IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES S.A., and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 14-1451-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP., Defendants.	Civil Action No. 14-1573-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC., Defendants.	Civil Action No. 14-1574-RGA

TRIAL OPINION

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August 31, 2017

ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc.,[1] RB Pharmaceuticals Limited,[2] and MonoSol Rx, LLC (collectively, "Plaintiffs") bring this suit against Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"),[3] Defendant Watson Laboratories, Inc.[4] ("Watson"), and Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corporation (collectively, "Par"). This opinion addresses allegations of infringement and invalidity with respect to U.S. Patent Nos. 8,603,514 ("the '514 patent") and 8,900,497 ("the '497 patent").

The Court held a four-day bench trial relating to these patents. (D.I. 299; D.I. 300; D.I. 301; D.I. 302).[5] The parties filed proposed findings of fact (D.I. 275), post-trial briefing with respect to infringement (D.I. 279; D.I. 285; C.A. No. 14-1574, D.I. 184; C.A. No. 14-1573, D.I. 203; D.I. 295), and post-trial briefing with respect to invalidity (D.I. 278; D.I. 288; D.I. 293). I have also considered letters submitted regarding *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017). (D.I. 309; D.I. 310). Having considered the documentary evidence and testimony, I make the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

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[1] Citations to "D.I.___" are to the docket in C.A. No. 14-1451 unless otherwise noted. Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is now known as Indivior Inc. (D.I. 228-2, Admitted Fact No. 2).

[2] Plaintiff Reckitt Benckiser Pharmaceuticals Limited is now known as Indivior UK Limited. (D.I. 228-2, Admitted Fact No. 4).

[3] DRL was substituted as a party in place of Teva Pharmaceuticals USA, Inc. following Teva's transfer of ownership of ANDA Nos. 205299 and 205806 to DRL. (D.I. 228-2, Admitted Fact No. 12 at n.2).

[4] Defendant Watson Laboratories, Inc. is now known as Actavis Laboratories UT, Inc. (D.I. 228-2, Admitted Fact No. 6).

[5] Although the official transcript is filed in four parts (D.I. 299; D.I. 300; D.I. 301; D.I. 302), citations to the transcript herein are generally cited as "Tr."

I. BACKGROUND

Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is the holder of approved New Drug Application No. 22-410 for Suboxone® sublingual film, which is indicated for maintenance treatment of opioid dependence. (D.I. 228-2, Admitted Fact Nos. 13–14, 20). The active ingredients of Suboxone® sublingual film are buprenorphine hydrochloride and naloxone hydrochloride. (D.I. 228-2, Admitted Fact No. 15). Suboxone® sublingual film is available in four dosage strengths (buprenorphine hydrochloride/naloxone hydrochloride): 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg. (D.I. 228-2, Admitted Fact Nos. 16–18). Since the approval of NDA No. 22-410, Suboxone® sublingual film has been exclusively manufactured in the United States by Plaintiff MonoSol and exclusively sold in the United States by Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. (D.I. 228-2, Admitted Fact No. 19).

The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," issued on December 10, 2013. (D.I. 228-2, Admitted Fact No. 21). The '514 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalences Evaluations (the "Orange Book") as covering Suboxone® sublingual film. (D.I. 228-2, Admitted Fact No. 23).

The '497 patent, entitled "Process for Making a Film Having a Substantially Uniform Distribution of Components," issued on December 2, 2014. (D.I. 228-2, Admitted Fact No. 27). Plaintiff MonoSol owns the '514 and '497 patents and Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is an exclusive licensee of the '514 and '497 patents. (D.I. 228-2, Admitted Fact Nos. 22, 28).

Plaintiffs are asserting claims 62–65, 69, 71, and 73 of the '514 patent against DRL. (D.I. 228-2, Admitted Fact No. 91; D.I. 279 at 1 n.1). Claim 62 of the '514 patent is an

independent claim. Claims 63, 64, 65, 69, 71, and 73 all depend from claim 62. (D.I. 228-2, Admitted Fact No. 92). The '514 patent was separately tried against Watson and Par. (C.A. No. 13-1674, D.I. 446).

The asserted independent claim of the '514 patent reads as follows.

> 62. A drug delivery composition comprising:
>
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active;
>
> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
>
> (ii) a particulate active substantially uniformly stationed in the matrix; and
>
> (iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;
>
> wherein the particulate active has a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being *dried* without loss of substantial uniformity in the stationing of said particulate active therein; and
>
> wherein the uniformity subsequent to casting and *drying* of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

(JTX-2, claim 62) (emphases added).

Plaintiffs are asserting claim 24 of the '497 patent against all Defendants. (D.I. 228-2, Admitted Fact Nos. 30, 64, 95). Claim 24 of the '497 patent depends from claim 1. (D.I. 228-2, Admitted Fact No. 96). Claims 1 and 24 of the '497 patent reads as follows.

> 1. A process for making a film having a substantially uniform distribution of components, comprising the steps of:
>
> (a) forming a flowable polymer matrix comprising an edible polymer, a solvent and a desired amount of at least one active, said matrix having a substantially uniform distribution of said at least one active;

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