IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| MERCK & CIE, BAYER PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,<br><br>Plaintiffs;<br><br>v.<br><br>WATSON LABORATORIES, INC.,<br><br>Defendant. | Civil Action No. 13-978-RGA<br>Civil Action No. 13-1272-RGA |

TRIAL OPINION

Jack B. Blumenfeld, Esq., Rodger D. Smith II, Esq., Derek J. Fahnestock, Esq., Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; Adam K. Mortara, Esq., J. Scott McBride, Esq., Rebecca T. Horwitz, Esq., Faye E. Paul, Esq., Bartlit Beck Herman Palenchar & Scott LLP, Chicago, IL, attorneys for Plaintiffs.

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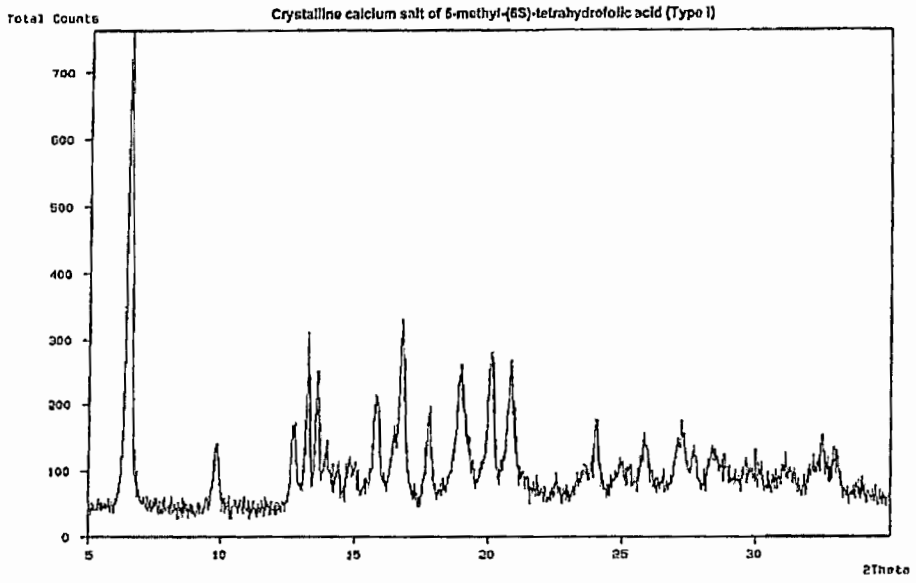
August 31, 2015

**ANDREWS, U.S. DISTRICT JUDGE:**

Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Merck" or "Plaintiff") brought this suit against Watson Laboratories, Inc. ("Watson" or "Defendant") alleging infringement of U.S. Patent No. 6,441,168 ("the '168 patent"). (D.I. 1). Watson filed two Abbreviated New Drug Applications ("ANDAs") seeking approval to engage in the commercial manufacture, importation, use, or sale of generic versions of Safyral® and Beyaz®. This action centers on one ingredient of the proposed drugs: the Type I crystal form of calcium 5-methyl-(6S)-tetrahydrofolate ("MTHF"). (Tr. 2025:8-10).[1]

Claim 4 of the patent recites: "A crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid with 2 theta values of 6.5, 13.3, 16.8, and 20.1 (Type I) said crystalline salt having a water of crystallization of at least one equivalent per equivalent of 5-methyltetrahydrofolic acid." ('168 patent, col. 10, ll. 57-61). The powder x-ray diffraction diagram in the specification shows peaks at the two theta values described in the claim:




[1] Citations to "Tr." refer to the transcript of the bench trial held on May 18, 2015 through May 21, 2015. Page numbers reflect the "PageID."

The specification also states that the solubility of the Type I crystal is 1.1%, which meets the United States Pharmacopeia ("USP") definition of "sparingly soluble." ('168 patent, col. 4, l. 58; PTX195 at p. 6). The water content of the Type I crystal is 14.5%. ('168 patent, col. 5, l. 67).

The parties stipulated that, if claim 4 of the '168 patent is valid and enforceable, (1) Defendant's filing of ANDA Nos. 203593 and 203594 would constitute an act of infringement and (2) commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's Safyral® ANDA Product and/or Beyaz® ANDA Product would infringe the claim. (D.I. 38). Watson asserts that claim 4 is not valid and enforceable. It contends that the asserted claim is invalid under the on-sale bar of 35 U.S.C. § 102(b), anticipated under 35 U.S.C. § 102(a), obvious under 35 U.S.C. § 103(a), and invalid under 35 U.S.C. § 112 for lack of written description. (D.I. 108 at p. 1).

## I. ON-SALE BAR

### A. Legal Standard

A patent claim is invalid under the on-sale bar of 35 U.S.C. § 102(b) if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." The on-sale bar requires proof of two conditions: (i) the product is "ready for patenting," and (ii) the invention is "the subject of a commercial offer for sale." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 66-68 (1998); *Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1370 (Fed. Cir. 2015). "An actual sale is not required for the activity to be an invalidating commercial offer for sale. An attempt to sell is sufficient so long as it is sufficiently definite that another party could make a binding contract by simple acceptance." *Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc.*, 726 F.3d 1370, 1374-75 (Fed. Cir. 2013) (internal

citations omitted). "[T]he question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood." *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001).

**B. Findings of Fact**

1. The application for the '168 patent was filed on April 17, 2000.
2. The '168 patent issued on August 27, 2002.
3. The '168 patent was ready for patenting by September 1998.
4. In 1997, Merck and Weider Nutrition International ("Weider") were exploring a strategic partnership to introduce dietary supplements with Merck ingredients into the United States.
5. On February 25, 1998, Merck and Weider entered into a Confidentiality and Noncompetition Agreement ("CDA"). Section 5.2 of the CDA provided, "Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction."
6. In August 1998, Weider notified Merck that it was no longer interested in an exclusive strategic partnership.
7. In August 1998, Weider inquired about a stand-alone purchase of two kilograms of MTHF.
8. Weider and Merck exchanged communications about the purchase throughout the fall of 1998.
9. On September 9, 1998, Roland Martin of Merck sent a fax to Weider with terms for the purchase, including price, quantity, delivery, and payment.

10. On September 16, 1998, Weider responded, confirming the delivery address and indicating that it would send a purchase order after receiving additional information required to add Merck as a supplier.

11. Weider did not receive the MTHF, and cancelled the purchase on January 9, 1999.

**C. Conclusions of Law**

In order to show that an invention was ready for patenting, there must be proof of a reduction to practice before the critical date or proof that the inventor prepared enabling drawings or descriptions of the invention. *Pfaff*, 525 U.S. at 67-68. Merck wrote to Weider on September 25, 1998 and stated that the MTHF to be delivered would be from Lot ESF-118. (DTX 27 at p. 2). Merck stipulated that (1) Lot ESF-118 is within the scope of claim 4 of the '168 patent, (2) the x-ray diffraction pattern of Lot ESF-118 is disclosed in Figure 1 of the patent, and (3) the x-ray diffraction pattern of Lot ESF-118 was obtained by Merck at least as of August 25, 1998. (D.I. 73 at 2). The MTHF was therefore ready for patenting by September 1998.

Watson argues that the September 9, 1998 and September 16, 1998 communications constitute a commercial sale. (Tr. 2800; D.I. 108 at p. 8). Watson contends that the September 9, 1998 fax contained all the material terms necessary for an offer to be sufficiently definite: a description of the product, quantity, price, delivery information, and payment terms. (D.I. 108 at p. 11). Watson argues that Weider understood at the time that a sale had occurred. (*Id.* at p. 11). It notes that Dr. Bucci of Weider testified that he was expecting Merck to deliver the MTHF. (Tr. 2240 at 3-7). Even if a sale did not occur for the purposes of the on-sale bar, Watson maintains that the September 9, 1998 fax constituted a commercial offer for sale. (D.I. 108 at p. 7).

Watson also argues that § 5.2 of the CDA did not operate to prevent a commercial sale. (*Id.* at p. 12). Watson maintains that a "transaction" for the purposes of the agreement does not include a stand-alone purchase, but rather refers to the larger joint venture the companies were exploring. (*Id.* at p. 14). In addition, Watson argues that the September correspondence was a "definitive agreement." (*Id.*). Watson further argues that, even if the CDA did apply to the stand-alone purchase, Merck waived § 5.2 by inviting Weider to follow a process for sale that did not comply with § 5.2. (*Id.*).

Finally, Watson argues that there were no remaining terms or conditions that needed to be determined before a sale could occur. (*Id.* at p. 17). Watson argues that Dr. Bucci expected delivery and Merck promised to "arrange everything" for "immediate delivery," both of which contradict Merck's contention that there were outstanding conditions. (*Id.* at pp. 17-18; DTX 133).

Merck maintains that, in light of § 5.2 of the CDA, there was no commercial sale or offer for sale. (D.I. 111 at p. 4). The CDA provides that a transaction is not legally binding until there is a definitive agreement signed by both parties. (*Id.*). Merck argues that there was no such signed agreement, and thus there cannot be a legally binding sale. (*Id.*). Merck notes that both Dr. Buchholz of Merck and Dr. Bucci of Weider testified that there was no obligation to deliver a product absent a formal written agreement. (*Id.* at p. 5). Dr. Buchholz testified, "The conversations and discussions we had did not create any obligation to Weider or from Weider to us unless we afterwards, after we had the discussion, signed a formal agreement and contract." (Tr. 2749:8-12). Dr. Bucci testified that it was his "understanding that until [they] had a signed agreement, it was all discussions." (*Id.* at 2227:6-8).

Merck argues that a "transaction" for the purposes of the CDA includes a stand-alone purchase, and is not limited to a long-term strategic partnership. (D.I. 111 at p. 13). Merck notes that in the September 1998 correspondence, the order was referred to as a "transaction." (*Id.*). Merck also argues that no document in the fall 1998 correspondence is signed by both parties. (*Id.* at p. 14). With respect to waiver, Merck contends that Watson's argument is circular because it would mean that the circumstances § 5.2 is designed to protect against would operate to waive it. (*Id.* at p. 15).

Merck further argues that a sale was not possible in the fall of 1998 because there were outstanding issues that needed to be resolved before a sale could occur. (D.I. 111 at p. 7). Merck contends that there could be no sale until toxicology tests were performed, intellectual property and regulatory matters were resolved, and liability apportionment was determined. (*Id.* at p. 8). Dr. Buchholz testified that it was industry standard to include safety information, liability apportionment, and intellectual property rights in a sale agreement. (Tr. 2750:19-2751:17). Merck argues that industry practice is a relevant consideration to determining whether there has been an offer for sale. (D.I. 111 at p. 8 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1348 (Fed. Cir. 2003))).

Merck further argues that contemporaneous documentary evidence confirms that neither Weider nor Merck believed that there was a binding sale or offer at the time. (*Id.*). On January 6, 1999, there was an internal Weider email exchange regarding MTHF. A Weider employee wrote, "we had indicated an interest for 2Kg" of MTHF and asked for clarification on the order status. (PTX094). Preston Zoller forwarded the email to Dr. Bucci and another Weider employee. He noted that "Merck wasn't expecting us to buy any immediately" and "there wouldn't be any dire consequences to cancelling the P.O., (if one exists) until such time as a new

5-MTHF product is actually approved for launch." (*Id.*). Merck argues that this exchange is consistent with there being no contract in place. (D.I. 111 at p. 9). Merck contends it also shows that Weider believed regulatory approval was required before there could be a launch, which demonstrates that there were outstanding issues to resolve. (*Id.*).

A commercial "offer must be sufficiently definite that another party could make a binding contract by simple acceptance." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008). "A manifestation of willingness to enter into a bargain is not an offer if the person to whom it is addressed knows or has reason to know that the person making it does not intend to conclude a bargain until he has made a further manifestation of assent." RESTATEMENT (SECOND) OF CONTRACTS § 26 (1981). It is undisputed that the CDA remained in effect at least through January 1999. (Tr. 2817:10-16). I agree with Merck that the discussions in the fall of 1998 would not constitute a legally binding sale until reduced to writing and signed by both parties. Because a further manifestation of assent was required, the correspondence was also not an offer that could be made binding upon acceptance.

I do not think that Merck waived § 5.2. As Merck noted, if its conduct were sufficient to waive § 5.2, that section would serve no purpose. The testimony at trial demonstrated that the parties understood that a signed agreement was necessary. In addition, contemporaneous evidence showed that Merck considered the discussions to be an indication of interest.

I also think that industry-standard terms were missing from the communications. It seems to me that determining liability apportionment for a potentially dangerous new drug would be very important to a sale. While an offer can sometimes be sufficiently definite with only the terms present in the September communications, which terms are necessary should be considered in light of the product. I do not think that the communications were sufficiently definite to

constitute an offer given that important safety and liability terms, which Dr. Buchholtz testified were standard in the industry, were missing.

In sum, there was not a commercial offer or sale of MTHF that would invalidate the '168 patent under the on-sale bar.

## II. ANTICIPATION

### A. Legal Standard

"To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010). "[E]very element of the claimed invention [must be described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). As with infringement, the court construes the claims and compares them against the prior art. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010).

### B. Findings of Fact

1. Different crystal structures of the same chemical entity are polymorphs.
2. A hydrate is a crystalline solid where water is a part of the structure.
3. The Type I crystal is the only currently known pentahydrate polymorph of MTHF.
4. Powder x-ray diffraction ("PXRD") is a method of determining whether a substance has a crystalline content.

5. PXRDs of crystalline substances have features, or peaks, at given two theta values.
6. PXRDs of amorphous substances show less defined, broader humps.
7. Dr. Marsden's and Dr. Rogers's experiments did not follow the procedure in U.S. Patent No. 5,350,850 ("the '850 patent").

**C. Conclusions of Law**

Watson argues that claim 4 of the '168 patent is anticipated by the '850 patent. (D.I. 108 at p. 18). Watson maintains that Example 3 of the '850 patent details a method of obtaining a crystalline pentahydrate of MTHF ("the '850 product"). (*Id.*). Watson argues that the Patent and Trademark Office examiner found that the '850 product was a pentahydrate of MTHF. (DTX 001 at pp. 216-17). Specifically, the examiner found that the '850 product had a moisture content of 15.27%, which corresponds to a pentahydrate. (*Id.*). Watson argues that Type I crystals are the only known crystalline pentahydrate of MTHF. (*Id.*). Watson's expert, Dr. Rogers, testified that it was "highly unlikely" that there is an undiscovered polymorph of MTHF. (Tr. 2428:14-18).

Watson further argues that the two theta values recited in claim 4 are inherently present in the '850 product. (D.I. 108 at p. 19). Watson notes that Dr. Rogers received a sample of MTHF from Dr. Marsden (Material 1), confirmed it was amorphous using PXRD, and performed the recrystallization process taught by the '850 patent. (*Id.* at p. 25). Dr. Rogers tested the resulting products (Materials 2 and 3) and found that they exhibited all four two theta values recited in claim 4. (*Id.*).

Merck argues that the '850 product is not a Type I crystal. (D.I. 111 at p. 17). Merck maintains that the '850 product is "practically insoluble," whereas the Type I crystal is "sparingly soluble." (*Id.*). "Practically insoluble" and "sparingly soluble" are terms of art understood by

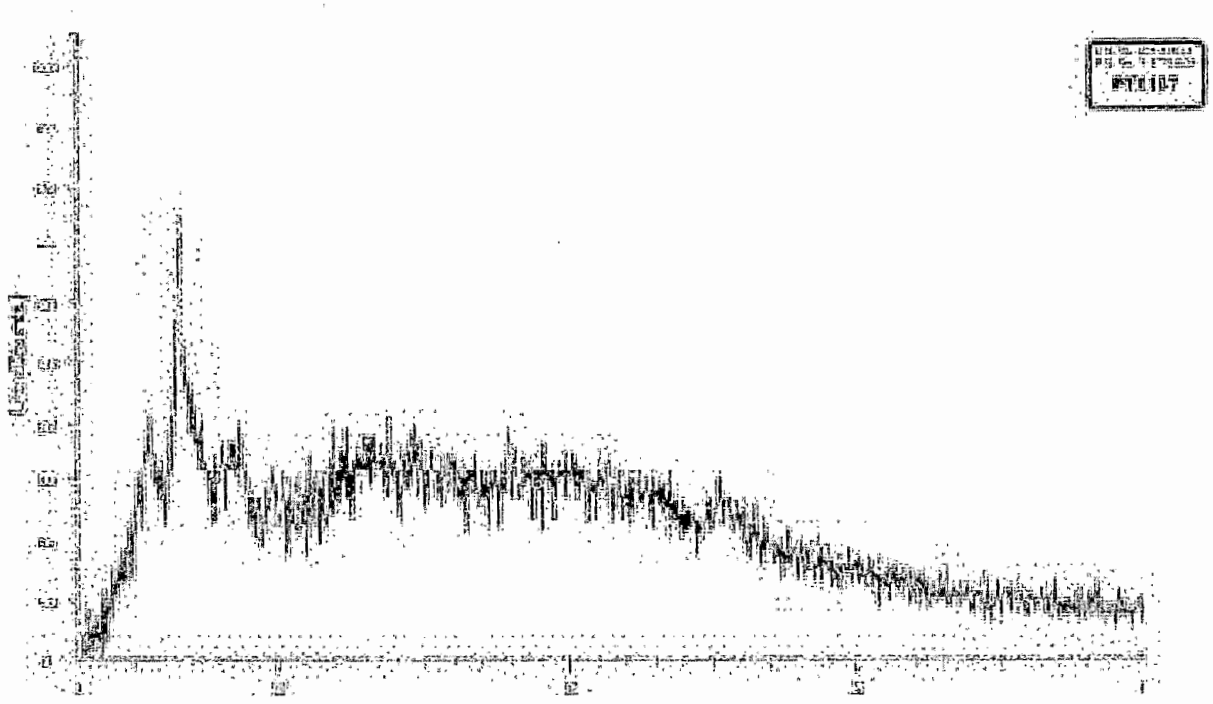
persons of ordinary skill. (*Id.* at 20). The USP defines "practically insoluble" as less than 0.001% solubility. (PTX195 at p. 6). The USP defines "sparingly soluble" as approximately 1% solubility. (*Id.*). Merck argues that the '850 product cannot be the Type I crystal because the Type I crystal is one hundred times more soluble than the '850 product. (D.I. 111 at p. 20).

Merck further argues that it is possible that there are undiscovered polymorphs of MTHF. Watson therefore cannot prove that the '850 product is the claimed invention based solely on the fact that it is a pentahydrate of MTHF. (*Id.* at p. 21). Merck contends that the company Merck hired to look for new MTHF polymorphs noted that further testing "may reveal other unknown modifications with varying water contents." (*Id.* at p. 22 (quoting DTX302 at 25)). It notes that new polymorphs are often discovered years after a substance has been in use. (*Id.*).

In addition, Merck maintains that Watson cannot show that following the '850 procedure results in a product with the two theta values recited in claim 4 because Watson's experts did not follow the '850 process. (*Id.* at p. 23). Dr. Marsden prepared Material 1 using a different process than the '850 process. Dr. Rogers therefore recrystallized a different material than that produced by the '850 process. Merck argues that a prior art process can only inherently anticipate if the claimed invention inevitably occurs when the prior art procedure is "faithfully followed." (*Id.* at p. 24 (quoting *Valeant Int'l (Barbados) SRL v. Watson Pharm., Inc.*, 2011 WL 6792653, at *5 (S.D. Fla. Nov. 8, 2011), *aff'd sub nom. Valeant Int'l Bermuda v. Actavis, Inc.*, 534 F. App'x 999 (Fed. Cir. 2013))). Because Dr. Rogers and Dr. Marsden did not follow the procedure, Merck argues that Dr. Rogers's experiment is not probative of what the '850 procedure would inevitably produce. (*Id.*).

Merck further argues that, even if Dr. Rogers's experiment were relevant, its results would be invalid because Material 1 was seeded with Type I crystals. (*Id.* at p. 26). Seeding is

adding a small amount of a crystal form to a sample to facilitate the formation of that type of crystal. (*Id.*). Merck notes that seeding does not need to be intentional, and can occur through inadvertent contamination. (*Id.*). Merck argues that Dr. Myerson's PXRD testing found that Material 1 was seeded with Type I crystals. (*Id.*). Dr. Myerson's PXRD of Material 1 showed a large, defined peak at 6.5. (*Id.*). Merck argues that the peak at 6.5 is the characteristic peak of Type I crystals. (*Id.*). Dr. Myerson's PXRD (PTX167) is below:



I find that the '850 patent does not anticipate claim 4. The '850 product and the Type I crystal have different solubilities, which is not consistent with them being the same product. In addition, I think Dr. Rogers's experiment fails to show inherent anticipation. As shown above, the PXRD has a distinct feature at 6.5. I think that Dr. Myerson's testimony that the peak demonstrates that Material 1 was seeded with a crystalline substance was credible.[2] Dr.

[2] I do not mean to imply that Watson purposefully attempted to manipulate the experiment. Seeding can occur inadvertently.

Myerson noted that those of skill in the art look for the biggest characteristic peak when searching for a substance in a mixed sample. (*Id.* at 1222:18-22). Dr. Rogers agreed that, when a sample has impurities, not all peaks will be visible. (Tr. 2453:4-10). Therefore, the fact that only the 6.5 peak is visible does not mean that Type I crystal was not present in Material 1. Dr. Rogers explained the peak by arguing that calcium salts of long molecules often have a peak at a low two theta value. (Tr. 2273:6-8). This argument, however, is unsupported by the evidence.

I also agree with Merck that an experiment that did not follow the '850 procedure is not probative of what would inevitably occur if the '850 procedure were followed. This Court has previously held that experiments that do not follow the prior art procedure alleged to inherently anticipate cannot show inherent anticipation. *In re Armodafinil Patent Litig. Inc. (%2C722 Patent Litig.)*, 939 F. Supp. 2d 456, 478-79 (D. Del. Mar. 30, 2013).

## III. OBVIOUSNESS[3]

### A. Legal Standard

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007).

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill

[3] Though Watson did not technically waive its obviousness and written description arguments, its post-trial briefing suggests that it gives little weight to those defenses. (*See* D.I. 108 (fewer than two pages for each argument), D.I. 105 (no obviousness argument and fewer than two pages on written description)).

in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *KSR*, 550 U.S. at 406 (internal citation omitted).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

**B. Findings of Fact**

1. The level of ordinary skill in the art is either (1) a person with a bachelor's degree in chemistry, chemical engineering, or a related field and at least three years of experience in the pharmaceutical industry doing crystallization or other tasks involving solid state form or (2) a person with an advanced degree in chemistry, chemical engineering, or a related field.
2. Different polymorphs of a substance have different chemical properties.
3. Crystalline calcium MTHF was a desired product with known therapeutic benefits.
4. There was motivation in the industry to find and characterize new crystalline polymorphs of MTHF.
5. Discovering an unknown polymorph is a process of trial and error.
6. Dr. Rogers testified that there was no evidence of industry acclaim with respect to the invention.

**C. Conclusions of Law**

Watson argues that claim 4 is obvious in light of the '850 patent alone or in combination with U.S. Patent No. 5,006,655 ("the '655 patent"). (D.I. 108 at p. 28). The '655 patent discloses the pentahydrate calcium MTHF. (Tr. 2834:3-6). Watson argues that a person of skill in the art would have a reasonable expectation of producing Type I crystals by combining the pentahydrate calcium MTHF with the recrystallization process taught in the '850 patent. (D.I. 108 at p. 28). Watson maintains that crystalline MTHF was known and preferred, and there was motivation in the industry to find and characterize crystalline forms. (*Id.*).

Merck argues that there was not a reasonable expectation of success of producing Type I crystals because discovering an unknown polymorph is a process of trial and error. (D.I. 111 at p. 28). Merck maintains that there cannot be a reasonable expectation of success where a process is "complicated, unpredictable, and largely conducted through trial and error." (*Id.* (quoting *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 971 (Fed. Cir. 2014))). Both Dr. Rogers and Dr. Myerson testified that finding an unknown polymorph is an unpredictable process of trial and error. (Tr. 2478:18-21, 2629:17-2630:7).

There was no post-trial briefing with respect to secondary considerations, and minimal testimony. I find that no secondary considerations have been proven.

Watson has not demonstrated that a person of skill in the art would have a reasonable expectation of success of producing Type I crystals in light of the prior art. For the reasons discussed above, the '850 patent does not anticipate claim 4. Adding the pentahydrate calcium MTHF disclosed in the '655 patent does not render the claim obvious. Both sides' experts agree that finding an unknown polymorph requires experimentation. While there may have been a motivation to discover new crystalline polymorphs of MTHF, doing so would have required a

process of trial and error. There was therefore no reasonable expectation of success of finding Type I crystals.

## IV. WRITTEN DESCRIPTION

### A. Legal Standard

The written description "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.Cir.2010) (en banc). The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* This requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.*

### B. Findings of Fact

1. The level of ordinary skill in the art is either (1) a person with a bachelor's degree in chemistry, chemical engineering, or a related field and at least three years of experience in the pharmaceutical industry doing crystallization or other tasks involving solid state form or (2) a person with an advanced degree in chemistry, chemical engineering, or a related field.

### C. Conclusions of Law

Watson argues that claim 4 lacks written description because the specification does not disclose any information from which a person of skill could conclude that the inventors possessed an MTHF polymorph with one water of crystallization, *i.e.*, a monohydrate. (D.I. 108 at pp. 29-30). Claim 4 calls for MTHF with "at least one" water of crystallization. ('168 patent, col. 10, l. 60). Dr. Rogers testified that the specification does not show that the inventors possessed MTHF with one water of crystallization. (Tr. 2370:3-9).

Merck responds that the patent states, "the Type I modification typically contains ≧3 equivalents of water." (D.I. 111 at p. 30 (quoting '168 patent, col. 2, ll. 15-16)). "Typically" is not limiting, meaning that sometimes Type I crystals have fewer than three waters of crystallization. (Tr. 2852:8-10, 2853:18-20).

I agree with Merck. A specification is not required to describe each and every embodiment of a claim. Disclosing that the Type I crystal typically has greater than three waters of crystallization does not indicate that it never has fewer.

## CONCLUSION

Watson did not prove by clear and convincing evidence that claim 4 of the '168 patent is invalid. Merck is directed to submit an agreed upon final judgment within two weeks.