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WATSON PHARMACEUTICALS, INC., WATSON
26 LABORATORIES, INC.-FLORIDA, WATSON PHARMA,
INC., and ANDA, INC.
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1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF CALIFORNIA
3 SAN FRANCISCO DIVISION

4 SHIRE LLC, and SUPERNUS
5 PHARMACEUTICALS, INC.,

6 Plaintiffs,

7 v.

8 IMPAX LABORATORIES, INC., WATSON
9 PHARMACEUTICALS, INC., WATSON
10 LABORATORIES, INC.–FLORIDA,
11 WATSON PHARMA, INC., and ANDA, INC.,

12 Defendants.

Case No. 10-CV-05467-RS

**JUDGMENT AND ORDER OF
PERMANENT INJUNCTION**

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AND RELATED COUNTERCLAIMS.

This action for patent infringement having been brought by Plaintiffs Shire LLC (“Shire”) and Supernus Pharmaceuticals, Inc. (“Supernus” and collectively with Shire, the “Plaintiffs”) against Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.–Florida, Watson Pharma, Inc., and Anda, Inc. (collectively, “Defendants”) for infringement of United States Patent Nos. 6,287,599 and 6,811,794 (“the ’599 Patent” and “the ’794 Patent” respectively, and collectively the “Shire Patents”) and U.S. Patent No. 5,854,290 (“the ’290 Patent”);

Defendants and Plaintiffs have entered into a Settlement Agreement (the “Settlement Agreement”) and Shire and Defendants have entered into a License Agreement (the “License Agreement”), under which Shire has granted Defendants a license to the Shire Patents (the “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”);

1 Defendants filed or caused to be filed Abbreviated New Drug Application (“ANDA”) No.
2 202110 (the “Watson ANDA”) containing a “paragraph IV certification” with respect to the Shire
3 Patents and seeking FDA approval to sell, offer for sale, use and/or import into the United States
4 a product under or described in the Watson ANDA (the “Watson Product”);

5 Defendants acknowledge that all the claims in the Shire Patents are valid and enforceable
6 with respect to the Watson Product;

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

9 Plaintiffs and Defendants now consent to this Judgment and Order.

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

11 1. This Court has jurisdiction over the parties and subject matter of this action.

12 2. Defendants admit that the Shire Patents are valid and enforceable with respect to
13 the Watson Product.

14 3. All affirmative defenses, claims and counterclaims, which have been or could have
15 been raised by Defendants in this action with respect to the '290 Patent and the Shire Patents are
16 dismissed with prejudice.

17 4. Except in the event the Shire Patents are asserted against Defendants with respect
18 to a product other than the Watson Product in any other or future cause of action or litigation,
19 Defendants shall not dispute that the Shire Patents are valid and enforceable.

20 5. Defendants admit that the sale, use or import of the Watson Product would
21 constitute infringement of the Shire Patents in the absence of the License.

22 6. Defendants are hereby also enjoined and estopped during the term of the Shire
23 Patents from making any challenge as to the infringement by the Watson Product of the Shire
24 Patents.

25 7. Neither this Judgment and Order nor the entry of this Judgment and Order may be
26 asserted by Plaintiffs against Defendants, and shall have no preclusive effect whatsoever, with
27 respect to any product other than the Watson Product.

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1 8. The foregoing injunctions against Defendants shall take effect immediately upon
2 entry of this Judgment and Order by the Court, and shall continue generally until the expiration of
3 the Shire Patents.

4 9. This Judgment and Order is binding upon and constitutes claim preclusion and
5 issue preclusion with respect to validity and enforceability of the Shire Patents (except in the
6 event the Shire Patents are asserted against Defendants with respect to a product other than the
7 Watson Product), and infringement by the Watson Product of the Shire Patents between the
8 parties in this action or in any other action between the parties (except in the event the Shire
9 Patents are asserted against Defendants with respect to a product other than the Watson Product).

10 10. Subject to paragraph 7 above, Defendants hereby agree not to aid, abet, assist,
11 enable or participate with any third party in a challenge to the validity or enforceability of the
12 Shire Patents or challenge the infringement by a the Watson Product of any of the Shire Patents.

13 11. Except as authorized and licensed by Shire, Defendants, its officers, agents,
14 servants, employees, affiliates, successors and all persons in active concert or participation with
15 Defendants, are permanently enjoined from using, promoting, offering for sale, importing, selling,
16 shipping, distributing or manufacturing in or to the United States and/or inducing others to use,
17 promote, offer for sale, import, sell, ship, distribute or manufacture in the United States the
18 Watson Product.

19 12. Nothing herein prohibits or is intended to prohibit Defendants from maintaining a
20 “Paragraph IV Certification” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (including as amended
21 or replaced) or pursuant to 21 C.F.R. § 314.94(a)(12) (including as amended or replaced) with
22 respect to the Shire Patents or the ‘290 Patent.

23 13. Nothing herein restricts or is intended to restrict the U.S. Food and Drug
24 Administration from approving the Watson ANDA.

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

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

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

IT IS SO ORDERED this 29th day of April 2013.



THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

TROUTMAN SANDERS LLP

KASOWITZ, BENSON, TORRES &
FRIEDMAN LLP

By: /s/ Heather Morehouse Ettinger
Heather Morehouse Ettinger

By: /s/ Laura Fahey Fritts
Laura Fahey Fritts

Attorneys for Plaintiffs and Counter-
Defendants SHIRE LLC and SUPERNUS
PHARMACEUTICALS, INC.

Attorneys for Defendants and Counter-Plaintiffs
WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.–FLORIDA,
WATSON PHARMA, INC., and ANDA, INC.

SIGNATURE ATTESTATION

Pursuant to Civil L.R. 5-1, I hereby attest that concurrence in the filing of the foregoing document has been obtained from counsel for Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc.–Florida, Watson Pharma, Inc., and Anda, Inc. as indicated by a “conformed” signature (/s/).

/s/ Heather Morehouse Ettinger
Heather Morehouse Ettinger