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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., and QUINTILES COMMERCIAL US, INC. Defendants.	Civ. No.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP") and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") hereby file this Complaint against Defendants BioDelivery Sciences International, Inc. ("BDSI") and Quintiles Commercial US, Inc. ("Quintiles") (collectively, "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement related to 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. Plaintiff RBP is the holder of New Drug Application ("NDA") 22-410 for Suboxone® sublingual film. On August 30, 2010, the United States Food and Drug Administration ("FDA") approved that NDA for the manufacture, marketing and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence.

3. Since the approval of NDA 22-410, Suboxone® sublingual film has been exclusively manufactured in the United States by Plaintiff MonoSol and exclusively sold in the United States by Plaintiff RBP. Suboxone® sublingual film is the leading treatment for opioid dependence in the United States.

3. BDSI submitted a New Drug Application under 21 U.S.C. § 355(b)(2) (the "505(b)(2) NDA") to the FDA seeking approval to manufacture and sell an infringing pharmaceutical drug product under the trade name Bunavail™. Like the patented Suboxone® film, Bunavail™ is also a film product, contains the same active ingredients and has been approved for the same medical indications.

4. BDSI's 505(b)(2) NDA was approved by the FDA on June 6, 2014, and, upon information and belief, BDSI is now in the midst of its nationwide commercial launch of Bunavail™

5. As reported in BDSI's Form 10Q quarterly report dated May 9, 2014 filed with the Securites and Exchange Commission, Quintiles and BDSI have entered into a Master Services Agreement with regard to Bunavail™. Under this agreement, Quintiles is supporting

the recruitment, training and deployment of a sales force to market Bunavail™ on BDSI's behalf in the United States.

6. Upon information and belief, for purposes of its on-going nationwide commercial launch of Bunavail™, BDSI has manufactured, or has had manufactured for it, and is continuing to manufacture, or have manufactured for it, the Bunavail™ film product, which it has offered for sale, continues to offer for sale, and, together with Quintiles, is selling throughout the United States.

THE PARTIES

7. Plaintiff MonoSol is a Delaware limited liability company having a principal place of business at 30 Technology Drive, Warren, New Jersey.

8. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

9. Defendant BDSI is a Delaware corporation having a principal place of business at 801 Corporate Center Drive, Suite 210, Raleigh, North Carolina.

10. Defendant Quintiles is a Delaware corporation having a principal place of business at 10 Waterview Boulevard, Parsippany, New Jersey.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 35 U.S.C. § 271.

12. This Court has personal jurisdiction over BDSI because of, *inter alia*, BDSI'S continuous and systematic contacts with corporate entities within this judicial district and its marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to

residents of this judicial district. In particular, upon information and belief, BDSI has marketed and sold its infringing Bunavail™ product in this District and has employed representatives to market its Bunavail™ product to prescribers in this District.

13. This Court has personal jurisdiction over Quintiles because Quintiles resides in this judicial district and because of, *inter alia*, Quintiles' continuous and systematic contacts with corporate entities within this judicial district and its marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district. In particular, upon information and belief, Quintiles has marketed and sold the infringing Bunavail™ product in this District and has employed representatives to market the Bunavail™ product to prescribers in this District.

14. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE ASSERTED PATENT

15. Plaintiff MonoSol is the lawful owner of the '167 patent. The '167 patent, entitled "Uniform Films for Rapid-dissolve Dosage Form Incorporating Anti-tacking Compositions," was duly and legally issued on July 1, 2014, naming Garry L. Myers, Pradeep Sanghvi, Andrew Phillip Verall, Vimala Francis and Laura Moss as inventors. A true copy of the issued '167 patent is attached hereto as **Exhibit A.**

16. RBP is an exclusive licensee of MonoSol for the '167 patent and holds the exclusionary rights to market and sell Suboxone® sublingual film in the United States.

BDSI's BUNAVAIL™ PRODUCT

17. BDSI's Bunavail™ product, like Suboxone® film, is a mucoadhesive, polymer film that dissolves in the mouth.

18. Bunavail™ is sold in three nominal strengths: 2.1 mg buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone; and 6.3 mg buprenorphine/1.0 mg naloxone.

19. Defendants are marketing Bunavail™ as a product that is directly competing with RBP's Suboxone® sublingual film. In a press release dated August 9, 2013, BDSI stated that "[i]f approved, BUNAVAIL will be the first buccal film dosage form containing buprenorphine for the treatment of opioid dependence that will compete with the market leader Suboxone . ..."

20. It has been reported that at an Investor & Analyst Update webcast on September 5, 2014, BDSI stated, as part of a slide presentation in regard to its launch of Bunavail™, that "major wholesaler contracts are finalized," and confirmed that BDSI had "released and published the price" of Bunavail™ "which will be at parity with Suboxone film." During that same presentation, , BDSI stated that it and Quintiles had "made 1700 phone calls" to their top sales targets, and BDSI's President described BDSI's ongoing pharmacy stocking program regarding Bunavail™, stating:

> we have been active on the trade side. We have products where the pre-field is completely setup, our wholesale contracts are finalized. We are in a position where we will have a 115 distribution centers that will have product in them at launch which is alliance of about the 15 top wholesalers across the country.
>
> Of course there are three that make up the majority of that business that we are dealing with very closely. We have a pharmacy, a very aggressive pharmacy stocking program in place that's been positioned currently as of today. And our trade letter and all of our follow-up starts next week, early next week . . . we will start in at least 115 DSAs at launch.

21. A few days later, BDSI's President and CEO, speaking at a Morgan Stanley Healthcare Conference on September 9, 2014, described some of BDSI's commercial marketing activities for Bunavail™, including BDSI's plans to have a 60 person strong sales force "hit the ground" during the week of September 22, 20014 following a national sales meeting the previous week:

> The nice thing about this category is that it's really consolidated geographically and in the physician base as well there is about 5,000 physicians that treat opioid addiction and 80% of the business is consolidated East to the Mississippi. And because of such small group of physicians you can cover with a small number of sales representatives. So for a company like us launching our first product, it's very manageable in terms of the commercial spends, we're going to have about 60 sales people for regional managers and two individuals, one at Quintiles because this is a contract sales force and then David Acheson who have got sales and manage markets for us overseeing the entire effort.
>
> So we're set to launch our national sales meeting is actually is this Friday it runs through early next week and we'll have our feet on the ground the following week. We've had five MSLs, Medical Science Liaison on individuals out in the field since last April, sort of paving the way first talking about the technology and then after the approval talking about the product itself. So we've been in some of the highest practicing offices in this space for about six months. Sales force of course will hit the ground as I said week after next. Again about 60 people targeted 80% of these individuals would be East of the Mississippi the rest in Texas, Phoenix and West Coast.

COUNT I
(Infringement as to U.S. Patent No. 8,765,167)

22. Plaintiffs reallege the paragraphs above as if fully set forth herein.

23. On information and belief, BDSI's Bunavail™ product is covered by one or more claims of the '167 patent.

24. On information and belief, without license or authorization to do so, and in violation of 35 U.S.C. § 271(a), Defendants have directly infringed one or more of the claims of the '167 patent in the United States by making, using, offering to sell, selling, and/or importing products that infringe the '167 patent, including Bunavail™ film products, in the United States.

25. On information and belief, and in violation of 35 U.S.C. §§ 271(b) and/or 271(c), Defendants have indirectly infringed one or more claims of the '167 patent by inducing or contributing to the direct infringement by causing others -- specifically, for example, medical professionals and patients -- to perform acts that Defendants know will infringe one or more claims of the '167 patent.

26. On information and belief, Defendants know (a) that the Bunavail™ product is

especially made or adapted for use in infringing one or more claims of the '167 patent and (b) that the Bunavail™ product is not suitable for any substantial noninfringing use.

27. On information and belief, Defendants' continued manufacture, use, sale and/or offer for sale of the Bunavail™ film products constitute willful infringement of the '167 patent.

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

DEMAND FOR JURY TRIAL

29. Plaintiffs hereby demand a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment holding that Defendants have infringed the '167 patent under 35 U.S.C. § 271;

B. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial, including both pre-judgment and post-judgment interest;

C. A permanent injunction, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, contributing to, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or other products, claimed in the '167 patent;

D. A judgment finding that Defendants' infringement of the '167 patent has been willful and awarding treble damages under 35 U.S.C. § 284;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees; and

F. Any and all other relief as the Court deems just and proper.

Dated: September 22, 2014

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