

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

ORTHOPEDIATRICS CORP., et al.,

Plaintiffs,

v.

WISHBONE MEDICAL, INC., et al.,

Defendants.

CASE NO. 3:20-CV-929-JD-MGG

OPINION AND ORDER

Pending and ripe before the Court is Plaintiffs' Second Motion to Strike Defendants' Affirmative Defenses pursuant to [Federal Rule of Civil Procedure 12\(f\)](#). For the reasons stated below, Plaintiffs' motion is **GRANTED IN PART** and **DENIED IN PART**. [DE 82].

I. RELEVANT BACKGROUND

Plaintiffs OrthoPediatrics, Corp. ("OP") and Orthex, LLC ("Orthex") filed the instant action on October 30, 2020, alleging the following claims against Defendants Wishbone Medical, Inc. ("Wishbone") and Nick A. Deeter: (1) infringement of U.S. Patent No. 10,258,377 ("the '377 patent") under [35 U.S.C. §§ 1 et seq.](#); (2) unfair competition and false advertising under the Lanham Act, [15 U.S.C. §§ 1051 et seq.](#); and (3) breach and violation of contract, defamation, interference with contractual relationships, and interference with business relationships, all under Indiana law. [DE 1]. Defendants responded to the complaint by filing a Motion to Dismiss for Failure to State a Claim on December 16, 2020. [DE 28].

Plaintiffs then filed their First Amended Complaint on January 6, 2021, adding Vilex LLC (“Vilex”) as a Plaintiff and alleging the following seven counts against Defendants: infringement of the ‘377 patent (Counts I and II); unfair competition and false advertising under the Lanham Act, 15 U.S.C. §§ 1051 *et seq.* (Count III); and breach of contract, defamation, and tortious interference with existing and prospective contractual relationships under Indiana law. (Counts IV-VII). [DE 33].

Defendants moved to dismiss Plaintiffs’ first amended complaint, resulting in dismissal of Count III (Plaintiffs’ unfair competition and advertising claim under the Lanham Act) as well as Counts V through VII (Plaintiffs’ claims of defamation *per se*, tortious interference with contractual relationships, and tortious interference with prospective contractual relationships under Indiana law). Accordingly, Plaintiffs’ patent infringement claims under 35 U.S.C. §§ 100 *et seq.* (Counts I and II) and Plaintiffs’ breach of contract claim under Indiana state law (Count IV) remained.

Defendants filed their answer, affirmative defenses, and counterclaim on September 21, 2021. Plaintiffs moved to strike this responsive pleading on October 12, 2021, and Defendants subsequently filed an amended answer, affirmative defenses, and counterclaim, causing Plaintiffs to file the instant Second Motion to Strike. Through this Second Motion to Strike, Plaintiffs seek an order striking Defendants’ First, Second, Third, Fourth, Fifth, Ninth, Tenth, Eleventh, and Twelfth Affirmative Defenses, contending that Defendants’ first and twelfth affirmative defenses are not actually affirmative defenses under federal law, that Defendants’ second and third affirmative defenses are redundant of Defendants’ counterclaims, and that Defendants failed to

sufficiently plead their fourth, fifth, ninth, tenth, eleventh, and twelfth affirmative defenses.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(f) provides that “[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent or scandalous matter.” Although this is a patent case, the Seventh Circuit's Rule 12(f) standards govern Plaintiffs’ instant motion. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009) (explaining that “procedural matter[s]” are “governed by the law of the regional circuit”); see also *Norix Grp., Inc. v. Corr. Techs., Inc.*, No. 20 C 1158, 2021 WL 5050281, at *1 (N.D. Ill. Nov. 1, 2021).

Motions to strike are generally disfavored “as they consume scarce judicial resources and may be used for dilatory purposes.” *Oswalt v. Rekeweg*, No. 117CV00278TLSSLC, 2017 WL 5151205, at *1 (N.D. Ind. Nov. 7, 2017) (internal citation omitted). But a motion to strike removing “unnecessary clutter” is considered to expedite a matter and should be granted. See *id.* Ultimately, whether to strike an affirmative defense under Rule 12(f) is within the court’s “sound discretion.” *Livesay v. Nat'l Credit Sys., Inc.*, No. 4:22-CV-19-TLS-JEM, 2022 WL 1210728, at *1 (N.D. Ind. Apr. 25, 2022) (citing *Talbot v. Robert Matthews Distrib. Co.*, 961 F.2d 654, 665 (7th Cir. 1992)).

An affirmative defense is a pleading that consists of “a defendant’s assertion of facts and arguments that, if true, will defeat the plaintiff’s . . . claim, even if all the allegations in the complaint are true.” *Bell v. Taylor*, 827 F.3d 699, 705 (7th Cir. 2016) (internal citation omitted). Accordingly, an affirmative defense “requires a responding

party to *admit* a complaint's allegations but then permits the responding party to assert that for some legal reason it is nonetheless excused from liability (or perhaps from full liability).” *Reis Robotics USA, Inc. v. Concept Indus., Inc.*, 462 F. Supp. 2d 897, 906 (N.D. Ill. 2006) (emphasis in original) (internal citation omitted). “As with any . . . defense upon which a party bears the burden of proof, the court must assume the truth of all factual allegations . . . for purposes of a motion . . . to strike for insufficiency.” *Rego-Fix AG v. Techniks, Inc.*, No. 1:10-CV-1188-JMS-TAB, 2011 WL 471370, at *2 (S.D. Ind. Feb. 2, 2011); *see also Norix Grp., Inc.*, 2021 WL 5050281, at *1 (“In resolving . . . Rule 12(f) motions, the court assumes the truth of the operative pleadings’ well-pleaded factual allegations . . .”

To determine whether an affirmative defense is sufficient, the court applies a three-part test: “(1) whether the matter is properly pled as an affirmative defense; (2) whether the affirmative defense complies with [Federal Rules of Civil Procedure 8](#) and [9](#); and (3) whether the affirmative defense can withstand a [Rule 12\(b\)\(6\)](#) challenge.” *Do It Best Corp. v. Heinen Hardware, LLC*, No. 1:13-CV-69, 2013 WL 3421924, at *2 (N.D. Ind. July 8, 2013) (internal citations omitted); *see also Cincinnati Ins. Co. v. Kreager Bros. Excavating*, No. 2:12-CV-470-JD-APR, 2013 WL 3147371, at *1 (N.D. Ind. June 18, 2013) (internal citations omitted). If an affirmative defense fails to meet any of these considerations, it may be stricken. *See Do It Best Corp.*, 2013 WL 3421924, at *2; *see also Reger v. Arizona RV Centers, LLC*, No. 3:16-CV-778-MGG, 2018 WL 2434040, at *2 (N.D. Ind. May 30, 2018).

As to the first part of this test, [Federal Rule of Civil Procedure 8\(c\)](#) enumerates several affirmative defenses, including: accord and satisfaction; arbitration and award; assumption of risk; contributory negligence; duress; estoppel; failure of consideration; fraud; illegality; injury by fellow servant; laches; license; payment; release; res judicata; statute of frauds; statute of limitations; and waiver. In addition to these affirmative defenses listed in Rule 8(c), “a defense is an affirmative defense (a) ‘if the defendant bears the burden of proof’ under state law or (b) ‘if it [does] not controvert the plaintiff’s proof.’” *Winforge, Inc. v. Coachmen Indus., Inc.*, 691 F.3d 856, 872 (7th Cir. 2012) (internal citations omitted).

As to the second and third prongs of this test, affirmative defenses are pleadings, and therefore, must set forth a “short and plain statement of the claim” as required by [Federal Rule of Civil Procedure 8\(a\)](#). The Seventh Circuit has not addressed whether affirmative defenses must meet the “plausibility” pleading standards articulated in *Twombly* and *Iqbal* or whether affirmative defenses must instead only meet a lesser standard as articulated in *Heller Fin., Inc. v. Midwehy Powder Co., Inc.*, 883 F.2d 1286, 1294 (7th Cir. 1989). Courts in this district have continued to follow the latter standard as articulated in *Heller Fin., Inc.*, which found that affirmative defenses must be stricken “only when they are insufficient on the face of the pleadings.” *Id.*; see also [Reger, 2018 WL 2434040](#), at *2. Accordingly, under this standard, affirmative defenses “will not be struck if they are sufficient as a matter of law or if they present questions of law or fact.” *Heller*, 883 F.2d at 1294. Likewise, “an affirmative defense supplemented with a brief statement of direct facts or facts inferred from the complaint or answer will defeat a

motion a strike.” *Reger*, 2018 WL 2434040, at *2. However, an affirmative defense must still consist of more than “bare bones conclusory allegations,” and the court must strike an affirmative defense which “omits any short and plain statement of facts and fails totally to allege the necessary elements of the alleged claims.” *Heller*, 883 F.2d at 1294-95.

III. DISCUSSION

a. Defendants’ First Affirmative Defense: Lack of Standing

Plaintiffs’ instant motion moves to strike Defendants’ first affirmative defense, which states “Plaintiffs lack standing to file suit on [the] ‘377 Patent. In particular, Dror Paley, a named inventor of the ‘377 patent had an obligation to assign his rights in the invention to a third party, IMED Surgical, LLC, and failed to do so. As such, Plaintiffs are not actual owners of the ‘377 Patent and have no standing to sue for infringement of the ‘377 Patent.” [DE 80 at 55].

Plaintiffs move to strike this affirmative defense, contending that lack of standing is not considered an affirmative defense under federal law. Defendants do not provide any arguments to the contrary; rather, Defendants instead appear to argue that this was merely “misabeled” and that there is no prejudice to justify striking it. [DE 85 at 10].

A lack of standing is not one of the affirmative defenses specifically enumerated in [Federal Rule of Civil Procedure 8\(c\)](#). Accordingly, under the first prong of the test, the court must consider whether “the defendant bears the burden of proof” or whether this would “controvert the plaintiff's proof.” *Winforge*, 691 F.3d at 872. Here, the instant affirmative defense is based upon Defendants’ assertion that Plaintiffs are “not the actual owners of the ‘377 Patent.” [DE 80 at 55]. However, Defendants do not bear the

burden of proof on this issue. Rather, Plaintiffs bear the burden of proving ownership of the asserted patent. See *Abbott Point of Care Inc. v. Epocal, Inc.*, 666 F.3d 1299, 1302 (Fed. Cir. 2012).

As Defendants do not bear the burden of proof as to ownership of the asserted patent, the Court cannot find that lack of standing is appropriately stated as an affirmative defense in this circumstance. This is also consistent with other courts in this circuit finding that lack of standing is not an affirmative defense under federal law. See *Newland N. Am. Foods, Inc. v. Zentis N. Am. Operating, LLC*, No. 2:13-CV-74-PPS-PRC, 2013 WL 2470273, at *3 (N.D. Ind. June 6, 2013) (citing *Native Am. Arts, Inc. v. The Waldron Corp.*, 253 F.Supp.2d 1041, 1045 (N.D.Ill.2003) (“It is apparent, therefore, that standing is a plaintiff’s requirement to plead and prove. Accordingly, standing is not an affirmative defense.”)).

Moreover, Defendants also previously asserted lack of standing on Plaintiffs’ patent infringement claims in their Motion to Dismiss Plaintiffs’ Amended Complaint [DE 37, DE 38 at 11]. The Court denied Defendants’ motion on this ground, stating that “[t]he Court reaches this decision with the understanding that an ultimate determination of constitutional standing can be made when the parties and Court have the benefit of a more complete factual record.” [DE 68 at 10]. Accordingly, while standing is not appropriately pled as an affirmative defense, to the extent that Defendants have a basis to assert lack of standing as the instant action progresses, Defendants may bring an appropriate motion at that time. See *SecurityProfiling, LLC v. Trend Micro Am., Inc.*, No. 616CV01165RWSJDL, 2017 WL 5150682, at *8 (E.D. Tex. Mar.

21, 2017), *report and recommendation adopted*, No. 616CV01165RWSJDL, 2017 WL 1950810 (E.D. Tex. May 11, 2017) (striking affirmative defense alleging lack of standing but noting that defendant may file a motion if it believes plaintiff lacks standing). Moreover, “[i]f the Court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.” [Fed. R. Civ. P. 12\(h\)\(3\)](#).

The first prong of the three-prong test considers whether a defense is appropriately pled as an affirmative defense. [Do It Best Corp.](#), 2013 WL 3421924, at *2. As lack of standing is not appropriately pled as an affirmative defense, Plaintiffs’ Motion to Strike Defendants’ First Affirmative Defense is **GRANTED**.

b. Defendants’ Second and Third Affirmative Defenses

Plaintiffs also seek an order striking Defendants’ second and third affirmative defenses, which state:

Second Affirmative Defense (Invalidity or Unenforceability)

The ‘377 Patent and each of the claims thereof are invalid and/or unenforceable for failure to comply with one or more requirements of the United States Code and the rules, regulations, and laws pertaining thereto, including, without limitation, the requirements of [35 U.S.C. §§ 101, 102, 103, and/or 112](#).

The ‘377 Patent is invalid as being anticipated under [35 U.S.C. § 102](#) or obvious under [35 U.S.C. § 103](#) in light of numerous prior art references, including WO 2012/102685, and other products or publications that predate the filing of the application that ripened into the ‘377 Patent. Further, the claims of the ‘377 Patent are invalid pursuant to [35 U.S.C. § 112](#) because the specification does not contain an adequate written description of the alleged invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which the alleged invention pertains to make and use the alleged invention. . . .

Third Affirmative Defense (Non-infringement)

Defendant Wishbone and the Accused System have not infringed and do not infringe any valid, enforceable claim of the ‘377 Patent, directly, contributorily, or through inducement. [DE 80 at 56].

Likewise, Defendants' first and second counterclaims seek declaratory judgment of non-infringement of the '377 patent and declaratory judgment of invalidity/unenforceability of the '377 patent.

Plaintiffs assert that the Court should strike Defendants' second and third affirmative defenses because they are redundant of these counterclaims. Defendants, however, contend that these affirmative defenses are not merely redundant of Defendants' counterclaims, explaining that courts have recognized that affirmative defenses and counterclaims accomplish different ends and that any doubt of redundancy should be resolved in favor of Defendants.

Considering these counterclaims in relation to the instant affirmative defenses, however, Defendants' first counterclaim for declaratory judgment of non-infringement includes the same sentence that Defendants also stated as their third affirmative defense [*Compare* DE 80 at 65, ¶26 to DE 80 at 56]. Moreover, Defendants' second counterclaim for declaratory judgment of invalidity/unenforceability of '377 patent directly incorporates factual allegations from their second affirmative defenses: "[a]s outlined in Defendants' Affirmative Defense and incorporated herein, the '377 Patent is invalid for failure to comply with one or more of the requirements of patentability As outlined in Defendants' Affirmative Defenses and incorporated herein, [Dror] Paley and [Abraham] Lavi made material misstatements . . ." [DE 80 at 66, ¶¶ 31, 34]. Based on this, and without more from Defendants as to the differences between these affirmative defenses and these counterclaims, the Court can only find that these pleadings are duplicative or redundant.

Defendants further contend that “the mere presence of redundant material, however, may not be a sufficient ground for granting a motion to strike when it does not affect the substance of a pleading.” [DE 85 at 11, quoting [FEDERAL PRACTICE AND PROCEDURE § 1381](#)]. While the instant action is primarily a patent infringement matter, this court must follow Seventh Circuit precedent on procedural matters such as the instant motion to strike. *Exergen Corp.*, 575 F.3d at 1318. Courts in this district strike redundant or duplicative pleadings. *See, e.g., Lincoln Nat'l Corp. v. Steadfast Ins. Co.*, No. 1:06-CV-58, 2006 WL 1660591, at *2 (N.D. Ind. June 9, 2006) (“[R]epetitious and unnecessary pleadings, such as a counterclaim that merely restates an affirmative defense, or which seeks the opposite effect of the complaint, should be stricken regardless of whether prejudice has been shown.”); *see also Manago v. Auto-Owners Ins. Co.*, No. 2:17-CV-267, 2018 WL 620381, at *3 (N.D. Ind. Jan. 30, 2018). This is also consistent with courts in this district finding that a motion to strike removing “unnecessary clutter” expedites a matter and should be granted. *Oswalt*, 2017 WL 5151205, at *1.

Accordingly, as these affirmative defenses consist of the same arguments as Defendants’ counterclaims and these counterclaims directly incorporate factual allegations from the affirmative defenses¹, Defendants’ second and third affirmatives

¹ To the extent that the Defendants’ counterclaims incorporate and rely on their affirmative defenses, the Defendants may wish to amend their counterclaims to ensure that all necessary factual allegations are contained therein. *See Greene v. Will*, No. 3:09-CV-510-PPS-MGG, 2016 WL 5662099, at *3 (N.D. Ind. Oct. 3, 2016) (dismissing a redundant counterclaim but allowing for amendment of answer or affirmative defense to incorporate facts raised in dismissed counterclaim as deemed necessary).

and Defendants' counterclaims are repetitious. Accordingly, Plaintiffs' Motion to Strike Defendants' second and third affirmative defenses is **GRANTED**.

c. Defendants' Fourth Affirmative Defense: Inequitable Conduct

In their fourth affirmative defense, Defendants allege that the '377 patent is unenforceable due to inequitable conduct: "The '377 Patent is unenforceable due to inequitable conduct. Plaintiffs committed inequitable conduct before the United States Patent Office in connection with the '377 Patent because Dror Paley and/or Abraham Lavi, listed inventors, failed to disclose material prior art and material information regarding the novelty of the claimed method, and/or misrepresented inventorship, in violation of the duty of disclosure and with the specific intent to deceive the [United States] Patent Office. . . . "[DE 80 at 56-57]

Inequitable conduct occurs when an individual breaches their duty "to prosecute patent applications in the [United States Patent Office] with candor, good faith, and honesty." *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007); 37 C.F.R. § 1.56(a). A finding of inequitable conduct on "any single claim renders the entire patent unenforceable." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011). Accordingly, "inequitable conduct, while a broader concept than fraud, must be pled with particularity" under Rule 9(b). *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). Rule 9(b) requires that a party "state[s] with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."

The elements of an inequitable conduct claim are: “(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the [United States Patent Office].” *Exergen Corp.*, 575 F.3d at 1327, n.3. This first prong – often referred to as the “materiality” prong of the inequitable conduct test – requires “identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Id.* at 1327.

Plaintiffs contend that Defendants’ inequitable conduct affirmative defense fails to sufficiently plead the who, what, where, when, and how required by the materiality prong. Specifically, Plaintiffs first contend that this affirmative defense fails to identify which asserted claims, and which elements of those claims, to which the alleged omission is relevant. Moreover, Plaintiffs further contend that Defendants fail to allege facts showing the “what” and “where” of the alleged omission, which are also necessary to show “why” the withheld material is necessary. Next, Plaintiffs also contend that this affirmative defense fails to identify specific information or a specific reference that was withheld. Finally, Plaintiffs contend that this affirmative defense only generally states that the listed inventors “failed to disclose material prior art and material information” but fails to explain “how” an examiner would have used this material in assessing patentability. [DE 83 at 9-10].

Defendants do not dispute Plaintiffs’ characterization of their pleading or the applicable pleading requirements. Instead, Defendants contend that this Court’s local

patent rules “obviate the need for any heightened pleading of invalidity contentions” based upon the rules’ requirements regarding disclosure of invalidity contentions. [DE 85 at 14]. In support, Defendants direct the Court to *Rockwell Automation, Inc. v. Beckhoff Automation, LLC*, 23 F. Supp. 3d 1236, 1248 (D. Nev. 2014) (declining to dismiss an invalidity defense and counterclaim even though they failed to comport with Rules 8(a) and 8(c) because local patent rules “obviate these pleading requirements in patent infringement cases”); *Helperich Pat. Licensing, LLC v. J.C. Penney Corp.*, No. 11 CV 9143, 2012 WL 3776892, at *2 (N.D. Ill. Aug. 28, 2012) (noting that “dismissal at the pleading stage would thwart the purposes of the Local Patent Rules, which require more particularized information to be disclosed during the Invalidity Contentions stage”); and *Graphic Packaging Int’l, Inc. v. C.W. Zumbiel Co.*, No. 1:10-CV-3008-AT, 2011 WL 5829674, at *4 (N.D. Ga. Aug. 1, 2011) (stating that “the Patent Local Rules operate to make further factual pleading unnecessary” as they “require an invalidity claimant to file a heightened pleading of invalidity contentions soon after it files its claims”).

While Defendants’ authority supports the proposition that the Court should not dismiss an affirmative defense for invalidity due to the disclosure requirements in this court’s local patent rules, inequitable conduct is not an invalidity defense. Rather, as explained by Plaintiffs, inequitable conduct is an unenforceability defense. See *Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1569 (Fed. Cir. 1992) (noting that “proving inequitable conduct does not ‘invalidate’ a patent. Rather, it renders the patent unenforceable”). In other words, “[u]nlike validity defenses, which are claim specific . . . inequitable conduct regarding any single claim

renders the entire patent unenforceable.” *Therasense*, 649 F.3d at 1288 (internal citation omitted). Accordingly, as an unenforceability defense, inequitable conduct is not necessarily incorporated into Defendants’ invalidity contentions, and this court’s local patent rules do not otherwise require disclosure of unenforceability contentions. *See* N.D. Ind. L.P.R. 3-1(e); N.D. Ind. L.P.R. 5-1(b); *see also Fleming v. Escort, Inc., No. CV 09-105-S-BLW, 2011 WL 1542126, at *5 (D. Idaho Apr. 21, 2011), on reconsideration in part, No. CV 09-105-S-BLW, 2011 WL 2173796 (D. Idaho June 2, 2011)* (observing that local rule patent rules do “not expressly apply to unenforceability contentions generally, or inequitable conduct specifically, but refers only to invalidity contentions” and that “most local rules do not require disclosure of unenforceability contentions”).

Affirmative defenses must meet the pleading requirements of Rules 8 or 9 under the second prong of the three-part test for affirmative defenses. *See Do It Best Corp., 2013 WL 3421924, at *2*. For the reasons stated above, the Court cannot find that the local patent rules obviate the need to meet requisite pleading requirements for inequitable conduct. Without any other argument from Defendants to why their pleading is sufficient under the heightened pleading requirements for fraud under Rule 9(b), the Court can only find that the instant affirmative defense fails to meet the second prong of the applicable three-part test. *Id.* Accordingly, Plaintiffs’ Motion to Strike Defendants’ Fourth Affirmative Defense is **GRANTED**.

d. Defendants’ Fifth Affirmative Defense: Patent Misuse

Defendants’ fifth affirmative defense alleges that Plaintiffs’ claims are barred by patent misuse:

Plaintiffs' claims are barred by patent misuse. Plaintiffs have alleged infringement of the '377 Patent against WishBone's fixator frame as stated in Plaintiffs' Motion for Leave to file Surreply Brief in Opposition to Defendants' Motion to Dismiss (Dkt. 53) and Brief in Support (Dkt. 53-1). Plaintiffs have repeatedly conflated any use of a fixator frame with infringement of the '377 Patent, interchanging words like "Accused Product" and "Accused System" in an attempt to expand coverage of the '377 Patent. When a patent owner impermissibly broadens the physical or temporal scope of a patent with anticompetitive effect, the patent becomes unenforceable. Plaintiffs' attempt to extend coverage of the '377 Patent fits squarely within the definition of patent misuse. [DE 80 at 57-58].

"[T]o plead patent misuse, Defendants must allege facts justifying a reasonable inference that [Plaintiffs] (1) acted with bad faith and improper purpose in bringing the suit and (2) impermissibly broadened the scope of the patent grant with anticompetitive conduct." *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, No. 16 C 6097, 2017 WL 1101092, at *15 (N.D. Ill. Mar. 22, 2017).

Plaintiffs move to strike Defendants' patent misuse affirmative defense contending that Defendants merely recite the general theory of patent misuse with conclusory statements and fail to adequately allege facts in support. Specifically, Plaintiffs contend that the only facts Defendants allege in support come not from Plaintiffs' complaint, but from a chart in a motion for leave to file a surreply brief where Plaintiffs quoted statements made by Defendants.

Defendants do not dispute Plaintiffs' characterization of their pleading. Instead, Defendants effectively concede that their pleading is deficient by again contending that this Court's local patent rules regarding disclosure of invalidity contentions "obviates the need for any heightened pleading of invalidity contentions." [DE 85 at 14].

However, like Defendants' inequitable conduct claim discussed *supra*, patent misuse is also considered an unenforceability defense, not an invalidity defense. See *C.R. Bard*,

Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998) (“Patent misuse arises in equity, and a holding of misuse renders the patent unenforceable until the misuse is purged; it does not, of itself, invalidate the patent.”); *see also B. Braun Med., Inc. v. Abbott Lab'ys*, 124 F.3d 1419, 1427 (Fed. Cir. 1997) (“When used successfully, this [patent misuse] defense results in rendering the patent unenforceable until the misuse is purged. It does not, however, result in an award of damages to the accused infringer.”)

Affirmative defenses must meet the pleading requirements of Rules 8 or 9 under the second prong of the three-part test for affirmative defenses. *See Do It Best Corp.*, 2013 WL 3421924, at *2. Here, the Court cannot find that the local patent rules regarding disclosure of invalidity contentions obviate the need to meet requisite pleading requirements for patent misuse, which is an unenforceability defense. Without any other argument from Defendants to why their pleading is sufficient, the instant affirmative defense fails to meet the second and third prongs of the applicable three-part test. *See id.* Accordingly, Plaintiffs’ Motion to Strike Defendants’ Fifth Affirmative Defense is **GRANTED**.

e. Defendants’ Ninth Affirmative Defense: Estoppel and Waiver

Defendants’ ninth affirmative defense contends that:

Plaintiffs’ claims for relief are barred, in whole or in part, by one or more of the equitable doctrines of estoppel, waiver, and/or other applicable equitable defenses. Dror Paley assisted Response Ortho² with software development on the Accused System in 2018 while simultaneously prosecuting the patent application that ripened into the ‘377 Patent. Paley is estopped from enforcing the ‘377 Patent because he was aware of Response Ortho’s Smart Correction system (Accused Product) and not

² As stated in Defendants’ answer, Response Ortho is a wholly owned subsidiary of Defendant Wishbone. [DE 80 at 18].

only allowed the development of Smart Correction, but assisted Response Ortho in its development. Response Ortho relied on Paley's conduct, which has now resulted in the current allegations of patent infringement. For the same reasons, the '377 Patent is also unenforceable under the doctrine of implied waiver. [DE 80 at 59-60].

The first portion of this affirmative defense states that Plaintiffs' claims are barred, in whole or in part, by equitable estoppel. For equitable estoppel, Defendants must plead that "(1) the patentee engages in misleading conduct that leads the accused infringer to reasonably infer that the patentee does not intend to assert its patent against the accused infringer; (2) the accused infringer relies on that conduct; and (3) as a result of that reliance, the accused infringer would be materially prejudiced if the patentee is allowed to proceed with its infringement action." *John Bean Techs. Corp. v. Morris & Assocs.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018).

Plaintiffs contend that "[a]s is plain from the elements of estoppel, there must be a misrepresentation *by the party against whom estoppel is asserted.*" [DE 83 at 12 (emphasis in original)]. Plaintiffs assert that the Court should strike this affirmative defense because Defendants have instead only alleged facts showing that Dr. Dror Paley, a party not named in the instant action, engaged in conduct relied upon by Response Ortho, another party not named in the lawsuit. In response, Defendants contend that they have pled a short and plain statement of facts that provide Plaintiffs with fair notice of the instant affirmative defense. Defendants do not directly address Plaintiffs' contention that they must allege acts by a named party to properly plead the elements of equitable estoppel. Defendants' response instead points to actions by inventor Dror Paley and explains that Wishbone's wholly owned subsidiary, Response Othro, relied

on these actions. Defendants contend that Dror Paley's conduct was relied upon and has resulted in the instant action alleging patent infringement.

As to Plaintiffs' contention that this affirmative defense must allege misleading conduct or misrepresentation by the named Plaintiffs, courts have considered equitable estoppel against a plaintiff when the factual allegations refer to conduct by a patentee's predecessor interest. See *High Point Sarl v. Sprint Nextel Corp.*, 817 F.3d 1325, 1330 (Fed. Cir. 2016) (concluding that the plaintiff's "predecessors' misleading course of conduct caused [Defendants] to reasonably infer that they would not assert the patents-in-suit while [Defendants] purchased unlicensed infrastructure to build its network); see also *Barnes & Noble, Inc. v. LSI Corp.*, 849 F. Supp. 2d 925, 931 (N.D. Cal. 2012) (observing that "there are a number of cases" suggesting that a predecessor-in-interests' conduct may imputed to patentee under theory of estoppel and discussing cases).

Here, considering the brief statement of direct facts alleged by Defendants as part of the affirmative defense as well as facts inferred from the complaint, answer, and attached to other filings, Dr. Dror Paley was one of the listed applicants for the '377 patent [DE 33-4 at 2], and Dr. Paley conveyed the patent to Orthex [DE 39 at 13-16; DE 40-1; DE 40-2, DE 68 at 8]. Moreover, in their answer, Defendants have explained that Response Ortho is a wholly owned subsidiary of Defendant Wishbone. Defendants have also alleged that Dr. Dror Paley assisted Response Ortho in developing the accused system while also prosecuting the '377 patent. As the instant defense alleges the necessary elements of equitable estoppel and is supplemented with a brief statement of facts, the Court cannot find that it is insufficient on its face. *Heller*, 883 F.2d at 1294

Accordingly, it is sufficient to survive the instant motion to strike. *Reger*, 2018 WL 2434040, at *2 (citing *Heller*, 883 F.2d at 1294).

Next, this affirmative defense also states that Plaintiffs' claims are barred in whole or part by implied waiver under these same facts. Implied waiver "occurs when the patentee's conduct was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished." *Core Wireless Licensing S.A.R.L v. Apple Inc.*, 899 F.3d 1356, 1365 (Fed. Cir. 2018). Notably, "[b]ecause implied waiver . . . may render an entire patent enforceable, the doctrine 'should only be applied in instances where the patentee's misconduct resulted in [an] unfair benefit'" or where there is "prejudice or egregious misconduct sufficient to justify the sanction of unenforceability of the patent at issue." *Id.* at 1368.

As to this defense, Plaintiffs contend that Defendants have merely "summarily asserted" it and that it fails to put Plaintiffs on notice of any prejudice or egregious misconduct. [DE 83 at 13]. While it is true that implied waiver should only be applied in situations involving an unfair benefit, prejudice, or egregious misconduct, at this stage of the instant action, the Court is only considering whether Defendants' pleading is sufficient to survive Plaintiffs' Motion to Strike. Here, Defendants have alleged a brief statement of facts regarding the elements of this defense. Accordingly, the Court cannot find that this pleading is insufficient on its face, and accordingly, this defense also survives the instant motion to strike. *Reger*, 2018 WL 2434040, at *2 (citing *Heller*, 883 F.2d at 1294).

Finally, Defendants' ninth affirmative defense also states that the Plaintiffs' claims are barred by "other applicable equitable defenses." The Court construes this portion of Defendants' affirmative defense as a reservation to assert additional equitable defenses. The Court cannot find that this is sufficient on its face as it fails to give Plaintiffs notice of the legal bases of these defenses. If Defendants wish to assert other equitable defenses, Defendants may file a motion to amend their affirmative defenses under Rule 15. *See, e.g., Archer Daniels Midland, Inc. v. LNG Indy, LLC*, No. 4:20-CV-60, 2021 WL 2754978, at *3 (N.D. Ind. July 2, 2021); *see also Schmitz v. Four D Trucking, Inc.*, No. 2:13-CV-214-RL-PRC, 2014 WL 309190, at *2 (N.D. Ind. Jan. 28, 2014).

Based on the foregoing, Defendants' ninth affirmative defenses of equitable estoppel and implied waiver meet the requisite three-part test to survive Plaintiffs' instant Motion to Strike. Accordingly, Plaintiffs' Motion to Strike is **DENIED** as to Defendants' equitable estoppel and implied waiver defenses but **GRANTED** as to Defendants' conclusory assertion of "and/or any other applicable equitable defenses."

f. Defendants' Tenth Affirmative Defense: Unclean Hands

Defendants' tenth affirmative defense states that "Plaintiffs' claims for relief are barred, in whole or in part, by the equitable doctrine of unclean hands. Dror Paley failed to disclose relevant facts to the United States Patent Office, such as Tamer Isin's demonstration of a system to Paley in 2010 that is nearly identical to the system as described and claimed in the '377 patent. The demonstration in 2010 predated by three years the filing of the provisional application that eventually ripened into the '377

Patent and Plaintiffs obtained the '377 Patent as a result of their deceptive conduct during prosecution of the '377 Patent." [DE 80 at 60].

"[U]nclean hands may be reached when 'misconduct' of a party seeking relief 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation,' i.e., 'for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court.'" *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018); *see also Natera, Inc. v. Genosity Inc.*, No. CV 20-1352, 2022 WL 767602, at *5 (D. Del. Mar. 14, 2022) ("[T]o establish an unclean hands defense, a defendant must show that '(1) a party seeking affirmative relief (2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith (3) directly related to the matter in issue (4) that injures the other party (5) and affects the balance of equities between the litigants.'")

Here, Defendants' unclean hands defense consists of the same facts and arguments alleged in support of their inequitable conduct defense. Accordingly, this defense also hinges a proper pleading of inequitable conduct. *See Edge Sys. LLC v. Cartessa Aesthetics, LLC*, 571 F. Supp. 3d 13, 21 (E.D.N.Y. 2021) ("Claims of unclean hands, absent allegations of fraud, are pled under the plausibility standard of Fed. R. Civ. P. 8. By contrast, claims of inequitable conduct must be plead under the heightened Fed. R. Civ. P. 9(b) . . .);" *see also Gilead Scis.*, 888 F.3d at 1240 n.3 (observing "that the unclean-hands doctrine operates in harmony with, and does not override, this court's inequitable-conduct standards governing unenforceability challenges based on prosecution communications with the PTO").

Pleading inequitable requires that “(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the [United States Patent Office].” *Exergen Corp.*, 575 F.3d at 1327, n.3. Here, Plaintiffs contend that Defendants’ unclean hands affirmative defenses fails to sufficiently allege the second element, deceptive intent, and that Defendants failed to allege enough facts from which such intent can be inferred. In response, Defendants contend that they alleged sufficient facts to support the inference of deceptive intent by alleging that Tamer Isin provided a demonstration of a nearly identical system to Dr. Dror Paley three years before Dr. Paley filed an application for the ‘377 patent. Defendants contend that this is sufficient to permit the inference of deceptive intent, citing to the court’s analysis in *Biomet Inc. v. Bonutti Skeletal Innovations LLC*, No. 3:13-CV-176 JVB, 2015 WL 13657627, at *2 (N.D. Ind. Apr. 27, 2015) (finding sufficient facts to infer deceptive intent and granting leave to amend complaint alleging inequitable conduct).

To plead deceptive intent, a “pleading must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* (internal citation omitted). A district court may infer from indirect or circumstantial evidence that there is deceptive intent, as “direct evidence of deceptive intent is rare.” *Id.* In doing so, however, “the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the

evidence.” *Id.* (internal citation omitted). Accordingly, “when there are multiple reasonable inferences, intent to deceive cannot be found.” *Id.* (internal citation omitted).

As to this, Plaintiffs contend that Defendants have failed to allege sufficient facts to show that deceptive intent is the “single most reasonable inference able to be drawn from the evidence.” [DE 86 at 15]. Plaintiffs further assert that, based on the facts alleged by Defendant, it is also reasonable that Dr. Dror Paley did not disclose the alleged art because it was not material.

Defendants contend that their allegation supports the inference of deceptive intent, relying on *Bonutti*. However, in *Bonutti*, the court found that it could infer deceptive conduct based on facts alleging that the defendant personally drafted or cited to articles about the prior art, of which the “key innovative aspects of the inventions” were described, and facts alleging that the defendant personally participated in the use of and sale on matters related to the inventions. [2015 WL 13657627](#), at *3. The Court also observed that the defendant was a sophisticated patent applicant due to owning more than a hundred patents. *Id.* at *4. Here, however, Defendants have alleged, without further explanation, that Dr. Paley saw a demonstration of a nearly identical system. Without more, the Court cannot find that the single most reasonable inference from this allegation is deceptive intent.

An affirmative defense must meet the pleading requirements of Rule 8 and be capable of surviving a [Rule 12\(b\)\(6\)](#) analysis. *Do It Best Corp.*, [2013 WL 3421924](#), at *2. Based on the foregoing, Defendants’ tenth affirmative fails these prongs of the

applicable three-part test. Accordingly, Plaintiffs' Motion to Strike Defendants' Tenth Affirmative Defense is **GRANTED**.

g. Defendants' Eleventh Affirmative Defense: Safe Harbor

Defendants' eleventh affirmative defense contends that "[t]o the extent Plaintiffs claim that use of the Accused System is an act of infringement, Defendants are exempt from liability pursuant to the safe harbor provision of 35 U.S.C. § 271(e). As stated in the [First Amended Complaint], Defendants' Smart Correction® External Fixation System received 510(k) clearance from the United States Food and Drug Administration ("FDA"). Any activities by Defendants reasonably related to the development and submission of information regarding the Accused System to the FDA fall under 35 U.S.C. § 271(e)." [DE 80 at 60-61].

Ordinarily "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent." 35 U.S.C. § 271(a). However, under § 271(e)(1), "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." While this "safe harbor" provision originally applied only to generic drugs, it has been extended to include medical devices and other products that are subject to FDA approval. See *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-74 (1990). !

Safe harbor under § 271(e)(1) is appropriately pled as an affirmative defense. *See, e.g., UCB, Inc. v. Catalent Pharma Sols., Inc.*, No. 5:21-CV-00038-GFVT, 2021 WL 5576327, at *4 (E.D. Ky. Nov. 29, 2021). Plaintiffs contend that the Court should strike Defendants' safe harbor affirmative defense because Defendants have failed to properly assert that "their use of the accused methods are 'solely' related to clearance from the FDA and fail to provide any allegations that would support this conclusion." [DE 83 at 14-15]. In response, Defendants contend that Plaintiffs "mischaracterize" their safe harbor affirmative, contending that Defendants sufficiently alleged that the accused system obtained 510(k) clearance from the FDA and that any activities reasonably related to development and submission of the accused system to the FDA fall under § 271(e)(1). [DE 85 at 20]. In reply, Plaintiffs again assert that this not sufficient because § 271(e)(1) requires that "acts be 'solely for' those uses, not that *any* uses that are 'reasonably related to the development and submission' are protected." [DE 86 at 16 (emphasis in original)].

This "safe harbor" provision "provides a 'wide berth' for activities related to regulatory approval and 'extends to all uses ... that are reasonably related to the development and submission of *any* information under the FDCA.'" *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). "[B]y enacting this exemption, congress has said to the public: 'You may commit acts of *infringement* only so long as *those* acts are solely for uses reasonably related to gaining FDA approval to market your product. If you engage in infringing activities for other uses, the exemption will not protect you. But if you engage in *non-infringing* acts for other uses, you do not lose

the benefits of this statutory amendment.’” *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1277–78 (N.D. Cal. 1991), *aff’d sub nom. Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808 (Fed. Cir. 1993) (emphasis in original). Accordingly, “the inquiry is *not* generally whether the allegedly infringing party has engaged in conduct that shows that it has purposes beyond generating and presenting data to the FDA.” *Id.* (emphasis in original).

Put another way, courts have stated that the safe harbor defense “applies to *any* use of a patented invention as long as the use is ‘reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs....’” *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1355 (Fed. Cir. 2012) (emphasis in original). Based on this, the court cannot find that Defendants’ allegation contending that “any” activities reasonably related to obtaining FDA clearance fails to properly plead the necessary elements of this affirmative defense.

With Defendants’ brief statement of direct facts, as well considering facts inferred from the complaint or answer, the Court cannot find that this pleading is insufficient on its face. *Heller*, 883 F.2d at 1294 Accordingly, Defendants’ safe harbor affirmative defense is sufficient to defeat Plaintiffs’ Motion to Strike. *Reger*, 2018 WL 2434040, at *2 (citing *Heller*, 883 F.2d at 1294). Plaintiffs’ Motion to Strike Defendants’ Eleventh Affirmative Defense is therefore **DENIED**.

h. Defendants' Twelfth Affirmative Defense: Adequate Remedies

Finally, Plaintiffs also seek an order striking Defendants' twelfth affirmative defense, which states: "Plaintiffs' claims for equitable relief are barred to the extent there is an adequate remedy at law." [DE 80 at 61]. Plaintiffs contend that this affirmative defense should be stricken because it is not a defense and because it was insufficiently pled. As to this second argument, Plaintiffs contend that the defense is merely a conclusion of law and fails to allege any facts in support. In response, Defendants contend that this affirmative defense should not be stricken because it was merely mislabeled, and its inclusion does not prejudice Plaintiffs. [DE 85 at 11]. However, Defendants do not dispute or otherwise address Plaintiffs' arguments contending that the instant affirmative defense is insufficiently pled.

Although courts in this district have declined to require that affirmative defenses meet the "plausibility" standard found in *Twombly* and *Iqbal*, courts have still found that "a defense void of any factual allegations is insufficient and warrants striking." See [Archer Daniels Midland, Inc. v. LNG Indy, LLC](#), No. 4:20-CV-60, 2021 WL 2754978, at *3 (N.D. Ind. July 2, 2021); see also [Do It Best Corp.](#), 2013 WL 3421924, at *2. For instance, in *Archer Daniels*, the court struck several affirmative defenses asserted by a defendant, including "Plaintiff's claims are by setoff or recoupment" and "Plaintiff's claims are barred because Plaintiff failed to mitigate its damages" because these affirmative defenses were "conclusory allegations that contain[ed] no factual support." 2021 WL 2754978, at *1, *3.

Without any factual support or additional argument from Defendants, the Court cannot find that the instant affirmative defense meets the pleading requirements of Rule 8 or that it would survive a 12(b)(6) analysis under the second and third prongs of the three-part test. See *Do It Best Corp.*, 2013 WL 3421924, at *2. Accordingly, Plaintiffs' Motion to Strike Defendants' Twelfth Affirmative Defense is **GRANTED**³.

IV. CONCLUSION

Based on the foregoing, Plaintiffs' Second Motion to Strike [DE 82] is **GRANTED IN PART AND DENIED IN PART**, and the Court **STRIKES** Defendants' First, Second, Third, Fourth, Fifth, Tenth, and Twelfth Affirmative Defenses. The Court also **STRIKES** the portion of Defendants' Ninth Affirmative Defense alleging "other applicable equitable defenses" as outlined in more detail this order.

SO ORDERED this 28th day of September 2022.

s/Michael G. Gotsch, Sr.

Michael G. Gotsch, Sr.
United States Magistrate Judge

³ Finally, Plaintiffs, without citation to legal authority, assert that the Court should strike Defendants' affirmative defenses with prejudice, contending that Defendants have failed to cure pleading defects on two occasions and that Plaintiffs have already expended significant resources addressing these defects. While the Court can empathize with Plaintiffs' frustration regarding repetitive motions, Defendants' ability to amend its affirmative defenses shall be in accordance with the Court's scheduling order, which provides that: "[t]he last date for the parties to amend the pleadings without leave of court is two months before end of fact discovery [and t]hereafter, any amendments to the pleadings must be by motion and leave of court." [DE 79 at 3]. See also *Biomet Inc. v. Bonutti Skeletal Innovations LLC*, 2015 WL 13657627, at *4 (allowing plaintiff to amend complaint in part because discovery was still in process and the claim construction order had just been issued). Further, here, the parties agreed in their Report of Parties Planning Meeting [DE 77] that "[t]he last date for [each party to] seek permission to join additional parties and to amend the pleadings is two months before end of fact discovery." Fact discovery closes "90 days after the Court issues its claim construction order" [id.], which means that the deadline for the parties to seek permission to amend pleadings is 30 days after the issuance of the claim construction order.