IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

PFIZER INC., PHARMACIA & UPJOHN COMPANY, PHARMACIA & UPJOHN COMPANY LLC, SUGEN, INC., and C.P. PHARMACEUTICALS INTERNATIONAL C.V.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
MYLAN INC., and MYLAN PHARMACEUTICALS INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company, Pharmacia & Upjohn Company LLC, Sugen, Inc., and C.P. Pharmaceuticals International C.V. (collectively "Pfizer"), for their Complaint, allege as follows:

1. This is an action for infringement of U.S. Patent Nos. 6,573,293 ("the '293 patent"), 7,125,905 ("the '905 patent"), and 7,211,600 ("the '600 patent"). This action arises out of the submission by defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan") of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's breakthrough cancer treatment product, SUTENT®, prior to the expiration of the '293, '905, and '600 patents.

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Pharmacia & Upjohn Company was a Delaware corporation that was converted into a Delaware limited liability company and changed its name to Pharmacia & Upjohn Company LLC on August 14, 2004. Pharmacia & Upjohn Company LLC has offices located at 7000 Portage Road, Kalamazoo, Michigan 49001.

4. Plaintiff Sugen, Inc. is a corporation organized under the laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff C.P. Pharmaceuticals International C.V. ("CPPI CV") is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 24280998. CPPI CV is a wholly owned subsidiary of Pfizer Inc. and has a place of business at 235 East 42nd Street, New York, New York 10017.

6. On information and belief, Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. has a place of business at White Birch Tower II, 5th Floor, 1311 Pineview Drive, Morgantown, West Virginia 26505 and/or at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

7. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of West Virginia, and has a place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

JURISDICTION AND VENUE

8. Jurisdiction is proper in this judicial district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

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

10. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposefully availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products in this judicial district, which are sold in this judicial district, with the authorization, participation, or assistance of, or in concert with, Mylan Pharmaceuticals.

11. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products in this judicial district, which are sold in this judicial district, with the authorization, participation, or assistance of, or in concert with, Mylan Inc.

12. On information and belief, both Mylan Inc. and Mylan Pharmaceuticals are subject to personal jurisdiction in this judicial district because they each maintain and conduct ongoing business out of offices in this judicial district. On information and belief, Mylan Inc. and/or Mylan Pharmaceuticals maintains a headquarters in West Virginia and manufacturing operations in West Virginia. Mylan Inc. and Mylan Pharmaceuticals Inc. are also registered to do business in West Virginia and have appointed registered agents in West Virginia for service of process.

13. According to Mylan Inc.'s Web site, "Mylan is one of the world's leading generics and specialty pharmaceutical companies, providing products to customers in more than 140 countries and territories," and is "[t]he second largest generic pharmaceutical company in the U.S. by sales volume." According to its website, "Mylan Pharmaceuticals has one of the largest product portfolios in the U.S., consisting of more than 200 products. According to IMS Health, one of every 12 prescriptions dispensed in the U.S. is a Mylan product."

14. On information and belief, Mylan Inc. and/or Mylan Pharmaceuticals regularly do business in West Virginia and have engaged in a persistent course of conduct within West Virginia by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including West Virginia, and/or by directly selling pharmaceutical products in West Virginia. Mylan Inc. and Mylan Pharmaceuticals have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

15. On information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan Inc. includes within its Annual Report the activities of Mylan Pharmaceuticals, including the revenue earned. The Mylan Web site, appearing at www.mylan.com, provides information about both Mylan Inc. and Mylan Pharmaceuticals. Mylan Inc. is divided into a number of business units, including the "Generics" business. On information and belief, Mylan Pharmaceuticals in whole or in part comprises this "Generics" business, particularly within the United States.

16. On information and belief, Mylan Inc. and Mylan Pharmaceuticals have overlapping officers and directors, with management and operation of Mylan Pharmaceuticals and the Generics business occurring, at least in part, at the respective headquarters of both Mylan Inc. and Mylan Pharmaceuticals. On information and belief, Mylan Inc. issues press releases

when generic drugs are approved by FDA or when other events concerning the commercialization of a generic drug occur involving its Generics business.

17. On information and belief, Mylan Inc. and Mylan Pharmaceuticals conduct business throughout the United States, including West Virginia, under the trade name "Mylan Pharmaceuticals."

18. On information and belief, Mylan Inc. and/or Mylan Pharmaceuticals manufactures in the United States and sells more than 14 billion tablets and capsules per year, including, on information and belief, tablets and capsules that are manufactured and sold in West Virginia.

19. On information and belief, Mylan Pharmaceuticals' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia.

20. On information and belief, Mylan Inc. and/or Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are developed, manufactured, sold, used and/or consumed within West Virginia.

21. On information and belief, litigating patents covering FDA-approved branded drug products is a central feature of Mylan Inc. and Mylan Pharmaceuticals' business model. According to a May 25, 2010 press release, "Mylan has 142 ANDAs pending FDA approval representing $95.6 billion in annual brand sales" and "[t]hirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $19.6 billion in annual brand sales." On information and belief, the "first-to-file" opportunities referred to in Mylan's press release are Paragraph IV challenges to brand pharmaceutical company patents, such as the one in this case. Indeed, Mylan's February 26, 2010 Form 10-K states that "we expect to achieve growth in our

U.S. business by launching new products for which we may attain U.S. Food and Drug Administration first-to-file status with Paragraph IV certification."

22. On information and belief, Mylan Inc. and Mylan Pharmaceuticals regularly consent to jurisdiction in this District.

BACKGROUND

23. SUTENT® is a pharmaceutical agent used for the treatment of cancer. SUTENT® is FDA-approved and is indicated for the treatment of gastrointestinal stromal tumor (after prior therapy) and for the treatment of advanced renal cell carcinoma.

24. Pfizer Inc. and CPPI CV sell SUTENT® in the United States in various dosage strengths, including 12.5 mg, 25 mg, 37.5 mg and 50 mg, pursuant to New Drug Application (NDA) Nos. 021-938 and 021-968 approved by the FDA.

25. SUTENT® has annual sales of about $1 billion, with substantial U.S. sales attributed to the treatment of gastrointestinal stromal tumor. The treatment of gastrointestinal stromal tumor is a substantial use of SUTENT®.

26. According Mylan's most recent Form 10-K, dated February 26, 2010, Mylan Inc. and Mylan Pharmaceuticals "concentrate [their] generic product development activities on branded products with significant sales in specialized or growing markets or in areas that offer significant opportunities and other competitive advantages."

27. On information and belief, Mylan develops generic drugs, files ANDAs, and challenges patents referencing those branded drugs with significant, or the potential for significant, total sales, regardless whether the sales result, in whole or in part, from a use of the drug that may not be an approved "indication" if the drug were to be sold by Mylan pursuant to an ANDA. On information and belief, Mylan's business strategy for its Generic business is to capture the entire brand market, including each and every use to which a brand drug like

SUTENT® is put. On information and belief, Mylan's pricing and distribution strategy for generic drugs sold as part of its Generic business is oriented to capture the entire brand market, including each and every use to which a brand drug like SUTENT® is put.

28. The '293 patent, entitled "Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors" (Exhibit A hereto), was duly and legally issued on June 3, 2003 to Sugen, Inc. and Pharmacia & Upjohn Company, as assignees. CPPI CV is exclusive licensee of the '293 patent.

29. The '905 patent, also entitled "Pyrrole Substituted 2-Indolinone Protein Kinase Inhibitors" (Exhibit B hereto), was duly and legally issued on October 24, 2006 to Sugen, Inc. and Pharmacia & Upjohn Co., as assignees.

30. The '600 patent, entitled "Methods of Modulating C-KIT Tyrosine Protein Kinase Function With Indolinone Compounds" (Exhibit C hereto), was duly and legally issued on May 1, 2007 to Sugen, Inc., as assignee.

31. SUTENT® and the use thereof are covered by one or more claims of the '293 patent, the '905 patent, and the '600 patent, which have been listed in connection with SUTENT® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."

32. Pfizer has all right, title, and interest in the '293 patent, the '905 patent, and the '600 patent, including the right to sue for infringement thereof.

33. By letter dated May 6, 2010 (the "Notice Letter"), Mylan notified Pfizer Inc., CPPI CV, Sugen Inc., Agouron Pharmaceuticals, Inc. and Pharmacia & Upjohn Company, that Mylan Pharmaceuticals had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 201275, for Mylan's Sunitinib Malate Capsules, 12.5 mg, 25 mg, 37.5 mg and 50 mg, a generic version of SUTENT® ("Mylan's ANDA Product"). The purpose of the ANDA

was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '293 patent, the '905 patent, and the '600 patent.

34. In the Notice Letter, Mylan also stated that, as part of its ANDA, it had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. 355(j)(2)(A)(vii)(VI) ("Paragraph IV certification") asserting that no valid claim of the '293 patent, the '905 patent, or the '600 patent will be infringed by the manufacture, use, sale or importation of Mylan's ANDA Product. The letter was signed by "Steven H. Flynn, Esq., Vice President & Associate General Counsel – Global IP" of "Mylan Inc.," on information and belief, on behalf of both Mylan Inc. and Mylan Pharmaceuticals.

35. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,573,293

36. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 35 hereof, as if more fully set forth herein.

37. Mylan's ANDA Product and certain uses thereof are covered by one or more claims of the '293 patent.

38. Mylan had knowledge of the '293 patent when it submitted ANDA No. 201275.

39. The Notice Letter does not provide any contention that or explanation why the claims of the '293 patent are not infringed by Mylan's ANDA Product, as would be required by 21 C.F.R. § 314.95(c)(6)(i) if Mylan contended that the claims were not infringed.

40. Mylan's submission of ANDA No. 201275 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA

Product before expiration of the ’293 patent was an act of infringement of the ’293 patent under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan’s ANDA Product would infringe one or more claims of the ’293 patent.

42. Upon information and belief, the use of Mylan’s ANDA Product as described in and/or directed by Mylan’s proposed labeling, ANDA, and other corporate documents for that product would infringe one or more claims of the ’293 patent. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the ’293 patent when its ANDA is approved.

43. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’293 patent, and that Mylan’s ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

44. The foregoing actions by Mylan constitute and/or will constitute infringement of the ’293 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the ’293 patent under 35 U.S.C. § 271(b), and/or contributing to the infringement by others of the ’293 patent under 35 U.S.C. § 271(c).

45. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Mylan on the other regarding Mylan’s infringement of the ’293 patent, active inducement of infringement of the ’293 patent, and/or contributing to the infringement by others of the ’293 patent.

46. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringement of the ’293 patent, for actively inducing infringement of the ’293 patent, and for contributing to the infringement by others of the ’293 patent.

47. Unless Mylan Inc. and Mylan Pharmaceuticals are enjoined from infringement of the ’293 patent, from actively inducing infringement of the ’293 patent, and from contributing to the infringement by others of the ’293 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 7,125,905

48. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 47 hereof, as if more fully set forth herein.

49. Mylan’s ANDA Product is covered by one or more claims of the ’905 patent.

50. Mylan had knowledge of the ’905 patent when it submitted ANDA No. 201275.

51. The Notice Letter does not provide any contention that or explanation why the claims of the ’905 patent are not infringed by Mylan’s ANDA Product, as would be required by 21 C.F.R. § 314.95(c)(6)(i) if Mylan contended that the claims were not infringed.

52. Mylan’s submission of ANDA No. 201275 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan’s ANDA Product before expiration of the ’905 patent was an act of infringement of the ’905 patent under 35 U.S.C. § 271(e)(2)(A).

53. The commercial manufacture, use, offer for sale, sale, and/or importation of Mylan’s ANDA Product would infringe one or more claims of the ’905 patent.

54. Upon information and belief, the use of Mylan's ANDA Product would infringe one or more claims of the '905 patent. Upon information and belief, Mylan plans and intends to, and will, actively induce infringement of the '905 patent when its ANDA is approved.

55. Upon information and belief, Mylan knows that its ANDA Product is especially made or adapted for use in infringing the '905 patent, and that Mylan's ANDA Product is not suitable for substantial noninfringing use.

56. The foregoing actions by Mylan constitute and/or will constitute infringement of the '905 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the '905 patent under 35 U.S.C. § 271(b), and/or contributing to the infringement by others of the '905 patent under 35 U.S.C. § 271(c).

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Mylan on the other regarding Mylan's infringement of the '905 patent, active inducement of infringement of the '905 patent, and/or contributing to the infringement by others of the '905 patent.

58. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringement of the '905 patent, for actively inducing infringement of the '905 patent, and for contributing to the infringement by others of the '905 patent.

59. Unless Mylan Inc. and Mylan Pharmaceuticals are enjoined from infringement of the '905 patent, from actively inducing infringement of the '905 patent, and from contributing to the infringement by others of the '905 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 7,125,600

60. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 59 hereof, as if more fully set forth herein.

61. Certain uses of Mylan's ANDA Product are covered by one or more claims of the '600 patent.

62. Mylan had knowledge of the '600 patent when it submitted ANDA No. 201275.

63. Mylan's submission of ANDA No. 201275 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product before expiration of the '600 patent was an act of infringement of the '600 patent under 35 U.S.C. § 271(e)(2)(A).

64. The use of Mylan's ANDA Product to treat gastrointestinal stromal tumor would infringe one or more claims of the '600 patent.

65. Mylan's Notice Letter does not provide any contention that or explanation why claims of the '600 patent are not infringed other than the assertion that its proposed labeling does not contain an "indication" to treat gastrointestinal stromal tumors. Mylan is silent with respect other parts of its label that, on information and belief, will describe, encourage, suggest, teach, and/or induce the use of Mylan's ANDA Product to treat gastrointestinal stromal tumors.

66. Upon information and belief, the use of Mylan's ANDA Product as described in and/or directed by Mylan's proposed labeling, ANDA, and other corporate documents for that product would infringe one or more claims of the '600 patent. Upon information and belief, the use of Mylan's ANDA Product as described in and/or directed by Mylan's proposed labeling, ANDA, and other corporate documents for that product will describe, encourage, suggest, teach, and/or induce the product's use, including its use to treat gastrointestinal stromal tumor.

Although Mylan asserts that its labeling "will not include any indications related to the treatment of gastrointestinal stromal tumors," on information and belief, other parts of Mylan's labeling will describe, encourage, suggest, teach, and/or induce the product's use to treat gastrointestinal stromal tumors.

67. On information and belief, Mylan developed its ANDA Product and submitted ANDA No. 201275 with knowledge of the significant sales of SUTENT® within the United States and with knowledge that those sales resulted, in part, from a significant use of the drug to treat gastrointestinal stromal tumor. On information and belief, Mylan's strategy for its generic version of SUTENT®, as evidenced, on information and belief, by its proposed labeling, ANDA, and corporate documents, is to capture the entire SUTENT® brand market, including each and every use for SUTENT®. On information and belief, Mylan knows and intends that its ANDA Product will be used to treat gastrointestinal stromal tumor. On information and belief, Mylan's pricing and distribution strategy for its generic version of SUTENT® will be oriented to capture the entire SUTENT® brand market, including those end-users using SUTENT® to treat gastrointestinal stromal tumor.

68. Upon information and belief, Mylan knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '600 patent, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

69. The foregoing actions by Mylan constitute and/or will constitute infringement of the '600 patent under 35 U.S.C. § 271(e)(2) and 35 U.S.C. § 271(a), active inducement of infringement of the '600 patent under 35 U.S.C. § 271(b), and contributing to the infringement by others of the '600 patent under 35 U.S.C. § 271(c).

70. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on the one hand and Mylan on the other regarding Mylan's infringement of the '600 patent, active inducement of infringement of the '600 patent, and contributing to the infringement by others of the '600 patent.

71. Upon information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringement of the '600 patent, for actively inducing infringement of the '600 patent and for contributing to the infringement by others of the '600 patent.

72. Unless Mylan Inc. and Mylan Pharmaceuticals are enjoined from infringement of the '600 patent, from actively inducing infringement of the '600 patent, from contributing to the infringement by others of the '600 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Mylan Inc. and Mylan Pharmaceuticals have infringed the '293 patent, the '905 patent, and the '600 patent, will actively induce infringement of the '293 patent, the '905 patent, and the '600 patent, and will contribute to the infringement by others of the '293 patent, the '905 patent, and the '600 patent.

(b) A judgment ordering that the effective date of any FDA approval for Mylan Inc. and Mylan Pharmaceuticals to commercially make, use, offer to sell, sell, or import into the United States Mylan's ANDA Product, be not earlier than the latest of the expiration dates of the '293 patent, the '905 patent, and/or the '600 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Mylan Inc. and Mylan Pharmaceuticals, and all persons acting in concert with Mylan Inc. and Mylan Pharmaceuticals, from infringing, actively inducing the infringement of, or contributing to the infringement by others of the ’293 patent, the ’905 patent, and the ’600 patent through the making, using, selling, offering for sale, or importing into the United States of Mylan’s ANDA Product, or any product or compound that infringes the ’293 patent, the ’905 patent, and the ’600 patent, prior to the latest of the expiration dates of the ’293 patent, the ’905 patent, and/or the ’600 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, or importing into the United States of Mylan’s ANDA Product, or any product or compound that infringes the ’293 patent, the ’905 patent, or the ’600 patent, prior to the expiration date of the respective patent, will infringe, actively induce infringement of, and will contribute to the infringement by others of the ’293 patent, the ’905 patent, and/or the ’600 patent;

(e) A declaration that this in an exceptional case and an award of attorneys’ fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

PFIZER INC.,
PHARMACIA & UPJOHN COMPANY,
PHARMACIA & UPJOHN COMPANY LLC,
SUGEN, INC., and
C.P. PHARMACEUTICALS INTERNATIONAL C.V.,
Plaintiffs

By: /s/ James F. Companion
Of Counsel

James F. Companion (WV Bar #790)
E-mail: jfc@schraderlaw.com
John Porco (WV Bar # 6946)
E-mail: jp@schraderlaw.com
SCHRADER BRYD & COMPANION, PLLC
The Maxwell Centre
32-20th Street, Suite 500
Wheeling, WV 26003
Telephone: (304) 233-3390
Facsimile: (304) 233-2769

Gerson A. Zweifach
(subject to admission *pro hac vice*)
Thomas H.L. Selby
(subject to admission *pro hac vice*)
Stanley E. Fisher
(subject to admission *pro hac vice*)
Sarah F. Teich
(subject to admission *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W
Washington, D.C. 20005
Telephone: (202) 434-5000
Fascimile: (202) 434-5029

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