Liza M. Walsh
Selina M. Ellis
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center,
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
lwalsh@walsh.law
sellis@walsh.law
jformichella@walsh.law

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

| | |
|---|---|
| ASTELLAS PHARMA INC.; ASTELLAS US LLC; and ASTELLAS PHARMA US, INC.,<br><br>Plaintiffs,<br><br>v.<br><br>SANDOZ, INC.,<br><br>Defendant. | C.A. No._____<br><br>JURY TRIAL DEMANDED |

**PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows for their Complaint against Defendant Sandoz Inc. ("Defendant" or "Sandoz"):

**THE PARTIES**

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. Plaintiff Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

3. Plaintiff Astellas Pharma US, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

4. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540-6604, United States.

## NATURE OF THE ACTION

5. This is an action for patent infringement of U.S. Patent No. 10,786,500 (the "'500 patent") arising under the patent laws of the United States, Title 35, United States Code, arising out of Defendant's filing of Abbreviated New Drug Application ("ANDA") No. 217683 with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Astellas's XOSPATA® (gilteritinib) tablets prior to the expiration of the '500 patent. Plaintiffs attach hereto a true and accurate copy of the '500 patent as Exhibit A.

## JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 *et seq*. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202.

7. On information and belief, Sandoz prepared and filed ANDA No. 217683 ("Sandoz's ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Astellas's XOSPATA® (gilteritinib) tablets ("Sandoz's Proposed ANDA Product") in

this District, and thus committed an act of patent infringement in this District pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

8. This Court has personal jurisdiction over Sandoz at least because Sandoz's principal place of business is located in this District, and thus Sandoz is present in this District, and Sandoz has committed an act of patent infringement in this District, and because Sandoz is doing business in this District and thus has purposefully availed itself to the privileges of conducting business in New Jersey.

9. On information and belief, Sandoz, itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District, and thus Sandoz regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Sandoz conducts marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. Upon information and belief, Sandoz is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity ID Nos. 0100097265 and 0101056767, and is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003732. On information and belief, if Sandoz's ANDA No. 217683 is approved, it will market and sell its generic version of XOSPATA® tablets in New Jersey.

10. This Court also has personal jurisdiction over Sandoz by virtue of the fact that Sandoz previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*, *Aragon Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 22-03044; *Par Pharmaceutical, Inc. v. Sandoz Inc.*, No. 18-14895 (D.N.J.); *Celgene Corporation v. Sandoz Inc.*, No. 18-11026 (D.N.J.); *Adamas Pharma, LLC v. Sandoz Inc.*, No. 18-09032 (D.N.J.). Upon information and belief, Sandoz has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g.*, *Sandoz, Inc. v. Daiichi Sankyo, Inc.*, No. 16-00994 (D.N.J.).

11. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b) and § 1391 because Sandoz has a regular and established place of business located at 100 College Road West, Princeton, New Jersey 08540-6604 and has committed acts of infringement in this District.

## BACKGROUND

### *U.S. Patent No. 10,786,500*

12. The '500 patent, entitled "Stable pharmaceutical composition for oral administration," issued on September 29, 2020, and names as inventors Masakazu Miyazaki, Ryohei Ishiba, Yuki Takaishi, and Fumiaki Uejo.

13. The claims of the '500 patent are valid, enforceable, and not expired.

14. The '500 patent is assigned to Astellas Pharma Inc.

15. Astellas US LLC holds an exclusive license to the '500 patent in the United States.

16. Astellas Pharma US, Inc. holds a sublicense to the '500 patent.

17. Claim 1 of the '500 patent reads as follows:

A pharmaceutical composition for oral administration comprising:

6-ethyl-3-({3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]phenyl}amino)-5-(tetrahydro-2H-pyran-4-ylamino)pyrazine-2-carboxamide hemifumarate, wherein a proportion of crystals of 6-ethyl-3-({3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]phenyl}amino)-5-(tetrahydro-2H-pyran-4-ylamino)pyrazine-2-carboxamide hemifumarate is 62% or more with respect to a total amount of 6-ethyl-3-({3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]phenyl}amino)-5-(tetrahydro-2H-pyran-4-ylamino)pyrazine-2-carboxamide hemifumarate in the pharmaceutical composition; and

at least one pharmaceutical additive selected from the group consisting of lactose, D-mannitol, anhydrous dibasic calcium phosphate, calcium stearate, and talc.

18. The drug compound 6-ethyl-3-({3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]phenyl}amino)-5-(tetrahydro-2H-pyran-4-ylamino)pyrazine-2-carboxamide hemifumarate is known as gilteritinib hemifumarate.

19. The ’500 patent is directed to pharmaceutical compositions of gilteritinib hemifumarate.

***XOSPATA®***

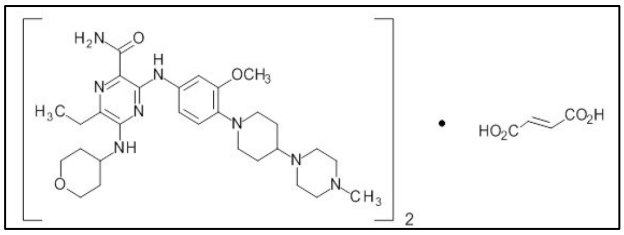
20. Plaintiff Astellas Pharma US, Inc. holds approved New Drug Application (“NDA”) No. 211349 for 40 mg tablets containing gilteritinib (as the hemifumarate) for the treatment of acute myeloid lymphoma (“AML”) in patients who have relapsed or refractory AML with FLT3 mutations, as further described in the XOSPATA® label.

21. Plaintiff Astellas Pharma US, Inc. markets the tablets under NDA 211349 in the United States under the registered trademark XOSPATA®.

22. In conjunction with NDA No. 211349, Astellas Pharma US, Inc. has listed with the FDA the following patents for XOSPATA® (gilteritinib) tablets: United States Patent Nos. 8,969,336; 9,487,491; 10,786,500. The FDA has published these patents in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the

"Orange Book." 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.

23. The active ingredient in XOSPATA® (gilteritinib) tablets is gilteritinib hemifumarate having an empirical formula $(C_{29}H_{44}N_8O_3)_2 \cdot C_4H_4O_4$ and the following structural formula:



24. Astellas' XOSPATA® (gilteritinib) tablets contain mannitol, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, hypromellose, talc, polyethylene glycol, titanium dioxide, and ferric oxide.

25. At least 62% of the gilteritinib contained in Astellas's XOSPATA® (gilteritinib) tablets is present as crystalline hemifumarate.

26. At least claim 1 of the '500 patent covers XOSPATA® (gilteritinib) tablets.

***Sandoz's Notice Letter, ANDA, and Infringement***

27. Sandoz prepared and submitted to the FDA ANDA No. 217683 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of gilteritinib fumarate film coated tablets, 40 mg ("Sandoz's Proposed ANDA Product"), as a generic version of Astellas's XOSPATA® (gilteritinib) tablets, prior to the expiration of the '500 patent.

28. On behalf of Sandoz, Mark H. Remus of Crowell & Moring LLP sent letters to Astellas Pharma Inc. and Astellas Pharma US, Inc. regarding the '500 patent ("Sandoz's Notice Letter"), each purporting to be a notice pursuant to Section 505(j)(2)(B)(i–iv) of the Federal Food,

Drug, and Cosmetic Act. Sandoz's Notice Letter purports to inform Plaintiffs that Sandoz's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '500 patent. Sandoz's Notice Letter bears the date January 18, 2023.

29. Plaintiff Astellas Pharma US, Inc. received Sandoz's Notice Letter on or about January 19, 2023.

30. Plaintiff Astellas Pharma Inc. received Sandoz's Notice Letter on or about January 23, 2023.

31. This action is being commenced before the expiration of 45 days from the date Plaintiffs received Sandoz's Notice Letter, which triggers a stay of FDA approval of Sandoz's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

32. Sandoz's Notice Letter states that "the active ingredient in the proposed drug product is gilteritinib fumarate; the strength of the proposed drug product is 40 mg; and the dosage form of the proposed drug product is oral tablets."

33. Sandoz's Notice Letter also states that ANDA No. 217683 contains any required bioavailability or bioequivalence data and a Paragraph IV Certification for the '500 patent.

34. Attached to Sandoz's Notice Letter is a statement of the purported factual and legal bases for Sandoz's position that the '500 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Proposed ANDA Product described in ANDA No. 217683.

35. In particular, Sandoz's Notice Letter alleges that the claims of the '500 patent are not infringed and are invalid.

36. Attached to Sandoz's Notice Letter is an Offer of Confidential Access to ANDA

No. 217683 ("the Offer"). The terms of the Offer would not allow Astellas to conduct a complete and full investigation of the information contained in the ANDA and of the representations about Sandoz's Proposed ANDA Product that appear in Sandoz's Notice Letter. For example, the Offer would only allow one outside law firm for Astellas to review the ANDA, would not allow in-house counsel for Astellas or external experts to review the ANDA without Sandoz's prior approval, and only obligates Sandoz to produce the portions of the ANDA that Sandoz may unilaterally redact or choose to produce rather the producing the entire ANDA. Thus, the Offer was inadequate and Astellas could not agree to the terms of the Offer.

37. On January 31, 2023, counsel for Astellas sent a letter to counsel for Sandoz in an attempt to negotiate the terms of the Offer. After counsel for Sandoz responded, counsel for Astellas followed up on February 14, 2023, by providing a redlined version of the Offer, setting forth terms for access that would be acceptable to Astellas.

38. Counsel for Sandoz responded on February 21, 2023, that it did not agree to Astellas's redlines and that it was not obligated to provide access to the entire ANDA No. 217683 or any portion of the Drug Master File cited in ANDA No. 217683. Counsel for Sandoz did not accept any of Astellas's proposals and, instead, referred Astellas back to the terms of Sandoz's original Offer, which Astellas had already explained were not acceptable.

39. The parties were not able to reach an agreement regarding access to ANDA No. 217683 prior to the expiry of the time period set forth in 21 U.S.C. § 355(j)(5)(B)(iii). Astellas thus makes these allegations based on information and belief, the laws and regulations regarding generic drugs, and Sandoz's Notice Letter.

40. Because Sandoz's Proposed ANDA Product has not yet been approved by FDA and is not yet commercially available, Astellas is not aware of any other means for obtaining

information about Sandoz's Proposed ANDA Product other than pursuant to an Offer of Confidential Access from Sandoz. In the absence of additional information, Astellas resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and present to the Court evidence that Sandoz's Proposed ANDA Product would infringe one or more claims of the '500 patent upon FDA approval.

41. In filing and maintaining ANDA No. 217683, Sandoz has requested and continues to request FDA's approval to market a generic version of Astellas's XOSPATA® (gilteritinib) tablets throughout the United States, including in New Jersey.

42. On information and belief, following FDA approval of ANDA No. 217683, Sandoz will offer for sale and sell its Proposed ANDA Product throughout the United States, including in New Jersey.

43. Sandoz's effort to seek FDA approval to market a generic version of XOSPATA® (gilteritinib) tablets prior to the expiration of the '500 patent constitutes an act of infringement pursuant to 35 U.S.C. § 271(e)(2). It also creates a justiciable controversy between the parties with respect to the subject matter of ANDA No. 217683 and the '500 patent, as further evidenced by Sandoz's Notice Letter.

44. Sandoz's Proposed ANDA Product contains gilteritinib fumarate. Specifically, Sandoz's Notice Letter states that Sandoz's Proposed ANDA Product is an oral tablet containing gilteritinib fumarate. On information and belief, like XOSPATA® (gilteritinib) tablets, Sandoz's Proposed ANDA Product comprises crystalline gilteritinib hemifumarate that is 62% or more with respect to the total amount of gilteritinib hemifumarate in the pharmaceutical composition, and

lactose, D-mannitol, anhydrous dibasic calcium phosphate, calcium stearate, and/or talc, or an equivalent of the foregoing.

**Count I: Infringement of the '500 Patent**

45. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

46. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sandoz has committed an act of infringement of the '500 patent by submitting ANDA No. 217683 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed ANDA Product in the United States prior to the expiration of the '500 patent.

47. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed ANDA Product prior to the expiration of the '500 patent would constitute infringement, either literally or under the doctrine of equivalents, of at least one of the claims of the '500 patent, including but not limited to claim 1.[1]

48. Sandoz's actions, including but not limited to, the development of Sandoz's Proposed ANDA Product, and the filing of an ANDA with a Paragraph IV Certification, reliably predict that Sandoz has made and will continue to make substantial preparation in the United States, including in the District of New Jersey, to manufacture, sell, offer to sell, and/or import Sandoz's Proposed ANDA Product, giving rise to an actual case or controversy between the parties over whether Sandoz's future manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed ANDA Product by Sandoz prior to the expiration of the '500 patent will constitute infringement of the '500 patent.

[1] Plaintiffs will identify all asserted claims of the '500 patent in accordance with this Court's Local Rules and/or scheduling order.

49. The commercial manufacture, importation, use, sale, or offer for sale of Sandoz's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

50. Unless and until Sandoz is enjoined from infringing the '500 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court stating that the effective date of approval of Sandoz's ANDA No. 217683 be a date that is not earlier than the expiration date of the '500 patent.

## JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues that are or may become so triable.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A) That judgment be issued that (1) Defendant has infringed one or more claims of the '500 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 217683 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking approval for the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Sandoz's Proposed ANDA Product prior to expiration of the '500 patent, and (2) that Defendant's commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of Sandoz's Proposed ANDA Product will constitute infringement of one or more claims of the '500 patent;

B) That an order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Defendant's ANDA No. 217683 shall be a date which is not earlier than the expiration date of the '500 patent, as extended by any applicable periods of exclusivity;

C) That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the '500 patent prior to expiration of the '500 patent, inclusive of any extensions;

D) That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by, or drug product whose use is covered by, the '500 patent prior to expiration of the '500 patent, inclusive of any extensions;

E) That a declaration be issued that the manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed ANDA Product before expiration of the '500 patent does and will infringe the '500 patent;

F) If Defendant engages in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Proposed ANDA Product disclosed in ANDA No. 217683 prior to the expiration of the '500 patent, as extended by any applicable period of exclusivity, judgment

awarding Plaintiffs damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found and/or assessed together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

G) That this case be declared an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

H) That the Court award costs and expenses in this action;

I) That an accounting be performed of Defendant's infringing activities not presented at trial and an award by the Court of additional damages for any such infringing sales; and

J) That this Court award such other and further relief as it may deem just and proper.

Dated: March 2, 2023

By: */s/ Liza M. Walsh*

Liza M. Walsh
Selina M. Ellis
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center,
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
lwalsh@walsh.law
sellis@walsh.law
jformichella@walsh.law

Jason Leonard
Jayita Guhaniyogi
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5400
jleonard@mwe.com
jguhaniyogi@mwe.com

OF COUNSEL *(pro hac vice forthcoming)*:
W. Chad Shear
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
(858) 678-5070
shear@fr.com

Elizabeth M. Flanagan
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(612) 335-5070
betsy.flanagan@fr.com

Andria Rae Crisler
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas TX 75201
(214) 747-5070
crisler@fr.com

Simon D. Roberts
Nitya Anand
Vincent Li
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5700
simonroberts@mwe.com
nanand@mwe.com
vli@mwe.com

*Counsel for Plaintiffs*
*Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc.*

**LOCAL RULE 11.2 CERTIFICATION**

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action.

Dated: March 2, 2023

By: */s/ Liza M. Walsh*

Liza M. Walsh
Selina M. Ellis
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center,
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
lwalsh@walsh.law
sellis@walsh.law
jformichella@walsh.law

Jason Leonard
Jayita Guhaniyogi
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5400
jleonard@mwe.com
jguhaniyogi@mwe.com

OF COUNSEL *(pro hac vice forthcoming)*:
W. Chad Shear
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
(858) 678-5070
shear@fr.com

Elizabeth M. Flanagan
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(612) 335-5070
betsy.flanagan@fr.com

Andria Rae Crisler
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas TX 75201
(214) 747-5070
crisler@fr.com

Simon D. Roberts
Nitya Anand
Vincent Li
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5700
simonroberts@mwe.com
nanand@mwe.com
vli@mwe.com

*Counsel for Plaintiffs*
*Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc.*

**LOCAL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: March 2, 2023

By: */s/ Liza M. Walsh*

Liza M. Walsh
Selina M. Ellis
Jessica K. Formichella
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center,
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
lwalsh@walsh.law
sellis@walsh.law
jformichella@walsh.law

Jason Leonard
Jayita Guhaniyogi
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5400
jleonard@mwe.com
jguhaniyogi@mwe.com

OF COUNSEL *(pro hac vice forthcoming)*:
W. Chad Shear
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
(858) 678-5070
shear@fr.com

Elizabeth M. Flanagan
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(612) 335-5070
betsy.flanagan@fr.com

Andria Rae Crisler
FISH & RICHARDSON P.C.
1717 Main Street, Suite 5000
Dallas TX 75201
(214) 747-5070
crisler@fr.com

Simon D. Roberts
Nitya Anand
Vincent Li
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5700
simonroberts@mwe.com
nanand@mwe.com
vli@mwe.com

*Counsel for Plaintiffs*
*Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc.*