of the '416 patent is attached hereto as Exhibit E.

21. BioMarin is the owner of all right, title, and interest in the '416 patent.

22. On November 6, 2012, the USPTO duly and lawfully issued the '797 patent, entitled "Methods of Administering Tetrahydrobiopterin," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Alejandro Dorenbaum, and Augustus O. Okhamafe. The '797 patent is a reissue of U.S. Patent No. 7,947,681. A copy of the '797 patent is attached hereto as Exhibit F.

23. BioMarin is the owner of all right, title, and interest in the '797 patent.

24. On November 27, 2012, the USPTO duly and lawfully issued the '745 patent, entitled "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride," to Merck Eprova AG as assignee of inventors Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Subsequently, Merck Eprova AG assigned the '745 patent to Merck & Cie KG, which then changed its name to Merck & Cie. A copy of the '745 patent is attached hereto as Exhibit G.

25. Merck is the owner of all right, title, and interest in the '745 patent. BioMarin is the exclusive licensee of the '745 patent.

The Kuvan® Drug Product

26. BioMarin holds approved New Drug Application ("NDA") No. 022181 for oral tablets containing 100 mg of sapropterin dihydrochloride, sold under the trade name Kuvan®.

27. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Kuvan®.

DRL's FDA Submission

28. Upon information and belief, DRL submitted to the FDA documentation purporting to constitute an ANDA pursuant to 12 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Kuvan® in the form of oral tablets containing 100 mg of sapropterin dihydrochloride ("DRL's Generic Product"), prior to the expiration of the '462, '714, '073, '126, '416, '797, and '745 patents.

29. DRL's purported ANDA relies upon the Kuvan® NDA and, according to DRL, contains the required data with respect to the bioavailability or bioequivalence of DRL's Generic Product to Kuvan®.

30. BioMarin and Merck received letters from DRL, dated October 3, 2014, with attached memoranda (collectively, "DRL's Notification"), stating that DRL included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's Generic Product (the "Paragraph IV certification"). Thus, DRL is seeking approval of its proposed Generic Product prior to the expiration of the patents-in-suit. Plaintiffs are filing this complaint within the 45-day interval from receipt of DRL's

Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of DRL's purported ANDA and Paragraph IV certification.

COUNT ONE: INFRINGEMENT OF THE '462 PATENT

31. Plaintiffs repeat and reallege the allegations of paragraphs 1–30 as though fully set forth herein.

32. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '462 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

33. Unless enjoined by this Court, upon FDA approval, DRL will infringe the '462 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling DRL's Generic Product in the United States.

34. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '462 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '462 patent and knowledge that its acts are encouraging infringement.

35. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '462 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '462 patent and that there is no substantial non-infringing use for DRL's Generic Product.

36. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '462 patent, warrant a finding that this case is an

exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

37. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '462 patent is not enjoined.

38. Plaintiffs do not have an adequate remedy at law.

COUNT TWO: INFRINGEMENT OF THE '714 PATENT

39. Plaintiffs repeat and reallege the allegations of paragraphs 1–38 as though fully set forth herein.

40. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '714 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

41. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '714 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '714 patent and knowledge that its acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '714 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '714 patent and that there is no substantial non-infringing use for DRL's Generic Product.

43. DRL does not contest infringement of claims 1-28 and 43-46 of the '714 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1-28 and 43-46 of the '714 patent, it was required by applicable regulations to state such basis in

DRL's Notification. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

44. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '714 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

45. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '714 patent is not enjoined.

46. Plaintiffs do not have an adequate remedy at law.

COUNT THREE: INFRINGEMENT OF THE '073 PATENT

47. Plaintiffs repeat and reallege the allegations of paragraphs 1–46 as though fully set forth herein.

48. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '073 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

49. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '073 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '073 patent and knowledge that its acts are encouraging infringement.

50. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '073 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had

and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '073 patent and that there is no substantial non-infringing use for DRL's Generic Product.

51. DRL does not contest infringement of claims 1, 2, 5, 6, and 8 of the '073 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1, 2, 5, 6, and 8 of the '073 patent, it was required by applicable regulations to state such basis in DRL's Notification. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

52. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '073 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

53. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '073 patent is not enjoined.

54. Plaintiffs do not have an adequate remedy at law.

COUNT FOUR: INFRINGEMENT OF THE '126 PATENT

55. Plaintiffs repeat and reallege the allegations of paragraphs 1–54 as though fully set forth herein.

56. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '126 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. Unless enjoined by this Court, upon FDA approval, DRL will infringe the '126 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling DRL's Generic Product in the United States.

58. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '126 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '126 patent and knowledge that its acts are encouraging infringement.

59. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '126 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '126 patent and that there is no substantial non-infringing use for DRL's Generic Product.

60. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '126 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

61. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '126 patent is not enjoined.

62. Plaintiffs do not have an adequate remedy at law.

COUNT FIVE: INFRINGEMENT OF THE '416 PATENT

63. Plaintiffs repeat and reallege the allegations of paragraphs 1–62 as though fully set forth herein.

64. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin

dihydrochloride prior to the expiration of the '416 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

65. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '416 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '416 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '416 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '416 patent and that there is no substantial non-infringing use for DRL's Generic Product.

67. DRL does not contest infringement of any claim of the '416 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of any claim of the '416 patent, it was required by applicable regulations to state such basis in DRL's Notification. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

68. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '416 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

69. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '416 patent is not enjoined.

70. Plaintiffs do not have an adequate remedy at law.

COUNT SIX: INFRINGEMENT OF THE '797 PATENT

71. Plaintiffs repeat and reallege the allegations of paragraphs 1–70 as though fully set forth herein.

72. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '797 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

73. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '797 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '797 patent and knowledge that its acts are encouraging infringement.

74. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '797 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '797 patent and that there is no substantial non-infringing use for DRL's Generic Product.

75. DRL does not contest infringement of claims 1, 3-8, 10-14, and 18-27 of the '797 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1, 3-8, 10-14, and 18-27 of the '797 patent, it was required by applicable regulations to state such basis in DRL's Notification. *See* 21 CFR 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or

invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

76. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '797 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

77. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '797 patent is not enjoined.

78. Plaintiffs do not have an adequate remedy at law.

COUNT SEVEN: INFRINGEMENT OF THE '745 PATENT

79. Plaintiffs repeat and reallege the allegations of paragraphs 1–78 as though fully set forth herein.

80. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '745 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

81. Unless enjoined by this Court, upon FDA approval, DRL will infringe the '745 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling DRL's Generic Product in the United States.

82. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '745 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '745 patent and knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '745 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '745 patent and that there is no substantial non-infringing use for DRL's Generic Product.

84. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '745 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

85. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '745 patent is not enjoined

86. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs BioMarin and Merck pray for a Judgment in their favor and against DRL, and respectfully request the following relief:

A. A Judgment be entered that DRL has infringed the '462, '714, '073, '126, '416, '797, and '745 patents;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining DRL, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering to sell, or selling DRL's Generic Product within the United States, or importing DRL's Generic Product into the United States, prior to the expiration of the patents-in-suit;

C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207685 under§ 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the patents-in-suit, including any extensions;

D. If DRL commercially manufactures, uses, offers to sell, or sells DRL's Generic Product within the United States, or imports DRL's Generic Product into the United States, prior to the expiration of the patents-in-suit including, any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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

Dated: November 17, 2014

By: s/ Charles M. Lizza

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