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7 UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
8

9 WATSON LABORATORIES, INC., a
10 Nevada corporation,

11 Plaintiff,

12 v.

13 TEVA WOMEN’S HEALTH, INC.,
14 f/k/a DURAMED PHARMACEUTICALS,
INC.,

15 Defendant.

Case No. 3:10-cv-114

**COMPLAINT FOR DECLARATORY
JUDGMENT OF PATENT INVALIDITY
AND NON-INFRINGEMENT**

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17 Plaintiff Watson Laboratories, Inc. (“Watson”) by way of its Complaint alleges the
18 following against Defendant Teva Women’s Health, Inc. (“TWH”), formerly known as Duramed
19 Pharmaceuticals, Inc.:

20 **Jurisdiction and Venue**

21 1. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and
22 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

23 2. This Court has subject matter jurisdiction based upon 28 U.S.C. §§ 1331, 1338(a),
24 2201 and 2202.

25 3. On information and belief, TWH engages in business in Nevada and in this District,
26 and has thus purposefully availed itself of the privilege of doing business in the State of Nevada and
27 in this District, both generally and specifically, by marketing pharmaceutical products throughout
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1 the State of Nevada, including but not limited to its Seasonique[®] and LoSeasonique[®] products that it
2 alleges are respectively protected by United States Patent Nos. 7,320,969 (“the ‘969 patent”) and
3 7,615,545 B2 (“the ‘545 patent”) (attached hereto as Exhibit A) at issue herein. This Court also has
4 personal jurisdiction over TWH because TWH has waived any objections to personal jurisdiction by
5 filing suit in this District against Watson alleging infringement of the ‘969 patent, which is related
6 and nearly identical to the ‘545 patent, by Watson’s proposed generic version of Seasonique[®],
7 which is the same product at issue in this complaint.

8 4. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), and
9 1400(b).

10 **The Parties**

11 5. Watson is a corporation organized and existing under the laws of the State of
12 Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

13 6. On information and belief, TWH is a corporation organized and existing under the
14 laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road,
15 Woodcliff Lake, New Jersey 07677. On information and belief, TWH was formerly known as
16 Duramed Pharmaceuticals, Inc., making TWH the successor in interest to Duramed. Both entities
17 will hereinafter be referred to interchangeably as TWH.

18 **Statement of the Case**

19 7. This is a declaratory judgment action seeking a declaration of non-infringement
20 and/or invalidity of the ‘545 patent. The ‘545 patent, assigned to TWH, issued on November 10,
21 2009 from an application that is a continuation of U.S. Application No. 10/309,313 (“the ‘313
22 application”), which later issued on January 22, 2008 as the ‘969 patent.

23 8. After the ‘969 patent issued, TWH instructed the U.S. Food and Drug Administration
24 (“FDA”) to list the ‘969 patent in the Approved Drug Products with Therapeutic Equivalence
25 Evaluations (“Orange Book”) with respect to its oral contraceptive product Seasonique[®]. On March
26 6, 2008, TWH sued Watson in this district for the alleged infringement of the ‘969 patent with
27 respect to Watson’s Abbreviated New Drug Application (“ANDA”) seeking FDA approval to
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1 market a proposed generic version of the Seasonique[®] oral contraceptive product.

2 9. After the nearly identical '545 patent issued, TWH instructed the FDA to list this
3 patent in the Orange Book in connection with a different oral contraceptive LoSeasonique[®]. The
4 '545 patent is not listed in the Orange Book with respect to Seasonique[®], although the claims of the
5 '545 patent could encompass methods for preventing pregnancy by the administration of the
6 Seasonique[®] dosing regimen.

7 10. TWH is willing to assert the '545 patent against Watson as seen by its recent suit
8 against Watson in the District of New Jersey, alleging infringement of the '545 patent by Watson's
9 proposed generic version of LoSeasonique[®]. To date, TWH has not agreed to Watson's request that
10 it provide a covenant not to assert the '545 patent against Watson's proposed generic version of the
11 Seasonique[®] product, and has already announced that it intends to pursue all legal remedies to keep
12 any generic version of Seasonique[®] off of the market. Accordingly, a justiciable case or
13 controversy exists and Watson requires a declaratory judgment that the manufacture, use, sale, offer
14 of sale in and/or importation into the United States of Watson's proposed generic version of
15 Seasonique[®] would not infringe the claims of the '545 patent, or alternatively that the '545 patent is
16 invalid.

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18 **Teva Women's Health's Similar Extended Female Oral Contraceptive Products,**
19 **Seasonique[®] and LoSeasonique[®] and Watson's ANDA**

20 11. On information and belief, TWH is the current holder of a New Drug Application
21 ("NDA") for a female oral contraceptive product marketed as Seasonique[®]. A woman that is
22 prescribed Seasonique[®] takes a tablet containing ethinyl estradiol ("EE") and levonorgestrel for 84
23 days and then takes a tablet containing EE by itself (*i.e.*, without levonorgestrel) for 7 days. The
24 tablets taken during the 84-day period contain 30 micrograms (μg) of EE and 150 μg of
25 levonorgestrel. The tablets taken during the following 7-day period contain 10 μg of EE.
26 Seasonique[®] was granted FDA approval on May 25, 2006 and is indicated for the prevention of
27 pregnancy. This product is marketed throughout the United States.

28 12. On information and belief, TWH is the current holder of a NDA for a female

1 contraceptive product marketed by TWH as LoSeasonique[®]. This oral contraceptive product
2 consists of the same dosing regime as Seasonique[®], only with slightly lower strengths of the active
3 ingredients taken during the initial 84-day period in that each of these tablets consists of 20 µg of
4 EE and 100 µg of levonorgestrel, followed by the identical 7 days of 10 µg of EE. LoSeasonique[®]
5 was granted FDA approval on October 24, 2008 and is indicated for the prevention of pregnancy.
6 This product is marketed throughout the United States.

7
8 **Defendant's Earlier-Issued Related Patent, the '969 Patent, and**
9 **Defendant's Action Against Watson in this District**

10 13. Watson's ANDA seeking permission to market a proposed generic version of
11 Seasonique[®] includes a "Paragraph IV certification," pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV),
12 asserting that the '969 patent is invalid, unenforceable and/or would not be infringed by the
13 commercial manufacture, use or sale of Watson's proposed generic version of Seasonique[®].

14 14. On or about January 23, 2008, in accordance with 35 U.S.C. § 355(j)(2)(B), Watson
15 provided notice to TWH that its ANDA contains a Paragraph IV certification regarding the '969
16 patent. The notice provided the factual and legal bases for Watson's opinion that the '969 patent is
17 invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of Watson's
18 proposed generic version of Seasonique[®], the subject of ANDA No. 78-834. The notice was
19 accompanied by an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C).

20 15. TWH filed suit against Watson in this District on March 6, 2008, alleging
21 infringement of the '969 patent by Watson's ANDA seeking FDA approval to market a proposed
22 generic version of Seasonique[®], *Duramed Pharmaceuticals, Inc. v. Watson Laboratories*,
23 3:08cv01116 (LRH-RAM) ("Duramed litigation"). Fact and expert discovery in the Duramed
24 litigation ended on June 12, 2009, and TWH's summary judgment motion that the patent is not
25 invalid, filed on August 14, 2009, has been fully briefed, and is currently pending before the Court,
26 after which the case will be set for trial, pursuant to the case scheduling order.

**Defendant's '545 Patent Applies Equally
Against Watson's Proposed Generic Version of Seasonique®**

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16. On information and belief, TWH is the current assignee of the '545 Patent, entitled "Oral Contraceptives to Prevent Pregnancy and Diminish Premenstrual Symptomatology," which issued from a continuation application of the '969 patent. Both patents have identical abstracts and disclosures, the same inventors and title, and overlapping claims.

17. After the '545 patent issued on November 10, 2009, TWH instructed the FDA to list the '545 patent in the Orange Book in connection with its NDA for LoSeasonique®, since the claims of the '545 patent recite methods that could encompass preventing pregnancy by the administration of, *inter alia*, the LoSeasonique® dosage regimen.

18. The claims of the '545 patent could encompass methods for preventing pregnancy by the administration of the Seasonique® dosage regimen.

19. TWH could, therefore, assert the '545 patent against Watson's proposed generic version of Seasonique®.

20. In Barr's SEC 10-K filing dated February 29, 2008, TWH announced that it intends to "prevent Watson from marketing a competing [SEASONIQUE®] product." TWH has, in fact, already filed one such lawsuit against Watson (*i.e.*, the Duramed litigation) in an attempt to prevent the marketing of Watson's proposed generic version of the Seasonique® product. Barr's Chairman and Chief Executive Bruce L. Downey stated in a March 5, 2008 press release that Barr, "remain[s] committed to enforcing [its] patent on [its] Seasonique extended-cycle oral contraceptive product and will pursue *all legal means necessary* to prevent Watson from launching a generic product." (emphasis added). (Barr Subsidiary Sues Watson for SEASONIQUE® Patent Infringement, Mar. 5, 2008, available at <http://www2.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/03-05-2008/0004768202>).

The Presence of a Case or Controversy

21. TWH has demonstrated its intent to prevent generic competition to its Seasonique® product.

22. TWH filed suit against Watson in this District, asserting that Watson's proposed

1 generic version of the Seasonique[®] product that is the subject of ANDA No. 78-834 infringes the
2 related '969 patent.

3 23. TWH has shown its willingness to assert the '545 patent and has already sued
4 Watson in the District of New Jersey, asserting that Watson's proposed generic version of the
5 LoSeasonique[®] product infringes the '545 patent. Every claim of the '545 patent that could
6 possibly cover LoSeasonique[®] would also cover Seasonique[®].

7 24. TWH has never disavowed an intent to assert that Watson's proposed generic
8 version of Seasonique[®], the product that is the subject of ANDA No. 78-834, infringes the '545
9 patent. To the contrary, TWH has not, to date, agreed to Watson's request that it provide Watson
10 with a covenant not to assert the '545 patent against Watson's proposed generic version of the
11 Seasonique[®] product.

12 25. Because TWH has previously sued Watson on both related products and related
13 patents and because it has to this date not agreed to provide Watson with a covenant that it would
14 not assert the '545 patent, Watson has a reasonable apprehension that TWH will sue Watson for
15 infringement of the '545 patent with respect to Watson's proposed generic version of the
16 Seasonique[®] product.

17 26. To avoid legal uncertainty and to protect its substantial investment in its proposed
18 generic version of the Seasonique[®] oral contraceptive product, Watson has brought these claims for
19 declaratory judgment against the '545 patent. An actual justiciable controversy exists between the
20 parties as to the infringement and invalidity of the '545 patent.

21 **Count I**

22 **Declaratory Judgment of Invalidity of
United States Patent No. 7,615,545 B2**

23 27. Watson realleges and incorporates by reference the allegations of paragraphs 1-26.

24 28. The '545 patent is invalid for failure to meet one or more of the requirements of
25 patentability under 35 U.S.C. § 101, *et seq.*, including but not limited to 35 U.S.C. §§ 102 and 103.

26 29. The claims of the '545 patent are invalid because the alleged inventions claimed
27 therein are anticipated in view of the prior art to one having ordinary skill in the art and thus fail to
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1 satisfy the conditions for patentability set forth in 35 U.S.C. § 102.

2 30. The claims of the '545 patent are invalid because the alleged inventions claimed
3 therein are obvious in view of the prior art to one having ordinary skill in the art and thus fail to
4 satisfy the conditions for patentability set forth in 35 U.S.C. § 103.

5 31. Watson is entitled to a declaratory judgment that the claim of the '545 patent are
6 invalid.

7
8 **Count II**
9 **Declaratory Judgment of Non-Infringement of**
10 **United States Patent No. 7,615,545 B2**

11 32. Watson realleges and incorporates by reference the allegations of paragraphs 1-31.

12 33. A case or controversy exists between Watson and TWH concerning the non-
13 infringement of the '545 patent requiring a declaration of rights by this Court.

14 34. Watson's submission of its ANDA No. 78-834 for the purpose of obtaining approval
15 to market a generic version of Seasonique[®] did not and does not infringe any valid and enforceable
16 claim of the '545 patent under 35 U.S.C. § 271(e)(2), nor would the manufacture, use, sale, offer of
17 sale in and/or importation into the United States of Watson's proposed generic version of
18 Seasonique[®] that is the subject of ANDA No. 78-834 infringe any valid and enforceable claim of
19 the '545 patent.

20 35. Watson is entitled to a declaration that the manufacture, use, sale, offer of sale in
21 and/or importation into the United States of the product that is the subject of Watson's ANDA No.
22 78-834 would not infringe any valid and enforceable claims of the '545 patent.

23 **PRAYER FOR RELIEF**

24 WHEREFORE, Watson respectfully requests that this Court enter a Judgment and Order in
25 its favor against TWH:

- 26 1. Declaring that the claims of the '545 patent are invalid and/or unenforceable;
27 2. Declaring that no valid and enforceable claim of the '545 patent has been infringed;
28 3. Permanently enjoining TWH, its officers, agents, directors, servants, employees,

1 subsidiaries, and assigns, and all those acting under the authority of or in privity with them or with
2 any of them, from asserting or otherwise seeking to enforce the '545 patent against either Watson or
3 its proposed generic version of the Seasonique[®] product;

4 4. Declaring that this case is an exceptional case under 35 U.S.C. § 285 and awarding
5 Watson its attorney's fees, costs, and expenses; and

6 5. Awarding Watson any further additional relief as the Court may deem just, proper
7 and equitable.

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9 DATED: February 25, 2010

Respectfully submitted,

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