

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

REBOTIX REPAIR, LLC,

Plaintiff /
Counterclaim Defendant,

v.

Case No. 8:20-cv-2274-VMC-TGW

INTUITIVE SURGICAL, INC.,

Defendant /
Counterclaim Plaintiff.

_____ /

ORDER

This matter comes before the Court upon consideration of the cross Motions for Summary Judgment filed by Plaintiff Rebotix Repair, LLC and Defendant Intuitive Surgical, Inc. (Doc. ## 108, 117). Both Motions have been fully briefed. (Doc. ## 141, 147, 148, 152). For the reasons that follow, both Motions are denied, and this case will proceed to trial.

I. Background

A. Intuitive's and Rebotix's business models

Defendant Intuitive designs, manufactures, and sells minimally invasive surgical robots (known as da Vinci Surgical Systems ("da Vincis")) along with accompanying instruments and accessories, to hospitals and surgery centers worldwide. (Doc. # 117 at ¶ 1; Doc. # 1 at ¶¶ 1, 6). The

surgical instruments used in da Vinci surgeries (e.g., graspers, forceps, scissors, etc.) are called "EndoWrists." (Doc. # 117 at ¶ 1; Doc. # 1 at ¶ 1). EndoWrists attach to the da Vinci's mechanical arms, and doctors use hand controls at the surgeon's console to manipulate EndoWrists to perform surgery. (Doc. # 117 at ¶ 2). It is undisputed that Da Vinci surgeries have improved outcomes and present fewer complications than alternative healthcare options. (Id. at ¶ 3). Only surgical instruments made by Intuitive (the EndoWrists) are compatible with da Vinci robots. (Doc. # 1 at at ¶¶ 11, 32).

Intuitive has developed four "generational platforms" of the da Vinci - the standard, the S, the Si, and the X / Xi. (Doc. # 117 at ¶ 4; Doc. # 117-56 at 5). All EndoWrists include a programmed memory chip that communicates with the da Vinci robot and counts each time an EndoWrist is used in surgery (the "use counter"). (Doc. # 117 at ¶ 6). After an EndoWrist is used the specified number of times, the use counter causes the EndoWrist to become nonoperational. (Id.).

The parties disagree as to whether the da Vincis and EndoWrists are sold, marketed, and/or tested as a single product. (Doc. # 117 at 6-7; Doc. # 147 at 1). It is undisputed, however, that when customers buy a da Vinci, they

sign a Sales, Licensing and Service Agreement ("SLSA") acknowledging that EndoWrists will be purchased via "separate orders placed by [the] Customer to Intuitive from time to time in accordance with" certain terms and conditions. (Doc. # 117 at ¶ 9). The SLSAs require customers to use EndoWrists consistent with Intuitive's "documentation" (e.g., manuals, labeling, and instructions for use) and, under the agreements, may not repair, refurbish, or recondition EndoWrists in a manner inconsistent with that documentation. (Id.). The SLSAs require customers to adhere to the EndoWrist use limits. (Id.).

The SLSAs also provide customers with a system warranty, which promises that the da Vinci robot "will be free from defects in material and workmanship and will conform in all material respects to the Documentation when used in accordance with the Documentation and Intuitive's instructions." (Id. at ¶ 10). The warranty is void, however, with respect to any claims (1) due to any misuse of the system; (2) to the extent the customer has not operated, repaired, or maintained the system in accordance with Intuitive documentation; and (3) to the extent that the customer has used the system with surgical instruments not approved by Intuitive. (Id. at ¶ 10).

According to the complaint, Plaintiff Rebotix “repairs” EndoWrists. (Doc. # 1 at ¶ 2). Hospitals that perform surgery with da Vinci robots will hire Rebotix to inspect and repair the EndoWrists. (Id.). As Rebotix stated in its complaint, because its business would be rendered “obsolete” by the EndoWrist use counter installed by Intuitive, it invested “substantial time, resources, and money (millions of dollars) to develop a workaround.” (Id. at ¶ 51). Specifically, “[w]hen Rebotix repairs the EndoWrists, Rebotix includes a Rebotix Interceptor, which resets the counter[.]” (Id.). Rebotix admits that it installs the Interceptor as part of its “repair” process so that customers’ EndoWrist instruments can continue to be used after they reach the maximum use limit imposed by Intuitive. (Doc. # 61 at 3). It is undisputed that the Interceptor does not work on the newer X or Xi models. (Doc. # 1 at ¶ 52; Doc. # 117 at ¶ 52).

Between 2019 and 2021, Rebotix sold its EndoWrist “repair” service to at least 17 customers with then-existing contracts with Intuitive. (Doc. # 117 at ¶¶ 40-41). Rebotix does not dispute that it had knowledge of these contracts but claims that it believed the contracts to be void and unenforceable. (Id. at ¶ 41; Doc. # 147 at ¶ 41). Rebotix arranged for hospitals to ship used EndoWrists to Rebotix’s

facility in Florida, where the Interceptor was installed, and Rebotix then shipped the "repaired" EndoWrist back. (Doc. # 117 at ¶ 42). Rebotix priced its repaired EndoWrists 40-50% lower than Intuitive's list prices for new EndoWrists. (Doc. # 108 at ¶ B.5).

Intuitive did not want hospitals to use Rebotix to "repair" EndoWrists because they felt it was unsafe. (Doc. # 147-24 at 279). Rebotix customers received notices from Intuitive warning them that if they used EndoWrists beyond the designated number of uses, Intuitive would void the warranty, terminate the contract, and would no longer service the hospital's da Vinci system. (Doc. # 147-23 at 224; Doc. # 147-25 at 126-27). As Rebotix's corporate representative testified, "The customers that we gained received notices from Intuitive that if they used us, they would cancel the service contracts on their robots, which frightened the customers to death." (Doc. # 117-26 at 33). Without ongoing service from Intuitive, the da Vinci robot will eventually become nonoperational. (Doc. # 147-27 at 76-77). Neither Intuitive nor Rebotix could point to any hospital that continued to use Rebotix's services after receiving these notices from Intuitive. (Doc. # 117-26 at 33, 238; Doc. # 147-23 at 226).

B. FDA History

By way of background, federal law requires that medical devices receive certain approvals from the United States Food and Drug Administration ("FDA"). The FDA approval process at issue in this case is called "Section 510(k)" clearance.¹

In 2014, Rebotix's predecessor company submitted an application for Section 510(k) clearance to the FDA for "Re-manufactured EndoWrist instruments." (Doc. # 117 at ¶ 27; Doc. # 147 at ¶ 27). In 2015, the FDA sent a deficiency letter to the predecessor company and requested additional information. (Doc. # 117 at ¶ 30; Doc. # 147 at ¶ 27). In December 2015, the predecessor company withdrew its Section 510(k) application, and since that time neither Rebotix nor the predecessor company have resubmitted a Section 510(k) application for the Interceptor technology. (Doc. # 117 at ¶¶ 33-34).

The parties disagree as to whether Rebotix's services and/or products require Section 510(k) clearance from the FDA. While the cross motions for summary judgment were

¹ "Section 510(k) clearance" is the regulatory process pursuant to which a medical device that is "substantially equivalent" to a device that is already on the market can be cleared for sale without undergoing the far more rigorous pre-market review and approval process. See 21 U.S.C. § 360(k); Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996).

pending, Rebotix informed the Court that the FDA, as of April 2022, had determined that Rebotix's activities constitute "remanufacturing," which requires Section 510(k) review and approval.² (Doc. # 172). Specifically, Rebotix submitted email correspondence from a "Team Lead" at the FDA stating as follows:

As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted. The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

(Doc. # 172-1 at 2).

Recently, Rebotix submitted additional correspondence with the FDA from July 2022 in which that same FDA Team Lead

² Under the pertinent regulations, a "remanufacturer" of a non-exempt, Class II medical device is required to obtain 510(k) clearance before introducing its remanufactured device into commercial distribution in the United States. 21 C.F.R. § 807.81(a)(2); 21 C.F.R. § 820.3(o); 21 C.F.R. § 807.20(a).

wrote that the FDA had not made an “official regulatory determination,” but had instead conducted a “preliminary informal assessment.” (Doc. # 180-1 at 2).

C. Procedural History

Rebotix alleges that Intuitive “uses its dominance in the market for minimally invasive surgical robots to monopolize a separate market: the market for replacements and repairs of EndoWrists.” (Doc. # 1 at ¶ 30). According to Rebotix, Intuitive’s anticompetitive behavior has prevented Rebotix from repairing EndoWrists and has therefore “almost eradicat[ed]” Rebotix’s business. (Id. at ¶ 3). In its complaint, Rebotix brings four antitrust claims against Intuitive: (1) anticompetitive tying, in violation of Section 1 of the Sherman Act (Count I); (2) exclusive dealing, in violation of Section 1 of the Sherman Act (Count II); (3) market monopolization, in violation of Section 2 of the Sherman Act (Count III); and (4) attempted market monopolization, in violation of Section 2 of the Sherman Act (Count IV). See generally (Id.). In March 2021, the Court dismissed those portions of Counts III and IV based on the usage counter, but otherwise allowed the claims to proceed. (Doc. # 52).

Intuitive, for its part, has filed the following counterclaims against Rebotix: (1) false advertising and unfair competition, in violation of the Lanham Act (Counterclaim Count I); (2) common-law unfair competition (Counterclaim Count II); (3) common-law tortious interference with contract (Counterclaim Count III); and (4) violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") (Counterclaim Count IV). (Doc. # 60).

Now, both parties seek summary judgment. Specifically, Rebotix seeks summary judgment as to (1) Intuitive's Lanham Act, unfair competition, and FDUTPA counterclaims to the extent they are based on Intuitive's allegations that Rebotix did not comply with FDA regulations; (2) Intuitive's affirmative defense of unclean hands; and (3) the merits of Intuitive's FDUTPA counterclaim. (Doc. # 108 at 1). Intuitive seeks summary judgment on all of Rebotix's claims and on its tortious-interference counterclaim. (Doc. # 117 at 1). Both Motions have been fully briefed and are ripe for review. (Doc. ## 141, 147, 148, 152).³

³ With the Court's permission, the parties first temporarily filed under seal their summary judgment motions, Daubert motions, the responses thereto, and the exhibits in support. The parties filed redacted copies of these documents on the public docket two weeks thereafter. The Court thus cites to the extent practicable, in this Order and its Orders ruling

II. Legal Standard

Summary judgment is appropriate "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). A factual dispute alone is not enough to defeat a properly pled motion for summary judgment; only the existence of a genuine issue of material fact will preclude a grant of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

An issue is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Mize v. Jefferson City Bd. of Educ., 93 F.3d 739, 742 (11th Cir. 1996) (citing Hairston v. Gainesville Sun Publ'g Co., 9 F.3d 913, 918 (11th Cir. 1993)). A fact is material if it may affect the outcome of the suit under the governing

upon the parties' various Daubert motions, those motions and exhibits that are filed on the public docket. However, the parties also filed motions to seal the confidential information cited in those motions and exhibits. (Doc. ## 118, 153). Upon review of the Motions to Seal, the motions and exhibits placed under seal, and being otherwise fully advised, the Court **GRANTS** the parties' Motions to Seal. The Court finds good cause to maintain these documents under seal because they contain sensitive and proprietary business information from both parties, including confidential product engineering and testing information, proprietary financial modeling, and hospital data. Accordingly, the Court will permit the sealing of those motions and exhibits cited in the Motions to Seal.

law. Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997). The moving party bears the initial burden of showing the court, by reference to materials on file, that there are no genuine issues of material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). "When a moving party has discharged its burden, the non-moving party must then 'go beyond the pleadings,' and by its own affidavits, or by 'depositions, answers to interrogatories, and admissions on file,' designate specific facts showing that there is a genuine issue for trial." Jeffery v. Sarasota White Sox, Inc., 64 F.3d 590, 593-94 (11th Cir. 1995) (quoting Celotex, 477 U.S. at 324).

If there is a conflict between the parties' allegations or evidence, the non-moving party's evidence is presumed to be true and all reasonable inferences must be drawn in the non-moving party's favor. Shotz v. City of Plantation, 344 F.3d 1161, 1164 (11th Cir. 2003). If a reasonable fact finder evaluating the evidence could draw more than one inference from the facts, and if that inference introduces a genuine issue of material fact, the court should not grant summary judgment. Samples ex rel. Samples v. City of Atlanta, 846 F.2d 1328, 1330 (11th Cir. 1988). But, if the non-movant's

response consists of nothing “more than a repetition of his conclusional allegations,” summary judgment is not only proper, but required. Morris v. Ross, 663 F.2d 1032, 1034 (11th Cir. 1981).

Finally, the filing of cross-motions for summary judgment does not give rise to any presumption that no genuine issues of material fact exist. Rather, “[c]ross-motions must be considered separately, as each movant bears the burden of establishing that no genuine issue of material fact exists and that it is entitled to judgment as a matter of law.” Shaw Constructors v. ICF Kaiser Eng’rs, Inc., 395 F.3d 533, 538-39 (5th Cir. 2004); see also United States v. Oakley, 744 F.2d 1553, 1555 (11th Cir. 1984) (“Cross-motions for summary judgment will not, in themselves, warrant the court in granting summary judgment unless one of the parties is entitled to judgment as a matter of law on facts that are not genuinely disputed” (quotation omitted)).

III. Analysis

A. FDCA preemption and/or preclusion

One of the parties’ fundamental disagreements here is whether this Court or a jury could, at any point, address the issue of whether Rebotix’s services and/or products require Section 510(k) clearance from the FDA.

The Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), imposes a comprehensive set of requirements upon medical devices. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001). Section 337(a) of the FDCA bars private enforcement of the statute, stating that "all such proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has observed that Section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." Buckman, 531 U.S. at 349 n.4. The Supreme Court held in Buckman that private litigants cannot pursue claims under state-law tort theories when such claims collide with the exclusive enforcement power of the federal government. Id. at 343, 349-50. Specifically, because allowing plaintiffs to pursue state-law fraud-on-the-FDA claims "would exert an extraneous pull on the scheme established by Congress," such claims are therefore preempted by federal law. Id. at 348, 353.

After Buckman, the Ninth Circuit held that "a private right of action brought under the Lanham Act may not be

pursued when . . . the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.” PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) (involving a dispute as to whether a new version of dermatological laser required pre-market 510(k) clearance separate from that obtained for an earlier version, and concluding that, where the FDA had not taken a position, the Lanham Act claims could not proceed). “PhotoMedex [was] not permitted to circumvent the FDA’s exclusive enforcement authority by seeking to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion.” Id. at 928.

Another district court has determined – in another case brought by a repair company against Intuitive – that Intuitive’s state-law counterclaims for false or misleading statements were due to be dismissed to the extent those claims were based on statements pertaining to Section 510(k) clearance. Restore Robotics, LLC v. Intuitive Surgical, Inc., No. 5:19-cv-55-TKW-MJF, 2019 WL 8063988, at *2-3 (N.D. Fla. Nov. 14, 2019) (concluding that “determining the truth or falsity” of plaintiffs’ statement that FDA approval of their services was not required would require the court to make

determinations more properly within the exclusive purview of the FDA and to substitute its own judgment for the FDA's judgment, such that Intuitive's counterclaims would be impermissibly premised on enforcement decisions that the FDA did not itself make).

That leads to the April 2022 correspondence between Rebotix and the FDA in which an FDA Team Lead informed Rebotix that the FDA believes Rebotix's activities constitute remanufacturing and thus require FDA review and clearance.⁴ (Doc. # 176-1). While this is a compelling development, the Court is not persuaded that this is the FDA's final, definitive decision. It is unclear what role a "Team Lead" plays at the FDA and whether such employee has the authority to announce agency policy or take final action on behalf of the agency. This understanding is reinforced by the July 2022 FDA correspondence submitted by Rebotix in which that same

⁴ In support of its reply brief, Rebotix filed a declaration from one of its attorneys, Richard Lyon, in which Mr. Lyon detailed a December 2021 telephone call he had with FDA officials. (Doc. # 141-3). Intuitive moved to strike this declaration for multiple reasons. (Doc. # 160). The Court need not consider Mr. Lyon's declaration as the FDA correspondence from April and July 2022 is the most recent evidence of the FDA's stance as to Rebotix's activities. Therefore, the motion to strike is **DENIED AS MOOT**.

FDA Team Lead wrote that this decision was not an official, final decision from the agency. (Doc. # 180-1).

Thus, without definitive and final guidance from the FDA, if the Court were to wade into the evidence and make a determination on this point, it would necessarily be intruding upon the FDA's exclusive area of authority and usurping the FDA's authority to enforce the FDCA. See PhotoMedex, 601 F.3d at 928 ("Testing the truth of PhotoMedex's claim would similarly require a court to usurp the FDA's prerogative to enforce the FDCA and to decide whether, under the FDCA and its regulations, the [second-generation laser] was similar enough to SurgiLight's laser to permit Defendants to rely on its 510(k) clearance."); see also Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) (rejecting a Lanham Act false advertising claim based on cough syrup labeling because it would be inappropriate for a court to "determine preemptively how a federal administrative agency will interpret and enforce its own regulations").

Despite Intuitive's arguments, the decisions in POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102 (2014), and Belcher Pharms., LLC v. Hospira, Inc., 1 F.4th 1374 (11th Cir. 2021), do not hold otherwise. Those cases both involved

Lanham Act claims based on labeling of beverages and prescription drugs, respectively. Specifically, POM Wonderful held that the FDCA does not preclude a private party from bringing a Lanham Act claim challenging as misleading a food label that is regulated by the FDCA. Applying POM Wonderful, the Eleventh Circuit held that “nothing in the text of the Lanham Act or the FDCA suggests a different rule for drug products.” Belcher Pharms., 1 F.4th at 1380. Crucially, the Eleventh Circuit in Belcher cited the PhotoMedex decision approvingly, writing that “there may be reasons to disallow label challenges involving certain drug claims that call on courts to contradict a conclusion of the FDA *or to make an original determination on an issue committed to the FDA’s discretion.*” Id. (emphasis added). The Belcher case, however, did not involve such a “potential exception” because Belcher was not asking the Court “to make any original determination that only the FDA could make.” Id. at 1381. Thus, this case falls outside the rules enunciated in POM Wonderful and Belcher.

For the reasons stated above, the Court will not at this juncture issue a determination with respect to whether or not Rebotix’s services and/or products require Section 510(k) clearance. It will not address the related question of whether

Rebotix's services constitute "remanufacturing." Such questions are for the FDA to determine in the first instance. There does exist the possibility, however, that the FDA could issue an official and final determination between now and the time of trial. Therefore, the Court will not, at this time, grant summary judgment on Intuitive's counterclaims to the extent they are based on allegations that Rebotix does not comply with FDA regulations.⁵ If, however, the FDA has not issued an official, final determination on this issue on the eve of trial, the Court invites Rebotix to renew its motion for summary judgment as to these counterclaims⁶ and the Court

⁵ Moreover, as the Court notes in Section III.C of this Order, *infra*, Intuitive identifies nine forms of false or misleading statements allegedly made by Rebotix that form the bases for its counterclaims. Only one of these allegedly false or deceptive statements is aimed at the issue of FDA 510(k) clearance. (Doc. # 60 at ¶¶ 9-13). As Rebotix acknowledges in its reply brief, it "does not seek to dispose of these other theories." (Doc. # 141 at 1).

⁶ Rebotix also attacks Intuitive's affirmative defense of "unclean hands." The defense raised by Intuitive states as follows: "Plaintiff's claims are barred, in whole or in part, by the doctrine of unclean hands because Plaintiff has acted contrary to applicable FDA regulations and/or engaged in other misconduct, including tortious interference with Intuitive's contracts and business relationships." (Doc. # 60 at 24). The Eleventh Circuit's prior opinions have not been clear as to whether the doctrine of "unclean hands" can independently bar an antitrust suit. See Tidmore Oil Co. v. BP Oil Co., 932 F.2d 1384, 1388 (11th Cir. 1991) (observing in dicta that "because the Supreme Court has rejected the application of the doctrine of *in pari delicto* in antitrust

will grant summary judgment at that time. For the reasons explained in Footnote 6 and later in this Order, the Court will not entertain renewed motions for summary judgment on the issue of antitrust standing or on Intuitive's counterclaims to the extent those counterclaims do not rely on the issue of Section 510(k) clearance.

The Court will allow the parties to produce evidence at trial regarding the FDA regulatory process to help jurors understand this process and Rebotix's efforts, or lack thereof, to obtain Section 510(k) clearance. The Court is persuaded that the issue of FDA clearance goes to causation and damages. The extent to which the jury should decide the FDA clearance issue vis-à-vis causation and damages is a matter that can be resolved closer to trial.

actions, an agreement may be challenged even by one of the parties who has acquiesced in the unlawful agreement"). But see Official Comm. of Unsecured Creditors of PSA, Inc. v. Edwards, 437 F.3d 1145, 1156 (11th Cir. 2006) (stating in dicta that "Perma Life Mufflers explicitly left open the possibility that a defense of active involvement could bar a complaint about an antitrust conspiracy"). The Court will allow this affirmative defense to proceed because it is not based entirely on whether Rebotix complied with FDA regulations. On its face, Intuitive also asserts the defense due to Rebotix's alleged "tortious interference with Intuitive's contracts and business relationships." Thus, Rebotix's request to grant summary judgment as to this affirmative defense is denied.

B. Rebotix's Antitrust Claims

In its complaint, Rebotix claimed that Intuitive used its dominance in the market for minimally invasive soft tissue surgical robots ("MIST robots") to monopolize a separate market: the market for EndoWrist replacement and repair. (Doc. # 1 at 1). Rebotix points to the SLSAs that Intuitive's customers sign, which: (1) expressly require that customers adhere to the maximum number of uses and, once the use limit is reached, purchase a new EndoWrist; (2) expressly prohibit customers from performing repairs on the EndoWrists; and (3) void the warranty if customers do not repair or maintain the system in accordance with Intuitive's instructions. There is record evidence that Intuitive sent letters to Rebotix's customers warning that if they used Rebotix's services, Intuitive would cancel service for the da Vinci robots and void the warranty.

Thus, Rebotix claims in Count I of the complaint that Intuitive is engaging in illegal "tying" arrangements, whereby "Intuitive has conditioned the sale and servicing of its da Vinci surgical robots on customers buying replacement EndoWrists from Intuitive instead of repairing the EndoWrists that the customers already have." (Doc. # 1 at 21). Similarly, it brings a claim (Count II) against Intuitive for "exclusive

dealing” because Intuitive’s agreements with its customers “require the customers to service and replace their EndoWrist instruments on an exclusive basis with Intuitive, thus foreclosing competition in the worldwide and domestic markets for repair and replacement of EndoWrist instruments.” (Id. at 22). Finally, Rebotix brings claims for monopolization and attempted monopolization (Counts III and IV), alleging that Intuitive’s anticompetitive conduct and exclusionary tactics have “forced customers to purchase unnecessary EndoWrists at supercompetitive prices, and [have caused] Rebotix [injury] . . . including through lost profits, lost customers, and damage to its reputation and goodwill.” (Id. at 22-23).

Intuitive seeks summary judgment on all four counts, arguing that Rebotix’s antitrust claims fail as a matter of law for three independent reasons: lack of antitrust standing, failure to define a relevant antitrust market, and failure to prove that Intuitive engaged in anticompetitive conduct. The Court will address each in turn.

1. Antitrust Standing

“A private plaintiff seeking damages under the antitrust laws must establish standing to sue.” Sunbeam Television Corp. v. Nielson Media Research, Inc., 711 F.3d 1264, 1270 (11th Cir. 2013). Antitrust standing requires more than a

mere demonstration of Article III standing. Id. Rather, to establish antitrust standing, a plaintiff must establish that it (1) has suffered “antitrust injury” and (2) is an “efficient enforcer” of the antitrust laws. Id. at 1271.

Intuitive attacks Rebotix’s antitrust standing on two fronts. First, it argues that it cannot establish antitrust injury because it cannot show that its business was lawful. Second, it urges dismissal of Rebotix’s claims related to the X and Xi EndoWrists because Rebotix does not have the ability to override the use counter in those devices.

a. Antitrust Injury

Intuitive claims that Rebotix’s business is unlawful because the FDA requires Section 510(k) clearance for installation of the Interceptor, and it is undisputed that Rebotix has failed to obtain such clearance. According to Intuitive, because Rebotix’s business is not (and was never) lawful, none of its claimed injuries are “directly attributable” to any anticompetitive conduct on the part of Intuitive. In other words, the Section 510(k) regulatory bar “break[s] the chain of causation.” Intuitive doubles down on this argument in the supplemental briefing ordered by the Court after the April 2022 FDA correspondence, arguing that: “Because Rebotix does not have, and never has had, 510(k)

clearance, its business is and was illegal, and it cannot meet its burden to prove antitrust injury.” (Doc. # 176 at 4).

Intuitive’s argument leans on what it paints as the “undisputed fact” that “both Rebotix and the FDA recognize[] that Rebotix’s business of installing the Interceptor into EndoWrists requires 510(k) clearance.” (Doc. # 117 at 20-21). But this issue is highly disputed. As explained above, the Court is not persuaded that the FDA has definitively spoken on this issue, and it will not issue a determination as to whether Rebotix’s products and/or services required Section 510(k) clearance. With legality a disputed issue, that alone is enough to reject Intuitive’s antitrust injury argument.

But even assuming the FDA’s April 2022 email chain to be a definitive final determination by the FDA that the EndoWrist “repair” business was unlawful without 510(k) clearance, that does not necessarily bar Rebotix’s antitrust claims.

Here, Rebotix seeks treble damages under the Clayton Act for Intuitive’s allegedly illegal conduct. (Doc. # 1 at 24). Therefore, Intuitive’s “proscribed anticompetitive conduct must be a [m]aterial cause of [Rebotix’s] injury.” Comfort Trane Air Conditioning Co. v. Trane Co., 592 F.2d 1373, 1383 (5th Cir. 1979); see also Zenith Radio Corp. v. Hazeltine

Research, Inc., 395 U.S. 100, 114 n.9 (1969) (“It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.”). Here, Rebotix moves under the theory that Intuitive’s insertion of certain clauses into the SLSAs and its follow-up conduct warning customers away from Rebotix was anticompetitive conduct that caused its injury. The critical issue in this case is not whether 510(k) clearance is required to override the use limits in the EndoWrists, but rather whether the material cause of Rebotix’s injuries was anticompetitive restrictions imposed on EndoWrist customers in the SLSAs (as Rebotix claims) or whether it was caused by the lack of FDA clearance and other factors unrelated to Intuitive (as Intuitive claims). And “the question of causation is generally a factual question for the jury.” Comfort Trane, 592 F.2d at 1383.

There is sufficient evidence to raise a genuine issue of material fact as to whether it was Intuitive’s allegedly anticompetitive conduct that was a material cause of Rebotix’s injuries because there is evidence that some hospitals were willing to use Rebotix’s services, at least until they received the cease-and-desist letters from

Intuitive. (Doc. # 117-26 at 33:7-12; Doc. # 128-24 at 126:21-127:1; Doc. # 128-22 at 226:3-22).

The Court has carefully read the line of cases cited by Intuitive in support of its argument that Rebotix lacks antitrust standing as a matter of law. See In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 163- 65 (3d Cir. 2017); In re Canadian Import Antitrust Litig., 470 F.3d 785, 791-92 (8th Cir. 2006); Modesto Irrigation Dist. v. Pac. Gas & Elec. Co., 309 F. Supp. 2d 1156, 1170 (N.D. Cal. 2004) aff'd, 158 F. App'x 807, 807 (9th Cir. 2005); JEM Mktg., LLC v. Cellular Telecomms. Inds. Ass'n, 308 N.J. Super. 160, 166 (N.J. App. Div. 1998). These cases, however, stand for the proposition that a regulatory or legislative bar can *factually* break the chain of causation between an antitrust defendant's challenged conduct and the plaintiff's injury. For example, in the Wellbutrin case, plaintiffs claimed that their injury (increased drug prices) was caused by defendants' conspiracy to delay the launch of a generic version of the drug. 868 F.3d at 142, 164-65. To meet their burden, plaintiffs pointed to evidence that another company would have timely launched its generic drug. Id. at 165. The problem with this argument is that there was a patent blocking the release of the generic drug. Id. Thus,

the generic drug could never have legally launched. Id. Because plaintiffs could not prove that the defendant's actions "actually cause[d] the [plaintiffs'] claimed injury," their claim failed. Id. at 166; see also In re Canadian Import, 470 F.3d at 791-92 (holding that where federal law excluded cheaper Canadian drugs from entering the U.S. market, plaintiffs could not show that defendants' exclusionary conduct was the cause of their harm).

It does not follow that lack of regulatory approval is a *per se legal* bar to an antitrust suit. Indeed, the Supreme Court has many times disapproved of the notion that a plaintiff's participation in its own illegal conduct would bar it from pursuing an antitrust claim, reasoning that the overriding public policy of the antitrust laws would be undermined if the plaintiff's alleged illegal conduct could be used by the defendant to avoid liability for its own anticompetitive conduct. See Perma Life Mufflers, Inc. v. Int'l Parts Corp., 392 U.S. 134, 138-39 (1968) (overruled on other grounds by Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752 (1984)); Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, 340 U.S. 211, 214 (1951) (also overruled on other grounds by Copperweld). The public policy balancing is even more weighted in favor of allowing antitrust actions to move

forward when it is a mere regulatory violation. See Semke v. Enid Auto. Dealers Ass'n, 456 F.2d 1361, 1369-70 (10th Cir. 1972). In Semke, the plaintiff, a used car dealer, claimed that the defendants, new car dealers, conspired to injure it in their efforts to sell new cars. The defendants argued that plaintiff's antitrust claim was barred because plaintiff had entered the new car dealership market illegally due to his failure to comply with a state licensing statute. The Tenth Circuit, citing Perma Life Mufflers, held that if participation by the plaintiff in an illegal conspiracy in restraint of trade does not bar an antitrust action, then a plaintiff's alleged violation of a state licensing statute which is unrelated to the antitrust laws would not bar his antitrust claim because "the superior public interest in enforcing . . . the antitrust laws" clearly outweighed any social value flowing from the Oklahoma state licensing statute. 465 F.2d at 1369-70.

Here, Intuitive admits that "Rebotix sold its EndoWrist 'repair' service to at least 17 customers with then-existing contracts with Intuitive." (Doc. # 117 at 13). And Rebotix has proffered evidence that absent Intuitive's "contractual restrictions and threats," at least some hospitals would have used Rebotix's services "to the full extent that Rebotix was

willing to provide.” (Doc. # 128-26 at 62:6-12; Doc. # 117-26 at 33:9-23). There is thus evidence that some facilities were using and were willing to use Rebotix’s services notwithstanding the fact that Rebotix did not have FDA clearance at any time. Viewing the evidence in the light most favorable to Rebotix, a jury could find that Rebotix would have continued to provide its EndoWrist “repair” service to at least some health care facilities during the relevant time period but for the restrictions imposed in the SLSAs and Intuitive’s cease and desist letters.

In sum, there is conflicting evidence on the issue of material causation that precludes summary judgment. To be sure, this new evidence regarding the FDA’s stance will likely be presented to the jury and be relevant to the issues of causation and damages. But it does not mean that Rebotix per se lacks antitrust standing. Intuitive’s Motion is denied on this ground.

b. Standing with respect to X and Xi EndoWrists

Moving on to Intuitive’s argument about X and Xi EndoWrists, Intuitive’s position is that Rebotix cannot show it is prepared to enter the market because it is undisputed that Rebotix cannot override use limits on X/Xi EndoWrists because it lacks the technological capability to do so.

Intuitive argues that Rebotix therefore cannot show “preparedness” to enter the market and is not an “efficient enforcer” of the antitrust laws.

In order to be an efficient enforcer for the purposes of antitrust standing, a plaintiff must be (or must prove the existence of) a competitor willing and able to enter the relevant market, but for the exclusionary conduct of the “incumbent monopolist.” Sunbeam, 711 F.3d at 1273. To this end, Rebotix must make a showing of “preparedness to enter the business.” Cable Holdings of Ga., Inc. v. Home Video, Inc., 825 F.2d 1559, 1562 (11th Cir. 1987). To establish preparedness, a party must take some affirmative step to enter the business. Gas Utils. Co. v. S. Nat. Gas Co., 996 F.2d 282, 283 (11th Cir. 1993).

For its part, Rebotix points out that it has not completed the X/Xi Interceptor because expending the resources to do so would be futile in light of Intuitive’s ongoing anticompetitive conduct. (Doc. # 147 at 18 (citing Sanger Ins. Agency v. Hub Int’l, Ltd., 802 F.3d 732, 740 (5th Cir. 2015) (“The degree to which a business must take affirmative steps is mitigated by the impact of the antitrust violation. . . . [N]ascent competitors need not pay a courtroom entrance fee in the form of an expenditure of

substantial resources in a clearly futile competitive gesture.”)). Moreover, Rebotix points to the following affirmative steps it has taken: (1) Rebotix “was and is operational” and “it remains ready to repair EndoWrists”; and (2) it has already staffed a team for its business, spent millions of dollars on research and development, and obtained two patents on its method for resetting the usage counter.

Whether certain “actions and circumstances are sufficient to show preparedness presents a question of fact.” Cable Holdings of Ga., Inc. v. Home Video, Inc., 572 F. Supp. 482, 491-92 (N.D. Ga. 1983); see also Sanger Ins., 802 F.3d at 738 (stating that sufficient evidence of preparedness precludes summary judgment). Given the disputed issues of fact here regarding Rebotix’s preparedness and the extent to which further development would have been futile, summary judgment is not appropriate. Intuitive’s Motion is denied on this ground.

2. Relevant Antitrust Market

Antitrust claims require market definition and “[d]efining the relevant market requires identification of both the product at issue and the geographic market for that

product.”⁷ Bailey v. Allgas, Inc., 284 F.3d 1237, 1246 (11th Cir. 2002); see also Spanish Broad. Sys. of Fla., Inc. v. Clear Channel Commc’ns, Inc., 376 F.3d 1065, 1074 (11th Cir. 2004) (“Like claims under Section One, Section Two claims require harm to competition that must occur within a ‘relevant,’ that is, a distinct market, with a specific set of geographical boundaries and a narrow delineation of the products at issue.”).

“Defining a relevant product market is primarily ‘a process of describing those groups of producers which, because of the similarity of their products, have the ability – actual or potential – to take significant amounts of business away from each other.’” U.S. Anchor Mfg., Inc. v. Rule Indus., Inc., 7 F.3d 986, 995 (11th Cir. 1993) (citing Gen. Indus. Corp. v. Hartz Mountain Corp., 810 F.2d 795, 805 (8th Cir. 1987)). “The reasonable interchangeability of use or the cross-elasticity of demand between a product and its substitutes constitutes the outer boundaries of a product market for antitrust purposes.” Id. (citing Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)). Cross-elasticity of demand measures the extent to which modest variations in the

⁷ There does not appear to be any dispute that the relevant geographic market here is the entire United States.

price of one good affect customer demand for another good.

"[A] high cross-elasticity of demand indicates that the two products in question are reasonably interchangeable substitutes for each other and hence are part of the same market." Jacobs v. Tempur-Pedic Int'l, Inc., 626 F.3d 1327, 1337 n.13 (11th Cir. 2010).

Defining the relevant product market is a fact-intensive endeavor. U.S. Anchor, 7 F.3d at 994. "Reliable measures of supply and demand elasticities provide the most accurate estimates of relevant markets." Id. at 995. "However, it is ordinarily quite difficult to measure cross-elasticities of supply and demand accurately. Therefore, it is usually necessary to consider other factors that can serve as useful surrogates for cross-elasticity data." Id. Thus, in addition to the cross-elasticity of demand and supply, the Eleventh Circuit has long looked to the factors (or "practical indicia") set forth by the Supreme Court in Brown Shoe in defining a relevant market or submarket: "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." Id.

Here, Rebotix attempts to define a relevant antitrust product market through its proffered expert witness, economist Dr. Russell Lamb. See Gulf States Reorganization Grp., Inc. v. Nucor Corp., 822 F. Supp. 2d 1201, 1234 (N.D. Ala. 2011) (“Eleventh Circuit precedent requires an antitrust plaintiff to proffer expert testimony to establish a relevant product market and a relevant geographic market.”). As set out in his expert report, it is Dr. Lamb’s opinion that: (1) the market for MIST robots like the da Vinci is a relevant antitrust product market; (2) the “EndoWrist Repair and Replacement Market” is a relevant antitrust product market; and (3) Intuitive leveraged its monopoly power in the tying market (MIST robots) to exert dominance in the tied market (EndoWrist Repair and Replacement). (Doc. # 147-3 at 16-73).

Intuitive levies three attacks on Rebotix’s attempts to demonstrate a relevant product market. First, it claims that Dr. Lamb’s opinions are inadmissible for the reasons stated in its Daubert motion. Second, a market defined from the perspective of the supplier must encompass all surgical instruments that Rebotix *could* conceivably repair and, thus, the market is not limited to EndoWrists. Third, even if defined from a customer’s point of view, the EndoWrist market

is not distinct from the da Vinci market because they are separate products.

None of these arguments support summary judgment. First, for the reasons explained in the Court's accompanying Daubert Order, Dr. Lamb's opinions are admissible.

Second, the Court turns to the parties' fundamental disagreement as to whether the relevant market should be determined from the perspective of the supplier, as Intuitive argues, or from the perspective of the customer, as Rebotix argues. In its previous order on Intuitive's motion to dismiss, this Court held that from either the customer-based or supplier-based point of view, Rebotix had alleged a relevant market in its complaint. (Doc. # 52 at 15). Although whether a plaintiff has proven a relevant product market is a question for the trier of fact, the Court is persuaded that the *perspective* from which the market should be defined is a question of law that the Court must resolve.

Intuitive argues that in antitrust cases brought by excluded or shut-out suppliers, the relevant market is defined from the perspective of the supplier (here, Rebotix) and includes any customer to which the supplier could sell its services. (Doc. # 117 at 27). In support, Intuitive cites to three out-of-circuit cases, but the Court finds this line

of cases distinguishable from the instant case because those cases concerned a monopsony, or buyer-side misconduct. See Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., 549 U.S. 312, 320 (2007) (“Monopsony power is market power on the buy side of the market.”).

As Justice Sotomayor explained while writing for the Second Circuit Court of Appeals, while the traditional horizontal conspiracy case involves a monopolistic agreement among sellers, the Sherman Act also applies to abuses of market power on the buyer side. Todd v. Exxon Corp., 275 F.3d 191, 201 (2d Cir. 2001). And the fact that a case involves a buyer-side conspiracy “affects how the market is defined.” Id. In fact, the relevant factors are reversed in buyer-side conspiracies. Id. at 202. “In such a case, the market is not the market of competing sellers but of competing buyers. This market is comprised of buyers who are seen by sellers as being reasonably good substitutes.” Id. (citation and quotation marks omitted); see also Shire US, Inc. v. Allergan, Inc., 375 F. Supp. 3d 538, 552 (D.N.J. 2019) (in antitrust cases, “perspective is critical”).

Intuitive’s cited cases illustrate this principle. For example, Little Rock Cardiology Clinic PA v. Baptist Health, 591 F.3d 591 (8th Cir. 2009), involved a cardiology clinic

and its physicians who alleged that a hospital (Baptist Health) and an insurance company (Blue Cross & Blue Shield of Alabama) conspired together to restrain trade and monopolize a market. Specifically, after the cardiologists opened a competing hospital: (1) Blue Cross terminated its network provider agreements with the physicians, (2) Baptist Health revoked the physicians' staff privileges, and (3) Blue Cross and Baptist Health formed their own HMO, agreeing that Baptist Health would be the HMO's exclusive in-network facility, all in an alleged bid to protect the existing hospital from competition. Id. at 594. The Eighth Circuit held that the relevant-market inquiry in that case hinged on whether there were other patients who were able to pay the cardiologists' fees, not just those who pay using private insurance. Id. at 597 ("[The physicians'] claims boil down to the allegation that, due to Baptist Health's allegedly unlawful actions, [they have] access to fewer patients. The relevant question, then, is to whom might the cardiologists at LRCC potentially provide medical service?").

In Little Rock, the cardiologists were the supplier (of their medical services) and the hospital was the buyer/consumer of those services, and the alleged antitrust conspiracy occurred on the buyers' side of the equation. Thus,

the market-definition question focused on whether *other buyers*, such as Medicare or self-pay patients, were reasonable substitutes.⁸ Here, however, the alleged anticompetitive conduct is on the side of the seller, Intuitive.

Moreover, the Court is persuaded by Rebotix's argument that the relationship among the parties here is similar to that confronted by the Supreme Court in Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451 (1992). There, the defendant, Kodak, was the manufacturer and seller of photocopiers and micrographic equipment. Id. at 455. Kodak also sold service and replacement parts for its equipment. Id. The plaintiffs were independent service organizations

⁸ Similarly, the First Circuit has held that where pharmacies were excluded or shut out by insurance networks offering prescription drugs at discount prices, the relevant product market was the sales of all retail drugs, not just financed or reimbursed sales. Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 59, 67 (1st Cir. 2004). Again, the conspiracy, which the court called a "classic exclusive dealing" arrangement, was on the side of the buyer of services. And in the final cited case, which involved the claims of an auto glass repair shop allegedly excluded from an insurer's refusal to cover long crack repair, the relevant market was the total market demand for the repair shop's services, not just the defendant's demand. Campfield v. State Farm Mut. Auto. Ins. Co., 532 F.3d 1111, 1118 (10th Cir. 2008) (holding that plaintiff's allegations, if true, would describe a "monopsony," which is one form of buyer-side market abuse).

(ISOs) that were in the business of servicing Kodak copying and micrographic equipment. Id. According to the ISOs, Kodak began adopting business policies – such as limiting the availability of parts – making it more difficult for the ISOs to compete with Kodak in servicing Kodak equipment. Id. This pattern of relationships fits squarely onto the facts before this Court. And in Eastman Kodak, the Supreme Court held that the relevant market for antitrust purposes is determined by the choices available to and the commercial realities faced by consumers. Id. at 481-82.

That leads to the next part of the puzzle: Assuming the market is defined from the customers' (the hospitals') point of view, is the market for MIST robots distinct from the market for EndoWrist Repair and Replacement?

Whether the market for surgical robots is distinct from the market for EndoWrist repair and replacement (i.e., whether they are two separate products) "turns not on the functional relation between them, but rather on the character of the demand for the two items." Jefferson Par. Hosp. v. Hyde, 466 U.S. 2, 19 (1984). That is, are the products "distinguishable in the eyes of buyers" or "separately priced and purchased from the buyer's perspective?" Id. at 19, 20.

There is conflicting evidence on this point, including the price differential between a MIST robot and Rebotix's repair services, how each was purchased, the terms of the SLSAs, and how hospitals viewed the products. This Court cannot say as a matter of law that the da Vinci surgical robots and the EndoWrists are the same product, especially as it is undisputed that an EndoWrist is designed to be discarded after 10 uses. See United States v. Microsoft Corp., 253 F.3d 34, 86 (D.C. Cir. 2001) ("The mere fact that two items are complements, that one . . . is useless without the other does not make them a single product for purposes of tying law."); see also Eastman Kodak, 504 U.S. at 463 (rejecting Kodak's argument that because there is no demand for parts separate from service, there cannot be separate markets for service and parts because "[b]y that logic, we would be forced to conclude that there can never be separate markets, for example, for cameras and film, computers and software, or automobiles and tires").

Whether the repair and replacement of EndoWrists has separate demand and is a separate product from the surgical robots is a disputed issue of genuine material fact. See Eastman Kodak, 504 U.S. at 463 (explaining that when enough doubt is cast on the claim of a unified market, the issue

should be resolved by the trier of fact); see also Thompson v. Metro. Multi-List, Inc., 934 F.2d 1566, 1573 (11th Cir. 1991) (“The parameters of a given market are a question of fact and therefore summary judgment is inappropriate if there are material differences of fact.”). Thus, Intuitive’s Motion for summary judgment is denied on this ground.

3. Anticompetitive Conduct

Finally, Intuitive argues that Rebotix cannot establish the alleged misconduct of anticompetitive tying or exclusive dealing.

“A tying arrangement is an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from another supplier.” Eastman Kodak, 504 U.S. at 461. “A tying arrangement violates [Section] 1 of the Sherman Act if the seller has market power and the tying arrangement affects a substantial volume of commerce in the tied product market.” Palmyra Park Hosp., Inc. v. Phoebe Putney Mem’l Hosp., 604 F.3d 1291, 1296 n.4 (11th Cir. 2010).

The Eleventh Circuit has noted that “the essence of illegality in a tying arrangement is the wielding of monopolistic leverage [by which] a seller exploits his

dominant position in one market to expand his empire into the next.” Kypta v. McDonald’s Corp., 671 F.2d 1282, 1284 (11th Cir. 1982) (citation omitted) (quoting Times-Picayune Publ’g Co. v. United States, 345 U.S. 594, 611 (1953)). Thus, Rebotix must demonstrate that Intuitive “forced or coerced the buyer into purchasing the tied product” that “he did not want or would have preferred to buy elsewhere on other terms.” Tic-X-Press, Inc. v. Omni Promotions Co. of Ga., 815 F.2d 1407, 1415-16 (11th Cir. 1987).

As an initial matter, the Court agrees with Intuitive that it should apply the “rule of reason,” rather than the “per se” rule, in this case. True, tying arrangements can be among those rare cases subject to the per se rule because certain of those arrangements “pose such a predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit, that they are deemed unlawful *per se*.” S. Card & Novelty, Inc. v. Lawson Mardon Label, Inc., 138 F.3d 869, 874 (11th Cir. 1998). “It is clear, however, that not every refusal to sell two products separately can be said to restrain competition.” Jefferson Par., 466 U.S. at 11. Because adoption of a per se rule requires a court to predict “with confidence” that the restraint is unreasonable, this Circuit has been reluctant to adopt the per se rule in

tying cases where the economic impact is not “immediately obvious.” S. Card & Novelty, 138 F.3d at 874.⁹

Having adopted the rule of reason approach in this case, the Court’s next step is to explain what the rule entails. “The rule of reason tests whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1064 (11th Cir. 2005).

To prove an illegal tying arrangement under the rule of reason, a plaintiff must establish: (1) that there are two separate products (a tying product and a tied product); (2) evidence of actual coercion by the seller that in fact forced the buyer to purchase the tied product; (3) that the seller has sufficient market power in the tying product market to force the buyer to accept the tied product; (4) anticompetitive effects in the tied market; and (5) involvement of a “not insubstantial” amount of interstate commerce in the tied product market. Amey, Inc. v. Gulf

⁹ Additionally, in this Circuit, exclusive dealing arrangements are “reviewed under the rule of reason.” DeLong Equip. Co. v. Washington Mills Abrasive Co., 887 F.2d 1499, 1508 n.12 (11th Cir. 1989).

Abstract & Title, Inc., 758 F.2d 1486, 1502-03 (11th Cir. 1985).

Here, Intuitive argues that Rebotix cannot establish any unlawful tying arrangement for two reasons. First, because Rebotix has no expert testimony defining a relevant market for the servicing of da Vincis, it cannot define a relevant market and cannot prove that Intuitive tied EndoWrists to da Vinci service. Second, it cannot show that Intuitive has unlawfully tied EndoWrists to da Vinci sales because (1) they are not separate products; (2) Rebotix has not shown that Intuitive has market power in the purported relevant market for MIST robots; and (3) Rebotix cannot show anticompetitive effects in the tied market.

As for the first argument, Rebotix points out that "the identified tying market is not the service of da Vincis" - it is the market for MIST robots, something Dr. Lamb did address. As for the second argument, for the reasons described above, there is a triable issue of fact as to whether the da Vincis and EndoWrists are separate products. Intuitive's second sub-argument hinges on its motion to exclude Dr. Lamb's testimony under Daubert, but for the reasons stated in the Court's accompanying Order, that motion is denied. Indeed, according to Dr. Lamb, Intuitive enjoys a 99% market share in the MIST

robot market. (Doc. # 114-2 at 51); see U.S. Anchor, 7 F.3d at 994 (explaining that the “principal judicial device for measuring actual or potential market power remains market share”).

That leaves Intuitive’s argument that Rebotix cannot establish evidence of anticompetitive effects in the tied product market (for EndoWrist Repair and Replacement). (Doc. # 117 at 36).

What constitutes “anticompetitive effects”? Primarily, supracompetitive prices, sub-competitive output, and sub-competitive quality. See, e.g., Duty Free Americas, Inc. v. Estee Lauder Cos., 797 F.3d 1248 (11th Cir. 2015) (noting that anticompetitive effects include, but are not limited to, reductions in output, increases in price, and deterioration in quality); Sterling Merch., Inc. v. Nestle, S.A., 656 F.3d 112, 231 (1st Cir. 2011) (“Injury to competition is ‘usually measured by a reduction in output or an increase in prices in the relevant market.’”); W. Penn Allegheny Health Sys. v. UPMC, 627 F.3d 85, 100 (3d Cir. 2010) (“Anticompetitive effects included increased prices, reduced output, and reduced quality.”). Here, Dr. Lamb provided evidence demonstrating that Intuitive charges supracompetitive prices and enjoys extremely high profit margins for both the tying

product (MIST robots) and the tied product (EndoWrists). (Doc. # 108, Ex. 1, ¶¶ 102, 124 & n.296).

Intuitive argues that it is entitled to summary judgment because Rebotix cannot establish that the combined price for da Vincis and EndoWrists would be lower in the "but-for world" (that is, a world without Intuitive's alleged anticompetitive conduct). (Doc. # 117 at 36-37 (citing Metzler v. Bear Auto. Serv. Equip. Co., SPX, 19 F. Supp. 2d 1345, 1361 (S.D. Fla. 1998) and Kypta v. McDonald's Corp., 671 F.2d 1282, 1285 (11th Cir. 1982))). But these cases merely stand for the proposition that, to determine actual injury in illegal tying arrangements, courts should determine the fair market value of both the tied and tying products and then determine if there is an overcharge in the "complete price." Kypta, 671 F.2d at 1285. Here, taking Rebotix's admissible evidence as true, Intuitive charges supracompetitive prices in both markets.

Moving on, "[u]nder Eleventh Circuit case law, alleged Section One agreements analyzed under the rule of reason require a plaintiff 'to prove (1) the anticompetitive effect of the defendant's conduct on the relevant market, and (2) that the defendant's conduct has no pro-competitive benefit or justification.'" Spanish Broad. Sys., 376 F.3d at 1071. By

comparing the negative and positive effects of a restraint on competition, a fact finder can “weigh[] all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.” NCAA v. Alston, 141 S. Ct. 2141, 2160 (2021). While Intuitive claims that selling the da Vinci robots and EndoWrists has certain pro-competitive benefits - minimizing risks to patients and providing guarantees regarding the reliability and safety of its system - this weighing of various factors is better left to a jury.

Finally, the Court turns to Rebotix’s claim of exclusive dealing. An exclusive dealing arrangement is permissible (and not a violation of the antitrust laws) unless it forecloses competition in the relevant market. See Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 333 (1961). Courts are required to pay attention to the “practical effect” of exclusive dealing arrangements, and the Eleventh Circuit has held that courts should “consider ‘market realities’ rather than ‘formalistic distinctions.’” McWane, Inc. v. FTC, 783 F.3d 814, 834-35 (11th Cir. 2015). Intuitive’s arguments here are based on the same product and pricing arguments that the Court discussed above. Moreover, the Court agrees with Rebotix that it is not necessary or proper for Dr. Lamb to

offer an opinion on the ultimate issue of whether or not Intuitive engaged in anticompetitive exclusive dealing.

In sum, there is evidence from Rebotix's expert economist from which a jury could conclude that the tying and exclusive dealing arrangements alleged in this case violate the rule of reason because (1) those restraints have an anticompetitive effect on the market and competition and (2) Intuitive's allegedly anticompetitive action outweighs any procompetitive rationale for the restraints. In light of this evidence, there are genuine issues of material fact, and summary judgment is not appropriate. See In re Wellbutrin, 868 F.3d at 170 n.64 ("noting that "the rule of reason inquiry is fact intensive and is not easy to resolve at the summary judgment stage"); see also Poller v. Columbia Broad. Sys., Inc., 368 U.S. 464, 473 (1962) ("[S]ummary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators, and hostile witnesses thicken the plot.").

C. Intuitive's Counterclaims

Intuitive's counterclaims center upon what it describes as Rebotix's false and misleading marketing of its EndoWrist "repair" services and its interference with Intuitive's

business relationships. In its counterclaim complaint, Intuitive identifies several different types of allegedly deceptive marketing:

- (1) Rebotix markets itself as "Rebotix Repair" and states that it is merely "repairing" EndoWrist instruments, but these representations do not describe the substantial modifications that are actually made by Rebotix. Rebotix does not merely tune up or calibrate the instruments; Rebotix *changes* those instruments in significant (and risky) ways.
- (2) Rebotix compounds its deception by offering a "complete repair" of EndoWrist instruments – further conveying a false message that the instruments are broken or defective when they reach their usage limit. But Rebotix knows that the usage limits are a *feature*, not a bug, of EndoWrist instruments, because they ensure proper and safe operation.
- (3) Rebotix similarly claims that, once serviced by Rebotix, the now-altered EndoWrist instruments are not replacement instruments, but rather "da Vinci manufactured instrument[s] that ha[ve] been repaired to original specifications." Rebotix claims that serviced EndoWrist instruments will "meet the quality and functional requirements of a new device." These claims are untrue. Moreover, Rebotix falsely asserts that the foregoing claims have been sufficiently validated even though (among other problems) Rebotix would have needed access to Intuitive's design history and other internal files to identify the "quality and functional requirements" of new EndoWrist instruments.
- (4) Rebotix has further disseminated statements, including talking points for contacts with customers, that misrepresent Intuitive's testing and safety protocols, as well as the safety of Rebotix's services.

- (5) Rebotix also conveys false and misleading messages concerning the purported legitimacy and legality of the "repair" services it offers, including the following: Rebotix fails to adequately convey to customers that its services are neither authorized nor approved by, nor otherwise affiliated with, Intuitive.
- (6) Rebotix informs customers that it has reasonably determined that its services do not require 510(k) premarket review and clearance by the FDA, when in fact Rebotix has not conducted a proper analysis of whether that was the case, nor, upon information and belief, consulted with the FDA to validate its assertion.
- (7) Additionally, Rebotix misrepresents its qualifications. Indeed, by the very acts of marketing and offering its services to Intuitive customers, Rebotix necessarily conveys that it is qualified and/or has the specialized training to work on highly technical EndoWrist instruments. That, too, is not the case.
- (8) Yet another category of false advertising is Rebotix's touting and purported validation of alleged cost savings for customers who turn to Rebotix to bypass usage limits instead of purchasing new EndoWrist instruments. Lacking any legitimate basis to make such claims, Rebotix's advertising fails to inform customers and/or affirmatively misrepresents the consequences for customers who use Rebotix's unauthorized services, such as the voiding of customers' warranties and jeopardizing of their service contracts with Intuitive.
- (9) Finally, Rebotix has leveled false accusations against Intuitive, including a baseless and inflammatory charge that the usage limits built into EndoWrist instruments are "arbitrary" and included solely for Intuitive's financial gain.

(Doc. # 60 at ¶¶ 9-13).

With this background in mind, the Court now turns to the parties' arguments with respect to two specific counterclaims.

1. Tortious Interference

Intuitive moves for summary judgment in its favor on this counterclaim, arguing that "[t]he undisputed facts show that Rebotix is liable as a matter of law for tortiously interfering with at least 17 Intuitive hospital contracts." (Doc. # 117 at 29). According to Intuitive, Rebotix knew that these contracts prohibited hospitals from using Rebotix's services but that Rebotix nevertheless "induce[d] the hospitals to break the contractual terms by using Rebotix's 'repair' services." (Id.).

The SLAs entered into between Intuitive and the hospitals prohibited any "repair, refurbishment, or reconditioning" of da Vinci instruments and accessories. (Doc. # 117-7 at 4). By way of factual support, Intuitive points to Rebotix's interrogatory response in which it identified 16 hospitals that "used EndoWrists beyond the maximum use requirement" and reported that the EndoWrists worked well. (Doc. # 117-40 at 15-16).

Under Florida law, the elements for a claim of tortious interference are: (1) the existence of a business

relationship under which the plaintiff (here, Intuitive) has legal rights; (2) Rebotix's knowledge of that relationship; (3) an intentional and unjustified interference with the relationship by Rebotix; and (4) damages to Intuitive as a result of that interference. Carlwood Safety, Inc. v. Wesco Distr., Inc., 446 F. Supp. 3d 970, 978 (M.D. Fla. 2020) (citing Palm Beach Cnty. Heath Care Dist. v. Prof'l Med. Educ., Inc., 13 So. 3d 1090, 1094 (Fla. 4th DCA 2009)).

Rebotix argues that summary judgment on this claim is not proper because, first, Intuitive has set forth no evidence in support of the "intentional or unjustified interference" or the damages element of a tortious interference claim. (Doc. # 108 at 32). Second, Rebotix argues that Intuitive's contracts with the hospitals are void as against public policy and a tortious-interference claim cannot be based on a contract that is void as against public policy. (Id.). Finally, Rebotix claims that its actions were simply legal, permissible competition in the marketplace. (Id. at 32-33).

Intuitive has not demonstrated that it is entitled to judgment as a matter of law on this issue. Fed. R. Civ. P. 56(a). Instead, the question of whether Rebotix's alleged interference with Intuitive's hospital contracts was "intentional and unjustified" is a factual issue better left

to the jury, as is the issue of whether and to what extent Intuitive may have been damaged by such interference.

Thus, the Court denies summary judgment as to this issue.

2. FDUTPA

A claim for damages under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") has three elements: (1) a deceptive act or unfair practice in the course of trade or commerce; (2) causation; and (3) actual damages. Cluck-U Chicken, Inc. v. Cluck-U Corp., 358 F. Supp. 3d 1295, 1312-13 (M.D. Fla. 2017).

Rebotix moves for summary judgment on this counterclaim, arguing that Intuitive lacks evidence of two "critical elements": actual consumer injury and actual damages. The Court will address the damages argument first. Intuitive's response helpfully narrows the issue here - it agrees that disgorgement is not an appropriate measure of damages and claims that, here, it is asserting only past lost profits, which it claims are an available remedy under FDUTPA. (Doc. # 148 at 30-31). Rebotix, however, disputes that past lost profits are available as damages under FDUTPA.

As two district courts in the Southern District of Florida recently pointed out, federal district courts are split on this issue. See Tymar Distr. LLC v. Mitchell Grp.

USA, LLC, No. 21-21976-CIV, 2021 WL 4077966, at *4-7 (S.D. Fla. Sept. 8, 2021) (collecting cases and holding that past lost profits are recoverable under FDUTPA); Midway Labs USA, LLC v. S. Serv. Trading, S.A., No. 19-24857-CIV, 2020 WL 2494608, at *6-7 (S.D. Fla. May 14, 2020) (analyzing the split of authority and concluding that past lost profits are *not* recoverable under FDUTPA).

The Florida Supreme Court has not decided the issue of whether past lost profits are "actual damages" (and therefore available) or "consequential damages" (and therefore unavailable) under FDUTPA. The Eleventh Circuit Court of Appeals has not resolved the split either. However, there appears to be a recent consensus forming in the Middle District of Florida, holding that businesses may recover past lost profits under FDUTPA. See Healthplan Servs., Inc. v. Dixit, No. 8:18-cv-2608-SDM-AAS, 2021 WL 4927434, at *8 (M.D. Fla. May 27, 2021), report and recommendation adopted, No. 8:18-cv-2608-SDM-AAS, 2021 WL 4926752 (M.D. Fla. July 22, 2021) (holding past lost profits are recoverable under FDUTPA); Crmsuite Corp. v. Gen. Motors Co., No. 8:20-cv-762-WFJ-AAS, 2021 WL 914170, at *6 (M.D. Fla. Mar. 10, 2021) (same); Gulf Coast Turf & Tractor LLC v. Kubota Tractor Corp., No. 8:17-cv-2787-SCB-AEP, 2019 WL 1446309, at *1-2 (M.D. Fla.

Apr. 1, 2019) (same); Glob. Tech Led, LLC v. Hilumz Int'l Corp., No. 2:15-cv-553-JES-CM, 2017 WL 588669, at *9 (M.D. Fla. Feb. 14, 2017) (same).

Moreover, this Court finds persuasive the reasoning in Tymar, where the court analyzed this issue and held that “the weight of Florida law holds past lost profits recoverable under [the] FDUTPA”:

The FDUTPA, which prohibits deceptive and unfair trade practices, only permits the recovery of “actual damages[,]” which the Act does not define. Fla. Stat. § 501.211(2) (alteration added). When the Florida legislature enacted the FDUTPA, it notably permitted only a “consumer” to state a claim for damages. . . . In 2001, the Florida Legislature amended the FDUTPA to replace the word “consumer” with “person,” causing Florida’s appellate courts to hold that corporate-competitor plaintiffs, rather than just consumers, can seek damages under the FDUTPA.

Of course, in a claim brought by a corporate competitor, there is no bargain giving rise to the expectancy measure of damages employed in traditional consumer cases. Corporate competitors instead suffer lost profits, lost revenue, reputational harm, and other damages commonly observed in business torts claims rather than contract-based causes of action.

Court decisions evaluating the damages available to a competitor company under the FDUTPA vary widely. Federal district courts are split: many have held past lost profits are available, and many others have refused to permit plaintiffs to seek lost profits at all, applying the benefit-of-the-bargain measure of damages. Yet, many of these cases did not engage in a significant analysis of the issue.

. . .

The Florida Supreme Court previously defined "actual damages" when construing a libel statute. See Ross v. Gore, 48 So. 2d 412, 414 (Fla. 1950). In Ross, the statute permitted recovery of "only actual damages[,]" Id. at 413 (alteration added), and the Florida Supreme Court stated "[s]ince [the term 'actual damages'] is used synonymously with 'compensatory damages' in many of our decided cases, we think it is fair to assume that 'actual damages' mean 'compensatory damages.'" Id. at 414 (alterations added). The Florida Supreme Court continues to use the terms actual damages and compensatory damages interchangeably. . . .

The Florida Supreme Court broadly defines compensatory damages as those which "arise from actual and indirect pecuniary loss, mental suffering, value of time, actual expenses, and bodily pain and suffering." And in claims with no underlying transaction, such as business torts, lost profits are often directly caused by a defendant's wrongful act and recoverable simply as compensatory damages. By contrast, courts generally limit their categorization of damages as "consequential" to claims sounding in contract, and the definition of consequential damages as those arising "from losses incurred by the non-breaching party in its dealings, often with third parties, which were a proximate result of the breach, and which were reasonably foreseeable by the breaching party at the time of contracting." Put another way, consequential damages are those that do not "flow[] directly from the parties' immediate transaction." Where, as here, the claim does not involve any breach of contract, warranty, or similar wrong sounding in contract, any line drawing between expectancy and consequential damages is rather inapt.

The above principles suggest a much larger universe of damages available in FDUTPA claims arising outside the consumer transaction context, when

considered alongside the liberal construction courts must afford the FDUTPA to accomplish its remedial purpose, see Fla. Stat. § 501.202. It makes considerable sense to permit a corporate-competitor plaintiff to seek lost profits damages when there is no transaction giving rise to the oft-used expectancy measure of damages.

The Court joins other federal district courts in holding a corporate-competitor plaintiff may seek lost profits damages under the FDUTPA.

Tymar, 2021 WL 4077966, at *4-7 (most citations omitted) (emphasis added).

This Court agrees with the Tymar court's reasoning and with the determination reached by other courts in the Middle District of Florida. Where a party brings an FDUTPA claim against a corporate competitor, as here, the aggrieved party may seek past lost profits damages under FDUTPA.

The Court now turns to Rebotix's other FDUTPA argument - that Intuitive has no evidence that any consumer suffered actual injury as a result of its actions. Summary judgment is not warranted on this claim because there remain genuine disputes of material fact.

Here, the "consumers" of Rebotix's services are hospitals. The question then becomes whether any hospitals were injured due to Rebotix's alleged deceptive practices or unfair acts. The Eleventh Circuit has recognized that, where a product or service has been misrepresented and thus deprives

the consumer of the benefit of his bargain, FDUTPA provides a remedy for diminution of market value. See Carriuolo v. Gen. Motors Co., 823 F.3d 977, 986-87 (11th Cir. 2016) (“The injury occurs at the point of sale because the false statement allows the seller to command a premium on the sales price.”); see also Point Blank Sols., Inc. v. Toyobo Am., Inc., No. 09-61166-CIV, 2011 WL 1833366, at *6 (S.D. Fla. May 13, 2011) (“Under FDUTPA, Plaintiffs suffered damages when they purchased something that was not what they were led to believe they were purchasing.”). Intuitive is proceeding under the theory that the hospitals did not get the benefit of their bargain because the “repaired” EndoWrist that they paid for was not as safe, “like new,” approved by Intuitive, etc., as they believed based on Rebotix’s marketing.

For these reasons, Rebotix’s Motion with respect to the FDUTPA counterclaim must be denied.


Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

- (1) Plaintiff Rebotix Repair, LLC’s Motion for Summary Judgment (Doc. # 108) is **DENIED**.
- (2) Defendant Intuitive Surgical, Inc.’s Motion for Summary Judgment (Doc. # 117) is **DENIED**.

- (3) The Motions to maintain certain filings under seal (Doc. ## 118, 153) are **GRANTED** for the reasons stated herein.
- (4) The Motion to Strike the Declaration of Richard Lyon (Doc. # 160) is **DENIED AS MOOT**.
- (5) The Clerk is directed to terminate the pending sealed versions of these motions (Doc. ## 97, 101). The Clerk is further directed to lift the stay of this case.
- (6) The Court will set new deadlines in this case by separate order.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 10th day of August, 2022.


VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE