IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. ACTAVIS LABORATORIES UT, INC., Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. ("Indivior"), Indivior UK Limited ("Indivior UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Amended Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 204383 to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of the 4 mg/1 mg (buprenorphine/naloxone) dosage strength of Plaintiff Indivior's Suboxone® sublingual film prior to the expiration of United States Patent Nos. 8,475,832 ("the '832 Patent"); 8,017,150 ("the '150 Patent"); and 8,603,514 ("the '514 Patent") (collectively, "the Patents-in-Suit").

THE PARTIES

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

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

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

5. On information and belief, Defendant Actavis is a Delaware corporation having a principal place of business at 577 Chipeta Way, Salt Lake City, Utah, 84108. Actavis previously operated under the name Watson Laboratories, Inc. ("Watson").

JURISDICTION AND VENUE

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

7. On information and belief, Defendant is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in Delaware and throughout the United States.

8. This Court has personal jurisdiction over Defendant because of, *inter alia*, Defendant's incorporation in Delaware, its continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of 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 generic pharmaceutical products to residents of this judicial district.

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

THE PATENTS-IN-SUIT

10. Plaintiff Indivior UK is the lawful owner of the ’832 Patent, and Plaintiff Indivior is an exclusive licensee of the ’832 Patent. The ’832 Patent, entitled “Sublingual and Buccal Film Compositions,” duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the ’832 Patent is attached hereto as Exhibit A.

11. Plaintiff MonoSol is the lawful owner of the ’150 Patent, and Plaintiff Indivior is an exclusive licensee of the ’150 Patent. The ’150 Patent, entitled “Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom,” duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’150 Patent is attached hereto as Exhibit B.

12. Plaintiff MonoSol is the lawful owner of the ’514 Patent, and Plaintiff Indivior is an exclusive licensee of the ’514 Patent. The ’514 Patent, entitled “Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions,” duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the ’514 Patent is attached hereto as Exhibit C.

SUBOXONE SUBLINGUAL FILM

13. Plaintiff Indivior is the holder 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 Indivior has sold Suboxone sublingual film under NDA No. 22-410 since its approval.

15. On August 30, 2010, Suboxone sublingual film was approved in 2 mg/0.5 mg and 8 mg/2 mg dosage strengths (buprenorphine/naloxone base equivalents).

16. On August 10, 2012, Suboxone sublingual film was approved in 4 mg/1 mg and 12 mg/3 mg dosage strengths (buprenorphine/naloxone base equivalents).

17. The ’832 Patent, the ’150 Patent, and the ’514 Patent (collectively, the “Orange Book-Listed Patents”) are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as covering Suboxone sublingual film.

THE DRUG APPROVAL PROCESS

18. 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 innovator 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.

19. Under 21 U.S.C. § 355(b)(1), the innovator drug manufacturer and NDA applicant is required to submit extensive testing and safety information concerning the drug. 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 the Orange Book.

20. In contrast, the Hatch-Waxman Act allows ANDA applicants to obtain FDA approval for generic versions of previously-approved drugs without having to repeat the extensive testing required for a new drug application. Under 21 U.S.C. § 355(j), ANDAs can rely on FDA's previous findings of safety and efficacy for an approved drug product, if they demonstrate, among other things, that the generic drug is bioequivalent to the previously-approved drug.

21. When a generic manufacturer submits an ANDA, the FDA conducts a preliminary review of the application to ensure it is sufficiently complete to permit a substantive review. *See* 21 C.F.R. § 314.101(b)(1). "Receipt of an [ANDA] means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review." *Id.*

22. Under 21 U.S.C. § 355(j)(2)(A)(vii), the ANDA must also include 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, and the generic will stay off the market until that 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).

23. If the ANDA includes a Paragraph IV certification, the Hatch-Waxman Act requires the ANDA applicant to give notice ("notice of Paragraph IV certification") to the patent owner of the factual and legal basis for the applicant's opinion that patents listed in the Orange Book are invalid or will not be infringed, "not later than 20 days after the date of the postmark on

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