IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ABBOTT LABORATORIES and ABBOTT RESPIRATORY LLC, | ) | |
| Plaintiffs, | ) | |
| | ) | C.A. No. _____ |
| v. | ) | |
| SANDOZ INC., | ) | |
| Defendant. | ) | |

**COMPLAINT**

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), for their Complaint against Defendant Sandoz Inc. ("Sandoz"), hereby allege as follows:

**NATURE OF THE ACTION**

This is an action for patent infringement of U.S. Patent Nos. 6,080,428 ("the '428 patent") and 6,469,035 ("the '035 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 201403 as filed by Sandoz with the U.S. Food and Drug Administration ("FDA") for approval to market 1000 mg, 750 mg and 500 mg niacin extended-release tablets that are generic versions of the 1000 mg, 750 mg and 500 mg strengths of Abbott's highly successful NIASPAN® drug product.

Abbott has filed several other patent infringement actions currently pending before this Court as described below:

- *Abbott Laboratories & Abbott Respiratory LLC v. Sandoz Inc.*, No. 10-538-SLR (D. Del.), which relates to ANDA No. 201403 filed by Sandoz for approval to market a

generic version of NIASPAN®, and involves the '428 patent and the '035 patent (along with U.S. Patent No. 6,818,229 (the "'229 patent"));

- *Abbott Laboratories & Abbott Respiratory LLC v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, No. 09-152-LPS (D. Del.), which relates to ANDA Nos. 90-4446, 90-860, and 90-892 filed by Lupin for approval to market generic versions of NIASPAN®, and involves the'428 patent, the '229 patent (and five other patents);
- Consolidated cases *Abbott Laboratories & Abbott Respiratory LLC v. Teva Pharmaceutical Industries, Ltd. & Teva Pharmaceuticals USA, Inc.*, Nos. 10-57-SLR-MPT, 10-302-SLR-MPT, 10-766-SLR (D. Del.), which relate to ANDA No. 200478 filed by Teva for approval to market generic versions of SIMCOR®, and *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, No. 10-373-SLR (D. Del.), which relates to ANDA No. 200601 filed by Watson for approval to market a generic version of SIMCOR®, both of which involves the '428 patent, the '229 patent, and the '035 patent (as well as the same five other patents at issue in the Lupin action;
- *Abbott Laboratories & Abbott Respiratory LLC v. Sun Pharmaceutical Industries Ltd. & Sun Pharma Global FZE*, Nos. 10-112-SLR-MPT, 10-488-SLR (D. Del.), which relate to ANDA Nos. 200484 and 201273 filed by Sun for approval to market generic versions of NIASPAN®, and involve the '428 patent and the '035 patent;
- *Abbott Laboratories & Abbott Respiratory LLC v. Mylan Inc. & Mylan Pharmaceuticals, Inc.*, No. 10-559-SLR (D. Del.), which relates to ANDA No. 201521 filed by Mylan for approval to market a generic version of SIMCOR®, and

involves the '428 patent, the 229 patent, and the '035 patent (as well as the same five other patents at issue in the Lupin action);

- *Abbott Laboratories & Abbott Respiratory LLC v. Impax Laboratories, Inc.*, No. 10-1029-SLR (D. Del.), which relates to ANDA No. 202149 filed by Impax for approval to market a generic version of NIASPAN®, and involves the '428 patent, the 229 patent, and the '035 patent (as well as the same five other patents at issue in the Lupin action).

## PARTIES

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. On information and belief, Sandoz is a corporation organized under the laws of the State of Colorado. Sandoz's corporate headquarters are located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

## JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

5. This Court has personal jurisdiction over Sandoz with respect to this Complaint because, *inter alia*: (1) Sandoz has committed, or aided, abetted, contributed to

and/or participated in the commission of, a tortious act of patent infringement in filing its ANDA that has led to foreseeable harm and injury to Abbott Respiratory, a Delaware corporation, and Abbott Laboratories, a corporation actively engaged in business in Delaware; (2) Sandoz has had and has systematic and continuous contacts with Delaware; (3) Sandoz has brought, by way of counterclaims in this district in C.A. No. 10-538-SLR, "an action for declaratory judgment of non-infringement and/or invalidity of one or more claims of" the '428, and '035 (and '229) patents (D.I. 7); and (4) upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 201403, Sandoz will sell its generic product throughout the United States.

**PATENTS IN SUIT**

6. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as Exhibit A. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

7. Abbott Respiratory is the owner by assignment of the '035 patent, entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid," which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the '035 patent is attached hereto as Exhibit B. The claims of the '035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '035

patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the ’035 patent.

8. Abbott Laboratories is the holder of New Drug Application (“NDA”) No. 20-0381 by which the FDA granted approval for 500 mg, 750 mg and 1,000 mg strength niacin extended-release tablets, which Abbott markets in the United States under the trade name “NIASPAN®”. The formulation, dosing, and method of administering NIASPAN® is covered by certain claims of the ’428 patent and the ’035 patent. The FDA’s official publication of approved drugs (the “Orange Book”) includes NIASPAN® together with the ’428 patent and the ’035 patent.

**INFRINGEMENT BY SANDOZ**

9. By letter dated January 3, 2011 (“the Notice Letter”), Sandoz notified Abbott that Sandoz had submitted “an amended Abbreviated New Drug Application (‘ANDA’) for Niacin Extended-Release Tablets, 1000 mg, 750 mg and 500 mg (‘the Sandoz Products’)” to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of generic niacin extended-release tablets before the expiration of the ’428 and ’035 patents. The letter states that the “FDA has assigned the Sandoz ANDA number 201403.” Upon information and belief, Sandoz intends to engage in commercial manufacture, use, and sale of generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

10. By filing an amended ANDA No. 201403, Sandoz has necessarily represented to the FDA that the components of its generic niacin extended-release tablets have the same active ingredients as those of the corresponding components of NIASPAN®, have the same route of administration, dosage form, and strengths as the corresponding components of NIASPAN®, and are bioequivalent to the corresponding components of NIASPAN®.

11. In the Notice Letter, Sandoz informed Abbott that its ANDA contains a Paragraph IV certification "which asserts that the claims of the ['428 and the '035] U.S. Patent(s) will not be infringed by the manufacture, use, importation, sale or offer for sale" of Sandoz's generic niacin extended-release tablets, and attached a "Detailed Statement of the factual and legal basis for Sandoz's opinion that the ['428 and the '035] Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the Sandoz Products."

12. This Complaint is being filed before the expiration of forty-five days from the date Abbott received the Notice Letter.

## COUNT I
## (INFRINGEMENT OF THE '428 PATENT)

13. Each of the preceding paragraphs 1 to 12 is incorporated as if fully set forth herein.

14. Upon information and belief, Sandoz's submission of ANDA No. 201403 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

15. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 201403, Sandoz will further infringe the '428 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

16. Upon information and belief, Sandoz had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 201403 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

17. If Sandoz's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

## COUNT II
### (INFRINGEMENT OF THE '035 PATENT)

18. Each of the preceding paragraphs 1 to 17 is incorporated as if fully set forth herein.

19. Upon information and belief, Sandoz's submission of ANDA No. 201403 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets prior to the expiration of the '035 patent constitutes infringement of one or more of the claims of the '035 patent under 35 U.S.C. § 271(e)(2)(A).

20. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 201403, Sandoz will further infringe the '035 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

21. Upon information and belief, Sandoz had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 201403 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

22. If Sandoz's infringement of the '035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

## PRAYER FOR RELIEF

WHEREFORE, Abbott prays that this Court grant the following relief:

a) A judgment that one or more claims of the '428 patent and the '035 patent are infringed by Sandoz's submission of ANDA No. 201403, and that Sandoz's making, using,

offering to sell, or selling in the United States, or importing into the United States, of generic niacin extended-release tablets will infringe the ’428 patent and the ’035 patent;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 201403 shall be a date which is not earlier than the latest expiration date of the ’428 patent or the ’035 patent, including any extensions or additional periods of exclusivity to which Abbott is or becomes entitled;

c) An order permanently enjoining Sandoz, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic niacin extended-release tablets until after the latest expiration date of the ’428 patent and the ’035 patent, including any extensions or additional periods of exclusivity to which Abbott is or becomes entitled;

d) Damages or other monetary relief to Abbott if Sandoz engages in commercial manufacture, use, offer to sell, sale, or importation in or into the United States of generic niacin extended-release tablets prior to the latest expiration date of the ’428 patent and the ’035 patent, including any extensions or additional periods of exclusivity to which Abbott is or becomes entitled.

e) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

Mary B. Graham (#2256)
Erich W. Struble (#5394)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
estruble@mnat.com
*Attorneys for Abbott Laboratories and Abbott Respiratory LLC*

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