IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS DEVELOPMENT, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	)	C.A. No._____

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Teva Pharmaceutical Industries Limited ("Teva Industries"), Teva Pharmaceuticals Development, Inc. ("Teva Development"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Defendants" or "Teva"). This action arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 215942 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of the 20 mg, 40 mg, and 60 mg strengths of CABOMETYX® (the "Teva ANDA Products") prior to the expiration of U.S. Patent Nos. 9,724,342, 10,039,757, and 10,034,873 (collectively, the "Asserted Patents").

PARTIES

2. Plaintiff Exelixis, Inc. ("Exelixis") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502. Exelixis is engaged in the business of creating, developing, and

bringing to market new medicines for difficult-to-treat cancers. Exelixis sells CABOMETYX® throughout the United States, including in Delaware.

3. Upon information and belief, Teva Industries is a corporation organized under the laws of Israel, with its principal place of business at 5 Bazel Street, Petah Tikva, 49551033 Israel. Upon information and belief, Teva Industries, itself and through its wholly-owned subsidiaries and agents, Teva Development and Teva USA, manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware.

4. Upon information and belief, Teva Development is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Upon information and belief, Teva Development is a wholly owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries. Upon information and belief, Teva Development manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of Teva Industries.

5. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, NJ 07054. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries. Upon information and belief, Teva USA manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of Teva Industries.

JURISDICTION AND VENUE

6. This case arises under the patent laws of the United States of America, 35 U.S.C.

§ 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Defendants because Defendants, among other things, have committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and each intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Exelixis, a Delaware corporation, in Delaware. For example, on information and belief, following approval of ANDA No. 215942, Defendants will make, use, import, sell, and/or offer for sale the Teva ANDA Products in the United States, including in Delaware, prior to the expiration of the Asserted Patents.

9. The Court also has personal jurisdiction over Defendants because, among other things, this action arises from Defendants' actions directed toward Delaware, and because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

10. Upon information and belief, Teva Industries directs the operations, management, and activities of Teva Development in the United States.

11. Upon information and belief, Teva Development and Teva Industries collaborate in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in Delaware.

12. Upon information and belief, Teva USA currently manufactures and distributes for sale hundreds of drug products throughout the United States, including in Delaware. Upon

information and belief, Teva USA maintains a website, www.tevagenerics.com, listing the drug products it manufactures, markets, and/or sells in the United States. On its website, Teva USA represents that it is "the largest generic pharmaceutical company in the country" and that "Teva Pharmaceuticals USA is a wholly owned subsidiary of Israeli-based Teva Pharmaceutical Industries, Ltd."

13. Upon information and belief, Teva Industries directs the operations, management, and activities of Teva USA in the United States.

14. Upon information and belief, Teva USA and Teva Industries collaborate in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in Delaware.

15. Teva Industries has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.).

16. Teva Development has previously availed itself of this forum by filing counterclaims in other actions pending before this Court, including *Biogen Inc. et al v. Teva Pharmaceuticals Development Inc.*, No. 21-389-LPS (D. Del.).

17. Teva USA has previously availed itself of this forum by affirmatively filing claims

and counterclaims in other actions pending before this Court, including *Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc. v. Torrent Pharmaceuticals Ltd. & Torrent Pharma Inc.*, No. 07-24-JJF (D. Del.); *Takeda Pharmaceutical Company Ltd., Tap Pharmaceutical Products Inc., & Ethypharm, S.A. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 07-331-SLR (D. Del); and *The Brigham & Women's Hospital, Inc., NPS Pharmaceuticals, Inc., & Amgen Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Barr Laboratories, Inc.*, No. 08-464-HB (D. Del.).

18. This Court has personal jurisdiction over Teva Industries by virtue of, among other things, its systematic and continuous contacts with Delaware.

19. On information and belief, Teva Industries' contacts with other states of the United States are no greater than its contacts with Delaware. Therefore, to the extent Teva Industries denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with Delaware, this Court has personal jurisdiction over Teva Industries pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

20. This Court has personal jurisdiction over Teva Development by virtue of, among other things, its systematic and continuous contacts with Delaware.

21. This Court has personal jurisdiction over Teva Development by virtue of, among other things, the fact that it is organized and exists under the laws of the State of Delaware.

22. This Court has personal jurisdiction over Teva USA by virtue of, among other things, its systematic and continuous contacts with Delaware.

23. This Court has personal jurisdiction over Teva USA by virtue of, among other things, that fact that it is organized and exists under the laws of the State of Delaware.

24. Venue is proper in this Court as to Teva Development under 28 U.S.C. § 1400(b)

because, upon information and belief, it is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

25. Venue is proper in this Court as to Teva USA under 28 U.S.C. § 1400(b) because, upon information and belief, it is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

26. Venue is proper in this Court as to Teva Industries under 28 U.S.C. § 1391(c)(3), because, upon information and belief, it is not a resident of the United States and may thus be sued in any judicial district.

BACKGROUND

27. U.S. Patent No. 9,724,342 (the "'342 Patent"), entitled "C-met Modulator Pharmaceutical Compositions," (Exhibit A hereto), was duly and legally issued on August 8, 2017. The '342 Patent will expire on July 9, 2033.

28. U.S. Patent No. 10,039,757 (the "'757 Patent"), entitled "C-met Modulator Pharmaceutical Compositions," (Exhibit B hereto), was duly and legally issued on August 8, 2017. The '757 Patent will expire on July 18, 2031.

29. U.S. Patent No. 10,034,873 (the "'873 Patent"), entitled "C-met Modulator Pharmaceutical Compositions," (Exhibit C hereto), was duly and legally issued on July 31, 2018. The '873 Patent will expire on July 18, 2031.

30. The claims of the '342, '757, and '873 Patents are valid, enforceable, and not expired. All rights and interests in the '342, '757, and '873 Patents are owned by and assigned to Exelixis.

31. CABOMETYX® (cabozantinib) is a tyrosine kinase inhibitor, for oral administration, approved by the FDA for the treatment of patients with advanced kidney cancer

(renal cell carcinoma) as a monotherapy and in combination with nivolumab. It is also approved to treat patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib. Exelixis sells CABOMETYX® in the United States pursuant to New Drug Application No. 208692, which was approved by the FDA in 2016.

32. CABOMETYX® is covered by, inter alia, at least claim 2 of the '342 Patent, at least claim 1 of the '757 Patent, and at least claim 1 of the '873 Patent. The Asserted Patents have been listed in connection with CABOMETYX® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "*Orange Book*."

33. By letter dated May 4, 2021 and received via Federal Express on May 5, 2021 (the "First Notice Letter"), Teva USA notified Exelixis that Teva USA had submitted ANDA No. 215942 to the FDA for Cabozantinib S-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

34. By letter dated May 17, 2021 and received via Federal Express on May 20, 2021 (the "Second Notice Letter") (collectively, "Teva's Notice Letters"), Teva Development represented to Exelixis that the First Notice Letter contained "[a] typographical error with regards to the name of the entity that submitted ANDA 215942." The Second Notice Letter notified Exelixis that Teva Development (not Teva USA) had submitted ANDA No. 215942 to the FDA for Cabozantinib S-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

35. Further to Offers of Confidential Access set forth in the Teva Notice Letters, the parties negotiated terms pursuant to which Teva would produce ANDA No. 215942 to Exelixis. Teva produced documents from ANDA No. 215942 to Exelixis' counsel on May 24, 2021.

36. By submitting ANDA No. 215942, Teva has necessarily represented to the FDA

that the Teva ANDA Products has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

37. In Teva's Notice Letters, Teva stated that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '342, '757, and '873 Patents and alleged that the Asserted Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Products.

38. Upon information and belief, Teva had knowledge of the Asserted Patents when ANDA No. 215942 was submitted to the FDA.

39. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products immediately and imminently upon approval of ANDA No. 215942.

40. This action is being commenced before the expiration of forty-five days from the date of Exelixis' receipt of the First Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF US PATENT NO. 9,724,342

41. Exelixis incorporates each of the preceding paragraphs 1 – 40 as if fully set forth herein.

42. Teva's submission of ANDA No. 215942 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products before the expiration of the '342 Patent constituted an act of infringement of at least claims 2, 5, and 6 of the '342 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

43. Teva's commercial manufacture, use, offer for sale, sale and/or importation of the

Teva ANDA Products prior to expiration of the '342 Patent, and Teva's inducement of and/or contribution to such conduct, would further infringe at least claims 2, 5, and 6 of the '342 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

44. Upon FDA approval of ANDA No. 215942, Teva will infringe at least claims 2, 5, and 6 of the '342 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Teva ANDA Products and/or by actively inducing and contributing to infringement of the '342 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Teva has notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products before the expiration of the '342 Patent.

45. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '342 Patent.

46. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Teva's making, using, offering to sell, selling, and/or importing the Teva ANDA Products, inducement thereof or contribution thereto, will infringe the '342 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Upon information and belief, Teva acted, and upon FDA approval of ANDA No. 215942, will act, without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '342 Patent. This is an exceptional case.

48. Unless Teva is enjoined from directly or indirectly infringing the '342 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT II: INFRINGEMENT OF US PATENT NO. 10,039,757

49. Exelixis incorporates each of the preceding paragraphs 1 – 48 as if fully set forth herein.

50. Teva's submission of ANDA No. 215942 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products before the expiration of the '757 Patent constituted an act of infringement of at least claims 1, 4, 5, and 6 of the '757 Patent, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

51. Teva's commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Products prior to expiration of the '757 Patent, and Teva's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 4, 5, and 6 of the '757 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

52. Upon FDA approval of ANDA No. 215942, Teva will infringe at least claims 1, 4, 5, and 6 of the '757 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Teva ANDA Products and/or by actively inducing and contributing to infringement of the '757 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Teva has notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products before the expiration of the '757 Patent.

53. Upon information and belief, use of the Teva ANDA Products in accordance with and as directed by Teva's proposed labeling for that product would infringe at least claims 1, 4, 5, and 6 of the '757 Patent. Unless enjoined by this Court, upon FDA approval of ANDA

No. 215942, Teva will actively induce infringement of at least claims 1, 4, 5, and 6 of the '757 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Teva ANDA Products in the United States in a manner that would directly infringe the '757 Patent. Upon information and belief, upon FDA approval of ANDA No. 215942, Teva will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '757 Patent and with knowledge that its acts are encouraging infringement.

54. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '757 Patent.

55. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Teva's making, using, offering to sell, selling, and/or importing the Teva ANDA Products, inducement thereof or contribution thereto, will infringe the '757 Patent pursuant, either literally or under the doctrine of equivalents, to 35 U.S.C. §§ 271(a), (b), and/or (c).

56. Upon information and belief, Teva acted, and upon FDA approval of ANDA No. 215942, will act, without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '757 Patent. This is an exceptional case.

57. Unless Teva is enjoined from directly or indirectly infringing the '757 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

COUNT III: INFRINGEMENT OF US PATENT NO. 10,034,873

58. Exelixis incorporates each of the preceding paragraphs 1 – 57 as if fully set forth herein.

59. Teva's submission of ANDA No. 215942 to obtain approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of the Teva's ANDA Product before the expiration of the '873 Patent constituted an act of infringement of at least claims 1, 4, 5, and 6 of the '873 Patent, under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

60. Teva's commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Products prior to expiration of the '873 Patent, and Teva's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 4, 5, and 6 of the '873 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

61. Upon FDA approval of ANDA No. 215942, Teva will infringe at least claims 1, 4, 5, and 6 of the '873 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Teva ANDA Products and/or by actively inducing and contributing to infringement of the '873 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Teva has notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Products before the expiration of the '873 Patent.

62. Upon information and belief, use of the Teva ANDA Products in accordance with and as directed by Teva's proposed labeling for that product would infringe at least claims 1, 4, 5, and 6 of the '873 Patent. Unless enjoined by this Court, upon FDA approval of ANDA No. 213878, Teva will actively induce infringement of at least claims 1, 4, 5, and 6 of the '873 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Teva ANDA Products in the United States in a manner that would directly infringe the '873 patent. Upon information and belief, upon FDA

approval of ANDA No. 215942, Teva will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '873 Patent and with knowledge that its acts are encouraging infringement.

63. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '873 Patent.

64. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Teva's making, using, offering to sell, selling, and/or importing the Teva ANDA Products, inducement thereof or contribution thereto, will infringe the '873 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

65. Upon information and belief, Teva acted, and upon FDA approval of ANDA No. 215942, will act, without a reasonable basis for believing that it would not be liable for directly and indirectly infringing the '873 Patent. This is an exceptional case.

66. Unless Teva is enjoined from directly or indirectly infringing the '873 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Exelixis asks that this Court grant the following relief:

(a) A judgment that the claims of the Asserted Patents are not invalid, are not unenforceable, and were infringed by Teva's submission of ANDA No. 215942 under 35 U.S.C. § 271(e)(2)(A), and that Teva's manufacture, use, offer to sell, sale, or importation of the Teva ANDA Products, inducement thereof or contribution thereto, prior to the expiration of the Asserted Patents, will infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of

any FDA approval of Teva's ANDA No. 215942 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(c) A declaratory judgment that Teva's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Teva ANDA Products prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

(d) An Order permanently enjoining Teva, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Teva, from making, using, offering to sell, selling, or importing the Teva ANDA Products until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(e) Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Exelixis if Teva engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Teva ANDA Products prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Exelixis is or becomes entitled;

(f) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
araucci@morrisnichols.com

Attorneys for Plaintiff Exelixis, Inc.

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Kevin Prussia
Timothy A. Cook
Stephanie T. Neely
Katherine P. Kieckhafer
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Kevin J. O'Brien
WILMER CUTLER PICKERING
HALE AND DORR LLP
2600 El Camino Real, Suite 400
Palo Alto, CA 94306
(650) 858-6000

Benjamin I. Dach
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Gerard A. Salvatore
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
(202) 663-6000

Cristina Salcedo
WILMER CUTLER PICKERING
HALE AND DORR LLP
350 South Grand Avenue, Suite 2400
Los Angeles, CA 90071 USA
(213) 443 5412

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