

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

BRISTOL-MYERS SQUIBB COMPANY,	)	
NOVARTIS CORPORATION and NOVARTIS	)	
PHARMA AG,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Bristol-Myers Squibb Company (“BMS”), Novartis Corporation, and Novartis Pharma AG (collectively “Novartis”), by their attorneys, hereby allege as follows:

**Nature of the Action**

1. This is an action for patent infringement of United States Patent Nos. 5,849,911 (“the ’911 patent”) and 6,087,383 (“the ’383 patent”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 91-673 filed by Teva Pharmaceuticals USA, Inc. (“Teva USA”) with the United States Food and Drug Administration (“FDA”) for approval to market a generic version of BMS’ Reyataz<sup>®</sup> drug product. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*

**Parties**

2. BMS is a Delaware corporation having its corporate headquarters at 345 Park Avenue, New York, New York.

3. BMS is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail in their fight against serious disease.

4. Novartis Corporation is a New York corporation having a principal place of business at 608 5th Avenue, New York, New York. Novartis Corporation regularly engages in business in this judicial district.

5. Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. Novartis is engaged in the business of creating, developing, and bringing to market innovative pharmaceutical products to prevent and cure diseases, to ease suffering, and to enhance patients' quality of life.

7. Upon information and belief, Teva USA is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania.

8. Upon information and belief, Teva USA is engaged in the business of manufacturing and marketing generic pharmaceuticals and is responsible for submission of ANDA No. 91-673.

#### **Jurisdiction and Venue**

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Teva USA by virtue of, *inter alia*, its incorporation in Delaware.

11. Venue is proper in this judicial district pursuant to, *inter alia*, 28 U.S.C. §§ 1391(b) and 1400(b).

**BMS' Reyataz<sup>®</sup> Product and Related Patents**

12. On December 15, 1998, the '911 patent, titled "Antivirally Active Heterocyclic Azahexane Derivatives," was duly and legally issued to Alexander Fässler, Guido Bold, Hans-Georg Capraro, Marc Lang, and Satish Chandra Khanna. Novartis is the owner of the '911 patent.

13. The '911 patent is valid and enforceable.

14. BMS has a worldwide exclusive license to the '911 patent.

15. A true and correct copy of the '911 patent is attached as Exhibit A.

16. The expiration date of the '911 patent is June 20, 2017.

17. On July 11, 2000, the '383 patent, titled "Bisulfate Salt of HIV Protease Inhibitor," was duly and legally issued to Janak Singh, Madhusudhan Pudipeddi, and Mark D. Lindrud. BMS is the owner of the '383 patent.

18. The '383 patent is valid and enforceable.

19. A true and correct copy of the '383 patent is attached as Exhibit B.

20. The expiration date of the '383 patent is December 21, 2018.

21. BMS is the holder of New Drug Application ("NDA") No. 21-567, by which the FDA granted approval for atazanavir sulfate capsules (Eq. 100 mg base, Eq. 150 mg base, Eq. 200 mg base, and Eq. 300 mg base), which are marketed and sold by BMS in the United States under the trade name Reyataz<sup>®</sup>. Reyataz<sup>®</sup> contains atazanavir bisulfate.

22. The Food and Drug Administration Center for Drug Equivalence Evaluations (the “Orange Book”) lists the ’911 and ’383 patents for each of the strengths of Reyataz<sup>®</sup> approved by the FDA under NDA No. 21-567.

**Teva USA’s ANDA Filing and Notice Letter**

23. Upon information and belief, Teva USA filed in the FDA ANDA No. 91-673, including a certification with respect to the ’911 and ’383 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, or sale of Atazanavir Sulfate Capsules, Eq. 300 mg base (the “Teva USA ANDA Product”) – a generic version of the FDA-approved Reyataz<sup>®</sup> capsule, Eq. 300 mg base – before the expiration date of the ’911 and ’383 patents.

24. Upon information and belief, the Teva USA ANDA Product contains atazanavir bisulfate.

25. Upon information and belief, the Teva USA ANDA Product will be manufactured by Teva USA.

26. Upon information and belief, Teva USA intends to – directly or indirectly – manufacture, use, market, sell, offer for sale, and distribute the product that is the subject of ANDA No. 91-673, including within this district, upon regulatory approval.

27. By letter dated October 19, 2009 (“Teva USA Notice Letter”), Teva USA notified BMS and Novartis Corporation that it had filed an ANDA for the Teva USA ANDA Product, including the certification with respect to the ’911 and ’383 patents, and that it sought approval of its ANDA prior to the expiration date of the ’911 and ’383 patents.

28. BMS received the Teva USA Notice Letter no earlier than October 20, 2009.

29. Novartis Corporation received the Teva USA Notice Letter no earlier than October 20, 2009.

30. This action is being commenced before the expiration of forty-five days from the date BMS and Novartis Corporation received the Teva USA Notice Letter.

**Count I**

**(Infringement of United States Patent No. 5,849,911)**

31. BMS and Novartis incorporate the preceding paragraphs as if fully set forth herein.

32. Teva USA's submission of the Teva USA ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva USA ANDA Product prior to the expiration of the '911 patent constitutes infringement of at least claims 1-3, 5, and 9-11 of the '911 patent under 35 U.S.C. § 271(e)(2)(A).

33. Teva USA actively and knowingly submitted, caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA 91-673 and the § 505(j)(2)(A)(vii)(IV) certification to the FDA.

34. Teva USA's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 91-673 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of at least claims 1-3, 5, and 9-11 of the '911 patent under 35 U.S.C. § 271(e)(2)(A).

35. Teva USA's commercial manufacture, use, offer to sell, sale, or importation of the Teva USA ANDA Product prior to the expiration of the '911 patent, and its inducement of and/or contribution to such conduct, would further infringe at least claims 1-3, 5, and 9-11 of the '911 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Teva USA's filing of the Teva USA

ANDA, its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Teva USA ANDA Product, and its intention to induce and/or contribute to such conduct upon receiving FDA approval create an actual case or controversy with respect to infringement of the '911 patent.

36. Upon FDA approval of the Teva USA ANDA, Teva USA will infringe at least claims 1-3, 5, and 9-11 of the '911 patent by making, using, offering to sell, selling, or importing the Teva USA ANDA Product, in the United States, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.

37. BMS and Novartis will be irreparably harmed if Teva USA's infringement is not enjoined. BMS and Novartis do not have an adequate remedy at law.

**Count 2**

**(Infringement of United States Patent No. 6,087,383)**

38. BMS incorporates the preceding paragraphs as if fully set forth herein.

39. Teva USA's submission of the Teva USA ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva USA ANDA Product prior to the expiration of the '383 patent constitutes infringement of claims 1 and 2 of the '383 patent under 35 U.S.C. § 271(e)(2)(A).

40. Teva USA actively and knowingly submitted, caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA 91-673 and the § 505(j)(2)(A)(vii)(IV) certification to the FDA.

41. Teva USA's active and knowing participation in, contribution to, aiding, abetting, and/or inducement of the submission to the FDA of ANDA No. 91-673 and the §

505(j)(2)(A)(vii)(IV) certification constitutes infringement of claims 1 and 2 of the '383 patent under 35 U.S.C. § 271(e)(2)(A).

42. Teva USA's commercial manufacture, use, offer to sell, sale, or importation of the Teva USA ANDA Product prior to the expiration of the '383 patent, and its inducement of and/or contribution to such conduct, would further infringe claims 1 and 2 of the '383 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Teva USA's filing of the Teva USA ANDA, its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Teva USA ANDA Product, and its intention to induce and/or contribute to such conduct upon receiving FDA approval create an actual case or controversy with respect to infringement of the '383 patent.

43. Upon FDA approval of the Teva USA ANDA, Teva USA will infringe claims 1 and 2 of the '383 patent by making, using, offering to sell, selling, or importing the Teva USA ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.

44. BMS will be irreparably harmed if Teva USA's infringement is not enjoined. BMS does not have an adequate remedy at law.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

- A. A declaration that the '911 and '383 patents are valid and enforceable;
- B. A declaration that Teva USA has infringed a claim or claims of the '911 and '383 patents by submitting the aforesaid ANDA and certification, and that Teva USA's making, using, offering to sell, selling, or importing the Teva USA ANDA Product and its inducement of and/or contribution to such conduct by others, will infringe the '911 and '383 patents;
- C. An Order providing that the effective date of any approval of the Teva USA ANDA shall be a date which is not earlier than the expiration of both the '911

and '383 patents and all exclusivities to which Plaintiffs are or become entitled;

- D. An Order permanently enjoining Teva USA and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell, selling, or importing the Teva USA ANDA Product and from inducing or contributing to such conduct by others, until after expiration of both the '911 and '383 patents and all exclusivities to which Plaintiffs are or become entitled;
- E. Damages or other monetary relief to BMS and Novartis if Teva USA engages in the commercial manufacture, use, offer to sell, sale, or importation of the Teva USA ANDA Product, or inducing or contributing to such conduct by others, prior to expiration of the '911 and '383 patent and all exclusivities to which Plaintiffs are or become entitled, and that any such damages or monetary relief be awarded to BMS and Novartis with prejudgment interest; and,
- F. Such further and other relief as this Court deems proper and just, including, but not limited to, reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by BMS and Novartis in this action.

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