IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	Civil Action No. 14-1382-RGA
ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and BARR LABORATORIES, INC., Defendants.	Civil Action No. 14-1389-RGA

TRIAL OPINION

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October 7, 2016

ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs brought these patent infringement actions against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal"), Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively, "Teva") in 2014. (D.I. 1).[1] On April 3, 2012, Amneal filed an Abbreviated New Drug Application ("ANDA"), seeking to engage in the commercial manufacture, use, and sale of generic versions of Endo's Opana ER CRF product.[2] (D.I. 130, Ex. 1 ¶ 14). Teva filed an ANDA on April 17, 2012, with amendments on May 4, 2012 and September 20, 2012, seeking to do the same. (*Id.* ¶ 16). Plaintiffs allege that these ANDAs infringe U.S. Patent No. 8,871,779 ("the '779 patent").

These cases concern two molecules. The first is 14-hydroxydihydromorphinone, also referred to as "oxymorphone" or "oxymorphone HCl."[3] The other is 14-hydroxymorphinone, also referred to as "oxymorphone ABUK." ABUK stands for alpha,beta-unsaturated ketone, an organic compound having a double bond between the ketone's alpha and beta carbons.

Oxymorphone HCl was first patented in 1955 and first approved by the FDA in 1959. (Trial Transcript ("Tr.") at 86:1-5, 11-14). Prior to 2002, manufacturers of oxymorphone HCl were aware of the presence of the impurity now known as oxymorphone ABUK. (Tr. at 229:9-230:4; *see also* JTX-23). During the period before 2002, manufacturers regularly sold oxymorphone HCl with oxymorphone ABUK levels in the range of hundreds of parts per million ("ppm"). (Tr. at 229:9-230:4). In 2002, the FDA informed Mallinckrodt and several other manufacturers that it was concerned about the levels of ABUK in certain products. (Tr. 217:9-

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[1] Unless otherwise indicated, all docket citations, except those in the implied license section, are to C.A. No. 14-1382. In the section on implied license, docket citations are to C.A. No. 14-1389.

[2] "CRF" stands for "crush-resistant formulation." (Tr. 614:16-20).

[3] Oxymorphone and oxymorphone HCl are actually different compounds, in that the latter is a salt formed when chloride is added. In this opinion, however, they are used interchangeably, as the key distinction in this case is between oxymorphone ABUK and oxymorphone without the ABUK double bond.

218:22). The FDA informed Mallinckrodt that it intended to impose limits on the levels of ABUK, and that it might require limits as low as 0.001 percent (or 10 ppm) ABUK. (Tr. 110:19-111:21, 218:7-18). In 2004, the FDA mandated that opioid manufacturers lower the levels of ABUK in opioid pharmaceuticals to less than 10 ppm. (Tr. 199:10-201:20, 218:7-18). In these cases, oxymorphone HCl which contains less than 10 ppm of oxymorphone ABUK—and thus complies with FDA's mandate—is called "low-ABUK oxymorphone."

In 2005, Mallinckrodt succeeded in reaching the low ABUK levels mandated by the FDA for oxymorphone HCl. Mallinckrodt applied for a patent on its new low-ABUK oxymorphone product. The application ultimately issued as the '779 patent. The asserted claims of the '779 patent[4] are all composition claims directed to low-ABUK oxymorphone. (Tr. 88:22-89:8, 111:13-21; DTX-17 at 37:58-38:61).

Independent claim 1 of the '779 patent reads:

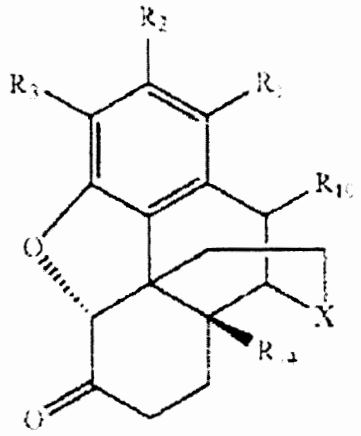
> A hydrochloride salt of oxymorphone comprising less than 0.001% of 14-hydroxymorphinone.

(DTX-17 at 37:58-59). Dependent claim 2 limits the level of 14-hydroxymorphinone to less than 0.0005%. (*Id.* at 37:60-61). Dependent claim 3 claims a pharmaceutically acceptable form of the hydrochloride salt in claim 1. (*Id.* at 37:62-63). Independent claim 4 reads:

> A hydrochloride salt of a morphinan-6-one compound corresponding to Formula (2):

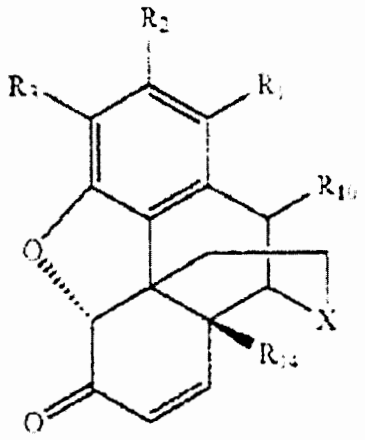
[4] Plaintiffs assert that all six claims of the '779 patent are infringed.

(2)



comprising less than 0.001% measured by HPLC of an α,β-unsaturated ketone compound corresponding to Formula (3):

(3)



wherein the morphinan-6-one compound is oxymorphone and wherein X is —N(R_{17})—;
R_1 and R_2 are hydrogen;
R_3 is hydroxy;
R_{10} is hydrogen;
R_{14} is hydroxy; and
R_{17} is methyl.

(*Id.* at 38:16-57). Dependent claim 5 limits the level of 14-hydroxymorphinone to 0.0005%. (*Id.* at 38:58-59). Dependent claim 6 claims a pharmaceutical formulation of the oxymorphone chloride in claim 4. (*Id.* at 38:60-61).

The Court held a bench trial on July 11-13, 2016. Both Amneal and Teva concede that their proposed products meet all the limitations of the '779 patent. (D.I. 150, Ex. 1 ¶¶ 18-20). Teva contends, however, that because it obtained an implied license from Mallinckrodt, it does not infringe. Both defendants argue that the '779 patent is invalid as obvious.

I. OBVIOUSNESS

A. Legal Standard

A patent claim is invalid as obvious under 35 U.S.C. § 103 "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 at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007). The determination of obviousness is a question of law with underlying factual findings. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1359-60 (Fed. Cir. 2012). "The underlying factual inquiries include (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations . . . ." *Western Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 (Fed. Cir. 2010) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

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). Relevant secondary considerations include commercial success, long felt but unsolved needs, failure of others, praise, unexpected results, and copying, among others. *Graham*, 383 U.S. at 17-18; *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662–63 (Fed.

Cir. 2000); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

A party asserting that a patent is invalid as obvious must "show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). That "expectation of success need only be reasonable, not absolute." *Id.* at 1364. "Whether an ordinarily skilled artisan would have reasonably expected success . . . . is measured as of the date of the invention[] . . . ." *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1362 (Fed. Cir. 2009).

B. Findings of Fact

1. The level of ordinary skill in the art is either (1) a person with a Ph.D. degree in medicinal chemistry, organic chemistry or a related discipline, and at least a few years of experience in synthetic organic chemistry; or (2) a person with a lesser degree in one of those fields, but with commensurately greater experience.

2. Weiss and Chapman are prior art.

3. Neither Weiss nor Chapman teach a person of ordinary skill that catalytic hydrogenation could be used to create low-ABUK oxymorphone.

4. There was no simultaneous invention of low-ABUK oxymorphone.

5. Low-ABUK oxymorphone would not have been obvious to one of ordinary skill in the art.

C. Conclusions of Law

Defendants contend that the low-ABUK oxymorphone claimed in the '779 patent would have been obvious to one of ordinary skill in the art. Specifically, Defendants argue that an ordinary-skilled artisan would have had a reasonable expectation of success in using catalytic hydrogenation to convert oxymorphone ABUK to oxymorphone HCl, thereby lowering the level of oxymorphone ABUK to below 10 ppm. Defendants rely on Weiss, a paper published in 1957, to demonstrate that a person of ordinary skill would understand that hydrogenation could be used to convert oxymorphone ABUK to oxymorphone HCl. (JTX-23). Defendants also rely on Chapman, a 2005 patent application which claims priority to a provisional application filed on March 30, 2004. (DTX-97; DTX-137). Defendants argue that the real-world experiment described in Chapman "corroborates" the expectation of success instilled by Weiss.[5]

The parties generally agree that the person of ordinary skill to whom the '779 patent is directed is a person with "a Ph.D. degree in medicinal chemistry, organic chemistry or a related discipline, and at least a few years of experience in synthetic organic chemistry" or a person with a lesser degree in one of those fields, but with greater experience. (Tr. 361:2-15, 67:19-68:22; D.I. 143 at p. 9 n.3). Plaintiffs' expert, Dr. Davies, opined that the person of ordinary skill would "also need [experience with] process chemistry involving natural products or compounds of

[5] In post-trial briefing, Defendants also rely on U.S. Patent No. 7,851,482 ("the Dung reference"). (DTX-100; *see, e.g.*, D.I. 139 at 22). Plaintiffs have moved to strike all discussions of Dung. (D.I. 183). At trial, Defendants sought to move Dung into evidence. (Tr. 113:5-114:1). Plaintiffs objected on the grounds that Dr. Heathcock had provided "nothing substantive about the document" in his report. (Tr. 114:2-7). The Court admitted the document into evidence for the limited purpose of "show[ing] that it really exist[ed]." (Tr. 114:15-19). There was no testimony about Dung during trial. Thus, Plaintiff's arguments regarding Dung are completely unsubstantiated by the trial record. Further, they seek to use evidence admitted for one purpose for an entirely different purpose, in violation of Fed. R. Civ. P. 105. Plaintiffs' motion to strike (D.I 149; C.A. No. 14-1389, D.I. 183) is therefore GRANTED.

related complexity." (Tr. 361:15-22). I do not think this addition makes a difference. In determining obviousness, I considered the person of ordinary skill upon which the parties agreed.

i. Scope and Content of the Prior Art

1. Weiss

Weiss generally describes the process of hydrogenating oxymorphone ABUK, thereby converting it into oxymorphone HCl. Weiss does not provide the all of the reaction conditions required to reproduce the described reaction. (Tr. 174:11-175:6, 347:20-22, 388:24-389:14, 390:21-391:11; *see also* JTX-23 at 1507). Specifically, Weiss lacks details about hydrogen pressure, amount of acid, amount and composition of catalyst, and reaction time.[6] (*Id.*). It is undisputed that Weiss does not provide any information about the level of oxymorphone ABUK or other impurities remaining after hydrogenation. (Tr. 107:22-108:11, 380:11-15, 389:15-21; *see* also JTX-23 at p. 1507). Further, analytical methods available at the time of Weiss would only have been able to determine the remaining ABUK levels in the hundreds of ppm. (Tr. 145:18-22, 380:11-15). Between the publication of Weiss in 1957 and the date of invention in 2005, no other prior art reference mentioned oxymorphone ABUK. (Tr. 146:22-147:19).

2. Chapman

The Chapman reference is a United States patent application filed on March 30, 2005. The parties dispute whether the Chapman reference is prior art. Defendants argue that Chapman qualifies as 35 U.S.C. § 102(e) prior art. That section provides that an invention described in an application for a U.S. patent filed before the invention under review is prior art. Since § 102(e) requires that the application predate "the invention," a patentee may "swear behind" a potential §

[6] The parties agree that Weiss lacks these parameters. Defendants' expert, Dr. Heathcock, opines that these could all be determined based on routine experimentation. (Tr. 213:3-215:23, 316:22-317:2). Dr. Heathcock stated that they were not recited because they were so simple. (Tr. 174:11-175:6).

102(e) reference. The dispute centers on the proper date of the invention for the '779 patent's claims, and whether Chapman is entitled to the filing date of an earlier provisional application. Specifically, while the parties agree that claims 1, 2, 4, and 5 of the '779 patent are entitled to a priority date of February 2, 2005, they disagree as to whether claims 3 and 6 are entitled to that date or the date of filing—March 2, 2007. (D.I. 139 at 13; D.I. 143 at pp. 13-14). Additionally, Plaintiffs argue that Defendants have not shown that Chapman is entitled to the filing date of the provisional application—March 30, 2004.

Since I conclude that the Chapman reference does not render obvious the claims of the '779 patent, I need not resolve these questions. I will accept that Chapman is valid § 102(e) prior art, and that the date of invention for all asserted claims is February 2, 2005.

Chapman does not discuss oxymorphone. Instead, Chapman describes a process for using hydrogenation to convert 14-hydroxycodeinone ("oxycodone ABUK") into oxycodone. Chapman uses a "double hydrogenation" process. (Tr. 382:12-384:3). This process involves an initial step of hydrogenating oxycodone ABUK, resulting in oxycodone which still contains relatively high levels of oxycodone ABUK. (Tr. 127:9-128:14, 382:12-383:6; DTX-97 at fig. 1, ¶ 13). Then, the oxycodone product from the first step is hydrogenated again under specific parameters, producing oxycodone with less than 25 ppm of oxycodone ABUK. (Tr. 127:9-128:14, 383:7-20; DTX-97 ¶ 20).[7]

[7] Chapman also states that the process may reduce the levels of oxycodone ABUK to below 15 ppm, 10 ppm, or 5 ppm. (DTX-97 ¶ 16). Chapman, in an experiment called Example 2, states that two different analytical methods showed levels of oxycodone ABUK at less than 5 ppm. (Tr. 194:20-23; DTX-97 ¶¶ 189-90). In Example 3, Chapman stated that two different analytical methods showed levels of oxycodone ABUK at 5 ppm and 10 ppm, respectively. (Tr. 194:10-19; DTX-97 ¶¶ 197-98).

iii. Comparing Prior Art and Claimed Subject Matter

Defendants' expert, Dr. Heathcock, opines that a hydrogenation action, like the one described in Weiss, carried out to its completion, would eventually result in a low concentration of the initial reactant—in this case oxymorphone ABUK. (Tr. 93:2-95:1, 96:9-99:14). Specifically, Dr. Heathcock testified that the driving force of hydrogenation would strongly propel the conversion of oxymorphone ABUK into oxymorphone. (Tr. 89:9-91:3). Dr. Heathcock stated that the prior art shows that the equilibrium constant[8] of a hydrogenation reaction is on the order of 10^{20}. (Tr. 94:3-98:15; DTX-114). Thus, according to Dr. Heathcock, if the hydrogenation reaction were carried out to completion—its equilibrium—the resulting mixture would contain 5 parts per million million million of oxymorphone ABUK, a level well below the 10 ppm required by the FDA. (Tr. 93:2-95:1, 96:9-99:14). In other words, according to Dr. Heathcock, if a person of skill in the art just ran a hydrogenation reaction for a sufficient amount of time, one would ultimately end up with low-ABUK oxymorphone. To support this conclusion, Dr. Heathcock relies on an illustration involving hydrogenating cyclohexene to cyclohexane. (Tr. 97:18- 99:14). Dr. Heathcock refers to all of this as "basic chemistry." (Tr. 135:11-136:14, 137:8-12).

One problem with Dr. Heathcock's "basic chemistry" theory is that there is simply no indication, and certainly no experimental evidence, that the hydrogenation procedure described in Weiss could result in ABUK levels below 10 ppm.[9] At the time of the invention, it was "very

[8] An equilibrium constant is essentially the ratio of the concentrations of the products and reactants at equilibrium.

[9] To achieve low-ABUK oxymorphone, Mallinckrodt did not use hydrogenation. (Tr. 207:14-208:4, 211:24-213:2). Instead, Mallinckrodt used a process involving sodium bisulfite and sulfurous acid to achieve low-ABUK oxymorphone. (*Id.*). Additionally, while two other manufacturers, Noramco and Johnson Matthey, were successful in making low-ABUK oxymorphone, no evidence in the record explains how or when these companies succeeded in making it. (Tr. 237:3-238:4).

unusual" and "very, very challenging" to remove impurities like ABUK to levels below 10 ppm. (Tr. 360:1-6, 370:23-371:8). These levels were described as "remarkable." (Tr. 401:22-403:8). Further, "[t]here are very few methods that will measure such low levels." (Tr. 371:4-5).

Dr. Heathcock's "basic chemistry" theory does not account for the complexities involved in reducing ABUK levels to below 10 ppm. Oxymorphone has numerous impurities, aside from the oxymorphone ABUK, the most important of which, for purposes of this case, is oxymorphone diol. Oxymorphone diol, or 8,14-dihydroxy-7,8-dihydromorphinone, is formed when water is added to the oxymorphone ABUK. Since oxymorphone diol lacks the ABUK double bond, it, unlike oxymorphone ABUK, is not converted to oxymorphone upon hydrogenation. (Tr. 350:8-21, 351:14-24, 414:22-415:16). When the diol becomes dehydrated, it converts back into oxymorphone ABUK. (Tr. 414:15-415:11). According to Dr. Davies, this creates a problem. Generally, to create oxymorphone, one first begins with a poppy straw, which is converted into thebaine. (Tr. 152:23-153:14). Then, through an oxidizing process, the thebaine is converted into oxycodone ABUK, which is then hydrogenated to form oxycodone. (Tr. 154:5-155:10). Then, the oxycodone is O-demethylated to form oxymorphone. (Tr. 420:9-11). During oxidation, "you will produce [oxycodone] diol because you have water present with the Oxycodone ABUK." (Tr. 420:2-8). During O-demethylation, the oxycodone diol that formed will be converted in oxymorphone diol. (Tr. 420:9-421:15).

Oxymorphone diol will be converted into oxymorphone ABUK "under acid and heat." (Tr. 422:4-8; *see also* Tr. 414:15-415:11). When working-up[10] the reaction, "you filter the acidic reaction mixture." (Tr. 422:17-19). Then, during purification, "you do a crystallization which

[10] "Work[-]up is the processing of a reaction product mixture in order to remove unwanted components such as solvents and inorganic materials that may be resulting from the reaction, and to obtain the intended products, normally the organic products." (Tr. 156:21-157:3).

involves heating it in a solvent . . . .[,] [a]nd then you heat dry the product." (Tr. 422:19-22). In each stage of this process, the oxymorphone diol may regenerate the oxymorphone ABUK, even if the ABUK had previously been reduced to extremely low levels. (Tr. 422:17-423:2; *see also* 415:17-416:21, 424:24-430:20). Thus, the diol can act like a "reservoir" for regenerating oxymorphone ABUK. (Tr. 388:6-23, 415:2-11, 428:13-28). This was described at various times as the "reappearing ABUK." (*See, e.g.*, Tr. 170:2-7, 189:5-12).[11] This regeneration is significant, since the FDA requires, and the '779 patent claims, such low levels of oxymorphone ABUK.

Defendants argue that Weiss had removed the oxymorphone diol from his starting material for the hydrogenation reaction, and that it would therefore have no impact on the levels of the ABUK. Defendants rely on the statement in Weiss that "[t]he solid residue was kept at room temperature for about 24 hr. with 60 ml. acetone, which dissolved the [oxymorphone diol] present." (JTX-23 at p. 1506).

In response, Dr. Davies testified that "it's very hard to remove the Oxymorphone diol." (Tr. 416:20-21). Dr. Davies testified that the acetone wash described in Weiss—a process called trituration—would not "completely remove the compound you're trying to wash away." (Tr. 416:22-417:24). Since it is a "very crude technique," it could not be expected to completely remove the oxymorphone diol. (Tr. 417:14-418:4).

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[11] This "reappearing ABUK" problem occurred in Chapman, in the context of hydrogenating oxycodone ABUK to form oxycodone. In Example 5, oxycodone ABUK levels were undetectable before work-up, and after work-up, were measured at 11 ppm. (Tr. 426:9-427:21; DTX-97 ¶¶ 267-69). In Example 3, no oxycodone ABUK was detected after work-up, "but during the purification[,] . . . 5 or 10 ppm of ABUK have reappeared." (Tr. 427:18-428:23; DTX-97 ¶¶ 192-98).

Thus, while a person of ordinary skill would reasonably expect the Weiss hydrogenation procedure to reduce the levels of oxymorphone ABUK, a person of ordinary skill would not reasonably expect that the Weiss hydrogenation procedure to lower ABUK levels below 10 ppm.

Defendants contend that Chapman "corroborates" the hydrogenation procedure described in Weiss. (Tr. 133:19-24; *see also* Tr. 136:5-14). The Chapman hydrogenation procedure differs from Weiss in some critical respects, however. Most importantly, Chapman describes the hydrogenation of oxycodone, rather than oxymorphone. (Tr. 186:9-187:13, 382:2-11). While oxycodone and oxymorphone are both morphinan-6-ones that may form an ABUK, the evidence demonstrates that oxycodone and oxymorphone react in different ways. These differences are attributable to certain structural variations. Oxycodone and oxycodone ABUK contain anisole, a benzene ring with an OCH_3 (methoxy) group attached. (Tr. 411:1-6). Oxymorphone and oxymorphone ABUK, on the other hand, contain phenol, a benzene ring with an OH (hydroxy) group attached. (*Id.*).

Two prior art references illustrate how these structural variations result in reactivity differences. A prior art patent from 1965, U.S. Patent No. 3,193, 584 ("the '584 patent"), compares the hydrogenation of phenol with anisole. (PTX-90; Tr. 410:21-411:19). Table 1 of the '584 patent indicates that, under basic, neutral, and acidic conditions, phenol hydrogenates faster than anisole. (PTX-90; Tr. 411:1-19). This means that the six-membered ring to which the methoxy group or hydroxy group is attached, is reduced.[12] (Tr. 412:18-413:15). This reduction fundamentally changes the molecule; it ceases to be oxymorphone or oxycodone. (Tr. 413:16-

[12] In this context, a reduction occurs when each of the three double bonds in the six-membered ring is reduced to a single bond, resulting in an additional hydrogen atom bonding to each carbon atom in the ring. (*See* Tr. 412:18-413:19).

414:4). The '584 patent indicates that this is more likely to occur in oxymorphone than in oxycodone. (Tr. 412:6-17, 413:8-414:14).

In Schmidhammer, a prior art paper published in 1990, a hydrogenation reaction was performed on two ABUK molecules with similar structures to oxycodone ABUK and oxymorphone ABUK. (PTX-79). When hydrogenating these two molecules, the anisole compound yielded 92%, while the phenol compound yielded 76%. (PTX-79; Tr. 407:2-410:5). In other words, the compound similar to oxycodone ABUK hydrogenated more efficiently than the compound similar to oxymorphone ABUK. (Tr. 409:1-410:1). Dr. Davies therefore opined that a person of ordinary skill is "less likely to succeed with [the] Chapman [process] on Oxymorphone ABUK than . . . on oxycodone ABUK." (Tr. 409:21-410:1).

Dr. Davies also explained that the higher amount of diol present in oxymorphone would lead an ordinary-skilled artisan to believe that hydrogenation of oxymorphone ABUK would be less effective than hydrogenation of oxycodone ABUK. Dr. Davies refers to oxymorphone diol as an ABUK precursor, since it is formed by adding water to the ABUK double bond, and can convert back into ABUK when dehydrated. (Tr. 414:15-415:8). Weiss explains that, in alkaline solution, oxymorphone ABUK is converted to oxymorphone diol "with unexpected ease." (JTX-23 at p. 1507; Tr. 168:4-10, 169:8-170:7). In other words, oxymorphone diol is "produced very, very easily from Oxymorphone ABUK." (Tr. 418:5-14). On the other hand, oxycodone ABUK hydrates to form oxycodone diol "much less readily than" oxymorphone ABUK hydrates to form oxmorphone diol. (JTX-23 at p. 1506; Tr. 170:8-171:2, 405:7-407:1). As explained previously, the oxymorphone diol "act[s] like a reservoir for regenerating ABUK." (Tr. 388:6-23, 428:13-28). Therefore, "ABUK precursors"—the oxymorphone diols—would "just . . . regenerate ABUK at the end of the day." (Tr. 436:5-16).

Weiss does not, on its own, disclose low-ABUK oxymorphone. (Tr. 380:6-15). That is, it does not teach that the hydrogenation procedure described would result in the low-ABUK oxymorphone claimed in the '779 patent. "Although published subject matter is 'prior art' for all that it discloses, in order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method."[13] *In re Kumar*, 418 F.3d 1361, 1365 (Fed. Cir. 2005) (quoting *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989)); *see also In re Payne*, 606 F.2d 303, 314-15 (C.C.P.A. 1979). Since Weiss does not disclose low-ABUK oxymorphone, Defendants must "establish that a person of ordinary skill would have nonetheless been able to make [the claimed invention]." *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1303 (Fed. Cir. 2010); *see also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1365 (Fed. Cir. 1998). If the Weiss hydrogenation procedure would not actually produce low-ABUK oxymorphone, it cannot be said that the prior art enables those of skill in the art to make low-ABUK oxymorphone. While Dr. Heathcock opines that the hydrogenation would result in the claimed invention, Dr. Davies opines that an experiment would be required to verify that prediction. (Tr. 94:3-99:14, 389:22-390:4). Dr. Heathcock did not run any experiments to confirm that a hydrogenation process would indeed result in low-ABUK oxymorphone. (Tr. 151:1-8, 174:4-10, 390:5-391:11). Therefore, Defendants have failed to show that a person of ordinary skill in the art could make low-ABUK oxymorphone using hydrogenation.

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[13] "Under § 103, . . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003); *see also Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) ("While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103."); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) ("Even if a reference discloses an inoperative device, it is prior art for all that it teaches."). Whether the prior art enables one skilled in the art to produce the claimed invention is, however, a different question.

Even if the Weiss hydrogenation procedure could produce low-ABUK oxymorphone, however, Defendants would still have much of their work ahead of them. The prior art must actually "suggest to one of ordinary skill in the art how to [make the claimed apparatus] with a reasonable likelihood of success." *Rockwell*, 147 F.3d at 1365. Neither Weiss, nor Chapman, disclose low-ABUK oxymorphone. Additionally, Defendants have not proven that the combination of those references would enable a person of ordinary skill to make low-ABUK oxymorphone with a reasonable expectation of success. *See Geo. M. Martin*, 618 F.3d at 1303; *Rockwell*, 147 F.3d at 1365. In fact, the Chapman inventors, when seeking to lower ABUK levels in oxycodone, found that a single hydrogenation reaction was insufficient to reach the desired ABUK levels. (Tr. 396:5-397:6; *see also* Tr. 32:2-384:3). "[T]here can be little better evidence negating an expectation of success than actual reports of failure." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003). Although the Chapman inventors succeeded in creating low-ABUK oxycodone with a double hydrogenation process, due to the differences between oxycodone and oxymorphone, that would not suggest to a person having ordinary skill that the same process would have been effective in creating low-ABUK oxymorphone. (Tr. 403:2-13, 414:5-14). Thus, Defendants have not shown that a person of ordinary skill "would have had a reasonable expectation of success in" "achiev[ing] the claimed invention . . . ." *Pfizer*, 480 F.3d at 1361.

Defendants discuss, at length, the Federal Circuit's recent decision in *Purdue Pharma L.P. v. Epic Pharma., LLC*, 811 F.3d 1345 (Fed. Cir. 2016). To the extent the conclusions in *Purdue* are relevant to this case,[14] they do not suggest that low-ABUK oxymorphone would have

[14] Defendants repeatedly cite to facts described in *Purdue*. This is improper. "The reports of [decisions] may be referred to as expositions of law upon the facts there disclosed, but they are not evidence of those facts in other cases." *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1570 (Fed. Cir. 1993) (alteration in original) (quoting *MacKay v. Easton*, 86 U.S. (19 Wall.) 619, 632 (1873)).

been obvious to one of ordinary skill in the art. In *Purdue*, the patentee—in applications which continued from Chapman—claimed low-ABUK oxycodone. "The district court found that the prior art taught that oxidation of thebaine produced [oxycodone ABUK] and that it was well known in the art that [oxycodone ABUK] could be removed using hydrogenation." *Id.* at 1351. The patentee, in arguing for the patent's validity, argued that the discovery of the source of oxycodone ABUK—the 8α isomer of oxycodone diol—rendered its solution non-obvious. The Federal Circuit confirmed that the discovery of 8α as the source of the ABUK was not necessary to the claimed invention, which was directed to low-ABUK oxycodone as an end product. "One need not know that the [oxycodone ABUK] was derived from 8α" to know that it was obvious to use hydrogenation to remove the oxycodone ABUK. *Id.* at 1353.

I fail to see the relevance of *Purdue Pharma*. Purdue's validity position hinged on discovering the source of the oxycodone ABUK. Plaintiffs here make no analogous argument. Additionally, the Federal Circuit's conclusion that low-ABUK oxycodone was obvious does not command a conclusion that low-ABUK oxymorphone is obvious. As stated above, the evidence reveals significant differences between oxycodone and oxymorphone, such that an ordinary-skilled artisan would not reasonably expect that what had been successful with oxycodone would have been successful with oxymorphone.

I conclude that Defendnats have failed to make a *prima facie* showing that the '779 patent would have been obvious to one of ordinary skill in the art.

iv. Secondary Considerations

"[S]econdary considerations, when present, must be considered in determining obviousness." *Ruiz*, 234 F.3d at 667; *see also Cyclobenzaprine*, 676 F.3d at 1076 ("[E]vidence on these secondary considerations is to be taken into account *always*, not just when the

decisionmaker remains in doubt after reviewing the art." (internal quotation marks omitted) (quoting *Cable Elec. Prods. v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985))). Here, Plaintiff did not present any evidence on any secondary considerations. Defendants, however, argue that there is evidence of near-simultaneous invention by others in the industry. "Independently made, simultaneous inventions, made 'within a comparatively short space of time,' are persuasive evidence that the claimed apparatus 'was the product only of ordinary mechanical or engineering skill.'" *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1305 (Fed. Cir. 2010) (quoting *Concrete Appliances Co. v. Gomery*, 269 U.S. 177, 184 (1925)).

Defendants assert that Chapman's invention of low-ABUK oxycodone through a process involving hydrogenation is a "near-simultaneous invention." (D.I. 139 at 35; DTX-97 ¶¶ 185-90). Since low-ABUK oxycodone is not low-ABUK oxymorphone, I do not think there is any evidence of simultaneous invention. Thus, there are no secondary considerations to be contemplated here.

Having considered the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art, I conclude that Defendants have not carried their burden of showing that "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 at the time the invention was made to a person having ordinary skill in the [pertinent] art." 35 U.S.C. § 103.

II. IMPLIED LICENSE

Teva concedes that its ANDA meets every limitation of the asserted claims of the '779 patent, but maintains, as an affirmative defense, that Plaintiffs' infringement claims are barred by its implied license defense. (D.I. 150 ¶ 16).

A. Legal Standard

"[A]n implied license, like an express license, is a defense to patent infringement." *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 878 (Fed. Cir. 1995). A license may be inferred based on "[a]ny language used by the owner of [a] patent, or any conduct on his part exhibited to another from which that other may properly infer that the owner consents to his use of the patent in making or using it, or selling it . . . ." *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997) (quoting *De Forest Radio Tel. Co. v. United States*, 273 U.S. 236, 241 (1927)). The Federal Circuit has acknowledged that there are "various avenues to an implied license." *Id.* "[I]mplied licenses arise by acquiescence, by conduct, by equitable estoppel (estoppel in pais), or by legal estoppel." *Id.* "[J]udicially implied licenses are rare under any doctrine." *Id.* at 1581.

In *Wang Laboratories*, the Federal Circuit confirmed the existence of an implied license where:

> the jury necessarily found that (1) a relationship existed between [the parties], (2) within that relationship, [the patentee] granted to [the accused infringer] a right to use its . . . inventions, (3) [the patentee] received valuable consideration for that grant of right, (4) [the patentee] denied that [the accused infringer] had an implied license, and (5) [the patentee's] statements and conduct created the impression that [the patentee] consented to [the accused infringer] making, using, or selling [the] patented inventions . . . .

Id. at 1579. "Courts grant implied licenses to preclude patent holders from suing purchasers for infringement where, at the time of sale, the patentee led the purchaser to believe that his manufacture, use, or sale of the patented article was permissible." *Monsanto Co. v. Good*, 2004

WL 1664013, at *7 (D.N.J. July 23, 2003). "A mere sale," however, "does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred." *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 (Fed. Cir. 1984). "[T]he alleged infringer . . . ha[s] the burden of establishing the existence of an implied license as an affirmative defense." *Carborundum*, 72 F.3d at 878. Whether an implied license exists, based on the underlying facts, is a question of law. *Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343, 1348 (Fed. Cir. 2003).

B. Factual Background

Teva and Mallinckrodt, in 2008, entered into a supply agreement for the supply of non-low-ABUK oxymorphone to Teva. (D.I. 154 ¶ 7).[15] That agreement expired in 2009. (*Id.*). In late 2010 and early 2011, Teva purchased two batches of low-ABUK oxymorphone API[16] from Mallinckrodt pursuant to stand-alone purchase orders. (*Id.* ¶¶ 11-12). Those purchase orders were dated October 31, 2010 and February 3, 2011, respectively. (*Id.*). Mallinckrodt shipped the requested quantities of low-ABUK oxymorphone API, and Teva paid Mallinckrodt the amount due. (*Id.* ¶¶ 13-14). Since those purchase orders, Teva has not purchased any low-ABUK oxymorphone API from Mallinckrodt. (*Id.* ¶ 16).

Mallinckrodt maintains a Drug Master File ("DMF") with the FDA, which contains confidential and proprietary information about its low-ABUK oxymorphone API. (D.I. 154 ¶ 17). This DMF is numbered 14502. (D.I. 154 ¶ 17). In February 2012, Teva requested a Letter

[15] For the implied license phase of the trial, the parties submitted a joint stipulation of facts. (D.I. 154). Since the underlying facts material to Teva's implied license defense are not in dispute, the stipulation is adopted as the Court's findings of fact.

[16] API means "active pharmaceutical ingredient." (D.I. 154 ¶ 1). Mallinckrodt is in the business of, among other things, manufacturing and selling API for use in pharmaceutical products. (*Id.*). Teva is in the business of, among other things, manufacturing and selling finished dosage forms which contain API. (*Id.* ¶ 3).

of Authorization ("LOA") for low-ABUK oxymorphone API from Mallinckrodt. (D.I. 154 ¶ 18). On March 8, 2012, Mallinckrodt sent a copy of an LOA for low-ABUK oxymorphone API to Teva. (D.I. 154 ¶ 20; DTX-501). This LOA allowed the FDA to review, in connection Teva's ANDA filing, the information contained in Mallinckrodt's DMF, without Mallinckrodt having to share that information with Teva. (Tr. 564:2-13; 694:1-695:2). In other words, the LOA provided a mechanism whereby Teva could cross-reference information about Mallinckrodt's low-ABUK oxymorphone API in its ANDA, without Mallinckrodt having to reveal that information to Teva. As explained by Teva's industry expert, Dr. Fabian, the LOA accomplished two things: (1) Mallinckrodt authorized Teva to incorporate by reference the information from its DMF into an ANDA, and (2) Mallinckrodt authorized the FDA to review its DMF when considering Teva's ANDA application. (Tr. 703:17-704:3). Mallinckrodt only knew that Teva sought to use DMF No. 14502 in a product; it did not know the particular product for which Teva sought the LOA. (Tr. 748:23-749:15).

On April 17, 2012, Teva submitted an ANDA to the FDA, requesting approval for its generic version of Endo's Crush-Resistant Formulation of Opana ER ("Teva CRF ANDA"). (D.I. 154 ¶ 22). Teva incorporated DMF No. 14502 into the Teva CRF ANDA. (*Id.* ¶ 24). Mallinckrodt is the only supplier of low-ABUK oxymorphone API referenced in the Teva CRF ANDA. (*Id.* ¶ 25). Teva has the ability, however, to amend its ANDA to qualify additional suppliers of low-ABUK oxymorphone API. (*Id.* ¶ 26).

In August 2012, Mallinckrodt and Teva began negotiating a supply agreement for low-ABUK oxymorphone API. (D.I. 154 ¶ 30). On August 3, 2012, Ayne Klein of Teva sent Stephanie Bucalo and Nick Litzsinger of Mallinckrodt a draft supply agreement via email. (*Id.* ¶ 31; JTX-300; JTX-301). Mr. Litzsinger, on September 5, 2012, emailed Ms. Klein a counter-

proposal. (D.I. 154 ¶ 32; JTX-302; JTX-303). Teva did not respond with any further proposals. (D.I. 154 ¶ 33). Several months later, on or around November 29, 2012, Ms. Klein sent an email to Mr. Litzsinger which memorialized a discussion which had occurred the previous day. (*Id.* ¶ 34). In the email, Ms. Klein wrote: "3) Oxymorphone – we agreed we would complete Morphine supply agreement and then tackle the Oxymorphone." (*Id.* ¶ 34; DTX-542). The parties never reached an agreement for the supply of low-ABUK oxymorphone API. (D.I. 154 ¶ 36).

In 2012 and 2013, Mallinckrodt and Endo were parties to Patent Interference No. 105,893 in the PTO, which related to U.S. Patent Application No. 11/915,606—which issued as the '779 patent—and U.S. Patent No. 7,851,482 ("the '482 patent").[17] (*Id.* ¶ 38). On May 15, 2013, Endo filed a patent infringement lawsuit against Mallinckrodt, alleging that a Mallinckrodt ANDA filing infringed the '482 patent. (*Id.* ¶ 39). On December 16, 2013, Endo and Mallinckrodt settled the interference proceedings and the district court litigation, and entered into two license agreements. (*Id.* ¶ 41; JTX-3; PTX-10). Pursuant to the agreement settling the interference proceedings, Mallinckrodt granted Endo an exclusive license to the patent which ultimately issued as the '779 patent. (*Id.* ¶ 42; JTX-3). After settling with Endo, Mallinckrodt did not withdraw or modify the LOA it had issued to Teva. (*Id.* ¶¶ 47-51). Because of its agreement with Endo, Mallinckrodt is unwilling to sell low-ABUK oxymorphone API to Teva for use in the product described in the Teva CRF ANDA. (*Id.* ¶ 44). Mallinckrodt remains willing to sell low-ABUK oxymorphone API to Teva for use in an immediate release oxymorphone product. (*Id.* ¶ 45).

[17] Endo had previously acquired U.S. Patent No. 7,851,482 from Johnson Matthey. (*Id.* ¶ 40).

On November 7, 2014, less than two weeks after the issuance of the '779 patent, Endo and Mallinckrodt sued Teva for infringement of the '779 patent. (*Id.* ¶ 43).

D. Conclusions of Law

In a Hatch-Waxman case, a plaintiff's infringement claim is based on the accused infringer's future conduct, rather than past acts of infringement.[18] "The filing of an ANDA is considered an act of infringement under § 271(e)(2)(A), but this 'act' is merely a vehicle 'to create case or controversy jurisdiction to enable a court to promptly resolve' a dispute concerning infringement that will happen in the future." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)). Thus, for an implied license defense to succeed, the accused infringer must demonstrate that the patentee consented to its use of the claimed invention in "the ANDA product that is likely to be sold following FDA approval." *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1336 (Fed. Cir. 2015). Here, Teva has failed to make such a showing.

Teva's implied license defense relates only to API which may be supplied by Mallinckrodt. (D.I. 175 at p. 3 n.2).[19] According to Teva, since Mallinckrodt is the only API supplier identified in the Teva CRF ANDA, the product that is likely to be sold—should Teva's ANDA be approved—will contain Mallinckrodt API. Put another way, Teva argues that, to the extent any infringing low-ABUK oxymorphone API ends up in its product, that API will come from Mallinckrodt. Based on Mallinckrodt's past conduct, Teva argues that it must be entitled—

[18] Otherwise infringing acts, undertaken in connection with the development and submission of an ANDA, are immunized from liability. 35 U.S.C. § 271(e)(1).

[19] Teva concedes this and also acknowledges that "[n]o case or controversy exists today regarding whether the sale of a hypothetical future product that includes API purchased from a supplier other than Mallinckrodt would infringe the '779 patent." (*Id.*).

or, impliedly licensed—to use low-ABUK oxymorphone API that it receives from Mallinckrodt.[20] Under these circumstances, to succeed in an implied license defense, Teva must show that Mallinckrodt consented to Teva's use of the patented invention in the product likely to be sold. Under the facts here, there is no such license.

Teva's argument focuses on the 2010 and 2011 purchase orders, and the 2012 LOA. The 2010 and 2011 purchase orders concerned discrete, stand-alone purchases. (D.I. 154 ¶¶ 11-15; Tr. 602:18-605:11). On each, Teva included written terms and conditions. No evidence suggests that Mallinckrodt objected to these terms and conditions. (D.I. 154 ¶ 15). Each purchase order included an integration clause which provided that, "[e]xcept as expressly set forth in writing executed by [Teva], the terms and conditions set forth in this order constitute the entire agreement between the parties regarding the subject matter . . . ." (DTX-502; DTX-503). Thus, these terms and conditions constitute the entirety of the agreement with respect to each purchase order. Under the terms and conditions in each order, Mallinckrodt agreed "to exonerate, indemnify and hold harmless [Teva] from and against any and all liability . . . which may accrue to, or be sustained by [Teva] on account of any claim . . . brought against [Teva] . . . for . . . infringement of any patent . . . by reason of the manufacture of goods covered by this order . . . ." (DTX-502; DTX-503). By the terms of the purchase orders, Mallinckrodt granted Teva permission to use the low-ABUK oxymorphone API however it wished. As the terms and conditions of the purchase orders make clear, however, the scope of that permission does not extend beyond the "manufacture of goods covered by th[e] [purchase] order." (DTX-502; DTX-503). The only material covered by the terms and conditions is the low-ABUK oxymorphone

[20] There is some intuitive appeal to the argument that Mallinckrodt should not be able to sue a buyer for using the product it sold. In such a scenario, however, Teva would likely obtain a license not by virtue of Mallinckrodt's past conduct, but through the terms of a later transaction. The question here is whether the conduct hitherto undertaken by Mallinckrodt suffices to show that Mallinckrodt licensed the '779 patent.

API Teva actually purchased. No evidence suggests that, by selling low-ABUK oxymorphone API to Teva on two occasions, Mallinckrodt consented to Teva's commercial sale of products embodying the '779 patent through the use of low-ABUK oxymorphone API not covered by the purchase orders. The two purchases of low-ABUK oxymorphone API do not create an implied license.

Aside from the purchase orders, Teva relies heavily on the LOA issued by Mallinckrodt. An LOA is a regulatory document. In an LOA, a DMF holder grants an ANDA applicant "permission to incorporate their API into the ANDA." (Tr. 697:21-698:6). As conceded by Teva's expert, Dr. Fabian, these documents create no binding commercial obligations. (Tr. 706:4-707:5). Dr. Fabian testified that "the issue of successful or unsuccessful consummation of a Supply Agreement is a completely independent issue as to whether or not permissions have been granted based on actions of certain parties." (*Id.*). Further, Dr. Fabian testified that "there is no obligation to purchase [API] because an LOA has been received." (Tr. 698:19-699:6). Thus, while Mallinckrodt is the only supplier listed on the Teva CRF, it is not under any obligation to supply low-ABUK oxymorphone API to Teva. Similarly, no witness testified that the LOA itself confers a patent license.

Teva argues that because Mallinckrodt chose not to withdraw or modify the LOA, Mallinckrodt "suggested [to Teva] that it could file ANDA 204324 without being sued for infringing the '779 patent." (D.I. 175 at p. 10). This inference draws on a misapprehension about the significance of a LOA. Since a LOA places no binding obligation on Mallinckrodt, it would have no reason to withdraw the LOA. Additionally, leaving the LOA in place allows the FDA to review Teva's ANDA while Teva seeks to find, and qualify, additional suppliers of low-ABUK oxymorphone API. (Tr. 724:16-726:1). This is standard within the industry, as ANDA

applicants seek to qualify multiple suppliers for pharmaceutical products. (Tr. 617:13-618:3, 699:8-22). Indeed, Dr. Fabian testified that, when an API supplier is asked for a LOA from a manufacturer, the API supplier "would have no reason to believe" that "they would be the primary supplier to the applicant." (Tr. 699:8-22). This is because "API suppliers realize that ANDA sponsors mitigate [their] risk . . . by including more than a single supplier in their ANDA." (*Id.*). Thus, while an ANDA applicant might request an LOA so that it can eventually "market a dosage form on the market with [the DMF holder's] API in that dosage form," that is not the only possible scenario. (Tr. 698:2-18).

Teva has amassed considerable evidence for the unremarkable proposition that Teva could use the low-ABUK oxymorphone API supplied by Mallinckrodt in pursuing its ANDA. Mallinckrodt did not place any limits on the low-ABUK oxymorphone API Teva purchased in 2010 and 2011, and indeed, explicitly agreed to "exonerate, indemnify and hold harmless" Teva from any patent infringement liability. (DTX-502; DTX-503). Ms. Klein testified, based on the preceding facts, that Teva believed it was authorized to include Mallinckrodt's low-ABUK oxymorphone API in its ANDA. (Tr. 574:2-16). Additionally, to the extent Teva used the low-ABUK oxymorphone API for a purpose reasonably related to its ANDA, such activity is protected by § 271(e)(1). Mallinckrodt is not, however, suing Teva for using the low-ABUK oxymorphone API it previously supplied. Rather, Mallinckrodt is suing Teva for including low-ABUK oxymorphone API in the product that is likely to be sold in the future. Teva has not pointed to any evidence demonstrating that Mallinckrodt granted Teva a license to include low-ABUK oxymorphone API in the CRF product it ultimately sells. That is a fatal shortcoming.

In support of its theory of implied license, Teva introduced evidence about the way these sorts of interactions might ordinarily proceed between an entity like Teva and an entity like

Mallinckrodt. Ms. Klein summarized the relevant process as follows: "You order a product. You test the product. You put it into your drug product towards the ultimate goal of submitting to FDA, having a review, having the product approved and selling it commercially. And the fact that somebody . . . sells you the API and gives you that Letter of Authorization, this is the process." (Tr. 574:7-16). Ms. Klein testified that she "never had anyone provide [her] with a letter of authorization, put them in the [ANDA] and then have them sue me for using their product." (Tr. 575:7-10). Mr. Litzsinger similarly testified that Mallinckrodt had never "given an LOA to a customer and then sued that customer for filing an ANDA that included the API related to that LOA." (Tr. 829:13-18). Dr. Fabian also stated that, in his experience, he had never "seen a case where . . . a DMF holder . . . provided [a] LOA to the ANDA applicant and then subsequently . . . sued them." (Tr. 729:4-22). I think this testimony suggests that, in the majority of circumstances, a party in Teva's shoes could expect to eventually enter into an API supply agreement with a party in Mallinckrodt's shoes. That did not happen here. Teva cannot pretend that it did in order to sustain an implied license defense. This is perhaps an unusual situation, but it is not one where an implied license arises. While Teva may have hoped that Mallinckrodt would eventually supply it low-ABUK oxymorphone API, despite Mallinckrodt's assertions for the last twenty months that it would not (D.I. 154 ¶ 44; Tr. 646:21-647:13), "an implied license cannot arise out of unilateral expectations or even reasonable hopes of one party." *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1558 (Fed. Cir. 1983).

Teva briefly argues that its product may not contain low-ABUK oxymorphone after all. Plaintiff relies on the FDA's requirement that an opioid manufacturer must show either that (1) the drug contains less than 10 ppm of ABUK, or (2) that levels above that amount are not

genotoxic. (D.I. 166 at pp. 13-14).[21] This argument fails for at least two reasons. First, the specification in the Teva CRF ANDA limits the amount of oxymorphone ABUK to less than 10 ppm. (D.I. 154 ¶ 24). Second, Teva never raised this argument in the Final Pretrial Order, and it is therefore waived.

Teva argues that it has proven the five facts that the Federal Circuit found sufficient to create an implied license in *Wang Laboratories*. I disagree. In *Wang Laboratories*, the Federal Circuit concluded that the jury necessarily found that the patentee granted the accused infringer a right to use the claimed invention. *Wang Laboratories*, 103 F.3d at 1579. Here, as discussed above, Mallinckrodt only granted Teva the right to use the low-ABUK oxymorphone API which was the subject of the two purchase orders.

Additionally, in *Wang Laboratories*, the patentee had "received valuable consideration for [the] grant of [a] right [to use the claimed invention]." *Id.* Here, the only consideration paid to Mallinckrodt was the purchase price of the two stand-alone purchases. In short, Teva paid for two quantities of low-ABUK oxymorphone API; it did not pay for rights regarding future sales of low-ABUK oxymorphone API. Teva argues that Mallinckrodt received consideration for the LOA "in the form of potential future sales of commercial quantities of [low-ABUK] [o]xymorphone API." (D.I. 166 at pp. 9-10). As Dr. Fabian testified, however, commercial supply is an issue entirely separate from a LOA authorization. (Tr. 706:4-707:5). Since a LOA does not create a binding commercial obligation, Mallinckrodt is under no obligation to sell any low-ABUK oxymorphone API to Teva. "[W]here the promisor may perform or not, solely on the condition of his whim, his promise will not serve as consideration." *Wallach v. Eaton Corp.*, 125 F. Supp. 3d 487, 493-94 (D. Del. 2015) (quotation marks omitted) (quoting 3 Samuel

[21] This argument is premised on JTX-4, which was not admitted into evidence or supported by any testimony.

Williston & Richard A. Lord, *Williston on Contracts* § 7.7 (4th ed. 1992)), *appeal filed*, No. 15-3320 (3d Cir. Sept. 29, 2015).

I therefore conclude that Teva has failed to demonstrate the existence of an implied license.

III. CONCLUSION

Defendants failed to prove by clear and convincing evidence that any of the asserted claims of the '779 patent are invalid. Teva failed to prove its affirmative defense of implied license by a preponderance of the evidence.

Plaintiffs should submit an agreed upon form of final judgment within two weeks.