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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MONOSOL RX, LLC,

Plaintiff,

Civ. No. 10-cv-5695 FLW-DEA

v.

BIODELIVERY SCIENCES
INTERNATIONAL, INC., MEDA
PHARMACEUTICAL INC., and AVEVA
DRUG DELIVERY SYSTEMS, INC.,

Defendants.

MONOSOL RX, LLC'S SECOND AMENDED COMPLAINT

Plaintiff MonoSol Rx, LLC, by its attorneys, hereby alleges as follows:

PARTIES

1. Plaintiff MonoSol Rx, LLC ("MonoSol") is a limited liability company organized and existing under the laws of the State of New Jersey, with its principal place of business at 30 Technology Drive, Warren, New Jersey 07059. MonoSol specializes in the development and commercialization of film pharmaceutical and over-the-counter drug products.

2. Defendant BioDelivery Sciences International, Inc. ("BDSI") is a corporation organized and existing under the laws of the State of North Carolina, with its principal place of business at 801 Corporate Center Drive, Suite 210, Raleigh, North

Carolina 27607.

3. Defendant MEDA Pharmaceuticals Inc. (“MEDA”) is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 265 Davidson Ave., Suite 300, Somerset, New Jersey 08873.

4. Defendant Aveva Drug Delivery Systems, Inc. (“Aveva”) is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 3250 Commerce Parkway, Miramar, Florida 33025.

NATURE OF THE ACTION

5. This is an action for the infringement of United States Patent Nos. 7,357,891 (“the ‘891 patent”); 7,425,292 (“the ‘292 patent”); and 7,824,588 (“the ‘588 patent”) and for false patent marking arising under the patent laws of the United States, specifically under 35 U.S.C. § 292.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States (35 U.S.C. §§ 1 et seq.). This court has jurisdiction over the subject-matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), as well as 35 U.S.C. § 292.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

8. BDSI is subject to personal jurisdiction in New Jersey because BDSI has purposely availed itself of the privileges of conducting business there by reaching out and transacting business with MEDA, a New Jersey corporation, in connection with the allegations in this Second Amended Complaint. For instance, BDSI has licensed the marketing of Onsolis™ film products to MEDA.

9. MEDA is subject to personal jurisdiction in New Jersey because MEDA is a New Jersey corporation. In addition, MEDA has purposely availed itself of the privileges of conducting business in New Jersey by directing activities there in connection with the allegations in this Complaint. For instance, MEDA has directed the manufacture, sale, and distribution of the accused Onsolis™ film products from New

Jersey.

10. Aveva is subject to personal jurisdiction in New Jersey because Aveva has purposely availed itself of the privileges of conducting business there by reaching out and transacting business with MEDA, a New Jersey corporation, in connection with the allegations in this Complaint. For instance, Aveva has manufactured Onsolis™ film products at the direction of MEDA.

THE PATENTS IN SUIT

11. On April 15, 2008, the '891 patent entitled "Process for Making an Ingestible Film" was duly and legally issued to inventors Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz, and assigned to MonoSol.

12. MonoSol owns all rights, title, and interest to the '891 patent, including the right to sue and to recover for any current or past infringement of that patent. A copy of the '891 patent is attached as Exhibit A.

13. On September 16, 2008, the '292 patent entitled "Non-Self-Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom" was duly and legally issued to inventors Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz, and assigned to MonoSol.

14. MonoSol owns all rights, title, and interest to the '292 patent, including the right to sue and to recover for any current or past infringement of that patent. A copy of the '292 patent is attached as Exhibit B.

15. On November 2, 2010, the '588 patent entitled "Method of Making Self-Supporting Therapeutic Active-Containing Film" was duly and legally issued to inventors Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz, and assigned to MonoSol.

16. MonoSol owns all rights, title, and interest to the '588 patent, including the right to sue and to recover for any current or past infringement of that patent. A copy of the '588 patent is attached as Exhibit C.

ACTS GIVING RISE TO INFRINGEMENT

17. BDSI, MEDA, and Aveva (collectively, “Defendants”) make, use, offer to sell, and/or sell certain pharmaceutical films under the Onsolis™ name. The accused Onsolis™ film products are manufactured in a manner that infringes one or more claims of the ‘292, ‘891 and ‘588 patents.

18. Aveva manufactures the Onsolis™ film products, and MEDA markets the Onsolis™ film products, both under license from BDSI. The Onsolis™ film products are sold to distributors, retailers, and/or customers who resell and/or use the Onsolis™ film products throughout the United States, including in the State of New Jersey.

19. Defendants do not have a license or other authority to practice the inventions claimed in the patents asserted herein.

FALSE MARKING

20. U.S. Patent No. 5,800,832 (“the ‘832 patent”) is entitled “Bioerodable Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces.” The ‘832 patent issued on September 1, 1998. A copy of the ‘832 patent is attached as Exhibit D.

21. Claim 1, the sole claim of the ‘832 patent, requires that the film contain a chemical called dyclonine hydrochloride (*See* Exhibit D, claim 1 (“... and said pharmaceutical or combination of pharmaceuticals comprises dyclonine HCl.”)). Dyclonine hydrochloride is known as an anesthetic.

22. BDSI, MEDA, and Aveva have marked and continue to mark Onsolis™ film products with the ‘832 patent. A copy of the published prescribing information (section 17.3) for Onsolis™ is attached as Exhibit E.

23. Onsolis™ film products have been on sale since October 2009. *See* Ex. F, BioDelivery Sciences International, Inc., Form 10-Q, at 16 (Nov. 3, 2009) (“[I]n October 2009, MEDA achieved the first commercial sale of ONSOLIS in the United States.”).

24. By marking Onsolis™ film products with the ‘832 patent, BDSI, MEDA, and Aveva intend recipients of Onsolis™ film products to believe that Onsolis™ is covered by the ‘832 patent.

25. However, Onsolis™ is not covered by the ‘832 patent. Specifically, according to the published prescribing information, Onsolis™ film products do not contain dyclonine hydrochloride. (*See* Exhibit F, at 11 (“Active ingredient” and “inactive ingredients”).)

26. BDSI, MEDA, and Aveva have purposely and knowingly falsely marked the Onsolis™ film products with the ‘832 patent for the purpose of deceiving the public. For example, Defendants were involved in the development of Onsolis™ film products and knew exactly what chemical compounds (active or inactive) are in such products and in what amounts. Defendants were thus fully aware that Onsolis™ film products do not contain dyclonine hydrochloride and do not embody the single claim of the ‘832 patent.

27. Defendants’ deceptive intent is also demonstrated by a pattern of falsely stating, when perceived to be advantageous to obtain regulatory approval or to promote the sale of Onsolis™ film products, that the Onsolis™ film products are patented. (*See* Exhibit G, Press Release, MEDA A.B., MEDA Acquires World-Wide Right to Onsolis (Jan. 5, 2009) (“The product [Onsolis] is unique, **patented** and fills an important medical need.”); Exhibit H., Press Release, MEDA A.B., Onsolis Receives FDA Approval (July 17, 2009).) (“This new and **patented** product is indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying cancer pain.”); Exhibit I, 2009 Annual Report, MEDA A.B., at 31 (“Onsolis (fentanyl) is a new **patented** drug that is designed to treat breakthrough pain in patients with cancer.”) (emphasis added)).

28. The false marking statute, 35 U.S.C. § 292, was recently amended (the Leahy-Smith America Invents Act, Pub. L. 112-29, § 16, enacted on September 16, 2011 (“the Act”). The Act amended § 292(b) to read as follows: “A person who has suffered a competitive injury as a result of a violation of this section may file a civil action in a district court of the United States for recovery of damages adequate to compensate for the injury.”

29. MonoSol competes with BDSI, MEDA, and Aveva in the pharmaceutical film product industry.

30. BDSI has publicly identified MonoSol as “developing potentially

competitive thin-film technologies” to their products. *See* Exhibit J, Annual Report for the Fiscal Year Ended December 31, 2010, BioDelivery Sciences International, Inc., at 15.

31. By marketing and selling Onsolis™ with the ‘832 patent, the Defendants have falsely created an impression that Onsolis™ is the product of patented technology (when it is not) and thereby caused competitive harm to MonoSol and its film technology.

CAUSES OF ACTION

COUNT I INFRINGEMENT OF THE ‘891 PATENT (All Defendants)

32. MonoSol incorporates each of the preceding paragraphs 1-31 as if fully set forth herein.

33. MEDA and Aveva have been, and currently are, directly infringing one or more claims of the ‘891 patent, in violation of 35 U.S.C. § 271, by making, using, offering to sell, and/or selling the Onsolis™ film products.

34. MEDA and Aveva have had constructive notice of the ‘891 patent pursuant to 35 U.S.C. § 287(a).

35. As a result of MEDA and Aveva’s infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless MEDA and Aveva are permanently enjoined by this Court from infringing the claims of the ‘891 patent.

36. As a result of MEDA and Aveva’s infringement of one or more claims of the ‘891 patent, MonoSol has suffered damages.

37. BDSI has been, and currently is, inducing the infringement of one or more claims of the ‘891 patent, in violation of 35 U.S.C. § 271.

38. BDSI actively induces the infringement of one or more claims of the ‘891 patent by Defendants MEDA and Aveva, with specific intent that the ‘891 patent be infringed and/or deliberate indifference to a known risk of such infringement.

39. BDSI has had constructive notice of the ‘891 patent pursuant to 35 U.S.C.

§ 287(a).

40. BDSI's infringement of the '891 patent is willful.

41. As a result of BDSI's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless BDSI is permanently enjoined by this Court from infringing the claims of the '891 patent.

42. As a result of BDSI's infringement of one or more claims of the '891 patent, MonoSol has suffered damages.

COUNT II
INFRINGEMENT OF THE '292 PATENT
(All Defendants)

43. MonoSol incorporates each of the preceding paragraphs 1-42 as if fully set forth herein.

44. MEDA and Aveva have been, and currently are, directly infringing one or more claims of the '292 patent, in violation of 35 U.S.C. § 271, by making, using, offering to sell, and/or selling the Onsolis™ film products.

45. MEDA and Aveva have had constructive notice of the '292 patent pursuant to 35 U.S.C. § 287(a).

46. As a result of MEDA and Aveva's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless MEDA and Aveva are permanently enjoined by this Court from infringing the claims of the '292 patent.

47. As a result of MEDA and Aveva's infringement of one or more claims of the '292 patent, MonoSol has suffered damages.

48. BDSI has been, and currently is, inducing the infringement of one or more claims of the '292 patent, in violation of 35 U.S.C. § 271.

49. BDSI actively induces the infringement of one or more claims of the '292 patent by Defendants MEDA and Aveva, with specific intent that the '292 patent be infringed and/or deliberate indifference to a known risk of such infringement.

50. BDSI has had constructive notice of the '292 patent pursuant to 35 U.S.C. § 287(a).

51. BDSI's infringement of the '292 patent is willful.

52. As a result of BDSI's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless BDSI is permanently enjoined by this Court from infringing the claims of the '292 patent.

53. As a result of BDSI's infringement of one or more claims of the '292 patent, MonoSol has suffered damages.

COUNT III
INFRINGEMENT OF THE '588 PATENT
(All Defendants)

54. MonoSol incorporates each of the preceding paragraphs 1-53 as if fully set forth herein.

55. MEDA and Aveva have been, and currently are, directly infringing one or more claims of the '588 patent, in violation of 35 U.S.C. § 271, by making, using, offering to sell, and/or selling the Onsolis™ film products.

56. MEDA and Aveva have had constructive notice of the '588 patent pursuant to 35 U.S.C. § 287(a).

57. As a result of MEDA and Aveva's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless MEDA and Aveva are permanently enjoined by this Court from infringing the claims of the '588 patent.

58. As a result of MEDA and Aveva's infringement of one or more claims of the '588 patent, MonoSol has suffered damages.

59. BDSI has been, and currently is, inducing the infringement of one or more claims of the '588 patent, in violation of 35 U.S.C. § 271.

60. BDSI actively induces the infringement of one or more claims of the '588 patent by Defendants MEDA and Aveva, with specific intent that the '588 patent be infringed and/or deliberate indifference to a known risk of such infringement.

61. BDSI has had constructive notice of the '588 patent pursuant to 35 U.S.C. § 287(a).

62. BDSI's infringement of the '588 patent is willful.

63. As a result of BDSI's infringing activities, MonoSol has suffered and will continue to suffer irreparable injury, unless BDSI is permanently enjoined by this Court from infringing the claims of the '588 patent.

64. As a result of BDSI's infringement of one or more claims of the '588 patent, MonoSol has suffered damages.

**COUNT IV
FALSE MARKING OF THE '832 PATENT
(All Defendants)**

65. MonoSol incorporates each of the preceding paragraphs 1-64 as if fully set forth herein.

66. Defendants have falsely marked the Onsolis™ film products with the '832 patent, with the intent to deceive one or more members of the public, including competitors, potential competitors, purchasers, and potential purchasers, in violation of 35 U.S.C. § 292.

67. As a direct and proximate result of Defendants' acts of false marking, MonoSol has suffered and continues to suffer a competitive injury and has sustained and will continue to sustain actual damages.

DEMAND FOR JUDGMENT

68. WHEREFORE, MonoSol requests the following relief:

69. A judgment that BDSI's, MEDA's and Aveva's making, using, offering to sell, and/or selling, within the State of New Jersey and elsewhere in the United States, the accused Onsolis™ film products infringes one or more claims of the '891, '292, and '588 patents, in violation of 35 U.S.C. § 271;

70. A judgment that BDSI, MEDA, and Aveva have willfully infringed the '891, '292, and '588 patents;

71. An award of damages adequate to compensate for Defendants' infringement of the '891, '292, and '588 patents under 35 U.S.C. § 284, together with interest and costs as fixed by the Court;

72. An award of enhanced damages against BDSI, MEDA, and Aveva for the

willful infringement of the '891, '292, and '588 patents;

73. A determination that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award of MonoSol's reasonable attorneys' fees;

74. An injunction, pursuant to 35 U.S.C. § 283, permanently prohibiting Defendants from infringing any claims of the '891, '292, and '588 patents prior to their expiration dates, including any extensions;

75. A judgment that Defendants have violated the provisions of 35 U.S.C. § 292 as alleged herein;

76. Damages adequate to compensate for the injury suffered as a result of the false patent marking of the Onsolis™ film products;

77. A permanent injunction enjoining Defendants from marking the Onsolis™ film products with the '832 patent; and

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

JURY DEMAND

79. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, MonoSol requests a trial by jury on all triable issues.

Respectfully submitted,

Dated: September 26, 2011

/s/ Edward R. Mackiewicz

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