IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	)	Civ. No. 5:13-cv-760

COMPLAINT

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") ("collectively, "Plaintiffs") hereby file this Complaint against Defendant BioDelivery Sciences International, Inc. ("BDSI"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,475,832 ("the '832 patent"), arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202.

2. Pursuant to New Drug Application 22-410, the United States Food and Drug Administration ("FDA") authorized Plaintiffs to market a pharmaceutical drug product used to treat opioid dependence that is sold under the name Suboxone®. Suboxone® is a sublingual, transmucosal film that contains the active ingredients buprenorphine hydrochloride and naloxone

hydrochloride. Plaintiffs have manufactured and continue to manufacture and sell Suboxone® for the U.S. market.

3. BDSI has 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 a competing pharmaceutical drug product to Suboxone® that contains the same active ingredients and is intended to treat the same medical indications. BDSI intends to market its competing product under the name Bunavail™.

4. BDSI's submission of its application to the FDA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Furthermore, a real and justiciable controversy exists between Plaintiffs and BDSI regarding whether Bunavail™ infringes the '832 patent. Therefore, Plaintiffs also seek a declaration that the sale of BDSI's proposed product will infringe the '832 patent under 35 U.S.C. § 271(a)-(c).

THE PARTIES

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

6. Plaintiff RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

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

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

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271.

10. This Court has personal jurisdiction over BDSI because BDSI resides in this judicial district.

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

THE PATENT-IN-SUIT

12. Plaintiff RBP UK is the lawful owner of the '832 patent. The '832 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on July 2, 2013, to Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. The named inventors assigned their rights to MonoSol, who subsequently assigned its rights in the '832 patent to Reckitt Benckiser Healthcare (UK) Limited, which then assigned its rights to RBP UK. MonoSol manufactures Suboxone® for the US market. A true copy of the '832 patent is attached hereto as Exhibit A.

PLAINTIFFS' SUBOXONE® PRODUCTS

13. Plaintiff RBP is the owner of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

14. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film since its approval.

15. RBP also owns NDA No. 20-733 for Suboxone® sublingual tablet. Suboxone® sublingual tablet contains the same active ingredients as Suboxone® sublingual film (buprenorphine hydrochloride and naloxone hydrochloride).

BDSI's ATTEMPT TO CIRCUMVENT THE HATCH-WAXMAN ACT

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act" and codified at 21 U.S.C. § 355. The Hatch-Waxman Act was intended to balance two important public policy goals. First, Congress wanted to ensure that drug manufacturers would have meaningful patent protection and a period of marketing exclusivity to enable them to recoup their investments in the development of valuable new drugs. Second, Congress sought to ensure that, once the patent protection and marketing exclusivity for these drugs expire, consumers would benefit from the availability of lower priced generic versions of approved drugs.

17. Under 21 U.S.C. § 355(b)(1), the NDA applicant is required to submit extensive testing and safety information concerning the drug ("505(b)(1) applications"). In addition, the NDA applicant must submit information on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted." Once the NDA is approved, the FDA lists this patent information in its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

18. Both the NDA for the Suboxone® sublingual film and the NDA for the Suboxone® sublingual tablet are 505(b)(1) applications. The '832 patent is listed in the FDA's Orange Book as covering Suboxone® sublingual film. There are no unexpired patents listed on the Orange Book for Suboxone® sublingual tablet.

19. The Hatch-Waxman Act amended the FD&C Act to provide for applications filed under 21 U.S.C. § 355(b)(2) ("505(b)(2) applications"), which allow applicants to obtain FDA approval for other versions of previously-approved drugs without having to repeat the extensive

testing required for a new drug application. Section 505(b)(2) applications can rely, in part, on FDA's previous findings of safety and efficacy for an approved drug product.

20. If a 505(b)(2) applicant relies on previous FDA findings of safety and efficacy for a previously-approved drug product, the 505(b)(2) applicant must identify the drug application which formed the basis for FDA approval ("Reference Listed Drug" or "RLD").

21. Under 21 U.S.C. § 355(b)(2)(A), the 505(b)(2) applicant must make one of the following four certifications with respect to each of the patents listed in the Orange Book for the previously-approved drug product: (i) that the patent information has not been filed ("Paragraph I" certifications); (ii) that the patent has expired ("Paragraph II" certifications); (iii) that the patent will expire on a specific date ("Paragraph III" certifications); or (iv) that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" ("Paragraph IV" certifications).

22. If a 505(b)(2) applicant makes a Paragraph IV certification, the Hatch-Waxman Act, 21 U.S.C. § 355(b)(3), requires the 505(b)(2) applicant to give notice to the patent owner of the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed.

23. If the 505(b)(2) application includes a Paragraph IV certification, the patent owner can file an infringement action within 45 days of receiving the notice of Paragraph IV certification. Such a filing by the patent owner triggers a 30-month injunction or stay of FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(c)(3)(C). This 30-month period is intended to allow time for judicial resolution on the merits of any patent infringement, validity, and/or enforceability claims, before the competitor is allowed entry into the market.

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