IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT IP,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN LABORATORIES LTD. and AGILA SPECIALITIES INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Mallinckrodt IP ("Plaintiff") for its Complaint against defendants Mylan Laboratories Ltd. and Agila Specialties Inc. (collectively, "Defendants"), alleges as follows:

PARTIES

1. Plaintiff is a company organized and existing under the laws of Ireland, having a registered address of Damastown Industrial Estate, Mulhaddart, Dublin 15, Ireland. Plaintiff is a wholly-owned subsidiary of Mallinckrodt plc. As set forth herein, Plaintiff is the assignee of U.S. Patent No. 9,399,012 (the "Patent-in-Suit").

2. Upon information and belief, Defendant Agila Specialties Inc. ("Agila") is a New Jersey Corporation, having a principal place of business at 201 South Main Street, Suite #3, Lambertville, New Jersey 08530. Upon information and belief, Agila is the authorized United States agent for Mylan Laboratories Limited. Upon information and belief, Agila is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Agila regularly conducts business in Delaware.

3. Upon information and belief, Defendant Mylan Laboratories Limited (formerly known as Agila Specialties Private Limited, Inc.) ("Mylan") is a Private Limited Liability

Corporation having a principle place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India, 560076. Upon information and belief, Mylan is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Mylan regularly conducts business in Delaware.

NATURE OF THE ACTION

4. This is a civil action for infringement of the Patent-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

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

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

7. Upon information and belief, Agila regularly and continuously transacts business within the State of Delaware, either on its own or through its affiliates, including selling such pharmaceutical products as adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid. Upon information and belief, Agila 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.

8. In addition, Agila has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes. *See, e.g.*, *Cubist Pharmaceuticals, Inc. v. Strides, Inc., et al.*, No. 13-1679-GMS (D. Del.); *Cephalon, Inc. v. Agila Specialties Inc., et al.*, No. 13-2080-GMS (D. Del.); *Cadence Pharmaceuticals, Inc., et al. v. Agila Specialties Private Limited, et al.*, No. 14-1499-LPS (D. Del.). Agila has also purposely availed itself of this forum by asserting counterclaims, in at least the following actions: *Cubist Pharm., Inc. v. Strides, Inc., et al.*, No. 13-1679-GMS (D. Del.); *Cephalon, Inc. v. Agila Specialties Inc., et al.*, No. 13-2080-GMS (D. Del.).

9. Upon information and belief, Agila's systematic and continuous business contacts within Delaware render it at home in Delaware.

10. Upon information and belief, this Court has personal jurisdiction over Agila for the reasons stated herein, including, *inter alia*, Agila's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Agila at home in the forum.

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

12. Upon information and belief, Mylan regularly and continuously transacts business within the state of Delaware, either on its own or through its affiliates, including selling such pharmaceutical products as adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid.

13. Upon information and belief, Mylan has agreements with pharmaceutical retailers, wholesalers, or distributors providing for the distribution of its products in the State of Delaware.

14. Upon information and belief, Mylan 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.

15. In addition, Mylan has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes. *See, e.g.*, *Cubist Pharmaceuticals, Inc. v. Strides, Inc., et al.*, No. 13-1679-GMS (D. Del.); *Cadence Pharmaceuticals, Inc., et al. v. Agila Specialties Private Limited, et al.*, No. 14-1499-LPS (D. Del.). Mylan has also purposely availed itself of this forum by asserting counterclaims in at least the following action: *Cubist Pharm., Inc. v. Strides, Inc., et al.*, C.A. No. 13-1679-GMS (D. Del.).

16. Upon information and belief, Mylan's systematic and continuous business contacts within Delaware render it at home in Delaware.

17. Upon information and belief, this Court has personal jurisdiction over Mylan for the reasons stated herein, including, *inter alia*, Mylan's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent.

18. Alternatively, this Court also has personal jurisdiction over Mylan under FEDERAL RULE OF CIVIL PROCEDURE 4(k)(2).

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

20. The Patent-in-Suit, titled "Reduced Dose Intravenous Acetaminophen," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on July 26, 2016, to Plaintiff. The named inventors assigned the Patent-in-Suit to Cadence Pharmaceuticals, Inc. ("Cadence"), which subsequently assigned the Patent-in-Suit to Plaintiff. Plaintiff is now the sole assignee of the Patent-in-Suit. A true and correct copy of the Patent-in-Suit is attached as Exhibit A.

21. Claim 1 of the Patent-in-Suit 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."

22. Claim 39 of the Patent-in-Suit recites "[t]he method of claim 1**,** wherein the administered dose of acetaminophen is 650 mg, and further comprising repeating intravenous administration of 650 mg acetaminophen at least once at an interval of about 3 hours to about 5 hours."

OFIRMEV®

23. Cadence obtained approval from the FDA for New Drug Application ("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, Plaintiff is now the holder of NDA No. 022450.

24. OFIRMEV® was approved by the Food and Drug Administration (the "FDA") on November 2, 2010. OFIRMEV® is indicated for the treatment of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

25. 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 Patent-in-Suit was timely listed in the Orange Book with respect to OFIRMEV®.

DEFENDANTS' INFRINGEMENT OF THE PATENT-IN-SUIT

26. Upon information and belief, Mylan submitted NDA No. 20-6610 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 acetaminophen for injection 10 mg/mL ("Mylan's Generic Product"), prior to the expiration of U.S. Patent Nos. 6,028,222 (the "'222 patent") and 6,992,218 (the "'218 patent"), both of which were listed in the Orange Book with respect to OFIRMEV® and expire before the Patent-in-Suit.

27. By a letter received by Plaintiff, Cadence, and SCR Pharmatop on November 12, 2014, Mylan stated that it had submitted NDA No. 20-6610 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Mylan's Generic Product prior to the expiration of the '222 patent and '218 patent, both of which expire before the Patent-in-Suit.

28. Pursuant to 21 U.S.C. §§355(b)(2)-(3), because it was timely listed in the Orange Book, Mylan is obligated to provide a patent certification with respect to the Patent-in-Suit and

to notify Plaintiff of its certification. That listing occurred on or about August 17, 2016. Despite the foregoing, Plaintiff has not received any certification from Mylan with respect to the Patent-in-Suit. However, Mylan's submission of its NDA seeking approval for Mylan's Generic Product is an act of infringement with regard to one or more claims of the Orange Book-listed Patent-in-Suit pursuant to 35 U.S.C. § 271(e)(2).

29. Upon information and belief, Mylan has represented to the FDA that Mylan's Generic Product will have the same active ingredient as OFIRMEV®; have the same route of administration, dosage form, and strength as OFIRMEV®; and be bioequivalent to OFIRMEV®.

30. Upon information and belief, Mylan has taken substantial steps to prepare to begin the importation, marketing, commercial manufacture, sale and/or offer for sale of Mylan's Generic Product.

31. Upon information and belief, the FDA will require the labeling for Mylan's Generic Product to be substantially identical to the approved labeling for OFIRMEV®, and Mylan's Generic Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for OFIRMEV®.

32. 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 B.

33. 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."

34. 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."

35. Section 2.4 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 vial 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 vial and place the measured dose in a separate empty, sterile container (e.g. glass bottle, plastic intravenous container, or syringe) for intravenous infusion . . . ."

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

37. Section 12.1 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.

38. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least Claims 1 and 39 of the Patent-in-Suit.

39. 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 . . . ."

40. As such, on information and belief, the FDA will not allow said information to be excised from a proposed labeling for acetaminophen injection products that allegedly are bioequivalent to OFIRMEV®.

41. 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).

42. Upon information and belief, the FDA will require the labeling for Mylan's Generic Product, 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours.

43. Upon information and belief, based on the labeling that is likely to be required by the FDA for Mylan's Generic Product, if approved, Mylan's Generic 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours, which administration will constitute direct infringement of at least Claims 1 and 39 of the Patent-in-Suit. Upon information and belief, this will occur at Defendants' active behest, and with Defendants' intent, knowledge, and encouragement. Upon information and belief, Defendants will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the Patent-in-Suit.

44. Upon information and belief, Mylan's Generic Product is a composition especially made for use in 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours, and is not a staple article or commodity of commerce suitable for any substantial noninfringing use.

45. Mylan's submission of NDA No. 20-6610 to the FDA constitutes infringement of the Patent-in-Suit under 35 USC § 271(e)(2)(A). Moreover, Defendants intend to commercially manufacture, import, use, offer for sale, or sell Mylan's Generic Product and/or induce or contribute to such conduct. Said actions would constitute infringement of the Patent-in-Suit under 35 USC § 271(a), (b), and/or (c).

46. Upon information and belief, Defendants were aware of the application that subsequently issued as the Patent-in-Suit while continuing to seek approval of NDA No. 20-6610, and their actions render this an exceptional case under 35 U.S.C. § 285.

47. Upon information and belief, Mylan and Agila collaborated and acted in concert in the decision to file and also in the filing of NDA No. 20-6610.

48. The acts of infringement by Defendants set forth above will cause Plaintiff irreparable harm for which it has no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I
(Infringement of the Patent-in-Suit by Defendants)

49. Plaintiff incorporates each of the preceding paragraphs 1 to 48 as if fully set forth herein.

50. Defendants' submission of NDA No. 20-6610 constitutes infringement of the Patent-in-Suit pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

51. Upon information and belief, upon FDA approval of NDA No. 20-6610, Defendants will infringe the Patent-in-Suit by making, using, offering to sell, or selling Mylan's Generic Product in the United States and/or importing Mylan's Generic Product into the United States, in violation of 35 U.S.C. § 271.

52. Upon information and belief, upon FDA approval of NDA No. 20-6610, doctors, nurses, and other medical professionals will directly infringe at least claims 1 and 39 of the Patent-in-Suit by using Mylan's Generic Product, in violation of 35 U.S.C. § 271(a). Mylan's Generic 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours, which administration will constitute direct infringement of at least Claims 1 and 39 of the Patent-in-Suit.

53. Upon information and belief, this direct infringement will occur at Defendants' active behest, and with Defendants' intent, knowledge, and encouragement. Defendants will intentionally encourage infringement of at least Claims 1 and 39 of the Patent-in-Suit at least by way of the labeling for Mylan's Generic 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours.

54. Upon information and belief, Defendants are aware of the Patent-in-Suit, which is listed in the Orange Book with respect to OFIRMEV®, and will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the Patent-in-Suit, in violation of 35 U.S.C. § 271(b).

55. Upon information and belief, Mylan's Generic Product is a composition for use in practicing at least Claims 1 and 39 of the Patent-in-Suit. Claims 1 and 39 of the Patent-in-Suit require administration of intravenous acetaminophen. Mylan's Generic Product is intravenous acetaminophen. Accordingly, Mylan's Generic Product constitutes a material part of the invention of the Patent-in-Suit.

56. Upon information and belief, Defendants are aware of the labeling for OFIRMEV®, which instructs how to use OFIRMEV® to practice the methods of at least Claims

1 and 39 of the Patent-in-Suit. Accordingly, upon information and belief, Defendants know that Mylan's Generic Product, which is proposed as a generic version of OFIRMEV®, is especially made or especially adapted for use in practicing at least Claims 1 and 39 of the Patent-in-Suit and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Defendants will intentionally encourage infringement of at least Claims 1 and 39 of the Patent-in-Suit at least by way of the labeling for Mylan's Generic Product which the FDA likely will require to 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 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours.

57. Upon information and belief, Defendants are aware of the Patent-in-Suit, which is listed in the Orange Book with respect to OFIRMEV®, and will contribute to infringement of the Patent-in-Suit by offering to sell or selling within the United States or importing into the United States Mylan's Generic Product, in violation of 35 U.S.C. § 271(c).

58. Upon information and belief, Defendants had actual and constructive knowledge of the application that later issued as the Patent-in-Suit prior to filing NDA No. 20-6610 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the Patent-in-Suit upon its issuance.

COUNT II
(Declaratory Judgment of Infringement of the Patent-in-Suit by Defendants)

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

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

61. Plaintiff is entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Mylan's Generic Product within the United States, import Mylan's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the Patent-in-Suit under 35 U.S.C. § 271(a), (b) and/or (c).

62. An actual controversy has arisen and now exists between the parties concerning whether Defendants will directly or indirectly infringe the Patent-in-Suit.

63. Plaintiff will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Defendants infringed and are infringing the Patent-in-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of Defendants' NDA No. 20-6610 shall not be earlier than the expiration date of the Patent-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;

C. A declaration that if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Mylan's Generic Product within the United States, import Mylan's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the Patent-in-Suit;

D. A preliminary and permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them,

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 Mylan's Generic Product until the expiration of the Patent-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;

E. That Plaintiff be awarded monetary relief if Defendants commercially manufacture, use, offer for sale, or sell their generic version of Plaintiff's OFIRMEV® brand product, or any other product that infringes or induce or contribute to the infringement of the Patent-in-Suit, within the United States before the latest expiration date of the Patent-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is 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

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