Case 1:13-cv-01674-RGA Document 347-1 Filed 10/23/15 Page 1 of 22 PageID #: 9504 **HIGHLY CONFIDENTIAL**

PROPOSED JOINT PRETRIAL ORDER EXHIBIT 1 **JOINT STATEMENTS OF ADMITTED FACTS**



Case 1:13-cv-01674-RGA Document 347-1 Filed 10/23/15 Page 2 of 22 PageID #: 9505 HIGHLY CONFIDENTIAL

I. The Parties

- 1. Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. ("RBP") is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.
 - 2. Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is now known as Indivior Inc.
- 3. Plaintiff RB Pharmaceuticals Limited ("RBP UK") is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.
- 4. Plaintiff Reckitt Benckiser Pharmaceuticals Limited is now known as Indivior UK Limited.
- 5. Plaintiff MonoSol Rx, LLC ("MonoSol") is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey 07059.
- 6. Defendant Watson Laboratories, Inc. is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.
- 7. Watson Laboratories, Inc. has changed its name and is now known as Actavis Laboratories UT, Inc. PTX 420.¹
- 8. Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation having a place of business at One Ram Ridge Rd, Chestnut Ridge, New York 10977.
- 9. Defendant IntelGenx Technologies Corp. ("IntelGenx") is a Delaware corporation having a place of business at 6425 Abrams, Ville St-Laurent (Quebec), Canada.

¹ Throughout this document, "Watson" shall be understood to collectively refer to the entity formerly known as Watson Laboratories, Inc. and now known as Actavis Laboratories UT, Inc.

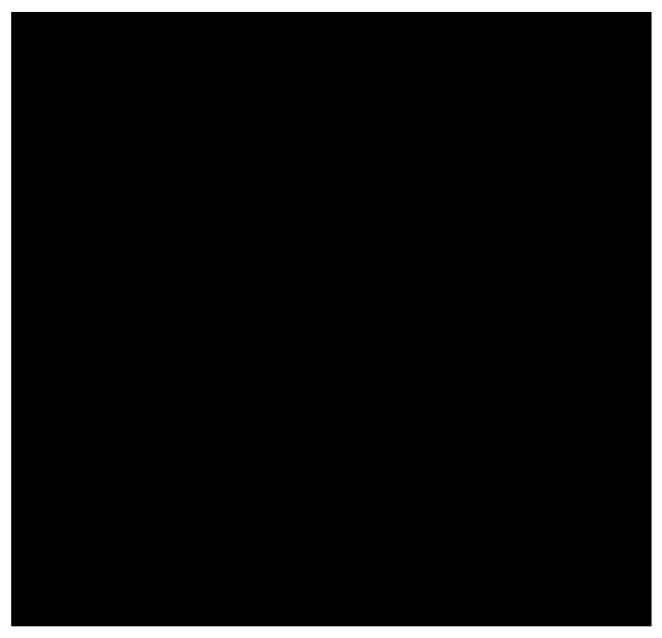


II. Plaintiffs' NDA and Suboxone® Sublingual Film

- 10. Plaintiff RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone sublingual film.
- 11. On August 30, 2010, the United States Food and Drug Administration ("FDA") approved NDA No. 22-410 for the manufacture, marketing and sale of Suboxone sublingual film. *See* PTX 283 and 293.
- 12. The active ingredients in Suboxone sublingual film are buprenorphine hydrochloride and naloxone hydrochloride.
- 13. In August 2010, Suboxone sublingual film was approved in 2 mg/0.5 mg and 8 mg/2 mg dosage strengths (buprenorphine/naloxone base equivalents). *See* PTX 284.
- 14. On August 10, 2012, Suboxone sublingual film was approved in a 12 mg/3 mg (buprenorphine/naloxone base equivalents) dosage strength.
- 15. On August 10, 2012, Suboxone sublingual film was approved in a 4 mg/1 mg (buprenorphine/naloxone base equivalents) dosage strength.
- 16. The Suboxone sublingual film product label states that Suboxone sublingual film is indicated for maintenance treatment of opioid dependence. *See* PTX 284.
- 17. Suboxone® Sublingual Film is a sublingual film whose active ingredients are buprenorphine hydrochloride and naloxone hydrochloride in the following dosage strengths: 2 mg/0.5 mg (Equivalent Base); 4 mg/1 mg (Equivalent Base); 8 mg/2 mg (Equivalent Base); 12mg/3mg (Equivalent Base).



Case 1:13-cv-01674-RGA Document 347-1 Filed 10/23/15 Page 4 of 22 PageID #: 9507 HIGHLY CONFIDENTIAL



- 19. Suboxone® Sublingual Film contains buprenorphine HCl.
- 20. Suboxone® Sublingual Film contains naloxone HCl.
- 21. Suboxone® Sublingual Film contains citric acid, anhydrous and sodium citrate, anhydrous.

III. The Asserted Patents

22. Application Serial No. 12/537,571 was filed with the United States Patent and Trademark Office ("USPTO") on August 7, 2009.



Case 1:13-cv-01674-RGA Document 347-1 Filed 10/23/15 Page 5 of 22 PageID #: 9508 HIGHLY CONFIDENTIAL

- 23. Application Serial No. 12/537,571 issued as United States Patent No. 8,475,832 (the "'832 Patent") on July 2, 2013. It was entitled "Sublingual and Buccal Film Compositions" and named Garry L. Myers, Samuel D. Hilbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. PTX 3.
 - 24. Plaintiff RBP UK owns the '832 Patent.
 - 25. Plaintiff RBP is an exclusive licensee of the '832 Patent.
 - 26. Application Serial No. 11/775,484 was filed with the USPTO on July 10, 2007.
- 27. Application Serial No. 11/775,484 issued as United States Patent No. 8,603,514 (the "'514 Patent") on December 10, 2013. It was entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions" and named Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. PTX 2.
 - 28. Plaintiff MonoSol owns the '514 patent
 - 29. Plaintiff RBP is an exclusive licensee of the '514 patent.
 - 30. Application Serial No. 12/107,389 was filed with the USPTO on April 22, 2008.
- 31. Application Serial No. 12/107389 issued as United States Patent No. 8,017,150, (the "'150 Patent") on September 13, 2011. It was entitled "Polyethylene Oxide Based Films and Drug Delivery Systems Made Therefrom" and named Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. PTX 1.
 - 32. Plaintiff MonoSol owns the '150 Patent
 - 33. Plaintiff RBP is an exclusive licensee of the '150 Patent.
- 34. Plaintiffs caused the FDA to list the '832, '514, and '150 Patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") entry for Suboxone sublingual film.



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

