IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JOHNSON & JOHNSON, ETHICON, INC., ETHICON US, LLC, and JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.,	)	
Plaintiffs,	)	Case No. 20-cv-3471
v.	)	Judge Robert M. Dow, Jr.
ADVANCED INVENTORY MANAGEMENT, INC., d/b/a eSUTURES.COM, ANTHONY IADEROSA, JR., JASON EINHORN, MIKE PHIPPS, and MUDASSAR SHAH,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Johnson & Johnson, Ethicon, Inc., Ethicon US, LLC, and Johnson & Johnson Health Care Systems, Inc. ("Plaintiffs") bring suit against Defendants Advanced Inventory Management, Inc. d/b/a eSutures.com ("AIM"), Anthony Iaderosa, Jr., Jason Einhorn, Mike Phipps, and Mudassar Shah ("Defendants") for federal trademark infringement and related federal and state claims arising out of Defendants' alleged sale of counterfeit, contaminated, and expired Ethicon medical devices, as well as medical devices that have been separated from their outer packaging and instructions for use. A temporary restraining order ("TRO") and seizure order have already been entered in this case. This matter is currently before the Court on confirmation of the seizure order and entry of preliminary injunction [10], as well as Defendants' motion to strike Geoffrey Potter declarations [157] and Plaintiffs' motion to preclude the expert testimony of J. Lester Alexander [195]. For the reasons explained below, Plaintiffs' motion for preliminary injunction [10] is granted and the seizure order is confirmed. Plaintiffs shall be required to increase their bond to $750,000. The Court will hold periodic status hearings to revisit the scope of the

injunction and the amount of the bond based on more complete information and any relevant new developments. The terms of the injunction and bond are set out in a separate document in accordance with the Seventh Circuit's guidance in *MillerCoors LLC v. Anheuser-Busch Companies, LLC*, 940 F.3d 922 (7th Cir. 2019). Defendants' motion to strike [157] and Plaintiffs' *Daubert* motion [195] are both denied. The parties' motions to file certain briefs under seal, [237], [250], [255], are granted. The Court is cognizant that testing and sampling of the seized product remains ongoing under the supervision of Magistrate Judge Cummings. The parties are directed to file joint status reports on the last business day of each month indicating their views on whether the scope of the injunction and/or the amount of the bond should be altered based on further developments in this litigation, and the Court may seek Judge Cummings' input on those matters as well.

I. Background

Plaintiffs filed this action on June 15, 2020, see [1], and immediately moved for an *ex parte* seizure order, TRO, asset freeze order, expedited discovery, alternative service, and order to show cause for a preliminary injunction [10]. See also [13] (TRO brief) and [15]-[26] (declarations). The following day, the Court issued an *ex parte* TRO [29], an asset freeze order [30], and a seizure order [31]. Plaintiffs posted a $50,000 bond. See [37]. The parties agreed by stipulation to extend the TRO to accommodate expedited discovery and an agreed schedule for briefing the motion for preliminary injunction to confirm the seizure. See [48].

Defendants responded to the motion for preliminary injunction on July 31, 2020. See [161] (response brief), [162]-[163] (exhibits). Plaintiffs replied on August 10, 2020. See [176] (reply brief) and [177], [179]-[194], [197] (exhibits). The preliminary injunction hearing was held August 14, 2020. See [209]. The parties were given the opportunity to file additional briefs, with

Defendants filing their sur-reply on August 24, 2020, see [221], and Plaintiffs filing their sur-sur-reply on September 3, 2020, see [238]. Plaintiffs also have been filing weekly updates concerning testing and sampling of seized devices. See [150], [156], [173], [208], [216], [225], [239], [245], [252], [258]. Most recently, the Court requested supplemental briefs concerning the financial records of Defendants AIM and Anthony Iaderosa ("Iaderosa"), which the parties filed on September 16 ([249], Plaintiffs' brief) and September 21, 2020 ([253], Defendants' brief). As the record reflects, the briefing on this motion—and several other resolved and pending motions—has been voluminous.

In this action, Plaintiffs seek injunctive relief to stop Defendant AIM's alleged sale and distribution of counterfeit Ethicon surgical devices, as well as Ethicon surgical devices that have expired, been recalled, and/or removed from their outer packaging and separated from their instructions for use. The following factual background is drawn from the governing first amended complaint [154] ("Complaint"), the parties' voluminous preliminary injunction briefs and exhibits, the parties' presentations at the preliminary injunction hearing, Plaintiffs' weekly updates on testing, and other portions of the record where relevant.

Plaintiff Johnson & Johnson holds registered trademarks on a variety of medical devices that are used during surgery, including the three trademarks at issue here: SURGICEL, LIGACLIP, and ETHICON SECURESTRAP. Plaintiff Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Johnson & Johnson and manufactures the three medical devices. Plaintiff Ethicon US, LLC ("Ethicon US") is an indirect subsidiary of Ethicon Inc. & Johnson & Johnson and distributes the three medical devices in the United States. Plaintiff Johnson & Johnson Health Care Systems Inc. ("JJHCS") is a wholly owned operating subsidiary of Johnson & Johnson and provides account management, contracting, supply chain, and business services to health care customers, including

hospital systems and group purchasing organizations, for products manufactured by Johnson & Johnson subsidiaries, including Ethicon.

Defendant AIM is an Illinois corporation with a principal place of business in Mokena, Illinois. It employs 47 people and operates out of a 65,000 square foot warehouse. Defendant Iaderosa is AIM's founder, president, and CEO and Defendant Jason Einhorn ("Einhorn") is its director of operations. Defendant Mike Phipps ("Phipps") is an employee of AIM. It is disputed whether Defendant Mudassar Shah ("Shah") is also an AIM employee (with Plaintiffs contending that he is, and Defendants denying this).

AIM describes itself as a "leading participant in the vibrant secondary market for surgical supplies." [161] at 14. According to AIM, "[b]usinesses in this industry, including AIM and its competitors, purchase surgical supplies that are not of use to the hospitals, surgery centers, doctor's offices, and veterinarians selling them." *Id*. They then "sell this inventory, usually in small quantities, to an array of customers that need it for different purposes." *Id*. AIM's "customers include hospitals and surgical centers that need supplies on an emergency basis, veterinarians who require smaller quantities of product than human medical providers typically do, charities, and research laboratories that use the products purchased for scientific rather than medical purposes." *Id*. AIM's customers also include product manufacturers, including Johnson & Johnson affiliated companies, who "buy their competitors' products from AIM for competitive research purposes." *Id*.

AIM represents that it buys its products "directly from" institutions such as hospitals, surgical centers, doctors' offices, charities, and veterinarians and "indirectly through other vendors in the secondary market." [161] at 14-15. AIM also occasionally buys products directly from manufacturers or their official distributors. *Id*. at 15. According to AIM, it maintains sophisticated

inventory management and other internal controls to track its inventory. Its current inventory management system, "ICS," was developed and implemented in 2018 and 2019 to track the movement of each individual product in AIM's inventory. ICS also alerts AIM to any recalls on its products. AIM has a process in place to remove any recalled products from its shelves and place them in a designated quarantine area.

AIM admittedly sells some products that are past their expiration date. Defendants explain that "when a customer attempts to purchase expired product through AIM's website, a message appears that says: 'I understand that I am purchasing product that is expired, or past the listed manufacturer's expiration date. I agree to abide by all laws and regulations, foreign and domestic, that these products cannot be used on live humans. Additionally, I agree to not resell these products for live human use. I understand that clicking the button below will log my acknowledgement of this notice, and log my IP as my digital signature.'" [161] at 19. "The buyer must then enter his or her name and click 'Yes, I acknowledge' before being allowed to complete the transaction." *Id*.

In this action, Plaintiffs allege that AIM has sold thousands of counterfeit Ethicon products across at least three different product categories: SURGICEL and SURGICEL FIBRILLAR hemostat devices, which are used during surgery to control bleeding and act as an antimicrobial agent and are left inside the patient's body after surgery to be absorbed; LIGACLIP ligating clips, which are used during open and endoscopic ligation to close off blood vessels or other ducts; and ETHICON SECURESTRAP devices, which are multi-use laparoscopic absorbable fixation devices used by surgeons to affix mesh to repair hernias inside the abdominal wall. See [153] at 8-11. The allegedly counterfeit Ethicon devices came from at least three distributors: Medserve in India, Medifelix in Turkey, and a third distributor in the United States, which allegedly received

its counterfeit goods from Medserve. AIM denies being a counterfeiter and represents that it "neither makes nor knowingly buys or sells counterfeit goods." [161] at 20.

In their Complaint, preliminary injunction briefs, and voluminous supporting exhibits, Plaintiffs detail how they discovered the alleged counterfeits and Defendants' involvement. The declaration [15] of Plaintiff's lead counsel in this matter, Geoffrey Potter, provides a helpful summary of background events. Mr. Potter has represented Johnson & Johnson for more than fifteen years. Johnson & Johnson asked him to investigate the distribution and sale of counterfeit SURGICEL after it received complaints from a neurosurgeon at the University of Kentucky in May 2019. In July 2019, Johnson & Johnson filed suit against XS Supply, LLC ("XS Supply") in the Middle District of Florida, Case No. 8:19-cv-1673-T-33AEP. According to Mr. Potter, XS Supply is a Florida-based gray-market distributor[1] that sold counterfeits to the University of Kentucky. Johnson & Johnson obtained an *ex parte* seizure order against XS Supply. Documents obtained through execution of the seizure order disclosed that XS Supply had purchased the counterfeits from Florida-based gray-market distributor Lion Heart Surgical Supply, LLC ("Lion Heart Surgical"). Johnson & Johnson obtained a seizure order against Lion Heart Surgical, and thereby obtained documents showing the counterfeits originated from a company known as M/S Medserve ("Medserve") and its principal, Pritamdas Arora ("Arora"), both located in India.

Through weeks of additional investigation in India, Plaintiffs learned that Mr. Arora's residence and Medserve's offices and warehouse were located in Delhi. Ethicon obtained *ex parte* seizure and asset freeze orders from the Florida Court as well as from a court in India. On October 14, 2019, the *ex parte* seizure order was executed on Medserve's offices and Arora's apartment. Stacks of unused and unsealed SURGICEL pouches (allegedly counterfeit) and packets of gauze

[1] "Gray market" goods typically means goods sold outside of authorized distribution channels by entities that do not have a relationship with the producer of the goods.

were found. During the seizure, a shipment of thousands of allegedly counterfeit LIGACLIP Extra Ligating Clips were delivered to Mr. Arora's apartment from an address in China. Mr. Potter's declaration (as well as the Complaint, see [153] at 19-20), provides photographs of the allegedly counterfeit materials, which were found in nonsterile conditions. During the seizure, over half a million electronic documents were also collected, from email accounts, WhatsApp accounts, cell phones, computers, and servers of Medserve and its principals and employees.

Ethicon's counsel did not gain access to these documents until late January 2020. By the time it had an opportunity to review the documents, the global COVID-19 pandemic had begun, hampering Plaintiffs' efforts to continue their investigation. These documents revealed to Plaintiffs for the first time the extent of AIM's alleged involvement in Medserve's counterfeiting. In executing the Court's June 16 order, Ethicon seized nearly one thousand suspected counterfeit Ethicon surgical devices from AIM's warehouse. Using information that AIM was required to provide under that order, Ethicon also was able to track down and recover from AIM's customers hundreds of allegedly dangerous counterfeits before they were used on patients. See [153] at 35-37; [176] at 33-35 and exhibits cited therein (detailing recovery of allegedly counterfeit Ethicon devices from specific medical providers).

All told, evidence gathered by Plaintiffs' thus far—and this case is still in its early stages—shows that AIM purchased from Medserve, imported, and sold to hospitals and other medical providers nationwide more than 7,000 counterfeit Ethicon medical devices. See [13] at 26-29, 33-41 & exhibits cited therein; [176] at 27-30 (chart detailing medical institutions to which alleged counterfeits were sold). Even more troubling, the evidence disclosed to the Court thus far suggests that up to 6,000 of those devices may have already been used in patients. See *id.* According to scientific analyses conducted at Plaintiffs' direction, the counterfeits do not work, are bacterially

contaminated, and pose serious risks to the health and lives of patients. See [13] at 23-25, 39-40 and exhibits cited therein; [19] (declaration of Benjamin D. Fitz); [180] (first declaration of Diana Harbach); [192] (second declaration of Diana Harbach); [176] at 35-36 and exhibits cited therein.

Plaintiffs also present evidence that, in addition to selling counterfeit products, AIM coordinated with Mr. Arora to distribute expired Ethicon surgical devices in counterfeit packaging. According to Plaintiffs, AIM procured expired Ethicon devices and, at Medserve's direction, sent them to Medserve to be repackaged and shipped back to AIM for distribution in the United States. Removing the devices from their original packaging, as Mr. Arora is alleged to have done with his bare hands, contaminates them and poses an infection risk to patients in whom they are implanted. In one particularly disturbing voice message recording seized during the course of Plaintiffs' investigation, Mr. Arora appears to have rejected long-expired stock offered to him by AIM and told Defendant Einhorn (AIM's director of operations) to use "common sense" so that their counterfeits would not "kill anyone." [176] at 120; see also [153] at 3. Nevertheless, records show that AIM and Medserve proceeded to distribute expired Ethicon products, with the expired product being unsealed and repackaged by hand in Mr. Arora's Delhi apartment under unsanitary conditions. When asked about this topic at deposition, all of AIM's witnesses with knowledge invoked their Fifth Amendment rights.

Plaintiffs allege, and Defendants deny, that AIM and the individual Defendants acted knowingly when they purchased, imported, and sold Medserve's "Ethicon" devices. Plaintiffs' position is supported by the record, which includes among other things evidence of the following:

In early 2019, Defendant Iaderosa set up a shell company called Magellan Medical Supply F.Z.E. ("Magellan") in the United Arab Emirates to import into the United States medical devices obtained from unregistered gray-market suppliers abroad, including Medserve. See [176] at 51-

55 and exhibits cited therein. Plaintiffs explain that FDA regulations require foreign exporters of medical devices to complete a registration process with the U.S. government in order to receive authorization to sell medical devices into the United States, and it is unlawful to import a medical device from a foreign entity that is not registered. See 21 C.F.R. § 807(40). The use of Magellan appears to have allowed AIM to bypass the foreign registration requirement. See [176] at 53. Magellan's registration with the FDA as a medical device importer lists Defendant Shah, rather than Mr. Iaderosa, as Magellan's contact, at a Dubai address and phone number. See *id*. at 52 & Ex. 80. AIM's vendor list indicates that it has purchased hundreds of thousands of dollars of medical devices from Magellan, rather than recording the name of the original vendor that supplied the product. Despite Plaintiffs' discovery requests, AIM has not provided any sworn information concerning the balance of or transactions in Magellan Medical's accounts. Ms. Tuzik admitted that none of the vendors who passed shipments though Magellan were permitted to import into the United States and that Magellan was used to bring their products into the country. See [176] at 53 and exhibits cited therein.

In addition, AIM received shipments from Medserve in a highly suspicious manner. In March 2019, the FDA Office of Criminal Investigation ("OCI") executed a search warrant on AIM's offices and warehouse to investigate counterfeiting. Following the raid, AIM directed Medserve to send products to employees' personal residences, rather than to AIM's offices, and to strip the shipments of any reference to AIM. See [176] at 44-48 and exhibits cited therein. This was not in accordance with AIM's policies and was done only in connection with counterfeit Ethicon devices. When asked whether the Medserve shipments were sent to employees' homes because they were counterfeits, Defendants Einhorn and Iaderosa both invoked their Fifth Amendment rights. *Id.* at 47. Defendants have no legitimate explanation for this behavior, which

Ms. Tuzik acknowledged is not the appropriate protocol and should never happen, in part because the delivery would not be properly inventoried in AIM's database. See *id.* at 46 (detailing Ms. Tuzik's testimony).

Plaintiffs' preliminary review of Defendants' banking records shows that although AIM imported a large volume of alleged counterfeits from Medserve, it did not pay for those devices, except for a single early transaction. See [249] at 2-4 and exhibits cited therein. Plaintiffs maintain that this evidence is consistent with the theory that AIM and Medserve were knowing partners in a counterfeiting scheme, with AIM providing Medserve with expired surgical devices that Medserve repackaged into counterfeit packaging with fake expiration dates, with some of the counterfeits being shipped back to AIM as payment. Defendants deny this, and assert that AIM treated Medserve like it does many other secondary market vendors: because Medserve wished to purchase certain products from AIM and AIM wished to purchase other products from Medserve, the two companies utilized a trade balance rather than paying one another cash. [253] at 2; see also [253-1] (declaration of Anne Tuzik). Defendants provide a list of several other dozen vendors with whom it has allegedly used trade balances. *Id*. at 5.

Plaintiff's evidence shows that Defendant Shah was involved in nearly all of the transactions with Medserve and had numerous detailed conversations with AIM and Medserve about the counterfeits. See [176] at 31-32, 65-66 & Exs. 22-32. He also arranged for counterfeits to be sold directly to Ethicon's private investigators. See [13] at 31; [25] (declaration of Rao Zaman). In addition, Shah used his @eSutures.com email address to transmit an AIM invoice for its sale of SURGICEL® devices to Medserve—*i.e.*, expired product to be repackaged into counterfeit packaging—sent through a Chinese logistics company to evade Customs. See [13] at 37-38; [15] (Potter declaration) & Ex. 37. During the course of discovery in the Florida Action,

Ethicon identified Mr. Shah as a counterfeiter, and found evidence that he had a connection with AIM (although Ethicon did not know at the time that Shah was an employee of AIM). In August 2019, Ethicon served on AIM two non-party subpoenas seeking information about its purchases and sales of SURGICEL devices. Ethicon also advised AIM's outside counsel that Mr. Shah was a counterfeiter and that AIM had likely sold dangerous counterfeit SURGICEL devices to be used on patients. In response, Defendants continue to downplay Mr. Shah's connection to AIM. However, banking records, testimony from Ms. Tuzik, and other records (including letters confirming Mr. Shah's employment) establish that Mr. Shah was a salaried employee of AIM during the time relevant to this suit. See [176] at 74-78 and exhibits cited therein.

A second company from which AIM allegedly acquired counterfeit products is Medifelix, a Turkish company. Plaintiffs present uncontested evidence that on September 25, 2018, AIM purchased from Medifelix 50 boxes of counterfeit STRAP25 products and 12 boxes of counterfeit OPSTRAP20 products—both of which are product codes for different ETHICON SECURESTRAP devices. See [176] at 40 and exhibits cited therein. On November 6, 2018, Medifelix informed AIM that the STRAP25 products that AIM had purchased were counterfeit. Medifelix offered to take the products back and issue a refund. At the time it received that warning from Medifelix, AIM had not sold any of the counterfeit STRAP25 or OPSTRAP20 products. See *id.* However, instead of removing the product from the shelves, records show that AIM began rapidly selling the counterfeit ETHICON SECURESTRAP devices, making nine different sales of varying quantities to seven different customers, including multiple hospitals and surgery centers. See *id.* at 40. When Mr. Einhorn was asked at his deposition about AIM's decision to continue selling the counterfeits after being warned by its vendor, he asserted his rights under the Fifth Amendment.

The third alleged supplier of counterfeit products identified in Plaintiffs' preliminary injunction materials is based in the United States and allegedly obtained its counterfeit devices from Medserve. The record shows that in October 2019, AIM purchased more than 2,000 counterfeit LIGACLIP devices from that supplier. See [176] at 38 and exhibits cited therein. In March 2020 that supplier, after receiving a letter from Ethicon's counsel as part of its counterfeiting investigation, sent AIM an email warning that the LIGACLIP devices it sold AIM were either contaminated or counterfeit, and advising AIM to set aside any remaining inventory and warn any customers who had received the product. See *id.* AIM took no action in response to the warning. After receiving notice that the devices were contaminated or counterfeit, AIM continued to sell them, making sales on March 27 and May 4, 2020. See *id.* at 39 and Exs. 190 & 196. The dangerous counterfeits were sold to a urology practice, where they were implanted in patients. *Id.* at 39. Mr. Einhorn invoked his Fifth Amendment rights when asked why AIM did not remove the LIGACLIPs from its inventory. See *id.* at 39-40.

Apart from its alleged sale of counterfeit products and products packaged in counterfeit packaging, AIM is also alleged to have removed nearly all of the Ethicon inventory in its warehouse from its outer boxes to sell them as "eaches," without their instructions for use. See [176] at 158-59; [183] (declaration of Joshua Stein). Plaintiffs contend that this process renders the medical devices "materially different" from genuine Ethicon devices and makes AIM's sale of the devices as "eaches" a violation of Plaintiffs' registered trademarks. According to Plaintiffs, the "eaches" discovered in AIM's warehouse were commingled without regard to their lot numbers, the vendors from whom they were purchased, whether any of those lot numbers had been recalled, and without attention to specific expiration dates. See [176] at 159 and Exs. 157, 158. Records show that AIM sold and shipped "eaches" loosely in envelopes to hospitals, medical

centers, and others without the outer packaging and instructions for use. See *id*. at 159-160 & Ex. 224.

There appear to be no material disputes of fact concerning the differences between the Ethicon products as sold by AIM and the same products as they are sold by Ethicon, the manufacturer. Defendants do not dispute that the "eaches" in its warehouse were removed from their original outer packaging and separated from their instructions for use, contending that it is sufficient that the individual "eaches" remained in their original inner packaging. Defendants also do not dispute that some of the "eaches" it sells are expired or subject to recalls. By comparison, Ethicon sells only fresh product in its full original packaging accompanied by printed instructions for use.

The record shows that Ethicon ships its products in outer packaging that has undergone rigorous testing to ensure that the surgical devices are not compromised by the shipping process, as the inner packaging alone is not designed to withstand shipping. Plaintiffs emphasize that the integrity of their surgical devices during shipping process is very important: if, for example, a reload cartridge of surgical staples became misaligned during shipping, it could cause the surgical stapler to misfire, causing serious injury to the patient. See [176] at 168; [188] (declaration of Reynaldo Librojo). Plaintiffs' position is that, by discarding Ethicon's authentic outer packaging and then shipping the Ethicon devices loose in plain shipping envelopes and boxes, AIM violates FDA regulations and ensures that the Ethicon products are shipped and handled under substandard conditions.

Plaintiffs present unrebutted evidence that AIM obtains at least some of its "eaches" through improper means. This includes purchasing them one or two at a time from hospital staff who have taken them from hospitals. It also includes working with employees of surgery centers

and other medical facilities to purchase Ethicon surgical devices under their employers' heavily discounted contracts with Ethicon and divert them to AIM. See [176] at 81-90 and exhibits cited therein (detailing specific instances where AIM allegedly bribed hospital employees and purchased stolen product from hospital employees).

In their latest supplemental brief, Plaintiffs have called into question the accuracy of Defendants' banking records, through which Plaintiffs have been attempting to "follow the money" so they can trace AIM's alleged counterfeiting. [249] at 2. For example, the bank records show that Defendant Iaderosa regularly deposited business checks made out to AIM into his personal checking account. See *id.* at 2-4. Iaderosa moved substantial funds from his personal accounts into CoinBase, a platform that trades in cryptocurrencies like Bitcoin. See *id.* at 4. Iaderosa then engaged in multiple transfers of cryptocurrency with third parties, consistent with a purchase or sale of goods (receiving over $1 million and sending $250,000). See *id.* at 5. Iaderosa has invoked his Fifth Amendment rights in response to questions about these transactions.

In their twelve-count complaint, Plaintiffs seek injunctive relief to stop the sale of the counterfeit and misbranded Ethicon medical devices. Specifically, Plaintiffs bring claims for violation of Section 32 of the Lanham Act (15 U.S.C. § 1114); false descriptions and false designations of origin in commerce in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and 815 Ill. Comp. Stat. 510 et seq.; trademark dilution in violation of Section 43 of the Lanham Act (15 U.S.C. § 1125) and 765 Ill. Comp. Stat. 1036/65; and common-law breach of contract, unjust enrichment, unfair competition, and tortious interference with contract.

II. Legal Standard

The decision whether to issue a preliminary injunction involves a two-step inquiry, with a threshold phase and a balancing phase. See *Vendavo, Inc. v. Long*, 397 F. Supp. 3d 1115, 1128

(N.D. Ill. 2019). First, the party seeking the preliminary injunction has the burden of making a threshold showing: (1) that it will suffer irreparable harm absent preliminary injunctive relief during the pendency of his action; (2) inadequate remedies at law exist; and (3) it has a reasonable likelihood of success on the merits. See *Valencia v. City of Springfield*, 883 F.3d 959, 965 (7th Cir. 2018); *Mays v. Dart*, -- F.3d --, 2020 WL 5361651, at *5 (7th Cir. Sept. 8, 2020); *Illinois Republican Party v. Pritzker*, -- F.3d --, 2020 WL 5246656, at *2 (7th Cir. Sept. 3, 2020).

If the movant succeeds in its threshold showing, the Court then must engage in a balancing analysis, to determine whether the balance of harm favors the moving party or whether the harm to other parties or the public sufficiently outweighs the movant's interests. *Mays*, 2020 WL 5361651, at *5. The Court "employs a sliding scale approach" to the balancing analysis; "[t]he more likely the plaintiff is to win, the less heavily need the balance of harms weigh in his favor; the less likely he is to win, the more need it weigh in his favor." *Valencia*, 883 F.3d at 966 (internal quotations marks and citation omitted); see also *Mays*, 2020 WL 5361651, at *5.

The Seventh Circuit has recently clarified the third component of the threshold showing, "reiterat[ing] that a plaintiff must demonstrate that 'its claim has some likelihood of success on the merits,' not merely a 'better than negligible' chance," as some decisions from this Circuit, see, e.g., *Whitaker v. Kenosha Unified School District No. 1 Board of Education*, 858 F.3d 1034, 1046 (7th Cir. 2017), have stated. *Mays*, 2020 WL 5361651, at *8 (quoting *Eli Lilly & Co. v. Arla Foods, Inc.*, 893 F.3d 375, 381 (7th Cir. 2018)). "[P]roof by a preponderance" is not required, as "that would spill too far into the ultimate merits for something designed to protect both the parties and the process while the case is pending." *Illinois Republican Party*, 2020 WL 5246656, at *2. But the "likelihood of success" requirement "normally includes a demonstration of how the applicant proposes to prove the key elements of its case." *Id.* "What amounts to 'some'"

likelihood of success "depends on the facts of the case at hand" due to the "sliding scale approach." *Mays*, 2020 WL 5361651, at *8. "Ultimately, the moving party bears the burden of showing that a preliminary injunction is warranted." *Courthouse News Serv. v. Brown*, 908 F.3d 1063, 1068 (7th Cir. 2018).

III. Analysis

A. Defendants' Motion to Strike Potter Declarations [157]

Along with their response to the motion for preliminary injunction, Defendants filed a motion to strike three declarations provided by Plaintiffs' lead counsel Mr. Potter, who is a partner at Patterson Belknap Webb & Tyler LLP. As noted in the background section, the first declaration provides a summary of key events that led to the filing of this lawsuit, including Mr. Potter's participation in investigating and filing suit in *Johnson & Johnson et al. v. XS Supply, LLC et al*., Case No. 8:19-cv-1673-T-33AEP, in the Middle District of Florida (the "Florida Action"). See [15]. The second declaration similarly concerns the underlying investigation and the events precipitating the execution of the Court's seizure order and materials recovered in this case. See [40] at Ex. A. The third declaration is provided in support of Ethicon's Memorandum Concerning the Testing of Seized Product in Response to the Court's June 25, 2020 Order and to put certain facts and documents before the Court. See [127-1].

Defendants move to strike the three declarations and to "exclude Mr. Potter from providing further sworn testimony as a material fact or opinion witness in support of Plaintiffs' request for a preliminary injunction, the confirmation of the seizure order, and in their case in chief." [157] at 1. Invoking the advocate-witness rule and American Bar Association "ABA" Model Rule 3.7, Defendants contend that "Mr. Potter's decision to be both a fact and opinion witness, as well as an attorney advocate for Plaintiffs, is fundamentally unfair … and should not stand" because, "[a]s a

result of Mr. Potter's status as Plaintiffs' counsel of record, … Defendants are precluded from challenging Mr. Potter's credibility by deposition, a prohibition that necessarily prejudices … Defendants' ability to defend themselves in the preliminary injunction and seizure hearing." *Id.* at 2. Defendants maintain that striking the declarations, "at least to the extent they proffer testimonial facts or opinions which purport to be probative of substantive elements of proof in this action, as well as excluding further testimony by Mr. Potter in support of Plaintiffs' action for preliminary injunction, is necessary to protect … Defendants from undue prejudice resulting from Mr. Potter continuing to provide substantive evidence while being shielded from deposition and cross-examination." *Id*. at 10-11.

The Court begins its analysis with ABA Model Rule 3.7, which provides that "[a] lawyer shall not act as advocate at a trial in which the lawyer is likely to be a necessary witness unless: (1) the testimony relates to an uncontested issue; (2) the testimony relates to the nature and value of legal services rendered in the case; or (3) disqualification of the lawyer would work substantial hardship on the client." *Smith v. Chicago Transit Authority*, 2015 WL 328838, at *2 (N.D. Ill. Jan. 26, 2015). The Court has discretion to determine whether the advocate-witness rule should bar counsel from testifying. See *id.* (citing *United States v. Jones*, 600 F.3d 847, 862 (7th Cir. 2010)). "For a lawyer to be disqualified under Rule 3.7" as a "necessary" witness, "it must be 'likely' that the lawyer will be called upon to provide testimony that is relevant and material." *Walton v. Diamond*, 2012 WL 6587723, at *2 (N.D. Ill. Dec. 14, 2012) (quoting ANNOTATED MODEL RULES OF PROFESSIONAL CONDUCT 375 (Ellen J. Bennett et al. eds., 7th ed. 2011)) (internal quotation marks omitted). "A 'necessary' witness under Rule 3.7 is one whose testimony is unobtainable elsewhere." *Id.* "If the evidence that would be offered by having an opposing attorney testify can be elicited through other means, then the attorney is not a necessary

witness." *Id.* "This is a high hurdle, because when one party argues that an opponent's attorney is a necessary witness and moves to disqualify that attorney ... courts view the opponent's asserted need to call the attorney more skeptically and must be concerned about the possibility that the motion to disqualify is an abusive tactic to hurt the opponent's ability to pursue his case." *Dawaji v. Kohlhoss*, 2013 WL 6197161, at *2–3 (N.D. Ill. Nov. 27, 2013) (internal citation and quotation marks omitted); *United States v. Hollnagel*, 2011 WL 3898033, at *4 (N.D. Ill. Sept. 6, 2011).

Defendants' motion to strike does not identify anything in the declarations for which Mr. Potter would or might be the only witness at trial (or for which he was the only witness at the preliminary injunction hearing). Instead, the declarations summarize evidence that could, presumably, be presented at trial through any number of other means. The declarations provide a convenient way of organizing voluminous materials for purposes of the preliminary injunction phase of the case. They cite and attach voluminous records, the contents of which Defendants do not seriously challenge. The documents include, for instance, the prior seizure orders and investigation in related actions that led to the discovery of Defendants' sale of the products in question; documents produced in connection with the subpoenas; excerpts from documents received from Defendants; correspondence between counsel; court submissions by Defendants in related actions; and excerpts of materials received in response to discovery requests in the related actions. Using attorney declarations to introduce such evidence into the preliminary injunction record is not uncommon and has been allowed in comparable cases in which Mr. Potter was involved. See *United States v. Shayota*, 186 F. Supp. 3d 1052, 1058-59 (N.D. Cal. 2016) (taking into consideration declaration submitted by Geoffrey Potter detailing basis for request for seizure order, and noting the ways in which the declaration "trace[d] the course of [the] investigation as to the source of counterfeit [products]"); *Roche Diagnostics Corp. et al v. Priority Healthcare*

Corp. et al, 2:18-CV-1479-KOB (N.D. Ala. Oct. 30, 2019); cf. generally *Instant Technology, LLC v. DeFazio*, 2012 WL 357031, at *3 (N.D. Ill. Feb. 1, 2012) ("When considering a motion for preliminary injunction, 'the court may consider affidavits and verified pleadings as evidence.'" (quoting *Hunter v. Atchison, T. & S.F. Ry. Co*., 188 F.2d 294, 298 (7th Cir.1951)).

More generally, the Seventh Circuit recognizes that the advocate-witness rule is applied with "flexibility" in non-jury proceedings, because "[a] judge, as compared with a jury, may be better able to take account of a witness-[advocate's] adversarial role in weighing the objectivity of his testimony." *United States v. Johnston*, 690 F.2d 638, 644 (7th Cir. 1982); see also *Coolsavings.com Inc. v. E-Centives, Inc*., 2000 WL 1262929, at *5 (N.D. Ill. Sept. 1, 2000). The Court can and will simply disregard Mr. Potter's declarations to the extent they go beyond his personal knowledge, the attached exhibits, or the other materials provided by the parties to date. It would be a pointless exercise to parse the declarations to eliminate any portions that might arguably constitute an opinion not supported by the underlying exhibits. See *Soos & Assocs., Inc. v. Five Guys Enterprises, LLC*, 425 F. Supp. 3d 1004, 1010 (N.D. Ill. 2019) ("[m]otions to strike are generally disfavored because they potentially serve only to delay" (internal citation and quotation marks omitted)). For these reasons, Defendants' motion to strike [157] is denied.

B. Reasonable Likelihood of Success on the Merits

Plaintiffs bring twelve, largely overlapping claims arising out of Defendants' sale of allegedly counterfeit and materially different Ethicon medical devices. Given their common factual nucleus, the Court finds it unnecessary to discuss each claim in detail. The Court focuses on Plaintiffs' first claim, for willful trademark infringement in violation of 15 U.S.C. § 1114(1)(a). This claim is based on Defendants' alleged sale of counterfeit SURGICEL, LIGACLIP, and

ETHICON SECURESTRAP devices, as well as Defendants' sale of Ethicon medical devices as "eaches" removed from their outer packaging and instructions. See [154] at 62-63. In particular, Plaintiffs allege:

> In violation of 15 U.S.C. § 1114(1)(a), Defendants, independently and in conspiracy with one another, used in commerce, without Ethicon's consent, either a reproduction, counterfeit, copy, or colorable imitation of the SURGICEL Trademarks, the LIGACLIP trademark, the ETHICON SECURESTRAP trademark, the Ethicon Trademarks, and the SURGICEL Trade Dress, the LIGACLIP Trade Dress, and the ETHICON SECURESTRAP Trade Dress (collectively, the "Ethicon Marks and Trade Dress") and in connection with the sale, offering for sale, distribution, or advertising of counterfeit SURGICEL®, LIGACLIP®, and ETHICON SECURESTRAP®; in connection with the sale, offering for sale, distribution, or advertising of diverted and/or altered Ethicon products that are materially different from authentic Ethicon products authorized for sale by Ethicon in the United States and that are not subject to and subvert Ethicon's quality-control measures; and in connection with which such use that is likely to cause confusion, or to cause mistake, or to deceive.

[154] at 62-63.

The facts laid out by Plaintiffs in support of their trademark infringement claim are in the main uncontested. By executing the seizure order at AIM's warehouse and recovering some product from AIM's customers, Plaintiffs have gathered evidence thus far that AIM purchased from Medserve, imported, and sold to hospitals, medical professionals, and others nationwide more than 7,000 counterfeit Ethicon medical devices. Defendants essentially have no response to this evidence and have represented that they "would not appeal an injunction" prohibiting them from selling SURGICEL, LIGACLIP, and ETHICON SECURESTRAP medical devices. [221] at 23.

While not denying that they have sold counterfeit products, Defendants try to paint themselves as innocent victims who have been duped into purchasing counterfeits from a few bad actors, most notably Medserve. They even suggest that it is Plaintiffs fault that the counterfeits

were not discovered earlier, because of Plaintiffs' alleged delay in notifying them of Plaintiffs' suspicions that AIM was selling counterfeit devices.

Defendants' actions prior to and during the course of this litigation paint a very different picture. Among other actions identified in Plaintiffs' voluminous preliminary injunction briefing, there is evidence in the record that:

- AIM ignored warnings from its vendors that AIM had received counterfeit devices, instead selling the counterfeits to customers. For instance, in November 2018, Medifelix informed AIM that certain ETHICON SECURESTRAP devices it had purchased in September were counterfeit and offered to take the product back and issue a refund. See [176] at 40 and Exs. 53, 56. Yet AIM made nine additional sales of the counterfeit devices to seven customers, including hospitals and surgery centers. See *id.* at 40-41. Defendant Einhorn then contacted Medifelix trying to buy more of the counterfeit product. See *id.* at 42 & Ex. 61. In March 2020, a U.S.-based vendor sent Defendant Einhorn an email alerting AIM that the LIGACLIP devices it sold AIM were either contaminated and counterfeit and directing AIM to set any remaining product aside and warn any customers who had already received the product. See [176] at 38 & Ex. 191. Yet AIM made two additional sales of the counterfeit devices. See *id.* at 39 & Exs. 190, 196.

- After the FDA raided AIM's warehouse in March 2019 to investigate AIM's potential trafficking in counterfeits, AIM began having counterfeits shipped directly to the residences of Defendants Einhorn and Phipps, rather than AIM's warehouse. See [176] at 44-46 & Ex. 17.

- AIM worked with Medserve to falsify paperwork to conceal that AIM was selling expired SURGICEL FIBRILLAR product to Medserve in India, which was then used by Medserve to manufacture counterfeits. Medserve never paid for the product but repackaged the expired product in counterfeit packaging and sent some of it back to AIM as payment. See [13] at 33-38.

- Defendant Iaderosa created Magellan as a shell company in Dubai so AIM could import product from unregistered foreign suppliers to bypass the FDA's foreign registration requirement and avoid FDA scrutiny. See [176] at 53.

- AIM recruited and bribed employees of hospitals and surgical centers to use their employers' credentials to make purchases of discounted Ethicon product on AIM's behalf. See [176] at 81-86 and exhibits cited therein (providing details concerning three hospital employees involved in alleged bribery).

- AIM purchased stolen Ethicon product from hospital employees. See [176] at 87 & exhibits cited therein (providing details on seven hospital employees who sold "eaches" to AIM).

- During the course of discovery in the Florida action, AIM responded to non-party subpoenas by concealing inculpatory communications showing that Shah was an employee of AIM and had numerous conversations with AIM and Medserve about purchasing counterfeits and sending expired product to Medserve. See [15] at 7-8 & Ex. 7; [176] at 64-66.

- After the Court issued a TRO in this case, prohibiting AIM from purchasing any Ethicon products, see [29] at 1-2, AIM purchased thousands of Ethicon-branded devices. See [176] at 57 & Ex. 91.

- When AIM produced its purchase and sales information in this litigation, it represented that AIM did not sell any Ethicon products that had been supplied by Medserve. See [78] at Ex 1. AIM later admitted that it had no records of Medserve because it recorded all transactions with Medserve under the alias "Little India Trading," with an address in Hong Kong. [176] at 61.

- When AIM agreed to send Plaintiffs the Ethicon SURGICEL products it had in stock so Ethicon could assess whether they were counterfeit, AIM allegedly cherry-picked only the SURGICEL devices it knew were authentic and withheld several hundred allegedly counterfeit SURGICEL hemostats, which Defendant Phipps had sent to his home in August 2019 and then delivered to Defendant Einhorn. See [176] at 66-67.

- AIM has repeatedly denied employing Defendant Shah, despite Ms. Tuzik confirming that Defendant Iaderosa had hired Shah and directed her to draft a written offer of employment paying Shah $5,000 per month. See [176] at 74-75 & Exs. 111 & 113; see also [13] at 7 (bank records showing Shah received "salary" of $5,000 or more monthly from AIM).

- According to a forensic exam obtained by Plaintiffs, Defendant Iaderosa deleted over a hundred messages—and perhaps thousands of messages—from his personal cell phone after he knew it was subject to the seizure order but before it could be imaged by Ethicon's electronic discovery vendor. See [176] at 79 (citing declaration of Vikram Masson).

These actions certainly raise cause for concern and reasonable grounds for thinking that Defendants have willfully participated in counterfeiting.

Moreover, if an innocent (or even neutral) explanation exists, Defendants have not been forthcoming in presenting it. To the contrary, everyone at AIM who might be able to provide

Plaintiffs (and the Court) with the information necessary to determine how AIM came to sell counterfeits—or to determine the true scope of counterfeiting, beyond what Plaintiffs' limited examination has revealed thus far—has asserted the Fifth Amendment right to remain silent. See *Ruiz-Cortez v. City of Chicago*, 931 F.3d 592, 603 (7th Cir. 2019) ("When a defendant in a civil case invokes the Fifth Amendment, juries are permitted, but not required, to draw a negative inference against the defendant."); *Harris v. City of Chicago*, 266 F.3d 750, 753 (7th Cir. 2001) ("'the Fifth Amendment does not forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them'" (quoting *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976))).

Ethicon has tried to "follow the money" to determine the full scope of the counterfeiting in which Defendants have engaged, [249] at 2, as well as to help the Court in assessing the extent to which it was accidental or purposeful, but progress to that end has been slow and incomplete. Some of the delay can be chalked up to AIM itself, as it has filed a flurry of motions to delay, strike, or otherwise prevent Ethicon from gathering and presenting evidence to the Court. Only recently did Ethicon obtain key banking records because of AIM's motion practice, which included a motion to quash that Magistrate Judge Cummings denied, followed by objections under Federal Rule of Civil Procedure 72, which this Court overruled.

Plaintiffs' initial examination of Defendants' banking records shows that AIM was receiving large quantities of medical devices from Medserve but was not entering the purchases on its books. The goods were then sent to the homes of AIM's employees, rather than to AIM's warehouse as other purchases were handled. This all suggests that AIM and Medserve were not arms-length participants in the resale of medical devices, but rather were working together to bring counterfeit Ethicon devices—as well as expired Ethicon devices repackaged in unsanitary

conditions in counterfeit packaging—to the United States for sale to hospitals and medical institutions throughout the country.

Defendants claim that there is nothing suspicious about AIM receiving product from Medserve without paying for it. Supported by a declaration from Ms. Tuzik, Defendants assert that "[n]ot knowing that Medserve might be engaged in counterfeiting, AIM treated Medserve like it does many other secondary market vendors—because Medserve wished to purchase certain products from AIM and AIM wished to purchase other products from Medserve, the two companies utilized a trade balance rather than paying one another cash." [253] at 2. Ms. Tuzik avers that AIM does the same "often on a much larger scale, with dozens of other vendors," *id.*, and attaches a list of 36 such vendors. See [253-1]. However, Ms. Tuzik's declaration does not address how "trade balance" transactions with Medserve or any other of the identified vendors are recorded in AIM's books or its inventory system. In general, the declaration raises more questions than it answers. What is AIM sending these vendors? In exchange for what? How is the value of the trade determined? Does the product go through normal shipping channels, or are these products shipped to employees' homes as well? More fundamentally, Ms. Tuzik's declaration is based on what the record suggests is a faulty proposition—that AIM had no idea Medserve was engaged in counterfeiting.

Considering the preliminary injunction record as a whole, Plaintiffs have demonstrated that they have more than a reasonable likelihood of success on their trademark infringement claims based on Defendants' alleged sale of counterfeit Ethicon devices and expired devices in counterfeit Ethicon packaging. They also have demonstrated they are likely to succeed in showing that Defendants' infringement was willful. Defendants simply have engaged in too many questionable practices and offered hopelessly incomplete and thoroughly unconvincing explanations for how

those practices led to innocent rather than willful placement of thousands of counterfeit products in the market.

Still, the suspected or confirmed counterfeits make up just a small percentage of the Ethicon devices that AIM sells. Over 1 million devices were seized, but Plaintiffs have evidence of counterfeiting for only about 7,000 of the devices (at least so far, with discovery still in early stages), which come from three vendors and concern three of Plaintiffs' trademarks. Defendants do not seriously dispute that an injunction would be justified as to the specific product types for which there is evidence of counterfeiting, but argue that the injunction must be dissolved as to the remainder of its seized goods, and those goods returned to Defendants. They explain that it would impose a massive hardship on their business to be prohibited from selling genuine Ethicon medical devices during the pendency of this lawsuit. However, they do not attempt to explain in any detail where they obtain their other Ethicon products, how they ensure that the products are genuine, or indeed, why the Court should believe Defendants' assurances that most of its products are legitimate when it appears to have been a knowing, willful participant in the importation and sale of thousands of counterfeit Ethicon devices. Plaintiffs, by contrast, argue that Defendants' egregious conduct as to the counterfeited products entitles them to a broad injunction prohibiting Defendants from selling *any* of their products, including authentic products.

The Court is inclined to agree with Plaintiffs at least in the short term, until further discovery and testing can shed brighter light on the scope of the counterfeiting in which Defendants have engaged. The Supreme Court and Seventh Circuit have recognized the district courts' "discretion to issue a broad injunction in cases where 'a proclivity for unlawful conduct has been shown.'" *Russian Media Group, LLC v. Cable America, Inc*., 598 F.3d 302, 307 (7th Cir. 2010) (quoting *McComb v. Jacksonville Paper Co*., 336 U.S. 187, 192 (1949)). "The district court may

even enjoin certain otherwise lawful conduct when the defendant's conduct has demonstrated that prohibiting only unlawful conduct would not effectively protect the plaintiff's rights against future encroachment." *Id.* (citing *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428–30 (1957)). Here, Defendants are alleged to have knowingly caused thousands of counterfeit and contaminated devices to enter the market, where then have been implanted into patients during surgical procedures. Defendants' conduct has made it extremely difficult for Plaintiffs to identify additional counterfeits. Defendants used Magellan to obscure the sources of the Ethicon product they sell. Defendants removed the Ethicon product from its packaging and, for a large percentage of its goods, failed to keep track of lot numbers and vendor information. During the litigation, Defendants have resisted Plaintiffs' efforts to obtain banking records and denied what appear to be basic facts, such as that Mr. Shah is employed by AIM.

Defendants pre-litigation conduct also makes it very difficult for Plaintiffs to determine if more goods might be counterfeit. Defendants' warehouse is filled with large plastic bins of individually wrapped Ethicon surgical devices, removed from their outer packaging and their instructions for use and mixed together, sometimes with other manufacturers' products. Counterfeits could be randomly intermixed with authentic product that was fraudulently obtained, stolen off hospital shelves, or recalled by Ethicon. For over 95% of the more than 1.2 million seized devices, AIM failed to maintain basic information about the product, including its lot number or who sold that particular device. Given Defendants' evasions, the Court believes that at minimum Plaintiffs are entitled to a reasonable amount of time to conduct additional discovery into AIM's alleged counterfeiting operation before any of the seized Ethicon products are returned to Defendants. As Plaintiffs emphasize, lives are at stake.

More information on the supposedly "legitimate" portion of AIM's business might give the Court more assurance that AIM should immediately be allowed to sell Ethicon devices other than the four devices that have been discovered to be counterfeit.[2] But Defendants are on weak ground in complaining about the speed of Plaintiffs' investigation. Plaintiffs have presented strong evidence of counterfeiting, which has taken place in the context of certain unorthodox business practices consistent with knowledge on both ends of the transaction that something improper was afoot, followed by silence and stonewalling in the face of routine written discovery requests and deposition questions. Defendants have a lot to answer for, yet they have offered very little to assuage the Court's concerns. And, again, we are talking here about implantable medical devices, not watches or purses.

Yet the hold on Defendants' business operations cannot be unlimited in scope or indefinite in duration. Absent discovery of additional proof of counterfeiting beyond the universe of approximately 7,000 devices identified thus far, the Court would have difficulty concluding that AIM should be barred from selling *any* Ethicon devices—including indisputably authentic ones—simply because, for a small percentage of its inventory, AIM knowingly sold counterfeits. The allegations concerning counterfeiting and attempts to defraud Plaintiffs and this Court are extremely troubling. But for how long can they justify seizing and holding $24 million worth of product, especially if only 2.3% of the total product value is confirmed or suspected to be counterfeit?

Testing of the seized product remains ongoing under the supervision of Magistrate Judge Cummings, with Plaintiffs filing weekly updates. When the sample size becomes large enough to

[2] According to Plaintiffs, their preliminary investigation of AIM's suppliers shows that many are simply individuals not associated with any company, while others are companies that have no websites, corporate registrations, or registrations with the FDA, and only P.O. boxes for physical addresses. See [176] at 87-90 and exhibits cited therein.

permit a reasonable determination as to the scope of the counterfeiting, this Court will consider revising the scope of the injunction. See, e.g., *Russian Media*, 598 F.3d at 307-308 (concluding in case involving Illinois Cable Piracy Act claim that preliminary injunction barring cable television companies from transmitting any Russian-language programming to 20 apartment houses was not overbroad in scope, even though injunction also prevented legal programming transmissions, where cable companies had pattern of misconduct and record of dishonesty and refusing to comply with district court's orders; noting that "[i]f the defendants can show that they have a plan to compete legally for business in the twenty subject properties, they should seek a modification from the district court that issued the injunction"). To assist the Court in determining the appropriate time for making a further assessment, the parties will file the joint status report described above (see p. 2, supra) on the last business day of each month. The Court also may seek input from Judge Cummings on the issue.

In any event, even if the continued broad injunction and seizure of all Ethicon devices (not just those known or suspected to be counterfeits) were not justified based on Ethicon's apparent willful sale of some counterfeit devices, it would stand because all (or nearly all) of the devices are encompassed by Plaintiffs' claim that the sale of "eaches" stripped of outer packaging and instructions for use constitutes trademark infringement, on which Plaintiffs also have a reasonable likelihood of success. "Ordinarily, trademark law does not protect against the sale of genuine goods bearing a true mark even when the sale is not authorized by the mark owner." *Slep–Tone Entertainment Corp. v. Sellis Enterprises, Inc*., 87 F. Supp. 3d 897, 905 n.5 (N.D. Ill. 2015); see also *Ty Inc. v. Perryman*, 306 F.3d 509, 513 (7th Cir. 2002); *Leonel & Noel Corp. v. Cerveceria Centro Americana, S.A.*, 758 F. Supp. 2d 596, 603 (N.D. Ill. 2010). However, this rule "does not apply to trademarked goods that are materially different than those sold by the trademark owner."

Slep-Tone, 87 F. Supp. 3d at 905 n.5. "Materially different" goods have been described as goods that, while genuine, are "of degraded quality," *id*., of "inferior quality," *Genin, Trudeau & Co., Ltd. v. Integra Development Int'l*, 845 F. Supp. 611, 615–16 (N.D. Ill. 1994), or containing a "defect (or potential defect) … that the customer would not be readily able to detect that likely would result in consumer confusion," *Leonel*, 758 F. Supp. 3d at 603. Put another way, goods are not "materially different" and their sale does not violate trademark law if they are "genuine, unaltered products," *Trans Union LLC v. Credit Research, Inc*., 142 F. Supp. 2d 1029, 1039 n.6 (N.D. Ill. 2001), that are "qualitatively equivalent to those produced by plaintiff," *Glovaroma, Inc. v. Maljack Productions, Inc.*, 71 F. Supp. 2d 846, 856 (N.D. Ill. 1999).

Goods have been found to be "materially different" where they do not conform to the trademark holder's quality control standards. See *Standard Process, Inc. v. Banks*, 554 F. Supp. 2d 866, 870 (E.D. Wis. 2008) (recognizing that seller may violate trademark holder's "quality control standards to the point of compromising the genuineness of the products themselves"); *Standard Process Inc. v. AVC Infinite, LLC*, 2020 WL 103841, at *5 (W.D. Wis. Jan. 8, 2020) ("Products sold outside a manufacturer's authorized distribution system are not genuine products unless sold in their original packaging, within expiration dates, and otherwise sold consistent with the manufacturer's quality controls pursuant to the 'first sale' date." (citing *Zino Davidoff SA v. CVS Corp.*, 571 F.3d 238, 243 (2d Cir. 2009)); see also *Zino Davidoff*, 571 F.3d at 243; ("goods are not genuine if they do not conform to the trademark holder's quality control standards"); *Shell Oil Co. v. Comm. Petro. Inc.*, 928 F.2d 104, 107 (4th Cir. 1991) ("A product is not truly 'genuine' unless it is manufactured and distributed under quality controls established by the manufacturer."). This interpretation of trademark law rests on the rationale that "interference with the trademark holder's legitimate steps to control quality unreasonably subjects

the trademark holder to the risk of injury to the reputation of its mark." *Zino Davidoff*, 571 F.3d at 243-44; see also *El Greco Leather Products Co., Inc. v. Shoe World, Inc*., 806 F.2d 392, 395 (2d Cir. 1986) ("One of the most valuable and important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark.").

Based on the materials provided by the parties, Plaintiffs have at least a reasonable likelihood of succeeding on their claim that Defendants' sale of Ethicon medical devices as "eaches" under the circumstances alleged here constitutes the sale of "materially different" devices in violation of Plaintiffs' registered trademarks. Defendants largely do not dispute the facts laid out by Plaintiffs concerning "eaches." AIM's "eaches" are stored at its warehouse and shipped to its customers without their outer packaging or instructions for use. Some of the "eaches" are shipped to medical professionals and facilities.

In support of their "materially different" argument, Plaintiffs present a largely unrebutted declaration from Reynaldo Librojo, Ethicon's Senior Director of Global Regulatory Affairs, Wound Closure and Repairs, establishing the importance of Ethicon's packaging to the quality of its medical devices. Mr. Reynaldo explains that Ethicon designs its products, including its packaging, labeling, and instructions for use, to comply with FDA regulations. [188] at 3. The FDA approves each Ethicon medical device at the "box level," with the packaging and labeling considered part of the device. *Id*. According to Mr. Librojo, a medical device "must remain in its FDA-cleared or -approved packaging during the duration of its chain of distribution" to "ensure[] that the device(s) within will remain protected and undamaged and thus perform safely and effectively as intended," as well as to "ensure[] that all required information is provided to the end user to ensure its safe and effective use." *Id*. at 3.

The outer cartons of Ethicon devices are important, Mr. Librojo explains, because they "ensure[] that the devices are not damaged or compromised in any way by the shipping process. [188] at 3. Mr. Librojo provides several examples of how such damage might occur. "For example, Ethicon sells cartridges for use with Ethicon surgical staplers that allow surgeons to quickly load surgical stapling devices. If a reload cartridge of surgical staples becomes damaged during shipping, it could cause the surgical stapler to malfunction, which could potentially result in serious injury to the patient." *Id*. at 4. A second example: "[T]he outer packaging (box) and inner packaging (individual pouch) of Ethicon's suture products are both designed to ensure sterility. If an individually packaged suture is removed from its validated packaging configuration, the sterile barrier could be impacted or breached. That would render the suture non-sterile, which is a risk factor for infection. Removal of the individually wrapped suture from its protective outer box could also expose the suture to unwanted transportation or handling stresses, which could impact the suture's attachment to the needle or damage to the needle itself. This too could cause unexpected and adverse performance of the suture." *Id*.

Mr. Reynaldo also explains that Ethicon requires that all medical devices intended for sale in the United States be sold with their instructions for use. Ethicon's products, such as its sutures, are sold in boxes containing multiple individually sealed devices, with a single printed copy of the instructions for use. According to Mr. Reynaldo, "Ethicon does not currently have the ability to satisfy FDA regulations by publishing Instructions for Use electronically for all of its thousands of product codes." [188] at 5.

Defendants argue that they are not required to sell "eaches" with their instructions for use because the "eaches" are prescription devices intended for use only by medical professionals and, therefore, are exempt from the FDA's labeling requirements, 21 U.S.C. § 352(f), pursuant to

regulation, 21 C.F.R. § 801.109. Plaintiffs do not address this regulation, and Defendants do not delve into it in sufficient detail for the Court to determine with any accuracy how the regulation applies to the facts at hand. It is ultimately an unconvincing counterweight to the evidence in support of issuing the preliminary injunction. Nothing in the statute or regulation (or another regulation that AIM relies on to argue that it is a "wholesaler" exempt from labeling requirements, 21 C.F.R. § 807.3(t)) gives Defendants any right to sell medical devices that are materially different than those sold by Ethicon, as alleged to be the case here for reasons wholly apart from the instructions for use.

Defendants contend that Plaintiffs fail to establish that devices sold as "eaches" are materially different than devices sold by Ethicon, because "[t]here is no evidence that anything about AIM's sales of 'eaches' (other than the quantity of product itself) is relevant to the purchaser's decision to buy, or that the purchaser is misled in any way about what it is purchasing." [221] at 37. Defendants' argument presumes, however, that customers who buy "eaches" expect that, except for being available in smaller quantities, the devices are of the same quality as devices purchased from Ethicon—sterile and undamaged. Mr. Reynaldo's declaration establishes that by removing the devices from their outer packaging and shipping them to customers, AIM risks contaminating and damaging them. This information seems likely to influence a decision about whether to purchase medical devices from AIM or use them in patients' surgeries.

Defendant's purported "disclaimer" that it is a wholesaler does not absolve Defendants of responsibility for selling allegedly materially different medical devices. Defendants do not purport to disclose that the "eaches" it sells have been stripped of their outer packaging or instructions, or that they will be shipped in packaging that was never designed or tested to be used for shipping. Nor do they disclose that AIM's method of sale undermines Plaintiffs' quality control standards

and could be result in damage to the product or injury to the patient. These are considerations that anyone purchasing, using, or having medical devices used in their bodies would certainly find material in comparing the devices Ethicon sells directly with the devices sold by AIM. A consumer using AIM's website—or using/receiving the products purchased from AIM's website—could very well be "confus[ed]" where, "relying on the reputation of [Plaintiffs'] trademark," they "buy a product that they think is safe or of a certain quality, and then subsequently find out that they have actually purchased an inferior item." *Polymer Tech. Corp. v. Mimran*, 37 F.3d 74, 80 (2d Cir. 1994).

Defendants claim that "Plaintiffs' allegation that individual devices are rendered unsafe when removed from their outer boxes rings hollow and is undercut by Plaintiffs' own practices," because "Ethicon's instructions for use say nothing about keeping products in their outer boxes." [221] at 39. "The instructions do not warn hospitals against transporting individual packages removed from their outer box out of the hospital and across town for use by an ambulatory surgery center affiliated with the hospital." *Id*. But Defendants are comparing two very different things. A hospital breaking up a box once it is in its possession does not present the same quality control and contamination concerns as AIM's system—where, apparently, a hospital employee might take a device off the shelf at work and mail it to AIM, where it is stored commingled with other devices and then shipped to the customer without the protective outer packaging that was approved by the FDA. If the purchaser chooses to remove individual packages after taking control of the intact (and still sterile) box, it can maintain the integrity of the product with its own sterile practices. Not so using Defendants' practices.

Defendants also claim that "Ethicon's own authorized distributors sell products by the "each," including the surgical staple cartridges described in Plaintiffs' briefs. Plaintiffs

acknowledge that Medline, an Ethicon authorized distributor, appears recently to have been selling "eaches" on its website. However, as soon as Plaintiffs became aware of this, they promptly sent Medline a cease and desist letter instructing it to end that practice. The Court agrees with Plaintiffs that the fact that one of Ethicon's authorized distributors sold "eaches" does not absolve AIM of its own alleged infringement. See *Stabilisierungsfonds Fur Wein v. Kaiser Stuhl Wine Distribs. Pty. Ltd.*, 647 F.2d 200, 207 (D.C. Cir. 1981) (plaintiff is not required to bring suit against all infringers).

In short, Plaintiffs have demonstrated that they have more than a reasonable likelihood of success on their trademark infringement claim for all (or nearly) all of the Ethicon products seized from AIM's warehouse: the alleged counterfeit devices, as well as all the devices that are purchased, stored, and sold as "eaches" without their outer packaging and instructions for use.

D. Irreparable Harm and Inadequate Remedy at Law

The Court next considers whether Plaintiffs have made a sufficient showing that absent a preliminary injunction, they will suffer irreparable harm for which there is no adequate remedy at law. Irreparable harm is "harm that 'cannot be repaired' and for which money compensation is inadequate." *Orr v. Shicker*, 953 F.3d 490, 502 (7th Cir. 2020) (quoting *Graham v. Med. Mut. Of Ohio*, 130 F.3d 293, 296 (7th Cir. 1997)). "'The moving party must demonstrate that he will likely suffer irreparable harm absent obtaining preliminary injunctive relief.'" *Id.* (quoting *Whitaker*, 858 F.3d at 1044). It is not enough to show a "mere possibility of harm." *Id.*

Plaintiffs easily satisfy this standard by identifying harm that cannot be "fully rectified in a final judgment." *Authenticom, Inc. v. CDK Global, LLC*, 874 F.3d 1019, 1024 (7th Cir. 2017). In this case, the potential harm to Plaintiffs is stark and intertwined with the potential harm to the public. Plaintiffs have presented the Court with essentially unrebutted evidence that AIM's

customers have received counterfeit Ethicon devices, as well as expired devices repackaged in counterfeit packaging. These devices are contaminated and dangerous. They could make patients sick or even kill them if used during surgery. Many of these devices appear to have already been implanted in patients. AIM's introduction of counterfeit and contaminated devices into the market confuses customers who, "relying on the reputation of [Plaintiffs'] trademark," "buy a product that they think is safe or of a certain quality, and then subsequently find out that they have actually purchased an inferior item." *Polymer Tech.*, 37 F.3d at 80. This harms Plaintiffs' reputation and the value of their trademarks.

If Defendants could show that they were simply unwitting victims of a vendor who sold them counterfeit goods, they would have a much stronger case for policing themselves during the pendency of this action. But that appears to be far from the case. Plaintiffs have presented ample direct and circumstantial evidence that Defendants' participation in counterfeiting was knowing and intentional. Plaintiffs have also shown how Defendants have tried to evade detection and resisted the Court's orders to prevent (or at least delay) Plaintiffs from uncovering the full scope of Defendants' involvement in counterfeiting. Finally, Defendants fully admit that they sell Ethicon medical devices as "eaches," which Plaintiffs' unrebutted evidence shows undermines Plaintiffs' quality control and risks damage to the product during shipping and resultant injury to the patient. In sum, Plaintiffs have amply demonstrated that the potential harm to both Plaintiffs and the public is irreparable and cannot be adequately compensated through the award of money damages at the conclusion of this action.

E. Balancing Analysis

Finally, the Court considers whether the balance of harms favors Plaintiffs or whether the harm to other parties or the public sufficiently outweighs the movant's interests. *Mays*, 2020 WL

5361651, at *5. As just discussed, the potential harm to the public weighs heavily in favor of issuing an injunction. That leaves Defendants' interests to be balanced. The Court has already determined that Plaintiffs have a strong likelihood of success on the merits; thus "the more [the Defendants] need the balance of harms [to] weigh in [their] favor" in order to successfully resist an injunction. *Valencia*, 883 F.3d at 966; see also *Speech First, Inc. v. Killeen*, 968 F.3d 628, 637 (7th Cir. 2020). At a minimum, any harm to Defendants is much more easily compensable in money damages than injury or death caused by allowing Defendants' counterfeit products to continue entering the market during the pendency of the lawsuit. And from the Court's perspective, that risk will remain unacceptably large at least until the parties can more fully develop the record and complete additional testing to determine (or at least better estimate) the full extent of counterfeit Ethicon products that have passed through Defendants' inventory in recent years. How many have there been; how many have left Defendants' warehouses for doctor's offices, hospitals, and other medical care providers; how many have been traced and intercepted; how many have been implanted in unsuspecting patients by unsuspecting doctors?

Defendants argue that their business would suffer great harm if a broad injunction were to be entered. Defendants' expert J. Lester Alexander calculates that the fair value of the AIM inventory seized totals $23,853,603.28.12; and that the average daily sales and average daily profit lost by AIM as a result of the seizure are $33,675 and $13,677, respectively. See [163-5] at 146-163 (declaration of J. Lester Alexander and supporting exhibits). Based on his assumption that this litigation will last 35 to 40 months from the date of seizure, Mr. Alexander concludes that Defendants' total lost profits will be between approximately $14.6 million and $16.6 million. Defendants submit Alexander's work not only in opposition to the motion for preliminary

injunction, but also is support of a substantially increased bond in the event that the Court does grant injunctive relief.

Plaintiffs challenge Mr. Alexander's expert report via a *Daubert* motion [195] rather than offering their own estimation of a reasonable bond. Plaintiffs challenge the admissibility of Mr. Alexander's report on several grounds: it does not adequately disclose his methodology; it contains unexampled gaps and contradictions; and it is not helpful to the trier of fact. Unfortunately, Plaintiffs have offered very little to assist the Court in setting an appropriate bond, either upon the entry of the original TRO or at any time since. While the Court has no reason to doubt Plaintiffs' representations that their parent company, Johnson & Johnson, has enormous resources and easily could satisfy any judgment entered against its subsidiaries, Rule 65(c) appears not to contemplate that kind of a reassurance of payment. Rather, it provides that the Court may "issue a preliminary injunction ... only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party [later] found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c); see also *Ty, Inc. v. Publications Int'l Ltd.*, 292 F.3d 512, 516 (7th Cir. 2002) ("The purpose of an injunction bond is to compensate the defendant, in the event he prevails on the merits."); *USA-Halal Chamber of Commerce, Inc. v. Best Choice Meats, Inc*., 402 F. Supp. 3d 427, 441 (N.D. Ill. 2019). To be sure, "[t]he appropriate amount of the bond is subject to the court's discretion." *Monster Energy Co. v. Wensheng*, 136 F. Supp. 3d 897, 910 (N.D. Ill. 2015) (citing Fed. R. Civ. P. 65(c); *Gateway E. Ry. Co. v. Terminal R.R. Ass'n of St. Louis*, 35 F.3d 1134, 1141 (7th Cir. 1994)). However, the Seventh Circuit cautions district courts to "err on the high side" because "the damages for an erroneous preliminary injunction cannot exceed the amount of the bond." *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000).

In examining the related issues of the *Daubert* challenge to Defendants' expert and the need to set an appropriate bond, the Court starts with the proposition that where the gatekeeper and the factfinder are one and the same—that is, the judge—the need to make such decisions prior to hearing the testimony is lessened. See *In re Salem*, 465 F.3d 767, 777 (7th Cir. 2006). While the Court would need to formally resolve any *Daubert* objections prior to any presentation of Alexander's testimony to a jury, it can truncate the analysis here as the issue is raised in the context of expedited briefing on a motion for a preliminary injunction and presented to the Court alone for disposition. See *Kansas City S. Ry. Co. v. Sny Island Levee Drainage Dist.*, 831 F.3d 892, 900 (7th Cir. 2016) (explaining that where, as here, the Court is acting as the finder of fact, it "need not conduct a *Daubert* (or Rule 702) analysis before the presentation of evidence"). Although the Court finds some aspects of the Alexander analysis illuminating, other assumptions (discussed below) are less well-grounded and supported, and thus less persuasive. For present purposes, the Court concludes that (a) it can give the Alexander analysis the weight that it deserves without formally admitting or rejecting it *in toto* and (b) it can set a reasonable (and adjustable) bond without deferring entirely to either side's assessment (or lack thereof).

The Court believes that the potential harm to Defendants can be protected by requiring Plaintiffs to post an adequate bond. Mr. Alexander sets that amount at $20 million, but his calculations lack supporting detail and documentation. He provides a one-page summary of AIM's profits and expenses, but not the general ledger on which he says he relied. The general ledger has never been disclosed to Plaintiffs, making it difficult or impossible for them to evaluate Mr. Alexander's assumptions and analysis on any substantive level. There are at least a few reasons to question its accuracy, beyond the sheer size of the bond requested. For instance, it is unclear why Mr. Alexander assumed a 40.61 percent incremental profit, while Ms. Tuzik estimated AIM's

average net profit margin at 30 percent. Furthermore, the fair market value of Defendants' inventory must be discounted by the proposition that thousands of counterfeits have been intermingled with a much larger share of presumably non-counterfeit products—though the precise share remains elusive without further analysis. Mr. Alexander does not appear to have taken this value into account, or the value of any profits AIM presumably might be able to recover by selling the seized product if/when it is returned to AIM.

Mr. Alexander assumes this case will take 35 to 40 months to resolve. However, at least some of the delay factored in Mr. Alexander is a self-inflicted wound, as Defendants' own conduct (ignoring warnings, shipping items to employees' homes, resisting valid discovery requests) has given rise to reasonable suspicion, complicated the tracing process, and prolonged the preliminary investigation phase of this litigation. Given that the amount of the bond always can be increased, there is no basis for taking a worst-case scenario of the time from filing to disposition, especially in a case that is just over three months old and approaching 300 docket entries.

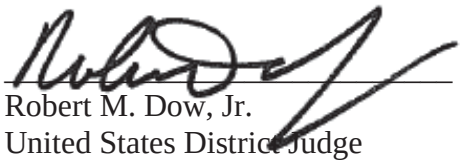
With all of that said, Plaintiffs are required "to pay the costs and damages sustained by any party [later] found to have been wrongfully enjoined or restrained," Fed. R. Civ. P. 65(c), and the Court is directed to "err on the high side," *Mead Johnson*, 201 F.3d at 888. Even if AIM's daily profit is reduced considerably from Mr. Alexander's calculations, it remains substantial. It is also unrealistic to think that the litigation can be concluded in less than six months. The Court therefore concludes that it is reasonable to raise the bond to $750,000. As noted above, the parties are directed to file periodic status reports to address their respective views on whether the Court should

revisit the amount of the bond (and the scope of the injunction) based on more complete information and any relevant new developments.[3]

IV. Conclusion

For these reasons, Plaintiffs' motion for preliminary injunction [10] is granted and the seizure order is confirmed. Plaintiffs shall be required to increase their bond to $750,000. The terms of the injunction and bond are set out in a separate document in accordance with the Seventh Circuit's guidance in *MillerCoors LLC v. Anheuser-Busch Companies, LLC*, 940 F.3d 922 (7th Cir. 2019). Defendants' motion to strike [157] and Plaintiffs' *Daubert* motion [195] are both denied. The parties' motions to file certain briefs under seal, [237], [250], [255], are granted. Finally, in view of the ongoing testing and sampling of the seized product under the supervision of Magistrate Judge Cummings, the parties are directed to file joint status reports on the last business day of each month indicating their views on whether the scope of the injunction and/or the amount of the bond should be altered based on further developments in this litigation, and the Court may seek Judge Cummings' input on those matters as well.

Dated: October 16, 2020



Robert M. Dow, Jr.
United States District Judge

[3] As further protection for Defendants, the Lanham Act provides a cause of action for "[a] person who suffers damage by reason of a wrongful seizure." 15 U.S.C. 1116(d)(11); see also *General Elec. Co. v. Speicher*, 877 F.2d 531, 537 (7th Cir. 1989).