



“License”), pursuant to the terms and conditions in the Settlement Agreement and License Agreement;

Shire currently markets in the United States pursuant to New Drug Application No. 22-037 an extended-release tablet containing guanfacine hydrochloride for the treatment of attention deficit hyperactivity disorder, all strengths of which Shire currently sells under the trade name Intuniv (the “Intuniv Product”);

Sandoz filed or caused to be filed Abbreviated New Drug Application (“ANDA”) No. 202568 (the “Sandoz ANDA”) containing a “paragraph IV certification” with respect to the Shire Patents and seeking FDA approval to sell, offer for sale, use and/or import into the United States a product under or described in the Sandoz ANDA (the “Sandoz Product”);

Sandoz acknowledges that all the claims in the Shire Patents are valid and enforceable with respect to Sandoz Product, and any other pharmaceutical product, which is submitted to the United States Federal Drug Administration for regulatory approval pursuant to an Abbreviated New Drug Application as a Therapeutic Equivalent (as defined in the current edition of the “Approved Drug Products with Therapeutic Equivalence Evaluations”) to the Intuniv Product (a “Generic Equivalent Intuniv Product”);

The Parties have agreed to terminate the pending litigation by the entry of this Judgment and Order; and

Plaintiffs and Sandoz now consent to this Judgment and Order.

**IT IS HEREBY ORDERED, ADJUDGED AND DECREED:**

1. This Court has jurisdiction over the parties and subject matter of this action.
2. Sandoz admits that the Shire Patents are valid and enforceable with respect to the Sandoz Product and any Generic Equivalent Intuniv Product.

3. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Sandoz in this action with respect to the Shire Patents are dismissed with prejudice.

4. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Sandoz or the Plaintiffs in this action with respect to the '290 Patent are dismissed with prejudice.

5. Except in the event the Shire Patents are asserted against Sandoz with respect to a product other than the Sandoz Product or any Generic Equivalent Intuniv Product in any other or future cause of action or litigation, Sandoz shall not dispute that the Shire Patents are valid and enforceable.

6. Sandoz admits that the sale, use or import of the Sandoz Product would constitute infringement of the Shire Patents in the absence of the License.

7. Sandoz is hereby also enjoined and estopped during the term of the Shire Patents from making any challenge as to the infringement of the Sandoz Product of the Shire Patents.

8. Neither this Judgment and Order nor the entry of this Judgment and Order may be asserted by Plaintiffs against Sandoz, and shall have no preclusive effect whatsoever, with respect to any product other than the Sandoz Product or any Generic Equivalent Intuniv Product.

9. The foregoing injunctions against Sandoz shall take effect immediately upon entry of this Judgment and Order by the Court, and shall continue generally until the expiration of the Shire Patents.

10. This Judgment and Order is binding upon and constitutes claim preclusion and issue preclusion with respect to validity and enforceability of the Shire Patents as against the Sandoz Product and shall have no preclusive effect whatsoever with respect to any product other

than the Sandoz Product or any Generic Equivalent Intuniv Product, and infringement by the Sandoz Product of the Shire Patents between the parties in this action or in any other action between the parties (except in the event the Shire Patents are asserted against Sandoz with respect to a product other than the Sandoz Product or any Generic Equivalent Intuniv Product).

11. Subject to paragraph 8 above, Sandoz hereby agrees not to aid, abet, assist, enable or participate with any third party in a challenge to the validity or enforceability of the Shire Patents or challenge the infringement by a Generic Equivalent Intuniv Product of any of the Shire Patents.

12. Except as authorized and licensed by Shire, Sandoz, its officers, agents, servants, employees, affiliates, successors and all persons in active concert or participation with Sandoz, are permanently enjoined from using, promoting, offering for sale, importing, selling, shipping, distributing or manufacturing in or to the United States and/or inducing others to use, promote, offer for sale, import, sell, ship, distribute or manufacture in the United States the Sandoz Product or any Generic Equivalent Intuniv Product.

13. The parties waive all right to appeal from this Judgment and Order.

14. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment and Order.

15. Each party is to bear its own costs and attorneys' fees.

DATED this 18th day of April, 2013.

BY THE COURT:



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R. Brooke Jackson  
United States District Judge

Respectfully submitted this 16th day of April, 2013.

*Attorneys for Plaintiffs*

*Attorneys for Defendant*

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