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

ACTELION PHARMACEUTICALS LTD., and ACTELION PHARMACEUTICALS US, INC., Plaintiffs, v. NATCO PHARMA LIMITED and SYNEOS HEALTH LLC, Defendants.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc., for their Complaint against Defendants Natco Pharma Limited, ("Natco Ltd.") and Syneos Health LLC (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 Natco Ltd. is an Indian company organized and existing under the laws of India, with its principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, Telangana, India 500034.

6. Upon information and belief, Defendant Syneos Health LLC is a company organized and existing under the laws of Delaware, with a principal place of business at 1030 Sync Street, Morrisville, North Carolina 27560. Upon information and belief, Syneos Health LLC maintains regular and established places of business at 500 Atrium Drive Somerset, New Jersey, 08873, and 301 College Road East, Princeton, New Jersey 08540.

7. Upon information and belief, Defendant Syneos Health LLC is the authorized United States agent for Natco Ltd., and is in the business of, among other things, performing contract drug manufacturing, research, commercialization, and sales for pharmaceutical companies.

8. 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.

9. 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 Natco ANDA Product, throughout the United States, including in this District.

10. Upon information and belief, Defendants prepared and filed ANDA No. 213154 in concert with each other and will be involved in development, manufacture, regulatory approval, marketing, sale, and/or distribution of the Natco ANDA Product in the United States, including in this District, if ANDA No. 213154 is approved.

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, a process for their preparation, 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 April 16, 2019 (the "Natco Notice Letter"), Natco Ltd. notified Plaintiffs that it had submitted to the FDA ANDA No. 213154 (the "Natco ANDA") for Natco's 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. (the "Natco ANDA Product").

17. Upon information and belief, Natco Ltd. itself and/or through its agent, Syneos Health LLC, submitted the Natco 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 Natco ANDA Product prior to the expiration of the '126 patent.

18. In the Natco Notice Letter, Natco Ltd. notified Plaintiffs that, as part of the Natco ANDA, Natco Ltd. 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. 213154 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 Natco ANDA Product.

19. The use of the Natco 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 Natco 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 Natco Notice Letter, which Plaintiffs received on or about April 17, 2019.

22. Under 21 U.S.C. § 355(c)(3)(C), Plaintiffs have 45 days after receipt of Natco's Notice Letter to sue for infringement of the '126 patent to trigger a 30-month stay during which the FDA cannot approve Natco's 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 Natco Ltd. because Natco Ltd. has consented to jurisdiction in New Jersey.

26. This Court has personal jurisdiction over Syneos Health LLC because Syneos Health LLC has consented to jurisdiction in New Jersey.

27. This Court has personal jurisdiction over Natco Ltd. and Syneos Health LLC by virtue of the fact that, *inter alia*, Natco Ltd. and Syneos Health LLC 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, Natco Ltd. and Syneos Health LLC are actively preparing to make the proposed generic copies of TRACLEER (bosentan) 32 mg Tablets for Oral Suspension that are the subject of Natco's ANDA No. 213154, 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. 213154, Natco Ltd. and Syneos Health LLC know and intend that the Natco ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

28. Upon information and belief, Natco Ltd., alone and/or together with its affiliate and/or agent Syneos Health LLC, 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.

29. Upon information and belief, Natco Ltd. and Syneos Health LLC, as affiliates and/or agents of each other, actively worked in concert to prepare and file the Natco ANDA with the FDA that is at issue in this patent infringement suit.

30. Natco Ltd. and Syneos Health LLC therefore committed an act of infringement in the State of New Jersey, by participating in the preparation, filing, and submission of ANDA No. 213154 pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act to FDA, accompanied by a Paragraph IV certification.

31. By submitting ANDA No. 213154 to FDA, Natco Ltd. and Syneos Health LLC have made clear that they intend to use their distribution channels to market the Natco ANDA Product in the State of New Jersey. If ANDA No. 213154 is approved, the Natco 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.

32. Upon information and belief, Natco Ltd., directly and/or through its US agent Syneos Health LLC, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

33. Upon information and belief, Natco Ltd. and Syneos Health LLC 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 Natco's ANDA Product for which they have sought approval from the FDA.

34. Upon information and belief, Natco Ltd. and Syneos Health LLC 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 Natco's ANDA Product for which they have sought approval from the FDA.

35. Upon information and belief, Syneos Health LLC provides various services as part of its business model. These services include, among other things, providing contract commercialization services to pharmaceutical companies to assist in the use and sale of pharmaceutical products throughout the United States.

36. Upon information and belief, Syneos Health LLC's client roster for contract commercialization services "consists of more than 550 leading Pharmaceutical, Biotechnology, Life Sciences, and Healthcare Payer companies and all of the top 50 of the largest global biopharmaceutical companies." Syneos Health "has deployed more than 150 sales teams in the last five years across all major therapeutic areas – more than the top 25 pharmaceutical companies combined. In a recent five-year period, Syneos Health has helped to develop or commercialize 91% of novel new drugs approved by the FDA[.]" (Syneos Health Website, attached hereto as Exhibit B.)

37. Upon information and belief, Syneos Health LLC, as the U.S. agent and/or "US front-end partner" and/or "marketing partner" of Natco Ltd., intends to assist Natco Ltd. in at least the use and sale of the Natco ANDA product throughout the United States and in New Jersey. Natco Pharma Ltd. represented in their 2017-2018 Annual Report that "[a]part from a strong foundational business in India, NATCO's global presence is led through well-known front-end partners in the USA and our own front-end in subsidiaries." (Natco 2017-2018 Annual

Report at 8, attached hereto as Exhibit C). Natco Pharma Ltd. represented in their 2016-2017 Annual Report "through a comprehensive partnership approach model, we at NATCO have been dedicated to providing access to medicines for the US patients." (Natco 2016-2017 Annual Report at 18, attached hereto as Exhibit D). Natco "is also focused on complex generics for the US market and has adopted and successfully implemented partnership strategy for international formulations products . . .[m]oreover, it has entered into de-risked arrangements with marketing partners; with the partner typically responsible for the litigation and regulatory process to secure the ANDA approval. Profit sharing arrangements with front-end partners ensure NATCO participates in the up-side." (Natco 2016-2017 Annual Report at 45).

38. Upon information and belief, Syneos Health LLC will financially benefit from the manufacture, use, and sale of the Natco ANDA Product throughout the United States and New Jersey, through a profit-sharing arrangement with Natco Ltd.

39. This Court has personal jurisdiction over Syneos Health LLC by virtue of, among other things, (1) its consent to jurisdiction 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 in New Jersey at 500 Atrium Drive Somerset, New Jersey, 08873, and 301 College Road East, Princeton, New Jersey 08540, (6) its registration to do business in New Jersey, (7) it's appointment of an agent for service of process at 12 Christopher Way #200, Eatontown, New Jersey, 07724, and (8) its conduct by, through, and in concert with Natco Ltd.

40. This Court has personal jurisdiction over Natco Ltd., by virtue of, among other things, (1) its consent to jurisdiction 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) its mailing of the Natco Notice letter to two Actelion entities, Actelion Pharmaceuticals Ltd. and Actelion Clinical Research Inc., in New Jersey; and (6) its conduct by, through, and in concert with Syneos Health LLC.

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

42. Upon information and belief, Natco Ltd. has continuous and systemic contacts with the United States, including New Jersey, directly and through its US agent, Syneos Health LLC.

43. Natco 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.

44. Natco 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.

45. Upon information and belief, Natco Ltd. continuously and systematically places its products into the stream of commerce for distribution and consumption in New Jersey and throughout the United States. Natco Ltd. has, in its Annual Reports, consistently represented that the United States is a key market for the company. Natco Ltd. "sells its products in India, USA,

Europe, and several other emerging countries, totalling over 40 countries." (Natco 2017-2018 Annual Report at 89).

46. Natco Ltd.'s "FY 2017-2018 global strategy" included "focus[ing] more deeply into niche molecules for the US market," and "expand[ing] the base product pipeline of India and USA[.]" *Id*.

47. In 2016-2017, six Abbreviated New Drug Applications filed by Natco Ltd. were approved, allowing Natco Ltd. to manufacture, use, and sell generic pharmaceutical products in the United States. (Natco 2016-2017 Annual Report at 19). As of March 31, 2017, Natco Ltd. had "43 niche ANDA filings including 20 Para IV filings in the US – with 22 approved ANDAs[.]" (Natco 2016-2017 Annual Report at 45). As of March 31, 2018, Natco Ltd. had 29 approved ANDAs and 16 paragraph IV's yet to be approved and launched. (Natco 2017-2018 Annual Report at 39).

48. As of 2016-2017, "India and USA [were] the largest markets" for Natco Ltd. (Natco 2016-2017 Annual Report at 29).

49. As of Natco Ltd.'s most recent annual report, their "business operations are classified into two categories: Formulations and API. [Natco's] formulations business is categorized into a) domestic business and b) export business, primarily to the US, Canada, and RoW." (Natco 2017-2018 Annual Report at 37).

50. Upon information and belief, Natco Ltd. derives substantial revenue and income from sales of pharmaceutical products throughout the United States, including in the State of New Jersey. Since 2014, Natco Ltd. has made substantial sales for formulation exports to the US. For fiscal year 2017, of $8,370 million in international export formulation sales, $7,697 million were in the USA. (Natco 2016-2017 Annual Report at 19, 45). For fiscal year 2018, Natco Ltd.

earned $10,031.4 million in export formulation sales in the US. (Natco 2017-2018 Annual Report at 40).

51. Natco Ltd. has previously submitted to the jurisdiction of this Court. *See, e.g.*, *Gilead Sciences Inc. v. Natco Pharma Ltd.*, Ca. No. 3-18-cv-03592 (Dkt. No. 26); *Celgene Corp. v. Natco Pharma Ltd.*, Ca. No. 10-5197, 2014 WL 2196914 (Dkt. No. 18).

VENUE

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

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

54. Venue is proper in this jurisdiction over Natco Ltd. pursuant to 28 U.S.C. § 1391. Upon information and belief, Natco 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.

55. Venue is also proper in this jurisdiction over Natco Ltd. because Natco Ltd. has consented to venue in New Jersey.

56. Venue is proper in this jurisdiction over Syneos Health LLC pursuant to 28 U.S.C. § 1400(b). Upon information and belief, Syneos Health LLC has and will commit acts of infringement in New Jersey (*see* ¶¶ 28-40, 30-38) and has a regular and established place of business in this jurisdiction. Syneos Health has previously admitted that it maintains regular and established places of business in New Jersey. *See Celgene Corp. v. Natco Pharma Ltd.*, Ca. No. 10-5197, 2014 WL 2196914 (Dkt. No. 18).

57. Venue is also proper in this jurisdiction over Syneos Health LLC because Syneos Health LLC has consented to venue in New Jersey.

COUNT I: INFRINGEMENT OF THE '126 PATENT

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

59. The use of Natco's ANDA Product is covered by one or more claims of the '126 patent, including but not limited to Claims 4, 6, 7, 8, and 9.

60. The submission of Natco's ANDA No. 213154 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 Natco's 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, 7, 8, and 9 under 35 U.S.C. § 271(e)(2).

61. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Natco's 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, 7, 8, and 9 under 35 U.S.C. § 271, either directly, through induced infringement, or through contributory infringement.

62. The use of Natco's ANDA Product in accordance with and as directed by Natco's 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, 7, 8, and 9, under 35 U.S.C. § 271.

63. 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 Natco's ANDA Product immediately and imminently upon approval of the Natco ANDA.

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

65. Defendants know that Natco's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '126 patent, and that Natco's 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 Natco ANDA.

66. 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) and/or (g).

67. On information and belief, Defendants do not deny infringement of claims 4, 6, 7, 8, and 9 of the '126 patent separate and apart from asserting invalidity and/or unenforceability, and therefore have not presented any legally cognizable defense against direct and/or indirect infringement.

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

69. 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.

70. 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 Natco's ANDA No. 213154 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.

71. 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. 213154, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Natco's 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 Natco's ANDA No. 213154 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 Natco's 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 Natco 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: May 28, 2019

By: *s/ Keith J. Miller*

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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.

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