

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,
Plaintiffs,

vs.

ACTAVIS SOUTH ATLANTIC LLC,
AUROBINDO PHARMA LTD.,
AUROBINDO PHARMA USA INC.,
MYLAN PHARMACEUTICALS INC., PAR
PHARMACEUTICAL, INC., RANBAXY
INC., RANBAXY LABORATORIES
LIMITED, SUN PHARMACEUTICAL
INDUSTRIES, INC., SUN
PHARMACEUTICAL INDUSTRIES LTD,
TEVA PHARMACEUTICALS USA, INC.,
TORRENT PHARMA INC. and TORRENT
PHARMACEUTICALS LIMITED,
Defendants.

C.A. No. _____

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (“sanofi-aventis U.S.”), for their Complaint against Defendants Actavis South Atlantic LLC (“Actavis”), Aurobindo Pharma Ltd. (“Aurobindo Ltd.”), Aurobindo Pharma USA Inc. (“Aurobindo Inc.”), Mylan Pharmaceuticals Inc. (“Mylan”), Par Pharmaceutical, Inc. (“Par”), Ranbaxy Inc., Ranbaxy Laboratories Limited (“Ranbaxy Ltd.”), Sun Pharmaceutical Industries, Inc. (“Sun Inc.”), Sun Pharmaceutical Industries Ltd. (“Sun Ltd.”), Teva Pharmaceuticals USA, Inc. (“Teva”), Torrent Pharma Inc. (“Torrent Inc.”) and Torrent Pharmaceuticals Ltd. (“Torrent Ltd.”), hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Actavis is a Delaware limited liability company having a place of business at 13800 NW 2nd Street, Ste-190, Fort Lauderdale, Florida 33325.

4. Upon information and belief, Defendant Aurobindo Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

5. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Aurobindo Inc.

6. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, Defendant Par is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

8. Upon information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Ltd., having a place of business at 600 College Road East, Princeton, New Jersey 08540.

9. Upon information and belief, Defendant Ranbaxy Ltd. is an Indian corporation having a place of business at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Upon information and belief, Defendant Ranbaxy Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Ranbaxy Inc.

10. Upon information and belief, Defendant Sun Inc. was a Michigan corporation, and the wholly-owned subsidiary and agent of Defendant Sun Ltd., having a place of business at 29714 Orion CT, Farmington Hills, Michigan 48334 at the time it submitted its Abbreviated New Drug Application. Upon information and belief, Sun Inc. dissolved as a corporation on or about July 15, 2007. Upon information and belief, Defendant Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

11. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., itself and through its wholly-owned subsidiary and agent Defendant Sun Inc., manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Teva is a Delaware corporation having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

13. Upon information and belief, Defendant Torrent Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Torrent Ltd., having a place of business at 3585 Bellflower Drive, Portage, Michigan 49024.

14. Upon information and belief, Defendant Torrent Ltd. is an Indian company having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India. Upon information and belief, Defendant Torrent Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Torrent Inc.

Nature of the Action

15. This is a civil action for the infringement of United States Patent No. 4,661,491 (“the ‘491 patent”) (Exhibit A) and United States Patent No. 6,149,940 (“the ‘940 patent”) (Exhibit B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

18. This Court has personal jurisdiction over Defendant Actavis by virtue of the fact that, *inter alia*, Actavis is a Delaware limited liability company.

19. This Court has personal jurisdiction over Defendant Aurobindo Inc. by virtue of the fact that, *inter alia*, Aurobindo Inc. is a Delaware corporation.

20. This Court has personal jurisdiction over Defendant Aurobindo Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Aurobindo Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Aurobindo Inc.

21. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

22. This Court has personal jurisdiction over Defendant Par by virtue of the fact that, *inter alia*, Par is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Ranbaxy Inc. by virtue of the fact that, *inter alia*, Ranbaxy Inc. is a Delaware corporation.

24. This Court has personal jurisdiction over Defendant Ranbaxy Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy Inc.

25. This Court has personal jurisdiction over Defendant Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

26. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Sun Inc.

27. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

28. This Court has personal jurisdiction over Defendant Torrent Inc. by virtue of the fact that, *inter alia*, Torrent Inc. is a Delaware corporation.

29. This Court has personal jurisdiction over Defendant Torrent Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Torrent Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Torrent Inc.

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

The Patents

31. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral[®] brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral[®] in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral[®].

32. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral[®].

Acts Giving Rise to this Action

Count I – Infringement of the ‘491 Patent by Defendants Actavis and Par

33. Upon information and belief, Actavis submitted Abbreviated New Drug Application (“ANDA”) 79-055 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis’ Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the ‘491 patent.

34. Actavis alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the ‘491 patent are invalid. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

35. Actavis’ submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Actavis’ commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis’ Uroxatral® brand product would infringe the ‘491 patent.

36. Par is jointly and severally liable for Actavis’ infringement of the ‘491 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis’ submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

37. Par’s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the ‘491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Par’s

commercial manufacture, use, offer for sale or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

38. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '491 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

39. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement of the '940 Patent by Defendants Actavis and Par

40. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

41. Actavis has alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

42. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

43. Par is jointly and severally liable for Actavis' infringement of the '940 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or

induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

44. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Par's commercial manufacture, use, offer for sale or sale of its proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

45. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '940 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

46. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count III – Infringement of the '491 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

47. Upon information and belief, Aurobindo Ltd., through its subsidiary and agent Aurobindo Inc., submitted ANDA 79-060 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

48. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

49. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

50. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '491 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

51. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

52. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

53. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count IV – Infringement of the ‘940 Patent by Defendants
Aurobindo Ltd. and Aurobindo Inc.**

54. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

55. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

56. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

57. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '940 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

58. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the

FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

59. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

60. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count V – Infringement of the '491 Patent by Defendant Mylan

61. Upon information and belief, Mylan submitted ANDA 79-014 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

62. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

63. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.

§ 271(e)(2)(A). Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

64. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '491 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

65. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VI – Infringement of the '940 Patent by Defendant Mylan

66. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

67. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

68. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Mylan has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-014. However, given Mylan's claim of bioequivalence contained within ANDA 79-014, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation

or discovery that will demonstrate that Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

69. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '940 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

70. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**Count VII – Infringement of the '940 Patent by Defendants
Ranbaxy Ltd. and Ranbaxy Inc.**

71. Upon information and belief, Ranbaxy Ltd., through its subsidiary and agent Ranbaxy Inc., submitted ANDA 79-006 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-006 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

72. Ranbaxy Ltd. alleged in ANDA 79-006 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-006 on or about August 14, 2007.

73. Ranbaxy Ltd.'s submission of ANDA 79-006 to the FDA, through Ranbaxy Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the

'940 patent under 35 U.S.C. § 271(e)(2)(A). Ranbaxy Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

74. Ranbaxy Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted and/or induced Ranbaxy Ltd.'s submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

75. Ranbaxy Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Ranbaxy Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

76. This is an exceptional case under 35 U.S.C. § 285 because Ranbaxy Ltd. and Ranbaxy Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-006 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

77. Plaintiffs will be irreparably harmed by Defendant Ranbaxy Ltd.'s and Defendant Ranbaxy Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VIII – Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.

78. Upon information and belief, Sun Inc. acting as a subsidiary and agent of Sun Ltd., submitted ANDA 79-057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 79-057 seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of

alfuzosin hydrochloride per tablet. ANDA 79-057 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

79. Sun Inc. alleged in ANDA 79-057 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-057 on or about September 6, 2007.

80. Sun Inc.'s submission of ANDA 79-057 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Inc. has provided no information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-057. However, given Sun Inc.'s claim of bioequivalence contained within ANDA 79-057, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Sun Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

81. Sun Ltd. is jointly and severally liable for Sun Inc.'s infringement of the '940 patent. Upon information and belief, Sun Ltd. participated in, contributed to, aided, abetted and/or induced Sun Inc.'s submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

82. Sun Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Ltd.'s

commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

83. This is an exceptional case under 35 U.S.C. § 285 because Sun Inc. and Sun Ltd. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-057 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

84. Plaintiffs will be irreparably harmed by Defendant Sun Inc.'s and Defendant Sun Ltd.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IX – Infringement of the '491 Patent by Defendant Teva

85. Upon information and belief, Teva submitted ANDA 79-056 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

86. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

87. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C.

§ 271(e)(2)(A). Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

88. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '491 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

89. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count X – Infringement of the '940 Patent by Defendant Teva

90. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

91. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

92. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Teva has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-056. However, given Teva's claim of bioequivalence contained within ANDA 79-056, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or

discovery that will demonstrate that Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

93. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '940 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

94. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XI – Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.

95. Upon information and belief, Torrent Ltd., through its subsidiary and agent Torrent Inc., submitted ANDA 79-054 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

96. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

97. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its

proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

98. Torrent Inc. is jointly and severally liable for any infringement of the '491 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced Torrent Ltd.'s submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

99. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

100. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

101. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count XII – Infringement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.

102. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

103. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid and not

infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

104. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

105. Torrent Inc. is jointly and severally liable for Torrent Ltd.'s infringement of the '940 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

106. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

107. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

108. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Inc. and Torrent Ltd. have infringed the '491 patent;

B. That all Defendants have infringed the '940 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDAs identified in this Complaint shall not be earlier than the expiration dates of the '491 patent and '940 patent, including any extensions;

D. That Defendants Actavis, Aurobindo Ltd., Aurobindo Inc., Mylan, Par, Teva, Torrent Ltd. and Torrent Inc., their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

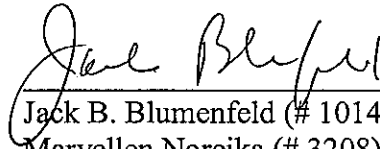
E. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic versions of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '940 patent, prior to the expiration of the '940 patent, including any extensions;

F. That this case is exceptional under 35 U.S.C. § 285;

G. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

H. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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