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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME LLC, MSD INTERNATIONAL GMBH, MSD INTERNATIONAL BUSINESS GMBH, and AIC246 AG & CO. KG,	
Plaintiffs,	Civil Action No. 24-10820
v.	*Document Electronically Filed*
ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED,	
Defendants.	

COMPLAINT

Plaintiffs Merck Sharp & Dohme LLC ("Merck LLC"), MSD International GmbH ("MSDIG"), MSD International Business GmbH ("MSDIB") (together, "Merck"), and AIC246 AG & Co. KG ("AiCuris") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

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 by defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Zydus") of Abbreviated New Drug Application ("ANDA") No. 216799 ("Zydus's ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of PREVYMIS® (letermovir) tablets, 240mg, 480mg ("Zydus's ANDA Product"), prior to the expiration of U.S. Reissued Patent No. RE 46,791 ("the RE '791 patent") (Exhibit A), that is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for PREVYMIS®. Zydus notified Plaintiffs that it had submitted Zydus's ANDA by a letter dated October 16, 2024 ("Notice Letter"). Upon information and belief, if Zydus's ANDA is approved by FDA, Zydus's ANDA Product will be marketed as a competing product to PREVYMIS®, a product developed by Plaintiffs for the prophylaxis of cytomegalovirus (CMV) infection and disease.

PARTIES

1. Merck LLC is a corporation organized and existing under the laws of New Jersey, having a place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065.

2. MSDIG is a company organized and existing under the laws of Switzerland, having a place of business at Tribschenstrasse 60, 6005 Lucerne, Switzerland.

3. MSDIB is a company organized and existing under the laws of Switzerland, having a place of business at Tribschenstrasse 60, 6005 Lucerne, Switzerland.

4. AiCuris is a company organized and existing under the laws of Germany, having a place of business at Friedrich-Ebert-Str. 475/ Building 302 42117 Wuppertal Germany.

5. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Zydus Lifesciences Limited, and is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

6. Upon information and belief, Defendant Zydus Lifesciences Limited is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

7. Upon information and belief, following any approval of Zydus's ANDA, Zydus USA and Zydus Lifesciences will act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within New Jersey.

8. Upon information and belief, following any approval of Zydus's ANDA, Zydus USA and Zydus Lifesciences intend to benefit directly if Zydus's ANDA is approved by participating in the development, regulatory approval, marketing, manufacture, importation, distribution, and/or sale of Zydus's ANDA Product.

JURISDICTION AND VENUE

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

10. Zydus USA is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus USA has its principal place of business in Pennington, New Jersey. Also upon information and belief, Zydus USA is involved in developing, manufacturing, marketing, selling, and/or

distributing a broad range of generic pharmaceutical products in the United States, including in New Jersey, and therefore transacts business within New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within New Jersey.

11. Zydus Lifesciences is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences, itself and through its wholly owned indirect subsidiary Zydus USA, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Lifesciences, itself and through its wholly owned subsidiary Zydus USA, is involved in developing, manufacturing, marketing, selling, and/or distributing a broad range of generic pharmaceutical products in the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. In addition, Zydus Lifesciences is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Zydus USA, and therefore the activities of Zydus USA in this jurisdiction are attributed to Zydus Lifesciences.

12. Upon information and belief, Zydus has sought approval in Zydus's ANDA to distribute Zydus's ANDA Product in the United States, including in New Jersey and will do so upon approval of Zydus's ANDA. The filing of Zydus's ANDA is therefore tied, in purpose and planned effect, to the deliberate making of sales in New Jersey, and indicates that Zydus plans to engage in the marketing of Zydus's ANDA Product in New Jersey.

13. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly import, market and/or sell Zydus's ANDA Product within the United States, including in New Jersey, consistent with Zydus's practices for the marketing and distribution of other pharmaceutical products on its own and/or through its affiliates.

14. Upon information and belief, if Zydus's ANDA is approved, Zydus's ANDA Product, under the direction and control of physicians practicing in New Jersey, will be administered to patients in New Jersey. These activities, as well as Zydus's marketing, selling, and/or distributing of Zydus's ANDA Product, would have a substantial effect within New Jersey and would constitute infringement of the RE '791 patent in the event that Zydus's ANDA Product is approved before the RE '791 patent expires.

15. For the reasons described above, among others, the filing of Zydus's ANDA was suit-related conduct with a substantial connection to New Jersey and this District, the exercise of personal jurisdiction over Zydus does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Zydus.

16. Venue is proper in this judicial district as to Zydus Lifesciences under 28 U.S.C. §§ 1391 and 1400(b) because Zydus Lifesciences is incorporated in the Republic of India and may be sued in any judicial district in the United States. Venue is also proper in this judicial district as to Zydus Lifesciences because, *inter alia*, Zydus Lifesciences is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district in, *e.g.*, *Supernus Pharmaceuticals, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 21-cv-17104-GC-LHG (D.N.J.); *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 22-cv-04499-JMV-JSA (D.N.J.); *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 24-cv-04330-MAS-JBD (D.N.J.), and on information and belief is subject to venue in this judicial district for the purpose of this case.

17. Venue is proper in this judicial district as to Zydus USA under 28 U.S.C. §§ 1391 and 1400(b) at least because Zydus USA has committed, or will commit, an act of infringement in this District and has its principal place of business in New Jersey and therefore resides in New

Jersey for purposes of venue.

BACKGROUND

18. PREVYMIS® is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) and prophylaxis of CMV disease in adult and pediatric patients who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient seronegative [D+/R-]).

19. The active pharmaceutical ingredient in PREVYMIS® is letermovir. Letermovir is an antiviral with the chemical name (S)-{8-fluoro-2-[4-(3-methoxyphenyl)-1-piperazinyl]-3-[2-methoxy-5-(trifluoromethyl)-phenyl]-3,4-dihydro-4-quinazolinyl}acetic acid. PREVYMIS® is approved in 240 mg and 480 mg tablet dosage forms (and other dosage forms not implicated by Zydus's ANDA).

20. Merck sells PREVYMIS® tablets in the United States pursuant to New Drug Application ("NDA") No. 209939, which has been approved by FDA.

21. Merck LLC is the holder of the approved NDA for PREVYMIS® tablets.

22. The RE '791 patent, titled "Substituted Dihydroquinazolines," was duly and legally issued on April 17, 2018. A copy of the RE '791 patent is attached as Exhibit A.

23. The RE '791 patent covers, *inter alia*, letermovir and pharmaceutical compositions containing letermovir.

24. AiCuris is the assignee of the RE '791 patent.

25. MSDIG and MSDIB are licensees and hold exclusive rights under the RE '791 patent.

26. There is an actual case or controversy between the parties regarding Zydus's

liability for its infringement of the RE ’791 patent.

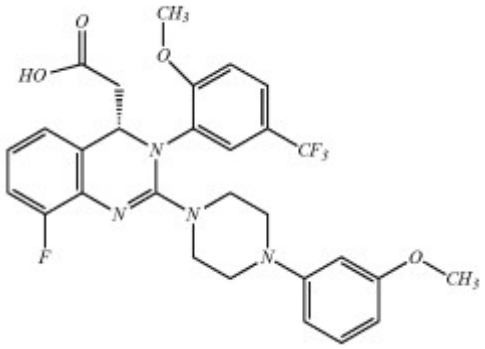
27. This action is being filed within 45 days of Plaintiffs’ receipt of Zydus’s Notice Letter.

COUNT I
(Infringement of the RE ’791 Patent)

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

29. The claims of RE ’791 cover letermovir, for example, at least in claims 23 and 24.

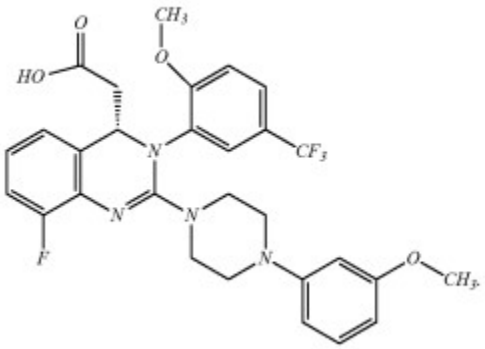
30. Claim 23 of the RE ’791 patent recites “[t]he compound of claim 1, wherein said compound is:



or a physiologically acceptable salt thereof.”

31. Claim 24 of the RE ’791 patent recites

The compound of claim 1, wherein said compound is:



32. Upon information and belief, Zydus's ANDA Product is covered by one or more claims of the RE '791 patent, including at least claims 23 and 24.

33. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product will infringe one or more claims of the RE '791 patent, including at least claims 23 and 24, either literally or under the doctrine of equivalents.

34. According to Zydus's Notice Letter, Zydus filed as part of Zydus's ANDA a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the claims of the RE '791 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, sale, or importation of Zydus's ANDA Product.

35. Zydus did not assert in its Notice Letter a basis for any assertion that Zydus's ANDA Product would not infringe at least claims 23 and 24 of the RE '791 patent.

36. The purpose of filing Zydus's ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the RE '791 patent.

37. On information and belief, letermovir is the active ingredient in Zydus's ANDA Product. On information and belief, Zydus's ANDA Product is a pharmaceutical formulation comprising letermovir oral tablets in 240 mg and 480 mg strengths.

38. On information and belief, Zydus's ANDA refers to and relies on the NDA for PREVYMIS® and contains data that, according to Zydus, demonstrates bioequivalence of Zydus's ANDA Product and PREVYMIS®, *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

39. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's

ANDA Product in the United States prior to the expiration of the RE '791 patent is an act of infringement of the RE '791 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Zydus intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon the approval of Zydus's ANDA and any amendments thereto, *i.e.*, prior to the expiration of the RE '791 patent.

41. Upon information and belief, Zydus has knowledge of the RE '791 patent at least because the RE '791 patent is listed in the FDA's Orange Book for Merck's PREVYMIS® drug product. Notwithstanding this knowledge, Zydus continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of Zydus's ANDA and any amendments thereto.

42. Upon information and belief, Zydus intends to sell Zydus's ANDA Product with a label that, *inter alia*, instructs and encourages the administration of 240 mg and 480 mg letermovir tablets for the prophylaxis of CMV infection and/or disease.

43. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the RE '791 patent when Zydus's ANDA and any amendments thereto are approved, and will do so with specific intent to induce infringement of the RE '791 patent. Further upon information and belief, Zydus plans and intends to, and will, do so immediately and imminently upon approval of Zydus's ANDA.

44. Upon information and belief, Zydus knows that Zydus's ANDA Product is especially made or adapted for use in infringing the RE '791 patent, and that Zydus's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Zydus plans

and intends to, and will, contribute to infringement of the RE '791 patent immediately and imminently upon approval of Zydus's ANDA and any amendments thereto.

45. The foregoing actions by Zydus constitute and/or will constitute direct infringement of the RE '791 patent, active inducement of infringement by others of the RE '791 patent, and contribution to the infringement by others of the RE '791 patent, either literally or under the doctrine of equivalents.

46. Unless Zydus is enjoined from directly infringing the RE '791 patent, actively inducing infringement by others of the RE '791 patent, and contributing to the infringement by others of the RE '791 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Zydus has infringed one or more claims of the RE '791 patent under 35 U.S.C. § 271(e)(2)(A) by submitting Zydus's ANDA to the FDA;

(b) A judgment that Zydus's making, using, offering to sell, selling, marketing, distributing, and/or importing into the United States of Zydus's ANDA Product prior to the expiration of the RE '791 patent will infringe, actively induce infringement of, and/or contribute to infringement by others of one or more claims of the RE '791 patent under 35 U.S.C. §§ 271(a), (b) and/or (c);

(c) A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Zydus to make, use, offer for sale, sell, market, distribute, or import Zydus's ANDA Product, or any product the use of which infringes the RE '791 patent, be not earlier than the expiration date of the RE '791 patent, inclusive of any extension(s) and additional

period(s) of exclusivity;

(d) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Zydus, and all persons acting in concert with Zydus, from making, using, selling, offering for sale, marketing, distributing, or importing Zydus's ANDA Product, or any product the use of which infringes the RE '791 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the RE '791 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: November 27, 2024

Respectfully submitted,

s/ Charles H. Chevalier
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