UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ENANTA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
PFIZER INC.	)	
	)	
Defendant.	)	

COMPLAINT

Enanta Pharmaceuticals, Inc. ("Enanta") files this Complaint against Pfizer Inc. ("Pfizer"). In support of its claims, Enanta alleges as follows:

INTRODUCTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq. Enanta seeks a judgment that Pfizer has infringed and continues to infringe U.S. Patent No. 11,358,953 (the "'953 Patent") and an award of damages adequate to compensate for Pfizer's infringement.

2. The '953 Patent discloses and claims compounds and pharmaceutically acceptable salts which inhibit coronavirus replication activity, and methods of treating a coronavirus infection.

3. Pfizer's infringing PAXLOVID™ product is nirmatrelvir tablets co-packaged with ritonavir for the treatment of COVID-19. Nirmatrelvir, the active ingredient in PAXLOVID™, inhibits coronavirus replication activity, and ritonavir is used to increase plasma concentrations of nirmatrelvir.

THE PARTIES

4. Enanta is a Delaware corporation having its principal place of business at 500 Arsenal Street, Watertown, Massachusetts. Enanta is a clinical stage biotechnology company dedicated to creating best-in-class oral drugs for viral infections, including COVID-19, and for liver diseases, with the goal of transforming the lives of patients through curative therapies.

5. On information and belief, Pfizer is a Delaware corporation having its principal place of business at 235 East 42nd Street, New York, New York.

JURISDICTION

6. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq.

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

8. This Court has personal jurisdiction over Pfizer because Pfizer regularly and continuously conducts business within Massachusetts, has a place of business within Massachusetts, and has committed acts of infringement in Massachusetts.

9. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Pfizer has a regular and established place of business in this district and has committed acts of infringement here. Pfizer maintains facilities in this district that include a laboratory facility at 1 Portland Street, Cambridge, Massachusetts, and a research and manufacturing facility at 1 Burtt Road, Andover, Massachusetts.

10. Pfizer has purposefully directed infringing activities in this district, including offering for sale and selling its PAXLOVID™ product in this district, thereby directly or indirectly infringing the ’953 Patent.

BACKGROUND

11. For the past twenty years, Enanta has focused its research and development on developing small molecule compounds for the treatment of liver diseases and viral infections, including compounds called protease inhibitors. Proteases are enzymes that aid in the breakdown of proteins, and a protease inhibitor is a molecule that inhibits the function of proteases. Viral proteases are essential for the replication of a virus. By binding to such enzymes, inhibitors of viral proteases block their ability to function, stopping the virus from reproducing.

12. Enanta is recognized for its expertise in the design and development of direct-acting antiviral compounds, including protease inhibitors that interfere with the process of viral replication. By interfering with the process of viral replication, Enanta's antiviral compounds have the ability to prevent the virus from spreading to infect other cells, reducing or even eliminating a patient's "viral load" and providing crucial time for a person's immune system to clear the infection. Enanta filed its first patent application on a direct-acting antiviral compound, directed to inhibitors of the hepatitis C viral protease, nearly twenty years ago, in 2003.

13. Enanta, in collaboration with the biopharmaceutical company AbbVie Inc. ("AbbVie"), conducted years of discovery work on hepatitis C virus ("HCV") protease inhibitors. Enanta's research contributed to two protease inhibitors that each was developed and commercialized as part of AbbVie's FDA-approved combination therapies for chronic HCV infection. The first of these therapies, VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir), was approved for sale in the United States in 2014. The therapy included the protease inhibitor paritaprevir in combination with ritonavir which was used to "boost" the plasma level of paritaprevir. The VIEKIRA PAK® therapy was only approved for certain subpopulations of HCV patients. AbbVie's second chronic HCV treatment regimen, MAVYRET®/MAVIRET®

(glecaprevir/pibrentasvir), approved for all HCV patient populations and sold worldwide since 2017, includes the protease inhibitor glecaprevir. Glecaprevir was invented at Enanta and does not require ritonavir-boosting.

14. Currently, Enanta is developing treatments for other viral infections, including respiratory syncytial virus ("RSV"), human metapneumovirus ("hMPV") and chronic hepatitis B virus ("HBV") infection. In 2021, Enanta announced positive data from two Phase 1 clinical studies of its EDP-514 compound, an HBV core inhibitor, for the treatment of chronic HBV. Enanta's N-protein inhibitor EDP-938 is currently in Phase 2 clinical studies for the treatment of RSV, a highly contagious, seasonal respiratory infection for which there currently is no therapeutic option. In 2021, Enanta also selected EDP-323, an RSV L-protein inhibitor candidate, for clinical development.

15. In early 2020, when SARS-CoV-2 was emerging as a global pandemic, Enanta determined that it could leverage its expertise in virology and, more specifically, in viral protease inhibitors, to identify compounds for use in treating patients infected with the new coronavirus. To that end, Enanta launched a two-pronged COVID-19 research program to discover direct-acting antivirals to disrupt replication of SARS-CoV-2. The first prong of the program focused on selecting compounds from Enanta's antiviral compound library and testing them for potential activity against SARS-CoV-2. The second prong of the program took advantage of Enanta's drug discovery expertise to design new compounds to treat COVID-19.

16. In furtherance of the second prong of its COVID-19 program, Enanta assembled a team of scientists to design direct-acting antivirals, including compounds to bind the 3CL protease of SARS-CoV-2. The 3CL protease, also referred to as the main protease or MPro, is the main protease involved in SARS-CoV-2 replication.

17. Enanta's team of scientists selected a number of promising antiviral 3CL protease inhibitor candidates for pre-clinical testing. In early 2021, Enanta identified its 3CL protease inhibitor EDP-235 as the lead compound for its COVID-19 program. Preclinical studies demonstrated that EDP-235 has good oral bioavailability, does not require ritonavir-boosting, and has potent antiviral activity against a variety of additional human coronaviruses, offering the potential for use as a pan-coronavirus treatment.

18. On February 16, 2022, Enanta announced that it had dosed its first human subject in a Phase 1 clinical study of EDP-235, a coronavirus 3CL protease inhibitor specifically designed as a once-daily, oral treatment for COVID-19.

19. On March 25, 2022, the U.S. Food and Drug Administration granted Fast Track designation for Enanta's EDP-235.

THE '953 PATENT

20. On July 20, 2020, Enanta filed U.S. Provisional Patent Application No. 63/054,048 (the "'048 Application"), entitled "Functionalized Peptides as Antiviral Agents." On July 19, 2021, Enanta filed a utility patent application claiming priority to the '048 Application.

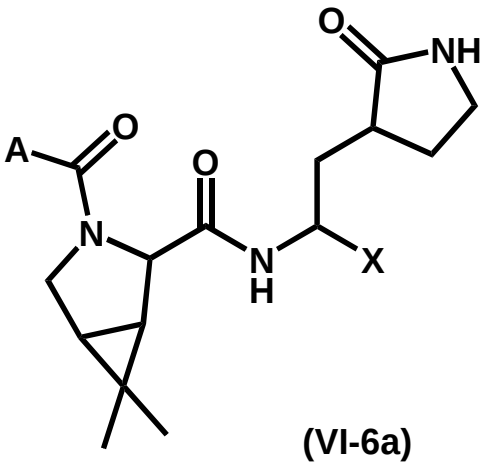
21. On November 9, 2021, Enanta filed U.S. Patent Application No. 17/522,176 (the "'176 Application"), a continuation application that likewise claims priority to the '048 Application.

22. After examining Enanta's '176 Application, the United States Patent Office recognized Enanta's innovation and allowed the claims of the '176 Application on March 31, 2022. On June 14, 2022, the '176 Application issued as the '953 Patent. Enanta owns by

assignment the entire right, title, and interest in and to the ’953 Patent. A true and accurate copy of the ’953 Patent is attached as Exhibit 1.

23. Claim 1 of the ’953 Patent recites:

A compound represented by Formula (VI-6a),



(VI-6a) ,

or a pharmaceutically acceptable salt thereof, wherein

X is -CN; and

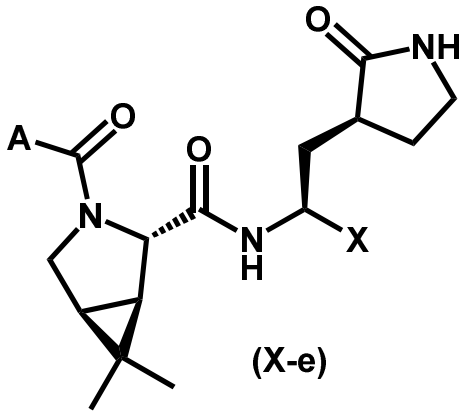
A is optionally substituted C_1-C_8 alkyl or optionally substituted heteroaryl.

24. Claim 2 of the ’953 Patent recites:

The compound of claim 1 wherein A is optionally substituted C_1-C_8 alkyl.

25. Claim 5 of the ’953 Patent recites:

The compound of claim 1 which is represented by Formula (X-e),



(X-e)

or a pharmaceutically acceptable salt thereof, wherein A and X are as defined in claim 1.

26. Claim 9 of the ’953 Patent recites:

The compound of claim 5 wherein A is optionally substituted C_1-C_8 alkyl.

27. Pfizer has known of the ’953 Patent since June 14, 2022, when Enanta brought the ’953 Patent to Pfizer’s attention.

PFIZER’S INFRINGING PAXLOVID™ PRODUCT

28. Pfizer currently sells PAXLOVID™ in the United States under emergency use authorization by the U.S. Food and Drug Administration for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

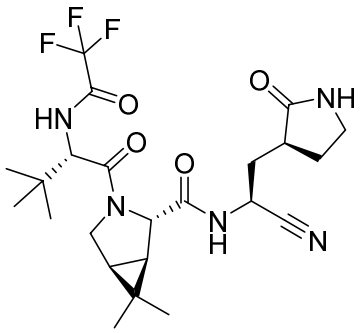
29. Pfizer describes PAXLOVID™ as “nirmatrelvir tablets co-packaged with ritonavir tablets.”

30. Pfizer's "Fact Sheet for Healthcare Providers: Emergency Use Authorization for PAXLOVID™" states that ritonavir is "an HIV-1 protease inhibitor but is not active against SARS-CoV-2 Mpro" and that "[r]itonavir inhibits the CYP3A-mediated metabolism of nirmatrelvir, resulting in increased plasma concentrations of nirmatrelvir."

31. Pfizer's nirmatrelvir is a SARS-CoV-2 3CL protease inhibitor.

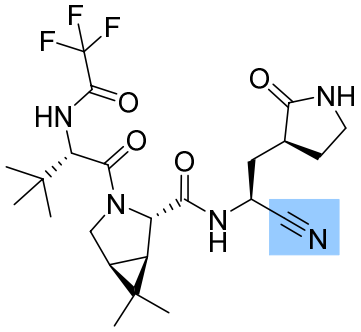
32. The chemical name of the active ingredient of nirmatrelvir is (1*R*,2*S*,5*S*)-N-((1*S*)-1-cyano-2-((3*S*)-2-oxopyrrolidin-3-yl)ethyl)-3-((2*S*)-3,3-dimethyl-2-(2,2,2-trifluoroacetamido)butanoyl)-6,6-dimethyl-3-azabicyclo[3.1.0]hexane-2-carboxamide.

33. According to Pfizer, nirmatrelvir has the following structural formula:



34. Pfizer's nirmatrelvir includes –CN, also referred to as cyano.

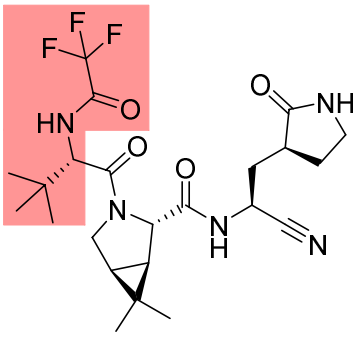
35. The cyano in Pfizer's nirmatrelvir is highlighted in the blue shading below.



36. Pfizer's nirmatrelvir includes a 2,2,2-trifluoroacetamide-substituted C_5 alkyl.

37. The 2,2,2-trifluoroacetamide-substituted C_5 alkyl in Pfizer's nirmatrelvir is an optionally substituted C_1-C_8 alkyl.

38. The optionally substituted C_1-C_8 alkyl in Pfizer's nirmatrelvir is highlighted in the red shading below:



39. In Pfizer's PAXLOVID™ product, nirmatrelvir is provided in the form of immediate-release, film-coated tablets. Each tablet contains 150 mg nirmatrelvir with a pharmaceutically acceptable carrier or excipient, namely, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, and sodium stearyl fumarate.

40. Pfizer's "Fact Sheet for Healthcare Providers: Emergency Use Authorization for PAXLOVID™" instructs healthcare providers to prescribe PAXLOVID™ containing nirmatrelvir for administration to patients with COVID-19 at a dose of 300 mg twice daily for 5 days, in order to treat coronavirus infection. The prescribed dose is a therapeutically effective amount of nirmatrelvir.

41. Attached as Exhibit 2 is a preliminary claim chart describing Pfizer's infringement of claims 1, 2, 5, and 7-10 of Enanta's '953 Patent. The preliminary claim chart is not intended to limit Enanta's right to modify the chart or to allege that other activities of Pfizer infringe the identified claims or any other claim of the '953 Patent or any other patents.

42. Pfizer has known of the ’953 Patent since June 14, 2022, when the ’953 Patent issued and Enanta provided written notice of the patent to Pfizer.

43. Pfizer’s infringement of the ’953 Patent is willful and deliberate. Pfizer knew or should have known that its making, importing, using, offering for sale, and selling PAXLOVID™ constituted an unjustifiably high risk of infringement of the ’953 Patent.

COUNT I
(Infringement of the ’953 Patent)

44. Enanta realleges and incorporates by reference the allegations contained in the foregoing paragraphs 1 to 43.

45. Pfizer has infringed and is continuing to infringe at least one claim of the ’953 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell and/or importing its PAXLOVID™ product within the United States and without authority.

46. Pfizer has infringed and is continuing to infringe at least one claim of the ’953 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacture, use, sale, or offer for sale within the United States, and/or by the import into the United States, of its PAXLOVID™ product. Pfizer intends that end users use the infringing PAXLOVID™ with the knowledge and specific intent that such end users directly infringe Enanta’s ’953 Patent.

47. Pfizer has infringed and is continuing to infringe at least one claim of the ’953 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering for sale within the United States or by importing into the United States its PAXLOVID™ product, knowing the same to be especially made or especially adapted for use in infringement of Enanta’s ’953 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

48. Pfizer has committed and continues to commit these acts of infringement without license or authorization.

49. Pfizer's infringement has damaged and will continue to damage Enanta, which is entitled to recover damages adequate to compensate for Pfizer's infringement in an amount to be determined at trial, and in any event no less than a reasonable royalty for the use made by Pfizer of Enanta's invention.

PRAYERS FOR RELIEF

WHEREFORE, Enanta Pharmaceuticals, Inc. respectfully requests that this Court:

a. Enter judgment that Pfizer has infringed the '953 Patent;

b. Award damages adequate to compensate Enanta for Pfizer's infringement together with pre-judgment and post-judgment interest and costs under 35 U.S.C. § 284;

c. Award treble damages for Pfizer's willful infringement;

d. Enter judgment that this case is exceptional and award Enanta its reasonable attorneys' fees, costs, and expenses, under 35 U.S.C. § 285; and

e. Award such other and further relief as this Court may deem just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Enanta hereby demands a jury trial as to all issues so triable.

Respectfully submitted,

ENANTA PHARMACEUTICALS, INC.
By its attorneys,

/s/ Barbara A. Fiacco

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Dated: June 21, 2022