IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HETERO USA INC, HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Biogen" or "Plaintiffs"), by way of Complaint against Defendants Hetero USA Inc. ("Hetero USA"), Hetero Labs Limited Unit-III ("HLL Unit-III") and Hetero Labs Limited ("Hetero Labs") (collectively, "Hetero" or "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Biogen International GmbH is a Swiss corporation with its principal place of business in Zug, Switzerland at Landis + Gyr-Strasse 3, 6300 Zug, Switzerland.

2. Plaintiff Biogen MA Inc. is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 225 Binney Street, Cambridge, Massachusetts 02142.

3. Biogen is in the business of developing, manufacturing and marketing innovative therapies for patients living with serious neurological, autoimmune, and rare diseases, including therapies for multiple sclerosis. Biogen's asserted patents cover Tecfidera®, which is marketed

and sold in this judicial district and throughout the United States for the treatment of relapsing forms of multiple sclerosis.

4. Upon information and belief, Hetero USA is a corporation organized under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

5. Upon information and belief, Hetero USA is a generic pharmaceutical company that develops, manufactures, markets and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States, including as an agent of HLL Unit-III and Hetero Labs.

6. Upon information and belief, Hetero USA is a partially-owned subsidiary of Hetero Labs.

7. Upon information and belief, HLL Unit-III is a corporation organized under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate Industrial Estate, Sanath Nagar, Hyderabad - 500 018, Telangana, India.

8. Upon information and belief, HLL Unit-III is a generic pharmaceutical company that develops, manufactures, markets and/or distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States, including through its agent Hetero USA Inc.

9. Upon information and belief, HLL Unit-III is a division of Hetero Labs.

10. Upon information and belief, Hetero Labs is a corporation organized under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate Industrial Estate, Sanath Nagar, Hyderabad - 500 018, Telangana, India.

11. Upon information and belief, Hetero Labs is a generic pharmaceutical company that develops, manufactures, markets and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States, including through its agent Hetero USA.

12. Upon information and belief, the acts of Hetero complained of herein were done with the cooperation, participation, and assistance of Hetero USA, HLL Unit-III and Hetero Labs.

NATURE OF THE ACTION

13. This is an action for patent infringement of U.S. Patent Nos. 6,509,376 ("the '376 patent"), 7,320,999 ("the '999 patent") and 8,399,514 ("the '514 patent") arising under the patent laws of the United States, Title 35, United States Code, §§ 100 *et seq*., including 35 U.S.C. § 271. This action relates to Hetero's filing of Abbreviated New Drug Application ("ANDA") No. 210500 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sell, offer to sell, and import generic dimethyl fumarate delayed-release capsules prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

14. Biogen realleges, and incorporates in full herein, each preceding paragraph.

15. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Hetero USA is incorporated in Delaware and HLL Unit-III and Hetero Labs are incorporated in India and may be sued in any judicial district in the United States, in which the defendants are subject to the court's personal jurisdiction.

17. This Court has personal jurisdiction over Hetero USA because Hetero USA is incorporated in Delaware.

18. Upon information and belief, Hetero USA has appointed W/K Incorporating Services, Inc. located at 3500 S DuPont Hwy, Dover, DE 19901 for receipt and service of process as its registered agent.

19. Upon information and belief, Hetero USA is registered to do business in Delaware (File No. 4837317). *See* https://icis.corp.delaware.gov/Ecorp/EntitySearch/NameSearch.aspx. (Accessed June 6, 2017).

20. This Court has personal jurisdiction over Hetero Labs and HLL Unit-III, *inter alia*, because Hetero Labs' subsidiary, Hetero USA, is incorporated in Delaware and, upon information and belief, filed ANDA No. 210500 as Hetero Labs and HLL Unit-III's agent and under Hetero Labs' direction and control.

21. Alternatively, this Court has personal jurisdiction over Hetero Labs and HLL Unit-III under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, both are organized under the laws of India.

22. This Court also has personal jurisdiction over Defendants because, *inter alia*, this action arises from activities of Defendants directed toward Delaware.

23. Hetero's ANDA filing, regarding the '376 patent, the '999 patent and the '514 patent, has a substantial connection with this district because it reliably and non-speculatively predicts activities by Hetero in this district.

24. Exercising personal jurisdiction over Hetero in this district would not be unreasonable given Hetero's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

25. This Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Defendants, either directly or through affiliates, currently sell significant quantities of generic drug products in the United States and in the State of Delaware. The website https://heteroworld.com describes "a portfolio of more than 200 marketed products and 150 ANDAs filed across major therapeutic areas" and "boast(s) of a global marketplace" including as a "large scale exporter of therapeutic drugs to . . . America." *See* https://heteroworld.com/pages/business-generics/ and https://heteroworld.com/pages/products-overview/, the contents of which are incorporated herein by reference. Upon information and belief, Defendants derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within the State of Delaware.

26. Defendants Hetero USA and Hetero Labs have availed themselves of Delaware courts through the assertion of counterclaims.

27. Upon information and belief, Hetero operates as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district.

28. Upon information and belief, the effort to seek approval for ANDA No. 210500 and to manufacture, import, market, and/or sell Defendants' generic products upon approval has been a cooperative and joint enterprise and venture between Hetero USA, HLL Unit-III and Hetero Labs.

29. Upon information and belief, Hetero USA, HLL Unit-III and Hetero Labs have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing,

filing and maintaining ANDA No. 210500 and in commercializing Defendants' generic products in the United States, including in this judicial district, in accordance with ANDA 210500 upon approval.

30. Upon information and belief, Hetero USA, HLL Unit-III and Hetero Labs have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 210500.

31. This Court also has personal jurisdiction over Hetero because at least one provision of 10 Del. C. § 3104(c) is satisfied. On information and belief, Hetero satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

32. Hetero "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, the District of Delaware and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 2017 WL 69716 (U.S. Jan. 9, 2017). Hetero's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. On information and belief, Hetero "intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them." *Id.* at 758. On information and

belief, Hetero will engage in marketing of its proposed ANDA product in Delaware upon approval of its ANDA.

33. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendants.

FIRST COUNT FOR PATENT INFRINGEMENT ('376 PATENT)

34. Biogen realleges, and incorporates in full herein, each preceding paragraph.

35. The U.S. Patent and Trademark Office ("PTO") issued the '376 patent on January 21, 2003, entitled "Utilization of Dialkyfumarates." The '376 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '376 patent is attached hereto as Exhibit A.

36. Biogen International GmbH is the owner of the '376 patent by virtue of assignment.

37. The '376 patent expires on October 29, 2019, excluding any pediatric exclusivity or patent term extension.

38. The '376 patent is directed to and claims, *inter alia*, pharmaceutical preparations and compositions.

39. The '376 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 204063 for dimethyl fumarate delayed-release capsules.

40. The FDA approved NDA No. 204063 on March 27, 2013, for the treatment of relapsing forms of multiple sclerosis.

41. Dimethyl fumarate delayed-release capsules are marketed in the United States under the trademark Tecfidera®.

42. Upon information and belief, Hetero submitted ANDA No. 210500 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell dimethyl fumarate delayed-release capsules containing 120 mg and 240 mg of dimethyl fumarate ("Defendants' generic products") in the United States.

43. Biogen received a letter from Hetero dated June 1, 2017 ("the Notice Letter"), purporting to include a Notice of Certification for ANDA No. 210500 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '376 patent. The Notice Letter alleged non-infringement of all claims of the '376 patent, but Hetero has not yet provided materials supporting this allegation.

44. Hetero thus has actual knowledge of the '376 patent.

45. Upon information and belief, Defendants' generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '376 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed at least one claim including at least claim 1 of the '376 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210500 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '376 patent. Upon information and belief, the products described in ANDA No. 210500 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '376 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Hetero will manufacture, market, import, use, sell and/or offer to sell Defendant's generic products in the United States in connection with ANDA No. 210500 upon approval.

48. Upon information and belief, Hetero will directly infringe at least one claim including at least claim 1 of the '376 patent when they proceed to manufacture, market, import, use, sell and/or offer to sell Defendants' generic products in the United States in connection with ANDA No. 210500 upon approval.

49. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 210500 complained of herein were done by and for the benefit of Hetero.

50. If Hetero's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '376 patent and all other relevant activities are not enjoined, Biogen will suffer substantial and irreparable harm for which there is no adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT ('999 PATENT)

51. Biogen realleges, and incorporates in full herein, each preceding paragraph.

52. The PTO issued the '999 patent on January 22, 2008, entitled "Dimethyl Fumarate for the Treatment of Multiple Sclerosis." The '999 patent identifies Rajendra Kumar Joshi and Hans-Peter Strebel as inventors of the claimed subject matter. A copy of the '999 patent is attached hereto as Exhibit B.

53. Biogen International GmbH is the owner of the '999 patent by virtue of assignment.

54. The '999 patent expires on May 18, 2020, which includes 202 days of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity or patent term extension.

55. The ’999 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

56. The ’999 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

57. The Notice Letter dated June 1, 2017 purported to include a Notice of Certification for ANDA No. 210500 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the ’999 patent. The Notice Letter did not allege non-infringement as to at least one claim of the ’999 patent.

58. Hetero thus has actual knowledge of the ’999 patent.

59. Upon information and belief, Defendants’ generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’999 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

60. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed at least one claim including at least claim 1 of the ’999 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 210500 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’999 patent. Upon information and belief, the products described in ANDA No. 210500 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the ’999 patent under 35 U.S.C. § 271(e)(2)(A).

61. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the ’999 patent by the use of Defendants’ generic products upon approval.

62. Upon information and belief, upon approval, Hetero will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 1 of the '999 patent, for the pecuniary benefit of Hetero. Pursuant to 21 C.F.R. § 314.94, Hetero is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Hetero will thus induce infringement of at least one claim including at least claim 1 of the '999 patent.

63. On information and belief, if the FDA approves ANDA No. 210500, Hetero will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim including at least claim 1 of the '999 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein Hetero knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Hetero in practicing at least one claim including at least claim 1 of the '999 patent, and wherein dimethyl fumarate delayed-release capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Hetero will thus contribute to the infringement of at least one claim including at least claim 1 of the '999 patent.

64. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 210500 complained of herein were done by and for the benefit of Hetero.

65. If Hetero's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '999 patent and all other relevant activities are not enjoined, Biogen will suffer substantial and irreparable harm for which there is no adequate remedy at law.

THIRD COUNT FOR PATENT INFRINGEMENT ('514 PATENT)

66. Biogen realleges, and incorporates in full herein, each preceding paragraph.

67. The PTO issued the '514 patent on March 19, 2013, entitled "Treatment for Multiple Sclerosis." The '514 patent identifies Matvey E. Lukashev and Gilmore O'Neill as inventors of the claimed subject matter. A copy of the '514 patent is attached hereto as Exhibit C.

68. Biogen MA Inc. is the owner of the '514 patent by virtue of assignment.

69. The '514 patent expires on February 7, 2028, excluding any pediatric exclusivity.

70. The '514 patent is directed to and claims, *inter alia*, methods of treating multiple sclerosis.

71. The '514 patent is listed in the Orange Book for NDA No. 204063 for dimethyl fumarate delayed-release capsules.

72. The Notice Letter dated June 1, 2017 purported to include a Notice of Certification for ANDA No. 210500 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) as to the '514 patent. The Notice Letter did not allege non-infringement as to at least one claim of the '514 patent.

73. Hetero thus has actual knowledge of the '514 patent.

74. Upon information and belief, Defendants' generic products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '514 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

75. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed at least one claim including at least claim 1 of the '514 patent by submitting, or causing

to be submitted, to the FDA, ANDA No. 210500 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '514 patent. Upon information and belief, the products described in ANDA No. 210500 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '514 patent under 35 U.S.C. § 271(e)(2)(A).

76. Upon information and belief, physicians and/or patients will directly infringe at least one claim including at least claim 1 of the '514 patent by the use of Defendants' generic products upon approval.

77. Upon information and belief, upon approval, Hetero will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products will be used by physicians and/or patients, in a manner that infringes at least one claim including at least claim 1 of the '514 patent, for the pecuniary benefit of Hetero. Pursuant to 21 C.F.R. § 314.94, Hetero is required to copy the FDA approved Tecfidera® labeling. Upon information and belief, Hetero will thus induce the infringement of at least one claim including at least claim 1 of the '514 patent.

78. On information and belief, if the FDA approves ANDA No. 210500, Hetero will sell or offer to sell its generic products specifically labeled for use in practicing at least one claim including at least claim 1 of the '514 patent, wherein Defendants' generic products are a material part of the claimed invention, wherein Hetero knows that physicians will prescribe and patients will use Defendants' generic products in accordance with the instructions and/or label provided by Hetero in practicing at least one claim including at least claim 1 of the '514 patent, and wherein dimethyl fumarate delayed-release capsules are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Hetero will

thus contribute to the infringement of at least one claim including at least claim 1 of the '514 patent.

79. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 210500 complained of herein were done by and for the benefit of Hetero.

80. If Hetero's marketing and sale of generic dimethyl fumarate delayed-release capsules prior to expiration of the '514 patent and all other relevant activities are not enjoined, Biogen will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Biogen respectfully requests that the Court enter judgment in its favor and against Defendant Hetero on the patent infringement claims set forth above and respectfully requests that this Court:

1. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim including at least claim 1 of the '376 patent through Hetero's submission of ANDA No. 210500 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '376 patent;

2. enter judgment under 35 U.S.C. § 271(a) that Hetero's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the '376 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271 (a);

3. order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration date of the '376 patent, or such later date as the Court may determine;

4. enjoin Hetero, and all persons acting in concert with Hetero, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '376 patent, or such later date as the Court may determine;

5. enjoin Hetero, and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero's ANDA No. 210500 until the expiration of the '376 patent, or such later date as the Court may determine;

6. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim including at least claim 1 of the '999 patent through Hetero's submission of ANDA No. 210500 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '999 patent;

7. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Hetero's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' generic products prior to the expiration of the '999 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271 (b) and/or (c);

8. order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration date of the '999 patent, or such later date as the Court may determine;

9. enjoin Hetero, and all persons acting in concert with Hetero, from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '999 patent, or such later date as the Court may determine;

10. enjoin Hetero, and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero's ANDA No. 210500 until the expiration of the '999 patent, or such later date as the Court may determine;

11. enter judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim including at least claim 1 of the ’514 patent through Hetero’s submission of ANDA No. 210500 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants’ generic products in the United States before the expiration of the ’514 patent;

12. enter judgment under 35 U.S.C. § 271(b) and/or (c) that Hetero’s commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants’ generic products prior to the expiration of the ’514 patent constitutes infringement of one or more claims of said patent under 35 U.S.C. § 271 (b) and/or (c);

13. order that the effective date of any approval by the FDA of Defendants’ generic products be a date that is not earlier than the expiration date of the ’514 patent, or such later date as the Court may determine;

14. enjoin Hetero, and all persons acting in concert with Hetero, from the manufacture, use, import, offer for sale and sale of Defendants’ generic products until the expiration of the ’514 patent, or such later date as the Court may determine;

15. enjoin Hetero, and all persons acting in concert with Hetero, from seeking, obtaining or maintaining approval of Hetero’s ANDA No. 210500 until the expiration of the ’514 patent, or such later date as the Court may determine;

16. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Biogen costs, expenses and disbursements in this action, including reasonable attorney fees; and

17. award such further and other relief as this Court deems proper and just.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashby-geddes.com
amayo@ashby-geddes.com

Attorneys for Plaintiffs
Biogen International GmbH
and Biogen MA Inc.

Of Counsel:

James B. Monroe
Li Feng
Sanya Sukduang
Andrew E. Renison
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

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