UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

G.D. SEARLE LLC and PFIZER ASIA PACIFIC PTE. LTD.,

Plaintiffs,

v.

Civil Action No. 2:13cv121

LUPIN PHARMACEUTICALS, INC.,
TEVA PHARMACEUTICALS USA, INC.,
MYLAN PHARMACEUTICALS INC.,
WATSON LABORATORIES, INC.,
APOTEX INC., and
APOTEX CORP.,

Defendants.

ORDER

This matter comes before the Court on the parties' cross motions for summary judgment (ECF Nos. 154, 166, 168). Plaintiffs G.D. Searle LLC ("Searle") and Pfizer Asia Pacific PTE, Ltd. ("Pfizer") (collectively "Plaintiffs") allege patent infringement of United States Reissue Patent No. RE 44,048 (the "'048 patent") by Defendants Lupin Pharmaceuticals, Inc. ("Lupin"), Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc. ("Mylan"), Watson Laboratories, Inc. ("Watson"), Apotex Inc. and Apotex Corp. (both "Apotex") (collectively "Defendants"). ECF No. 154. In response, Defendants argue for non-infringement and invalidity against Plaintiffs. ECF Nos. 166, 168.

On February 26, 2014, the Court heard oral argument regarding the parties' motions for summary judgment. For the reasons set forth below, the Court **GRANTS IN PART** Defendants' motions for summary judgment.

I. BACKGROUND

A. Undisputed Facts

Plaintiffs are prosecuting the defense of one patent, the '048 patent, which is a reissue of United States Patent No. 5,760,068 (the "'068 patent"), originally issued on June 2, 1998. Along

with United States Patent Nos. 5,466,823 ("the parent '823 patent") and 5,563,165 ("the divisional '165 patent"), these patents protect a Pfizer product known as Celebrex.

The parent '823 patent covers compounds, including a compound known as celecoxib, the active compound in Celebrex. The divisional '165 patent claims pharmaceutical compositions. The '068 patent (when it was enforced) and the '048 patent both claim methods of treatment, including the use of celecoxib. Specifically, the '048 patent contains claims directed to treating acute pain and symptoms of arthritis, osteoarthritis ("OA"), rheumatoid arthritis ("RA"), juvenile rheumatoid arthritis ("JRA"), ankylosing spondylitis or spondyloarthropathy ("AS"), and primary dysmenorrhea ("PD") or menstrual cramps. "Treating" these conditions involves relieving the signs and symptoms of the conditions. Pls.' Br. Supp. Pls.' Mot. Summ. J 7, ECF. No. 155; Claim Constr. Order 22, December 18, 2013, ECF No. 213.

The parent '823 patent and the divisional '165 patents expired on November 30, 2013. The United States Food and Drug Administration ("FDA") has extended that exclusivity until May 30, 2014, in light of pediatric testing by Pfizer. Sorenson Decl. Ex. 16 at WAT-CEL-00021014, ECF No. 167-17 at 2. The '048 patent, like the '068 patent, expires on June 2, 2015 with an extended period of exclusivity until December 2, 2015. *Id.*

In 2008, the Federal Circuit found the '068 patent invalid under the doctrine of obviousness-type double patenting. *Pfizer Inc. v. Teva Pharms. USA, Inc. (Pfizer II)*, 518 F.3d 1353, 1363 (Fed. Cir. 2008). The court explained that "[t]he claims at issue of the '068 patent merely recite methods of administering a 'therapeutically-effective amount' of the compositions found in claim 5 of the '165 patent." *Id.*

The Federal Circuit held that because the '068 patent was a continuation-in-part ("CIP") of the parent '823 patent, as opposed to a divisional of the parent '823 patent, the '068 patent was not protected by the safe harbor provisions found under 35 U.S.C. § 121 and that therefore,

the '068 patent was invalid. *Id.* at 1362–63. The court held that Pfizer's exclusivity as to celecoxib would end on November 30, 2013, with the expiration of the parent '823 and divisional '165 patents. Because the '068 patent claimed the same subject matter as the divisional '165 patent, the court could not extend Pfizer's exclusivity to June 2, 2015, its purported expiration date.

Following this ruling, Pfizer asked the United States Patent and Trademark Office ("PTO") to reissue the '068 patent as a divisional in order to correct the deficiencies noted by the Federal Circuit. Reissue Application No. 12/205,319 ("the reissue application") was filed on September 5, 2008.

Pfizer represented that it was amending the claims and specification "so that the '113 Application from which the '068 Patent issued qualifies as divisional application in compliance with the recent Federal Circuit opinion." Sorenson Decl. Ex. 14 at PFH_0000012, ECF No. 167-15 at 3. The PTO rejected this claim because "[f]ailure to 'timely' file a divisional application prior to issuance of the original patent is not correctable in reissue." *Id.* at PFH_0012327-29, ECF No. 167-15 at 13–15.

Pfizer then asserted that a reissue would be proper because the '068 patent contained indefinite claim terms and the applicant would need to include narrower claims than those found in the original patent. *See id.* at PFH_0036741, ECF No. 167-15 at 78.

On March 5, 2013, based on Pfizer's assertions, the PTO issued the '048 patent. That same day, Plaintiffs brought this suit against Defendants, alleging infringement of the '048 patent.

Plaintiffs allege that Defendants infringed the '048 patent by filing Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") that sought approvals to market generic versions of Pfizer's Celebrex drug prior to the expiration of the '048 patent and any related period of exclusivity. Defendants proposed generic products

contain celecoxib, the active ingredient in Celebrex. Pls.' Br. Supp. Pls.' Mot. Summ. J. 5, ECF No. 155. Defendants' proposed package inserts for their generic celecoxib products (with the exception of Lupin) provide that the products are indicated for the relief of the signs and symptoms of OA, RA, JRA, AS, acute pain and PD. *Id.* at 7–8. Defendant Lupin's proposed package insert omits only the PD indication. *Id.* at 8. Defendants plan to include these proposed package inserts to customers as part of marketing and commercial distribution. *Id.* at 10.

Defendants submitted the required Paragraph IV certifications[1] to the FDA, attesting that, to the best of their knowledge, the '048 patent is invalid or will not be infringed by the manufacture, use or sale of the new drugs for which applications were submitted. Defs.' Apotex, Lupin, Watson, Teva Br. Opp. Pls.' Mot. Summ. J 5–18, ECF No. 223 [hereinafter ALWT's Br. Opp. Pls.' Mot Summ. J]; Def. Mylan's Br. Opp. Pls.' Mot. Summ. J 2, ECF No. 270.

II. DISCOVERY RULINGS

Defendant Mylan objects (ECF No. 281) to Magistrate Judge Leonard's Order of December 30, 2013 (ECF No. 254) striking portions of Dr. Nancy Linck's Expert Report dated October 11, 2013. Magistrate Judge Leonard found that Dr. Linck improperly provided legal conclusions regarding the substantive patent law at issue in the case. Having reviewed the record, the Court finds that this non-dispositive pretrial ruling by Magistrate Judge Leonard is neither clearly erroneous nor contrary to law. *See* Fed. R. Civ. P. 72(a) (2013). Mylan's objection is **OVERRULED**.

III. STANDARD OF LAW

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

[1] In accordance with provisions of the Hatch-Waxman Act, 21 U.S.C. § 355, an ANDA *shall* contain a certification "in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2013) (emphasis added).

56(a) (2013). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986).

Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be considered by a court in its determination. *Id.* at 248.

After a motion for summary judgment is properly made and supported, the opposing party has the burden of showing that a genuine dispute of fact exists. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986).

At that point, the Court's function is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249.

In doing so, the Court must construe the facts in the light most favorable to the non-moving party, and may not make credibility determinations or weigh the evidence. *Id.* at 255. However, a court need not adopt a version of events that is "blatantly contradicted by the record, so that no reasonable jury could believe it." *Scott v. Harris*, 550 U.S. 372, 380 (2007). There must be "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249–50 (citations omitted). If there is "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party," the motion for summary judgment must be denied. *Id.* at 249.

IV. DISCUSSION

Defendant Mylan and Defendants Lupin, Watson and Apotex bring two motions for summary judgment, alleging invalidity of the '048 patent for (1) failing to meet reissue requirements and (2) obviousness-type double patenting.

Plaintiffs' defense of the obviousness-type double patenting claims hinges on their contention that the '048 patent was validly reissued as a divisional, and so can claim priority back to U.S. Patent Application No. 08/160,594 ("the original '594 application"), which was issued as the parent '823 patent. As a preliminary matter, the Court addresses claims regarding Plaintiffs' failure to meet reissue requirements first.

A. The Law of Reissue

1. Standard of law

"A reissue application is an application for a patent to take the place of an unexpired patent that is defective as a result of an error in the patent which was made without deceptive intention." Manual of Patent Examining Procedure ("MPEP") § 201.5 (8th ed., Rev. 9, 2012). An applicant may obtain reissue "[w]henever any patent is, through error, deemed wholly or partly inoperative or invalid, *by reason of a defective specification or drawing*, or *by reason of the patentee claiming more or less than he had a right to claim in the patent. . . .*" 35 U.S.C. § 251(a) (2013) (emphases added).

The reissue statute, 35 U.S.C. § 251, "is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally." *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986). However, it "was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application." *Id.* at 1582. The underlying principle is "to allow correction of those statutory rigors for which the penalty may be excessive under the circumstances." *In re Bennett*, 766 F.2d 524, 527 (Fed. Cir. 1985).

A reissue application is "fully examined in the same manner, and subject to the same rules as if being presented for the first time in an original non-reissue, nonprovisional application[.]" MPEP § 1440. Pursuant to 35 U.S.C. § 252, "every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form[.]" 35 U.S.C. § 252 (2014).

A reissue patent is entitled to the statutory presumption of validity under 35 U.S.C. § 282. *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735, 745 (Fed. Cir. 1993). If a reissue patent fails to meet the reissue requirements, it is invalid. *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1349 (Fed. Cir. 2005).

2. Analysis

Defendant Mylan asserts two arguments why the '048 patent is an invalid reissue: (1) new matter was added and (2) a claim was broadened more than two years after the original patent issued.

Defendants Lupin, Watson, and Apotex also assert two reasons why the '048 patent was not validly reissued: (1) failure to file a divisional is not correctable via reissue as a matter of law, and (2) intentional acts are not correctable via reissue. The Court addresses each claim in turn.

a. New matter added

Defendant Mylan contends that there are at least five compounds in the '048 reissue patent, examples 153–156 and 160 in Table VII, which were not present in the original '594 application. Plaintiffs admit that these compounds were omitted in the original '594 application, but argue that it is a "typographical error" that the Court should correct.

A district court has authority to correct a typographical error in a patent if the nature of the error is on the face of the patent. *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1356–57 (Fed. Cir. 2003). The Federal Circuit has limited a district court's power to correct a

utility patent to situations where "(1) the correction is not subject to reasonable debate based on consideration of the claim language and specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Id.* Here, a typographical error is obvious from the face of the '048 patent. Brackets are used to close off matters excluded from the reissue patent. The '048 patent contains at least one misplaced bracket—a closed bracket with no open bracket pairing—in the specification.[2] The prosecution history also does not contradict Plaintiffs' contention that the indicated material was supposed to be deleted. Accordingly, the Court may correct this typographical error. The Court finds that there is no new matter contained in the '048 patent and the reissue is not invalid under 35 U.S.C. § 251 for new matter added.[3]

b. Summary judgment is precluded as to whether a claim was broadened more than two years after the original patent issued because there exists a genuine dispute of a material fact

Defendant Mylan argues that the '048 patent is an invalid reissue because a claim was broadened more than two years after the original patent issued. Section 251 prohibits the addition of claims that broaden the scope of the claims of the original patent more than two years after the grant of the patent. 35 U.S.C. § 251(d); *see Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (finding that claims broadening the scope of the original patent more than two years after its grant contravene section 251); *In re Doll*, 419 F.2d 925, 927 (C.C.P.A. 1970) ("The reissue claims are also invalid because they are broader than the original claims and . . . [were] not claimed until more than two years after the original patent had been granted.").

[2] Plaintiffs claim that there are three misplaced brackets, but only one misplaced bracket is apparent on the face of the patent by virtue of its missing corresponding open bracket.

[3] The Court does not reach the question of whether "new matter" consists of any material not inherently contained in the original application, or whether "new matter" must be a substantive change to the invention.

The parties' experts dispute whether claim 25 of the '048 patent is broader in scope than any of the issued claims in the '068 patent. The '068 patent did not contain a claim for the treatment of menstrual cramps, but did have independent claims directed to methods for treating inflammation or an inflammation-associated disorders. Plaintiffs contend that the '068 patent defined menstrual cramps as an inflammation-associated disorder, as does the '048 patent. Likewise, Plaintiffs argue that the claims of the '068 patent encompass the treatment of menstrual cramps by claiming the treatment of pain.

Defendant Mylan maintains that claim 25 is broader in scope than any of the issued claims in the '068 patent because menstrual cramps are broader than inflammation or pain alone. This dispute raises a triable issue of fact. Summary judgment is precluded as to this issue.

c. The '048 patent is invalid under 35 U.S.C. § 251 for failure to file a divisional

"[T]he failure to file a divisional application, regardless of the propriety of the underlying restriction requirement, is not an error correctable by reissue under 35 U.S.C. § 251." *In re Watkinson*, 900 F.2d 230, 231 (Fed. Cir. 1990); *see also In re Doyle*, 293 F.3d 1355, 1358 (Fed. Cir. 2002) (same); *In re Weiler*, 790 F.2d at 1582 ("By acquiescing in the examiner's restriction requirement, and failing to file divisional applications on the subject matter of non-elected claims, [the applicant] foreclosed (because that was not error) his right to claim that subject matter.").

The parties do not dispute that Plaintiffs pursued a reissue application initially to correct its failure to file U.S. Patent Application No. 08/648,113, the national stage application, as a divisional application. It was that failure to file as a divisional that led to the invalidity of the '068 patent. Throughout the prosecution of the reissue application, the PTO repeatedly took the position that the failure to file a divisional was not correctable via reissue. *See* Sorenson Decl. Ex. 14 at PFH_0012327-29, ECF No. 167-15 at 13–15.

It was not until Pfizer filed a supplemental reissue declaration that "identifie[d] more than one error in claims 1, 2, 3, 7, 8, and 12" (*id.* at PFH_0025433-37, ECF No. 167-15 at 55–59) of the '068 patent and submitted additional claims 26–30 which were "narrower than original claim 1" (Martin Decl. Ex. 21at 9, ECF No. 200-15 at 10) that the PTO accepted the new reissue declaration and ultimately allowed the '048 patent. These errors were unrelated to the question of whether a reissue can be used to correct the failure to file a divisional.

The question in this suit is not whether reissue is permitted on another basis, but rather, whether the reissue in this case *could* be filed as a *divisional*. Plaintiffs contend that once an error under 35 U.S.C. § 251 forms a valid support for a reissue, correction of any other error is allowed. Patent law is not so forgiving. "Where more than one error is specified in the oath/declaration and some of the designated 'errors' are found to not be 'errors' under 35 U.S.C. § 251, any remaining error *which is an error under 35 U.S.C. § 251* will still support the reissue." MPEP 1414.II(B) (emphasis added); *see also Schering Corp. v. Mylan Pharm., Inc.*, No. 09-6383 (JLL), 2012 WL 1473329, at *16 (D.N.J. Apr. 27, 2012) (emphasis added) ("Once a proper basis for reissue is asserted, other *narrowing changes to the patent's claims* can be made without explanation.").

The designation of the reissue application as a divisional, as opposed to a CIP, is neither an error correctable under 35 U.S.C. § 251 nor a narrowing change to the patent's claims. Accordingly, the applicant could not use the reissue process to correct its failure to file a divisional application. The '048 patent must be deemed invalid under 35 U.S.C. § 251 for failure to file a divisional.

d. The '048 patent violates the reissue statute because intentional acts are not correctable via reissue

Defendants Lupin, Watson and Apotex also allege that Plaintiffs have improperly used the reissue process. These Defendants assert that Plaintiffs seek to avoid the consequences of

their prior deliberate and knowing choice to file a CIP application rather than a divisional of the original '594 application directed to methods of use.

"[T]he deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251." *In re Serenkin*, 479 F.3d 1359, 1362 (Fed. Cir. 2007). In *Serenkin*, the court considered "an applicant who intentionally and knowingly surrendered his right to a claim of priority, in exchange for a benefit, and [then became] unhappy with his choice." *Id.* at 1364. Specifically, the applicant made the choice during prosecution to forgo an earlier filing date in exchange for inclusion of drawings in his PCT application, and later tried to use reissue to obtain the earlier filing date. *Id.* at 1360–61. The court found that "the act of choosing a later filing date during prosecution of the PCT application in exchange for inclusion of missing drawings" does not constitute an error that is correctable under § 251. *Id.* at 1362. The court explained, "[t]he distinction is between a genuine error, or mistake, and a deliberate, but subsequently found to be disadvantageous, choice." *Id.* at 1364; *see also In re Mead*, 581 F.2d 251, 257 (C.C.P.A. 1978) ("When [appellant's] attorney made the conscious choice of breaking appellant's chain of copendency by letting the application issue . . . he knew, or should have known, that there could exist intervening references . . . which could defeat patentability of the disclosed but unclaimed subject matter in the original patent. That intentional omission of the appealed subject matter from the original application combined with the plan to claim it in the subsequent application, does not constitute 'error' under § 251 . . . .").

Plaintiffs do not dispute that the applicant did not intend to file a divisional when it filed U.S. Patent Application No. 08/223,629 ("the continuation-in-part '629 application") as a CIP to the original '594 application. They do not dispute that the applicant did not intend to file a divisional when it filed International Patent Application No. PCT/US94/12720 ("the PCT '720 application") and U.S. Patent Application No. 08/648,113 ("the national stage '113 application") from the PCT '720 application. All these applications were proper and timely filed.

Instead, Plaintiffs rely on *In re Wadlinger*, 496 F.2d 1200 (C.C.P.A. 1974) to liberally construe the term "error," as it is used in 35 U.S.C. § 251. Plaintiffs assert that "the use of the word 'error' in [35 U.S.C. 251] instead of the words 'inadvertence, accident or mistake,' which appeared in the corresponding section . . . of the patent statutes prior to the recodification of 1952, does not involve a substantive change, and the same type of error is necessary to justify a reissue after the enactment of the Patent Act of 1952." *Wadlinger*, 496 F.2d at 1206 (alteration and omission provided) (quoting *In re Byers*, 230 F.2d 451, 454 (C.C.P.A. 1956)). "'Inadvertence' and 'accident' may imply something other than deliberate action, but *'mistake' has a broad sweep and is certainly inclusive of actions taken in full consciousness.*" *Id.* at 1207 (emphasis added).

The Federal Circuit rejected this line of reasoning from the Court of Customs and Patent Appeals' *Wadlinger* decision. *Serenkin*, 479 F.3d at 1364–65 (finding the statement that the definition of error encompasses "to choose wrongly" was dicta); *see also Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 355 (1881) ("A claim may be enlarged in a reissued patent . . . only . . . when an actual mistake has occurred; not from a mere error of judgment . . . ."); *In re Orita*, 550 F.2d 1277, 1281 (C.C.P.A. 1977) ("Section 251 is not a panacea designed to cure every mistake which might be committed by an applicant or his attorney[.]").

Plaintiffs' intentional decision to file a CIP bestowed the benefit of an extended period of exclusivity as to celecoxib. It ultimately resulted in no protection from double patenting afforded under § 121. Because intentional acts are not correctable via reissue, the Court finds that the '048 patent violates the reissue statute § 251 as a matter of law and is invalid. *See N. Am. Container*, 415 F.3d at 1349.

3. Conclusion

The '048 patent is not invalid under 35 U.S.C. § 251 on the grounds that new matter was added. The disputed disclosure in the specification is not new matter, but an apparent typographical error on the face of the '048 patent, which the Court may correct.

Moreover, summary judgment is precluded as to whether a claim was broadened more than two years after the original patent issued because there exists a genuine dispute of a material fact as to whether the '068 patent contained a claim for the treatment of menstrual cramps.

However, the '048 patent is invalid under 35 U.S.C. § 251 because, even if other errors supported the reissue application under § 251, the failure to file a divisional is not an error correctable under 35 U.S.C. § 251, and is not a narrowing change to the patent's claims. Additionally, because the applicant intentionally filed a CIP application as opposed to a divisional, and intentional acts are not correctable via reissue, the '048 patent violates § 251 of the reissue statute as a matter of law and is invalid.

B. The '048 Patent is Invalid for Obviousness-type Double Patenting

1. Standard of Law

Obviousness-type double patenting is a judicially created doctrine that "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001) (citing *In re Longi,* 759 F.2d 887, 892 (Fed. Cir. 1985)). "[T]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *Id.* at 968 (quoting *In re Van Ornum,* 686 F.2d 937, 943–44 (C.C.P.A. 1982)) (first alteration provided; second alteration in the original) (internal quotation marks omitted).

The Federal Circuit has identified two steps in an obviousness-type double patenting analysis. First, "a court construes the claim[s] in the earlier patent and the claim[s] in the later

patent and determines the differences." *Id.* (citing *Ga.–Pac. Corp. v. United States Gypsum Co.,* 195 F.3d 1322, 1326 (Fed. Cir. 1999)) Second, it determines whether those differences render the claims patentably distinct. *Id.* "A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting." *Id.* (citing *In re Berg,* 140 F.3d 1428, 1431 (Fed. Cir. 1998)). "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Id.* (citing *In re Longi,* 759 F.2d at 896). The Federal Circuit has also held that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use[.]" *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385–86 (Fed. Cir. 2003).

However, if a divisional application is filed in response to a PTO restriction requirement, the safe harbor provision prevents it from being rejected for obviousness-type double patenting based on patents that issue from the parent application or divisionals of the parent application. 35 U.S.C. § 121. For this "safe harbor" to apply, there must be "consonance."[4]

2. Analysis

Defendants Lupin, Watson, Apotex and Mylan assert that the '048 patent is invalid for obviousness-type double patenting and the § 121 safe harbor provision does not apply.

a. The § 121 safe harbor provision does not apply because the application maturing into the '048 patent cannot be designated as a divisional

For the § 121 safe harbor provision to apply, Plaintiffs must show, among other things, that: (1) the application was specifically designated a "divisional" application; (2) the "divisional" application was filed "as a result of a restriction requirement made by the

[4] Consonance means that "the applicant must maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement." *Pfizer II*, 518 F.3d at 1359 (citing *Gerber Garment Tech. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990)). Restriction requirements do not carry over to later continuations. MPEP § 804.01.

examiner"; and (3) the "divisional" application was filed "before the issuance of the patent on the other application." *Pfizer II*, 518 F.3d at 1359–60 (quoting MPEP § 201.06); 35 U.S.C. § 121.

Plaintiffs cannot show that the application maturing into the '048 patent is designated as a divisional. As discussed above, a failure to file a divisional is not correctable via reissue, and the applicant did not intend to file a divisional when it filed the continuation-in-part '629 application, the PCT '720 application, and the national stage '113 application. These designations were made intentionally. Because intentional acts are not correctable via reissue, the '048 patent violates § 251 of the reissue statute, cannot be considered as a divisional, and is invalid as a matter of law. Having failed the first prong, the Court need not address the remaining requirements or proffered arguments to find that the '048 patent does not qualify for the § 121 safe harbor provision.[5]

Plaintiffs contend that the Court should give deference to the PTO's reading and application of 35 U.S.C. § 251 because the PTO is specifically charged with administering these statutory provisions. However, the Federal Circuit has counseled that it is a question of law as to whether a patent is invalid for violating the reissue statute or for double patenting. *See id.* at 1363; *Serenkin*, 479 F.3d at 1361.

b. The claims of the '048 patent are not patentably distinct from the claims of the '165 patent

Because the '048 patent cannot be considered a divisional of the '083 patent, the § 121safe harbor provision is inapplicable. The Court must next determine whether the claims of

[5] Plaintiffs contend that because the face of the '048 patent identifies the patent as a "division" of the original '594 application, which issued as the '823 patent, it must be a divisional that claims the priority date of that application, and was issued as a result of the restriction requirement. However, no application leading to the '048 patent was a divisional. Indeed, the national stage '113 application was filed as a CIP and claimed priority to the '629 application, which was filed as a CIP to the original '594 application. Both of these designations were intentional. Furthermore, the '629 application was filed as a CIP of the '594 application three months before there was a restriction requirement directed to the '594 application.

the '048 patent are patentably distinct from the claims of the '165 patent. *Pfizer II*, 518 F.3d at 1362. Being an invalid reissue of the '068 patent, Plaintiffs are not entitled to an injunction beyond the expiration date of the '165 patent. *See id.* at 1358.

The Federal Circuit previously recognized that "the '068 patent merely claim[ed] a particular use described in the '165 patent of the claimed compositions of the '165 patent." *Id.* at 1363. Since the '048 patent cannot claim to be a divisional, it is as vulnerable as the '068 patent—the '165 patent may be used to invalidate it.

3. Conclusion

For the reasons cited in *Pfizer II*, the '048 patent is invalid on the basis of obviousness-type double patenting.

C. Patent Infringement

Plaintiffs allege that the administration of Defendants' generic celecoxib products in accordance with Defendants' respective package inserts will both directly infringe, and also induce doctors and patients to infringe, claims 19–25 of the '048 patent. Defendants assert, as a defense, a good-faith belief that the '048 patent is invalid and unenforceable. Defendants contend that evidence of their good-faith belief creates, at minimum, a triable issue of fact.[6]

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[6] A defendant may have to seek to obtain an independent opinion of the validity of potentially relevant patents, on which it may reasonably rely in support of a good-faith belief of invalidity. *See Goss Int'l Ams. Inc. v. Graphic Mgmt. Assocs., Inc.*, 739 F. Supp. 2d 1089, 1115–16 (N.D. Ill. 2010) (finding that plaintiff had failed to provide triable evidence of inducement of infringement in light of an opinion letter received by the defendants from their patent attorney); *VNUS Med. Tech., Inc. v. Diomed Holdings, Inc.*, No. C-05-2972 MMC, 2007 WL 2900532, at *1 (finding a triable issue of fact as to whether any defendant was liable for acts of direct infringement where each defendant had "offered evidence that it sought and obtained the opinion of counsel, who, in each instance, provided an opinion the accused products did not infringe and/or the patents were invalid"); *Kolmes v. World Elastic Corp.*, No. 4:93CV00719, 1995 WL918081, at *10 (M.D.N.C. Sept. 18, 1995) (finding the plaintiffs had failed to prove induced infringement because the defendants had "consulted counsel and had a good-faith belief in the invalidity of the . . . patent, requesting reexamination by the PTO"). *This* type of "evidence of an accused inducer's good-faith belief of invalidity may negate the requisite intent for induced infringement. This is, of course, not to say that such evidence precludes a finding of induced infringement. Rather, it is evidence that should be considered by the fact-finder in determining whether an accused party knew 'that the induced acts constitute patent infringement.'" *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361,1368–69 (Fed. Cir. 2013) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011)) (footnote omitted).

The Federal Circuit has held that the failure of a party to obtain a non-infringement opinion may actually be probative of intent to induce infringement. *See Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 699 (Fed. Cir. 2008). The *Broadcom* and *Commil* decisions recognize that a party accused of induced infringement should obtain

Because the '048 patent is invalid on other grounds, Plaintiffs' Motion for Summary Judgment is moot.

V. CONCLUSION

The Court finds that the '048 patent violates the reissue statute because the failure to file a divisional is not correctable via reissue. Intentional acts also are not correctable via reissue. The Court finds the '048 patent is also invalid for obviousness-type double patenting.

Accordingly, the Court **GRANTS IN PART** the Joint Motion for Summary Judgment (ECF No. 166) filed by Defendants Lupin, Watson and Apotex, **GRANTS IN PART** Defendant Mylan's Motion for Summary Judgment (ECF No. 168), and **DENIES AS MOOT** Plaintiffs' Motion for Summary Judgment (ECF No. 154).

The Court **REQUESTS** that the parties prepare draft Judgments for the Court's consideration. These shall be filed by April 4, 2014.

IT IS SO ORDERED.

/s/
Arenda L. Wright Allen
United States District Judge

March 12, 2014
Norfolk, Virginia

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an opinion of counsel regarding any potential non-infringement and invalidity of the patent to support assertions of lack of intent, and should also expect that the absence of such an opinion may be used against it upon offering a defense of good-faith belief of non-infringement or invalidity. Defendants have offered no such evidence and, at oral argument, conceded that they did not in fact rely on opinions of counsel. Tr. 10:25, 11:10–11, 11:17, Feb. 26, 2013, ECF No. 350.

Defendants also agree that if the Court does not invalidate the claims of the '048 patent, doctors and patients administering Defendants' generic celecoxib products in accordance with Defendants' respective package inserts will directly infringe the claims of the '048 patent. Defendants acknowledge that selling their generic celecoxib products together with their proposed packet inserts would induce users to directly infringe claims 19–25 of the '048 patent. There exists no *genuine* dispute as to Defendants' specific intent to induce infringement.