IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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. 13-1674-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. 14-422-RGA

TRIAL OPINION

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June 3, 2016

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Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited, and MonoSol Rx, LLC (collectively, "Reckitt") brought this suit against Defendants Watson Laboratories, Inc. and Actavis Laboratories UT, Inc. (collectively, "Watson") (D.I. 1, 11, 287)[1] and Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corporation (collectively, "Par") (C.A. No. 14-422 D.I. 1, 9, 14; D.I. 80) alleging infringement of U.S. Patent Nos. 8,475,832 ("the '832 patent"); 8,603,514 ("the '514 patent"); and 8,017,150 ("the '150 patent"). Reckitt's suits against Watson and Par were consolidated for all pretrial proceedings. (D.I. 66; C.A. No. 14-422 D.I. 19). The Court held a four day bench trial. (D.I. 414, 415, 416, 417).[2] On November 3–4, 2015, the parties addressed the validity of the '150 and '514 patents and infringement of the '150 patent by Watson (D.I. 414, 415). On December 17–18, 2015, the parties addressed the validity of the '832 patent, infringement of the '150 patent by Par, and infringement of the '832 and '514 patents by Watson and Par (D.I. 416, 417). The parties filed post-trial briefing (D.I. 396, 397, 406, 407, 408, 410, 411) and proposed findings of fact (D.I. 400).[3] Having considered the documentary evidence and testimony, the Court makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

[1] Citations to "D.I.___" are to the docket in C.A. No. 13-1674 unless otherwise noted.
[2] Although the official transcript is filed in four parts (D.I. 414, 415, 416, 417), citations to the transcript herein are generally cited as "Tr."
[3] Reckitt also submitted a notice of supplemental authority on March 28, 2016 (D.I. 424), informing the Court of the final written decisions of the Patent Trial and Appeal Board in *inter partes* review proceedings of a patent related to the '514 patent.

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I. BACKGROUND

A. Overview

Plaintiff Reckitt Benckiser Pharmaceuticals is the holder of approved New Drug Application ("NDA") No. 22-410 for Suboxone® sublingual film, which is indicated for maintenance treatment of opioid dependence. (D.I. 353-1 at ¶¶ 10, 16). The active ingredients of Suboxone® sublingual film are buprenorphine hydrochloride and naloxone hydrochloride. (*Id.* at ¶ 17). Buprenorphine is an opioid. (Tr. 1292:7–11; DFF137).[4] Naloxone is an opioid antagonist that prevents the action of opioids like buprenorphine when delivered simultaneously to the bloodstream of a user. (Tr. 1293:3–17, 1474:9–14). Suboxone® sublingual film includes both buprenorphine and naloxone to prevent unintended diversion of the product for abuse. (Tr. 1474:9–14).

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. 353-1 at ¶ 17). Plaintiff RB Pharmaceuticals Limited is the assignee of the '832 patent, entitled "Sublingual and Buccal Film Compositions." (*Id.* at ¶ 24; '832 patent, (54) & (73)). Plaintiff MonoSol Rx, LLC is the assignee of the '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," and the '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." (D.I. 353-1 at ¶¶ 28, 32; '514 patent, (54) & (73); '150 patent, (54) & (73)). Plaintiff Reckitt Benckiser Pharmaceuticals is an exclusive licensee of the '832, '514, and '150 patents. (D.I. 353-1 at ¶¶ 25, 29, 33). The '832, '514, and '150 patents are listed in the Food and Drug

[4] Citations to "PFF," "DFF," "DPRF," and "DWRF" herein are to the Corrected Joint Proposed Findings of Fact and related responses filed at D.I. 400.

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Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") entry for Suboxone® sublingual film. (*Id.* at ¶ 34).

Watson and Par each filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic versions of the 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg dosage strengths of Suboxone® sublingual film prior to the expiration of the '832, '514, and '150 patents. (*Id.* at ¶¶ 42, 45, 118). Watson seeks approval for its ANDA Product through ANDA Nos. 204383 and 207087.[5] (*Id.* at ¶¶ 43, 45). Par seeks approval for its ANDA Product through ANDA No. 205854. (*Id.* at ¶ 118). Watson's ANDAs and Par's ANDA contain Paragraph IV certifications alleging that the '832, '514, and '150 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic products proposed in the ANDAs. (*Id.* at ¶¶ 43, 44, 46, 119). Reckitt received notices of Watson's and Par's Paragraph IV certifications and initiated the present litigation. (*Id.*; D.I. 1, 11, 80, 287).

B. Asserted Patents

1. '832 Patent

The '832 patent is directed to pharmaceutical film compositions and formulations that contain buprenorphine and naloxone. ('832 patent, 23:58–25:6). Reckitt asserts independent claims 1 and 15 and dependent claims 3, 6, and 16–19 against Watson and Par. (PFF21). The '832 patent issued on July 2, 2013. ('832 patent, (45)). The asserted claims of the '832 patent are entitled to a priority date of August 7, 2009. (D.I. 353-1 at ¶ 120).

Claim 1 of the '832 patent reads:

A film dosage composition comprising:

[5] "Watson's ANDA Product" and "Par's ANDA Product" refer to the parties' respective proposed generic drug formulations.

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