IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL PRODUCTS IP LIMITED, MALLINCKRODT HOSPITAL PRODUCTS INC., and NEW PHARMATOP L.P.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ALTAN PHARMA LTD.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt Hospital Products IP Limited, Mallinckrodt Hospital Products Inc., and New Pharmatop L.P. ("Plaintiffs"), by their attorneys, file this Complaint for patent infringement against Defendant Altan Pharma Ltd. ("Defendant" or "Altan") and allege as follows:

PARTIES

1. Plaintiff Mallinckrodt Hospital Products IP Limited ("Mallinckrodt Hospital Products IP") is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt Hospital Products IP is a wholly-owned subsidiary of Mallinckrodt plc. As set forth herein, Mallinckrodt Hospital Products IP is the assignee of U.S. Patent No. 9,399,012 (the "'012 patent"), U.S. Patent No. 9,610,265 (the "'265 patent"), and U.S. Patent No. 9,987,238 (the "'238 patent"), and is the exclusive sub-licensee of U.S. Patent No. 6,992,218 (the "'218 patent") (collectively, the "Patents-in-Suit").

2. Plaintiff Mallinckrodt Hospital Products Inc. ("Mallinckrodt Hospital Products"), formerly Cadence Pharmaceuticals, Inc. ("Cadence"), is a company organized and existing under the laws of Delaware, having a principal place of business at 675 McDonnell Blvd., Hazelwood, Missouri 63042. Mallinckrodt Hospital Products is a wholly-owned subsidiary of Mallinckrodt plc.

3. Plaintiff New Pharmatop L.P. ("New Pharmatop") is a Delaware limited partnership having its registered office c/o Corporation Services Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware. As set forth herein, New Pharmatop is the current assignee of the '218 patent.

4. Upon information and belief, Defendant Altan Pharma Ltd. is a company organized under the laws of Ireland, having a principal place of business at 2 Harbour Square, Crofton Road, Dun Laoghaire, Co. Dublin, Ireland. Upon information and belief, Altan is in the business of manufacturing, distributing, and selling pharmaceutical products throughout Europe, Latin America, and Asia, and intends to expand sales to the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of the Patents-in-Suit 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. §§ 301 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

7. This Court has personal jurisdiction over Altan by virtue of actions Altan has taken for purposes of engaging in injury-causing and wrongful market conduct in this District.

See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625, 196 L. Ed. 2d 580 (2017).

8. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan has submitted New Drug Application ("NDA") No. 209841 (the "Altan NDA"), claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product, and Altan is currently seeking nationwide approval of its proposed product. By a letter dated February 8, 2019 and received after that date (the "Altan Letter"), Altan stated that it had submitted NDA No. 209841 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Acetaminophen Solution for Infusion 10 mg/mL (the "Altan NDA Product") prior to the expiration of the '218 Patent. Altan's submission of the Altan NDA constitutes infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 271(e). Altan's tortious act of infringing the Patents-in-Suit causes concrete harm to Plaintiffs.

9. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan, through the submission of the Altan NDA, intends to commercially manufacture, use, import, market, offer for sale, and sell the Altan NDA Product throughout the United States, including in this District, in the event the United States Food and Drug Administration ("FDA") approves the Altan NDA.

10. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan is in the business of developing pharmaceutical drug products that it distributes in Europe, Latin America, and Asia, and intends to distribute in the United States, including in this District.

11. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan, itself or through one of its business partners and/or affiliates,

intends to enter into agreements with pharmaceutical retailers, wholesalers, or distributors, providing for the distribution of its products throughout the United States, including in this District.

12. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan, itself or through one of its business partners or affiliates, intends to distribute pharmaceutical drug products throughout the United States, including in this District.

13. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan intends to sell pharmaceutical drug products in pharmacies throughout the United States, including in this District.

14. This Court has personal jurisdiction over Altan because, *inter alia*, upon information and belief, Altan intends to derive substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in this District.

15. Alternatively, this Court has jurisdiction over Altan under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Plaintiffs' claims arise under federal law; (b) Altan is a foreign defendant not subject to general personal jurisdiction in the Courts of any state; and (c) Altan has sufficient contacts with the United States as a whole, not least through its commercialization of a drug in the United States, such that this Court's exercise of jurisdiction over Altan satisfies due process.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b). Upon information and belief, Altan is a foreign entity that may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction. As set forth *supra*, Altan is subject to the Court's personal jurisdiction in this District.

17. This action involves patents that have already been at issue in prior actions before this Court. The ’218 Patent was at issue in the following exemplary actions: *Cadence Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, No. 11-733; *Cadence Pharmaceuticals, Inc. v. InnoPharma Licensing LLC*, No. 14-1225; *Mallinckrodt IP v. Mylan Laboratories Ltd.*, No. 14-1499; and *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-365. The ’012 Patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. InnoPharma Licensing LLC*, No. 16-1116; *Mallinckrodt IP v. Mylan Laboratories Ltd.*, No. 16-1115; and *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-365. The ’265 patent was previously at issue in the action captioned *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-660. The ’238 patent was previously at issue in the action captioned *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 18-1090.

THE PATENTS-IN-SUIT

18. The ’218 patent, titled “Method for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on January 31, 2006. Named inventors Francois Dietlin and Daniele Fredj assigned the application which issued as the ’218 patent to SCR Pharmatop (“Pharmatop”).

19. Pharmatop, which subsequently assigned the ’218 patent to New Pharmatop, granted an exclusive license to the ’218 patent to Bristol-Myers Squibb Company (“BMS”) with a right to sublicense. BMS granted Cadence (now Mallinckrodt Hospital Products) a sublicense, which was exclusive even to BMS, to the ’218 patent with regard to all rights pertinent hereto. As a result of the corporate restructuring following the purchase of Cadence by Mallinckrodt plc, Mallinckrodt Hospital Products IP is the exclusive sub-licensee of the ’218 patent. A true and correct copy of the ’218 patent is attached as Exhibit A.

20. Claim 1 of the ’218 patent recites: “[a] method for preparing an aqueous solution with an active nature susceptible to oxidation, which is paracetamol, while preserving for a prolonged period, comprising deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm, and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm, and optionally the deoxygenation of the solution is completed by addition of an antioxidant.”

21. The ’012 patent, titled “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on July 26, 2016. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the ’012 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited Company (“Mallinckrodt IP Unlimited”), which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the ’012 patent. A true and correct copy of the ’012 patent is attached as Exhibit B.

22. Claim 1 of the ’012 patent recites “[a] method for the treatment of pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, comprising administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen; and repeating said administration at least once at an interval of about 3 to about 5 hours.”

23. The ’265 patent, titled “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on April 4, 2017. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the ’265 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited, which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the ’265 patent. A true and correct copy of the ’265 patent is attached as Exhibit C.

24. Claim 1 of the ’265 patent recites “[a] method of treating pain in a human subject weighing at least 50 kg comprising: co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount a second pharmaceutical composition comprising an opioid analgesic; wherein the first pharmaceutical composition is administered to the subject intravenously.”

25. The ’238 patent, “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on June 5, 2018. Named inventors Mike Allan Royal and James Bradley Breitmeyer assigned the application that issued as the ’238 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP, which subsequently changed its name to Mallinckrodt IP Unlimited, which subsequently assigned that application to Mallinckrodt Hospital Products IP. Mallinckrodt Hospital Products IP is now the sole assignee of the ’238 patent. A true and correct copy of the ’238 patent is attached as Exhibit D.

26. Claim 1 of the ’238 patent recites “[a] method of treating pain in a human subject, in need thereof, weighing at least 50 kg comprising: administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to

about 750 mg of acetaminophen; and repeating the administration at least once every four hours; wherein the pharmaceutical composition is administered to the subject intravenously; and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours."

OFIRMEV®

27. Cadence obtained approval from the FDA for NDA No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt Hospital Products IP is now the holder of NDA No. 022450. Mallinckrodt Hospital Products distributes OFIRMEV®.

28. OFIRMEV® was approved by the FDA on November 2, 2010. OFIRMEV® is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

29. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations. Each of the '218, '012, '265, and '238 patents were timely listed in the Orange Book with respect to OFIRMEV®.

30. Based on revisions made to the OFIRMEV® package insert based on data from a randomized, placebo controlled, multicenter study of intravenous acetaminophen for the treatment of acute pain in pediatric patients to fulfill a post-marketing requirement, OFIRMEV® was granted exclusivity until July 27, 2020.

31. On information and belief, no application referencing OFIRMEV® as a reference listed drug will be finally approved until after the expiration of said exclusivity in July 2020.

ALTAN'S INFRINGEMENT OF THE PATENTS-IN-SUIT

32. Upon information and belief, Altan submitted the Altan NDA to the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of the Altan NDA Product prior to the expiration of the '218, '012, '265, and '238 patents, all of which are listed in the Orange Book with respect to OFIRMEV®.

33. In the Altan Letter, Altan stated that it had submitted the Altan NDA seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of the Altan NDA Product prior to the expiration of the '218 patent.

34. The Altan Letter also states that the Altan NDA contains a certification under 21 U.S.C. § 355(b)(2)(A)(iv) (the "Paragraph IV certification") alleging that the '218 patent is "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Altan's NDA."

35. Pursuant to statute, the Paragraph IV notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." *See* 21 U.S.C. § 355(b)(3)(D)(ii). The Altan Letter asserts in a conclusory manner that Altan does not practice the claims of the '218 Patent, but provides no factual basis for that assertion. Notably, the Altan Letter does not describe the Altan-proposed manufacturing process for the Altan NDA Product.

36. Pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III), the Altan Letter included an Offer of Confidential Access ("OCA"). Altan included a wide variety of proposed terms and restrictions in its draft OCA, and asked that Plaintiffs accept the draft OCA in order to access certain portions of Altan's NDA. Among those terms and restrictions, Altan proposed that it could redact its NDA at its sole discretion.

37. Plaintiffs responded to Altan's OCA on March 1, 2019, sending a proposed redline version of the OCA that would, for example, allow Plaintiffs to have an expert review Altan's confidential materials, prohibit Altan from redacting information other than patient names from its NDA, and provide full access to the Altan NDA, including all correspondence with FDA regarding the Altan NDA and the NDA Product described therein.

38. Altan's outside counsel responded to Plaintiffs on March 15, 2019, rejecting many of Plaintiffs' proposed terms. Altan maintained an ability to redact information from its NDA at its sole discretion and only committed to producing the proposed formulation and labeling in unredacted form. Altan further rejected Plaintiffs' proposal that it include FDA correspondence regarding the Altan NDA within the scope of the OCA.

39. Plaintiffs responded the next business day with another redline proposal, accepting certain of Altan's proposed terms and proposing compromises for others. Plaintiffs rejected Altan's proposed unilateral right to redact information other than patient names from the Altan NDA and again proposed that FDA correspondence regarding the Altan NDA fall within the scope of the OCA.

40. As of the date of filing of this Complaint, Altan has not responded to Plaintiffs' March 18 correspondence and updated OCA proposal.

41. Altan's submission of the Altan NDA to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Altan commercially manufactures, imports, uses, offers for sale, or sells the Altan NDA Product or induces or contributes to such conduct, said actions would constitute infringement of the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

42. Upon information and belief, the only viable way of preparing an acetaminophen solution with prolonged stability is to deoxygenate the solution (or an equivalent thereof) to below 2 ppm oxygen. For instance, the proposed generic Exela Pharma Sciences product was found by this Court to have infringed claims of the '218 patent, and the Cadence product was deemed to be a commercial embodiment thereof. *See Cadence Pharm., Inc. v. Exela Pharma Scis., LLC*, No. 11-733, 2013 WL 11083853 (D. Del. Nov. 14, 2013), *aff'd*, 780 F.3d 1364 (Fed. Cir. 2015). Both the Exela and Cadence intravenous acetaminophen products are deoxygenated to below 2 ppm during preparation by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent). *See id.*

43. OFIRMEV® was the first aqueous injectable acetaminophen product approved by the FDA. Accordingly, since November 2, 2010, the only commercially available aqueous injectable acetaminophen product in the United States has employed the invention(s) set forth in various claims of the '218 patent.

44. Wockhardt Bio AG ("Wockhardt") and Agila Specialties Inc. ("Agila") have stipulated to infringement of one or more claims of the '218 patent with regard to their proposed generic versions of OFIRMEV®. *Cadence Pharm., Inc. et al. v. Wockhardt Ltd. et al.*, C.A. No. 14-94 (LPS), D.I. 9 (D. Del. Apr. 2, 2014); *Cadence Pharm., Inc. et al. v. Agila Specialties Inc. et al.*, C.A. No. 14-1499 (LPS), D.I. 177 (D. Del. Jan. 12, 2017). Thus, those products likewise are deoxygenated to below 2 ppm by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent).

45. A significant number of sophisticated pharmaceutical companies have taken a license to the '218 patent, thereby availing themselves of the invention(s) claimed therein. Thus, BMS, Cadence, Mallinckrodt, Wockhardt, Agila, Paddock Laboratories, Inc. ("Paddock"),

Fresenius Kabi USA, LLC ("Fresenius"), Sandoz, Inc. ("Sandoz"), B. Braun Medical Inc., and Aurobindo Pharma USA, Inc. ("Aurobindo") each have taken a license to the '218 patent. And Perfalgan, the European counterpart of OFIRMEV®, is deoxygenated to below 2 ppm oxygen by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent). *See Cadence*, 2013 WL 11083853, at *5, *34 n.34.

46. The FDA has approved three other aqueous injectable acetaminophen products that reference OFIRMEV® as the reference listed drug—ANDA products from Sandoz and Paddock (the ANDA for which was subsequently transferred to Custopharm, Inc.), as well as a 505(b)(2) NDA product from Fresenius. Each of those entities has licensed the '218 patent technology, but the licenses do not commence until December 6, 2020. Accordingly, the only FDA-approved aqueous injectable acetaminophen products (the three products above and OFIRMEV® itself) fall under licenses to the '218 patent.

47. On information and belief, and because it is the only viable method of preparing an injectable aqueous solution of acetaminophen, the Altan NDA Product will be deoxygenated to below 2 ppm oxygen, within the scope of at least one claim of the '218 Patent. That dissolved oxygen level will be achieved by bubbling with at least one inert gas and/or placing under vacuum (or an equivalent).

48. Altan's submission of the Altan NDA to the FDA, constitutes an act of infringement of the '012 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Altan commercially manufactures, imports, uses, offers for sale, or sells the Altan NDA Product or induces such conduct, said actions would constitute infringement of the '012 patent under 35 U.S.C. § 271(a) and/or (b).

49. Under the Hatch-Waxman Act, the evaluation of infringement involves what the applicant will "likely market if its application is approved." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)).

50. Upon information and belief, *inter alia*, Altan's proposed labeling will encourage, promote, and/or recommend a method of administering the Altan NDA Product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Upon information and belief, if approved, the Altan NDA Product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, *inter alia*, Altan will commercially manufacture, import, use, offer for sale, or sell the Altan NDA Product and recommend usage of the Altan NDA Product. Upon information and belief, this will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Upon information and belief, Altan will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent.

51. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a

therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours. A true and correct copy of the OFIRMEV® labeling is attached as Exhibit E.

52. On information and belief, Altan did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Altan NDA Product labeling.

53. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same information concerning said trials.

54. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same statements.

55. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the ’012 patent. On information and belief, the Altan NDA Product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the ’012 patent.

56. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, “[t]ake care

when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

57. Upon information and belief, the Altan NDA Product will be administered to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Upon information and belief, this will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Upon information and belief, Altan will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent.

58. Altan's submission of the Altan NDA to the FDA constitutes an act of infringement of the '012 patent under 35 USC § 271(e)(2)(A). Moreover, Altan intends to commercially manufacture, import, use, offer for sale, or sell the Altan NDA Product and/or induce or contribute to such conduct. Said actions would constitute infringement of the '012 patent under 35 USC § 271(a) and/or (b).

59. Upon information and belief, Altan was aware of the '012 patent prior to filing the Altan NDA, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

60. The acts of infringement by Altan set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

61. Altan's submission of the Altan NDA to the FDA constitutes an act of infringement of the '265 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Altan commercially manufactures, imports, uses, offers for sale, or sells the Altan NDA Product or induces such conduct, said actions would constitute infringement of the '265 patent under 35 U.S.C. § 271(a) and/or (b).

62. Upon information and belief, *inter alia*, Altan's proposed labeling will instruct encourage, promote, and/or recommend the administration of the Altan NDA Product to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least Claim 1 of the '265 patent. Upon information and belief, if approved, the Altan NDA Product will be used to treat mild to moderate pain in adult and pediatric patients two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, Altan will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least Claim 1 of the '265 patent.

63. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously. (*See* Exhibit E.)

64. For example, Section 1 of the OFIRMEV® labeling provides that "OFIRMEV (acetaminophen) injection is indicated for the . . . Management of moderate to severe pain with adjunctive opioid analgesics."

65. On information and belief, Altan did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Altan NDA Product labeling.

66. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same information concerning said trials.

67. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same statements.

68. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the '265 patent.

On information and belief, the Altan NDA Product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the '265 patent.

69. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, "[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

70. Upon information and belief, the Altan NDA Product will be administered to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least Claim 1 of the '265 patent. Upon information and belief, this will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Upon information and belief, Altan will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '265 patent.

71. Altan's submission of the Altan NDA to the FDA constitutes an act of infringement of the '265 patent under 35 USC § 271(e)(2)(A). Moreover, Altan intends to

commercially manufacture, import, use, offer for sale, or sell the Altan NDA Products and/or induce such conduct. Said actions would constitute infringement of the '265 patent under 35 USC § 271(a) and/or (b).

72. Upon information and belief, Altan was aware of the '265 patent prior to filing NDA No. 209841, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

73. The acts of infringement by Altan set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

74. Altan's submission of the Altan NDA to the FDA constitutes an act of infringement of the '238 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Altan commercially manufactures, imports, uses, offers for sale, or sells the Altan NDA Product or induces such conduct, said actions would constitute infringement of the '238 patent under 35 U.S.C. § 271(a) and/or (b).

75. Upon information and belief, *inter alia*, Altan will encourage, promote, and/or recommend the administration of the Altan NDA Product to treat pain in a human subject weighing at least 50 kg by administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the '238 patent. Upon information and belief, if approved, the Altan NDA Product will be used to treat mild to moderate pain in adult and pediatric patients

two years and older, moderate to severe pain in conjunction with adjunctive opioid analgesics in the same population, and for the reduction of fever in adult and pediatric patients. Upon information and belief, Altan will market its proposed products to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least Claim 1 of the ’238 patent.

76. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising 650 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously. (*See* Exhibit E.)

77. On information and belief, Altan did not perform its own clinical trials, and instead will rely on the clinical trials referenced in the OFIRMEV® labeling for the Altan NDA Product labeling.

78. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same information concerning said trials.

79. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo. On information and belief, the Altan NDA Product labeling will contain the same or substantially the same statements.

80. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claim 1 of the ’238 patent. On information and belief, the Altan NDA Product labeling will instruct, recommend, promote, and/or encourage medical care providers to practice the methods of at least Claim 1 of the ’238 patent.

81. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, “[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death.” The Highlights continue: “Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . .”

82. Upon information and belief, Altan’s NDA Product will be administered to treat pain in a human subject weighing at least 50 kg by administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen, and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the ’238 patent. Upon information and belief, this will occur at Altan’s active behest, and with Altan’s intent, knowledge, and encouragement. Upon information and belief, Altan will actively induce, encourage, and abet

this infringement with knowledge that it is in contravention of the Mallinckrodt Plaintiffs' rights under the '238 patent.

83. Altan's submission of the Altan NDA to the FDA constitutes an act of infringement of the '238 patent under 35 USC § 271(e)(2)(A). Moreover, Altan intends to commercially manufacture, import, use, offer for sale, or sell the Altan NDA Products and/or induce such conduct. Said actions would constitute infringement of the '238 patent under 35 USC § 271(a) and/or (b).

84. Upon information and belief, Altan was aware of the '238 patent prior to filing NDA No. 209841, and its willful actions render this an exceptional case under 35 U.S.C. § 285.

85. The acts of infringement by Altan set forth above will cause the Mallinckrodt Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I
(INFRINGEMENT OF THE '218 PATENT BY THE ALTAN NDA PRODUCT)

86. Plaintiffs incorporate each of the preceding paragraphs 1 to 85 as if fully set forth herein.

87. Altan's submission of the Altan NDA, including its Paragraph IV certification, constitutes infringement of the '218 patent by Altan pursuant to 35 U.S.C. § 271(e)(2).

88. Upon information and belief, upon FDA approval of the Altan NDA, Altan will infringe the '218 patent by making, using, offering to sell, or selling the Altan NDA Product in the United States, and/or importing the Altan NDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b), and/or (c).

89. Upon information and belief, Altan had actual and constructive knowledge of the ’218 patent prior to filing of the Altan NDA and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ’218 patent.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’218 PATENT BY THE ALTAN NDA PRODUCT)

90. Plaintiffs incorporate each of the preceding paragraphs 1 to 89 as if fully set forth herein.

91. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. Plaintiffs are further entitled to a declaration that, if Altan, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Altan NDA Product within the United States, imports the Altan NDA Product into the United States, or induces or contributes to such conduct, Altan would infringe the ’218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

93. Plaintiffs are entitled to an injunction restraining and enjoining Altan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Altan’s NDA Product until the expiration of the ’218 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

94. Plaintiffs will be irreparably harmed by Altan’s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III
(INFRINGEMENT OF THE '012 PATENT BY THE ALTAN NDA PRODUCT)

95. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 94 as if fully set forth herein.

96. Altan's submission of the Altan NDA constitutes infringement of the '012 patent pursuant to 35 U.S.C. § 271(e)(2).

97. Upon information and belief, upon FDA approval of the Altan NDA, Altan will induce and/or contribute to infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling the Altan NDA Product in the United States, and/or importing the Altan NDA Product into the United States, in violation of 35 U.S.C. § 271.

98. Upon information and belief, upon FDA approval of the Altan NDA, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '012 patent by using the Altan NDA Product, in violation of 35 U.S.C. § 271(a). Upon information and belief, Altan's proposed labeling and promotion of the Altan NDA Product will encourage, promote, and/or recommend a method of administering that product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least Claim 1 of the '012 patent. Additionally, Altan will otherwise promote, encourage, and/or instruct use of the Altan NDA Product for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition

comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

99. Upon information and belief, this direct infringement will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Altan will intentionally encourage infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling the Altan NDA Product and by recommending and/or instructing use of the Altan NDA Product. Furthermore, Altan will intentionally encourage infringement of at least Claim 1 of the '012 patent at least by way of the labeling for the Altan NDA Product which will contain recommendations and/or instructions for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours. Additionally, Altan will otherwise promote, encourage, and/or instruct use of the Altan NDA Product for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

100. Upon information and belief, Altan is aware of the '012 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Altan will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent, in violation of 35 U.S.C. § 271(b).

101. Upon information and belief, Altan had actual and constructive knowledge of the application that later issued as the ’012 patent prior to filing NDA No. 209841 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the ’012 patent upon its issuance.

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’012 PATENT BY THE ALTAN NDA PRODUCT)

102. Plaintiffs incorporate each of the preceding paragraphs 1 to 101 as if fully set forth herein.

103. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

104. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Altan, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Altan NDA Product within the United States, imports the Altan NDA Product into the United States, or induces or contributes to such conduct, Altan would infringe the ’012 patent under 35 U.S.C. § 271(a) and/or (b).

105. An actual controversy has arisen and now exists between the parties concerning whether Altan will directly or indirectly infringe the ’012 patent.

106. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Altan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Altan NDA Product until the expiration of the ’012 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

107. The Mallinckrodt Plaintiffs will be irreparably harmed by Altan's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT V
(INFRINGEMENT OF THE '265 PATENT BY THE ALTAN NDA PRODUCT)

108. Plaintiffs incorporate each of the preceding paragraphs 1 to 107 as if fully set forth herein.

109. Altan's submission of NDA No. 209841 constitutes infringement of the '265 patent pursuant to 35 U.S.C. § 271(e)(2).

110. Upon information and belief, upon FDA approval of NDA No. 209841, Altan will induce infringement of at least Claim 1 of the '265 patent by making, using, offering to sell, or selling the Altan NDA Product in the United States, and/or importing the Altan NDA Product into the United States, in violation of 35 U.S.C. § 271.

111. Upon information and belief, upon FDA approval of NDA No. 209841, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '265 patent by using the Altan NDA Product, in violation of 35 U.S.C. § 271(a). The Altan NDA Product will be administered to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least Claim 1 of the '265 patent.

112. Upon information and belief, this direct infringement will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Altan will intentionally

encourage infringement of at least Claim 1 of the ’265 patent at least by way of the labeling for the Altan NDA Product which will contain recommendations and/or instructions for treating pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously. Additionally, Altan will otherwise promote, encourage, and/or instruct use of the Altan NDA Product for treating pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously.

113. Upon information and belief, Altan is aware of the ’265 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Altan will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs’ rights under the ’265 patent, in violation of 35 U.S.C. § 271(b). Upon information and belief, Altan had actual and constructive knowledge of the application that later issued as the ’265 patent prior to filing NDA No. 209841 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ’265 patent upon its issuance.

COUNT VI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’265 PATENT BY THE ALTAN NDA PRODUCT)

114. Plaintiffs incorporate each of the preceding paragraphs 1 to 113 as if fully set forth herein.

115. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Altan, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Altan NDA Product within the United States, imports the Altan NDA Product into the United States, or induces such conduct, Altan would infringe the '265 patent under 35 U.S.C. § 271(a) and/or (b).

117. An actual controversy has arisen and now exists between the parties concerning whether Altan will directly or indirectly infringe the '265 patent.

118. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Altan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Altan NDA Product until the expiration of the '265 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

119. The Mallinckrodt Plaintiffs will be irreparably harmed by Altan's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT VII
(INFRINGEMENT OF THE '238 PATENT BY THE ALTAN NDA PRODUCT)

120. Plaintiffs incorporate each of the preceding paragraphs 1 to 119 as if fully set forth herein.

121. Altan's submission of the Altan NDA constitutes infringement of the '238 patent pursuant to 35 U.S.C. § 271(e)(2).

122. Upon information and belief, upon FDA approval of the Altan NDA, Altan will induce and/or contribute to infringement of at least Claim 1 of the ’238 patent by making, using, offering to sell, or selling the Altan NDA Product in the United States, and/or importing the Altan NDA Product into the United States, in violation of 35 U.S.C. § 271.

123. Upon information and belief, upon FDA approval of the Altan NDA, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the ’238 patent by using the Altan NDA Product, in violation of 35 U.S.C. § 271(a). Upon information and belief, Altan’s proposed labeling and promotion of the Altan NDA Product will encourage, promote, and/or recommend a method of administering that product to treat pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours, which administration will constitute direct infringement of at least Claim 1 of the ’238 patent. Additionally, Altan will otherwise promote, encourage, and/or instruct use of the Altan NDA Product for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours.

124. Upon information and belief, this direct infringement will occur at Altan's active behest, and with Altan's intent, knowledge, and encouragement. Altan will intentionally encourage infringement of at least Claim 1 of the '238 patent by at least making, using, offering to sell, or selling the Altan NDA Product and by recommending and/or instructing use of the Altan NDA Product. Furthermore, Altan will intentionally encourage infringement of at least Claim 1 of the '238 patent at least by way of the labeling for the Altan NDA Product which will contain recommendations and/or instructions for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours. Additionally, Altan will otherwise promote, encourage, and/or instruct use of the Altan NDA Product for treating pain in a human subject, in need thereof, weighing at least 50 kg by administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and repeating the administration at least once every four hours, wherein the pharmaceutical composition is administered to the subject intravenously, and wherein the therapeutic effect of the pharmaceutical composition is comparable to the standard of care treatment of 1000 mg of acetaminophen administered orally every 6 hours.

125. Upon information and belief, Altan is aware of the '238 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Altan will actively induce, encourage, and

abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '238 patent, in violation of 35 U.S.C. § 271(b).

126. Upon information and belief, Altan had actual and constructive knowledge of the application that later issued as the '238 patent prior to filing NDA No. 209841 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '238 patent upon its issuance.

COUNT VIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '238 PATENT BY THE ALTAN NDA PRODUCT)

127. Plaintiffs incorporate each of the preceding paragraphs 1 to 126 as if fully set forth herein.

128. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

129. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Altan, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Altan NDA Product within the United States, imports the Altan NDA Product into the United States, or induces or contributes to such conduct, Altan would infringe the '238 patent under 35 U.S.C. § 271(a) and/or (b).

130. An actual controversy has arisen and now exists between the parties concerning whether Altan will directly or indirectly infringe the '238 patent.

131. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Altan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Altan NDA Product until the expiration

of the ’238 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

132. The Mallinckrodt Plaintiffs will be irreparably harmed by Altan’s infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Altan infringed and is infringing each of the Patents-in-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of the Altan NDA shall not be earlier than the expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

C. A declaration that if Altan, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells the Altan NDA Product within the United States, imports Altan NDA Product into the United States, or induces or contributes to such conduct, Altan would infringe the Patents-in-Suit;

D. A preliminary and permanent injunction restraining and enjoining Altan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of the Altan NDA Product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. That Plaintiffs be awarded monetary relief if Altan commercially manufactures, uses, offers for sale, or sells its generic version of Plaintiffs' OFIRMEV® brand product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the United States before the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled;

F. A declaration that this is an exceptional case and an award to Plaintiffs of their reasonable expenses including attorneys' fees pursuant to 35 U.S.C. § 285;

G. An award to Plaintiffs of costs in this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com
skraftschik@mnat.com

Attorneys for Mallinckrodt Hospital Products IP Limited, Mallinckrodt Hospital Products Inc., and New Pharmatop L.P.

OF COUNSEL:

Daniel G. Brown
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Marc N. Zubick
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

Laura K. Guillod
LATHAM & WATKINS LLP
200 Clarendon Street
Boston, MA 27001
(617) 948-6000

Attorneys for Mallinckrodt Hospital Products IP Limited and Mallinckrodt Hospital Products Inc.

Brian T. Moriarty
Lawrence P. Cogswell, III, Ph.D.
HAMILTON, BROOK,
SMITH & REYNOLDS, P.C.
Seaport West
155 Seaport Boulevard
Boston, MA 02210
(617) 607-5900

Attorneys for New Pharmatop L.P.

March 22, 2019