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

MONOSOL RX, INC., Plaintiff, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	)	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff MonoSol Rx, LLC ("MonoSol"), by its attorneys, hereby files this Complaint against Defendant BioDelivery Sciences International, Inc. ("BDSI") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,765,167 (the '167 patent), arising under the Patent Laws of the United States, Title 35 of the United States Code.

2. Defendant BDSI markets and sells BELBUCA® (buprenorphine) buccal film ("BELBUCA"), which is a pharmaceutical drug product that infringes at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent.

3. BDSI submitted a New Drug Application ("NDA") under 21 U.S.C. § 355(b)(2) (NDA No. 207932), seeking approval to manufacture, market and sell BELBUCA throughout the United States, including in this Judicial District. BDSI's NDA was approved by the Food and Drug Administration ("FDA") on October 23, 2015. According to its own website, BDSI markets and sells its BELBUCA product nationwide.

4. BDSI has had knowledge of the '167 patent since at least October of 2014. On September 22, 2014, MonoSol (together with co-Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. and RB Pharmaceuticals Limited) sued BDSI for infringement of the '167 patent for BDSI's infringing Bunavail™ film product. The complaint was served on October 13, 2014. On October 28, 2014, BDSI filed four separate petitions for *inter partes* review ("IPR") of the '167 patent with the Patent Trial and Appeal Board ("PTAB"). In particular, in IPR2014-00167, BDSI challenged claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent. The PTAB declined to institute BDSI's petition on all of these claims, finding that BDSI could not "establish[] a reasonable likelihood that it would prevail as to its challenges of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent on any of the grounds presented in the Petition." IPR2014-00167, Paper No. 6, p.31 (May 20, 2015 Decision Denying Institution).

5. With full knowledge of the '167 patent, and despite having been previously sued for other products that infringe the '167 patent, BDSI has willfully launched BELBUCA, a new product that infringes the '167 patent. In this case, however, BDSI is subject to the one-year statutory bar under 35 U.S.C. § 315(b); and consequently, BDSI cannot obtain an *inter partes* review of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent.

PARTIES

6. Plaintiff MonoSol Rx, LLC 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.

7. Defendant BioDelivery Sciences International, Inc. is a Delaware corporation, having incorporated in the State of Delaware on April 18, 2002, file number 3515699. BDSI has

a principal place of business at 4131 Park Lake Ave., Suite 225, Raleigh, North Carolina 27612.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to Title 28, Sections 1331 and 1338(a) of the United States Code because this action arises under the Patent Act (35 U.S.C. §§ 1 *et seq*.).

9. Venue is proper in this Judicial District under Title 28, Sections 1391 and 1400(b) of the United States Code at least because BDSI transacts business in this District and because BDSI has committed and continues to commit acts of patent infringement in this District as alleged herein.

10. This Court has personal jurisdiction over BDSI at least because BDSI transacts business in the State of New Jersey and in this Judicial District, as well as throughout the United States, directly or through intermediaries, including by conducting at least a portion of the infringement alleged herein, regularly doing or soliciting business in New Jersey, maintaining continuous and systematic contacts in New Jersey, purposefully availing itself of the privileges of doing business in New Jersey, or deriving substantial revenue from goods or services provided to individuals in New Jersey, or some combination of the foregoing.

11. For example, BDSI regularly conducts business in New Jersey and this Judicial District. On information and belief, BDSI derives revenue from the sale of its products in New Jersey and in this Judicial District and throughout the United States. BELBUCA has been marketed and sold in New Jersey, and BDSI has employed representatives to market its products to prescribers in New Jersey. According to its website, BDSI sells or offers for sale its infringing BELBUCA products throughout the United States, including in New Jersey. BDSI has also purposefully availed itself of the privilege of conducting activities in New Jersey by, *inter alia*, entering into a commercialization and distribution agreement with a New Jersey company to

market and sell other of BDSI's products.

12. On information and belief, BDSI is amenable to litigating in this forum based on its conduct in other litigations in this District. In particular, BDSI has previously availed itself of the rights and privileges of this and has submitted to this Court's jurisdiction by consenting to personal jurisdiction and asserting counterclaims in a civil action initiated in this jurisdiction. *See MonoSol Rx, LLC v. BioDelivery Sciences International, Inc. et al*, CA No. 3:10-cv-05695 (D.N.J. Trenton).

13. MonoSol has legitimate and significant reasons for bringing this action in this District. For example, MonoSol's principal place of business is in this District. MonoSol's primary witnesses are in, or are regularly in, this District, as is the bulk of MonoSol's evidence and records currently in its possession, custody, or control. BDSI's course of conduct is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff, which is a New Jersey corporation. Further, BDSI would not suffer hardship, undue or otherwise, by being summoned to this District.

THE PATENT-IN-SUIT

14. MonoSol is a specialty pharmaceutical company that uses its proprietary PharmFilm® technology to deliver drugs in films. Through years of research and development, MonoSol has obtained over 150 patents and several FDA approvals.

15. On July 1, 2014, the '167 patent, entitled "Uniform Films for Rapid-dissolve Dosage Form Incorporating Anti-tacking Compositions," was duly and legally issued to inventors Garry L. Myers, Pradeep Sanghvi, Andrew Philip Verrall, Vimala Francis, and Laura Moss. That patent was assigned to MonoSol. A true and correct copy of the '167 patent is attached as Exhibit A.

16. The '167 patent generally relates to rapidly dissolving films that incorporate anti-

tacking agents and/or that contain an active component—such as a drug—that is evenly distributed throughout the film. *See, e.g.*, Exhibit A at Abstract. Oral films have several advantages as alternatives to tablets, pills, and the like. *See, e.g.*, *id.* at 1:26-47.

17. The inventors of the ’167 patent conceived of pioneering improvements in the making of films, improvements that enable uniform distribution of components therein and that prevent undesired aggregations of components in the final film product. Their improvements are set forth in the claims of the ’167 patent. For example, Claim 95 recites:

> An oral film for delivery of a desired amount of an active component comprising:
> an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;
> at least one anti-tacking agent comprising sodium benzoate;
> a substantially uniform distribution of said desired amount of said active component within said polymer matrix,
> wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof,
> said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution;
> wherein said film is self-supporting and the active component is substantially uniformly distributed, whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.

18. MonoSol presently, and during all relevant times, owns all rights, title, and interest to the ’167 patent, including the right to sue and to recover for any current or past infringement of that patent.

THE ACCUSED PRODUCT

19. BDSI makes, or directs the making of BELBUCA. Prior to January 6, 2017, BDSI sold and offered for sale BELBUCA to end-consumers through a third-party licensee. On December 8, 2016, this licensee announced its intent to terminate its license to BDSI’s patents

and that NDA No. 207932 would revert to BDSI, effective January 6, 2017. Presently, BDSI sells and offers for sale BELBUCA in the United States. *See* Exhibit B.

20. According to publicly available documentation about BELBUCA, including documentation from BDSI's website and the FDA, BDSI sells its infringing product in various dosage strengths, including 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg. *See* Exhibit C, FDA Prescribing Information at 1.

21. BELBUCA is a buccal film providing transmucosal delivery of buprenorphine hydrochloride. *Id*. at 17.

22. The strength of each BELBUCA film is dependent on the buprenorphine concentration in the formulation and the surface area of the film. *Id*. The film size and strength for each dosage is listed in the table below. *Id*.

Table 6: BELBUCA Identifier & Size

Buprenorphine Strength (mcg)	BELBUCA Identifier	Film Size (cm^2)
75	E0	1.215
150	E1	2.431
300	E3	0.934
450	E4	1.400
600	E6	1.867
750	E7	2.334
900	E9	2.801

23. The active ingredient in BELBUCA is buprenorphine hydrochloride. *Id*. BELBUCA also contains carboxymethylcellulose sodium USP, citric acid anhydrous USP, hydroxyethylcellulose NF, hydroxypropylcellulose NF, methylparaben NF, monobasic sodium phosphate anhydrous USP, peppermint oil NF, polycarbophil USP, propylene glycol USP, propylparaben NF, sodium benzoate NF, sodium hydroxide NF, saccharin sodium NF, titanium dioxide USP, vitamin E acetate USP, yellow iron oxide, purified water USP, and TekPrintTM SW-9008 black ink (shellac NF, black iron oxide NF). *Id*.

COUNT I – INFRINGEMENT OF THE ’167 PATENT

24. MonoSol incorporates each of the preceding paragraphs 1-23 as if fully set forth herein.

25. BDSI makes, offers to sell, and/or sells certain pharmaceutical films under the BELBUCA name. BELBUCA infringes the ’167 patent.

26. According to its website and BDSI’s financial filings, BDSI has received to date payments and milestones totaling at least $125 million to develop and make the infringing BELBUCA.

27. According to announcements by BDSI on or around December 8, 2016, the world-wide license that BDSI had granted to commercialize BELBUCA was transferred back to BDSI, and BDSI currently markets and sells BELBUCA throughout the United States, including in the State of New Jersey.

28. In addition to claim 95 of the ’167 patent, BDSI has been, and currently is, directly infringing, either literally or under the doctrine of equivalents, at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the ’167 patent, in violation of 35 U.S.C. § 271(a), by making, selling, and/or offering to sell BELBUCA without consent or license from MonoSol.

29. MonoSol has not granted a license to the ’167 patent or given any other authority to BDSI—or to anyone else—to make, use, sell, and/or offer for sale BELBUCA.

30. BDSI’s infringement of the ’167 patent has caused and will continue to cause MonoSol irreparable injury and harm for which there is no adequate remedy at law unless and until BDSI is permanently enjoined by this Court from infringing the ’167 patent.

31. MonoSol is entitled to recover from BDSI the damages it has sustained as a result of BDSI’s infringing activities in an amount subject to proof at trial, and in any event not less

than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

32. BDSI has had constructive notice of the ’167 patent pursuant to 35 U.S.C. § 287(a). BDSI has had actual notice of the ’167 patent since at least October 13, 2014, when BDSI received a Waiver of Service from MonoSol regarding litigation for infringement of the ’167 patent for BDSI’s infringing Bunavail™ film product, and then on October 28, 2014, when BDSI filed a petition in IPR2014-00167 to challenge claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the ’167 patent. On May 20, 2015, the PTAB declined to institute an IPR, finding that BDSI failed to establish a reasonable likelihood that it would prevail in showing the unpatentability of any of those claims. Paper No. 6, p.31. Under 35 U.S.C. § 315(b), BDSI cannot file an IPR petition challenging those claims.

33. BDSI’s infringement of the ’167 patent has been willful since at least (i) BDSI’s first making, using, offering to sell, and/or selling BELBUCA or (ii) October 13, 2014.

34. This is an exceptional case under 35 U.S.C. § 285, and MonoSol is entitled to enhanced damages, attorneys’ fees, and litigation expenses incurred.

COUNT II – INDIRECT INFRINGEMENT OF THE ’167 PATENT

35. MonoSol incorporates each of the preceding paragraphs 1-34 as if fully set forth herein.

36. BDSI has induced the direct infringement of the ’167 patent in violation of at least 35 U.S.C. § 271(b) by, among other things, knowingly and with intent, actively encouraging others to make, use, sell, and/or offer for sale BELBUCA in a manner that constitutes direct infringement, either literally or under the doctrine of equivalents, of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the ’167 patent. This

inducing activity occurred at least since the time that BDSI received actual notice of the '167 patent.

37. BDSI, in violation of at least 35 U.S.C. § 271(c), has contributed to the direct infringement, either literally or under the doctrine of equivalents, of at least claims 13, 33, 39, 45, 52, 66, 73, 83, 89, 95-98, 100-103, 105, 107, 108, 117 and 118 of the '167 patent by having BELBUCA made, used, sold, and/or offered for sale by others in the United States, knowing that such products infringe and are not staple articles or commodities of commerce suitable for a substantial noninfringing use.

DEMAND FOR JUDGMENT

WHEREFORE, MonoSol requests the following relief:

1. A judgment that BDSI's making, using, offering to sell, and/or selling, within the State of New Jersey and elsewhere in the United States, the accused BELBUCA film products infringes one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(a);

2. A judgment that BDSI has actively induced others to infringe one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(b);

3. A judgment that BDSI has contributed to others' infringement of one or more claims of the '167 patent, in violation of 35 U.S.C. § 271(c);

4. A judgment that BDSI has willfully infringed the '167 patent;

5. An award of damages adequate to compensate for BDSI's infringement of the claims of the '167 patent under 35 U.S.C. § 284, together with interest and costs as fixed by the Court;

6. An award of enhanced damages against BDSI for the willful infringement of the '167 patent;

7. 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;

8. An injunction, pursuant to 35 U.S.C. § 283, permanently prohibiting BDSI from infringing any claims of the '167 patent prior to its expiration, including any extensions;

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

JURY DEMAND

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: January 13, 2017

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil rule 11.2, counsel for Plaintiff MonoSol hereby certifies, to the best of his knowledge, that the matter in controversy is not the subject of any other action currently pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 13, 2017

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