IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC., Plaintiffs, v. ACTAVIS ELIZABETH LLC, ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 17-205-CFC

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MEMORANDUM OPINION

March 12, 2019
Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

This patent suit was filed by Plaintiffs Orexo AB and Orexo US, Inc. (collectively, "Orexo") against Defendants Actavis Elizabeth LLC, Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively, "Defendants"). Presently before me is Orexo's motion for summary judgment that issue preclusion bars Defendants from relitigating the validity of U.S. Patent No. 8,454,996 (the "#996 patent").[1] D.I. 172. The matter is fully briefed. D.I. 173, 174, 203, 205, 210, 216, 218. For the reasons discussed below, I will deny Orexo's motion.

I. BACKGROUND

Orexo alleges in its complaint that Actavis Elizabeth LLC's generic versions of Suboxone® and Subutex® infringe the #996 patent. D.I. 1. In an earlier case filed in this court, Orexo sued Actavis Elizabeth and its parent company, Actavis, Inc., alleging, among other things, that Actavis Elizabeth's generic versions of

[1] Plaintiffs previously filed a motion pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f) to dismiss and strike Defendants' allegations that the claims of the #996 patent are invalid. D.I. 53. Because Plaintiffs' motion to dismiss similarly argues that issue preclusion bars Defendants from relitigating the validity of the #996 patent, I will rule on the motion for summary judgment and dismiss as moot the motion to dismiss. *See Szubielski v. Pierce*, 2018 WL 456873, at *1 n.1 (D. Del. Jan. 17, 2018) (ruling on motion for summary judgment and dismissing as moot a motion to dismiss because both motions raised the same issues).

Zubsolv® infringe the #996 patent. *Orexo AB v. Actavis Elizabeth LLC*, 217 F. Supp. 3d 756 (D. Del. 2016) [the "Zubsolv litigation"], *rev'd on other grounds*, 903 F.3d 1265 (Fed. Cir. 2018). In response to Orexo's complaint in the Zubsolv litigation, Actavis Elizabeth and Actavis, Inc. asserted as an affirmative defense and in a counterclaim that claims of the #996 patent are "invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112." D.I. 173, Ex. A at 16; *see also id.* at 11, 17.

In September 2014, the parties in the Zubsolv litigation filed, and the court approved, a stipulation to dismiss Actavis, Inc. from the Zubsolv litigation. D.I. 203 at ¶ 12. Under the terms of the stipulation, "Actavis, Inc. including all affiliates and subsidiaries thereof . . . agree[d] to be bound by any judgment . . . rendered as to Actavis Elizabeth LLC in the Action (including appeals) as if they were named defendants." *Id.* (quoting D.I. 173, Ex. C at ¶¶ 1, 5). At the time the stipulation was entered by the court, Defendant Actavis Pharma, Inc., like Actavis Elizabeth, was a wholly-owned subsidiary of Actavis, Inc. *Id.* at ¶ 13. It is undisputed that Actavis Elizabeth and Actavis Pharma (collectively, "Actavis" or the "Actavis entities") are bound by the stipulation and the judgment ultimately issued in the Zubsolv litigation. *Id.* at ¶¶ 12–14.

In July 2015, Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively "Teva") announced that Teva had

agreed to purchase certain Actavis, Inc. assets, including Actavis Elizabeth and Actavis Pharma (the "Actavis transaction"). D.I. 203 at ¶¶ 19, 21.

In June 2016, before the Actavis transaction was consummated, the Zubsolv litigation proceeded to a bench trial before the now retired Honorable Sue L. Robinson. *Orexo AB*, 217 F. Supp. 3d at 759. In the proposed pre-trial order filed jointly by the parties in the Zubsolv litigation, Actavis Elizabeth identified as one of three "substantive issues remaining to be litigated . . . whether the Asserted Claims [of the #996 patent] are invalid as obvious under 35 U.S.C. § 103." Joint Proposed Pretrial Order, *Orexo AB v. Actavis Elizabeth LLC*, No. 14-cv-829-SLR (D. Del. May 4, 2016), D.I. 164-1, Ex. 5 at 1. Actavis Elizabeth did not identify any other theories of invalidity in the pre-trial order that remained to be litigated, and the only theory of invalidity it presented at trial was obviousness. *See Orexo AB*, 217 F. Supp. 3d at 762–69.

On August 2, 2016—after trial but before entry of a judgment in the Zubsolv litigation—the Actavis transaction closed and Teva acquired Actavis Elizabeth and Actavis Pharma. D.I. 203 at ¶¶ 19, 21. The terms of the transaction were set forth in a "Master Purchase Agreement." Pursuant to that agreement, Teva assumed Actavis's "Liabilities and Claims." *See* D.I. 173, Ex. E at 35; Tr. of Feb. 28, 2019 Hr'g at 36:8–39:3.

In an opinion issued on November 15, 2016, Judge Robinson held that the asserted claims of the #996 patent "are not invalid as obvious" and that Actavis Elizabeth infringed the asserted claims. *Orexo AB*, 217 F. Supp. 3d at 781; *see also* D.I. 203 at ¶ 27. Actavis Elizabeth did not appeal Judge Robinson's rulings with respect to the #996 patent.[2]

In February 2017, Orexo filed this action. Orexo alleges in its complaint that Actavis Elizabeth's manufacturing and Actavis Pharma's distribution of generic versions of Suboxone® and Subutex® infringe the #996 patent. D.I. 1 at ¶¶ 47–48, 74–75. Orexo alleges that Teva infringes the #996 patent by manufacturing, selling, offering for sale and/or importing into the United States generic Suboxone® and Subutex® products "either indirectly through [its] subsidiaries or affiliates or directly." *Id.* at ¶¶ 49, 76.

In their answer to the complaint, Defendants asserted as an affirmative defense and counterclaim that "one or more claims of the [#]996 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112." D.I. 50

[2] In the Zubsolv litigation, Judge Robinson also held that U.S. Patent No. 8,940,330 (the "#330 patent") was invalid as obvious under 35 U.S.C. § 103. *Orexo AB*, 217 F. Supp. 3d at 769–76. Orexo appealed Judge Robinson's ruling with respect to the #330 patent and the Federal Circuit reversed, holding that Actavis Elizabeth did not establish obviousness by clear and convincing evidence. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1274 (Fed. Cir. 2018). Neither party has argued that the Federal Circuit's decision to reverse Judge Robinson's decision with respect to the #330 patent implicates Judge Robinson's rulings with respect to the #996 patent.

at 51; *see also id.* at 22. Defendants, however, now seek only to assert that the #996 patent is invalid under §§ 103 and 112. D.I. 205, Ex. 2 at 23, 41.

II. LEGAL STANDARDS FOR SUMMARY JUDGMENT

"The court shall grant summary judgment 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. 56(a). "[T]he party moving for summary judgment . . . bears the burden of demonstrating the absence of any genuine issues of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party has carried its burden, the non-moving party must then "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)).

Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Id.* A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the

materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams v. Borough of W. Chester*, 891 F.2d 458, 461 (3d Cir. 1989).

The court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). "[T]he facts asserted by the nonmoving party, if supported by affidavits or other evidentiary material, must be regarded as true . . . ." *Aman v. Cort Furniture Rental Corp.*, 85 F.3d 1074, 1080 (3d Cir. 1996). If "there is any evidence in the record from any source from which a reasonable inference in the [nonmoving party's] favor may be drawn, the moving party simply cannot obtain a summary judgment . . . ." *Id.*

III. DISCUSSION

Orexo argues in its summary judgment motion that "validity is a single issue" as a matter of law and that, therefore, the doctrine of issue preclusion bars Defendants from challenging the validity of the #996 patent in this action. D.I. 172. Defendants disagree that validity is a single issue, but they do not dispute that if validity is deemed to be a single issue then the Actavis entities are precluded from challenging the #996 patent's validity in this action. D.I. 203 at ¶ 11.

Defendants contend that Teva is not bound by any judgment or rulings issued in the Zubsolv litigation regardless of whether validity is a single issue. *See* D.I. 210 at 3–9.

In their papers filed in opposition to Orexo's motion, Defendants asserted as a factual matter that "[t]he identical issue of the [#]996 patent's validity was not previously litigated" in the Zubsolv litigation. D.I. 203 at 12; *see also id.* at 12–14; D.I. 210 at 9–11. In support of this assertion, Defendants stated that § 112 defenses they intend to assert in this action and certain prior art references they intend to offer as part of an obviousness defense under § 103 in this action were not presented in the Zubsolv litigation. D.I. 203 at 12–14. Orexo does not dispute that § 112 and the prior art references cited by Defendants were not presented or adjudicated in the Zubsolv litigation. Orexo simply contends that Defendants are precluded from asserting these invalidity defenses in this action because validity is a single issue and "validity under § 103 was actually litigated, adjudicated, and necessary to the judgment [in the Zubsolv litigation]." D.I. 216 at 5.

A. Legal Standards Governing Issue Preclusion

In a patent case in this district, Third Circuit law governs the application of issue preclusion generally, and Federal Circuit law governs those aspects of issue preclusion "that may have special or unique application to patent cases." *Voter Verified, Inc. v. Election Sys. & Software LLC*, 887 F.3d 1376, 1382 (Fed. Cir.

2018). As the party asking the court to apply issue preclusion, Orexo bears the "burden of demonstrating the propriety of its application." *Suppan v. Dadonna,* 203 F.3d 228, 233 (3d Cir. 2000).

The doctrine of issue preclusion, sometimes called collateral estoppel, bars "'successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment,' even if the issue recurs in the context of a different claim." *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 748–49 (2001)). Issue preclusion is related to but different from claim preclusion, sometimes referred to as *res judicata*. Claim preclusion bars "successive litigation of the very same claim, whether or not relitigation of the claim raises the same issues as the earlier suit." *Taylor*, 553 U.S. at 892 (quoting *New Hampshire*, 532 U.S. at 748).

Although courts, including the Supreme Court and the Federal Circuit, routinely refer to "invalidity claims" in their opinions,[3] the Federal Circuit has explicitly held that "[a]n assertion of invalidity of a patent by an alleged infringer is not a 'claim' but a defense to the patent owner's 'claim.'" *Foster v. Hallco Mfg.*

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[3] *See, e.g., Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 135 (2007); *United States v. Glaxo Grp. Ltd.*, 410 U.S. 52, 56 (1973); *Cummins, Inc. v. TAS Distrib. Co.*, 700 F.3d 1329, 1337 (Fed. Cir. 2012); *Baseload Energy, Inc. v. Roberts*, 619 F.3d 1357, 1361–62 (Fed. Cir. 2010); *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338, 1340 (Fed. Cir. 2010).

Co., 947 F.2d 469, 479 (Fed. Cir. 1991).[4] Because it deemed invalidity only a defense to a claim of infringement and not a claim itself, and because a judgment of infringement embraces only the products that were found to have infringed the patent in question, the Federal Circuit held in *Foster* that claim preclusion applies to invalidity only if the products in the two lawsuits are "essentially the same." *Id.* As the generic versions of Suboxone® and Subutex® differ from the generic versions of Zubsolv®, Orexo has understandably not sought summary judgment based on claim preclusion.

The rationales for claim preclusion and for issue preclusion are the same. "Application of both doctrines is central to the purpose for which civil courts have been established, the conclusive resolution of disputes within their jurisdictions." *Montana v. United States*, 440 U.S. 147, 153 (1979). As the Court explained in *Montana*, "[a] fundamental precept of common-law adjudication . . . is that a 'right, question or fact distinctly put in issue and directly determined by a court of competent jurisdiction . . . cannot be disputed in a subsequent suit between the same parties or their privies . . . .'" *Id.* (quoting *S. Pac. R.R. Co. v. United States,* 168 U.S. 1, 48–49 (1897)). Precluding parties from litigating matters they had a

[4] It is not clear to me if *Foster* can be reconciled with the Supreme Court's holding in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 96 (1993), that "[a] party seeking a declaratory judgment of invalidity presents a claim independent of the patentee's charge of infringement."

full and fair opportunity to litigate in an earlier case "protects their adversaries from the expense and vexation attending multiple lawsuits, conserves judicial resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions." *Id.* at 153–54.

The Third Circuit has identified four "standard requirements" for the application of issue preclusion: "(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) (internal quotation marks and citation omitted), *cert. denied*, 549 U.S. 1305 (2007).

B. Analysis

The parties dispute whether Orexo has established three of the four factors required for issue preclusion to apply in this action. They agree that Judge Robinson's rulings with respect to the #996 patent's validity were necessary to her decision. But they dispute whether the identical issue was previously litigated and adjudicated in the Zubsolv litigation (requirements 1 and 2) and whether Teva was fully represented in the Zubsolv litigation (requirement 4).

Resolution of the parties' dispute with respect to the first and second requirements of issue preclusion hinges on the question of whether, as a matter of

law, invalidity is a single issue for purposes of issue preclusion. Orexo does not challenge Defendants' factual assertion that, because of § 112 arguments they seek to make and new prior art references they seek to present to establish obviousness in this action, the invalidity defenses in the two actions are not identical. Orexo's only response to this assertion is that "Defendants could have raised [in the Zubsolv litigation] the additional § 112 arguments and prior art they seek to raise here." D.I. 216 at 8. Issue preclusion, however, applies only to issues actually litigated in the prior action, not issues that could have been litigated.[5] Accordingly, as the party bearing the burden of demonstrating that issue preclusion should apply, Orexo can prevail on summary judgment only if validity, as a matter of law, is a single issue for purposes of effectuating estoppel.

Discerning the dimensions of an "issue" for estoppel purposes can be difficult in any setting, but it is especially challenging in the context of patent validity, a subject matter once described by Chief Judge Hand to be "as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of

[5] Claim preclusion bars a party from making arguments it could have raised in a prior action, *CoreStates Bank, N.A v. Huls Am., Inc.*, 176 F.3d 187, 191 (3d Cir. 1999); but, as noted above, because the accused products in this case and the Zubsolv litigation are different, *Foster*, assuming it can be reconciled with *Cardinal Chemical*, *see supra* at n. 4, would appear to bar Orexo from asserting claim preclusion in this action.

legal concepts." *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950). As noted in the commentary to Restatement of Judgments 2d § 27 cmt. c (1982):

> One of the most difficult problems in the application of the rule of [issue preclusion] is to delineate the issue on which litigation is, or is not, foreclosed by the prior judgment. The problem involves a balancing of important interests: on the one hand, a desire not to deprive a litigant of an adequate day in court; on the other hand, a desire to prevent repetitious litigation of what is essentially the same dispute.

In a patent case there is an additional important interest to consider in the requisite balancing—namely, "the strong federal policy favoring the full and free use of ideas in the public domain." *Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969). Owing to that "strong federal policy," the Federal Circuit has recognized a "well-established policy of freely allowing challenges to the validity of claimed intellectual property protection." *Nasalok Coating Corp. v. Nylok Corp.*, 522 F.3d 1320, 1327 (Fed. Cir. 2008).

Neither the Third Circuit nor the Federal Circuit has addressed whether validity is a single issue for estoppel purposes. The two judges of this court who have considered the question reached opposite conclusions. Chief Judge Stark treated validity as a single issue in *Astrazeneca UK Ltd. v. Watson Laboratories, Inc.*, 905 F. Supp. 2d 596, 603 (D. Del. 2012). Judge Andrews held in *TASER International, Inc. v. Karbon Arms, LLC*, 6 F. Supp. 3d 510, 519 (D. Del. 2013)

that "each theory of invalidity is a separate issue." At least 12 courts in other districts have confronted the question; each court treated validity as a single issue.[6]

Notwithstanding the fact that the overwhelming majority of court opinions support Orexo's position on the question, I will decline Orexo's invitation to adopt a per se rule that validity is a single issue for purposes of issue preclusion. My decision is largely informed by authorities not cited by the parties: *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), Third Circuit case law that discusses when issues should be adjudged identical for purposes of issue preclusion, and Federal Circuit case law that discusses how the various invalidity defenses are legally separate and distinct. I find also that

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[6] *See XpertUniverse, Inc. v. Cisco Sys., Inc.*, 2018 WL 2585436, at *4 (N.D. Cal. May 8, 2018); *Rudolph Techs., Inc., v. Camtek Ltd.*, 2016 WL 8668504, at *6 (D. Minn. Aug. 8, 2016); *PPC Broadband, Inc. v. Corning Gilbert Inc.*, 2014 WL 347802, at *3–*5 (N.D.N.Y. Jan. 31, 2014); *Abbott GMBH & Co., KG v. Centocor Ortho Biotech, Inc.*, 870 F. Supp 2d 206, 221 n.16 (D. Mass. 2012); *Roche Palo Alto LLC v. Apotex, Inc.*, 526 F. Supp 2d 985, 996 (N.D. Cal. 2007), *aff'd on other grounds*, 531 F.3d 1372 (Fed. Cir. 2008); *Meritor Transmission Corp. v. Eaton Corp.*, 2006 WL 3951711, at *6 (W.D.N.C. Sept. 26, 2006); *Crossroads Sys. (Tex.), Inc. v. Dot Hill Sys. Corp.*, 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 352 F. Supp. 2d 1119, 1124–26 (C.D. Cal. 2005); *Advanced Display Sys., Inc. v. Kent State Univ.*, 2002 WL 1489555, at *10 (N.D. Tex. July 10, 2002); *Unique Coupons, Inc. v. Northfield Corp.*, 2000 WL 631324, at *1 (N.D. Ill. May 16, 2000); *Pall Corp. v. Fisher Sci. Co.*, 962 F. Supp. 210, 213 (D. Mass. 1997); *Zip Dee, Inc. v. Dometic Corp.*, 905 F. Supp. 535, 537–38 (N.D. Ill. 1995).

treating validity as a single issue as a matter of law conflicts with important policies underlying the issue preclusion doctrine and the federal patent laws.

1. *Blonder-Tongue*

For most of the 20th century, issue preclusion was limited by the doctrine of mutuality of parties. Under that doctrine, a party could not use a prior judgment to collaterally estop another party from litigating a matter unless both parties were bound by the judgment. Based on that doctrine, the Supreme Court held in *Triplett v. Lowell*, 297 U.S. 638 (1936), that a determination of patent invalidity in a prior action did not bar a plaintiff from relitigating the validity of a patent in a subsequent action against a different defendant.

In *Blonder-Tongue*, the Supreme Court abandoned the requirement of mutuality of parties for issue preclusion and explicitly overruled *Triplett.* 402 U.S. at 350. The Court's analysis in *Blonder-Tongue* makes clear that it understood invalidity to encompass multiple issues for purposes of issue preclusion. For example, in rejecting the argument that patentees should have the right to relitigate patent validity because "patent litigation [i]s so technical and difficult as to present unusual potential for unsound adjudications," 402 U.S. at 330, the Court wrote:

> [I]t cannot be sensibly contended that all issues concerning patent validity are so complex and unyielding. Nonobviousness itself is not always difficult to perceive and decide and other questions on which patentability depends are more often than not no more

> difficult than those encountered in the usual nonpatent case.
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> * * * *
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> We are not persuaded, therefore, that the *Triplett* rule, as it was formulated, is essential to effectuate the purposes of the patent system or is an indispensable or even an effective safeguard against faulty trials and judgments. Whatever legitimate concern there may be about the intricacies of some patent suits, it is insufficient in and of itself to justify patentees relitigating validity issues as long as new defendants are available.

Id. at 332, 334. The Court's references to "all issues concerning patent validity" and "relitigating validity issues" (plural), and its comparison of nonobviousness to "other questions on which patentability depends," demonstrate that the Court deemed nonobviousness an issue separate from (albeit within) the broader subject of invalidity.

That invalidity is not a single issue as a matter of law is confirmed to my satisfaction by the following passage from *Blonder-Tongue*:

> [W]e do not suggest . . . that a plea of estoppel by an infringement . . . defendant must automatically be accepted once the defendant in support of his plea identifies the issue in suit as the identical question finally decided against the patentee or one of his privies in previous litigation. Rather, the patentee-plaintiff must be permitted to demonstrate, if he can, that he did not have "a fair opportunity procedurally, substantively and evidentially to pursue his claim the first time." . . .
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> Determining whether a patentee has had a full and fair chance to litigate the validity of his patent in an earlier case is of necessity not a simple matter. In addition to the considerations of choice of forum and

> incentive to litigate . . . , certain other factors immediately emerge. For example, if the issue is nonobviousness, appropriate inquiries would be whether the first validity determination purported to employ the standards announced in *Graham v. John Deere Co.*, [383 U.S. 1 (1966)]; whether the opinions filed by the District Court and the reviewing court, if any, indicate that the prior case was one of those relatively rare instances where the courts wholly failed to grasp the technical subject matter and issues in suit; and whether without fault of his own the patentee was deprived of crucial evidence or witnesses in the first litigation. But as so often is the case, no one set of facts, no one collection of words or phrases, will provide an automatic formula for proper rulings on estoppel pleas. In the end, decision will necessarily rest on the trial courts' sense of justice and equity.
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> . . . Arguably, [] *the availability of estoppel to one charged with infringement of a patent previously held invalid* will merely shift the focus of litigation from the merits of the dispute to the question whether the party to be estopped had a full and fair opportunity to litigate his claim in the first action. It would seem [a] sufficient answer to note that *once it is determined that the issue in both actions was identical, it will be easier to decide whether there was a full opportunity to determine that issue in the first action than it would be to relitigate completely the question of validity.*

Id. at 332–34, 347 (emphasis added). If validity were a single issue, then there would be no reason for the district court to make a "determin[ation] that the issue in both actions was identical" where the patent was found to be invalid in the first action. That district courts are required to make that determination when a

defendant seeks to preclude a plaintiff from relitigating the validity of a patent previously held to be invalid necessarily means that validity is not a single issue.

2. Third Circuit and Federal Circuit Case Law

Under Third Circuit law, "[i]dentity of the issues [for estoppel purposes] is established by showing that the same general legal rules govern both cases and that the facts of both cases are indistinguishable as measured by those rules." *Suppan*, 203 F.3d at 233 (internal quotation marks and citation omitted); *see also Nat. Med. Imaging, LLC v. Ashland Funding, LLC*, 648 F. App'x 251, 256 (3d Cir. 2016); *Hitchens v. Cty. of Montgomery*, 98 F. App'x 106, 112 (3d Cir. 2004); *Burlington N. R.R. Co. v. Hyundai Merchant Marine Co.*, 63 F.3d 1227, 1237 (3d Cir. 1995).

The legal rules that govern the invalidity defenses available to defendants sued for infringement vary significantly. A patent is invalid under § 101, for example, if it claims unpatentable subject matter. To make that determination, the court must first ascertain whether the patent's claims are drawn to a patent-ineligible concept (i.e., a law of nature, natural phenomenon, or abstract idea); and then, if the claims are not so drawn, decide if "the elements of each claim both individually and as an ordered combination" reveal an "inventive concept." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). By contrast, a patent is invalid under § 102 as anticipated if a single prior art reference explicitly or

implicitly discloses each and every limitation of the claimed invention. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 973 (Fed. Cir. 2014).

Under § 103, "[a] patent is invalid for obviousness '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.'" *Id.* at 961 (quoting 35 U.S.C. § 103(a)). "A party seeking to invalidate a patent as obvious must demonstrate '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 from doing so.'" *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014) (quoting *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)).

Under § 112, a patent can be invalid for indefiniteness, lack of enablement, or lack of an adequate written description. *See, e.g., Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1361 (Fed. Cir. 2004); *Sw. Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1297–98 (Fed. Cir. 2000). Although these concepts can overlap at times, they are each governed by different legal standards, and they have been described by the Federal Circuit as separate and distinct. *See, e.g., Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1340 (Fed. Cir. 2014)

("Appellants' arguments appear to be based on the wrong legal standard, i.e., written description or enablement as opposed to indefiniteness."); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2 (Fed. Cir. 1999) ("[D]efiniteness and enablement are analytically distinct requirements [of validity], even though both concepts are contained in 35 U.S.C. § 112."); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("[Section 112's] require[ment] [of] a 'written description of the invention' [] is separate and distinct from the enablement requirement.").

There is, in short, no uniformity among the rules that govern the invalidity defenses afforded to an accused infringer. Accordingly, applying Third Circuit and Federal Circuit precedent, I find that validity should not, as a matter of law, be treated as a single issue for estoppel purposes.

3. Public Policies

Public policies underlying the patent laws and the doctrine of issue preclusion counsel against adopting a per se rule that validity is a single issue. Treating validity as a single issue conflicts with the "well-established policy of freely allowing challenges to the validity of claimed intellectual property protection." *Nasalok*, 522 F.3d at 1327. And it is hard to see how the adoption of a per se rule would promote the public interests that prompted courts to adopt the doctrine of issue preclusion in the first place. Indeed, my sense is that such a rule

could cause defendants to litigate in full every possible invalidity theory as opposed to pursuing a streamlined defense focused on noninfringement and one or two of the most promising invalidity theories. If that were the case, litigation costs would rise, trials would become more complicated, jury confusion would likely increase, and precious judicial resources would be wasted. I therefore conclude that important public interests would be disserved by a holding that validity is a single issue for estoppel purposes.[7]

* * * *

Because validity is not a single issue for estoppel purposes and because Orexo does not challenge Defendants' factual assertion that the invalidity defense presented in the Zubsolv litigation is not identical to the invalidity defense Defendants seek to present in this action, Orexo has failed to meet its burden to establish the first two requirements for issue preclusion to apply. I therefore need not address whether the fourth requirement for issue preclusion is established; and I will deny Orexo's motion for summary judgment.

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[7] I can see how the treatment of particular invalidity defenses as single issues could conserve judicial resources and reduce litigation costs, and not conflict with the policy of liberally allowing validity challenges. If obviousness, for example, were treated as a single issue, a defendant would be precluded from relitigating that theory in a second action even where it sought to present in the second action prior art references not presented in the first action; but the defendant would be free to challenge the patent in question on other grounds, such as lack of enablement or lack of patentable subject matter. Orexo did not argue, and I therefore do not consider, whether obviousness is a single issue for estoppel purposes.

IV. CONCLUSION

For the reasons stated above, Orexo's motion for summary judgment is denied.

The Court will issue an order consistent with this Memorandum Opinion.