IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P. et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 15-1155-RGA-SRF
	)	
MYLAN PHARMACEUTICALS INC. and MYLAN INC.,	)	
	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action is a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6), filed by defendants Mylan Inc. ("Mylan") and Mylan Pharmaceuticals Inc. ("MPI") (collectively, "defendants"). (D.I. 23) For the following reasons, I recommend that the court deny the motion.

II. BACKGROUND

A. The Patent-In-Suit

This action arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") No. 203915 to the United States Food and Drug Administration ("FDA") on November 2, 2015. (D.I. 1 at ¶¶ 1, 31) Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc., and Rhodes Technologies (collectively, "plaintiffs") assert that defendants' ANDA filing constitutes infringement of United States Patent No. 9,073,933 ("the '933 patent"), which relates to plaintiffs' OxyContin® brand oxycodone hydrochloride. (*Id.* at ¶¶ 1-2) OxyContin® is an extended-release pain medication. (*Id.* at ¶ 2)

The '933 patent, entitled "Oxycodone Hydrochloride Having Less Than 25 PPM 14-Hydroxycodeinone," was issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. (*Id.* at ¶ 30) The '933 patent is directed to an oxycodone hydrochloride active pharmaceutical ingredient ("API") with low levels of 14-hydroxycodeinone ("14-hydroxy"), and the processes for making the oxycodone hydrochloride composition. ('933 patent, col. 1:25-27) 14-hydroxy belongs to a class of potentially toxic compounds known as alpha, beta unsaturated ketones ("ABUKs") found in oxycodone compositions. (*Id.*, col. 6:51-54); *Chapman v. Casner*, 315 F. App'x 294, 295 (Fed. Cir. 2009).

In a July 1, 2014 office action, the United States Patent and Trademark Office ("PTO") issued a non-final rejection of then-pending claims 71-90 of the '933 patent as unpatentable for obviousness-type double patenting[1] over certain prior art references. Specifically, the examiner rejected the claims as being unpatentable over claims 1 to 14 of U.S. Patent No. 7,683,072 ("the '072 patent"), claims 1 to 9 of U.S. Patent No. 7,674,799 ("the '799 patent"), and claims 38 to 55 of U.S. Patent No. 7,674,800 ("the '800 patent;" together with the '072 patent and the '799 patent, the "low-ABUK patents"), among others.[2] (D.I. 25, Ex. 8 at 7/1/14 Office Action, ¶¶ 10, 12, 13) The low-ABUK patents share a common specification and priority date with the '933 patent and, like the '933 patent, are directed to reducing the amount of 14-hydroxy in an oxycodone hydrochloride preparation.

[1] Claims 71-90 of the '933 patent were also rejected as obvious pursuant to 35 U.S.C. § 103 because the examiner found the claims to be unpatentable over U.S. Patent No. 6,177,567 ("Chiu"), which teaches the preparation of oxycodone by hydrogenation of 14-hydroxy, and other references. (D.I. 25, Ex. 8 at 7/1/14 Office Action, ¶ 6)

[2] The Southern District of New York issued a decision invalidating the low-ABUK patents on January 14, 2014, prior to the office actions and ultimate allowance of the '933 patent. *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014).

In response to the obviousness-type double patenting rejection, plaintiffs filed terminal disclaimers on October 1, 2014[3] to dispose of the double-patenting rejection, stating that "[a]pplicants traverse these rejections, but submit herewith terminal disclaimers . . . in an effort to expedite prosecution." (*Id.*, 10/1/14 Response at 13) Plaintiffs expressly stated that "[t]hese terminal disclaimers are being submitted solely for the purpose of removing the double patenting rejections. The filing of these terminal disclaimers is neither an admission of the propriety of the rejections nor an admission that the inventions claimed in present claims 71-90 are not 'independent and distinct' from the inventions of" the low-ABUK patents. (*Id.*)

The PTO issued a final rejection of the '933 patent application on October 31, 2014, rejecting claims 71-90 as obvious under § 103 after concluding that it would have been obvious to one skilled in the art to prepare an oxycodone hydrochloride composition with a reduced amount of 14-hydroxy by dehydrating 8α in view of the FDA's instructions to prepare oxycodone salt with reduced amounts of 14-hydroxy. ('933 patent, 10/31/14 Final Rejection at ¶ 3) The examiner further noted that parent patent application 11/391,897 (the "Chapman application") was invalidated based on an obviousness rejection during an interference proceeding. On January 29, 2015, the examiner held a telephonic interview with plaintiffs to discuss the adverse decision on the claims at issue in the interference proceedings regarding the Chapman application. Plaintiffs filed a response after final rejection on March 4, 2015, further amending the claims to distinguish them from the Chapman application by independently requiring 8α as an element of the claimed composition or process. The PTO issued a notice of

[3] Plaintiffs re-filed the terminal disclaimers on May 8, 2015, noting that the previously-filed terminal disclaimers "inadvertently omitted the name of one of the assignees of the instant application (i.e., Rhodes Technologies)." A terminal disclaimer review decision was issued on May 27, 2015 approving the terminal disclaimers.

allowance of the amended claims 71-90, renumbered as claims 1-20, on March 23, 2015, after concluding that the arguments filed on March 4, 2015 were persuasive in overcoming the obviousness rejections and the addition of the 8α limitation rendered the claims patentably distinct from the claims at issue in the Chapman interference proceedings.

B. The *Teva* Litigation

Plaintiffs previously sued Teva Pharmaceuticals, USA ("Teva") in the Southern District of New York,[4] alleging infringement of the low-ABUK patents. *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014). The claims of the '799 and '072 patents are directed to oxycodone hydrochloride, with the '799 patent claiming an "oral dosage form" of low-ABUK oxycodone hydrochloride. *Id.* at 387-88. The asserted claims of the '800 patent recite a process for preparing an oxycodone salt substantially free of 14-hydroxy. *Id.* at 387. The Southern District of New York held that Teva infringed all of the asserted product-by-process claims, but concluded that those claims were invalid for obviousness pursuant to 35 U.S.C. § 103. *Id.* at 403 ("For purposes of validity, the Court considers only the product limitations of a claim, not process limitations or source limitations that add no patentable significance to the end product."). The court acknowledged that plaintiffs discovered 8α as the source of the 14-hydroxy problem,

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[4] Plaintiffs also previously sued Mylan for infringement of the low-ABUK patents. The Federal Circuit set forth the procedural history of the litigation over the low-ABUK patents as follows:

> In March 2011, Purdue sued Teva for infringement of the low-ABUK patents in response to Teva's filing of an ANDA seeking FDA approval to market generic versions of Reformulated OxyContin®. Between November 2011 and January 2013, Purdue filed similar lawsuits against Epic, Mylan, and Amneal. In addition, in June 2012, Grunenthal and Purdue jointly sued Teva for infringement of the '383 patent. The two Teva cases were consolidated and joined with the Epic, Mylan, and Amneal cases, along with six actions involving other defendants, in multi-district litigation for pretrial purposes.

Purdue Pharma L.P. v. Epic Pharma, LLC, 811 F.3d 1345, 1350 (Fed. Cir. 2016) ("*Teva*").

and noted that 8α was unknown in the prior art, but the court ultimately did not consider the derived-from-8α language in the low-ABUK patent claims in reaching its conclusion because process limitations in product-by-process claims are disregarded in the obviousness inquiry, and 8α was "largely irrelevant to the process used by Purdue to obtain the product claimed by the patents." *Id.* at 405.

On February 1, 2016, the Federal Circuit affirmed the Southern District of New York's decision regarding the invalidity of the low-ABUK patents, relying on principles specific to product-by-process claims and concluding that the district court did not err in disregarding the 8α limitations in the obviousness inquiry. *Teva*, 811 F.3d at 1352-54. The district court's invalidity determination was therefore upheld with respect to claims 3 and 19 of the '799 patent, claims 30-34 and 76-79 of the '800 patent, and claims 1, 4, and 5 of the '072 patent. *Id.*; *In re OxyContin*, 994 F. Supp. 2d at 438. On April 1, 2016, plaintiffs petitioned for rehearing en banc of the Federal Circuit's decision in the *Teva* appeal. (D.I. 28, Ex. 1) Plaintiffs' petition for rehearing en banc was denied by the Federal Circuit on May 4, 2016, and plaintiffs' subsequent petition for a writ of certiorari before the United States Supreme Court was denied on November 14, 2016. (D.I. 33; D.I. 51)

C. The Chapman Application

The low-ABUK patents and the '933 patent are continuations of the Chapman application, which was filed on March 29, 2006. *In re OxyContin*, 994 F. Supp. 2d at 388. The Chapman application recited a "process for preparing oxycodone hydrochloride having less than 25 ppm [14-hydroxy]." *Id.* During an interference proceeding on April 19, 2007 involving claims 96-188 of the Chapman application, the Board of Patent Appeals and Interferences (the

"BPAI")[5] declared an interference between the Chapman application and U.S. Patent No. 7,153,966 ("Casner"). On March 18, 2008, the BPAI found that independent claim 96 of the Chapman application and the dependent claims thereof were invalid as obvious in view of U.S. Patent No. 7,153,966 ("*Casner*"), and the Federal Circuit affirmed. *See Chapman v. Casner*, C.A. No. 08-1427, 315 F. App'x 294, 295 (Fed. Cir. Mar. 11, 2009); (D.I. 25, Ex. 10, 3/13/08 Order). The adjudicated Chapman application claims related to a method for making oxycodone API using a hydrogenation step to remove 14-hydroxy, but they did not require that some of the remaining 14-hydroxy be derived from the 8α isomer. *Teva*, 811 F.3d at 1349. In holding that the claims at issue were unpatentable under § 103, the BPAI relied on the lack of any reference in the claims to 8α as the source of the 14-hydroxy, noting that "[b]ecause the claims did not specify the source of the 14-hydroxy, any prior art reference that disclosed conditions under which either 8α or 8β converted to 14-hydroxy would render the claim obvious." *Id.* (citing *Chapman*, 315 F. App'x at 297). Because the prior art references disclosed conditions under which 8β converts to 14-hydroxy, the BPAI determined that the Chapman application claims were obvious in view of the prior art. *Id.*

III. LEGAL STANDARD

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and view them in the light most favorable to the plaintiff. *Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008).

[5] Pursuant to the America Invents Act of 2011, the BPAI subsequently changed its name to the Patent Trial and Appeal Board ("PTAB") when the legislation went into effect on September 16, 2012.

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555-56.

When determining whether dismissal is appropriate, the court must take three steps.[6] *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must identify the elements of the claim. *Iqbal*, 556 U.S. at 675. Second, the court must identify and reject conclusory allegations. *Id.* at 678. Third, the court should assume the veracity of the well-pleaded factual allegations identified under the first prong of the analysis, and determine whether they are sufficiently alleged to state a claim for relief. *Id.*; *see also Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The third prong presents a context-specific inquiry that "draw[s] on [the court's] experience and common sense." *Id.* at 663-64; *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). As the Supreme Court instructed in *Iqbal*, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not 'show[n]' - 'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

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[6]Although *Iqbal* describes the analysis as a "two-pronged approach," the Supreme Court observed that it is often necessary to "begin by taking note of the elements a plaintiff must plead to state a claim." 556 U.S. at 675, 679. For this reason, the Third Circuit has adopted a three-pronged approach. *See Santiago v. Warminster Twp.*, 629 F.3d 121, 130 n.7 (3d Cir. 2010); *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011).

IV. DISCUSSION

In support of their motion to dismiss, defendants contend that collateral estoppel bars plaintiffs from relitigating the previously-adjudicated issue of the invalidity of claims requiring oxycodone products with low levels of 14-hydroxy. (D.I. 24 at 8-18) In response, plaintiffs allege that the '933 patent has never been adjudicated and includes limitations that have never been addressed in previous litigations. (D.I. 28 at 8) Moreover, plaintiffs argue that applying collateral estoppel to different patent claims from those previously adjudicated requires an intense factual analysis that would be premature at this stage of the litigation. (*Id.* at 11)

As a preliminary matter, the court notes that collateral estoppel may be decided on a motion to dismiss under Rule 12(b)(6). *M & M Stone Co. v. Pennsylvania*, 388 F. App'x 156, 162 (3d Cir. 2010). In considering the motion, the court "may consider 'matters incorporated by reference integral to the claim, items subject to judicial notice, matters of public record, orders [and] items appearing in the record of the case.'" *Thibault v. Del. Tech. & Cmty. Coll.*, C.A. No. 11-1080-MPT, 2012 WL 2073847, at *2 (D. Del. June 8, 2012) (quoting *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006)). Matters of public record may include prior judicial opinions and patent prosecution histories, among other things. *See M & M Stone*, 388 F. App'x at 162; *Genetic Techs Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014).

In *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), the Supreme Court held that defensive collateral estoppel may be used in the patent context if the accused infringer shows: "(1) that a patent was found invalid in a prior case that had proceeded through final judgment and in which all procedural opportunities were available to the patentee; (2) that the issues litigated were identical; and (3) that the party against whom estoppel is applied had a full and fair opportunity to litigate." *Abbott Labs. v. Andrx Pharma.,*

Inc., 473 F.3d 1196, 1203 (Fed. Cir. 2007). Regional circuit law controls the determination of whether prior findings invoke collateral estoppel pursuant to these guidelines. *Id.* at 1202-03. In this regard, the Third Circuit has held that collateral estoppel applies when "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citations omitted). Although collateral estoppel may apply even when the previously-litigated patent claims are not identical to the claims at issue in the patent-in-suit, "the differences between the unadjudicated patent claims and adjudicated patent claims" cannot "materially alter the question of invalidity." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

For the reasons set forth below, I recommend that the court deny the pending motion to dismiss. At this stage of the proceedings, defendants have failed to establish that the invalid claims of the previously-litigated low-ABUK patents are sufficiently identical to the disputed claims of the '933 patent. The claims of the '933 patent contain limitations not set forth in the low-ABUK patents, but whether these limitations are material to the patentability of the '933 patent is a question of fact to be reserved for a later stage of the proceedings.

A. Product Claims 1 & 16 of the '933 Patent

1. 8α limitation

The inclusion of the 8α limitation as a required element in claims 1 and 16 of the '933 patent distinguishes those claims from the claims of the low-ABUK patents and the Chapman application. Specifically, independent claims 1 and 16 of the '933 patent claim "[a]n oxycodone hydrochloride composition," which "comprises . . . 8α, 14-dihydroxy-7, 8-dihydrocodeinone."

The "well understood" definition of "comprising" is "including but not limited to." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009); *see also Glaxo Group LTD v. Teva Pharms. USA, Inc.*, 2009 WL 1220544, at *2 (D. Del. Apr. 30, 2009) (Comprising "is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.") (internal quotations omitted).

In contrast, the product-by-process claim language of the low-ABUK patents does not necessarily require the 8α required by the '933 patent product claims. The '072 patent claims "[a]n oxycodone hydrochloride active pharmaceutical ingredient having less than 25 ppm 14-hydroxycodeinone, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7, 8-dihydrocodeinone." ('072 patent, col. 34:57-60) Claim 1 of the '799 patent claims "[a]n oral dosage form comprising particles . . . wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7, 8-dihydrocodeinone." ('799 patent, col. 34:54-59) Claim 38 of the '800 patent claims "[a]n oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone . . . wherein at least a portion of the 14-hydroxycodeinone in the composition having more than 100 ppm 14-hydroxycodeinone was derived from the 8α, 14-dihydroxy-7, 8-dihydrocodeinone component during the conversion of the oxycodone free base to the oxycodone salt." ('800 patent, col. 36:1-21) The "derived from 8α" language of the low-ABUK product-by-process patent claims does not transform 8α into a required claim limitation, unlike the "comprises" language in the '933 patent product claims. Whether the 8α limitation in the '933 patent renders claims 1 and 16 patentably distinct from the invalid low-ABUK claims is a question of fact not properly resolved at this stage of the proceedings.

The Federal Circuit and district court decisions in the *Teva* litigation illustrate why the invalidity determination regarding the low-ABUK patents is insufficient to have collateral estoppel effect on the validity of the '933 patent at this stage of the proceedings. In *Teva*, the Federal Circuit concluded that determining the source of 14-hydroxy in the end product did not need to be resolved to arrive at the claimed invention, which was an oxycodone API with low-ABUK levels. *Teva*, 811 F.3d at 1352. The Federal Circuit also held that identification of the source of the remaining 14-hydroxy as being 8α had no effect on the structure or nature of the low-ABUK oxycodone product. *Id.*; *see also In re OxyContin*, 994 F. Supp. 2d at 405. The Federal Circuit's reasoning was based on the fact that the "derived from 8α" limitation in the low-ABUK patents was a process limitation in a product-by-process claim that was thus immaterial to the obviousness analysis. *Id.* at 1353-54 ("Because the source of the 14-hydroxy has no effect on its structure or its removal through hydrogenation, the limitation that it be 'derived from 8α' cannot be a structural limitation.").

"A product-by-process claim is 'one in which the product is defined at least in part in terms of the method or process by which it is made.'" *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n. (1989)). "In determining validity of a product-by-process claim, the focus is on the product and not the process of making it" because "an old product is not patentable even if it is made by a new process." *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012) (quoting *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009)) (internal quotation marks omitted); *see also SmithKline*, 439 F.3d at 1317. As a result, "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a

different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). However, if the process limitations impart "structural and functional differences" to the product, converting the product into something that is actually "new," the structural and functional differences are relevant to the analysis even when they are "not explicitly part of the claim[s]." *Amgen*, 580 F.3d at 1367, 1370.

Unlike the product-by-process claims of the low-ABUK patents, claims 1 and 16 of the '933 patent are product claims with a mandatory 8α limitation. Although the "derived from 8α" limitation in the low-ABUK patents had no bearing on the invalidity determination because the 8α process was immaterial to the obviousness analysis, the 8α limitation present in the '933 patent claims must be evaluated to determine the validity of the claims. The 8α limitation in the '933 patent could therefore be material to patentability, and it would be premature to grant the motion to dismiss before a factual analysis of this issue occurs. The prosecution history of the '933 patent also confirms the significance of the 8α limitations in the claims of the '933 patent, as plaintiffs overcame the Chapman application by demonstrating that "[t]he claims at issue in the interference proceedings . . . did not recite" 8α. ('933 patent, 3/4/14 Applicant Arguments / Remarks Made in an Amendment at 5; 3/23/15 Notice of Allowance at ¶ 4)

Defendants refer to the PTO's double patenting rejection of the '933 patent and plaintiffs' terminal disclaimers of the low-ABUK patents in response thereto in support of their contention that the validity issues for the '933 patent are substantially identical to the validity issues that rendered the low-ABUK patents invalid. (D.I. 24 at 9-10) A double patenting rejection is issued when a continuation application,[7] defined as "a second application for the same invention

[7] Continuation applications allow inventors to file new patent applications based on the disclosures of previous applications, without having the previous applications treated as

claimed in a prior nonprovisional application," MPEP § 201.07 (9th ed. 2014), is not patentably distinct from the parent, *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). "Uniformly, unlike examination for obviousness based on prior art, the issue of obviousness-type double patenting is directed to whether the invention claimed in a later patent is an obvious variant of the invention claimed in an earlier patent." *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 625 F.3d 719, 722 (Fed. Cir. 2010). As such, "the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims." *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992); *see also In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986) ("In considering the question [of obviousness-type double patenting], the patent disclosure may not be used as prior art.").

The purpose of the judicially-created doctrine of obviousness-type double patenting is "to prevent improper timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not 'patentably distinct' from the claims of a first patent." *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991). The filing of a terminal disclaimer overcomes an obviousness-type double patenting rejection by "foregoing that portion of the term of the second patent that extends beyond the term of the first." *In re Berg*, 140 F.3d at 1432 (citing *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993)). As a result, the "filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection." *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) (concluding that a terminal disclaimer "is not an admission of obviousness of the later-filed claimed invention in light of the earlier-

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invalidating prior art. *Word to Info, Inc. v. Google Inc.*, 140 F. Supp. 3d 986, 991 (N.D. Cal. 2015).

filed disclosure, for that is not the basis of the disclaimer."); *see also Edwards Lifesciences Corp. v. St. Jude Med., Inc.*, 2003 WL 25784357, at *11 n.19 (C.D. Cal. Aug. 29, 2003) ("[A]n obviousness-type double-patenting rejection is issued when the PTO considers pending claims obvious in view of another patent by the same inventor; such rejection does not mean that the respective claims are considered the same.").

In the present matter, defendants filed terminal disclaimers, but expressly stated that "[t]hese terminal disclaimers are being submitted solely for the purpose of removing the double patenting rejections. The filing of these terminal disclaimers is neither an admission of the propriety of the rejections nor an admission that the inventions claimed in present claims 71-90 are not 'independent and distinct' from the inventions of" the low-ABUK patents. (D.I. 25, Ex. 8 at 10/1/14 Response at 13) The filing of the terminal disclaimers does not constitute acquiescence to the merits of the rejection. *See Quad Envtl.*, 946 F.2d at 874; *Edwards Lifesciences*, 2003 WL 25784357, at *11 n.19. Thus, the only practical effect of the terminal disclaimers was to limit the term of the '933 patent to the full statutory term of the low-ABUK patents. The foregoing analysis of the claim language of the '933 patent compared to the low-ABUK patents further demonstrates that the '933 patent contains additional limitations not required by the low-ABUK patents, and it is premature for the court determine with certainty that these limitations do not render the claims patentably distinct from the low-ABUK patents.

Defendants also rely on the doctrine of inherency in support of their argument that the '933 patent should be invalidated based on its similarities to the invalid low-ABUK patents. (D.I. 24 at 13-14; D.I. 31 at 3-7) Pursuant to the doctrine of inherency, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for

the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

As a result, "[t]he express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. §§ 102 or 103." MPEP § 2112. "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In re Oelrich, 666 F.2d 578, 581 (C.C.P.A. 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)). A party must meet a high standard to rely on inherency in establishing the existence of a claim limitation in the prior art in an obviousness analysis. *Par Pharm. Inc. v. Twi Pharms., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014). "Whether a claim limitation is inherent in a prior art reference . . . is also a question of fact." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1362 (Fed. Cir. 1999); *see also S.O.I.Tec Silicon On Insulator Techs., S.A. v. MEMC Elec. Materials, Inc.*, 745 F. Supp. 2d 489, 513 (D. Del. 2010) ("Inherency is a factual issue."); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991).

The inherency doctrine does not apply under the facts presently before the court. As previously discussed in conjunction with the obviousness-type double patenting analysis, the low-ABUK patents are not prior art references in relation to the '933 patent because the '933

patent is a continuation of the low-ABUK patents. *Gen. Foods Corp.*, 972 F.2d at 1277. Defendants cite the Southern District of New York's decision in *Abbvie Inc. v. Kennedy Trust for Rheumatology Research*, 2014 WL 3360722, at *6-7 (S.D.N.Y. July 9, 2014), to support the application of the inherency doctrine to non-prior art references to establish collateral estoppel. In *Abbvie*, the court granted summary judgment, invalidating the patent claims on grounds of collateral estoppel based on an obviousness-type double patenting rejection. *Id.* The court discussed inherency without acknowledging that the previously-litigated patents were not prior art. *Id.* This case contradicts the Federal Circuit's decision in *Quad Environmental Technologies*, which held that the filing of a terminal disclaimer did not raise estoppel issues on the merits of the double patenting rejection. 946 F.2d at 874. It is also inconsistent with the decision in *Bourns, Inc. v. United States*, which observed that "[a] domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim." 537 F.2d at 493. In this instance, I recommend that the court follow Federal Circuit precedent over the Southern District of New York's unpublished decision in *Abbvie*.

Even if the court were to credit defendants' authority, courts have routinely held that the inherent teaching of a prior art reference is a question of fact. *See Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320-21 (Fed. Cir. 2004); *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995). As previously stated, fact-based inquiries are premature for resolution at this stage of the proceedings. This is particularly true where, as here, the case authorities relied upon by the defendants represent decisions on summary judgment or thereafter. *See Abbvie*, 2014 WL 3360722, at *6-7 (decided on summary judgment). None of defendants' authority was decided on a motion to dismiss, and a question of fact remains in the present case regarding whether the

differences between the unadjudicated patent claims and the adjudicated claims materially alter the question of validity. *See Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311 (Fed. Cir. 2015) (post-verdict judgment as a matter of law); *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333 (Fed. Cir. 2013) (summary judgment); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362 (Fed. Cir. 2012) (post-trial appeal of final judgment); *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344 (Fed. Cir. 2012) (post-trial appeal of final judgment); *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011) (review of BPAI decision assessing whether obviousness determinations were based on substantial evidence); *Bourns Inc. v. U.S.*, 537 F.2d 486 (Ct. Cl. 1976) (summary judgment); *Westwood Chem., Inc. v. U.S.*, 525 F.2d 1367 (Ct. Cl. 1975) (summary judgment). As such, resolution at this stage of the proceedings would be premature.

2. 95% limitation

The low-ABUK patent claims do not recite any percentage of oxycodone hydrochloride, whereas claims 1 and 16 of the '933 patent specify that the composition must comprise at least 95% oxycodone hydrochloride. ('933 patent, col. 6:3-8; '072 patent, col. 5:65-6:3) Defendants refer to the low-ABUK patent specification, which indicates that the composition "preferably" contains at least 95% oxycodone hydrochloride or higher, as evidence that plaintiffs did not intend to exclude this limitation from the low-ABUK patent claims. (D.I. 24 at 12-13) However, the claims of the low-ABUK patents do not recite the 95% limitation. To the extent that the 95% limitation is identified in the patent specifications of the low-ABUK patents, the court notes that patent claims are evaluated for invalidity. Although the claims must be analyzed in view of the specification, preferred embodiments identified in the specification cannot be

improperly imported into the language of the claims themselves. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323-24 (Fed. Cir. 2005).

As previously explained in connection with the 8α limitation, whether a product containing 95% oxycodone is novel over the low-ABUK patents is a question of fact not properly resolved on a Rule 12(b)(6) motion to dismiss. The *Teva* decision does not discuss the percentages of oxycodone in the prior art. Therefore, it would be inappropriate at this stage of the proceedings for the court to conclusively rule that the 95% limitation does not materially affect the patentability of the '933 patent.

3. 5 ppm limitation

Claim 16 of the '933 patent contains another limitation requiring that the composition "comprises . . . less than 5 ppm of codeinone." This limitation was not present in the low-ABUK patent claims, and codeinone was not discussed in the course of the *Teva* litigation or the Chapman interference proceedings. Whether the limitation represents only a slight difference that does not render claim 16 patentably distinct from the adjudicated low-ABUK claims is an issue of fact not properly resolved on a motion to dismiss. The fact that the low-ABUK patent specification states that the present invention may reduce other ABUKs, such as codeinone, does not establish that codeinone is necessarily present in the specific 5 ppm quantity in the adjudicated claims. *See Phillips*, 415 F.3d at 1323-24. Moreover, the 5 ppm limitation of claim 16 is narrower than the low-ABUK claims, which have limits of 25 ppm, and the adjudicated low-ABUK claims therefore cover oxycodone hydrochloride that is less pure than the recitation of oxycodone hydrochloride with less than 5 ppm of 14-hydroxy in claim 16 of the '933 patent. *See Bourns*, 537 F.2d at 493 ("A domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, is inappropriate since it improperly gives

prior-art effect to the subject matter of an invalid claim."). Because the *Teva* litigation did not address the narrower 5 ppm limitation, and the question of whether the difference in claim language materially alters the patentability of claim 16 is fact-intensive, the court cannot rule at this stage of the proceedings that collateral estoppel should apply to invalidate claim 16 of the '933 patent.

B. Process Claim 10 of the '933 Patent

The claimed processes in claim 10 of the '933 patent require the step of removing 8α from an oxycodone base composition. ('933 patent, col. 34:27-35:27) In contrast, the Federal Circuit in *Teva* declined to consider process limitations in concluding that the disputed product-by-process claims were invalid. *See Teva*, 811 F.3d at 1354 ("We also conclude that, because 'derived from 8α[]' is a process limitation, the district court did not err in disregarding the limitation in its obviousness analysis."). Questions regarding whether hydrogenation was well-known in the art and whether the process of removing 8α from an oxycodone base composition is material to the patentability of the '933 patent claims are factual in nature and are not properly resolved on a motion to dismiss. Moreover, the process claims at issue in the Chapman interference proceedings did not recite an 8α limitation.

A petition for rehearing en banc before the Federal Circuit in the *Teva* litigation was denied on May 4, 2016. (D.I. 33, Ex. 1) On November 14, 2016, the United States Supreme Court denied the petitions for writ of certiorari. *Purdue Pharma L.P., et al. v. Epic Pharma, LLC, et al.*, 137 S. Ct. 475 (2016); *Grunenthal GmbH v. Teva Pharms. USA, Inc., et al.*, 137 S. Ct. 476 (2016).

V. CONCLUSION

For the foregoing reasons, I recommend that the court deny defendants' motion to dismiss pursuant to Rule 12(b)(6). (D.I. 23)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: March 1, 2017

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE