Keith J. Miller (kmiller@rwmlegal.com)
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2761 (Facsimile)

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

ACTELION PHARMACEUTICALS LTD., and ACTELION PHARMACEUTICALS US, INC., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA), INC. and CADILA HEALTHCARE LIMITED Defendants.	Civil Action No. #:##-cv-#####-XXX

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc., (collectively, "Plaintiffs") for their Complaint against Defendants Zydus Pharmaceuticals (USA), Inc., and Cadila Healthcare Ltd. d/b/a/ Zydus Cadila ("Zydus Cadila") (collectively, "Defendants") to the best of their knowledge, information and belief, hereby 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, Title 35, United States Code, in response to the submission of an Abbreviated New Drug Application ("ANDA") by Defendants to the United States Food and Drug Administration (the "FDA") seeking approval to engage in the commercial manufacture, use,

offer for sale, sale and/or importation of a generic version of Plaintiffs' TRACLEER® (bosentan) tablets for oral suspension, 32 mg, prior to the expiration of U.S. Patent No. 8,309,126 (the "'126 patent").

THE PARTIES

2. Plaintiff Actelion Pharmaceuticals Ltd. is a company organized and existing under the laws of Switzerland, with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

3. Plaintiff Actelion Pharmaceuticals US, Inc. is a company organized and existing under the laws of the state of Delaware, with its principal place of business at 5000 Shoreline Court, Suite 200, South San Francisco, California 94080.

4. Plaintiffs are research-based pharmaceutical companies that discover, develop, and bring to market revolutionary pharmaceutical products in areas of unmet medical need. Plaintiffs are leaders in the science and medicine of pulmonary arterial hypertension, a chronic and life-threatening disorder. Plaintiffs' portfolio of products includes, among other things, treatments for pulmonary arterial hypertension using formulations of the drug bosentan. Plaintiffs sell pediatric (32 mg tablets for oral suspension) formulations of bosentan under the trade name TRACLEER® in this District and throughout the United States.

5. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a company organized and existing under the laws of New Jersey, with its principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534.

6. Upon information and belief, Defendant Cadila Healthcare Ltd. is an Indian company organized and existing under the laws of India, with its principal place of business at Zydus Tower, Satellite Cross Roades, Ahmedabad, Gujarat 380015, India.

7. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Cadila Healthcare Ltd.

8. Upon information and belief, Defendants prepared and filed ANDA No. 213981 in concert with each other and will be involved in development, manufacture, regulatory approval, marketing, sale, and/or distribution of the product that is the subject of ANDA No. 213981 (the "Zydus ANDA Product") in the United States, including in this District, if ANDA No. 213981 is approved.

9. Upon information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, develop, manufacture, import, market, distribute, and/or sell generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this District.

10. Upon information and belief, Defendants are agents of each other and/or work in concert with respect to the development, manufacture, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products, including the Zydus ANDA Product, throughout the United States, including in this District.

THE PATENT-IN-SUIT

11. The '126 patent, entitled "Dispersible Bosentan Tablet," was duly issued by the United States Patent and Trademark Office on November 13, 2012, naming as inventors Lovelace Holman and Timm Trenktrog. A copy of the '126 patent is attached hereto as Exhibit A.

12. The '126 patent claims dispersible bosentan tablets, methods for making the same and a method for treating pulmonary arterial hypertension using dispersible bosentan tablets.

13. Plaintiffs lawfully own all right, title and interest in the '126 patent, including the right to sue and to recover for past infringement.

PLAINTIFFS' TRACLEER (BOSENTAN) DISPERSIBLE TABLETS FOR ORAL SUSPENSION, 32 MG

14. Plaintiffs sell TRACLEER (bosentan) Tablets for Oral Suspension (dispersible tablets), 32 mg, in the United States pursuant to a New Drug Application ("NDA") No. 209279 that has been approved by the FDA. Actelion Pharmaceuticals Ltd. is the holder of NDA No. 209279. TRACLEER (bosentan) Tablets for Oral Suspension, 32 mg, are dispersible tablets that are indicated for the treatment of pediatric patients with pulmonary arterial hypertension.

15. The FDA issues a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). In accordance with 21 U.S.C. § 355(b)(1), the '126 patent is listed in the Orange Book in connection with NDA No. 209279 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale" of the TRACLEER (bosentan) 32 mg dispersible Tablets for Oral Suspension.

DEFENDANTS' ANDA SUBMISSION

16. By letter dated November 19, 2019 (the "Zydus Notice Letter"), Zydus Pharmaceuticals (USA) Inc. notified Plaintiffs that it had submitted to the FDA ANDA No. 213981 (the "Zydus ANDA") for Zydus' Bostenan Tablets for Oral Suspension, 32 mg, a drug product that is a generic version of the TRACLEER (bosentan) 32 mg dispersible tablets for Oral Suspension.

17. Upon information and belief, Defendants submitted the Zydus ANDA for the purpose of obtaining approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, and/or sale of the Zydus ANDA Product prior to the expiration of the '126 patent.

18. In the Zydus Notice Letter, Zydus Pharmaceuticals (USA) Inc. notified Plaintiffs that, as part of the Zydus ANDA, Zydus Pharmaceuticals (USA) Inc. had filed certifications of the type described in Section 505(j)(1) and (2)(A) of the FDCA, 21 U.S.C. § 355(j)(1) and (2)(A), with respect to the '126 patent. Upon information and belief, Defendants submitted ANDA No. 213981 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '126 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Zydus ANDA Product.

19. The use of the Zydus ANDA Product is covered by one or more claims of the '126 patent.

20. Defendants had knowledge of the '126 patent when they submitted the Zydus ANDA.

THE FILING OF THIS SUIT

21. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Zydus Notice Letter, which Plaintiffs received on or about November 21, 2019.

22. Under 21 U.S.C. § 355(c)(3)(C), Plaintiffs have 45 days after receipt of Zydus' Notice Letter to sue for infringement of the '126 patent to trigger a 30-month stay during which the FDA cannot approve Zydus' ANDA.

JURISDICTION

23. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.* generally and 35 U.S.C. § 271(e)(2) specifically.

24. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and 35 U.S.C. § 271.

25. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. because it is incorporated in New Jersey.

26. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. by virtue of the fact that, *inter alia*, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including to Plaintiffs Actelion Pharmaceuticals Ltd., and Actelion Pharmaceuticals US, Inc., in New Jersey. For example, upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. are actively preparing to make the proposed generic copies of TRACLEER (bosentan) 32 mg Tablets for Oral Suspension that are the subject of Zydus' ANDA No. 213981, and to use, sell, and offer for sale such generic copies in this State and this judicial district. Upon information and belief, following any FDA approval of ANDA No. 213981, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. know and intend that the Zydus ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

27. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., alone and/or together with its affiliate Cadila Healthcare Ltd. have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and including to Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. in New Jersey.

28. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd., as affiliates and/or agents of each other, actively worked in concert to prepare and file the Zydus ANDA with the FDA that is at issue in this patent infringement suit.

29. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. therefore committed an act of infringement in the State of New Jersey, by participating in the preparation, filing, and submission of ANDA No. 213981 pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act to FDA, accompanied by a Paragraph IV certification.

30. By submitting ANDA No. 213981 to FDA, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. have made clear that they intend to use their distribution channels to market the Zydus ANDA Product in the State of New Jersey. If ANDA No. 213981 is approved, the Zydus ANDA Product would, among other things, be marketed and distributed in the State of New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within the State of New Jersey, all of which would have a substantial effect on the State of New Jersey.

31. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. are in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

32. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products in New Jersey and throughout the United States and will do the same with respect to Zydus' ANDA Product for which they have sought approval from the FDA.

33. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products in New Jersey and throughout the United States and will do the same with respect to Zydus' ANDA Product for which they have sought approval from the FDA.

34. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. by virtue of, among other things, (1) its incorporation in New Jersey, (2) its continuous and systematic contacts with the United States, including New Jersey, (3) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey, (4) its sale of a substantial volume of prescription drugs in New Jersey, (5) it's maintenance of regular and established places of business and appointment of an agent for service of process in New Jersey at 73 Route 31 North, Pennington, New Jersey, 08534, (6) its registration to do business in New Jersey, (7) its mailing of the Zydus Notice letter to two Actelion entities, Actelion Pharmaceuticals Ltd. and Actelion Clinical Research Inc., in New Jersey; and (8) its conduct by, through, and in concert with Cadila Healthcare Ltd.

35. Zydus Pharmaceuticals (USA) Inc. has previously submitted to the jurisdiction of this Court. *See, e.g., Celgene Corp. v. Zydus Pharm. (USA) Inc.*, No. 18-cv-11267, D.I. 13 (D.N.J. Aug 22, 2018); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 18-cv-02620, D.I. 90 (D.N.J. Apr. 12, 2018); *Takeda Pharm. Co. Ltd. et al. v. Zydus Pharm. (USA) Inc. et al.*, No. 18- cv-01994, D.I. 22 (D.N.J. Mar. 29, 2018); *Celgene Corp. v. Zydus Pharm. (USA) Inc. et al.*, No. 17-cv-02528, D.I. 19 (D.N.J. Aug. 7, 2017).

36. This Court has personal jurisdiction over Cadila Healthcare Ltd., by virtue of, among other things, (1) its continuous and systematic contacts with the United States, including

New Jersey, (2) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey, (3) its sale of a substantial volume of prescription drugs in New Jersey, and (4) its conduct by, through, and in concert with Zydus Pharmaceuticals (USA) Inc.

37. In the alternative, this Court has personal jurisdiction over Cadila Healthcare Ltd. under Federal Rule of Civil Procedure 4(k)(2)(A) because (a) Plaintiffs' claims arise under federal law, (b) Cadila Healthcare Ltd. is a foreign company not subject to personal jurisdiction in the court of any state, and (c) Cadila Healthcare Ltd. has sufficient contacts with the United States as a whole such that exercising jurisdiction over Cadila Healthcare Ltd. in this District comports with due process.

38. Upon information and belief, Cadila Healthcare Ltd. has continuous and systemic contacts with the United States, including New Jersey, directly and through its US agent, Zydus Healthcare (USA) Inc.

39. Cadila Healthcare Ltd. has continuous and systemic contact with the United States and New Jersey, through, *inter alia*, applications to sell pharmaceutical products and sales of pharmaceutical products throughout the United States.

40. Cadila Healthcare Ltd. has continuous and systemic contact with the United States and New Jersey through its ANDA seeking approval to sell bosentan 32 mg Tablets for Oral Suspension.

41. Upon information and belief, Cadila Healthcare Ltd. continuously and systematically places its products into the stream of commerce for distribution and consumption in New Jersey and throughout the United States. Cadila Healthcare Ltd. does business as "Zydus Cadila." The Zydus Pharmaceuticals (USA) Inc. website search states "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Cadila

Healthcare. Zydus Cadila is a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States."

42. The Zydus Cadila website states "Zydus' global business has a strong presence in the regulated markets of the US[.]" It further states "[t]he group has manufacturing sites and research facilities spread across five states . . . in India and in the US and Brazil."

43. The Cadila Healthcare Ltd. 2018-2019 Annual Report states "[t]he Company has a global presence and sells its products in the United States, India, Europe, and emerging markets including countries in Latin America, Asia Pacific region and Africa." The Annual Report further explains "The global sales of prescription pharmaceutical drugs is expected to grow in low to mid-single digit and cross US$ 1.5 trillion by 2023. The key geographies of growth will continue to be the United States and emerging markets, which are likely to grow in mid to high single digit over a period of next five years."

44. Cadila Healthcare Ltd. has previously submitted to the jurisdiction of this Court. *See, e.g., Impax Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-13476 (D.N.J. April 11, 2018), *Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010), and *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Group*, No. 3:15-cv-5982 (PGS)(TJB) (D.N.J. Sept. 16, 2015).

VENUE

45. The preceding paragraphs are incorporated as if set forth fully herein.

46. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

47. Venue is proper in this jurisdiction over Cadila Healthcare Ltd. pursuant to 28 U.S.C. § 1391. Upon information and belief, Cadila Healthcare Ltd. is not a resident in the United States, and therefore may be sued in any judicial district where it is subject to the Court's personal jurisdiction.

48. Venue is further proper over Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. § 1400(b). Zydus Pharmaceuticals (USA) Inc. is incorporated in New Jersey. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. has and will commit acts of infringement in New Jersey (*see* ¶¶ 26-33) and has a regular and established place of business in this jurisdiction. Zydus Pharmaceuticals (USA) Inc. has previously admitted that it maintains regular and established places of business in New Jersey. *See, e.g., Takeda Pharmaceuticals Co. v. Zydus Pharmaceuticals (USA) Inc.*, No. 18-01994 (FLW)(TJB) (D.N.J. March 29, 2018), *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528 (SDW)(LDW) (D.N.J. Aug. 7, 2017), and *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Group*, No. 3:15-cv-5982 (PGS)(TJB) (D.N.J. Sept. 16, 2015).

COUNT I: INFRINGEMENT OF THE '126 PATENT

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

50. The use of Zydus' ANDA Product is covered by one or more claims of the '126 patent, including but not limited to Claims 4, 6, and 8.

51. On information and belief, Defendants do not deny infringement of claims 1-4, 6, 8, 10 and 11 of the '126 patent separate and apart from asserting invalidity and therefore have not presented any legally cognizable defense against direct and/or indirect infringement.

52. The submission of Zydus' ANDA No. 213981 with a Paragraph IV certification regarding the '126 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus' ANDA Product before the expiration of

the ’126 patent constitutes infringement of one or more claims of the ’126 patent, including but not limited to Claims 4, 6, and 8, under 35 U.S.C. § 271(e)(2).

53. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus’ ANDA Product before the expiration of the ’126 patent would infringe one or more claims of the ’126 patent, including but not limited to Claims 4, 6, and 8, under 35 U.S.C. § 271, either directly, through induced infringement, or through contributory infringement.

54. The use of Zydus’ ANDA Product in accordance with and as directed by Zydus’ proposed labeling for that product before the expiration of the ’126 patent would infringe one or more claims of the ’126 patent, including but not limited to claims 4, 6, and 8, under 35 U.S.C. § 271.

55. Unless enjoined by this Court, Defendants intend to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus’ ANDA Product immediately and imminently upon approval of the Zydus ANDA.

56. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the ’126 patent when the Zydus ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

57. Defendants know that Zydus’ ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’126 patent, and that Zydus’ ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement ’126 patent immediately and imminently upon approval of the Zydus ANDA.

58. The foregoing actions by Defendants prior to the expiration of the '126 patent constitute and/or will constitute infringement, active inducement of infringement, and or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b), (c), (e), and/or (g).

59. Defendants have knowledge of the '126 patent and will be knowingly and willfully infringing the '126 patent.

60. Unless Defendants are enjoined from infringing the '126 patent, actively inducing infringement of the '126 patent, and/or contributing to the infringement of the '126 patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law. Pursuant to 35 U.S.C. § 271(e)(4)(B) and § 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered to prevent further infringement.

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Zydus' ANDA No. 213981 to be a date which is not earlier than the date on which the '126 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled.

62. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. Judgment in favor of Plaintiffs and against Defendants;

B. Judgment that the '126 patent is valid and enforceable;

C. Judgment that Defendants have infringed, literally or by the doctrine of equivalents, the '126 patent by the submission of ANDA No. 213981, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Zydus' ANDA

Product in the United States will constitute infringement, contributory infringement, and actively inducing infringement of the ’126 patent;

D. Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Zydus’ ANDA No. 213981 shall be no earlier than the date of expiration of the ’126 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and § 283 and Fed. R. Civ. P. 65 enjoining Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation or privity with them, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Zydus’ ANDA Product and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the ’126 patent, before the expiration of the ’126 patent and any additional periods of exclusivity;

F. Damages or other monetary relief, including pre-judgment and post-judgment interest, if Defendants engage in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Zydus ANDA Product, or any product or compound that infringes the ’126 patent, or actions constituting inducement of infringement and/or contributory infringement of the ’126 patent, before the expiration of the ’126 patent and any additional periods of exclusivity;

G. A declaration that this is an exceptional case and an award of reasonable attorneys’ fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

H. Plaintiffs’ reasonable costs of suit incurred in bringing and prosecuting this action; and

I. Such further and other relief as this Court may deem just and proper.

Dated: December 31, 2019

By: *s/ Keith J. Miller*

Keith J. Miller (kmiller@rwmlegal.com)
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2761 (Facsimile)

Attorneys for Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc.

Of Counsel
John M. Desmarais
Bindu Donovan
Todd L Krause
Amanda Potter
Karl Mullen
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
Telephone: 212-351-3400
Facsimile: 212-351-3401
jdesmarais@desmaraisllp.com
bdonovan@desmaraisllp.com
tkrause@desmaraisllp.com
apotter@desmaraisllp.com
kmullen@desmaraisllp.com

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding.

s/Keith J. Miller
Keith J. Miller (kmiller@rwmlegal.com)
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2761 (Facsimile)

Attorneys for Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc.