

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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. _____

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. (“MPI”), 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 corporation organized and existing under the laws of the State of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia. MPI has registered to do business in Delaware. MPI maintains a registered agent in Delaware. MPI may be served with process in Delaware via the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware.

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 Delaware and throughout the United States.

10. This Court has personal jurisdiction over MTI because of, *inter alia*, MTI'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, MTI 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.

11. This Court has personal jurisdiction over MPI at least because MPI has registered to do business in Delaware and maintains a registered agent in Delaware, and because MPI may be served with process in Delaware via its registered agent, the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Further, MPI 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. MPI has also availed itself of the protections of this Court as a plaintiff in this 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. This Court also has personal jurisdiction over each of the Defendants because upon information and belief (1) MPI and MTI have submitted to jurisdiction in this District in patent cases, including *Endo Pharms. Inc. v. Mylan Techs. Inc.*, C.A. No. 11-220-GMS; and (2) Mylan 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.

16. 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 including in Delaware. Such products include the generic buprenorphine hydrochloride and naloxone hydrochloride sublingual film ("Mylan's generic product") that is described in ANDA No. 207607.

17. 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, corporations organized under the laws of the State of Delaware, 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"). Mylan purposefully directed its activities to Plaintiff Indivior and Plaintiff Monosol, both Delaware corporations.

18. On information and belief, if ANDA No. 207607 is approved, the generic product will, among other things, be marketed and distributed by Mylan, directly and/or through its agents, in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware.

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

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

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 A.

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 B.

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

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