UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

PAR PHARMACEUTICAL, INC., Plaintiff, v. INDIVIOR INC. and INDIVIOR UK LIMITED, Defendants.	Civil Action No.

COMPLAINT

Plaintiff Par Pharmaceutical, Inc. ("Par"), for its Complaint against Indivior Inc. ("Indivior") and Indivior UK Limited ("Indivior UK") (and collectively "Defendants"), alleges as follows:

PRELIMINARY STATEMENT

1. Par seeks redress from Defendants' gamesmanship and forum shopping in asserting its invalid U.S. Patent No. 9,687,454 ("the '454 patent") against Par. Par and Defendants have been in active litigation since 2014, after Par filed with FDA an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic buprenorphine and naloxone sublingual film product used to treat opioid dependence. Defendants sued Par at that time in the United States District Court for the District of Delaware, asserting that Par's ANDA product infringed Defendants' patents directed to buprenorphine and naloxone sublingual films. The parties fully litigated that case through trial. After trial, the Delaware Court held that the asserted claims of U.S. Patent No. 8,475,832 ("the '832 patent") were invalid, and that Par did

not infringe that patent. As set forth in detail below, the invalidated '832 patent is not colorably different from the '454 patent at issue in this Complaint.

2. After the Delaware Court's invalidity judgment with respect to the '832 patent, Defendants promptly submitted new claims to the United States Patent and Trademark Office ("USPTO") in a pending patent application Defendants had on file. The pending application was a "continuation" application to the application that resulted in the invalidated '832 patent, meaning that it contains a word-for-word identical specification as the '832 patent, and is legally entitled to the same priority date as that patent. Defendants' new claims simply rearranged and reworded the limitations in the claims of the '832 patent that the Delaware Court already held to be invalid. To convince the patent Examiner to issue the '454 patent, Defendants misleadingly asserted that the prior art did not disclose the newly recapitulated claim elements. Defendants specifically failed to tell the Examiner that the prior art Suboxone tablet—the same prior art that the Delaware Court held invalidated the related '832 patent—had the identical weight ratios and achieved the absorption parameters set forth in the claim elements Defendants asserted rendered the new claims non-obvious. Defendants also did not tell the Examiner that the Delaware Court had made fact findings that contradicted (and in fact precluded) Defendants' assertions that the prior art did not disclose these claim limitations. But for Defendants' misleading representations, the USPTO would not have issued the '454 patent.

3. To assert the newly-issued '454 patent, Defendants were understandably desperate to avoid the Delaware Court that had invalidated their related '832 patent. Defendants therefore sought a new forum to sue Par on its improperly issued '454 patent, and sued Par in the Southern District of New York—where Par resides and is headquartered. That Court assigned a Judge and set a scheduling conference, and Par was fully engaged with Defendants to address the

requirements of that Court. But Defendants apparently concluded that the Judge and/or schedule in New York were unfavorable to them, and voluntarily dismissed the case before Par filed an answer. On the same day, Defendants filed another suit in New Jersey.

4. Defendants' actions reflect unabashed forum shopping. Defendants filed suit in New Jersey even though venue was blatantly improper as to Par. Plaintiffs did not even bother to allege that Par resides in New Jersey or has a regular or established place of business there. Rather, Defendants attempted to manufacture venue in New Jersey by improperly naming Par's parent companies to the New Jersey suit—even though Defendants had never filed suit against (or otherwise involved in any way) those entities in the previous four years of litigation with Par. Defendants have not served the New Jersey complaint on Par or its parent companies, despite filing the complaint over a month ago. Par is moving to dismiss the New Jersey suit for improper venue over Par, and for lack of personal jurisdiction over its parent company.

5. Par now seeks a declaratory judgment of invalidity and non-infringement in this Court—where Defendant Indivior has its principal place of business and a regular and established place of business, and where Defendant Indivior UK exclusively licensed the '454 patent to Indivior. The present action is the only properly-filed action between Par and Defendants regarding the '454 patent that is currently pending.

NATURE OF ACTION

6. Par seeks declaratory judgment of non-infringement and invalidity of the '454 patent pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

PARTIES

7. Par is a corporation organized and existing under the laws of New York, having a place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Par develops, manufactures, and markets safe, innovative, and cost-effective generic pharmaceutical products that help improve patient quality of life. Par also offers differentiated, specialty dosage and sterile injectable drug products and is advancing a R&D pipeline of potential new products.

8. On information and belief, Defendant Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 4300, Richmond, Virginia.

9. On information and belief, Defendant Indivior UK is a corporation organized under the laws of the United Kingdom having a principal place of business at 103-105 Bath Road, Slough, UK.

10. On information and belief, both Defendant Indivior and Defendant Indivior UK are wholly-owned subsidiaries of Indivior PLC.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a); 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

12. This Court has personal jurisdiction over Indivior. On information and belief, Indivior has a principal place of business in Richmond, Virginia, where it leases over 70,000 square feet of commercial real estate. On information and belief, Indivior is registered to do business in this judicial district and maintains a corporate agent for service of process in this judicial district, at Corporation Service Company, 1111 E. Main Street, 16th Floor, Richmond, Virginia 23219-3531. On information and belief, Indivior regularly does business in this judicial district. On information and belief, Indivior PLC, Indivior's parent, is a predominantly U.S. business, with its operational headquarters in Richmond, Virginia.

13. On information and belief, Indivior has previously been sued in this judicial district and has not challenged personal jurisdiction or venue. *See, e.g.*, *Lemons v. Indivior, Inc.*, No. 3:16-cv-00937-JAG (E.D.Va.).

14. On information and belief, Indivior further availed itself of the jurisdiction of this Court by filing counterclaims in this judicial district. *See, e.g.*, *Lemons v. Indivior, Inc.*, No. 3:16-cv-00937-JAG (E.D.Va.).

15. This Court has personal jurisdiction over Indivior UK. On information and belief, Indivior UK exclusively licensed the '454 patent to Indivior, which regularly does business in this judicial district, and Indivior UK has authorized Indivior to practice the '454 patent, enforce the '454 patent, and defend the validity of the '454 patent in this judicial district.

16. Alternatively, this Court has jurisdiction over Indivior UK under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Par's claims arise under federal law; (b) Indivior UK is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Indivior UK has sufficient contacts with the United States as a whole, not least through its enforcement of the '454 patent in the United States (*see, e.g.*, *Indivior Inc. and Indivior UK Ltd. v. Par Pharm., Inc.*, No. 17-7020-KBF (S.D.N.Y.); *Indivior Inc. and Indivior UK Ltd. v. Par Pharm., Inc., et al.*, No. 17-7997-KM-CLW (D.N.J.); *Indivior Inc. and Indivior UK Ltd. v. Alvogen Pine Brook, Inc.*, No. 17-7106-KM-CLW (D.N.J.); *Indivior Inc. and Indivior UK Ltd. v. Dr. Reddy's Laboratories S.A., et al.*, No. 17-7111-KM-CLW (D.N.J.); *Indivior Inc. and Indivior UK Ltd. v. Teva Pharms. USA, Inc.*, No. 17-7115-KM-CLW (D.N.J.); *Indivior Inc. and Indivior UK Ltd. v. Actavis Labs. UT, Inc.*, No. 17-1034-DBP (D. Utah); and *Indivior Inc. and Indivior UK Ltd. v. Mylan Technologies Inc., et al.*, No. 17-157 (Keeley) (N.D.W.Va.)), such that this Court's exercise of jurisdiction over Indivior UK satisfies due process.

17. Alternatively, this Court has personal jurisdiction over Defendant Indivior UK under 35 U.S.C. § 293. On information and belief, Indivior UK sought and has the privileges and protections of patent ownership in the United States. Defendant Indivior UK is the owner assignee of record of the '454 patent, and is a "patentee not residing in the United States" under 35 U.S.C. § 293. Indivior UK has not filed with the USPTO a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the patent or rights thereunder. 35 U.S.C. § 293. Indivior UK has purposefully availed itself of the privileges of patent ownership through its contacts with the USPTO in this judicial district.

18. Venue is proper in this judicial district under 28 U.S.C. § 1391, 21 U.S.C. § 355(j)(5)(C)(i)(II), and 35 U.S.C. § 293. Defendant Indivior UK is a foreign corporation not resident in the United States and may be sued in any judicial district. Defendant Indivior has its principal place of business and a regular and established place of business in this judicial district.

FACTUAL BACKGROUND

19. The '454 patent, titled "Sublingual and Buccal Film Compositions," issued on June 27, 2017. A true and correct copy of the '454 patent is attached hereto as Exhibit A.

20. On information and belief, the '454 patent is listed in the Orange Book as having an expiration date of August 7, 2029.

21. On information and belief, Indivior UK is the owner of the '454 patent, and Indivior is the exclusive licensee of the '454 patent.

22. On information and belief, Indivior is the holder of New Drug Application ("NDA") No. 022410 for buprenorphine hydrochloride and naloxone hydrochloride sublingual film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, marketed under the brand name Suboxone. Suboxone is a sublingual film indicated for treatment of opioid dependence. In

connection with NDA No. 022410, Indivior caused the U.S. Food and Drug Administration ("FDA") to list the '454 patent in the Orange Book.

23. Par submitted Abbreviated New Drug Application No. 205854 ("Par's ANDA") to FDA requesting regulatory approval to engage in the commercial manufacture, use, or sale of buprenorphine hydrochloride and naloxone hydrochloride sublingual film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg ("Par's ANDA Product"). Par amended Par's ANDA to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '454 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's ANDA Product.

24. On August 7, 2017, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Par provided notice to Defendants of the Paragraph IV Certification to the '454 patent that Par included in its ANDA ("Par's 2017 Notice Letter"), together with an Offer of Confidential Access to Par's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Par's 2017 Notice Letter included a detailed statement of the factual and legal bases why the '454 patent is invalid, unenforceable, and/or will not be infringed.

25. On information and belief, Indivior received Par's 2017 Notice Letter on August 8, 2017. On information and belief, Indivior UK received Par's 2017 Notice Letter on August 9, 2017.

26. Par's provision of Par's 2017 Notice Letter to Defendants triggered a 45-day statutory period during which Defendants had an opportunity to initiate patent infringement litigation. 21 U.S.C. § 355(j)(5)(B)(iii).

27. On September 14, 2017, Defendants filed a suit against Par in the Southern District of New York. *Indivior Inc. v. Par Pharm., Inc.*, Civ. No. 17-7020-KBF (S.D.N.Y.)

("New York complaint"). ECF No. 1 in Civ. No. 17-7020. After Defendants filed suit, the case was assigned to Judge Katherine B. Forrest.

28. On September 22, 2017, Judge Forrest issued an Order setting an initial pre-trial conference in the New York case for October 25, 2017. ECF No. 6 in Civ. No. 17-7020.

29. Judge Forrest's Form Scheduling Order for a Patent Case (attached as Exhibit B) states that fact discovery should be complete "within 6 months of commencement of action unless good reason," and that expert discovery should be complete "25 days after the close of fact discovery; may of course be ongoing throughout."

30. On October 6, 2017, Defendants voluntarily dismissed the New York complaint against Par without prejudice. ECF No. 7 in Civ. No. 17-7020. Defendants did not serve the New York complaint on Par.

31. The same day they dismissed the New York action, Defendants filed in the District of New Jersey a second complaint (Civ. No. 17-7997-KM-CLW) ("New Jersey complaint") asserting infringement of the '454 patent against Par, Par Pharmaceutical Companies Inc. ("PPC"), and Endo International PLC ("Endo International").

32. Paragraph 46 of the New Jersey complaint contains the same infringement allegation of the '454 patent against Par as paragraph 24 of the New York complaint. *Compare* ECF No. 1 in Civ. No. 17-7020 (S.D.N.Y.) ¶ 24 with ECF No. 1 in Civ. No. 17-7997 (D.N.J.) ¶ 46. However, the New Jersey complaint specifies two defendants that were not included in the New York Complaint—PPC and Endo International.

33. Venue is not proper over Par or PPC in New Jersey, and Endo International is not a proper party to the suit. The New Jersey complaint does not aver that either Par or PPC is incorporated in or has a regular and established place of business in New Jersey. The New

Jersey complaint does not aver that the U.S. District Court for the District of New Jersey has authority to exercise specific personal jurisdiction over Endo International. As a result, Par, PPC, and Endo International are filing a motion to dismiss the New Jersey complaint under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction over Endo International and under Federal Rule of Civil Procedure 12(b)(3) for improper venue as to Par and PPC.

34. Defendants' New Jersey complaint was not filed within the 45-day statutory period for filing suit, i.e., by September 22, 2017 for Indivior, and September 23, 2017 for Indivior UK. 21 U.S.C. § 355(j)(5)(B)(iii). Because the 45-day statutory period following Defendants' receipt of Par's 2017 Notice Letter has expired, Par is entitled to bring a declaratory judgment action with respect to the '454 patent. 21 U.S.C. § 355(j)(5)(C)(i).

35. To date, Defendants have not served the New Jersey complaint on Par, PPC, or Endo International.

36. Given related litigation between Par and Defendants involving Par's ANDA (Civ. No. 13-1674-RGA (D. Del.), Case No. 16-2277 (consolidated) (Fed. Cir.), and Civ. No. 14-1573-RGA (D. Del.)), Defendants' actions with respect to the '454 patent (e.g., Civ. No. 17-7020-KBF (S.D.N.Y.) and Civ. No. 17-7997-KM-CLW (D.N.J.)) give rise to a substantial controversy regarding the '454 patent between Par and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the '454 patent is not infringed, invalid, and/or unenforceable.

THE PREVIOUS ANDA LITIGATION BETWEEN THE PARTIES

37. The controversy regarding the '454 patent is one in a series of patent disputes beginning in 2014 between Defendants and Par regarding Par's ANDA.

38. On April 4, 2014, Defendants filed a complaint in the District of Delaware against Par and IntelGenx Technologies Corporation (Par's development partner for Par's ANDA), alleging that Par's ANDA infringed the '832 patent (attached as Exhibit C), and two other patents. *Reckitt Benckiser Pharms. Inc., et al. v. Par Pharm., Inc., et al.*, Civ. No. 14-422-RGA (consolidated with 13-1674-RGA) (D. Del.) ("Delaware Action"). Defendants asserted that Par's ANDA Product will infringe claims 1, 3, 6, and 15-19 of the '832 patent. The patent-in-suit in this case, the '454 patent, issued from U.S. Patent Application No. 14/989,669 ("the '669 application"), and claims priority to the application that issued as the '832 patent. The '454 patent is related to the '832 patent and they share a common specification.

39. The Delaware Court held a bench trial in December 2015. On June 3, 2016, the Delaware Court issued a decision holding that asserted claims 1, 3, and 6 of the '832 patent are invalid as obvious over the prior art, and for failing to meet the statutory definiteness requirement. ECF No. 446 in Civ. No. 13-1674-RGA (D. Del. Jun. 3, 2016) (attached as Exhibit D). The Delaware Court also held claims 15-19 of the '832 patent invalid as obvious. *Id*. The Delaware Court further found that Par's ANDA Product does not infringe claims 1, 3, or 6 of the '832 patent because it does not meet the "local pH" limitation. *Id*. Claims 1, 3, 6, and 15-19 were the only claims of the '832 patent Defendants asserted against Par's product. Accordingly, on June 28, 2016, the Delaware Court entered final judgment of invalidity and non-infringement with respect to the '832 patent. ECF No. 452 in Civ. No. 13-1674-RGA (D. Del. June 28, 2016) (attached as Exhibit E).

40. The Delaware Court found that Suboxone sublingual tablets, PCT Publication WO 2008/025791 to Euro-Celtique ("Euro-Celtique"), PCT Publication WO 2008/040534 to LabTec ("LabTec"); Cassidy et al., "Controlled buccal delivery of buprenorphine," *Journal of*

Controlled Release (1993) ("Cassidy"); U.S. Patent Application Publication No. 2005/0085440 to Birch ("Birch"), and the European Medicines Agency Initial Marketing-Authorisation Document, Scientific Discussion, Oct. 19, 2006 for Suboxone tablets ("European Medicines Agency Document") are prior art to the '832 patent.

41. The Delaware Court found that claims 1, 3, and 6 of the '832 patent are invalid as obvious in light of the Suboxone sublingual tablet, Euro-Celtique, LabTec, Cassidy, and Birch.

42. The Delaware Court also found that claims 15-19 of the '832 patent are invalid as obvious in light of Euro-Celtique and the European Medicines Agency Document.

43. The Delaware Court found that LabTec instructed making non-mucoadhesive orally disintegrating pharmaceutical films intended for gastrointestinal tract absorption that mimic the pharmacokinetic profile and bioabsorption of orally administered drug products such as tablets.

44. The Delaware Court found that LabTec identified Suboxone sublingual tablets as a drug of interest to make into a bioequivalent film.

45. The Delaware Court found that a person of ordinary skill would read the disclosure in LabTec to instruct making a pharmaceutical film mimicking the transmucosal absorption of the Suboxone tablet.

46. The Delaware Court found that formulating a dosage form to achieve specific pharmacokinetic values was routine and formulating orally dissolving films designed for sublingual mucosal absorption was disclosed in Euro-Celtique.

47. The Delaware Court found that Euro-Celtique instructed a person of skill in the art to make pharmaceutical films containing buprenorphine and preferably naloxone.

48. The Delaware Court found that Euro-Celtique disclosed the preferred pharmacokinetic parameters for buprenorphine in its oral dosage forms.

49. The Delaware Court found that Euro-Celtique instructed that "[a]s far as drug substitution therapy is concerned, the effectiveness of the afore-described amounts and pharmacokinetic parameters of buprenorphine and optionally naloxone are known from the pharmaceutical preparations of Subutex® and Suboxone®."

50. The Delaware Court found that the European Medicines Agency Document states the pharmacokinetic parameters of naloxone in Suboxone sublingual tablets.

51. The Delaware Court found that Suboxone sublingual tablets included an "acidic buffer of sodium citrate and citric acid that was effective in pHs ranging from 3.0 to 6.2."

52. The Delaware Court found that a person of ordinary skill in the art would have expected that the lower end of the operative pH range of the Suboxone tablet's sodium citrate and citric acid buffer would achieve the targeted selective bioabsorption parameters for buprenorphine and naloxone.

53. The Delaware Court found that a skilled artisan would have copied the Suboxone tablet's buffer and its pH in creating a film dosage form of buprenorphine and naloxone.

54. The Delaware Court found that a person of skill in the art who did not have access to directly measure the dissolution pH of the Suboxone tablet would have formulated a bioequivalent film within the operative pH range of the buffer and routinely and iteratively modified the formulation to achieve the target bioabsorption parameters.

55. Claims 15-19 of the '832 patent were also held unpatentable in a final written decision by the Patent Trials and Appeals Board, which was affirmed by the Federal Circuit. *BioDelivery Sciences Int'l, Inc. v. RB Pharms. Ltd.*, IPR2014-00325 (attached as Exhibit F),

aff'd, *RB Pharms. Ltd. v. BioDelivery Sciences Int'l, Inc.*, Case No. 2016-1044 (Fed. Cir. Aug. 10, 2016).

THE '454 PATENT

56. While the Delaware Action on the '832 patent was ongoing, Defendants filed the '669 application, which issued as the '454 patent. The '669 application is a continuation of three applications that were abandoned, all of which claim priority to the application that issued as the '832 patent. Ex. A ('454 patent) at cover page.

57. Three months after the Delaware Court invalidated claims 1, 3, 6, and 15-19 of the '832 patent, on September 9, 2016, Defendants submitted new claims in the '669 application that are not patentably distinct from the invalidated claims of the '832 patent. At the same time, Defendants submitted a terminal disclaimer to the '669 application, agreeing that the term of any patent to issue from the '669 application would not extend past the term of the '832 patent.

58. The Patent Office issued the '454 patent on June 27, 2017.

59. The subject matter recited by the claims of the '454 patent is simply a rearrangement and recapitulation of the limitations recited in the claims of the '832 patent that the Delaware Court already held to be invalid.

60. An "oral, self-supporting" film comprising "water-soluble polymer matrix" recited in claim 1 of the '454 patent is an orally dissolving film.

61. Film dosage compositions that are administered to the user through buccal administration or sublingual administration include films that are mucoadhesive to the sublingual mucosa or the buccal mucosa and that when applied on the sublingual mucosa or the buccal mucosa, result in absorption of buprenorphine and naloxone.

62. The subject matter described by the phrase "an oral, self-supporting, [] mucoadhesive film comprising … about 40 wt % to about 60 wt % of a water-soluble polymeric matrix" does not exclude "a film dosage composition comprising a polymeric carrier matrix, wherein said polymeric carrier matrix comprises at least one polymer in an amount of at least 25% by weight of said composition."

63. A pharmaceutically acceptable salt of buprenorphine is a salt of buprenorphine.

64. A pharmaceutically acceptable salt of naloxone is a salt of naloxone.

65. An acidic buffer is a buffer.

66. The ratio of about 2 mg of buprenorphine or a salt thereof to about 0.5 mg of naloxone or a salt thereof is about 4:1.

67. The ratio of about 16 mg of buprenorphine or a salt thereof to about 4 mg of naloxone or a salt thereof is about 4:1.

68. A ratio about 2:1 to about 1:5 by weight of buffer to buprenorphine includes a ratio of about 2:1 to about 1:5 of an acidic buffer to buprenorphine.

69. The phrase "a buprenorphine $C_{(max)}$ from about 0.624 ng/ml to about 5.638 ng/ml" is synonymous with the phrase "a C_{max} of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine."

70. As used in the '832 and '454 patents, the term AUC refers to the mean area under the plasma concentration-time curve value after administration of the compositions formed herein. Given that meaning, the phrase "a buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml" is synonymous with the phrase "mean AUC of between about 5.431 hr*ng/ml to about 56.238 hr*ng/ml for buprenorphine."

71. The phrase "naloxone $C_{(max)}$ from about 41.04 pg/ml to about 323.75 pg/ml" is synonymous with the phrase "C_{max} of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone."

72. As used in the '832 and '454 patents, the term AUC refers to the mean area under the plasma concentration-time curve value after administration of the compositions formed herein. Given that meaning, the phrase "naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml" is synonymous with the phrase "mean AUC of between about 102.88 hr*ng/ml to about 812.00 hr*ng/ml for naloxone."

PRIOR ART TO THE '454 PATENT

Suboxone Sublingual Tablets

73. Indivior (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) previously sold the Suboxone sublingual tablet. Suboxone tablets were approved by FDA in October 2002, and Reckitt Benckiser Pharmaceuticals Inc. launched Suboxone tablets in 2003. *See* ECF No. 358 in Civ. No. 13-1674-RGA, at ¶¶ 151, 191.

74. The Suboxone sublingual tablet, and the tablet label (Ex. G), are prior art to the '832 patent. *See id*. at ¶ 123.

75. Suboxone sublingual tablets contained both buprenorphine and naloxone and were indicated for the treatment of opioid dependence. Ex. G (Suboxone tablet label) at 13.

76. Suboxone sublingual tablets were available in dosage strengths of 2 mg buprenorphine with 0.5 mg naloxone and 8 mg buprenorphine with 2 mg naloxone. Ex. G (Suboxone tablet label) at 7.

77. Suboxone sublingual tablets contain about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof.

78. Suboxone sublingual tablets contain about 0.5 mg to about 16 mg of naloxone or a pharmaceutically acceptable salt thereof.

79. Suboxone sublingual tablets contain citric acid and sodium citrate. Ex. G (Suboxone tablet label) at 8.

80. Suboxone sublingual tablets contain an acidic buffer.

81. Suboxone sublingual tablets contain buprenorphine with naloxone at a ratio of 4:1. Ex. G (Suboxone tablet label) at 10.

82. Suboxone sublingual tablets contain a weight ratio of buprenorphine to naloxone of about 4:1.

83. Suboxone sublingual tablets are administered sublingually. Ex. G (Suboxone tablet label) at 22.

84. Suboxone sublingual tablets have a weight ratio of acidic buffer to buprenorphine from 2:1 to 1:5.

85. Application of Suboxone sublingual tablets on the sublingual mucosa results in differing absorption between buprenorphine and naloxone.

86. The administration of 4 mg buprenorphine and 1 mg naloxone from Suboxone sublingual tablets resulted in a buprenorphine C_{max} of 1.84 ng/ml and 2.33 ng/ml, and the administration of 8 mg buprenorphine and 2 mg naloxone from Suboxone sublingual tablets resulted in a buprenorphine C_{max} of 3.0 ng/ml and 3.53 ng/ml. Ex. G (Suboxone tablet label) at 10; Ex. H (European Medicines Agency Document) at 12-13.

87. The administration of 4 mg buprenorphine and 1 mg naloxone from Suboxone sublingual tablets resulted in a buprenorphine AUC of 12.52 hr*ng/ml and 13.09 hr*ng/ml, and the administration of 8 mg buprenorphine and 2 mg naloxone from Suboxone sublingual tablets

resulted in a buprenorphine AUC of 20.22 hr*ng/ml and 23.23 hr*ng/ml. Ex. G (Suboxone tablet label) at 10; Ex. H (European Medicines Agency Document) at 12-13.

88. The administration of 4 mg buprenorphine and 1 mg naloxone from Suboxone sublingual tablets resulted in a naloxone C_{max} of 120 pg/ml, and the administration of 8 mg buprenorphine and 2 mg naloxone from Suboxone sublingual tablets resulted in a naloxone C_{max} of 250 pg/ml. Ex. H (European Medicines Agency Document) at 12-13.

89. The administration of 4 mg buprenorphine and 1 mg naloxone from Suboxone sublingual tablets resulted in a naloxone AUC of 120 hr*pg/ml, and the administration of 8 mg buprenorphine and 2 mg naloxone from Suboxone sublingual tablets resulted in a naloxone AUC of 300 hr*pg/ml. Ex. H (European Medicines Agency Document) at 12-13.

90. The application of Suboxone sublingual tablets on the sublingual mucosa resulted in a buprenorphine C_{max} from about 0.624 ng/ml to about 5.638 ng/ml.

91. The application of Suboxone sublingual tablets on the sublingual mucosa resulted in a buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml.

92. The application of Suboxone sublingual tablets on the sublingual mucosa resulted in a naloxone C_{max} from about 41.04 pg/ml to about 323.75 pg/ml.

93. The application of Suboxone sublingual tablets on the sublingual mucosa resulted in a naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml.

Euro-Celtique

94. Euro-Celtique discloses oral mucoadhesive films. Ex. I (Euro-Celtique) at 20, 25.

95. Euro-Celtique discloses oral mucoadhesive films having a matrix comprising water-soluble polymers. Ex. I (Euro-Celtique) at 17.

96. Euro-Celtique discloses that the polymer matrix comprising water-soluble polymers of oral mucoadhesive films may be between 3-98% by weight, 7-80% by weight, and 20-50% by weight. Ex. I (Euro-Celtique) at 19.

97. Euro-Celtique discloses oral mucoadhesive films comprising buprenorphine between approximately 0.1-16 mg buprenorphine or the equivalent amounts of a pharmaceutically acceptable salt thereof. Ex. I (Euro-Celtique) at 4.

98. Euro-Celtique discloses films comprising 2 mg buprenorphine hydrochloride and 0.5 mg naloxone, and 8 mg buprenorphine hydrochloride and 2 mg naloxone hydrochloride. Ex. I (Euro-Celtique) at 11.

99. Euro-Celtique discloses that pH modifiers such as citric acid can be incorporated into the film. Ex. I (Euro-Celtique) at 15.

100. Euro-Celtique discloses a weight ratio of 4:1 buprenorphine to naloxone. Ex. I (Euro-Celtique) at 11.

101. Euro-Celtique discloses application of oral mucoadhesive films on the sublingual mucosa results in absorption of buprenorphine.

102. Euro-Celtique discloses films having a buprenorphine C_{max} of 1.5-2.5 (1.7-2 preferred) ng/ml for a 4 mg buprenorphine film, 2.5-3.5 (2.75-3.25 preferred) ng/ml for an 8 mg buprenorphine film, and 5-7 (5.5-6.5 preferred) ng/ml for a 16 mg buprenorphine film, when administered. Ex. I (Euro-Celtique) at 9.

103. Euro-Celtique discloses films having a buprenorphine AUC of 10-15 (12-13 preferred) hr*ng/ml for a 4 mg buprenorphine film, 15-25 (20-22 preferred) hr*ng/ml for an 8 mg buprenorphine film, and 25-40 (30-35 preferred) hr*ng/ml for a 16 mg buprenorphine film, when administered. Ex. I (Euro-Celtique) at 9.

104. Euro-Celtique discloses films with the same amounts of buprenorphine and naloxone as Suboxone sublingual tablets, and the same efficacy. Ex. I (Euro-Celtique) at 22.

LabTec

105. LabTec discloses a film product that mimics the pharmacokinetics of an innovator's product, and that follows the same metabolic and bioabsorption pathways as the innovator's product, to ensure that the dosage form achieves the proven clinical efficacy of the innovator product. Ex. J (LabTec) at 3.

106. LabTec identifies Suboxone sublingual tablets as a drug to make into a bioequivalent film. Ex. J (LabTec) at 23.

107. LabTec discloses pharmacokinetic parameters for Suboxone sublingual tablets. Ex. J (LabTec) at 23.

108. LabTec discloses a buprenorphine C_{max} of 1.84 ng/ml for a 4 mg buprenorphine dose from Suboxone sublingual tablets, 3.0 ng/ml for an 8 mg buprenorphine dose from Suboxone sublingual tablets, and 5.95 ng/ml for a 16 mg buprenorphine dose from Suboxone sublingual tablets, when administered. Ex. J (LabTec) at 23.

109. LabTec discloses a buprenorphine AUC of 12.52 hr*ng/ml for a 4 mg buprenorphine dose from Suboxone sublingual tablets, 20.22 hr*ng/ml for an 8 mg buprenorphine dose from Suboxone sublingual tablets, and 34.89 hr*ng/ml for a 16 mg buprenorphine dose from Suboxone sublingual tablets, when administered. Ex. J (LabTec) at 23.

110. LabTec discloses a naloxone C_{max} of 111-280 ng/ml for a 1-4 mg naloxone dose from Suboxone sublingual tablets, when administered. Ex. J (LabTec) at 23.

111. LabTec discloses that pH adjusting agents can be used to adjust the pH of the film. Ex. J (LabTec) at 16.

THE ’454 PATENT IS UNENFORCEABLE

112. Defendants sought and obtained claims in the ’454 patent that are surreptitiously re-arranged combinations of limitations from the invalidated claims of the ’832 patent. The claims of the ’454 patent are invalid as obvious over the same prior art and for the same reasons that the Delaware Court found claims 1, 3, 6, and 15-19 of the ’832 patent to be invalid.

113. At least prosecuting attorney Edward Grieff and on information and belief other individuals associated with the filing and prosecution of the ’669 application and its related applications on behalf of Defendants (“Defendants’ Representatives”) knew that the claims submitted during the prosecution of the ’669 application that issued in the ’454 patent were not patentable in light of material prior art on which the Delaware Court relied in finding claims 1, 3, 6, and 15-19 of the ’832 patent to be invalid and in light of the Delaware Court’s highly material findings based thereon, and yet Defendants’ Representatives failed to bring that material information to the attention to the Examiner responsible for examining the ’669 application with the specific intent to mislead the Examiner into allowing the claims issued in the ’454 patent.

114. 37 C.F.R. § 1.56 imposed on Defendants’ Representatives a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability as defined in 37 C.F.R § 1.56.

115. On September 9, 2016, Defendants Representatives’ submitted claims in the ’669 application directed to a mucoadhesive film comprising (a) about 40 wt% to about 60 wt% of a water-soluble polymeric matrix; (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof; (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and (d) a buffer; wherein the film is mucoadhesive to

the sublingual mucosa or the buccal mucosa; wherein the weight ratio of (b):(c) is about 4:1; and wherein the weight ratio of (d):(b) is from 2:1 to 1:5, thereby providing a buprenorphine Cmax from about 0.624 ng/ml to about 5.638 ng/ml and a buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml; and a naloxone Cmax from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone ACU from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml [sic, naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml]. *See, e.g.*, Claim 11, 9/9/2016 Amendment.

116. On September 23, 2016, the Examiner rejected the claims described above in ¶ 115 under 35 U.S.C. § 103 as unpatentable over Euro-Celtique (referred to as "Oksche" by the Examiner). *See* 9/23/2016 Office Action. The Examiner stated that it would have been obvious to the ordinarily skilled artisan to modify the teachings in Euro-Celtique to identify the optimal range of pH/dosage/ratio of naloxone to buprenorphine in an effort to identify formulations that would provide absorption of both agonist and antagonist as recited in the claims submitted by Defendants' Representatives, and that identification of the optimal pH/dosage was a matter of routine experimentation.

117. In response to the Examiner's rejection described above in ¶ 116, on December 13, 2016, Defendants' Representatives argued that the submitted claims were not obvious over Euro-Celtique. Specifically, Defendants' Representatives argued that Euro-Celtique "provides no teaching or suggestion of the importance of the presently claimed weight ratio of buprenorphine to naloxone and weight ratio of buffer to buprenorphine that is necessary to simultaneously maximize the mucosal absorption of buprenorphine and minimize the mucosal absorption of naloxone, which results in the presently claimed buprenorphine and naloxone C_{max} and AUC, which provides the therapeutic efficacy of the formulation in treating opioid

dependence. Without any understanding of the importance or function of the buffer in mucosal absorption of buprenorphine and naloxone that are used in a ratio of 4:1, the skilled artisan would have no reason or motivation to optimize the buffer based on the teachings in [Euro-Celtique]." 12/13/2016 Response.

118. Defendants' Representatives further argued in response to the rejection described above in ¶ 116 that "it was unexpectedly discovered, as shown by Examples 6-8, that the claimed invention unexpectedly provides a buffer having the capacity to simultaneously produce the desired absorption of buprenorphine and the inhibition of naloxone absorption."

119. Defendants' Representatives further argued in response to the rejection described above in ¶ 116 that because Euro-Celtique "does not teach the importance of the claimed weight ratio of buprenorphine to naloxone from 4:1 and the claimed weight ratio of buffer to buprenorphine from 2:1 to 1:5, which are both necessary to provide a pH that simultaneously maximizes buprenorphine absorption and inhibits naloxone absorption, the skilled artisan would not be motivated to arrive at the presently claimed invention based on the teachings in [Euro-Celtique]."

120. On information and belief, at the time that Defendants' Representatives made the representations to the USPTO described above in ¶¶ 117-119, Defendants' Representatives were aware that the prior-art Suboxone sublingual tablet had a weight ratio of buffer to buprenorphine from 2:1 to 1:5, and which resulted in the claimed buprenorphine and naloxone C_{max} and AUC, but concealed that fact from the USPTO. That information was material to the patentability of the claims submitted by Defendants' Representatives in the '669 application on September 9, 2016, and the claims that issued in the '454 patent.

121. On information and belief, at the time that Defendants' Representatives made the representations to the USPTO described above in ¶¶ 117-119 of this Complaint, Defendants' Representatives were also aware that the Delaware Court had found that Suboxone tablets contained an acidic buffer, that a skilled artisan "would have copied the buffer and pH of the Suboxone tablet in creating a film dosage form of buprenorphine and naloxone," and that a skilled artisan "would have expected that the lower end of the operative pH range of the Suboxone tablet's sodium citrate and citric acid buffer would achieve the targeted selective bioabsorption parameters for buprenorphine and naloxone." Ex. D (ECF No. 446 in Civ. No. 13-1674-RGA) at 13. That information was material to the patentability of the claims submitted by Defendants' Representatives in the '669 application on September 9, 2016, and the claims that issued in the '454 patent.

122. Defendants' Representatives intentionally obscured the Delaware Court's findings described above in ¶ 121 of this Complaint from the USPTO by including only a citation to the Delaware Court's 61-page ruling on an Information Disclosure Statement (IDS) among a voluminous list of 323 mostly less relevant references.

123. Defendants' Representatives' arguments during prosecution of the '669 application opposing the USPTO's arguments of unpatentability that it was unexpected that the buffer in the claimed invention had the capacity to produce the claimed buprenorphine and naloxone C_{max} and AUC was inconsistent with the fact that the prior-art Suboxone sublingual tablet contained a buffer that produced the claimed buprenorphine and naloxone C_{max} and AUC, and contrary to the prior findings by the Delaware Court that a skilled artisan would have copied the buffer in the Suboxone sublingual tablet to achieve the same levels of absorption of buprenorphine and inhibition of naloxone absorption.

124. The Suboxone sublingual tablet, in combination with at least Euro-Celtique, establishes a *prima facie* case of unpatentability of the claims submitted by Defendants' Representatives in the '669 application on September 9, 2016, and the claims that issued in the '454 patent.

125. But for Defendants' Representatives' arguments that the prior art did not disclose that the weight ratio of buffer to buprenorphine resulted in the claimed buprenorphine and naloxone C_{max} and AUC, the Examiner would not have withdrawn her rejection over Euro-Celtique and allowed the claims.

126. But for Defendants' Representatives' concealment of the weight ratio of buffer to buprenorphine in the Suboxone sublingual tablet, the Examiner would not have withdrawn her rejection that it would have been obvious to modify the teachings of Euro-Celtique to provide the claimed buprenorphine and naloxone C_{max} and AUC.

127. But for Defendants' Representatives' actions in obscuring the findings from the Delaware court that a skilled artisan would have copied the buffer in the Suboxone sublingual tablet to make a film dosage form of buprenorphine and naloxone to achieve the claimed buprenorphine and naloxone C_{max} and AUC, the Examiner would not have withdrawn her rejection that it would it would have been obvious to modify the teachings of Euro-Celtique to provide the claimed buprenorphine and naloxone C_{max} and AUC.

128. Defendant Indivior (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) has admitted that it developed and sold Suboxone sublingual tablets. On information and belief, the information regarding Suboxone sublingual tablets described above in paragraphs ¶ 120 and the Delaware Court's findings related thereto described above in ¶ 121 of this Complaint was known to Defendants' Representatives. By withholding such material information from the

USPTO, Defendants' Representatives engaged in a pattern of deceptive behavior and acted with specific intent to deceive the USPTO.

COUNT ONE
Declaratory Judgment Regarding Invalidity of U.S. Patent No. 9,687,454

129. Par reasserts and realleges each paragraph above as if fully set forth herein.

130. An actual and justiciable controversy exists between the parties with respect to the '454 patent. Par is entitled to a declaratory judgment that the '454 patent is invalid.

131. The claims of the '454 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

132. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

COUNT TWO
Declaratory Judgment Regarding Collateral Estoppel

133. Par reasserts and realleges each paragraph above as if fully set forth herein.

134. An actual and justiciable controversy exists between the parties with respect to the '454 patent. Par is entitled to a declaratory judgment that Defendants are collaterally estopped from asserting that the claims of the '454 patent are non-obvious based on the findings in the district court litigation in *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc.*, Civ. No. 13-1674-RGA (D. Del.), and the final written decision in *BioDelivery Sciences International, Inc. v. RB Pharmaceuticals Limited*, IPR2014-00325 (Paper No. 43), *aff'd*, *RB Pharmaceuticals Limited v. BioDelivery Sciences International, Inc.*, Case No. 2016-1044 (Fed. Cir. Aug. 10, 2016) regarding the '832 patent.

135. The issues of whether the claims of the '454 patent are invalid as obvious in light of the prior art Suboxone sublingual tablet, Euro-Celtique, LabTec, and the European Medicines

Agency Document are identical to the issues previously adjudicated with respect to obviousness of claims 1, 3, 6, and 15-19 of the ’832 patent in the Delaware Action and in IPR2014-00325.

136. The issues regarding obviousness of claims 1, 3, 6, and 15-19 of the ’832 patent were actually litigated, in the Delaware Action and in IPR2014-00325.

137. The resolution of the issues of obviousness of claims 1, 3, 6, and 15-19 of the ’832 patent in the Delaware Action and in IPR2014-00325 was essential to the final judgments in those actions.

138. The judgments in the Delaware Action and in IPR2014-00325 are final and valid.

139. Defendants had a full and fair opportunity to litigate the issues regarding obviousness of claims 1, 3, 6, and 15-19 of the ’832 patent in the Delaware Action and in IPR2014-00325.

140. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys’ fees.

COUNT THREE
Declaratory Judgment Regarding Non-Infringement of U.S. Patent No. 9,687,454

141. Par reasserts and realleges each paragraph above as if fully set forth herein.

142. An actual and justiciable controversy exists between the parties with respect to the ’454 patent. Par is entitled to a declaratory judgment that the ’454 patent is not infringed.

143. Par’s submission to FDA of Par’s ANDA did not infringe any valid claim of the ’454 patent, because, *inter alia*, Par’s ANDA Product does not contain an “acidic buffer” as required by every claim of the ’454 patent.

144. The commercial manufacture, use, offer for sale, sale, or importation of Par’s ANDA Product will not infringe any claim of the ’454 patent, because, *inter alia*, Par’s ANDA Product does not contain an “acidic buffer” as required by every claim of the ’454 patent.

145. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

COUNT FOUR
Declaratory Judgment Regarding Unenforceability of U.S. Patent No. 9,687,454

146. Par reasserts and realleges each paragraph above as if fully set forth herein.

147. An actual and justiciable controversy exists between the parties with respect to the '454 patent. Par is entitled to a declaratory judgment that the '454 patent is unenforceable due to inequitable conduct before the USPTO. This conduct includes withholding and/or obscuring material information regarding the prior-art Suboxone sublingual tablet and the Delaware Court's findings regarding the related '832 patent, and making material, intentionally misleading statements that were inconsistent with the record from the Delaware Action, all with the specific intent to deceive the USPTO.

148. But for the withheld and/or obscured material information and/or material misleading statements, the USPTO would not have allowed the claims of the '669 application over the Euro-Celtique reference.

149. This is an exceptional case, and Par is entitled to its costs and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the claims of the '454 patent are invalid;

B. Declare that Defendants are collaterally estopped from asserting that the claims of the '454 patent are non-obvious;

C. Declare that Par's ANDA does not infringe any valid claim of the '454 patent;

D. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par's ANDA Product will not infringe any valid claim of the '454 patent;

E. Declare that the '454 patent is unenforceable;

F. Award Par its costs and reasonable attorneys' fees; and

G. Award Par such other and further relief as the Court deems just and proper.

Dated: November 13, 2017

Respectfully Submitted,

/s/ Maximilian A. Grant

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