

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

INDIVIOR INC., INDIVIOR UK LIMITED,
and MONOSOL RX, LLC,

Plaintiffs,

v.

MYLAN TECHNOLOGIES INC., MYLAN
PHARMACEUTICALS INC., and MYLAN
N.V.,

Defendants.

C.A. No. 1:15-CV-209 (Keeley)

Electronically filed: 11/05/2015

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 Defendants Mylan Technologies Inc. (“MTI”), Mylan Pharmaceuticals Inc. (“MPT”), and Mylan N.V. (collectively, “Mylan” or “Defendants”) 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 MTI’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, MTI is a West Virginia corporation having a principal place of business at 110 Lake Street, Saint Albans, Vermont.

6. On information and belief, MPI is a West Virginia corporation having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia.

7. On information and belief, Mylan N.V. is a corporation organized and existing under the laws of the Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England.

JURISDICTION AND VENUE

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

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

10. This Court has personal jurisdiction over MTI because of, *inter alia*, MTI's incorporation and registration in the State of West Virginia; its continuous and systematic contacts with the State of West Virginia; 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.

11. This Court has personal jurisdiction over MPI because of, *inter alia*, MPI's incorporation and registration in the State of West Virginia; its continuous and systematic contacts with the State of West Virginia; 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.

12. This Court has personal jurisdiction over Mylan N.V. at least under Fed. R. Civ. P. 4(k)(2), and because Mylan N.V., MPI, and MTI operate as an integrated, unitary pharmaceutical business, whereby, on information and belief, Mylan N.V. controls and/or dominates subsidiaries MTI and MPI.

13. Mylan holds itself out and publicly represents itself as a single global entity. For example, Mylan N.V. reports revenue on a consolidated basis that includes its subsidiaries MTI and MPI. Mylan N.V.'s August 6, 2015 Quarterly Report states that Mylan has a consolidated "Generics" segment that conducts business on a global basis. On information and belief, Mylan N.V. issues press releases for its subsidiaries MPI and/or MTI regarding FDA approval of generic drugs, commercialization of generic drugs, and litigations involving the filing of ANDAs or NDAs.

14. On information and belief, Mylan N.V., MPI, and MTI have an integrated management structure, including overlapping officers and directors.

15. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale,

and distribution of pharmaceutical products throughout the United States. Such products include the generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film (“Mylan’s generic product”) that is described in ANDA No. 207607.

16. On information and belief, MTI, as the agent of Mylan N.V., and in concert with MPI, sent or caused to be sent a letter dated September 23, 2015 to Plaintiff Indivior and Plaintiff Monosol, stating that MTI had submitted ANDA No. 207607 seeking approval to commercially manufacture, use, import, offer for sale and sell Mylan’s generic product (the “Notification Letter”).

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

18. On November 4, 2015, Plaintiffs filed a complaint against Mylan for patent infringement in the United States District Court for the District of Delaware based on the filing of ANDA No. 207607. The resulting Delaware action is presently pending. A copy of the complaint in the Delaware action (the “Delaware Action”), excluding exhibits, is attached hereto as Exhibit A.

19. Based on Mylan’s continuous and systematic business contacts with Delaware, Mylan should be subject to personal jurisdiction in the District of Delaware; however, Mylan may assert that it is not subject to such jurisdiction.

20. Plaintiffs are therefore filing the instant complaint, which has identical infringement claims against Mylan as the Delaware Action, to preserve their right to a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

THE PATENTS-IN-SUIT

21. 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 B.

22. 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 C.

23. 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 D.

SUBOXONE® SUBLINGUAL FILM

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

25. 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.

26. 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.

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