IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and MONOSOL RX, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior"), Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendant Sandoz Inc. ("Sandoz") 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 Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiffs' 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 Sandoz is a Colorado corporation having a principal place of business at 100 College Road West, Princeton, New Jersey. On information and belief, Sandoz has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

JURISDICTION AND VENUE

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

7. On information and belief, Sandoz 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. Such products include the generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Sandoz's generic product") that is described in ANDA No. 205477.

8. This Court has personal jurisdiction over Sandoz because of, *inter alia*, Sandoz's continuous and systematic contacts with the State of Delaware; its previous submission to the jurisdiction of this judicial district, including, *inter alia*, by affirmatively invoking this Court's jurisdiction by filing counterclaims in this 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. Further, Sandoz has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to

distribute generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

9. This Court also has personal jurisdiction over Sandoz because, upon information and belief, Sandoz has submitted to jurisdiction in this District in patent cases, including, for example, *Cephalon Inc. v. Sandoz Inc. et al.*, 15-cv-00178-GMS; *Forest Laboratories, LLC et al. v. Apotex Corp. et al.*, 15-cv-00018-GMS; *Sanofi et al. v. Sandoz Inc.*, 14-cv-01434-RGA; *Teva Pharms. USA, Inc. et al. v. Sandoz Inc.*, 14-cv-01171-GMS; *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, 14-cv-00916-RGA; *Allos Therapeutics, Inc. et al. v. Teva Pharms. USA, Inc. et al.*, 14-cv-00778-RGA; and *ALZA Corp. et al. v. Sandoz Inc.*, 14-cv-00744-RGA. This Court also has personal jurisdiction over Sandoz because, upon information and belief, Sandoz has affirmatively availed itself of this Court's jurisdiction as a plaintiff, including, for example, in *Sandoz Inc. v. Pfizer, Inc. et al.*, 10-cv-00104-LPS.

10. This Court also has personal jurisdiction over Sandoz because Sandoz has purposefully availed itself of the privilege of doing business in the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States including the State of Delaware, and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware.

11. On information and belief, Sandoz sent or caused to be sent a letter dated October 1, 2015 to Plaintiff Indivior and Plaintiff MonoSol, corporations organized under the laws of the State of Delaware, stating that Sandoz had submitted ANDA No. 205477 seeking approval to commercially manufacture, use, import, offer for sale and sell Sandoz's generic product (the

"Notification Letter"). Sandoz purposefully directed its activities to Plaintiff Indivior and Plaintiff Monosol, both Delaware corporations.

12. On information and belief, if ANDA No. 205477 is approved, the generic product will, among other things, be marketed and distributed by Sandoz, directly and/or through its agents, in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware.

13. On information and belief, Sandoz intends its generic product to be distributed and sold in the United States, including in Delaware.

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

THE PATENTS-IN-SUIT

15. 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," was duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hilbert, 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.

16. 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," was 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.

17. 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," was 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

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

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

20. The patents-in-suit 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

21. 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.

22. 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

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