IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME B.V.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 13-2088-GMS
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

In this patent infringement action, plaintiff Merck Sharp & Dohme B.V. ("Merck") alleges that a pharmaceutical product proposed by defendants Warner Chilcott Company, LLC and Warner Chilcott (US), LLC (collectively "Warner Chilcott") infringe the asserted claims of U.S. Patent No. 5,989,581. (D.I. 1.) The court held a four-day bench trial in this matter on January 19 through January 22, 2016. Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patent-in-suit. (D.I. 140–141.)

Pursuant to Federal Rule of Civil Procedure 52(a), and having considered the entire record in this case and the applicable law, the court concludes that (1) the asserted claims of the '581 patent are not invalid as anticipated under 35 U.S.C. § 102(b); (2) the asserted claims of the '581 are invalid as obvious under 35 U.S.C. § 103; and (3) each of the parties' Rule 52(c) motions are granted in part and denied in part. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT[1]

A. The Parties

1. Plaintiff Merck Sharp & Dohme B.V. ("Merck") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. (D.I. 1.)

2. Plaintiff is a wholly owned subsidiary, through intervening affiliated companies, of Merck & Co., Inc., a Delaware corporation. (D.I. 1.)

3. Warner Chilcott Company LLC is a limited liability company organized and existing under the laws of Puerto Rico, having a place of business at Union Street, Road 195, Km 1.1, Fajardo, Puerto Rico 00738-1005. (D.I. 11.)

4. Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 100 Enterprise Drive, Suite 280, Rockaway, New Jersey 07866. (D.I. 11.)

5. Warner Chilcott Company LLC and Warner Chilcott (US) LLC are collectively referred to herein as "Warner Chilcott" or "Defendants."

6. The court has subject matter jurisdiction, as well as personal jurisdiction over all parties.

B. Background

7. Organon USA Inc., a company affiliated with the Plaintiff, holds an approved New Drug Application ("NDA") No. 21-187, under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ethinyl estradiol and etonogestrel vaginal ring, 0.015 mg/day and 0.12 mg/day, which is sold under the trade name NuvaRing. (D.I. 1.)

8. NuvaRing was approved by the FDA in October 2001 as a contraceptive and is indicated for the prevention of pregnancy.

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[1] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 110, Ex. A.) The court takes most of its findings of fact from the parties' uncontested facts. Where necessary, the court has overruled objections to the inclusion of these facts. The court has also reordered and renumbered some paragraphs, corrected some spelling and formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional.

The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in the Discussion and Conclusions of Law section of this opinion, preceded by the phrase "the court finds" or "the court concludes."

9. The Plaintiff and its corporate predecessors have been marketing and selling NuvaRing since 2002.

10. The active pharmaceutical ingredients of NuvaRing are etonogestrel, a progestogenic steroid, and ethinyl estradiol, an estrogenic steroid.

11. The '581 patent is currently listed the Orange Book with respect to NuvaRing.

12. The current NuvaRing prescribing information states that NuvaRing "is a non-biodegradable, flexible, transparent, colorless to almost colorless, combination contraceptive vaginal ring containing two active components, a progestin, etonogestrel (13-ethyl-17-hydroxy-11-methylene-18,19-dinor-17α-pregn-4-en-20-yn-3-one) and an estrogen, ethinyl estradiol (19-nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol). When placed in the vagina, each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use."

C. The Patent-in-Suit

13. U.S. Patent No. 5,989,581 ("the '581 patent"), which is entitled "Drug Delivery System for Two or More Active Substances" and lists Rudolf Johannes Joseph Groenewegen as the sole inventor, issued on November 23, 1999.

14. The '581 patent issued from U.S. Patent Application No. 09/056,700, filed in the United States Patent and Trademark Office ("USPTO") on April 8, 1998.

15. U.S. Patent Application No. 09/056,700 purports to claim priority to European Patent Office Application No. 97/201,098 ("the '098 application"), filed on April 11, 1997.

16. The '581 patent is assigned to Akzo Nobel N.V.

17. According to FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), the '581 patent expires on April 8, 2018.

D. The Asserted Claims

18. The claims of the '581 patent that are asserted in this action are 2–4 and 8–11.

19. Claim 2 of the '581 patent recites: "A drug delivery system according to claim 1,[2] wherein the delivery system has a substantially ring-shaped form and is intended for vaginal administration of the mixture of the progestogenic and estrogenic compounds."

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[2] Claim 1 of the '581 patent recites:

> A drug delivery system comprising at least one compartment which comprises a thermoplastic polymer core and a thermoplastic polymer skin covering the core, said core comprising a mixture of a steroidal progestogenic compound and a steroidal estrogenic compound in a ratio by weight that allows a direct release of both said progestogenic compound and said estrogenic compound in physiologically required amounts, said

20. Claim 3 of the '581 patent recites: "A drug delivery system according to claim 1, wherein at least the skin material comprises ethylene-vinyl acetate copolymer as the thermoplastic polymer."

21. Claim 4 of the '581 patent recites: "A drug delivery system according to claim 1, wherein the amount of progestogenic compound dissolved in the thermoplastic core material is 2 to 5 times the amount necessary for obtaining saturation concentration."

22. Claim 6 of the '581 patent recites:

> A drug delivery system according to claim 5,[3] wherein the thermoplastic polymer used for the core material is an ethylene-vinylacetate copolymer, the thermoplastic polymer used for the skin material is an ethylene-vinylacetate copolymer, the thermoplastic polymer used for the skin material is an ethylene-vinylacetate copolymer, said core comprising a mixture of a progestogenic compound etonogestrel and an estrogenic compound ethinyl estradiol in a ratio of 10 parts to 2-4 parts, said core comprising from 0.3 up to about 1% by weight of etonogestrel and from about 0.05 to about 0.3% by weight of ethinyl estradiol.

23. Claim 8 of the '581 patent recites: "A drug delivery system according to claim 6, characterised in that the skin is an ethylene-vinylacetate copolymer skin having a thickness ranging from 40 to 300 μm and a vinylacetate content ranging from 5 to 15%."

24. Claim 9 of the '581 patent recites: "A drug delivery system according to claim 8, characterised in that the skin thickness is 80 to 150 μm and the vinyl acetate content is 9-10%."

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progestogenic compound being initially dissolved in said polymer core material in a degree of super saturation of 1 to about 6 times of the amount by weight necessary for obtaining saturation concentration of said progestogenic compound in said polymer core material at 25 °C, said estrogenic compound being dissolved in said polymer core material in a concentration lower than that of said progestogenic compound, and said thermoplastic skin being permeable for said progestogenic and estrogenic compounds.

[3] Claim 5 of the '581 patent recites:

> A drug delivery system in a substantially ring-shaped form and suitable for vaginal administration comprising at least one compartment which comprises a thermoplastic polymer core and a thermoplastic polymer skin covering said core, said core comprising a mixture of a progestogenic steroidal compound and an estrogenic steroidal compound in a ratio by weight of 10 parts of the progestogenic compound to 1.5-5 parts of the estrogenic compound, said progestogenic compound being initially dissolved in said polymer core in a degree of supersaturation of 1 to about 6 times of the amount by weight necessary for obtaining saturation concentration of said progestogenic compound in said polymer core material at 25° C., and said polymer skin being permeable for both the progestogenic and the estrogenic compounds.

25. Claim 10 of the '581 patent recites: "A drug delivery system according to claim 5, wherein the core material is comprised of an ethylene-vinylacetate copolymer with a 25 to 35% vinyl acetate content."

26. Claim 11 of the '581 patent recites: "A drug delivery system according to claim 5, wherein the core material comprises 0.55 to 0.8% by weight of etonogestrel and 0.12 to 0.18% by weight of ethinyl estradiol."

E. Claim Construction

27. On February 24, 2014, the court ordered the parties' stipulation that no construction was necessary for the term "said progestogenic compound being initially dissolved in said polymer core." (D.I. 93.)

28. On February 25, 2016, the court construed the term "physiologically required amount" to mean "the amounts of the progestogenic compound and the estrogenic compound required by the body to achieve the full therapeutic effect."

F. Warner Chilcott's ANDA

29. Warner Chilcott filed Abbreviated New Drug Application ("ANDA") No. 204305 ("Warner Chilcott's ANDA") under Section 505(j) of the FFDCA to the FDA, seeking approval to market and sell a generic ethinyl estradiol and etonogestrel vaginal ring ("Warner Chilcott's ANDA Product") prior to the expiration of the '581 patent.

30. Warner Chilcott's ANDA contains a certification, pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV), alleging that the '581 patent is invalid, unenforceable, and/or will not be infringed by the activities described in Warner Chilcott's ANDA.

31. No earlier than November 6, 2013, Warner Chilcott sent written notice of its ANDA certification relating to the '581 patent to Plaintiff, informing Plaintiff that Warner Chilcott seeks approval to market its ANDA Product before the expiration of the '581 patent.

32. Warner Chilcott's ANDA Product is a contraceptive vaginal ring containing two active pharmaceutical ingredients, a progestogenic compound, etonogestrel, and an estrogenic compound, ethinyl estradiol.

33. The proposed indication for Warner Chilcott's ANDA Product is the prevention of pregnancy.

G. Infringement

34. For purposes of this litigation only, Warner Chilcott stipulated that its ANDA Product would infringe, if marketed, all limitations of the asserted claims of the '581 patent. (D.I. 126.)

III. DISCUSSION AND CONCLUSIONS OF LAW

The court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338, and 2201. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b). After having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court concludes that: (1) the asserted of the '581 patent are not invalid as anticipated under 35 U.S.C. § 102(b); (2) the asserted of the '581 are invalid as obvious under 35 U.S.C. § 103; and (3) each of the parties' Rule 52(c) motions are granted in part and denied in part. The court's reasoning follows.

A. Anticipation

Warner Chilcott argues that the '581 patent is anticipated by PCT '015 (JTX-30).

1. The Legal Standard

"[I]nvalidity by anticipation requires that the four corners of a single[] prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). In *Verizon Services Corp. v. Cox Fibernet Virginia, Inc.*, the Federal Circuit discussed the standards for inherent disclosure:

> [A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. However, a patent claim cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled. The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. It is well-settled that utility or efficacy need not be demonstrated for a reference to serve as anticipatory prior art under section 102.

602 F.3d 1325, 1337 (Fed. Cir. 2010) (alteration in original) (internal quotation marks and citations omitted).

A patent is presumed to be valid. 35 U.S.C. § 282. The party asserting invalidity bears the burden of establishing invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011). This burden of proof remains constant, even when a patent invalidity attack relies on the same prior art previously considered by the PTO. *See Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) ("The burden does not suddenly change to something higher—'extremely clear and convincing evidence' or 'crystal clear and convincing evidence'—simply because the prior art references were considered by the PTO.") Practically speaking, however, "it may be harder to meet the clear and convincing burden when the invalidity contention is based upon the same argument on the same reference that the PTO already considered." *Id.* Whether a prior art reference anticipates a patent claim is a question of fact. *Advanced Display Sys.*, 212 F.3d at 1281.

2. The Parties' Contentions and Discussion

Warner Chilcott's anticipation argument is based on one prior art document, PCT '015. PCT '015 is a patent application that was filed on July 4, 1995 by Akzo Nobel, N.V., Organon's then-parent. (JTX-30.1.) One of the inventors of PCT '015, Mr. Groenwegen, is also the inventor of the '581 patent. (JTX-1.1.) PCT '015 discloses a two-compartment vaginal ring composed of polyethylene vinyl acetate with 28% vinyl acetate ("PEVA 28"). (Tr. 160:11–162:5 (Kiser).) The first compartment contains a progestogenic compound, etonogestrel ("ETO"), and the second compartment contains a mixture of ETO and an estrogenic compound, ethinyl estradiol ("EE"). (JTX-30.10.) The target release rates for the PCT '015 ring are 90–150 μg/day ETO and 10–20 μg/day EE. (JTX-30.6 at 26–68.) For the second compartment, PCT '015 discloses a preferred

range of 0.05–3% w/w EE and 0.05–5% ETO. (JTX-30.6 at 20–24.) PCT '015 also discloses that the lengths of the compartments can be adjusted, such that the "[r]atios of the lengths of the first and second compartment are contemplated to be between 30:1 and 1:30. . . ." (JTX-30.5 at 22–24.)

The parties do not dispute that PCT '015 discloses several of the asserted limitations, including the same polymer and steroids claimed by the '581 patent. The court therefore focuses on the claim terms in dispute: (1) supersaturated progestin; (2) physiologically required amounts; (3) a lower concentration of estrogen than progestin; and (4) fixed ratios and concentrations of estrogen and progestin. The court addresses each in turn.

i. Supersaturated Progestin

All of the asserted claims of the '581 patent require a supersaturated progestogenic steroid. Claims 2, 3, and 8–11 of the '581 patent require supersaturation "from 1 to about 6 times of the amount by weight necessary for obtaining saturation concentration of said progestogenic compound in said polymer core material at 25 °C." '581 patent at 7:37–41. Claim 4 requires 2–5 degrees of supersaturation. The parties stipulated that saturation concentration of ETO in PEVA 28 is 0.35% w/w. (D.I. 136 at ¶ 3.) Therefore, the claimed levels of supersaturation are 0.35% to 2.1% w/w for claims 2, 3, and 8–11 (Tr. 150:14-21 (Kiser)), and 0.7% to 1.75% w/w for claim 4 (Tr. 183:12-25 (Kiser)).

The parties dispute whether PCT '015 discloses a progestogenic compound dissolved at a supersaturated concentration. Although PCT '015 never explicitly mentions supersaturation, Warner Chilcott argues that it inherently discloses supersaturated ETO. As support, Warner Chilcott points to Example 2, which describes rings with ETO concentrations between 0.45% and 0.8% w/w in PEVA 28. (JTX-30.10.) This falls within the claimed ranges. Merck responds that Example 2 only discloses supersaturation if the ETO in that example is fully dissolved. (Tr. 165:2–

23 (Kiser).) Just as PCT '015 does not mention supersaturation, it does not mention whether the ETO in the second compartment is fully dissolved. Warner Chilcott's expert, Dr. Kiser, testified that if crystals were visible in the compartment, it would indicate the compound was not fully dissolved. (Tr. 165:13-23 (Kiser).) PCT '015 discloses crystalline progestogen in the first compartment (JTX-30.5 at 19–20), but it does not mention the presence of crystals in the second compartment. The court finds that this supports a strong inference that the ETO in the second compartment was fully dissolved. Further, Warner Chilcott notes that the manufacturing conditions for Example 2 of PCT '015 are the same as for several examples in the '581 patent. (*Compare* JTX-30.6–7 *and* JTX-30.10 *with* JTX-1.5–6, Exs. 1, 2, 4, and 5). The '581 patent discloses that all of the ETO is fully dissolved. Contrary to the Merck's assertions, the court finds no reason to presume that the ETO in Example 2 of PCT '015 is not fully dissolved. Accordingly, the court concludes that PCT '015 inherently discloses the supersaturated progestin limitation.

ii. Physiologically Required Amounts

Claims 2–4 of the '581 patent require one compartment to release the progestogenic and estrogenic compound "in physiologically required amounts." (JTX-1.6 at 7:30–36.) The court construed this term to mean "the amounts of the progestogenic compound and the estrogenic compound required by the body to achieve the full therapeutic effect." (D.I. 138 at 2.) For PCT '015 to disclose this limitation, the second compartment must be capable of releasing ETO and EE in amounts required to achieve contraception.

Warner Chilcott's theory for how PCT '015 meets this claim limitation proceeds as follows. First, the second compartment in PCT '015 is "structurally and chemically identical" to the compartment in asserted claims 2–4. (D.I. 141 at 19). Merck does not dispute this point. Second, PCT '015 expressly lists the physiologically required amounts for contraception: at least 90 μg/day

of ETO and 10 μg/day of EE. (JTX-30.6 at 26–28.) Third, the concentration ranges disclosed for the second compartment (0.05%–3% w/w ETO and 0.05–5% w/w EE) encompass the concentrations used in NuvaRing (0.69% w/w ETO and 0.15% w/w EE). (*See* D.I. 141 at 20.) Fourth, PCT '015 discloses that the "lengths of the compartments of the ring-shaped device are chosen to give the required performance," and the second compartment can be up to 97% of the length of the ring. (*See* JTX-30.5 at 22–24 ("Ratios of the lengths of the first and second compartment are contemplated to be between 30:1 and 1:30. . . .").) Therefore, Warner Chilcott reasons, "[a] mixed compartment that is 97% of the length of the ring and has the same concentrations of ETO and EE as NuvaRing is essentially the same thing as NuvaRing and will thus certainly release 'physiologically required amounts.'" (D.I. 141 at 20–21.)

Merck argues that Warner Chilcott has failed to produce sufficient evidence to prove that PCT '015 anticipates this claim term. Merck notes that PCT '015 discloses two-compartment rings in which both compartments work together to deliver the physiologically required amounts of progestogenic and estrogenic compounds. PCT '015 lists the preferred steroidal release rates for only the ring as a whole, not for each separate compartment. (JTX-30.6 at 26–27.) It does not disclose the amount of ETO released from second compartment. Therefore, Merck contends, it does not disclose that the second compartment can release the physiologically required amounts of ETO and EE. Merck further argues that Warner Chilcott failed to adduce testimony that if the second compartment were lengthened, it would release the required amount of progestin.[4] (D.I. 140 at 10.)

[4] Dr. Kiser began to opine that the lengths of the two compartments in PCT '015 could be adjusted in order to meet this claim limitation. The court struck this portion of the testimony because it was outside the scope of his expert report. (Tr. 178:11–180:21 (Kiser).)

The court agrees with Merck. The '581 patent discloses "at least one compartment," so the existence of the first compartment in PCT '015 containing pure ETO does not automatically prevent it from meeting this limitation. But PCT '015 must still disclose that the second compartment can release ETO and EE at rates sufficient to cause contraception. Warner Chilcott may very well be correct that modifying the PCT '015 examples such that the second compartment comprises 97% of the ring would lead the second compartment release physiologically required amounts of ETO and EE. But the record lacks clear and convincing evidence to support that conclusion. There is no testimony that PCT '015 discloses an embodiment in which the second compartment would release sufficient ETO and EE. In short, attorney argument is not proof. PCT '015 does not disclose the "physiologically required amounts" limitation.

iii. More Progestin than Estrogen

Claims 2–4 of the '581 patent require the estrogenic compound to be dissolved "in a concentration lower than that of [the] progestogenic compound." '581 patent at 7:41–43. Warner Chilcott argues that PCT '015 discloses a second compartment with more progestin than estrogen. As support, it points to the broad ranges for the "most preferred ring-shaped device of the invention," which includes 0.05%–3% w/w ETO and 0.05%–5% w/w EE. (JTX-30.6 at 20–24.) From these ranges, a person of skill could fashion a ring which contains more ETO than EE (for example, 3% ETO and 2% EE).

Merck responds that none of the examples in PCT '015 disclose a second compartment with more progestin than estrogen. Moreover, the examples indicate that the first compartment would provide the ring with the majority of the required progestin. Therefore, Merck argues, PCT '015 does not contemplate a second compartment that includes more progestin than estrogen. Merck also notes that in PCT '015's most preferred embodiment, the second compartment is loaded with

0.25-0.5% w/w of ETO and 0.75-1.5% w/w of EE. (JTX-30.6 at 23–24.) This narrower embodiment does not permit the second compartment to contain more ETO than EE. Consequently, Merck contends that the broad ranges of preferred concentrations do not qualify as a disclosure of using more progestin than estrogen in the second compartment.

In response, Warner Chilcott notes that a prior art "reference need not always include an express discussion of the actual combination to anticipate." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1344 (Fed. Cir. 2016). The court agrees. The listed examples are not exhaustive, nor do they limit the scope disclosed of the reference. Nothing in PCT '015 states that the second compartment cannot have more progestin than estrogen. Therefore, a person of skill in the art would be free to select from the broad ranges a higher concentration of progestin than estrogen, as disclosed, if it were necessary for the ring design. The court concludes that PCT '015 discloses the limitation of a higher concentration of progestin than estrogen.

iv. Ratios and Concentrations of Progestin and Estrogen

Claims 8–11 require specific ratios and drug concentrations between the progestogenic and estrogenic compounds. Claims 8 and 9 require ETO and EE "in a ratio of 10 parts to 2–4 parts," at concentrations of 0.3–1% w/w of ETO and 0.05–0.3% w/w EE. (JTX-1.6 at 8:28–32.) Claims 10 and 11 require "a ratio by weight of 10 parts of the progestogenic compound to 1.5–5 parts of the estrogenic compound." (JTX-1.6 at 8:10–12.) Claim 11 further requires 0.55–0.8% w/w ETO and 0.12%–0.18% w/w EE. (JTX-1.6 at 8:47–49.) PCT '015 discloses broad concentration ranges of 0.05–3% w/w ETO and 0.05–5% w/w EE. (JTX-30.5 at 23–24.) During his testimony, Dr. Kiser used the claim language of the '581 patent to show that asserted ratios could be obtained from the ranges disclosed in PCT '015. (Tr. 188:23–190:15, 191:17–195:12 (Kiser).) Merck argues that

this was improper hindsight use of the '581 patent. The court agrees. PCT '015 does not disclose the specific ratios and concentrations in the asserted claims.

v. Conclusion

Warner Chilcott has not met its burden to prove the asserted claims are anticipated by PCT '015. Although PCT '015 disclosed the requirements for supersaturated progestin and more progestin than estrogen, the evidence at trial failed to establish disclosure of other limitations. For claims 2–4, PCT '015 did not disclose release of ETO and EE in "physiologically required amounts." For claims 8–11, PCT '015 did not disclose the claimed specific ratios and concentrations. For these reasons, the court concludes that none of the asserted claims are invalid as anticipated.

B. Obviousness

Warner Chilcott challenges the validity of each of the asserted claims of the '581 patent as obvious in light of the prior art. The court finds, for the reasons that follow, that Warner Chilcott has established by clear and convincing evidence that the patents-in-suit are obvious.

1. The Legal Standard

35 U.S.C. § 103(a) provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law that is predicated on several factual inquires. *See Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, the trier of fact is directed to assess four considerations: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved

need, failure of others, acquiescence of others in the industry that the patent is valid, and unexpected results. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

A party seeking to challenge the validity of a patent based on obviousness must demonstrate by "clear and convincing evidence" that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. As discussed above, this burden of proof remains constant, even when a patent invalidity attack relies on the same prior art previously considered by the PTO; still, "it may be harder to meet the clear and convincing burden when the invalidity contention is based upon the same argument on the same reference that the PTO already considered." *See Sciele Pharma*, 684 F.3d at 1260. Importantly, in determining what would have been obvious to one of ordinary skill in the art, the use of hindsight is not permitted. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) (cautioning the trier of fact against "the distortion caused by hindsight bias" and "arguments reliant upon ex post reasoning" in determining obviousness). In *KSR*, the Supreme Court rejected the rigid application of the principle that there should be an explicit "teaching, suggestion, or motivation" in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art, in order to find obviousness. *See KSR*, 550 U.S. at 415. The *KSR* Court acknowledged, however, the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does in an obviousness determination." *Takeda Chem. Indus. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 1356–57 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418) (internal quotation marks omitted).

"Obviousness does not require absolute predictability of success," but rather, requires "a reasonable expectation of success." *See Medichem, S.A. v. Rolado, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988)). To this end,

obviousness "cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). Moreover, while the Federal Circuit has noted that pharmaceuticals can be an "unpredictable art" to the extent that results may be unexpected, it also recognizes that, per *KSR*, evidence of a "finite number of identified, predictable solutions" or alternatives "might support an inference of obviousness." *See Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

2. The Level of Ordinary Skill in the Art

A person of ordinary skill in the art would have at least a Master's degree in polymer science, pharmacy, chemistry, pharmaceutics, chemical engineering, bioengineering, or a comparable field, and five years of relevant experience working with polymers. (*See* Tr. at 152:25–153:20 (Kiser); Tr. at 469:9–23 (Freeman).)

3. Scope and Content of the Prior Art and Differences Between the Claimed Subject Matter and the Prior Art

Warner Chilcott argues that the asserted claims are obvious, mostly in light of PCT '015. As with anticipation, the disputed claim terms are: (1) supersaturated progestin; (2) physiologically required amounts; (3) a lower concentration of estrogen than progestin; and (4) fixed ratios and concentrations of estrogen and progestin. The court addresses each contested element in turn.

i. Supersaturated progestin

Warner Chilcott argues that PCT '015 discloses supersaturated ETO even though it does not explicitly mention "supersaturation." "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995). Pursuant to the anticipation analysis above, the court concludes that PCT '015 inherently discloses supersaturated ETO. Example 2 describes rings with ETO concentrations

within the supersaturation range, and the court finds credible Dr. Kiser's testimony that the ETO in the example is supersaturated.

Of course, "proof of inherent anticipation is not the same as proof of obviousness." *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008). Merck argues that it would not have been obvious to use supersaturated progestin because the prior art does not disclose that a supersaturated ring would be stable for six months or longer. (Tr. 475:4–17 (Freeman).) Merck also contends that PCT '015 teaches away from supersaturation, because it states that "[p]articularly good release patterns are obtained when . . . the second compartment is loaded with a just saturated, and most preferably with a sub-saturated mixture of the progestogen and the estrogen." (JTX-30.5 at 7–10.)

The court does not find this sufficient to render the supersaturation limitation non-obvious. First, Merck does not dispute that a person of skill in the art could easily calculate the supersaturation concentration of ETO. (Tr. 300:1–8 (Kiser).) With the knowledge of the supersaturation concentration, a person of skill in the art would recognize that Example 2 of PCT '015 discloses supersaturated ETO. Second, although PCT '015 does not teach that a supersaturated ring would be stable, it also does not indicate that a supersaturated ring would be *unstable*. It is silent on the issue. Merck does not produce any prior art indicating that such a ring loaded with supersaturated progestin would be unstable. This therefore would not discourage a person of ordinary skill from proceeding with a supersaturated ring. Third, although PCT '015 encourages using a sub-saturated concentration of progestin, it does not *discourage* using a supersaturated concentration (as it certainly does not discourage a person of ordinary skill from using one of its disclosed examples). Further, it states that good release patterns may be obtained from a "just saturated" concentration. This actually correlates to the degree of supersaturation claimed by the

'581 patent, which includes the saturation concentration. (Tr. 150:14–25 (Kiser).) Therefore, the court concludes a person of ordinary skill would have found it obvious to load a ring with supersaturated progestin.

ii. Physiologically Required Amounts

Warner Chilcott claims that the prior art would encourage a person of ordinary skill in the art to create a ring in which one compartment released the physiologically required amounts of each steroid. Merck mainly argues that the "physiologically required amounts" limitation is not obvious because the prior art teaches away from using a one-compartment ring. Because the '581 patent also covers multiple-compartment rings, the court finds the relevant inquiry is not whether the prior art teaches away from one-compartment rings, but whether it teaches away from loading physiologically required amounts of progestin and estrogen into a single compartment.

Merck argues that the teachings of PCT '015 would discourage a person of ordinary skill from loading physiologically required amounts of ETO and EE into one compartment. Dr. Kiser agreed that the teaching of PCT '015 is "to separate out the physiologically required amounts of the progestin and estrogen so that you could dial them up independently." (Tr. 256:5–12 (Kiser).) According to Merck, delivering the full physiologically required amounts of progestin and estrogen from the second compartment "would compromise the ability to use those two compartments to independently control the release of each drug." (Tr. 491:2–7 (Freeman).)

Describing prior art one-compartment rings, PCT '015 states:

> "These above-mentioned one-compartment rings have the disadvantage that, when loaded with more than one active substance, release patterns of these substances can not be adjusted independently. Such devices usually show sub-optimum release patterns for the different substances, whereas it is generally preferred that all substances are released in a controlled rate and during a similar duration of time. As a consequence the release ratio of the active substances undergoes a change after a period of time."

(JTX-30.3 at 21–26.) This highlights the drawbacks of loading certain one-compartment rings "with more than one active substance." But, contrarily, PCT '015 then discloses a ring in which one of its compartments is loaded with more than one active substance. (JTX-30.5 at 12–14 ("Preferred devices for contraceptive use have . . . a second compartment wherein the steroid hormone is a mixture of a progestogen and an estrogen.").) PCT '015 does not state that the second compartment containing both ETO and EE shows "sub-optimum release patterns." PCT '015 also does not state that the presence of progestin in the second compartment somehow undermines the ability of a person of skill to adjust the concentrations of both drugs. If the key to PCT '015 is the ability to independently adjust the steroidal release rates, then it must disclose that a person of skill in the art can accomplish such an adjustment even when both steroids are loaded in the same compartment. The court therefore finds that PCT '015 does not teach away from loading physiologically required amounts of ETO and EE into the same compartment. At most, it teaches away from replicating several failed one-compartment ring designs.

Merck points to several other prior art references that denigrate loading two drugs into a single compartment. U.S. Patent No. 5,596,576 (JTX-37), which issued in 1986, teaches that "[t]he simultaneous introduction of [progestin and estrogen] into one reservoir can however only purely accidentally lead to the desired release ratio." (JTX-37.5 at 1:54–56.) Another 1986 reference also teaches serious disadvantages of loading both steroids into a single compartment, namely "it is not possible to adjust the ratio of the amount of steroid released, because the same rate-controlling membrane is used for both steroids." (DTX-347.3.) These references seem to teach away from the "physiologically required amounts" claim limitation. They both, however, predate PCT '015 by over ten years. PCT '015 disproves these assertions by disclosing a ring in which one compartment is loaded with two steroids. In light of PCT '015, the court concludes that these references would

not have discouraged a person of ordinary skill from loading a single compartment with physiologically required amounts of estrogen and progestin.

Merck additionally points to the research of the Population Council, which reported in 1994 that they had abandoned their one-compartment vaginal ring due to poor steroidal release rates. (Tr. 315:25–317:6 (Kiser).) The Population Council made two changes in response: (1) they moved from one-compartment ring to a four compartment ring, and (2) they moved from a shell design to a core design. (DTX-351.3.) The article does not discuss whether both changes were necessary to "steady hormone release." (DTX-351.2.) The original ring's failure may have been caused by loading the drugs in a single compartment, by the shell design, or by a combination of both. This ambiguity leads the court to conclude that this prior art reference does not teach away from loading both progestin and estrogen into a single compartment.

Having disposed of Merck's "teaching away" arguments, the court examines whether a person of ordinary skill in the art would have been motivated to modify PCT '015 so that the second compartment delivered the full amount of progestin and estrogen. PCT '015 discloses a two-compartment ring in which the second compartment: (1) is loaded with both ETO and EE; (2) has a higher concentration of ETO than EE; and (3) comprises 97% of the ring. PCT '015 also discloses the "physiologically required amounts" of progestin and estrogen. Dr. Kiser testified that a person of ordinary skill would have used Fick's Law to optimize the second compartment to release these target amounts of ETO and EE. (Tr. 219:13–220:5 (Kiser).) Fick's Law "relates the flux of a drug to the diffusivity of the drug," and can be used to "predict the release rate of the drug from the diffusion coefficient of the drug in the skin and the concentration of the drug in the skin." (Tr. 219:13–16 (Kiser).) It has been known for over a century. (Tr. 219:24–25 (Kiser).) This testimony was not rebutted by Merck's expert, Dr. Freeman. In light of the prior art, the court finds that a

person of ordinary skill would have been motivated to optimize PCT '015 such that the second compartment released physiologically required amounts of ETO and EE.

The court also concludes that a person of ordinary skill would also have been motivated to create a one-compartment ring.[5] Dr. Kiser testified that a person of ordinary skill in the art would have been motivated to create a one-compartment ring in order to decrease manufacturing costs. (Tr. 225:6–19 (Kiser).) After concluding that the second compartment could release the necessary levels of estrogen and progestin, a person of ordinary skill would have little reason to keep the first compartment in place. In conclusion, the "physiologically required amounts" limitation is obvious in light of PCT '015 and Fick's Law.

iii. More Progestin than Estrogen

Merck argues that loading the second compartment with more progestin than estrogen is incompatible with the teaching of PCT '015. In support, Dr. Freeman testified that PCT '015 only disclosed small concentrations of ETO in the second compartment in order to "prevent any negative effects from the direct release of ethinyl estradiol onto the tissue." (Tr. 490:23–491:1, 484:11–18 (Freeman).) But as the Warner Chilcott notes, PCT '015 does not indicate that this is the reason for including progestin in the second compartment, and actually discloses an example of a second compartment with quite high concentrations of ETO. (JTX-30.10.) Dr. Freeman, although he is an expert in polymer science, does not have any experience with vaginal rings or studying the physiological effects of drugs such as estrogen. (*See* Tr. 466:6–469:3 (Freeman).) Merck did not offer any evidence to corroborate Dr. Freeman's statement regarding the use of ETO in the second compartment. The court does not find it reliable or supported by the evidence in this case.

[5] This conclusion is not required for the "physiologically required amounts" limitation to be obvious because the '581 patent also reads on multi-compartment rings.

As discussed in the anticipation analysis, the court finds that PCT '015 explicitly discloses using a higher concentration of progestin than estrogen. Although Merck puts great emphasis on PCT '015's teaching about separating the two steroids in order to provide better control over the release rate, the second compartment of PCT '015 contains both estrogen and progestin by design. PCT '015 does not indicate that a higher concentration of progestin than estrogen in the second compartment would undermine a person of ordinary skills' ability to reliably control the release rate of both drugs. Accordingly, nothing in PCT '015 teaches away from loading the second compartment with more progestin than estrogen. This limitation would have been obvious to a person of ordinary skill in the art.

iv. Ratios and Concentrations of Progestin and Estrogen

In light of the court's discussion regarding "physiologically required amounts," the court also concludes it would have been obvious for a person of skill to derive the claimed ratios of progestin and estrogen.

Dr. Kiser demonstrated that a person of ordinary skill could calculate the target loading ratios using Fick's Law. (Tr. 219:10–224:6 (Kiser).) To solve for the ratios of ETO and EE, a person of skill would need the target release rates and the partition coefficient. (Tr. 220:11–25 (Kiser).) PCT '015 discloses the target release rates. (Tr. 222:21–223:1 (Kiser).) Although not disclosed in the prior art, Dr. Kiser explained that the partition ratio is "an inherent property" that a person of ordinary skill could easily measure. (Tr. 221:4–9 (Kiser).) According to his calculations, PCT '015's disclosure provides a target dose ratio of 10 parts ETO to 2.3 parts EE. (Tr. 223:17–224:1 (Kiser).) This falls within the claimed ratios of 10 parts ETO to 1.5–5 parts parts EE (*see* JTX-1.6 at 8:9–12), and 10 parts ETO to 2–4 parts EE (*see* JTX-1.6 at 8:27–29). Merck argues that this use of Fick's Law is inappropriate because PCT '015 discloses those target release

rates for the ring as a whole, not for the second compartment by itself. But as discussed above, the court concludes it would have been obvious to modify PCT '015 such that the second compartment delivered the physiologically required amounts of ETO and EE—this corresponds to the ring's disclosed target release rates. The court finds Dr. Kiser's ratio calculations reliable. Accordingly, the claimed ratios would have been obvious in light of the prior art.

Dr. Kiser also testified that the concentrations disclosed in the '965 patent would have made it obvious for a person of ordinary skill in the art to derive ratios and concentrations that fall within those claimed. The '965 patent disclosed concentrations using the estrogenic compound estradiol and the progestogenic compounds levonogestrel and norethindrone. (JTX-38.11 at 5:25–35.) Dr. Kiser testified that the disclosed ratios overlap with the ratios of the '581 patent. (Tr. 215:9–217:18 (Kiser).) Merck countered Dr. Kiser's testimony by noting that he did not take into account the differences in potencies of ETO and EE compared to the disclosed progestins and estrogens in the '965 patent. (Tr. 284:10–291:2 (Kiser).) The ratios disclosed in the '965 patent would read on independent claim 5 of the '581 patent, which does not require a specific estrogen or progestin (Tr. 347:20–348:14 (Kiser)), but they would not overlap with the concentrations claimed in dependent claims 8–11, which specifically require ETO and EE (Tr. 287:15–18 (Kiser)). Dr. Kiser also admitted that a person of skill in the art would not use the ratios of the '965 patent because "the information was too old by 1997." (Tr. 289:8–20 (Kiser).) The '965 patent issued on October 6, 1981, almost two decades before the '581 patent and fifteen years before PCT '015. The court finds that a person of skill would not have relied on the disclosure of the '965 patent to determine the ideal ranges.

Even though Warner Chilcott failed to establish the '965 patent as a guide to disclosure of the claimed concentrations, the court finds the ranges provided by PCT '015 adequately disclose

these concentrations. There is a complete overlap between the concentration ranges in PCT '015 and those disclosed in the '581 patent. The asserted claims require concentrations of 0.3%–1% w/w ETO and 0.05–0.3% w/w EE (JTX-1.6 at 8:28–32), and 0.55–0.8% ETO and 0.12–0.18% w/w EE (JTX-1.6 at 8:47–49). Dr. Freeman agreed that "the ranges selected in the '581 patent are within the broad ranges of progestin and estrogen listed" in PCT '015. (Tr. 544:10–14 (Freeman).) "A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

In order to rebut this prima facie case, Merck can establish that the claimed range "achieves unexpected results relative to the prior art range" or show "that the prior art teaches away from the claimed invention in any material aspect." *Id.* at 1330–31. Merck has not attempted to establish either with respect to the claimed concentrations. The concentrations chosen were necessary in order to obtain a target physiological effect, but there is no evidence that they achieved unexpected results or that the prior art taught away from these claimed concentrations. Indeed, Mr. Groenewegen, the inventor, relied on clinicians and medical doctors to select the necessary release rates. (Groenewegen Dep. Tr. 58:4–60:4.) The court concludes that the claimed ratios and concentrations were obvious.

v. Conclusion

The court concludes that all asserted claims of the '581 patent are obvious in light of PCT '015.

4. Secondary Considerations of Non-obviousness

Merck contends that even if Warner Chilcott succeeded in presenting a prima facie case of obviousness, that secondary considerations of non-obviousness rebut this showing. *See Graham*,

383 U.S. at 17–18. "Although secondary considerations must be taken into account, they do not necessarily control the obviousness conclusion." *Pfizer*, 480 F.3d at 1372. Moreover, "[a] nexus between the merits of the claimed invention and evidence of secondary considerations is required in order for the evidence to be given substantial weight in an obviousness decision." *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008) (alteration in original) (quoting *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 668 (Fed. Cir. 2000)). The court finds that Merck's secondary considerations— commercial success, industry recognition and long-felt need, and copying—fail to rebut a determination of obviousness.

i. Commercial Success

Merck claims that NuvaRing is a commercial success. Merck's expert, Dr. Rainey, analyzed the product's sales totals, profits, profit margins, prescription totals, prescription growth, and market share. (Tr. 366:10-367:17 (Rainey).) Dr. Rainey testified that between 2008 and 2014, net sales of NuvaRing reached over $4.1 billion globally and $2.4 billion in the U.S. (Tr. 367:22–368:23 (Rainey).) He also testified that in that same time frame, NuvaRing generated gross profits of over $3.8 billion globally and over $2.2 billion in the U.S., and a gross profit margin of about 92% for the global market and about 95% for the U.S. (Tr. 369:7–370:18 (Rainey).) U.S. prescription totals for NuvaRing reached over 53 million from 2002 through June 2015. (Tr. 372:7–373:18 (Rainey).) Dr. Rainey testified that NuvaRing has been among the top two branded hormonal contraceptives since 2010. (Tr. 375:12–18 (Rainey).)

The court did not find Dr. Rainey's testimony reliable. First, he did not consider sales data from the first six years NuvaRing was on the market, even though that information was publically available. (Tr. 396:23-397:2 (Rainey).) The 2002 annual report from Akzo Nobel, the former parent to Organon, indicates that NuvaRing "took off slower than expected" when it was first

released in the U.S. market. (JTX-78.16, 24.) Second, Dr. Rainey did not consider the cost of research and development or the cost of marketing in determining the profitability of NuvaRing. (Tr. 403:16–406:5 (Rainey).) Third, Dr. Rainey also did not compare NuvaRing's product gross margin to other oral contraceptives, or other Merck pharmaceutical products. (Tr. 406:6–19 (Rainey).) Fourth, Dr. Rainey only compared NuvaRing's market share to other branded contraceptives, excluding the sales of generics from the market share of competing products. (Tr. 604:10–605:7 (McDuff).) Although the court disagrees with Dr. McDuff's assertion that the relevant market includes contraceptive methods such as sterilization and barrier methods (Tr. 605:21–25 (McDuff)), the court concurs that the proper market for evaluating NuvaRing's success should include all hormonal contraceptives. When the full market of prescription hormonal contraceptives is taken into account, NuvaRing is not the top pharmaceutical contraceptive, but the fifth. (Tr. 606:19–607:7 (McDuff).) The court finds that Merck has established at most a modest level of commercial success for NuvaRing.

Commercial success is only relevant to the non-obviousness inquiry if there is a nexus between the success and the claims of the '581 patent. Dr. Freeman testified that there was a nexus between the claimed invention and NuvaRing's success. He claimed the advantages of "effective contraception and release of a progestin and estrogen at therapeutic levels over a prolong period of time . . . derive from the structure of NuvaRing and the elements in the claims that we have been talking about that derive from the supersaturation." (Tr. 530:4–10 (Freeman).) But effective contraception is not a novel feature of the '581 patent. As Warner Chilcott correctly notes, those celebrated features were already disclosed in PCT '015, which stated that the objective was "to provide a safe ring-shaped device, with a good release pattern." (JTX-30.4 at 7–8.) The court is

not persuaded that the '581 patent's inventive features led to the success of NuvaRing. The court concludes that commercial success does not rebut a finding of obviousness.

ii. Industry Recognition and Long-Felt Need

Merck also fails to show a nexus between industry recognition or long-felt need and the patented features. Merck notes that NuvaRing won Time Magazine's 2001 award for Best Innovation of the Year for Health. (JTX-41.) But Time's recognition of NuvaRing lacks any connection to the patented features. The article mentions that NuvaRing is "a thin, flexible plastic ring that women can flatten like a rubber band and insert once a month into the vagina" and it releases "the same progestin and estrogen found in low-dose birth-control pills." (JTX-41.) PCT '015 shares all of these features. Merck's discussion of long-felt need focuses on the need for a hormonal contraceptive that is dosed once every 28 days, can be inserted and removed by the patient, cannot be seen and does not irritate the skin, and is rapidly reversible. (Tr. 439:4–441:5, 462:2–25 (Simon).) It may have taken "almost 30 years of industry efforts" to bring such a ring to the market (D.I. 140 at 37), but these advantages and long-felt need are not what is inventive in the '581 patent. Because there is no relationship between the inventive features and industry recognition or long-felt need, they do not weigh in favor of a finding of non-obviousness.

iii. Copying

Merck established that Warner Chilcott attempted several to design around NuvaRing, but failed to develop any of them into a commercial product. (Muldoon Dep. Tr. 37:02–37:17; 48:09-48:15, 54:25-55:17, 104:1-104:11, 115:07-12, 141:02-145:08, 149:21-150:4.) "A showing of copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations" *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000). Further, "demonstration that a defendant has copied a patented

invention is not compelling evidence of non-obviousness in the Hatch–Waxman context due to the unique nature of the ANDA process." *Allergan, Inc. v. Watson Labs., Inc.-Florida*, 869 F. Supp. 2d 456, 485 (D. Del. 2012). Therefore, the court does not find that copying is strong objective evidence of non-obviousness in this case. Merck has failed to rebut Warner Chilcott's prima facie case of obviousness.

IV. CONCLUSION

For the reasons stated above, the court concludes that: (1) the asserted claims of the '581 patent are not invalid as anticipated under 35 U.S.C. § 102(b); (2) the asserted claims of the '581 are invalid as obvious under 35 U.S.C. § 103; and (3) each of the parties' Rule 52(c) motions are granted in part and denied in part.

Dated: August 26, 2016

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME B.V., Plaintiff, v. WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC Defendants.	Civil Action No. 13-2088-GMS

ORDER

At Wilmington this 26th day of August, 2016, IT IS HEREBY ORDERED THAT:

1. The asserted claims of the '581 patent are not invalid as anticipated under 35 U.S.C. § 102(b);

2. The asserted claims of the '581 are invalid as obvious under 35 U.S.C. § 103;

3. The parties' Rule 52(c) motions (D.I. 140–41) are GRANTED IN PART AND DENIED IN PART.

UNITED STATES DISTRICT JUDGE