IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH, and BAYER HEALTHCARE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 12-cv-517 (GMS) CONSOLIDATED
WATSON LABORATORIES, INC., et al.	)	
Defendants.	)	

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") allege that defendants Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (collectively "Watson") infringed the asserted claims of U.S. Patent No. 8,613,950 ("the '950 patent" or "the patent-in-suit"). (C.A. No. 14-760-GMS, D.I. 1.)[1] The court held a six-day bench trial on April 6, 2015 through April 14, 2015. (D.I. 156-161.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning validity of the '950

[1] Bayer asserts claims 9 and 11 of the '950 patent. Originally at issue were two additional patents: U.S. Patent Nos. 6,362,178 ("the '178 patent") and 7,696,206 ("the '206 patent"). The parties filed a Stipulation and Order on May 28, 2013, concerning Watson's infringement of claims 1-5 and 7-8 of the '178 patent and claims 1-6 the '206 patent. (D.I. 38.) The court entered the Stipulation and Order on June 3, 2013. (D.I. 40.); (D.I. 133 at 4.) At the close of trial, the court ruled that the asserted claims of patents '206 and '178 were not obvious. Tr. 1171:7-9, 1172:4-16 (Court). The court also rejected Watson's indefiniteness defense at the close of trial. Tr. 1175:20- 1176:1 (Court). Subsequently, during the post-trial briefing process, Watson conceded infringement of the '950 patent. (D.I. 145.)

patent based upon Watson's defense of obviousness under 35 U.S.C. § 103. (D.I. 148, 149, 164, 165.)

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that the asserted claims of the '950 patent are not invalid due to obviousness. The findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT[2]

A. The Parties

1. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 6 West Belt, Wayne, New Jersey.

4. Defendant Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Watson Laboratories, Inc. is a wholly-owned subsidiary of Actavis, Inc.

5. Defendant Actavis, Inc. is a Nevada corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

6. Defendant Actavis Pharma, Inc. is a Delaware corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

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[2] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 133, Ex. 1.) 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."

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

B. Background

8. There are two important processes that tablets undergo before the active ingredient in the tablets can be absorbed by the body. First, the tablet has to disintegrate into smaller granules. Second, the active ingredient has to be released from those granules—that is, to dissolve into solution.

9. In a traditional tablet, disintegration and dissolution occur in the stomach. In an orally disintegrating tablet, ("ODT"), disintegration takes place in the mouth.

10. There are two distinct types of ODTs. In one type, the "delayed-release" ODT, the ODT disintegrates in the mouth, but the active pharmaceutical ingredient ("API") dissolves in the stomach. In the second type, "immediate release" ODT, the ODT disintegrates in the mouth, and the API begins to dissolve in the mouth as well.

11. The scientific principle of "bioavailability," refers to how much drug is present in the blood following dissolution of the API.

12. Bioequivalence is the conclusion that the blood levels of a drug produced by two different dosage forms of that drug are similar enough to be treated as interchangeable.

C. The Patent-in-Suit

13. United States Patent No. 8,613,950 ("the '950 patent"), entitled "Pharmaceutical Forms with Improved Pharmacokinetic Properties," naming Peter Serno, Roland Heinig, Kerstin Pauli, and Yutaka Hayauchi as inventors, issued on December 24, 2013. The application for the '950 patent claims priority to a German patent application that was filed on March 1, 2005.

14. Bayer Intellectual Property GmbH is the assignee of the '950 patent.

15. The '950 patent is listed in the Orange Book at the FDA in connection with STAXYN®.

1. <u>The Asserted Claims</u>

16. Bayer has asserted claims 9 and 11 of the '950 patent which cover particular orally disintegrating tablet formulations of vardenafil hydrochloride trihydrate.

ii. *'950 Patent, Claim 9*

17. Claim 9 of the '950 Patent reads: The drug formulation according to claim 8, wherein said sugar alcohols are a mixture of sorbitol and mannitol.[3]

iii. *'950 Patent, Claim 11*

18. Claim 11 of the '950 Patent reads: The drug formulation of claim 8, wherein at least one sugar alcohol is sorbitol.

a. Bayer and STAXYN®

19. On June 17, 2010, Bayer HealthCare Pharmaceuticals, Inc. received approval from the FDA to market vardenafil hydrochloride orally disintegrating tablets, 10 mg, under the trade name STAXYN® for the treatment of erectile dysfunction.

20. Bayer has asserted claims 1-5 and 7-8 of the '178 patent, and claims 1-6 of the '206 patent. These claims cover, among other things, the compound vardenafil hydrochloride trihydrate. Vardenafil hydrochloride trihydrate is the active ingredient in LEVITRA® and STAXYN®, two products marketed by Bayer for the treatment of erectile dysfunction.

21. Bayer has asserted claims 9 and 11 of the '950 patent.

b. *ANDA No.* 203689 *Submitted by Watson*

22. Watson submitted an Abbreviated New Drug Application ("ANDA") No. 203689 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to sell a generic version of STAXYN®, vardenafil hydrochloride orally disintegrating tablets, 10 mg, prior to the expiration of the '178 and '206 patents.

23. Watson sent Bayer a letter dated March 12, 2012 ("First Paragraph IV Notice Letter"), stating that Watson had submitted an Abbreviated New Drug Application ("ANDA") No. 203689 to the FDA under § 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 vardenafil hydrochloride orally disintegrating tablets, 10 mg, prior to the expiration of the '178 and '206 patents. Watson's First Paragraph IV Notice Letter stated that the claims of the '178 and '206 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the product described in ANDA No. 203689.

24. Bayer brought suit against Watson alleging infringement of the '178 and '206 patents under 35 U.S.C. § 100 et seq., including § 271(e)(2)(A) on April 25, 2012, within 45 days of receipt of Watson's First Paragraph IV Notice Letter. (D.I. 1.)

25. Subsequently, Watson sent Bayer a letter dated February 6, 2014 ("Second Paragraph IV Notice Letter"), stating that Watson had submitted ANDA No. 203689 to the FDA under § 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 vardenafil hydrochloride orally disintegrating

[3] Claim 8 of the '950 Patent reads: A drug formulation in the form of an uncoated tablet which disintegrates rapidly in the mouth and releases the drug in the mouth without swallowing the tablet comprising vardenafil hydrochloride trihydrate, and at least two sugar alcohols.

tablets, 10 mg, prior to the expiration of the '950 patent. Watson's Second Paragraph IV Notice Letter stated that the claims of the '950 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the product described in ANDA No. 203689.

26. Bayer brought suit against Watson alleging infringement of the '950 patent under 35 U.S.C. § 100 et seq., including § 271(e)(2)(A) on March 21, 2014, within 45 days of receipt of Watson's Second Paragraph IV Notice Letter. (C.A. No. 14-760-GMS, D.I. 1.)

D. Procedural History

27. On April 25, 2012, Bayer filed a complaint alleging infringement of the '178 and '206 patents by Watson. (D.I. 1.) Watson counterclaimed for declaratory judgment of noninfringement and invalidity of the '178 and '206 patents on June 25, 2012. (D.I. 13.) Watson filed an amended answer and counterclaims on April 5, 2013. (D.I. 31.) Bayer filed an answer to Watson's first amended counterclaims on April 29, 2013. (D.I. 32.)

28. The parties filed a Stipulation and Order on May 28, 2013, stipulating to infringement of claims 1-5 and 7-8 of the '178 patent and claims 1-6 of the '206 patent, provided that the claims are valid and enforceable. (D.I. 38.) The Court entered the Stipulation and Order on June 3, 2013. (D.I. 40.)

29. Bayer filed a complaint alleging infringement of the '950 patent by Watson on March 21, 2014. (C.A. No. 14-760-GMS, D.I. 1.) Watson counterclaimed for declaratory judgment of noninfringement and invalidity of the '950 patent on April 23, 2014. (C.A. No. 14-760-GMS, D.I. 15.) Bayer filed an answer to Watson's counterclaims on May 19, 2014. (C.A. No. 14-760-GMS, D.I. 27.)

30. The actions were consolidated for purposes of trial on August 5, 2014. (D.I. 76). These cases had also been consolidated for purposes of trial with C.A. No. 13-845-GMS, in which Bayer alleged infringement by Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") of the '178 and '206 patents (D.I. 59), and C.A. No. 14-761-GMS, in which Bayer alleged infringement by Par of the '950 patent. (D.I. 76). The actions against Par were dismissed without prejudice in September 2014. (D.I. 82, 83).

31. The court held a six-day bench trial in this matter on April 6 through April 14, 2015. (D.I. 156-161). The court rejected Watson's indefiniteness defense at the close of trial. Tr. 1175:20-1176:1 (Court). The court also ruled that the asserted claims of patents '178 and '206 were not obvious. Tr. 1171:7-9, 1172:4-16 (Court). Subsequently, during the post-trial briefing process, the parties stipulated to infringement of the '950 patent. (D.I. 145.) Thus, the only remaining issue is Watson's obviousness defense with respect to the '950 patent.

III. DISCUSSION AND CONCLUSIONS OF LAW

These consolidated actions arise under the patent laws of the United States, 35 U.S.C. The court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338, 2201

and 2202. Venue is proper in this court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b). The defendants challenge the validity of the '950 patent as obvious in light of the prior art. 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 Watson has not proven that the asserted claims of the '950 patent would have been obvious to a person of ordinary skill in the art as of the March 1, 2005 filing date. The asserted claims of the '950 patent are valid under 35 U.S.C. § 103. Watson's Rule 52(c) motion is denied and Bayer's Rule 52(c) motion is granted. The court's reasoning follows.

A. Obviousness

Watson challenges the validity of each of the asserted claims of the '950 Patent as obvious in light of the prior art. The court finds, for the reasons that follow, that the defendants have not established by clear and convincing evidence that the patent-in-suit was obvious.

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).

"Obviousness does not require absolute predictability of success," but rather requires "a reasonable expectation of success." *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 evidence of a "finite number of identified, predictable solutions" or alternatives "might support an inference of obviousness." *Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (analyzing and applying the flexible obviousness inquiry announced in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 414-16 (2007)).

"A patent shall be presumed valid." 35 U.S.C. § 282. A party seeking to challenge the validity of a patent based on obviousness must demonstrate by clear and convincing evidence[4] 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. Importantly, in determining what would have been obvious to one of ordinary skill in the art, the use of hindsight is not permitted. *KSR Int'l Co.*, 550 U.S. at 421 (cautioning the trier of fact against "the distortion caused by hindsight bias" and "arguments reliant upon ex post reasoning" in determining obviousness).

(1) <u>The Level of Ordinary Skill in the Art</u>

A person of ordinary skill in the art with respect to the '950 patent would be (1) a pharmaceutical scientist, who would also rely on other disciplines, such as analytical chemistry

[4] "Clear and convincing evidence is evidence that places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" *Alza Corp v. Andrx Pharms., LLC*, 607 F. Supp. 2d 614, 631 (D. Del. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

and, as needed, clinical pharmacokineticists and clinicians;[5] or (2) a Ph.D. in pharmaceutical sciences or a related discipline, with several years of experience in formulation of pharmaceutical dosage forms, including the design and development of ODT formulations.[6] The court concludes that the parties' definitions of a person of ordinary skill in the art do not differ in a meaningful way.

(2) The Scope and Content of the Prior Art and Differences Between the Claimed Subject Matter and the Prior Art

The court will first consider whether Watson has established a *prima facie* case of obviousness in light of the evidence adduced at trial. Watson argues that the asserted claims were obvious for two reasons: (1) combining vardenafil hydrochloride trihydrate with the sugar alcohol excipients mannitol and sorbitol into a known ODT dosage form was taught by the prior art and would have been obvious to the person of ordinary skill; and (2) competitive pressure would have motivated one skilled in the art to derive the claimed subject. (D.I. 149 at 2-3.) The court addresses each of these arguments in turn.

i. The Claimed Subject Matter Was Obvious to a POSA

1. Prior Art Taught Vardenafil ODTs

According to Watson, ODT formulations of erectile dysfunction drugs, and vardenafil in particular, were obvious in light of prior art. (D.I. 149 at 9-11.) Watson relies on the testimony of Dr. Jacobs and asserts that in 2005, the literature reported that Pfizer was working on an ODT formulation of sildenafil, a medication for erectile dysfunction that Pfizer launched under the brand name VIAGRA in 1998. (*Id.* at 10.) Dr. Jacobs testified that there was demand for ODT drugs in the erectile dysfunction market. Tr. 311:3-16, 316:18-318:10, 318:12- 319:1 (Jacobs).

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[5] The plaintiffs' identification of a person of ordinary skill in the art is derived from Dr. Wicks' testimony. Tr. 832:13-22 (Wicks).

[6] The defendants' description of a person of ordinary skill in the art is derived from Dr. Jacob's testimony. Tr. 303:25-304:8 (Jacobs).

In contrast, Bayer argues that there is no reason, absent the use of hindsight, that a POSA would have made a vardenafil ODT. (D.I. 148 at 23); Tr. 842:9-12 (Wicks). Bayer relies on Dr. Wick's testimony noting that vardenafil was on the market in March 2005 in a traditional, swallowed-tablet formulation marketed as LEVITRA®. Tr. 842:13-20 (Wicks). According to Dr. Wicks, the prior art did not identify any problem with LEVITRA® that would have provided a reason for the POSA to reformulate vardenafil into a different dosage form. Tr. 842:21-24 (Wicks). In addition, there was no reason for the POSA to focus on an ODT vardenafil because of the rarity of ODT formulations. Tr. 833:21-834:2 (Wicks). Moreover, the POSA would not have considered vardenafil to be a good candidate for formulation as an ODT because vardenafil was known as an erectile dysfunction medication and ODTs were not considered particularly applicable to this area. DTX-978 at 64; Tr. 349:2-24 (Jacobs); Tr. 852:13-853:4; 853:25-854:4 (Wicks).

Dr. Wicks and Dr. Jacobs offered competing testimony. Ultimately, the court concludes that Dr. Wicks' testimony was more persuasive for several reasons. As Dr. Wicks pointed out, Pfizer's work on this project was announced in May 1998 and by March 2005 Pfizer still had not brought the product to market. Tr. 853:5-20, 856:1-14 (Wicks); DTX-970 at 438- 39 (Table 2). Watson asserted that the Ghosh reference (DTX-972) disclosed that Pfizer was still developing the Zydis wafer formulation of sildenafil in 2005, but Dr. Wicks recognized that the discussion in Ghosh relied on a publication from 1998, and thus was not based on current information. DTX-972 at 274-75 & n.19 (citing a Pfizer press release from August 1998); Tr. 857:19- 859:11, 860:9-21, 918:2-920:4. (Wicks). The court also considers it important that prior art references from 2004 listing ODTs on the market and likely to come to market in the next few years did not list any drugs for the treatment of erectile dysfunction. DTX-970 at 438-39 (Table 2); Tr. 853:5-24

(Wicks); Tr. 349:25-350:17 (Jacobs). Indeed, no ODT of an erectile dysfunction drug was on the market by March 2005. Tr. 855:15-19 (Wicks); (D.I. 164 at 5). In conclusion, the court finds that Watson has not met its burden of establishing by clear and convincing evidence that a vardenafil ODT was obvious.

2. The Prior Art Taught Immediate-Release ODTs

Bayer argues that even if the POSA had chosen to make a vardenafil ODT, the POSA would not necessarily have made an immediate-release ODT rather than a delayed-release ODT. First, Bayer assets that the taste would have discouraged a POSA from creating a vardenafil ODT. A POSA would expect a vardenafil ODT to taste bitter because it has a pH value higher than water. (D.I. 148 at 16.) Dr. Wicks testified that a POSA motivated to make a vardenafil ODT would have pursued a delayed-release ODT to avoid release of vardenafil in the mouth and the issue of unpleasant taste. Tr. 864:4-7 (Wicks). Indeed, Dr. Wicks testified that Pfizer's work reflected that it was formulating sildenafil to avoid release in the mouth. Tr. 895:24-896:8 (Wicks); DTX-1084 (Bell-Huff); PTX-1214 (Itoh).

Watson responds that a POSA could taste vardenafil to determine whether a delayed-release ODT was needed. (D.I. 149 at 18.) The court finds that a POSA could not simply rely on his own personal taste to determine if a delayed-release ODT was needed. As Dr. Wicks testified, the taste of a drug is generally evaluated using a more complex and systematic method than a single subject taste-test. Tr. 881:8-882:20 (Wicks). In addition, in his expert testimony, Dr. Jacobs agreed with Dr. Wicks that a POSA would have expected a vardenafil ODT to have a bitter taste. Tr. 368:4-9, 368:20-369:20 (Jacobs). The court concludes that a POSA would have expected a bitter taste and this expectation would have taught away from creating a vardenafil ODT.

Bayer also contends that the LEVITRA® labeling taught away from formulating vardenafil as an immediate-release ODT. (D.I. 148 at 13.) The labeling suggests that an increase in bioavailability, which is an increase in vardenafil blood levels, would be a problem for older men. Tr. 871:25-872:19, 873:8-25 (Wicks). A POSA would consider this a major concern because, as an erectile dysfunction drug, the target population for LEVITRA® is older men. Tr. 358:9-11 (Jacobs). Watson asserts that the prior art taught that an increase in bioavailability was actually a benefit of ODTs (D.I. 149 at 16), but never addresses Bayer's evidence on bioavailability, most crucially, the labeling for LEVITRA®. Given that there is at least some ambiguity, the court declines to accept Watson's argument that the POSA would have known with certainty that an immediate-release ODT would have increased bioavailability. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1070 (Fed. Cir. 2012) (holding that an invention was not invalid for obviousness where there was insufficient evidence to conclude that one formulation over the other resulted in a particular foreseeable pharmacokinetic profile.)

In conclusion, the court finds that Bayer has failed to prove that the POSA would have found it obvious to make an immediate-release ODT. In assessing whether the prior art suggested an invention, a court must consider references that "teach away" from the invention. *Tec Air, Inc. v. Denso Mfg. Michigan Inc.,* 192 F.3d 1353, 1360 (Fed. Cir. 1999). In this case, the court finds that a POSA would recognize two fundamental concerns when considering an immediate-release formulation over a delayed release ODT formulation: (i) increased bioavailability; and (ii) taste. Tr. 863:22-864:18 (Wicks). These concerns would have taught away from the claimed subject matter.

3. The Prior Art Taught Mixing Mannitol and Sorbitol in an ODT

The court also rejects Watson's argument that a POSA would find it obvious to use mannitol and sorbitol in an ODT. Watson argues that the prior art specifically disclosed that combining sorbitol and mannitol provided an ODT that had the advantages of: (1) the favorable physical properties simplifying tablet manufacture from sorbitol; (2) favorable disintegration properties from mannitol; and (3) favorable taste profiles from both sugar alcohols. (D.I. 149 at 11.) Dr. Jacobs relied on the Bauer reference (DTX-897) and the Sparks patent (DTX-1077) for evidence that prior art suggested an ODT that contained mannitol and sorbitol. (D.I. 149 at 13.) Dr. Jacobs, one of the inventors on the Sparks patent, testified that he had used that combination in the patent because it was in the prior art. Tr. 331:16-20 (Jacobs).

In contrast, Bayer points out that every ODT on the market in the relevant prior art time frame contained only a single sugar alcohol: mannitol. (D.I. 148 at 17-21); Tr. 884:1-19 (Wicks); Tr. 386:13-19 (Jacobs). *See also* DTX 951; PTX 1265-1280; PTX 1544. Dr. Wicks testified that there were no known problems with the use of mannitol in the existing ODTs. Tr. 891:11-17 (Wicks). Additionally, there was nothing in the prior art that would have given the POSA a reason to use sorbitol in addition to mannitol in an ODT. Tr. 894:12-15 (Wicks). Indeed, Pfizer's work with the Zydis formulation only used mannitol. Tr. 895:17-23 (Wicks).

The court concludes that the tableting properties of the mannitol and sorbitol mixture were not obvious as Dr. Jacobs suggests. Dr. Jacobs relied on the Bauer reference for support (DTX-897), but later conceded that the portion of Bauer disclosing that mannitol and sorbitol could provide optimizing tablet properties was based on a 1978 article. Tr. 385:19-386:12 (Jacobs); DTX-897 at 203 & n.9 (citing to a 1978 article by Mendes & Roy). Watson also relied on a

commercial, off-the-shelf excipient containing a combination of mannitol and sorbitol, PHARMABURST B2, which came on the market in 2005. (D.I. 149 at 14); (DTX-858). In particular, Watson relies on statements in DTX-858, an advertisement piece for Pharmaburst, Tr. 335:23- 336:1 (Jacobs), that contains no working examples or experimental data. DTX-858 at BAYSTAX2000032.

Watson also asserts that the POSA would have wanted to use a mixture of mannitol and sorbitol to avoid the need for specialized packaging. (D.I. 149 at 192.) However, while Dr. Jacobs testified on direct examination that ODTs require specialized packaging, Tr. 328:3-15 (Jacobs), he also testified that "there is no need for specialized packaging" if one were to use a particular process, called direct compression, to manufacture the ODT. Tr. 301:16-302:1 (Jacobs). The court concludes that the prior art would not suggest to a POSA to use a mannitol and sorbitol mixture in the claimed subject matter.

Accepting as credible Dr. Wick's testimony that a person of skill in the art would not have found it obvious to create a vardenafil ODT that was immediate-release and that mixed mannitol and sorbitol, the court finds Watson's obviousness argument unpersuasive. For the reasons stated above, the court concludes that a person of skill in the art in 2005 would not have a reasonable expectation of success that combining the teachings and disclosures known in the prior art would create the subject claimed in the '950 patent. Watson has not satisfied its heavy burden to show by clear and convincing evidence that the claimed inventions are invalid for obviousness. *Microsoft Corp. v. I4I Ltd. P'ship*, 131 S. Ct. 2238, 2252 (2011).

ii. A POSA Would Have Been Motivated to Derive the Claimed Subject Matter

Watson additionally argues that a POSA would have been motivated to make an ODT of vardenafil. (D.I. 149 at 15); Tr. 338:2-20 (Jacobs). During trial, Dr. Jacobs described the benefits of ODTs that he testified would have provided the POSA with a reason to make a vardenafil ODT. Tr. 309:8-310:19, 345:2-6 (Jacobs); DTX-972 at 344; Tr. 59:14-22 (Watson) (identifying these benefits in its Opening Statement); (D.I. 149 at 8-9). In particular, Watson emphasizes three points. First, the POSA would have recognized that some patients would regard an ODT formulation of vardenafil as being more convenient and discreet than a tablet that had to be swallowed whole with water. (D.I. 149 at 15.) Secondly, an ODT that released drug in the mouth could improve bioavailability of vardenafil. (D.I. 149 at 16.) Finally, the competitive pressure from Pfizer's ODT, and the known therapeutic and commercial advantages of ODT line-extension products would have motivated one skilled in the art to derive the claimed subject. (D.I. 149 at 15-23.)

To this, Bayer responds that there were no known problems with LEVITRA® that would motivate the POSA to reformulate it as an ODT. (D.I. 148 at 29.) The court must agree for several reasons. First, Dr. Jacobs made several concessions that adversely affected the credibility of his testimony regarding this issue. On cross-examination, Dr. Jacobs testified that a POSA would have believed that the potential benefits of an ODT were more limited than he originally conveyed. He admitted that in his expert report he had opined that ODTs are only "marginally easier" to swallow than a tablet, that the POSA would have expected that the time of onset of LEVITRA® and a vardenafil ODT would be "fairly close," and that the POSA would not have been concerned about the bioavailability of LEVITRA®. Tr. 344:24-349:1 (Jacobs).

Dr. Jacobs' testimony is also substantially based upon hindsight. Dr. Jacobs relied on Bayer's invention of STAXYN® as proof of what the POSA would be motivated to do. Tr.

350:22-351:12, 351:22-352:11, 353:8-354:12 (Jacobs). In addition, at various points, Dr. Jacobs's trial testimony contradicted his expert reports and his deposition testimony regarding whether he relied on the existence of STAXYN® for analyzing the motivation of the POSA. Tr. 350:22-351:12, 351:22-352:11, 353:8-354:12. This use of hindsight is impermissible. "In retrospect, [the inventor's] pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of invention, the inventor's insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.,* 520 F.3d 1358, 1364 (Fed. Cir. 2008.)

The court is persuaded that the prior art would not motivate a POSA to reformulate vardenafil into a different dosage form. Tr. 842:21-24 (Wicks). In *KSR*, the Supreme Court acknowledged 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." *KSR Int'l Co.*, 550 U.S. at 418. Here the court finds that there was no such reason. The court concludes that a POSA would not have been motivated to create an immediate-release ODT of vardenafil.

(2) Secondary Considerations

Under relevant law, once a *prima facie* case of obviousness has been established, the burden then shifts to the applicant to present evidence of secondary considerations of non-obviousness to overcome this *prima facie* showing. *See, e.g.*, *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996). The Supreme Court has made clear that secondary considerations can include, among other things, evidence of commercial success, long felt but unsolved needs, and/or the failure of others. *See Graham*, 383 U.S. at 17-18. A plaintiff may also rebut an obviousness contention by demonstrating that there were unexpected results created by the claimed invention,

unexpected properties of the claimed invention, licenses showing industry respect for the invention, and/or skepticism of skilled artisans before the invention. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

"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)). In other words, the secondary considerations must be commensurate in scope—"coextensive"—with the claimed features of the invention. *Id.*; *see also MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1264–65 (Fed. Cir. 2013).

Here, the plaintiffs argue, that even should the court determine that the defendants established a *prima facie* case on this issue, the secondary considerations of copying and unexpected results sufficiently rebut this *prima facie* case. (D.I. 202 at 137); *see Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1373 n.9 (Fed. Cir. 2004). Although the defendants have not established a prima facie case, the court will briefly address each of the secondary conditions that the plaintiffs raise.

i. Copying

Bayer first offers evidence that Watson copied the claimed invention, relying on the testimony of Dr. Wicks. (902:25-903:19.) Bayer argues that Watson considered design-around alternatives to the formulations claimed in claims 9 and 11, but instead copied them. (D.I. 148 at 34-35.) Specifically, Watson decided not to use ODT formulation that only contained mannitol.

Watson responds that copying is not relevant to non-obviousness in the ANDA context. (D.I. 165 at 14). *See Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc.*, 642 F. Supp. 2d 329, 373-74 (D. Del. 2009) (stating that demonstrating 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). Bayer counters that the facts surrounding copying in this case present a different issue than in the typical ANDA case. (D.I. 148 at 34-35.) In particular, Bayer insists that Watson did not simply copy in order to bring a Paragraph IV challenge; its conduct shows that it desired the claimed subject matter and is probative objective evidence of non-obviousness. (*Id.*) The court agrees with Bayer that Watson's copying is evidence of non-obviousness in this case. *See Friskit, Inc. v. Real Networks, Inc.*, 306 Fed. Appx. 610, 617 (Fed. Cir. 2009) (copying is probative evidence of nonobviousness where alternative development efforts by the infringer were unsuccessful.)

ii. Skepticism/Unexpected Results

Bayer further asserts that STAXYN® produced increased oral bioavailability, which was an unexpected result and objective evidence of nonobviousness. (D.I. 148 at 25.) Specifically, Bayer avers that a POSA would not have expected that the bioavailability curves for STAXYN® compared to LEVITRA® would have an increase in bioavailability and no increase in the maximum concentration of vardenafil in the bloodstream. Tr. 898:21-899:1, 899:15-22 (Wicks); 1065:9-16, 1073:8-10 (Goldstein). These results lead STAXYN® to have a longer duration of action without added side effects. Tr. 1110:24-1111:8 (Goldstein). In contrast, a POSA would have thought that an immediate-release ODT was more likely to result in an increase in bioavailability than a delayed-release ODT, and thus an immediate-release ODT would be less likely to achieve bioequivalence. Tr. 866:21-868:10 (Wicks). Thus, according to Bayer, a POSA

making an ODT formulation of vardenafil would have wanted to formulate the ODT such that it was bioequivalent to LEVITRA®. Tr. 866:7-20 (Wicks). As support, Bayer relies on Dr. Goldstein's testimony that the Heinig paper demonstrated an increased duration of therapeutic activity over LEVITRA®. (D.I. 148 at 33-34); Tr. 1065:9-16, 1073:11-20 (Goldstein) (averring that an increase in overall bioavailability without an increase in Cmax would have been unexpected to the POSA); Tr. 900:2-18 (Wicks). Dr. Goldstein testified that Example 6 of the '950 Patent provides further evidence of the unexpected properties. DTX-850; Tr. 974:20-978:8 (Serno).

Watson responds that other experts in the field who reviewed the data in Heinig did not draw the same conclusion as Dr. Goldstein. (D.I. 149 at 24.) Moreover, Watson contends that even Dr. Goldstein conceded that the data do not prove that there is a clinical difference between the claimed ODT and LEVITRA. Therefore, Watson concludes that the alleged unexpected result also has no nexus to the claims. (*Id.*)

The court found the testimony of Dr. Goldstein credible as to the increased duration of action of STAXYN® relative to LEVITRA® without an increase in adverse side effects. Tr. 1065:9-16, 1066:2-5, 1066:9-24 (Goldstein); DTX 981 at 32, Figure 1; Tr. 698:18-699:2, 701:7-15 (Levine); Tr. 898:21-899:1, 899:23-900:1 (Wicks). In addition, although Dr. Heinig did not offer the exact same analysis as Dr. Goldstein, Dr. Heinig did acknowledge the "possibility of increased duration of action" and reasoned that more clinical research is needed to conclusively prove that this is a benefit of STAXYN® compared to LEVITRA. Tr. 434:3-9 (Heinig.) Moreover, Dr. Goldstein accounted for the lack of clinical studies comparing STAXYN® and LEVITRA® by explaining that it would be nearly impossible to conduct a blind, clinical trial. Tr. 2-71:14-25 (Goldstein.) Ultimately, clinically-significant results are not necessarily required to

support unexpected results. *See, e.g., Bone Care Int'l LLC v. v. Roxane Labs., Inc.,* 2012 WL 2126896, at *20-22 (D. Del. June 11, 2012).

In conclusion, the court finds that the bioavailability profile of the STAXYN® formulation would have been unexpected by a POSA at the time. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.,* 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *In re Soni,* 54 F.3d 746, 750 (Fed. Cir. 1995)) (stating that unexpected results may be evident where "the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.") In addition, because STAXYN® and Example 6 of the '950 patent are covered by claims 9 and 11, there is a nexus to the unexpected results. *See Simmons Fastener Corp. v. Illinois Tool Works, Inc.,* 739 F.2d 1573, 1575 (1984) ("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.").

The evidence in the record on several relevant secondary considerations weighs against a finding of obviousness. In light of this finding, the court concludes the subject matter claimed under the '950 patent was not obvious.

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In sum, Watson has failed to present a *prima facie* case that the asserted claims of the patents-in-suit are invalid as obvious. Additionally, the court finds that the secondary, objective indicia point towards a finding of non-obviousness. The asserted claims are not invalid as obvious.

B. Watson's Request for Attorney's Fees

The court "in an exceptional case may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. Watson argues that this is an exceptional case because of Bayer's lack

of substantial evidence on this issue of obviousness and that it is entitled to attorney's fees. Having found in favor of Bayer on the issue of obviousness, the court finds that this is not an exceptional case and denies Watson's request that it be awarded fees. (D.I. 149 at 34.)

IV. CONCLUSION

For the reasons stated above, the court concludes that: (1) the '950 patent is not invalid due to obviousness; (2) Bayer's Rule 52(c) motions are granted and Watson's Rule 52(c) motions are denied.[7] An appropriate order will follow.

Dated: April 27, 2016

UNITED STATES DISTRICT JUDGE

[7] As noted, all parties submitted Proposed Findings of Fact and Conclusions of Law, requesting that the court find in its favor on the issue of obviousness. For the reasons stated above and based on the court's findings, the defendants' Rule 52(c) motion is denied and the plaintiffs' Rule 52(c) motion is granted.