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

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| RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP.,<br><br>Defendants. | ) | C.A. No. |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Reckitt Benckiser Pharmaceuticals Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Complaint against Defendants Par Pharmaceutical, Inc. ("Par"), and IntelGenX Technologies Corp. ("IGX") 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 Par's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of United States Patent Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

2. Plaintiffs also seek a declaratory judgment that: (1) some of Defendant Par's notices of Paragraph IV certification are premature, null and void, and ineffective to trigger the

ANDA patent litigation process in Case No. 1:13-cv-01461-RGA; and (2) there is no subject matter jurisdiction over Plaintiffs' claims and Defendants' counterclaims in Case No. 1:13-cv-01461-RGA because Defendant Par's premature notices are null and void.

## THE PARTIES

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

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

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

6. On information and belief, Defendant Par is a Delaware corporation having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

7. On information and belief, Defendant IGX is a Delaware corporation having a principal place of business at 6425 Abrams, Ville St-Laurent (Quebec), Canada.

## 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, Par is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware and throughout the United States.

10. Par has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example by bringing the patent infringement suit *Par Pharmaceutical Inc. v. Breckenridge Pharmaceutical Inc.*, C.A. No. 13-1114-SLR.

11. This Court has personal jurisdiction over Par because of, *inter alia*, Par'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.

12. On information and belief, IGX is a drug delivery company focused on the development of oral controlled-release products as well as rapidly disintegrating delivery systems.

13. IGX, directly or through its affiliates, has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example by voluntarily substituting in as defendant in the patent infringement suit *Biovail Laboratories International SRL v. IntelGenx Corp.*, C.A. No. 09-605-LPS.

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

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

## THE PATENTS-IN-SUIT

16. Plaintiff RBP UK is the lawful owner of the '832 patent, and Plaintiff RBP 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.

17. Plaintiff MonoSol is the lawful owner of the '150 patent, and Plaintiff RBP 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.

18. Plaintiff MonoSol is the lawful owner of the '514 patent, and Plaintiff RBP 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

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

20. 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 RBP has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

21. 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

22. 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.

23. 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 its Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

24. 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.

25. 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

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