IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT IP, MALLINCKRODT HOSPITAL PRODUCTS INC., and SCR PHARMATOP,	)	
Plaintiffs,	)	C.A. No. 17-365 (LPS)
v.	)	
	)	**PUBLIC VERSION**
B. BRAUN MEDICAL INC.,	)	
Defendant.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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Plaintiffs Mallinckrodt IP, Mallinckrodt Hospital Products Inc., and SCR Pharmatop ("Plaintiffs") for their Amended Complaint under FEDERAL RULE OF CIVIL PROCEDURE 15(a)(B), served within 21 days after service of a motion under Rule 12(b), against defendant B. Braun Medical Inc. ("Braun"), allege as follows:

PARTIES

1. Plaintiff Mallinckrodt IP is a company organized and existing under the laws of Ireland, having a registered address of Damastown Industrial Estate, Mulhaddart, Dublin 15, Ireland. Mallinckrodt IP is a wholly-owned subsidiary of Mallinckrodt plc. As set forth herein, Mallinckrodt IP is the assignee of U.S. Patent No. 9,399,012 ("the '012 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 SCR Pharmatop ("Pharmatop") is a business entity organized and existing under the laws of France, having its headquarters at 10, Square St. Florentin, 78150 Le Chesnay, France. As set forth herein, Pharmatop is the assignee of the '218 patent.

4. Upon information and belief, Defendant Braun is a company organized under the laws of Pennsylvania, having a principal place of business at 824 Twelfth Avenue, Bethlehem, Pennsylvania 18018. Upon information and belief, Braun is in the business of manufacturing, distributing, and selling pharmaceutical products throughout 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; 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 Braun because, upon information and belief, *inter alia*, Braun has registered to do business in Delaware pursuant to Del. Code Ann. Title 8, §§ 371(b)(2), 376(a), and has appointed an agent to accept service of process in Delaware. This Court has personal jurisdiction over Braun for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Braun because, *inter alia*, Braun has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

9. Upon information and belief, Braun regularly and continuously transacts business within the State of Delaware, including by distributing, selling, and/or leasing pharmaceutical products, medical equipment, and/or services in Delaware. Upon information and belief, Braun derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware. Upon information and belief, Braun provides maintenance and support services for its products in the State of Delaware.

10. Upon information and belief, Braun's medical equipment, including at least the Dialog+ Hemodialysis Systems, was distributed in the State of Delaware as of May 10, 2016. *See* https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm499127.htm (accessed

July 20, 2017). Upon information and belief, the Dialog+ Hemodialysis Systems were recalled in thirty states including Delaware because they "may cause serious injuries or death." *Id.*

11. Upon information and belief, Braun leases medical equipment, including at least infusion pumps such as the B. Braun Vista Basic Infusion Pump and Infusomat Space Infusion Pump, in and around Wilmington, Delaware. *See* http://www.rentittoday.com/search/medical-equipment-rentals/Infusion%20Pump/Wilmington/DE (accessed July 20, 2017).

12. Upon information and belief, Braun has registered with the Delaware Board of Pharmacy as a licensed "Pharmacy – Wholesale" under License Nos. A4-0000857 and A4-0001521. Upon information and belief, Braun has agreements with retailers, wholesalers, or distributors operating in the State of Delaware.

13. Braun has admitted that it "sells products within this district." *Hospira, Inc. v. B. Braun Med. Inc.*, No. 13-819, D.I. 8 at 3. Braun has further admitted that "it sells and offers to sell products and services in this judicial district, and introduces products and services into the stream of commerce knowing that they would be sold in this judicial district and elsewhere in the United States." *Rydex Techs. LLC v. B. Braun Med. Inc.*, No 13-663, D.I. 7 at 2. Upon information and belief, Braun also did not challenge this Court's exercise of personal jurisdiction over it in at least *Fresenius Kabi USA, LLC v. B. Braun Med. Inc.*, No. 16-250. Braun has purposefully availed itself of the benefits of this district by filing complaints for patent infringement in this district. *See B. Braun Melsungen AG v. Becton, Dickinson & Co.*, No. 16-411; *B. Braun Melsungen AG v. Terumo Med. Corp.*, No. 09-347. Braun has also filed patent-related counterclaims in this district. *See Hospira Inc. v. B. Braun Medical Inc.*, No. 13-819; *Rydex Techs. LLC v. B. Braun Med. Inc.*, No. 13-663. Braun has also availed itself of the

jurisdiction of the Delaware Court of Chancery. *See B. Braun Medical Inc. v. Moog Inc.*, No. 6264.

14. Upon information and belief, Central Admixture Pharmacy Services, Inc. ("CAPS") is a "B. Braun Medical Inc. company" that "is a partner to hospital pharmacies in twenty-four cities across the United States." *See* http://www.bbraunusa.com/8043.html (accessed July 20, 2017). Upon information and belief, CAPS is a Delaware corporation with its principal place of business in Santa Fe Springs, CA. Upon information and belief, CAPS has registered with the Delaware Board of Pharmacy as a licensed "Pharmacy – Wholesale" under License Nos. A4-0001769, A4-0002372, and A4-0002023. Additionally, CAPS has registered as a licensed "Outsourcing Facility – Distributor" under License No. AD-0000042 and has a further pending application. CAPS has furthermore registered as a licensed "Distributor/Manufacturer CSR" under License No. DM-0007847. Upon information and belief, CAPS is the "nation's largest network of outsourcing admixture pharmacies" that "make[s] over 300,000 local deliveries annually" and "operate[s] 365 days a year dispensing labeled, patient-specific and anticipatory IV prescriptions to health system pharmacy customers, nationwide." *See* http://www.capspharmacy.com/cps/rde/xchg/cw-capspharmacy-en-us/hs.xsl/7330.html (accessed July 20, 2017).

15. This Court has personal jurisdiction over Braun because, *inter alia*, upon information and belief, Braun has submitted New Drug Application ("NDA") No. 204957, claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product and seeking nationwide approval of its proposed product. Braun's submission of NDA No. 204957 constitutes infringement of the patents-in-suit pursuant to 35 U.S.C. § 271(e). Braun's tortious act of infringing the patents-in-suit causes concrete harm to Plaintiffs. By a letter received by

Plaintiffs on February 23, 2017 (the "Braun Letter"), Braun stated that it had submitted NDA No. 204957 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of [redacted] prior to the expiration of the '218 patent. By a second letter received by Plaintiffs on April 21, 2017 (the "Second Braun Letter"), Braun stated that it had contemporaneously submitted an amendment to its NDA "to further indicate and confirm its intent" to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of [redacted] prior to the expiration of the '012 patent. By a third letter received by Plaintiffs on July 13, 2017 (the "Third Braun Letter"), Braun stated that, [redacted] Braun stated that it contemporaneously submitted an amendment to its NDA to indicate that it would "engage in the commercial manufacture, use, or sale" of Braun's Generic Products prior to the expiration of U.S. Patent No. 9,610,265.

16. The Braun Letter and the Second Braun Letter were directed to Cadence (now Mallinckrodt Hospital Products), a Delaware corporation.

17. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) because Braun has "committed acts of infringement and has a regular and established place of business" in Delaware. *See* 28 U.S.C. § 1400(b).

18. 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)). In addition, this Court has held that, in the context of an action arising under the Hatch-Waxman Act, the filing of such an application is a formal act that reliably indicates plans to engage in marketing of its proposed generic drug in Delaware. Braun's submission of NDA No. 204957, claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product and seeking nationwide approval of Braun's Generic Products, is an act of infringement of the patents-in-suit in Delaware pursuant to 35 U.S.C. § 271(e) causing concrete harm to Plaintiffs. Moreover, the Braun Letter and the Second Braun Letter were directed to Cadence (now Mallinckrodt Hospital Products), a Delaware corporation. Thus, in the context of the Hatch-Waxman Act, Braun has committed an act of infringement directed to and/or within Delaware.

19. Braun has a regular and established place of business in Delaware because it "does business in that district through a permanent and continuous presence there." *See In re Cordis Corp.*, 769 F.2d 733, 737 (Fed. Cir. 1985). Plaintiffs incorporate and replead preceding paragraphs 9-15 as showing Braun's established place of business in Delaware. Upon information and belief, *inter alia*, Braun has registered to do business in Delaware pursuant to Del. Code Ann. Title 8, §§ 371(b)(2), 376(a), and has appointed an agent to accept service of process there. Upon information and belief, Braun utilizes the services of its registered agent, Corporation Service Company located at 2711 Centerville Rd., Suite 400, Wilmington, DE 19808, to conduct business in Delaware.

20. Thus, on information and belief, Braun has a regular and established place of business in Delaware and venue is proper in this judicial district under 28 U.S.C. § 1400(b).

21. This action involves patents that were at issue in other actions before this Court. The '218 patent was at issue in the actions captioned *Cadence Pharmaceuticals, Inc. v. Exela*

Pharma Sciences, LLC, No. 11-733 and *Cadence Pharmaceuticals, Inc. v. InnoPharma Licensing LLC*, No. 14-1225. The '012 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. InnoPharma Licensing LLC*, No. 16-1116, and *Mallinckrodt IP v. Mylan Laboratories Ltd.*, No. 16-1115. The '012 patent is currently at issue in the action captioned *Mallinckrodt IP v. B. Braun Medical Inc.*, No. 17-660, filed after Plaintiffs received the Second Braun Letter but before Plaintiffs received the Third Braun Letter.

THE PATENTS-IN-SUIT

22. 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. The named inventors assigned the application which issued as the '218 patent to Pharmatop.

23. 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 IP is the exclusive sub-licensee of the '218 patent. A true and correct copy of the '218 patent is attached as Exhibit A.

24. The '012 patent, titled "Reduced Dose Intravenous Acetaminophen," was duly and legally issued by the PTO on July 26, 2016. The named inventors assigned the application that issued as the '012 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP. Mallinckrodt IP is now the sole assignee of the '012 patent. A true and correct copy of the '012 patent is attached as Exhibit B.

25. 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."

OFIRMEV®

26. Cadence obtained approval from the Food and Drug Administration (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 IP is now the holder of NDA No. 022450. Mallinckrodt Hospital Products distributes OFIRMEV®.

27. 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.

28. 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, the '218 and '012 patents were timely listed in the Orange Book with respect to OFIRMEV®.

DEFENDANT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

29. Upon information and belief, Braun submitted NDA No. 204957 to the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Braun's Generic Products prior to the expiration of the '218 and '012 patents, both of which are listed in the Orange Book with respect to OFIRMEV®.

30. In the Braun Letter, Braun stated that it had submitted NDA No. 204957 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of [redacted] prior to the expiration of the '218 patent.

31. The Braun Letter also states that NDA No. 204957 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 manufacture, use, or sale of the product for [sic: which] B. Braun's NDA is submitted."

32. In the Second Braun Letter, Braun stated that it had submitted an amendment to NDA No. 204957 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of [redacted] prior to the expiration of the '012 patent.

33. The Second Braun Letter also stated that the amendment to NDA No. 204957 contained a Paragraph IV certification alleging that the '012 patent is "invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product for [sic: which] B. Braun's NDA is submitted."

34. In the Third Braun Letter, Braun stated that [redacted]

35. In the Third Braun Letter, Braun stated that it had submitted an amendment to NDA No. 204957 seeking approval to engage in the commercial manufacture, use, sale or, offer for sale, and/or importation of Braun's Generic Products prior to the expiration of the '265 patent.

36. The Third Braun Letter also stated that the amendment to NDA No. 204957 contained a Paragraph IV certification alleging that the '265 patent is "invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product for which B. Braun's NDA is submitted."

37. Pursuant to statute, the Paragraph IV notice must "include a detailed statement of the factual and legal basis of the opinion that the patent is not invalid or will not be infringed." *See* 35 U.S.C. § 355(b)(3)(D)(ii). The Third Braun Letter includes 21 pages reciting various alleged theories of invalidity with regard to the '012 patent claims. By way of contrast, the Third Braun Letter contains only about a page relating to infringement of the '012 patent, asserting that Braun will not itself practice the methods set forth in the claims of the '012 patent and cursorily asserting that there can be no direct infringement of the claims of the '012 patent and therefore no induced infringement. As to the '218 Patent, the Third Braun Letter states that Braun does not practice the claims of the '218 Patent but does not at all describe Braun's proposed manufacturing process.

38. On information and belief, the Braun proposed labeling will contain recommendations and instructions as to dosing both the [redacted] which will encourage, promote, and/or recommend the administration of, *inter alia*, said volumes by medical personnel.

39. Braun's submission of NDA No. 204957 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 Braun commercially manufactures, imports, uses, offers for sale, or sells Braun's Generic Products 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).

40. Upon information and belief, the only viable way of manufacturing an acetaminophen solution with prolonged stability is to deoxygenate the solution (or the 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)). Wockhardt Bio AG ("Wockhardt") and Agila Specialties Inc. ("Agila") have stipulated to infringement of the '218 patent with regard to their proposed generic versions of OFIRMEV®. BMS; Cadence; Mallinckrodt; Wockhardt; Agila; Paddock Laboratories, Inc.; Fresenius Kabi USA, LLC; and Sandoz, Inc. have taken licenses to the '218 patent. And Perfalgan, the European counterpart of OFIRMEV®, is deoxygenated to below 2 ppm oxygen. *See Cadence*, 2013 WL 11083853, at *5, *33 n.34.

41. Braun's submission of NDA No. 204957 to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the '012 patent under 35 U.S.C. § 271(e)(2)(A). In the event that Braun commercially manufactures, imports, uses, offers for sale, or sells Braun's Generic Products or induces such conduct, said actions would constitute infringement of the '012 patent under 35 U.S.C. § 271(a) and/or (b).

42. Braun's [redacted] is "about 550 mg" and, on information and belief, Braun's proposed labeling 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. Upon information and belief, *inter alia*, Braun will commercially manufacture, import, use, offer for sale, or sell the [redacted] and recommend usage of [redacted]. Upon information and belief, this will occur at Defendant’s active behest, and with Defendant’s intent, knowledge, and encouragement. Upon information and belief, Defendant will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs’ rights under the ’012 patent.

43. Upon further information and belief, Braun will otherwise encourage, promote, and/or recommend the administration of the Braun Generic Products 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. On information and belief, Braun 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.

44. Upon information and belief, the FDA will require the labeling for Braun’s Generic Products to be substantially identical to the approved labeling for OFIRMEV® with regard to issues associated with safety, and Braun’s Generic Products, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for OFIRMEV® in that regard.

45. 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 C.

46. For instance, Section 2.2 of the OFIRMEV® labeling recites that for adults and adolescents weighing 50 kg and over, "the recommended dosage of OFIRMEV is 1000 mg every 6 hours or 650 mg every 4 hours, with a maximum single dose of OFIRMEV of 1000 mg, a minimum dosing interval of 4 hours, and a maximum daily dose of acetaminophen of 4000 mg per day."

47. Table 1 of the OFIRMEV® labeling also contains recommended dosing information for adults and adolescents weighing 50 kg and over, reciting that the "[d]ose given every 4 hours" is "650 mg."

48. Section 2.5 of the OFIRMEV® labeling provides instructions and/or recommendations for dosing and recites, in pertinent part, that "[f]or doses less than 1000 mg, the appropriate dose must be withdrawn from the container and placed into a separate container prior to administration. Using aseptic technique, withdraw the appropriate dose (650 mg or weight-based) from an intact sealed OFIRMEV container and place the measured dose in a separate empty, sterile container (e.g., glass bottle, plastic intravenous container, or syringe) for intravenous infusion . . . ."

49. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours.

50. 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.

51. 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.

52. 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 . . . .”

53. 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)).

54. Upon information and belief, the FDA will require the labeling for Braun’s Generic Products, if approved, to contain recommendations and/or instructions that are identical or substantially identical to those set forth above from the OFIRMEV® labeling and, therefore, 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.

55. Upon information and belief, based on the labeling that is likely to be required for Braun's Generic Products, if approved, Braun's Generic Products 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 Defendant's active behest, and with Defendant's intent, knowledge, and encouragement. Upon information and belief, Defendant will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs' rights under the '012 patent.

56. Braun's submission of NDA No. 204957 to the FDA constitutes an act of infringement of the '012 patent under 35 USC § 271(e)(2)(A). Moreover, Braun intends to commercially manufacture, import, use, offer for sale, or sell Braun's Generic Products 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).

57. Upon information and belief, Braun was aware of the patents-in-suit prior to filing NDA No. 204957, and its actions render this an exceptional case under 35 U.S.C. § 285.

58. The acts of infringement by Defendant set forth above will cause Plaintiffs irreparable harm for which they has no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I

(INFRINGEMENT OF THE '218 PATENT BY [redacted])

59. Plaintiffs incorporate each of the preceding paragraphs 1 to 58 as if fully set forth herein.

60. Braun's submission of NDA No. 204957, including its Paragraph IV certification, constitutes infringement of the '218 patent by Braun pursuant to 35 U.S.C. § 271(e)(2).

61. Upon information and belief, upon FDA approval of NDA No. 204957, Braun will infringe the '218 patent by making, using, offering to sell, or selling [redacted] in the United States, and/or importing [redacted] 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).

62. Upon information and belief, Braun had actual and constructive knowledge of the '218 patent prior to filing of NDA No. 204957 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT II

(INFRINGEMENT OF THE '218 PATENT BY [redacted])

63. Plaintiffs incorporate each of the preceding paragraphs 1 to 62 as if fully set forth herein.

64. Braun's submission of NDA No. 204957, including its Paragraph IV certification, constitutes infringement of the '218 patent by Braun pursuant to 35 U.S.C. § 271(e)(2).

65. Upon information and belief, upon FDA approval of NDA No. 204957, Braun will infringe the '218 patent by making, using, offering to sell, or selling [redacted]

[redacted] in the United States, and/or importing [redacted] 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).

66. Upon information and belief, Braun had actual and constructive knowledge of the '218 patent prior to filing of NDA No. 204957 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT III
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '218 PATENT BY [redacted])

67. Plaintiffs incorporate each of the preceding paragraphs 1 to 66 as if fully set forth herein.

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

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

70. Plaintiffs are entitled to an injunction restraining and enjoining Defendant 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 [redacted] until the expiration of the '218 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

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

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '218 PATENT BY [redacted])

72. Plaintiffs incorporate each of the preceding paragraphs 1 to 71 as if fully set forth herein.

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

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

75. Plaintiffs are entitled to an injunction restraining and enjoining Defendant 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 [redacted] until the expiration of the '218 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

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

COUNT V

(INFRINGEMENT OF THE '012 PATENT BY [redacted]

77. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 76 as if fully set forth herein.

78. Braun's submission of NDA No. 204957 constitutes infringement of the '012 patent pursuant to 35 U.S.C. § 271(e)(2).

79. Upon information and belief, upon FDA approval of NDA No. 204957, Braun will induce and/or contribute to infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling [redacted] in the United States, and/or importing [redacted] into the United States, in violation of 35 U.S.C. § 271.

80. Upon information and belief, upon FDA approval of NDA No. 204957, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '012 patent by using [redacted], in violation of 35 U.S.C. § 271(a). [redacted] is "about 550 mg" and, on information and belief, Braun's proposed labeling and promotion of the [redacted] 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, Braun will otherwise promote, encourage, and/or instruct use of the [redacted] 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.

81. Upon information and belief, this direct infringement will occur at Braun's active behest, and with Braun's intent, knowledge, and encouragement. Braun will intentionally encourage infringement of at least Claim 1 of the '012 patent by at least making, using, offering to sell, or selling the [redacted] and by recommending and/or instructing use of the [redacted]. Furthermore, Braun will intentionally encourage infringement of at least Claim 1 of the '012 patent at least by way of the labeling for [redacted] 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, Braun will otherwise promote, encourage, and/or instruct use of the [redacted] 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.

82. Upon information and belief, Braun is aware of the '012 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Braun 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).

83. Upon information and belief, Braun had actual and constructive knowledge of the application that later issued as the '012 patent prior to filing NDA No. 204957 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 VI

(INFRINGEMENT OF THE '012 PATENT BY [redacted])

84. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 83 as if fully set forth herein.

85. Braun's submission of NDA No. 204957 constitutes infringement of the '012 patent pursuant to 35 U.S.C. § 271(e)(2).

86. Upon information and belief, upon FDA approval of NDA No. 204957, Braun will induce and/or contribute to infringement of at least Claim 1 of the '012 patent by making, using, offering to sell, or selling [redacted] in the United States, and/or importing [redacted] into the United States, in violation of 35 U.S.C. § 271.

87. Upon information and belief, upon FDA approval of NDA No. 204957, doctors, nurses, and other medical professionals will directly infringe at least Claim 1 of the '012 patent by using [redacted], in violation of 35 U.S.C. § 271(a). [redacted] 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.

88. Upon information and belief, this direct infringement will occur at Braun's active behest, and with Braun's intent, knowledge, and encouragement. Braun will intentionally encourage infringement of at least Claim 1 of the '012 patent at least by way of the labeling for [redacted] 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, Braun will otherwise promote, encourage, and/or instruct use of the [redacted] 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.

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

90. Upon information and belief, Braun had actual and constructive knowledge of the application that later issued as the '012 patent prior to filing NDA No. 204957 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 VII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '012 PATENT BY [redacted])

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

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

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

94. An actual controversy has arisen and now exists between the parties concerning whether Braun will directly or indirectly infringe the '012 patent.

95. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Defendant 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 [redacted] until the expiration of the '012 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

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

COUNT VIII
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '012 PATENT BY [redacted])

97. Plaintiffs incorporate each of the preceding paragraphs 1 to 96 as if fully set forth herein.

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

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

100. An actual controversy has arisen and now exists between the parties concerning whether Braun will directly or indirectly infringe the '012 patent.

101. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Defendant 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 [redacted] until the expiration of the '012 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

102. The Mallinckrodt Plaintiffs will be irreparably harmed by Braun'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 Defendant 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 Defendant's NDA No. 204957 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 Defendant, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Braun's Generic Products within the United States, imports Braun's Generic Products into the United States, or induces or contributes to such conduct, Defendant would infringe the patents-in-suit;

D. A preliminary and permanent injunction restraining and enjoining Defendant 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 Braun's Generic Products 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 Defendant 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 of attorneys' fees pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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