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

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.

23. 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.

24. 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.*

25. 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).

26. 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 the notice with which the [FDA] informs the applicant that the application has been filed." 21 U.S.C. § 355(j)(2)(B).

27. 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 the FDA approval, beginning on the date of receipt of the notice. *See* 21 U.S.C. § 355(j)(5)(B)(iii). 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.

28. Federal regulations also govern the timing of the notice of Paragraph IV certification by directing the generic manufacturer to send such notice "when it receives from FDA an acknowledgment letter stating that its [ANDA] is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

SANDOZ'S PARAGRAPH IV NOTICE

29. Plaintiffs received the Notification Letter from Sandoz dated October 1, 2015 stating that ANDA No. 205477 contains Paragraph IV certifications alleging that the '832, '150, and '514 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

30. The Notification Letter further states that Sandoz submitted ANDA No. 205477 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use,

and/or sale of Sandoz's generic product before expiration of the patents-in-suit. On information and belief, ANDA No. 205477 refers to and relies on Plaintiff Indivior's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Sandoz's generic product with Suboxone® sublingual film.

31. Plaintiffs commenced this action within 45 days of receiving the Notification Letter.

COUNT I
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

32. Plaintiffs reallege paragraphs 1–31 above as if fully set forth herein.

33. On information and belief, Sandoz's generic product is covered by one or more claims of the '832 patent.

34. By filing ANDA No. 205477 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Sandoz's generic product prior to the expiration of the '832 patent, Sandoz has committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

35. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 205477 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT II
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

36. Plaintiffs reallege paragraphs 1–31 above as if fully set forth herein.

37. On information and belief, Sandoz's generic product is covered by one or more claims of the '150 patent.

38. By filing ANDA No. 205477 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Sandoz's generic product prior to the expiration of the '150 patent, Sandoz has committed an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

39. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 205477 to be a date which is not any earlier than the expiration date of the '150 patent, including any extensions of that date.

COUNT III
(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

40. Plaintiffs reallege paragraphs 1–31 above as if fully set forth herein.

41. On information and belief, Sandoz's generic product is covered by one or more claims of the '514 patent.

42. By filing ANDA No. 205477 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Sandoz's generic product prior to the expiration of the '514 patent, Sandoz has committed an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

43. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 205477 to be a date which is not any earlier than the expiration date of the '514 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Sandoz has infringed each of the patents-in-suit by submitting and maintaining ANDA No. 205477;

B. Preliminary and permanent injunctions, restraining and enjoining Sandoz, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

C. An order that the effective date of any approval of ANDA No. 205477 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

D. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

E. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Sandoz commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Sandoz's generic product before the expiration of each patent-in-suit that Sandoz is found to infringe, including any extensions; and

F. Any and all other relief as the Court deems just and proper.

Dated: November 13, 2015

Respectfully submitted,

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