IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. _____

SANDOZ INC.

Plaintiff,

v.

PFIZER, INC.,
PFIZER IRELAND PHARMACEUTICALS,
C.P. PHARMACEUTICALS INTERNATIONAL C.V.,
WARNER-LAMBERT COMPANY and
WARNER-LAMBERT COMPANY LLC,

Defendants.

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**SANDOZ INC.'S COMPLAINT FOR DECLARATORY RELIEF (JURY TRIAL DEMANDED)**

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Sandoz Inc. ("Sandoz"), for its Complaint against Pfizer, Inc.; Pfizer Ireland Pharmaceuticals; C.P. Pharmaceuticals International C.V.; Warner-Lambert Company; and Warner-Lambert Company LLC (collectively "Pfizer"), alleges as follows:

## PARTIES

1. Sandoz is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz's Broomfield, Colorado, manufacturing facility spans 600,000 square feet and has an oral-dosage capacity of 10 billion units, making it the largest such manufacturing facility in the world.

2. Upon information and belief Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New

York, New York 10017.

3. Upon information and belief, Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

4. Upon information and belief, C.P. Pharmaceuticals International C.V. 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.

5. Upon information and belief Warner-Lambert Company has been a wholly owned subsidiary of Pfizer Inc. since June 2000. Warner-Lambert Company was converted to a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. It has offices at 235 East 42nd Street, New York, New York 10017.

## JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

## FACTUAL BACKGROUND

9. On October 3, 2000, the United States Patent and Trademark Office issued United States Patent No. 6,126,971 (the "'971 patent"), entitled "Stable Oral CI-981 Formulation and Process for Preparing Same," to Nancy Mills *et al.* According to the information on the face of the patent, it was assigned to Warner-Lambert Company. A copy of the '971 patent is attached hereto as Exhibit A.

10. On October 19, 1999 the United States Patent and Trademark Office issued United States Patent No. 5,969,156 (the "'156 patent"), entitled Crystalline [r- (R*,R*)]-2-(4-DFluorophenyl)-β,δ-Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Corbonyl]-1H-Pyrrole-1Heptanoic Acid Hemi Calcium Salt (Atorvastatin)," to Christopher A Briggs *et al.* According to the information on the face of the patent, it was assigned to Warner-Lambert Company. A copy of the '156 patent is attached hereto as Exhibit B.

11. On November 11, 1997 the United States Patent and Trademark Office issued United States Patent No. 5,686,104 (the "'104 patent"), entitled "Stable Oral CI-981 Formulation and Process of Preparing Same," to Nancy Mills *et al.* According to the information on the face of the patent, it was assigned to Warner-Lambert Company. A copy of the '104 patent is attached hereto as Exhibit C.

12. Upon information and belief, Warner-Lambert Company has been the owner of the '104, '156 and '971 patents since their issuance.

13. Upon information and belief, Pfizer Ireland Pharmaceuticals is the exclusive licensee of at least the '156 patent.

14. Upon information and belief Pfizer has all the right, title, and interest in the '104,

’156, and ’971 patents and the right to sue for infringement thereof.

15. Upon information and belief C.P. Pharmaceuticals International C.V. is the owner of approved New Drug Application (“NDA”) No. 21-540 for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including 5mg/80mg and 10mg/80mg compositions. Pfizer sells drug products under NDA 21-540 in the United States, including in this District, under the registered name Caduet®.

16. Pfizer has listed or caused to be listed in the Food and Drug Administration’s (“FDA’s”) *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation* (the “Orange Book”) the ’104, ’156, and ’971 patents and, among others, United States Patent No. 6,455,574 (the “’574 patent”), for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including dosage combinations comprising 5mg/80mg and 10mg/80mg of the active ingredients.

17. By listing, or causing to be listed, the ’574, ’104, ’156, and ’971 patents in the Orange Book Pfizer claims that formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including dosage combinations comprising 5mg/80mg and 10mg/80mg, infringe one or more claims of the ’574, ’104, ’156, and ’971 patents.

18. Sandoz submitted Abbreviated New Drug Application No. 91-462 (the “Sandoz ANDA”) to the FDA seeking approval to manufacture and market amlodipine besylate and atorvastatin calcium tablets, 5mg/80mg and 10mg/80mg compositions, (the “Sandoz ANDA Products”).

19. The Sandoz ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV certification”) stating that the ’574, ’104, ’156 and ’971

patents are either invalid or would not be infringed by the Sandoz ANDA Products.

20. On August 24, 2009, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Sandoz sent a Confidential Notice Letter (the "Sandoz Notice Letter") to Pfizer informing Pfizer of the filing of the Sandoz ANDA and explaining the basis of Sandoz's Paragraph IV certifications. The Sandoz Notice Letter included an Offer of Confidential Access to relevant sections of the Sandoz ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

21. By October 7, 2009, Pfizer filed actions in the District of Delaware and the District of Colorado asserting that the filing of the Sandoz ANDA was an act of infringement of the '574 patent.

22. To date Pfizer has not filed any action alleging that the filing of the Sandoz ANDA infringes any claim of the '104, '156 or '971 patents.

23. More than 45 days have elapsed since Sandoz provided notice of the filing of the Sandoz ANDA to Pfizer.

24. Sandoz intends to market the Sandoz ANDA Products in the United States as soon as legally permissible after approval of the 91-462 ANDA in light of potential third party exclusivity rights.

25. Pfizer's filing of actions in Delaware and Colorado asserting infringement of the '574 patent demonstrates Pfizer's intent to enforce its patent rights against Sandoz.

26. Upon information and belief, Pfizer is holding the '104, '156 and '971 patents patent in reserve in order to file future patent infringement suits and further delay Sandoz's entry into the United States market for products containing amlodipine besylate and atorvastatin calcium. This is contrary to the intent of the Hatch-Waxman Act, which encourages the

resolution of all patent disputes by the timely filing of patent litigation by NDA holders against ANDA applicants.

27. Based on Pfizer's ongoing litigation against Sandoz regarding the '574 patent, its representations to the FDA and the public regarding the scope of coverage of the '104, '156 and '971 patents, Pfizer's failure to bring suit against Sandoz to resolve the questions of validity and infringement regarding the '104, '156 and '971 patents, and Sandoz's intent to launch the Sandoz ANDA Products as soon as legally permissible, an actual and justiciable controversy exists between Pfizer and Sandoz regarding validity and infringement of the '104, '156 and '971 patents. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1316 (2009).

## FIRST CLAIM FOR RELIEF
**(Declaratory Judgment of Invalidity of the '104 Patent)**

28. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 27 of this Complaint.

29. The '104 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

30. There exists an actual controversy between Sandoz and Pfizer regarding the validity of the '104 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

## SECOND CLAIM FOR RELIEF
**(Declaratory Judgment of Noninfringement of the '104 Patent)**

31. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 30 of this Complaint.

32. Sandoz and the Sandoz ANDA Products do not infringe any valid enforceable claim of the '104 patent, directly or indirectly, either literally or under the doctrine of equivalents.

33. There exists an actual controversy between Sandoz and Pfizer regarding whether Sandoz infringes the '104 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

## THIRD CLAIM FOR RELIEF
**(Declaratory Judgment of Invalidity of the '156 Patent)**

34. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 33 of this Complaint.

35. The '156 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

36. There exists an actual controversy between Sandoz and Pfizer regarding the validity of the '156 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

**FOURTH CLAIM FOR RELIEF**
**(Declaratory Judgment of Noninfringement of the '156 patent)**

37. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 36 of this Complaint.

38. Sandoz and the Sandoz ANDA Products do not infringe any valid enforceable claim of the '156 patent, directly or indirectly, either literally or under the doctrine of equivalents.

39. There exists an actual controversy between Sandoz and Pfizer regarding whether Sandoz infringes the '156 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

**FIFTH CLAIM FOR RELIEF**
**(Declaratory Judgment of Invalidity of the '971 Patent)**

40. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 39 of this Complaint.

41. The '971 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

42. There exists an actual controversy between Sandoz and Pfizer regarding the validity of the '971 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

## SIXTH CLAIM FOR RELIEF
**(Declaratory Judgment of Noninfringement of the '971 patent)**

43. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 42 of this Complaint.

44. Sandoz and the Sandoz ANDA Products do not infringe any valid enforceable claim of the '971 patent, directly or indirectly, either literally or under the doctrine of equivalents.

45. There exists an actual controversy between Sandoz and Pfizer regarding whether Sandoz infringes the '971 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

## DEMAND FOR JURY TRIAL

Sandoz demands a trial by jury of any and all issues triable as of right by a jury in this action.

## PRAYER FOR RELIEF

WHEREFORE, Sandoz asks the Court to enter judgment in its favor and grant the following relief:

1. Declare that Sandoz has not infringed and is not infringing any valid enforceable claim of the '104, '156 and '971 patent;

2. Declare every claim of the '104, '156 and '971 patents invalid;

3. Find this an exceptional case and award Sandoz its costs, attorneys' fees, and expenses pursuant to 35 U.S.C. § 285; and

4. Grant such other and further relief as the Court may deem just and proper.

Dated: October 16, 2009

Respectfully submitted,

s/ David C. Doyle

David C. Doyle (CA Bar No. 70690)
Brian M. Kramer (CA Bar No. 212107)
Morrison & Foerster LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
Telephone: (858) 720-5100
Facsimile: (858) 720-5125
Email: DDoyle@mofo.com
BMKramer@mofo.com

J. Eric Elliff (CO Bar No. 16844)
Morrison & Foerster LLP
5200 Republic Plaza
370 Seventeenth Street
Denver, Colorado 80202-5638
Telephone: (303) 592-1500
Facsimile: (303) 592-1510
E-mail: JEelliff@mofo.com

Attorneys for Plaintiff
Sandoz Inc.