

John E. Flaherty
Ravin P. Patel
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444

Einar Stole
Michael N. Kennedy
Kristin M. Cobb
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Tel: (202) 662-6000

*Counsel for Plaintiffs AstraZeneca AB,
AstraZeneca Pharmaceuticals LP, and
AstraZeneca UK Limited*

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

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA AB, and
ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Limited (collectively, “Plaintiffs”), by their attorneys, for their complaint against Alkem Laboratories Ltd. (“Alkem”) allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(a-c, e). This action relates to an Abbreviated New Drug Application (“ANDA”) No. 212490 filed by or for the benefit of Alkem with the United States Food and Drug Administration (“FDA”) for approval

to market generic versions of Plaintiffs' DALIRESP® pharmaceutical products that are sold in the United States.

The Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

3. Plaintiff AstraZeneca AB is a public, limited-liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. Plaintiff AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA.

5. Plaintiffs AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Limited (collectively, "Plaintiffs" or "AstraZeneca") are all wholly-owned subsidiaries of AstraZeneca PLC.

6. Upon information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having its principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400013, India.

7. Upon information and belief, Alkem is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district.

Jurisdiction and Venue

8. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 8,536,206 (“the ’206 Patent”), U.S. Patent No. 8,604,064 (“the ’064 Patent”), and U.S. Patent No. 8,618,142 (“the ’142 Patent) (collectively, “the asserted patents”).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

10. This Court has personal jurisdiction over Defendant Alkem because, *inter alia*, on information and belief, Alkem has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell Alkem’s Infringing ANDA Product in the State of New Jersey upon approval of ANDA No. 212490.

11. On information and belief, Alkem controls and directs wholly owned subsidiaries in the United States, including The Pharma Network, LLC and Ascend Laboratories, LLC. On information and belief, The Pharma Network, LLC, which is located at 339 Jefferson Rd. # 101, Parsippany, New Jersey 07054, is a New Jersey limited liability company having its principal place of business in New Jersey. On information and belief, Ascend Laboratories, LLC, which is located at 339 Jefferson Rd. # 101, Parsippany, New Jersey 07054, is a New Jersey limited liability company having its principal place of business in New Jersey.

12. On information and belief, Alkem is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of

New Jersey, through its own actions and through the actions of its agents and subsidiaries, from which Alkem derives a substantial portion of its revenue.

13. On information and belief, Alkem, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of ANDA No. 212490, continues to engage in seeking FDA approval of this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Alkem's Infringing ANDA Product throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of ANDA No. 212490.

14. On information and belief, Alkem, through its own actions and through the actions of its agents and subsidiaries, prepared and submitted ANDA No. 212490 with a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. On information and belief, following FDA approval of ANDA No. 212490, Alkem intends to market, offer to sell, sell, or distribute Alkem's Infringing ANDA Product throughout the United States and within the State of New Jersey, that will, as explained below, infringe upon AstraZeneca's rights in the Patents-in-Suit protecting its DALIRESP[®] products. On information and belief, following FDA approval of ANDA No. 212490, Alkem knows and intends that Alkem's Infringing ANDA Product will be marketed, used, distributed, offered for sale, or sold in the United States and within the State of New Jersey.

16. Alkem has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases, including in this action, which arises out of Alkem's filing of ANDA No. 212490. *See, e.g., Celgene Corp. v. Alkem Labs. Ltd.*, No. 18-cv-11265, D.I. 15 (D.N.J. Aug. 29, 2018); *Otsuka Pharm. Co., Ltd. v. Alkem Labs. Ltd. et al.*, No. 16-cv-06067, D.I. 9 (D.N.J. Feb. 21, 2017); *AstraZeneca AB et al. v.*

Alkem Labs. Ltd. et al., No. 15-cv-06609, D.I. 10 (D.N.J. Nov. 9, 2015); *Boehringer Ingelheim Pharma GmbH et al. v. Teva Pharm. USA, Inc. et al.*, No. 14-cv-07811, D.I. 40 (D.N.J. Mar. 17, 2015). Alkem has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

17. This Court also has personal jurisdiction over Alkem at least because, *inter alia*, (a) Alkem has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Alkem's Infringing ANDA Product in the United States, including in the State of New Jersey; (b) Alkem, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Alkem's Infringing ANDA Product in the United States, including in the State of New Jersey and to residents of this Judicial District, upon approval of ANDA No. 212490, and will derive substantial revenue from the use or consumption of Alkem's Infringing ANDA Product in the State of New Jersey; and (c) Alkem has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States and within the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if ANDA No. 212490 is approved, Alkem's Infringing ANDA Product charged with infringing the Patents-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

18. In the alternative, this Court has personal jurisdiction over Alkem because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) AstraZeneca's claims

arise under federal law; (b) Alkem is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

19. On information and belief, Alkem has also engaged in substantial, systematic, and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over Alkem in New Jersey.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) because, on information and belief, Alkem is an Indian corporation and not resident in the United States.

Regulatory Requirements for New and Generic Drugs

21. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

22. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

23. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

24. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Approved Drug Product

25. AstraZeneca Pharmaceuticals LP is the current holder of NDA No. 022522, for DALIRESP®, Roflumilast Tablet 500 mcg, which was first approved by FDA on February 28, 2011. Plaintiffs market the approved drug product under the tradename DALIRESP®. DALIRESP® is approved as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. A copy of the complete prescribing information for DALIRESP® approved in NDA No. 022522 is attached as Exhibit A.

26. FDA has listed the '206, '064, and '142 Patents in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 022522.

27. AstraZeneca Pharmaceuticals LP maintains the listing of the '206, '064, and '142 Patents in the Orange Book.

28. AstraZeneca AB is the current owner by assignment of the '206, '064, and '142 Patents.

29. On April 29, 2016, AstraZeneca AB received ownership of the NDA No. 022522 from Forest Pharmaceuticals, Inc. and Forest Research Institute Inc.

30. AstraZeneca UK Limited is the exclusive licensee of the '206, '064, and '142 Patents.

ANDA No. 212490

31. Upon information and belief, on or before August 28, 2018, Alkem submitted to FDA an ANDA (ANDA No. 212490) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 500 mcg roflumilast tablets purportedly bioequivalent to DALIRESP[®]. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic DALIRESP[®] product.

32. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 212490 for the generic DALIRESP[®] product is a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation, *i.e.*, the same indication as that set forth in the approved labeling for DALIRESP[®].

33. Upon information and belief, Alkem sent AstraZeneca Pharmaceuticals LP and AstraZeneca AB a letter dated October 9, 2018 (the "Notice Letter"). The Notice Letter represented that Alkem had submitted to FDA ANDA No. 212490 with paragraph IV certifications for the '206, '064, and '142 Patents.

34. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of DALIRESP[®] before the expiration of

the patents listed in the Orange Book for NDA No. 022522. Hence, Alkem's purpose in submitting ANDA No. 212490 is to market products described therein before expiration of the '206, '064, and '142 Patents.

Count 1: Patent Infringement of the '206 Patent

35. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 34 above.

36. The '206 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on September 17, 2013. Plaintiff AstraZeneca AB is the owner of the '206 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '206 Patent. A true and complete copy of the '206 Patent is attached hereto as Exhibit B.

37. Upon information and belief, Alkem submitted ANDA No. 212490 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP[®] before the expiration of the '206 Patent.

38. Alkem's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '206 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. Upon information and belief, if approved, the generic DALIRESP[®] product for which approval is sought in Alkem's ANDA No. 212490 will be administered to human patients as treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '206 Patent. Upon information and belief, this infringement will occur at Alkem's behest, with its intent, knowledge, and encouragement,

and Alkem will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '206 Patent.

40. Alkem's manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic DALIRESP[®] product for which approval is sought in ANDA No. 212490 would actively induce and contribute to infringement of the '206 Patent, and Alkem would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

41. Upon information and belief, as part of the ANDA filing, Alkem purportedly provided written certification to FDA that the claims of the '206 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Alkem's generic version of DALIRESP[®].

42. Alkem gave written notice of its certification of invalidity and/or non-infringement of the '206 Patent, alleging that the claims of the '206 Patent are invalid and that certain claims would not be infringed by Alkem's generic version of DALIRESP[®], and informing Plaintiffs that Alkem seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to DALIRESP[®] prior to the expiration of the '206 Patent.

43. Alkem has infringed the '206 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 212490 with a Paragraph IV certification and seeking FDA approval of ANDA No. 212490 to market a generic version of DALIRESP[®] prior to the expiration of the '206 Patent. Moreover, if Alkem commercially uses, offers for sale, or sells its generic version of DALIRESP[®], or induces or contributes to such conduct, it would further infringe the '206 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

44. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

45. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing or contributing to infringement of the '206 Patent. Plaintiffs do not have an adequate remedy at law.

Count 2: Patent Infringement of the '064 Patent

46. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 34 above.

47. The '064 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on December 10, 2013. Plaintiff AstraZeneca AB is the owner of the '064 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '064 Patent. A true and complete copy of the '064 Patent is attached hereto as Exhibit C.

48. Upon information and belief, Alkem submitted ANDA No. 212490 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP[®] before the expiration of the '064 Patent.

49. Alkem's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '064 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. Upon information and belief, if approved, the generic DALIRESP[®] product for which approval is sought in Alkem's ANDA No. 212490 will be administered to human patients as treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '064 Patent. Upon information and belief, this infringement will occur at Alkem's behest, with its intent, knowledge, and encouragement,

and Alkem will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '064 Patent.

51. Alkem's manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic DALIRESP[®] product for which approval is sought in ANDA No. 212490 would actively induce and contribute to infringement of the '064 Patent, and Alkem would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

52. Upon information and belief, as part of the ANDA filing, Alkem purportedly provided written certification to FDA that the claims of the '064 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Alkem's generic version of DALIRESP[®].

53. Alkem gave written notice of its certification of invalidity and/or non-infringement of the '064 Patent, alleging that the claims of the '064 Patent are invalid and that certain claims would not be infringed by Alkem's generic version of DALIRESP[®], and informing Plaintiffs that Alkem seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to DALIRESP[®] prior to the expiration of the '064 Patent.

54. Alkem has infringed the '064 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 212490 with a Paragraph IV certification and seeking FDA approval of ANDA No. 212490 to market a generic version of DALIRESP[®] prior to the expiration of the '064 Patent. Moreover, if Alkem commercially uses, offers for sale, or sells its generic version of DALIRESP[®], or induces or contributes to such conduct, it would further infringe the '064 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

55. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

56. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing or contributing to infringement of the '064 Patent. Plaintiffs do not have an adequate remedy at law.

Count 3: Patent Infringement of the '142 Patent

57. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 34 above.

58. The '142 Patent, entitled "PROCESS FOR THE PREPARATION OF ROFLUMILAST," was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013. Plaintiff AstraZeneca AB is the owner of the '142 Patent. Plaintiff AstraZeneca UK Limited is the exclusive licensee of the '142 Patent. A true and complete copy of the '142 Patent is attached hereto as Exhibit D.

59. Upon information and belief, Alkem submitted ANDA No. 212490 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of DALIRESP[®] before the expiration of the '142 Patent.

60. Alkem's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '142 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

61. Upon information and belief, if approved, the generic DALIRESP[®] product for which approval is sought in Alkem's ANDA No. 212490 will be administered to human patients as treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbation in patients with severe COPD associated with chronic bronchitis and a history of exacerbation. This administration, in turn, would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '142 Patent. Upon information and belief, this infringement will occur at Alkem's behest, with its intent, knowledge, and encouragement,

and Alkem will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '142 Patent.

62. Alkem's manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic DALIRESP[®] product for which approval is sought in ANDA No. 212490 would actively induce and contribute to infringement of the '142 Patent, and Alkem would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

63. Upon information and belief, as part of the ANDA filing, Alkem purportedly provided written certification to FDA that the claims of the '142 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Alkem's generic version of DALIRESP[®].

64. Alkem gave written notice of its certification of invalidity and/or non-infringement of the '142 Patent, alleging that the claims of the '142 Patent are invalid and that certain claims would not be infringed by Alkem's generic version of DALIRESP[®], and informing Plaintiffs that Alkem seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to DALIRESP[®] prior to the expiration of the '142 Patent.

65. Alkem has infringed the '142 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 212490 with a Paragraph IV certification and seeking FDA approval of ANDA No. 212490 to market a generic version of DALIRESP[®] prior to the expiration of the '142 Patent. Moreover, if Alkem commercially uses, offers for sale, or sells its generic version of DALIRESP[®], or induces or contributes to such conduct, it would further infringe the '142 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

66. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

67. Plaintiffs will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing or contributing to infringement of the '142 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendant has infringed the '206, '064, and '142 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 212490 is not earlier than the expiration date of the '206, '064, and '142 Patents, or any later expiration of exclusivity for the '206, '064, and '142 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendant and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '206, '064, and '142 Patent, including the product described in ANDA No. 212490;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 212490 would constitute infringement of the '206, '064, and '142 Patents, or inducing or contributing to such conduct, by Defendant pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

November 21, 2018

Respectfully submitted,

OF COUNSEL:

Einar Stole
Michael N. Kennedy
Kristin M. Cobb
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Tel: (202) 662-6000

s/ John E. Flaherty
John E. Flaherty
Ravin P. Patel
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444

*Counsel for Plaintiffs AstraZeneca
AB, AstraZeneca Pharmaceuticals
LP, and AstraZeneca UK Limited*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

The undersigned hereby certifies that the matter in controversy is not the subject of any other action or proceeding in any Court or of a pending arbitration proceeding, and that no other action or arbitration proceeding is contemplated. However, the patents-at-issue were the subject of previous Hatch-Waxman cases before this court, all of which have settled¹:

- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. TORRENT PHARMA INC. AND TORRENT PHARMACEUTICALS LTD.*, Civil Action No. 16-cv-02091-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. MICRO LABS USA, INC. AND MICRO LABS LTD.*, Civil Action No. 15-cv-03376-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. STRIDES PHARMA, INC. AND STRIDES PHARMA GLOBAL PTE LIMITED*, Civil Action No. 15-cv-03378-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. APOTEX CORP. AND APOTEX INC.*, Civil Action No. 15-cv-03379-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. PRINSTON PHARMACEUTICAL INC.*, Civil Action No. 15-cv-03380-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. BRECKENRIDGE PHARMACEUTICAL INC.*, Civil Action No. 15-cv-03382-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. CITRON PHARMA LLC AND MSN LABORATORIES PRIVATE LIMITED*, Civil Action No. 15-cv-03383-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. MYLAN PHARMACEUTICALS INC.*, Civil Action No. 15-cv-03384-FLW-DEA (D.N.J);

¹ The following cases were consolidated into *In re Certain Consolidated Roflumilast Cases*, C.A. No. 15-03375-FLW-DEA (D.N.J).

- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. HETERO USA INC., HETERO LABS LIMITED UNIT-III, AND HETERO LABS LIMITED*, Civil Action No. 16-cv-03385-FLW-DEA (D.N.J);
- *TAKEDA GMBH, ASTRAZENECA PHARMACEUTICALS LP, AND ASTRAZENECA UK LIMITED v. ZYDUS PHARMACEUTICALS (USA) INC.*, Civil Action No. 15-CV-03377-FLW-DEA (D.N.J.).

Dated: November 21, 2018

Respectfully submitted,

OF COUNSEL:

Einar Stole
Michael N. Kennedy
Kristin M. Cobb
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Tel: (202) 662-6000

s/ John E. Flaherty
John E. Flaherty
Ravin P. Patel
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Tel: (973) 622-4444

*Counsel for Plaintiffs AstraZeneca
AB, AstraZeneca Pharmaceuticals
LP, and AstraZeneca UK Limited*