IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED,	)	
	)	C.A. No.
Plaintiff,	)	
v.	)	
BAXTER HEALTHCARE CORPORATION,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Mallinckrodt Pharmaceuticals Ireland Limited ("Mallinckrodt" or "Plaintiff"), by its attorneys, file this Complaint for patent infringement against Defendant Baxter Healthcare Corporation ("Defendant" or "Baxter") and allege as follows:

THE PARTIES

1. Plaintiff Mallinckrodt is an Irish Limited Company (LTD) organized and existing under the laws of the Republic of Ireland, having a registered address at College Business & Technology Park, Cruiserath Road, Blanchardstown, Dublin 15, D15 TX2V, Ireland. Mallinckrodt is the assignee of U.S. Patent No. 9,399,012 ("the '012 patent"), U.S. Patent No. 9,610,265 ("the '265 patent"), U.S. Patent No. 9,987,238 ("the '238 patent"), and U.S. Patent No. 10,383,834 ("the '834 patent") (collectively, the "Asserted Patents").

2. On information and belief, Defendant Baxter Healthcare Corporation is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015. On information and belief, Baxter manufactures, markets, distributes, and/or sells generic pharmaceutical products for use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

3. This is a civil action for infringement of the Asserted Patents 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

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

5. Upon information and belief, Baxter develops and manufactures generic versions of branded pharmaceutical products, and either directly or through one or more of its agents, markets, distributes, sells, and/or imports generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

6. Baxter sent Mallinckrodt a letter dated July 31, 2024 ("Baxter's Notice Letter"), stating that Baxter has submitted a prior approval supplement related to its Abbreviated New Drug Application No. 214331 ("Baxter's ANDA") that contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale (including within this Judicial District) of Acetaminophen Injection, 10 mg/mL ("Baxter's ANDA product"), before the expiration of the '012, '265, '238 and '834 patents, which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as "the Orange Book") with respect to Ofirmev® (Acetaminophen) Injection, 10 mg/mL.

7. Upon information and belief, the actions of Baxter, such as, causing Baxter's ANDA to be submitted with the FDA and maintaining distribution channels throughout the United States, including in the State of Delaware, establish that, if granted approval, Baxter will

commercially manufacture, use, offer to sell, sell, and/or import Baxter's ANDA Product throughout the United States, including in the State of Delaware.

8. This Court has personal jurisdiction over Baxter because, *inter alia*, it: (1) is incorporated in the State of Delaware; (2) has submitted the Baxter ANDA, claiming bioequivalence to Plaintiff's Ofirmev® injectable acetaminophen product, seeking nationwide approval of its proposed product; and (3) through the submission of its ANDA, intends to commercially manufacture, use, import, market, offer for sale, and sell the Baxter ANDA product throughout the United States, including in this judicial district.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b).

10. This action involves patents that have already been at issue in prior actions before this Court. 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; *Mallinckrodt IP v. B. Braun Medical Inc*., No. 17-365 and *Mallinckrodt IP v. Altan Pharma Ltd*., No. 19-552. The '265 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. B. Braun Medical Inc*., No. 17-660 and *Mallinckrodt IP v. Altan Pharma Ltd*., No. 19-552. The '238 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. B. Braun Medical Inc*., No. 18-1090 and *Mallinckrodt IP v. Altan Pharma Ltd*., No. 19-552.

11. Moreover, the Asserted Patents, as well as the Baxter ANDA, were at issue in *Mallinckrodt Hospital Products IP Limited, et al., v. Baxter Healthcare Corp.,* No. 1:20-cv-00434-LPS (D. Del. 2020).

THE ASSERTED PATENTS

12. Mallinckrodt owns the '012 patent, titled "Reduced Dose Intravenous Acetaminophen," which was duly and legally issued by the United States Patent Office ("PTO") on July 26, 2016. A true and correct copy of the '012 patent is attached as **Exhibit A**.

13. Mallinckrodt owns the '265 patent, titled "Reduced Dose Intravenous Acetaminophen," which was duly and legally issued by the PTO on April 4, 2017. A true and correct copy of the '265 patent is attached as **Exhibit B**.

14. Mallinckrodt owns the '238 patent, titled "Reduced Dose Intravenous Acetaminophen," which was duly and legally issued by the PTO on June 5, 2018. A true and correct copy of the '238 patent is attached as **Exhibit C**.

15. Mallinckrodt owns the '834 patent, titled "Reduced Dose Intravenous Acetaminophen," which was duly and legally issued by the PTO on August 20, 2019. A true and correct copy of the '834 patent is attached as **Exhibit D**.

OFFIRMEV®

16. Mallinckrodt is the holder of New Drug Application ("NDA") No. 022450, by which the FDA granted approval of the first intravenous formulation of acetaminophen available in the United States that is marketed under the trade name Ofirmev®.

17. Ofirmev® (acetaminophen) injection is indicated for the: (i) management of mild to moderate pain in adult and pediatric patients 2 years and older; (ii) management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older; and (iii) reduction of fever in adult and pediatric patients.

18. Pursuant to 21 U.S.C. § 355(b)(l), the Asserted Patents are listed in the FDA's Orange Book with respect to Ofirmev®.

THE PRIOR LITIGATION WITH BAXTER

19. On March 27, 2020, Mallinckrodt filed suit against Baxter alleging infringement of the Asserted Patents, as well as now expired U.S. Patent No. 6,992,218, stemming from Baxter's previous Notice Letter dated February 19, 2020, which stated that Baxter had submitted the ANDA No. 214331 and was seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Baxter's ANDA product prior to the expiration of the '218 patent. *See Mallinckrodt Hospital Products IP Limited, et al., v. Baxter Healthcare Corp.,* No. 1:20-cv-00434-LPS, Dkt. 1 ¶ 27.

20. Mallinckrodt and Baxter agreed to terms and conditions representing a negotiated settlement of that action, which included a License Agreement entered into between the parties. *Id.* at Dkt. 10.

21. On April 30, 2020, the case was resolved. *Id.*

22. The License Agreement entered into by the parties does not cover the prior approval supplement related to its Baxter's ANDA, which seeks approval to engage in the commercial manufacture, use or sale of an acetaminophen injection at the strength of 650 mg/65 mL (10 mg/mL).

ACTS GIVING RISE TO THIS ACTION

23. On information and belief, Baxter submitted the Baxter ANDA 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 Baxter ANDA product prior to the expiration of the '012, '265, '238, and '834 patents, which are listed in the Orange Book with respect to Ofirmev®.

24. The Baxter ANDA contains certifications under 21 U.S.C. § 355(j)(2)(B)(iv)(II) ("Paragraph IV certification") with respect to the Asserted Patents.

25. On or about July 31, 2024, Baster sent Mallinckrodt Baxter's Notice Letter, in which it represented that Baxter had submitted a prior approval supplement that contains a paragraph IV certification, referencing Mallinckrodt's Orange Book-listed Asserted Patents, to obtain approval to engage in the commercial manufacture, use, or sale of Acetaminophen Injection, 10 mg/mL, before the expiration of the Asserted Patents, and that Baxter's ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver with respect to Mallinckrodt's Ofirmev® (acetaminophen) injection, 1,000 mg/100 mL (10 mg/mL) single-dose vials as the Reference Listed Drug.

26. Mallinckrodt received Baxter's Notice Letter on or about August 1, 2024.

27. Mallinckrodt commenced this action within 45 days of the date of receipt of Baxter's Notice Letter.

COUNT I
(INFRINGEMENT OF THE '012 PATENT)

28. Mallinckrodt incorporates each of the preceding paragraphs 1 to 27 as if fully set forth herein.

29. By seeking approval of ANDA No. 214331 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '012 patent, Baxter has infringed the '012 patent under 35 U.S.C. § 271(e)(2)(A).

30. Mallinckrodt is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 214331 be a date that is not earlier than the expiration date of the '012 patent, including any patent term extensions and/or

patent term adjustments, the period of any pediatric exclusivity associated with the '012 patent, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled.

31. The commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product, if approved by the FDA before the expiration of the '012 patent, for use in accordance with its proposed labeling, would infringe, induce, and/or contribute to the infringement of the '012 patent.

32. Mallinckrodt is entitled to a declaration that, if Baxter commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Baxter's ANDA Product, or induces or contributes to any such conduct, it would further infringe the '012 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Upon information and belief, Baxter was aware of the existence of the '012 patent and was aware that the submission of ANDA No. 214331 to the FDA constituted an act of infringement of the '012 patent.

34. Upon information and belief, Baxter was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '012 patent would constitute an act of infringement of the '012 patent.

35. Mallinckrodt will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Mallinckrodt does not have an adequate remedy at law.

COUNT II
(INFRINGEMENT OF THE '265 PATENT)

36. Mallinckrodt incorporates each of the preceding paragraphs 1 to 35 as if fully set forth herein.

37. By seeking approval of ANDA No. 214331 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '265 patent, Baxter has infringed the '265 patent under 35 U.S.C. § 271(e)(2)(A).

38. Mallinckrodt is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 214331 be a date that is not earlier than the expiration date of the '265 patent, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the '265 patent, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled.

39. The commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product, if approved by the FDA before the expiration of the '265 patent, for use in accordance with its proposed labeling, would infringe, induce, and/or contribute to the infringement of the '265 patent.

40. Mallinckrodt is entitled to a declaration that, if Baxter commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Baxter's ANDA Product, or induces or contributes to any such conduct, it would further infringe the '265 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

41. Upon information and belief, Baxter was aware of the existence of the '265 patent and was aware that the submission of ANDA No. 214331 to the FDA constituted an act of infringement of the '265 patent.

42. Upon information and belief, Baxter was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of

Baxter's ANDA Product before the expiration of the '265 patent would constitute an act of infringement of the '265 patent.

43. Mallinckrodt will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Mallinckrodt does not have an adequate remedy at law.

COUNT III
(INFRINGEMENT OF THE '238 PATENT)

44. Mallinckrodt incorporates each of the preceding paragraphs 1 to 43 as if fully set forth herein.

45. By seeking approval of ANDA No. 214331 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '238 patent, Baxter has infringed the '238 patent under 35 U.S.C. § 271(e)(2)(A).

46. Mallinckrodt is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 214331 be a date that is not earlier than the expiration date of the '238 patent, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the '238 patent, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled.

47. The commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product, if approved by the FDA before the expiration of the '238 patent, for use in accordance with its proposed labeling, would infringe, induce, and/or contribute to the infringement of the '238 patent.

48. Mallinckrodt is entitled to a declaration that, if Baxter commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Baxter's

ANDA Product, or induces or contributes to any such conduct, it would further infringe the '238 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

49. Upon information and belief, Baxter was aware of the existence of the '238 patent and was aware that the submission of ANDA No. 214331 to the FDA constituted an act of infringement of the '238 patent.

50. Upon information and belief, Baxter was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '238 patent would constitute an act of infringement of the '238 patent.

51. Mallinckrodt will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Mallinckrodt does not have an adequate remedy at law.

COUNT IV
(INFRINGEMENT OF THE '834 PATENT)

52. Mallinckrodt incorporates each of the preceding paragraphs 1 to 51 as if fully set forth herein.

53. By seeking approval of ANDA No. 214331 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '834 patent, Baxter has infringed the '834 patent under 35 U.S.C. § 271(e)(2)(A).

54. Mallinckrodt is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 214331 be a date that is not earlier than the expiration date of the '834 patent, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the '834 patent, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled.

55. The commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product, if approved by the FDA before the expiration of the '834 patent, for use in accordance with its proposed labeling, would infringe, induce, and/or contribute to the infringement of the '834 patent.

56. Mallinckrodt is entitled to a declaration that, if Baxter commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, Baxter's ANDA Product, or induces or contributes to any such conduct, it would further infringe the '834 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Upon information and belief, Baxter was aware of the existence of the '834 patent and was aware that the submission of ANDA No. 214331 to the FDA constituted an act of infringement of the '834 patent.

58. Upon information and belief, Baxter was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product before the expiration of the '834 patent would constitute an act of infringement of the '834 patent.

59. Mallinckrodt will be irreparably harmed by Baxter's infringing activities unless those activities are enjoined by this Court. Mallinckrodt does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Baxter has infringed the Asserted Patents by submitting ANDA No. 214331 to the FDA;

B. A declaration that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Baxter's ANDA Product will infringe or induce or contribute to the infringement of the Asserted Patents;

C. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of the Baxter ANDA shall not be earlier than the expiration date of the Asserted Patents, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the Asserted Patents, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled;

D. A preliminary and permanent injunction restraining and enjoining Baxter, its directors, officers, agents, attorneys, affiliates, divisions, successors, 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 Baxter ANDA product before the latest expiration date of the Asserted Patents, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the Asserted Patents, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled;

E. An award to Mallinckrodt of monetary relief if Baxter commercially manufactures, uses, offers for sale, or sells its generic version of Plaintiff's Ofirmev® brand product, or any other product that infringes or induces or contributes to the infringement of the Asserted Patents, within the United States before the latest expiration date of the Asserted Patents, including any patent term extensions and/or patent term adjustments, the period of any pediatric exclusivity associated with the Asserted Patents, and additional periods of exclusivity to which Mallinckrodt is or becomes entitled;

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

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

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

/s/ Kelly E. Farnan

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