

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE XARELTO (RIVAROXABAN)('310))	MDL Docket No. 21-md-3017
PATENT LITIGATION)	
)	
)	
BAYER PHARMA AG, BAYER AG, and)	C.A. No. 23-1219-RGA
JANSSEN PHARMACEUTICALS, INC.,)	(Consolidated)
Plaintiffs,)	
)	
v.)	
TARO PHARMACEUTICAL INDUSTRIES)	
LTD. and TARO PHARMACEUTICALS)	
U.S.A., INC.,)	
Defendants.)	

**DEFENDANTS TARO PHARMACEUTICAL INDUSTRIES LTD. AND TARO
PHARMACEUTICALS U.S.A., INC.'s ANSWER TO PLAINTIFFS'
COMPLAINT FOR PATENT INFRINGEMENT AND COUNTERCLAIMS**

Defendants Taro Pharmaceutical Industries Ltd. (“Taro Ltd.”) and Taro Pharmaceuticals U.S.A., Inc. (“Taro U.S.A.”) (collectively, “Taro”), by and through their undersigned attorneys, hereby answer the Complaint for Patent Infringement of Plaintiffs Bayer Pharma AG (“Bayer Pharma”), Bayer AG (“Bayer AG”) and Janssen Pharmaceuticals, Inc. (“Janssen” and, collectively with Bayer Pharma and Bayer AG, “Plaintiffs”) in the above-captioned action as set forth below. Pursuant to Fed. R. Civ. P. 8(b)(3), Taro denies all allegations in Plaintiffs’ Complaint except those specifically admitted below.

Response to “Nature of the Action”

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission and amendment by Taro Pharmaceutical Industries Ltd. of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs’ 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 (“the ’310 patent”).

ANSWER: Taro admits Plaintiffs purport to bring their claims under the patent laws of the United States, Title 35, United States Code, against Taro. Taro further admits this action purports to relate to the Abbreviated New Drug Application (“ANDA”) submitted to FDA by Taro seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs’ 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 (“the ’310 patent”). Taro denies any remaining allegations in Paragraph 1.

Response to “The Parties”
Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

ANSWER: Taro lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

ANSWER: Taro lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies the same.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

ANSWER: Taro lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies the same.

Defendants

5. On information and belief, Defendant Taro Pharmaceutical Industries Ltd. (“Taro Ltd.”) is a corporation organized and existing under the laws of the State of Israel, with a place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

ANSWER: Taro admits Taro Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

6. On information and belief, Taro Pharmaceuticals U.S.A., Inc. (“Taro USA”) is a corporation organized and existing under the laws of the State of New York, with a place of business at 3 Skyline Drive, Hawthorne, NY 10532.

ANSWER: Taro admits Taro U.S.A. is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 3 Skyline Drive, Hawthorne, NY 10532.

7. On information and belief, Defendant Taro USA is the agent for service of process in the United States for Taro Ltd.

ANSWER: Taro admits Taro U.S.A. is listed as the authorized U.S. agent for service of process in the United States for Taro Ltd. Taro denies any remaining allegations set forth in Paragraph 7.

8. On information and belief, Taro USA is a wholly owned subsidiary of Taro Ltd., and is controlled and dominated by Taro Ltd.

ANSWER: Taro admits Taro U.S.A. is a wholly-owned subsidiary of Taro Ltd. Taro denies any remaining allegations set forth in Paragraph 8.

9. On information and belief, Taro Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Taro Ltd., acting in concert with Taro USA, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Taro Ltd., acting in concert with Taro USA, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“Paragraph IV Certifications”) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

ANSWER: Taro admits that Taro Ltd. manufactures, markets, distributes, offers for sale, and sells generic pharmaceutical drug products. Taro further admits Taro Ltd. has used Taro U.S.A. as its authorized U.S. agent in ANDA filings with FDA seeking approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products. Taro further admits that as a part of certain of those ANDA filings, Taro Ltd. has filed certifications known as Paragraph IV Certifications in order to gain approval for the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of certain United States patents that are associated with certain products. Taro denies any remaining allegations set forth in Paragraph 9.

10. On information and belief, Taro Ltd. and Taro USA acted in concert to prepare, submit, and amend ANDA No. 208557 for Taro Ltd.'s 2.5 mg rivaroxaban tablets ("Taro's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Taro Ltd.

ANSWER: Taro admits Taro U.S.A. is listed as the authorized U.S. agent in ANDA No. 208557. Taro further admits Taro Ltd. is the applicant for and owner of ANDA No. 208557. Taro denies any remaining allegations set forth in Paragraph 10.

11. On information and belief, Taro Ltd. and Taro USA are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Taro's ANDA Product at issue.

ANSWER: The allegations in Paragraph 11 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 11.

12. On information and belief, following any FDA approval of ANDA No. 208557, Taro Ltd. and Taro USA will act in concert to market, distribute, offer for sale, and sell Taro's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Taro."

ANSWER: Taro admits that Taro Ltd. and Taro U.S.A. are collectively referred to as “Taro” in the Complaint. Taro denies any remaining allegations set forth in Paragraph 12.

13. On information and belief, following any FDA approval of ANDA No. 208557, Taro will market, distribute, offer for sale, and sell Taro’s ANDA Product throughout the United States and within Delaware.

ANSWER: Taro admits, through preparation and submission of ANDA No. 208577 for approval of the ANDA Product, that Taro Ltd. is seeking approval to market, use, distribute, offer for sale, and sell Taro’s ANDA Product throughout the United States. Taro denies any remaining allegations set forth in Paragraph 13.

14. On information and belief, following any FDA approval of ANDA No. 208557, Taro knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

ANSWER: Taro denies the allegations set forth in Paragraph 14.

Response to “Jurisdiction”

15. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Taro repeats, reasserts, and incorporates by reference its responses to each and every allegation contained in Paragraphs 1 to 14 as if fully set forth herein.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in Paragraph 16 are legal conclusions to which no response is required. For the purposes of this action only, Taro does not contest subject matter jurisdiction. Taro denies any remaining allegations in Paragraph 16.

17. This Court has personal jurisdiction over Taro USA and Taro Ltd. because, among other things, on information and belief: (1) Taro USA and Taro Ltd. acted in concert to file an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Taro’s ANDA Product in the United States, including in Delaware; and (2) Taro USA and Taro Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Taro’s ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208557, and will derive substantial revenue from the use or consumption of Taro’s ANDA Product in the State of Delaware. On information and belief,

if ANDA No. 208557 is approved, the generic Taro product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

ANSWER: The allegations in Paragraph 17 are legal conclusions to which no response is required. To the extent a response is required, Taro admits it filed or caused to be filed ANDA No. 208557 with FDA requesting approval to market Taro's ANDA product. Taro denies the remaining allegations in Paragraph 17. For the purposes of this action only, Taro does not contest personal jurisdiction.

18. Alternatively, if Taro Ltd.'s connections with Delaware, including its connections with Taro USA, are found to be insufficient to confer personal jurisdiction, then upon information and belief, Taro Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Taro Ltd. in Delaware is consistent with the United States Constitution and laws. *See Fed. R. Civ. P. 4(k)(2).*

ANSWER: The allegations in Paragraph 18 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 18.

19. Taro USA and Taro Ltd. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and/or it has filed counterclaims in such cases. *See e.g., Bayer Pharma AG et al. v. Taro Pharmaceutical Industries Ltd. USA, Inc. et al.*, C.A. No. 21-1000 (D.I. 11); *Leo Pharma A/S et al. v. Taro Pharmaceuticals U.S.A. et al.*, C.A. 19-221 (D.I. 12); *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, C.A. No. 18-1673 (D.I. 38) (Taro USA); *Allergan, Inc. v. Taro Pharmaceutical Industries Ltd.*, C.A. No. 17-663 (D.I. 10) (Taro Ltd.).

ANSWER: Taro admits that it has filed counterclaims in the District of Delaware in one or more prior cases arising out of the filing of an ANDA. Taro denies any remaining allegations

set forth in Paragraph 19. Taro does not contest personal jurisdiction for the purposes of this action only.

Response to “Venue”

20. Venue is proper in this district for Taro Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Taro Ltd. is a private limited company organized and existing under the laws of Israel and is subject to personal jurisdiction in this judicial district.

ANSWER: The allegations in Paragraph 20 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations in Paragraph 20. For the purposes of this action only, Taro does not contest venue.

21. Venue is proper in this district for Taro USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Taro USA is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district and/or will consent to venue for the purpose of this case. *See e.g., Bayer Pharma AG et al. v. Taro Pharmaceutical Industries Ltd. USA, Inc. et al.*, C.A. No. 21-1000 (D.I. 11); *Leo Pharma A/S et al. v. Taro Pharmaceuticals U.S.A. et al.*, C.A. 19-221 (D.I. 12); *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, C.A. No. 18-1673 (D.I. 38).

ANSWER: The allegations in Paragraph 21 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations in Paragraph 21. For the purposes of this action only, Taro does not contest venue.

Response to “Factual Background”

22. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, and stroke) in adult patients with coronary artery disease (CAD); and (ii) to reduce the risk of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.

ANSWER: Taro admits XARELTO® has FDA approved indications and prescribing information. Taro admits the indications and prescribing information are indicated on the label

for XARELTO®. The label for XARELTO® speaks for itself. Taro denies any remaining allegations in Paragraph 22.

23. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

ANSWER: Taro admits the Orange Book lists Janssen as the NDA holder for NDA No. 022406 for rivaroxaban tablets sold under the trade name Xarelto. Taro further admits that NDA No. 022406 has been approved by FDA. Taro denies any remaining allegations in Paragraph 23.

24. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020. The '310 patent is attached as Exhibit A.

ANSWER: Taro admits the '310 patent is entitled "Reducing the Risk of Cardiovascular Events" and, on its face, has an issue date of November 10, 2020. Taro further admits a purported copy of the '310 patent is attached to Plaintiffs' Complaint as Exhibit A. On information and belief, Taro admits Bayer Pharma Aktiengesellschaft is the current assignee of the '310 patent. Taro denies any remaining allegations in Paragraph 24.

25. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

ANSWER: The allegations in Paragraph 25 are legal conclusions to which no response is required. To the extent a response is required, Taro admits Claim 1 of the '310 patent states "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in

reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily.”

Taro denies any remaining allegations set forth in Paragraph 25.

26. Bayer Pharma AG is the assignee of the '310 patent.

ANSWER: Taro admits that the '310 patent lists Bayer Pharma as the assignee of the '310 patent. Taro lacks knowledge or information sufficient to form a belief as to the truth of the current assignment of ownership of the '310 patent, and therefore denies the same. Taro denies any remaining allegations set forth in Paragraph 26.

27. Bayer AG is an exclusive licensee under the '310 patent.

ANSWER: Taro lacks knowledge or information sufficient to admit or deny the allegation Bayer AG is the exclusive licensee of the '310 patent, and therefore denies the same.

28. Janssen is an exclusive sublicensee under the '310 patent.

ANSWER: Taro lacks knowledge or information sufficient to admit or deny the allegation Janssen is an exclusive sublicensee of the '310 patent, and therefore denies the same.

29. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”) in connection with the 2.5 mg strength of XARELTO®.

ANSWER: Taro admits that the Orange Book lists the '310 patent in connection with Xarelto®. Taro denies any remaining allegations set forth in Paragraph 29.

Response to “Count I: Infringement of the '310 Patent

30. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Taro repeats, reasserts, and incorporates by reference its responses to each and every allegation contained in Paragraphs 1 to 29 as if fully set forth herein.

31. By letter dated June 11, 2021 (“Taro’s First Notice Letter”), Taro notified Bayer Pharma AG and Janssen that Taro Ltd. had submitted to the FDA ANDA No. 208557 for Taro’s ANDA Product and had submitted an amendment to that ANDA. This product is a generic version of the 2.5 mg strength of XARELTO®.

ANSWER: Taro admits on June 11, 2021, Taro sent a Notice Letter to Bayer Pharma AG and Janssen. Taro further admits, according to the Notice Letter, Taro submitted an amendment to ANDA No. 208557 to FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Taro denies any remaining allegations in Paragraph 31.

32. In Taro’s First Notice Letter, Taro indicated that, in connection with its ANDA No. 208557, Taro had filed a Paragraph IV Certification with respect to the ’310 patent.

ANSWER: Taro admits that in the Notice Letter, Taro Ltd. indicated a Paragraph IV Certification with respect to the ’310 patent had been filed. Taro denies any remaining allegations set forth in Paragraph 32.

33. In Taro’s First Notice Letter, Taro stated that Taro’s ANDA Product contains rivaroxaban.

ANSWER: Taro admits that in the Notice Letter, Taro Ltd. indicated the ANDA product contains rivaroxaban. Taro denies any remaining allegations set forth in Paragraph 33.

34. After receiving Taro’s First Notice Letter, Bayer and Janssen sued Taro Ltd. and Taro USA for infringement of the ’310 patent on July 7, 2021 in this district. The Pending ’310 Patent Action was consolidated before this Court for all purposes, including trial, in *Bayer Pharma AG et al. v. Lupin Limited et al.*, C.A. No. 21-314-RGA (D. Del. October 27, 2021) (“Consolidated Infringement Action”), D.I. 22, ¶ 1.

ANSWER: Taro admits Bayer and Janssen filed a Complaint against Taro on July 7, 2021 in the District of Delaware. Taro further admits that action was consolidated in *Bayer Pharma AG et al. v. Lupin Limited et al.*, C.A. No. 21-314-RGA (D. Del. October 27, 2021)

(“Consolidated Infringement Action”), D.I. 22, ¶ 1. Taro denies any remaining allegations in Paragraph 34.

35. By letter dated September 11, 2023 (“Taro’s Second Notice Letter”), Taro Ltd. notified Bayer and Janssen that “Taro has submitted, and the Food and Drug Administration (‘FDA’) has received, an amendment to Taro’s Abbreviated New Drug Application (‘ANDA’) under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, importation, offer for sale or sale of Taro’s proposed rivaroxaban 2.5mg tablet product . . . prior to the expiration of U.S. Patent No. 9,415,053 . . . and U.S. Patent No. 10,828,310.” Taro’s Second Notice Letter indicates that Taro seeks approval from the FDA to engage in the commercial manufacture, use or sale of Taro’s ANDA Product prior to the expiration of the ’310 Patent. Taro’s Second Notice Letter also indicates that it “exclusively relates to the Amendment to Taro’s ANDA due to the additional use codes” that were added to the ’310 Patent in connection with the 2.5 mg strength of XARELTO®, “necessitating the supplementation of [Taro’s] Paragraph IV certifications.”

ANSWER: Taro admits on September 11, 2023, Taro sent a Notice Letter to Bayer Pharma AG and Janssen. Taro further admits, according to the Notice Letter, due to the addition of use codes associated with the 2.5mg strength of XARELTO®, Taro submitted an amendment to ANDA No. 208557 to FDA under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Taro denies any remaining allegations in Paragraph 35.

36. Taro stipulated to infringement in the Consolidated Infringement Action. *See* D.I. 117, 119. On information and belief, the proposed labeling for Taro’s ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for Taro’s ANDA Product further directs the administration of Taro’s ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Taro’s ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

ANSWER: Taro admits a stipulation was entered in the Consolidated Action, the content of which is available at D.I. 117 and 119 in that action. The stipulation speaks for itself. Taro admits ANDA No. 208557 contains proposed labeling, including indications and instructions

for use of Taro's ANDA Product, as required by 21 U.S.C. 355(j)(2)(A)(i) and (v). Taro denies any other allegations set forth in Paragraph 36.

37. The purpose of ANDA No. 208557 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Taro's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Taro admits a purpose of ANDA No. 208557 was to obtain approval under the FFDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Taro's ANDA Product with the proposed labeling. Taro further admits that it filed a Paragraph IV certification relating to the '310 patent. Taro denies any remaining allegations set forth in Paragraph 37.

38. Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208557, *i.e.*, prior to the expiration of the '310 patent.

ANSWER: Taro admits it seeks FDA approval to sell Taro's ANDA Product. Taro denies the remaining allegations in Paragraph 38.

39. On information and belief, the manufacture, use (including in accordance with and as directed by Taro's proposed labeling for Taro's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product will infringe at least claim 1 of the '310 patent.

ANSWER: The allegations in Paragraph 39 are legal conclusions regarding claim 1 of the '310 patent to which no response is required. To the extent that a response is required, Taro denies the allegations set forth in Paragraph 39.

40. Taro has, and has had since the date of Taro's First Notice Letter, knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Taro has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208557. On information and belief, by such activities, Taro specifically intends to infringe the '310 patent.

ANSWER: Taro admits it is aware of the claims in the '310 patent. The allegations in Paragraph 40 are legal conclusions regarding the '310 patent to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 40.

41. On information and belief, Taro plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

ANSWER: The allegations in Paragraph 41 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 41.

42. On information and belief, Taro knows that Taro's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Taro's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. Taro's ANDA Product is a material part of the claimed invention. On information and belief, Taro plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 208557.

ANSWER: The allegations in Paragraph 42 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 42.

43. Taro's submission of ANDA No. 208557 and submission of an amendment to that ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Taro's ANDA Product were acts of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations in Paragraph 43 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 43.

44. On information and belief, Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Taro's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Taro denies the allegations in Paragraph 44.

45. Taro intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Taro's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

ANSWER: Taro denies the allegations in Paragraph 45.

46. The foregoing actions by Taro constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

ANSWER: The allegations in Paragraph 46 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 46.

47. Unless Taro is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: The allegations in Paragraph 47 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 47.

48. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received Taro's Second Notice Letter.

ANSWER: The allegations in Paragraph 48 are legal conclusions to which no response is required. To the extent a response is required, Taro admits it sent a copy of its Paragraph IV Notice Letter to Bayer and Janssen on September 11, 2023.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

49. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Taro repeats, reasserts, and incorporates by reference its responses to each and every allegation contained in Paragraphs 1 to 48 as if fully set forth herein.

50. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Taro on the other regarding Taro's liability for infringement and active inducement of infringement of the '310 patent.

ANSWER: The allegations in Paragraph 50 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 50.

51. An actual case or controversy exists between Plaintiffs and Taro with respect to Taro's liability for infringement of the '310 patent.

ANSWER: Taro admits the allegations of Paragraph 51.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Taro's ANDA Product will infringe and induce the infringement of the '310 patent.

ANSWER: The allegations in Paragraph 52 are legal conclusions to which no response is required. To the extent a response is required, Taro denies the allegations set forth in Paragraph 52.

Response to "Prayer for Relief"

Taro further denies each and every allegation of the Complaint to which Taro has not specifically admitted, denied, or otherwise responded herein. Taro denies that Plaintiffs are entitled to judgment or any of the relief prayed for in Paragraphs (a)-(g) of the Prayer for Relief in the Complaint. Taro demands judgment in its favor.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, Taro alleges and asserts the following affirmative defenses in response to Plaintiffs' allegations. Taro reserves the right to allege any and all defenses not presently known or revealed during discovery or other analysis. Taro does not assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof regardless of how such defenses are denominated herein.

First Affirmative Defense

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

Second Affirmative Defense

The claims of the '310 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/ or 112, and/or based on other judicially-created bases for invalidation.

Third Affirmative Defense

Taro has not infringed, is not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '310 patent.

Fourth Affirmative Defense

Taro's actions do not constitute an exceptional case under 35 U.S.C. § 285.

Fifth Affirmative Defense

Plaintiffs may not seek injunctive relief against Taro for at least the reason that Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

Additional Defenses

Taro reserves the right to allege additional affirmative defenses that may now exist or in the future as they become known through the course of discovery or further factual investigation in the case.

WHEREFORE, Taro prays this Court:

- A. Enter an order dismissing the Complaint, and all claims for relief contained therein, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;
- B. Deny Plaintiffs any award of damages, costs, or fees;
- C. Declare this case exceptional, and award Taro its costs, expenses, and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law as may apply; and
- D. Grant such other and further relief as this Court may deem just.

**COUNTERCLAIMS OF TARO PHARMACEUTICAL INDUSTRIES LTD.
AND TARO PHARMACEUTICALS U.S.A., INC.**

Without admitting any of the allegations of Plaintiffs Bayer Pharma AG (“Bayer Pharma”), Bayer AG (“Bayer AG”), (Bayer Pharma and Bayer AG are collectively referred to as “Bayer”), and Janssen Pharmaceuticals, Inc. (“Janssen”) (Bayer and Janssen are collectively referred to as “Counterclaim Defendants”) other than those expressly admitted herein, and without prejudice to Counterclaimants Taro Pharmaceutical Industries Ltd. (“Taro Ltd.”) and Taro Pharmaceuticals U.S.A., Inc. (“Taro U.S.A.”) (collectively, “Taro”) right to plead additional counterclaims as the facts of the matter warrant, Taro asserts the following counterclaims against Counterclaim Defendants:

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seek a declaratory judgment that Taro’s proposed products in Abbreviated New Drug Application (“ANDA”) No. 208557 do not and will not infringe any valid and enforceable claim of U.S. Patent No. 10,828,310

(“the ‘310 patent”) or U.S. Patent No. 9,415,053 (“the ‘053 patent”) (attached hereto as Exhibit 1), and that each and every claim of the ‘310 patent and the ‘053 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

THE PARTIES

2. Defendant-Counterclaimant Taro Ltd. is a corporation organized and existing under the laws of the State of Israel, with a place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

3. Defendant-Counterclaimant Taro U.S.A. is a corporation organized and existing under the laws of the State of New York, with a place of business at 3 Skyline Drive, Hawthorne, NY 10532.

4. On information and belief based on Counterclaim Defendants’ allegations, counterclaim defendant Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Millerstrasse 178, 13353 Berlin, Germany.

5. On information and belief based on Counterclaim Defendants’ allegations, counterclaim defendant Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Alle 1, 51368 Leverkusen, Germany.

6. On information and belief based on Counterclaim Defendants’ allegations, counterclaim defendant Janssen Pharmaceuticals, Inc. is a corporation organized and existing

under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

7. On information and belief, Counterclaim Defendants, by themselves and/or through their affiliates and agents, are in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Counterclaim Defendants based on, *inter alia*, their filing of this lawsuit in this jurisdiction.

10. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

11. According to the United States Food & Drug Administration (“FDA”) publication titled Approved Drug Products and Therapeutic Equivalence Evaluations (“the Orange Book”), Janssen holds approved New Drug Application (“NDA”) No. 022406 for rivaroxaban tablets sold under the trade name Xarelto®.

12. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to the FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes “claims the

drug for which the applicant submitted the [NDA] or which claims a method of using such drug.”

The FDA ministerially publishes these patents in the Orange Book.

13. Upon information and belief, and as stated in the Complaint in this matter, one or more of the Counterclaim Defendants are the owner, assignee, licensee, and/or sublicensee of the '310 patent.

14. Upon information and belief, one or more of the Counterclaim Defendants are the owner, assignee, licensee and/or sublicenses of the '053 patent.

15. Upon information and belief, one or more of the Counterclaim Defendant(s), itself or through its agents, caused the '310 patent and the '053 to be listed in the Orange Book as patents that claim rivaroxaban or methods of using rivaroxaban.

The '310 Patent Listed in the Orange Book for Xarelto®

16. The '310 patent, on its face, is entitled “Reducing the Risk of Cardiovascular Events” and has an issue date of November 10, 2020. A copy of the '310 patent is attached as an exhibit to the Complaint (C.A. No. 23-1219-RGA, D.I. 1, Ex. A).

17. On the face of the '310 patent and based on Counterclaim Defendants' allegations, Bayer Pharma Aktiengesellschaft is the assignee of the '310 patent.

18. Upon information and belief, including Counterclaim Defendants' allegations, Bayer AG is an exclusive licensee under the '310 patent and Janssen is an exclusive sublicensee under the '310 patent.

The '053 Patent Listed in the Orange Book for Xarelto®

19. The '053 patent, on its face, is entitled “Solid, Orally Administrable Pharmaceutical Composition” and has an issue date of August 16, 2016. A copy of the '053 patent is attached as Exhibit 1 hereto.

20. Upon information and belief and according to the USPTO Patent Assignment Database Bayer Intellectual Property GmbH is the assignee of the '053 patent.

21. Upon information and belief, Bayer AG is a licensee under the '053 patent and Janssen is a sublicensee under the '053 patent.

The Taro ANDA Product

22. Taro has submitted ANDA No. 208557 to FDA, seeking approval to engage in commercial manufacture, use, or sale of 2.5 mg rivaroxaban tablets (“the ANDA Product”) prior to the expiration of the '310 patent and the '053 patent.

23. ANDA No. 208557 contains a Paragraph IV certification under 21 U.S.C. §355G)(2)(A)(vii)(IV) that the '310 patent and the '053 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of the ANDA Product.

24. On or about June 11, 2021, Taro sent a notice letter providing notice of its submission of an amendment to ANDA No. 208557 to FDA (“the Notice Letter”) to Bayer and Janssen. The Notice Letter contained notifications of Taro’s Paragraph IV Certification to FDA that the '310 patent and the '053 patent are invalid and/or not infringed by the commercial manufacture, use, or sale of the ANDA Product.

25. On or about September 11, 2023, Taro sent a notice letter providing notice of its submission of an amendment to ANDA No. 208557 to FDA to Bayer and Janssen. The Notice Letter contained notifications of Taro’s Paragraph IV Certification to FDA that the '310 patent and the '053 patent are invalid and/or not infringed by the commercial manufacture, use, or sale of the ANDA Product.

26. On or around October 26, 2023, Counterclaim Defendants filed this lawsuit alleging that Taro infringes the '310 patent based on Taro's filing of and amendment to ANDA No. 208557. Counterclaim Defendants did not allege infringement of the '053 patent by Taro.

27. Taro denies that it infringes any valid claim of the '310 patent or the '053 patent.

28. Unless enjoined, Counterclaim Defendants could assert Taro infringes the '053 patent, leaving uncertainty for Taro and impairing Taro's ability to market the Taro ANDA Product, thereby causing irreparable harm to Taro.

29. Unless enjoined, Counterclaim Defendants will continue to assert that Taro infringes the '310 patent and will continue to impair Taro's ability to market the ANDA Products, thereby causing irreparable harm to Taro's business.

COUNT I

(Declaration of Invalidity of the '310 Patent)

30. Taro repeats, re-alleges, and incorporates by reference Paragraphs 1 – 29 of its Counterclaims as if fully set forth herein.

31. There is an actual, substantial, and continuing case or controversy between Taro and Counterclaim Defendants regarding, *inter alia*, the invalidity of the '310 patent.

32. One or more of the claims of the '310 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101, *et seq.*, including, *e.g.*, §§ 102, 103, 112, and/or other judicially-created bases for invalidation.

33. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201, *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '310 patent are invalid.

COUNT II

(Declaration of Noninfringement of the '310 Patent)

34. Taro repeats, re-alleges, and incorporates by reference Paragraphs 1 – 33 of its Counterclaims as if fully set forth herein.

35. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Counterclaim Defendants concerning the infringement of the '310 patent.

36. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '310 patent, either literally or under the doctrine of equivalents, at least because each of the claims of the '310 patent that Counterclaim Defendants could assert against Taro is invalid as set forth above in Count I of Taro's Counterclaims. An invalid claim cannot be infringed.

37. A definite and concrete, real and substantial, justiciable controversy exists between Taro and Counterclaim Defendants concerning the alleged infringement by the ANDA Products of the '310 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

38. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201, *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '310 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaration of Invalidity of the '053 Patent)

39. Taro repeats, re-alleges, and incorporates by reference Paragraphs 1 – 38 of its Counterclaims as if fully set forth herein.

40. There is an actual, substantial, and continuing case or controversy between Taro and Counterclaim Defendants regarding, *inter alia*, the invalidity of the '053 patent.

41. One or more of the claims of the '053 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101, *et seq.*, including, *e.g.*, §§ 102, 103, 112, and/or other judicially-created bases for invalidation.

42. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201, *et seq.*, Taro is entitled to a declaratory judgment that one or more claims of the '053 patent are invalid.

COUNT IV

(Declaration of Noninfringement of the '053 Patent)

43. Taro repeats, re-alleges, and incorporates by reference Paragraphs 1 – 42 of its Counterclaims as if fully set forth herein.

44. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Taro and Counterclaim Defendants concerning the infringement of the '053 patent.

45. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Products has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '053 patent, either literally

or under the doctrine of equivalents, at least because each of the claims of the '053 patent that Counterclaim Defendants could assert against Taro is invalid as set forth above in Count III of Taro's counterclaims. An invalid claim cannot be infringed.

46. A definite and concrete, real and substantial, justiciable controversy exists between Taro and Counterclaim Defendants concerning the ANDA Products of the '053 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

47. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201, *et seq.*, Taro is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '053 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Taro respectfully requests this Court enter judgment in its favor granting the following relief:

- A. Dismissing Plaintiffs' Complaint, and all claims for relief contained therein, with prejudice and denying each request for relief made by Plaintiffs;
- B. Declaring that all claims of the '310 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Taro ANDA Product;
- C. Declaring all claims of the '310 patent invalid;
- D. Declaring that all claims of the '053 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Taro ANDA Product;
- E. Declaring all claims of the '053 patent invalid;

F. Declaring that Taro has a lawful right to obtain FDA approval for the product as described in ANDA No. 208557, and that Taro has a lawful right to manufacture, import, use, sell, and/or offer to sell the product as described in ANDA No. 208557;

G. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Taro its attorneys' fees, costs, and expenses in this action;

H. Awarding Taro its costs and expenses in this action pursuant to 35 U.S.C. § 285 and 28 U.S.C. § 1920, or any other applicable statute and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

I. Awarding Taro such other and further relief as the Court deems just and proper.

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Dated: August 9, 2024


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CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire hereby certify that on August 9, 2024, I caused a true and correct copy of the foregoing document to be served by e-mail on the following counsel of record:

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