

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

HEATHER WANKE,

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Plaintiff,

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v.

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Case No. 3:19-cv-0692

Judge Aleta A. Trauger

INVASIX INC. and INMODE LTD.,

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Defendants.

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MEMORANDUM

Invasix Inc. (“Invasix”) has filed a Motion to Dismiss (Docket No. 67), to which Heather Wanke has filed a Response (Docket No. 74), and Invasix has filed a Reply (Docket No. 83). InMode Ltd. (“InMode”) has filed a separate Motion to Dismiss (Docket No. 69), to which Wanke has filed a Response (Docket No. 75), and InMode has filed a Reply (Docket No. 84). Wanke filed a Motion for Leave to File a Second Amended Complaint (Docket No. 80), to which Invasix and InMode have jointly filed a Response (Docket No. 85), and Wanke has filed a Reply (Docket No. 86). For the reasons set out herein, Wanke’s motion will be granted, InMode’s motion will be granted in part and denied in part as moot, and Invasix’s motion will be denied as moot.

I. BACKGROUND¹

“The Medical Device Amendments of 1976 (‘MDA’), 21 U.S.C. §§ 360c–360k, 379–379a, establishes the framework for federal regulation of medical devices. As amended, the MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation.” *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003 (7th Cir. 2020). “The devices

¹ Unless otherwise indicated, these facts come from Wanke’s Proposed Second Amended Complaint (Docket No. 80-12) and are taken as true for the purposes of the pending motions.

receiving the most federal oversight are those in Class III, which include,” among other things, “replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). A device is placed in Class III based on the risk entailed in its use and the lack of available information ensuring that it can be safely sold without prior review for safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C).

Generally speaking, Class III medical devices are subject to a “rigorous regime of premarket approval” administered by the FDA. *Riegel*, 552 U.S. at 317. In select situations, however, it is permissible to bring a Class III device to market without completing the full FDA approval process. Specifically, the MDA “grandfathered many [devices] that were already on the market,” allowing those devices to “remain on the market until the FDA promulgates, after notice and comment, a regulation requiring premarket approval.” *Id.* (citing 21 U.S.C. §§ 360c(f)(1), 360e(b)(1)). The MDA’s grandfathering provision applies not only to the specific devices that predated the MDA, but also any “substantially equivalent” devices. *Id.*

If a company seeks to sell a Class III device as “substantially equivalent” to a grandfathered device, it must submit the device to an FDA review “known as the § 510(k) process, named after the statutory provision describing the review.” *Id.* Although the § 510(k) process does entail submitting the device to some degree of regulatory scrutiny, it is generally understood that a § 510(k) review, because it is focused only on substantial equivalence, will be less comprehensive and onerous than a premarket review for a non-grandfathered Class III device.

InMode is an Israeli medical device corporation. Invasix is a Canada-based Delaware corporation that allegedly “acts as the North American division” of InMode. (Docket No. 80-12 ¶¶ 6, 8.) InMode and Invasix sell a Class III medical device under the trade name “Fractora,” which, according to Wanke, is “designed, manufactured and sold in North America by Invasix.”

(*Id.* ¶ 1.) The Fractora device consists of a console and a handheld applicator, with a disposable tip, designed to deliver radiofrequency electrical current to human skin. (*Id.* ¶ 14.) The Fractora device is used to “vaporize columns of skin,” which in turn “stimulates the body’s production of collagen” in order to “leave[] the skin looking and feeling smoother.” (*Id.* ¶ 15.) Invasix submitted a § 510(k) application for the Fractora device around late May of 2011, and it was ultimately approved as substantially equivalent to a grandfathered device. (*Id.* ¶ 12 n.1)

According to Wanke, however, the approval of the Fractora as a substantially equivalent device was the result, at least in part, of improper actions by the defendants during the device’s § 510(k) review. In particular, the defendants’ § 510(k) application described the intended application of the Fractora device in a manner that differed, in several key ways, from the uses for which the defendants ultimately marketed the device. (*Id.* ¶¶ 24–26.) As a result, Wanke alleges, the defendants were able to take the least challenging available route to approved sales of a Class III device—intended exclusively for devices that had already been used for many years or slight variations thereon—only to then market the Fractora as a “revolution in medical devices” to be used in ways that the FDA never considered.² (*Id.* ¶ 13.)

Wanke had a Fractora procedure performed on her face in Nashville on June 15, 2017, by Dr. Paulino E. Goco. She characterizes the procedure as “only to refresh her skin, which was virtually wrinkle-free with small pores and a healthy-looking olive complexion.” (*Id.* ¶ 43.) Dr. Goco had told Wanke that the procedure was “a very safe, cutting edge, painless and non-invasive alternative to face lift and [laser] procedures.” (*Id.* ¶ 44.) Dr. Goco used “extremely aggressive treatment parameters” during the procedure, meaning that Wanke was subjected to a particularly strong bombardment of tissue-destroying radiofrequency current. (*Id.* ¶¶ 44, 46–47.) Dr. Goco

² Wanke alleges several additional types of wrongdoing related to the promotion of the Fractora device. The details of those allegations are immaterial to the issues presented by the pending motions .

relied on a January 2015 Quick Reference Guide issued by Invasix to formulate his approach. (*Id.* ¶ 48.)

Rather than leaving Wanke looking and feeling rejuvenated, the Fractora procedure administered by Dr. Goco ultimately resulted in “severe, clawlike scarring on her right cheek, ice pick-like scarring to her entire face and changes to the texture of her skin, leaving her with an orange peel look.” (*Id.* ¶ 45.) Because it is not uncommon for cosmetic procedures to require some healing time, there is some dispute regarding when Wanke realized that the procedure had injured her permanently, rather than simply having required a more difficult than expected recovery period. According to Wanke’s original Complaint in this case,

Dr. Goco told Heather to expect less than five days downtime[,] so Heather knew something had gone terribly wrong when she remained swollen with puncture mark wounds all over her face at day 3 and 4 of her recovery. She remained housebound at day 7. Her skin looked even worse beginning at day 10—as the swelling subsided, Heather’s smooth, clear skin came to look and feel like orange peel, the skin under her eyes darkened[,] and burns left claw and moon shaped [scarring] on her cheeks, upper lip and chin and between her brow.

(Docket No. 1 ¶ 55.) According to that Complaint, Dr. Goco shared Wanke’s concerns, and Dr. Goco’s notes mention “hyperpigmentation” from the procedure no later than July 12, 2017, shortly after the procedure had been performed. (*Id.* ¶ 56.) On that date, he performed a “Facial Assessment Report” that showed that Wanke’s skin was in observably worse condition than it had been before the procedure. The original Complaint describes Wanke crying inconsolably during the appointment and alleges that, after the appointment, Dr. Goco left Wanke a personal voice mail message admitting that Wanke “would need multiple additional treatments to address the injuries sustained as a result of the Fractora treatment.” (*Id.* ¶ 57.) As the court will discuss later in this section, however, this version of events—in which Wanke knew that her procedure had gone seriously awry almost instantly—is no longer the version she wishes to assert.

On January 23, 2019, several individuals, including Wanke, entered into a Tolling Agreement with Invasix “and any other related and affiliated corporations and businesses” covering potential claims related to the Fractora. (Docket No. 80-4 at 1.) According to the Tolling Agreement, the parties were pursuing non-judicial resolution of the individuals’ potential claims. In furtherance of settlement discussions, they agreed to a “Tolling Period” beginning on the effective date of the agreement. (*Id.* at 1–2.) The parties agreed that any statute of limitations, laches, waiver, or timely action defenses would “be tolled during the Tolling Period,” but that the agreement would “have no effect on any Timing Defenses that may be available to Defendants, known or unknown, prior to the Effective Date.” (*Id.* at 2.) The Tolling Agreement was ultimately extended through April 18, 2019. (*Id.* at 8.)

Wanke did not settle her claims, and, on April 17, 2019, she, along with two co-plaintiffs, Mia Jones and Janice Newman, filed their original Complaint in the Central District of California. (Docket No. 1.) That Complaint named only Invasix as a defendant. (*Id.* at 1.) On May 15, 2019, the plaintiffs filed a Waiver of Service that had been signed by counsel for Invasix on May 3, 2019. (Docket No. 17.) On June 28, 2019, Invasix filed a Motion to Sever and Transfer Plaintiffs’ Claims. (Docket No. 20.) Invasix noted that Jones and Wanke were Tennessee residents, who had procedures performed on them in Tennessee, while Newman was a New York resident whose Fractora procedure was performed in New York. Moreover, Invasix argued, each plaintiff’s claims involved unique questions regarding each patient’s treatment, rendering joinder inappropriate. (Docket No. 20-1 at 9.) The plaintiffs opposed the motion, arguing that their claims were based on the same course of wrongdoing by Invasix and that the Central District of California was the most convenient forum for key non-party witnesses. (Docket No. 28 at 3, 14.) The court granted both

of Invasix’s requests, severing the plaintiffs’ cases and transferring each case to the plaintiff’s home district—that being, in Wanke’s case, the Middle District of Tennessee. (Docket No. 36.)

On October 22, 2019, Wanke filed an Amended Complaint adding InMode as a defendant. (Docket No. 58 at 1.) The Amended Complaint, like the original, includes language claiming that Wanke “knew something had gone terribly wrong” by the third or fourth day of her recovery. (*Id.* ¶ 54.) The Amended Complaint includes seven causes of action. The First Cause of Action is for breach of express warranty. (*Id.* ¶¶ 71–76.) The Second Cause of Action is for breach of implied warranty. (*Id.* ¶¶ 77–81.) The Third Cause of Action is for violation of the California Unfair Competition Statute (“CUCS”), Cal. Bus. & Prof. Code § 17200 *et seq.*³ The Fourth Cause of Action is for violation of the California False Advertising Law (“CFAL”), Cal. Bus. & Prof. Code § 17500 *et seq.* (*Id.* ¶¶ 90–96.) The Fifth Cause of Action is for common law fraud. (*Id.* ¶¶ 97–99.) The Sixth Cause of Action is for negligence, negligence *per se*, and gross negligence. (*Id.* ¶¶ 100–07.). The Seventh Cause of Action is for strict liability. (*Id.* ¶¶ 108–12.)

On November 6, 2019, Wanke filed a Notice with the court requesting the issuance of a summons to InMode. (Docket No. 60.) The proposed Summons identified InMode’s address as a particular post office box in Israel. (Docket No. 60-1 at 1.) A summons was issued the next day. (Docket No. 61.) A receipt provided initially by Wanke shows that she sent the Summons to InMode’s believed address by registered mail. (Docket No. 70-1 at 3.) According to an Affidavit by InMode’s counsel, InMode did receive the Summons, likely through the mail office of its Israeli facilities. (Docket No. 70-3 ¶¶ 5–10.)

The parties agreed to extend InMode’s time to file a responsive pleading until February 27, 2020, and the court entered an Order to that effect. (Docket No. 66.) On February 27, 2020, Invasix

³ Wanke has alleged that CUCS applies because the defendants’ “wrongful conduct . . . emanate[d] in California.” (*Id.* ¶ 87.)

and InMode filed separate Motions to Dismiss. (Docket Nos. 67 & 69.) Invasix argues that all of Wanke's claims are time-barred. (Docket No. 67 at 1.) InMode, which has, so far, only specially appeared in this court, argues both that the claims are time-barred and that InMode has not properly been served. InMode asks the court to dismiss the claims or, in the alternative, to quash the service of the summons. (Docket No. 69 at 1.)

On March 10, 2020, Wanke filed an Affidavit of Service regarding InMode. (Docket No. 72.) She explained that she had not yet received a return receipt confirming the delivery of the Summons. (*Id.* at 1.) She had therefore tried, in January, to send the Summons again, but she did not receive a return receipt for that delivery either. (*Id.*) The same day, Wanke filed a Motion for Leave to File a Second Amended Complaint. (Docket No. 73) The court denied that motion without prejudice based on Wanke's failure to comply with L.R. 15.01. (Docket No. 77.)

On March 12, 2020, Wanke filed an Amended Motion for Leave to File a Second Amended Complaint. (Docket No. 80.) The proposed Second Amended Complaint omits any claim that Wanke knew, almost immediately after her procedure, that something was "terribly wrong." Instead, it now includes a number of unnumbered paragraphs under the heading "Facts Concerning Statute of Limitations." (Docket No. 80-12 at 2-6.) Wanke now seeks to plead a decidedly different version of her understanding of her injuries after the procedure:

The Fractora procedure involves the intentional destruction of tissue so that new collagen will form, tightening and otherwise resurfacing the skin. All Fractora patients experience an injury and [patients] heal at different rates. Plaintiff was told by her treating physician that her procedure had gone normally and that her skin was and would continue healing. Subsequently, another physician told Plaintiff that she could expect her skin to continue healing for up to a year and that it would be impossible to determine whether she had any actual injury (as opposed to the intentional tissue damage and expected healing time for the Fractora) for at least a year after the procedure. Thus, based on a doctor's expert opinion, Plaintiff did not and could not through [the] exercise of reasonable diligence [have] known she suffered a cognizable injury as a result of the Defendant's wrongful conduct until June 15, 2018.

(*Id.* at 2–3.)

The new section also includes an explanation for why Wanke did not name InMode as a defendant earlier:

Plaintiff’s counsel, Amy E. Davis, has represented a number of other women injured by the Fractora procedure. In August and November 2014, Davis filed suit against Invasix (and not InMode) in District Court for Dallas County, Texas on behalf of two such women (collectively, the “Texas Claimants”). The Texas Claimants asserted causes of action for product liability, among other[] things. In August and December 2014, Invasix answered each lawsuit, specifically identifying itself as the “manufacturer of such medical device.” Invasix (and not InMode) defended both suits and, ultimately, settled the claims asserted by the Texas Claimants in late November 2015 and January 2016.

(*Id.* at 3.) According to Wanke’s counsel, she later began to suspect, based on language in Invasix’s Reply in support of its Motion to Sever and Transfer Claims filed on July 15, 2019 (Docket No. 30), that Invasix might begin denying that it was the actual manufacturer of the device. (Docket No. 80-12 at 5.)

Counsel for Wanke, however, did not immediately file an amended complaint. Rather, her plan—which she shared with counsel for Invasix—was to await Invasix’s answer (which she believed, from her opposing counsel’s statements, would be filed shortly), to see what it would deny and/or claim about who manufactured the Fractora device used in Wanke’s procedure. (*Id.*) “Defense counsel represented multiple times that an answer would be forthcoming, including in an email to this [c]ourt’s Judicial Assistant . . . dated December 11, 2019.” (*Id.* at 5.) Eventually, however, counsel for Wanke accepted that no answer would be filed any time soon, and she obtained consent from Invasix to amend the Complaint, at which point she added InMode. (*Id.* at 6.)

II. LEGAL STANDARD

A. Motion to Dismiss Based on Insufficient Service of Process

Rule 12(b)(5) authorizes the court to dismiss a complaint for insufficiency of service of process. *Metro. Alloys Corp. v. State Metals Indus., Inc.*, 416 F. Supp. 2d 561, 563 (E.D. Mich. 2006). The party on whose behalf service of process was made has the burden of establishing its validity. *Shires v. Magnavox Co.*, 74 F.R.D. 373, 377 (E.D. Tenn. 1977). In deciding a motion to dismiss under Rule 12(b)(5), the court may refer to record evidence in determining the sufficiency of service. *Thompson v. Kerr*, 555 F. Supp. 1090, 1093 (S.D. Ohio 1982). The court also may consider facts attested to in uncontroverted affidavits in ruling on a Rule 12(b)(5) motion to dismiss. *Shires*, 74 F.R.D. at 376–77.

B. Motion to Amend

Rule 15(a)(2) of the Federal Rules of Civil Procedure states that leave to amend should be freely given “when justice so requires.” In deciding whether to grant a motion to amend, courts should consider undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment. *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005). “Amendment of a complaint is futile when the proposed amendment would not permit the complaint to survive a motion to dismiss.” *Miller v. Calhoun Cty.*, 408 F.3d 803, 817 (6th Cir. 2005) (citing *Neighborhood Dev. Corp. v. Advisory Council on Historic Pres.*, 632 F.2d 21, 23 (6th Cir. 1980)).

III. ANALYSIS

A. InMode's Motion to Dismiss for Insufficient Service

InMode argues that Wanke has failed to properly serve her Complaint and Summons on it and that her claims should therefore be dismissed or, in the alternative, that the court should quash the service. Wanke responds that her mailing of the Summons and Complaint by registered mail was a permissible form of serving a complaint filed in U.S. District Court on an Israeli business entity, pursuant to the relevant governing laws.

The United States and Israel are both parties to the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil and Commercial Matters, Nov. 15, 1965 (“Hague Service Convention”), 20 U.S.T. 361, T.I.A.S. No. 6638, a “multilateral treaty [intended] to simplify, standardize, and generally improve the process of serving documents abroad.” *Water Splash, Inc. v. Menon*, 137 S. Ct. 1504, 1507 (2017). “To that end, the Hague Service Convention specifies certain approved methods of service and ‘pre-empts inconsistent methods of service’ wherever it applies.” *Id.* (quoting *Volkswagenwerk Aktiengesellschaft v. Schlunk*, 486 U.S. 694, 699 (1988)). At the heart of the Hague Service Convention structure is the requirement that “each state . . . establish a central authority to receive requests for service of documents from other countries.” *Schlunk*, 486 U.S. at 698–99 (citing 20 U.S.T. 362, T.I.A.S. 6638, Art. 2). Indeed, Wanke’s travails in attempting to navigate the international mail system for this case provide an example of the benefits of the “central authority” system. Each nation’s central authority provides a way to effect service without having to master the sometimes opaque logistics of getting a document into the hands of a private party in a foreign country (and obtaining documentation that you did so). Wanke did not comply with the standard Hague Convention process, choosing instead

to mail the Summons directly to InMode herself. InMode argues that, because she did so, her claims should be dismissed.

Article 10(a) of the Hague Service Convention, however, states that, “[p]rovided the State of destination does not object, the present Convention shall not interfere with . . . the freedom to send judicial documents, by postal channels, directly to persons abroad”⁴ InMode concedes that Israel does not object to Article 10(a). InMode argues, however, that Article 10(a) should be read to address only “send[ing]” documents but not *servicing* documents. In other words, InMode argues that the court should read Article 10(a) as merely preserving the right to rely on the mails for the transmission of all documents other than the select few for which formal service of process is required.

The U.S. Supreme Court, however, considered that argument at length in *Water Splash, Inc. v. Menon*, only to reject such a reading as “atextual” and “structurally implausible,” with “no sustained argument in support of it.” 137 S. Ct. at 1510. InMode, fails to address *Water Splash*, relying, instead, on Tennessee cases that pre-date the U.S. Supreme Court’s decision. The meaning of a treaty in domestic courts, however, is an issue of federal law, on which the U.S. Supreme Court has the final say. *See, e.g., Sanchez-Llamas v. Oregon*, 548 U.S. 331, 346–47 (2006) (“[W]here a treaty provides for a particular judicial remedy, there is no issue of intruding on the constitutional prerogatives of the States or the other federal branches. Courts must apply the remedy as a requirement of federal law.”); *see also* U.S. Const. art. VI, cl. 2 (“[A]ll Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).

⁴ The text and supporting documentation for the Hague Service Convention can be found at <https://www.hcch.net/en/instruments/conventions/full-text/?cid=17>.

Regardless of whether InMode has adequately addressed *Water Splash*, however, Wanke had an obligation to serve her Summons and Amended Complaint in accordance with the relevant law, as interpreted by that case. The Supreme Court, in *Water Splash*, set forth the rule for service by mail under the Hague Service Convention as follows:

In short, the traditional tools of treaty interpretation unmistakably demonstrate that Article 10(a) encompasses service by mail. To be clear, this does not mean that the Convention affirmatively authorizes service by mail. Article 10(a) simply provides that, as long as the receiving state does not object, the Convention does not “interfere with . . . the freedom” to serve documents through postal channels. In other words, in cases governed by the Hague Service Convention, service by mail is permissible if two conditions are met: first, the receiving state has not objected to service by mail; and second, service by mail is authorized under otherwise-applicable law.

Water Splash, 137 S. Ct. at 1513.

With regard to whether Israel objects to service by mail, InMode—despite ultimately conceding that it does not—seeks to rely on Israel’s Declaration under the Hague Service Convention, which states:

The State of Israel, in its quality as State of destination, will, in what concerns Article 10, paragraphs b) and c), of the Convention, effect the service of judicial documents only through the Directorate of Courts, and only where an application for such service emanates from a judicial authority or from the diplomatic or consular representation of a Contracting State

InMode argues that the Declaration, by referring to service “only through” Israel’s central authority, suggests that Israel does not consider Article 10(a) to create an exception for service by mail. That language, however, is expressly directed at parts of the Convention other than Article 10(a). Indeed, InMode ultimately does not even dispute that Israel has not objected to Article 10(a). That lack of objection is the end of the inquiry with regard to Israeli law, at least at this step of the analysis.

Service by mail was permissible under *Water Splash*, therefore, to the extent allowed by U.S. law. Service on foreign business entities⁵ in federal courts is governed by Rule 4(h)(2) of the Rules of Civil Procedure, which permits service “in any manner prescribed by Rule 4(f) for serving an individual, except personal delivery under (f)(2)(C)(i).” Rule 4(f) permits service as follows:

(1) by any internationally agreed means of service that is reasonably calculated to give notice, such as those authorized by the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents;

(2) if there is no internationally agreed means, or if an international agreement allows but does not specify other means, by a method that is reasonably calculated to give notice:

(A) as prescribed by the foreign country’s law for service in that country in an action in its courts of general jurisdiction’

(B) as the foreign authority directs in response to a letter rogatory or letter of request; or

(C) unless prohibited by the foreign country’s law, by: . . .

(ii) using any form of mail that the clerk addresses and sends to the individual and that requires a signed receipt; or

(3) by other means not prohibited by international agreement, as the court orders.

Fed. R. Civ. P. 4(f).

Rule 4(f)(3) is inapplicable here because Wanke did not receive prior authorization from the court to effect service by mail. *See Lexmark Int’l, Inc. v. Ink Techs. Printer Supplies, LLC*, 291 F.R.D. 172, 174 (S.D. Ohio 2013) (stating that service under Rule 4(f)(3) “must be directed by the court”). Wanke cannot rely on Rule 4(f)(2)—which covers situations where the relevant treaty “allows but does not specify” a particular method of service—because her mailing was not addressed and sent by the clerk of this court. *See Wright & Miller*, 4B Fed. Prac. & Proc. Civ. §

⁵ Technically, the method of service under Rule 4 depends on whether the service itself is performed abroad, not on the nationality of the business entity. Fed. R. Civ. P. 4(h)(2). For ease of reading, however, the court will refer to the service on a business entity outside the United States as service on a foreign business entity.

1134 (4th ed.) (“The rule requires that the mail must be addressed and sent to the party to be served by the clerk of the court. Service by mail is improper, therefore, if addressed and dispatched by the plaintiff.”). Wanke, therefore, must rely on Rule 4(f)(1), which permits service “by any internationally agreed means of service that is reasonably calculated to give notice, such as those *authorized by the*” Hague Service Convention. (Emphasis added.)

As the Supreme Court expressly stated in *Water Splash*, however, the Convention does not “affirmatively authorize[] service by mail.” 137 S. Ct. at 1513. It merely permits service by mail as long as the country of service does not object and “service by mail is authorized under otherwise-applicable law.” *Id.* The only “otherwise-applicable” law for serving a business entity in Israel under the Federal Rules, however, is service by Rule 4(f)(2) or (3), which, as the court has already explained, would not suffice to render Wanke’s service proper in this case. *See* 1 Moore’s Federal Practice–Civil § 4.52[2][d] (2020) (explaining that the manner for sending service by mail under the Federal Rules pursuant to *Water Splash*’s “otherwise-applicable law” rule is through Rule 4(f)(2)(C)(ii), requiring mail sent by the clerk).

Wanke argues that the court should hold that service by mail from the plaintiff is permissible here because it is an authorized form of service under Rule 4.04(10) of the Tennessee Rules of Civil Procedure. Wanke, however, does not explain why the Tennessee Rules would govern in this instance. Admittedly, state service rules play a role in most of this court’s civil cases. That, however, is because most of this court’s cases involve domestic service of process, which may be performed “following state law for serving a summons in an action brought in courts of general jurisdiction in the state where the district court is located or where service is made.” Fed. R. Civ. P. 4(e)(1), (h)(1)(A). No similar express incorporation of state law exists for foreign service of process. *See* Wright & Miller, 4B Fed. Prac. & Proc. Civ. § 1114 (4th ed.) (stating that the Rule

4(e) incorporation of state rule for serving a summons “applies to service ‘in a judicial district of the United States’”) (quoting Fed. R. Civ. P. 4(e)). Moreover, even if Tennessee’s Rules did apply, Rule 4.04 is expressly limited only to service within the state. Service on foreign corporations is governed by Rule 4A of the Tennessee Rules of Civil Procedure, which largely mirrors Rule 4(f) and (h) of the Federal Rules.

Wanke’s service on InMode was, therefore, improper. Usually, “[i]f a defendant is not served within 90 days after the complaint is filed, the court—on motion or on its own after notice to the plaintiff—must dismiss the action without prejudice against that defendant or order that service be made within a specified time.” Fed. R. Civ. P. 4(m). That rule, however, “does not apply to service in a foreign country under Rule 4(f), 4(h)(2), or 4(j)(1).” *Id.* Moreover, even where dismissal is permitted, “[t]he federal courts have broad discretion to dismiss the action or to retain the case but quash the service that has been made on the defendant. . . . When process is quashed, only the service need be repeated.” Wright & Miller, 5B Fed. Prac. & Proc. Civ. § 1354 (3d ed.). There is no evidence that InMode was prejudiced by the improper service, and the court sees no reason why the interests of justice would be served by dismissal. The court, accordingly, will, relying on its power to authorize the method of service under Rule 4(f)(3), order Wanke to serve the Summons as soon as reasonably practicable by any method not forbidden by applicable international agreements, including certified mail.

B. Motion to Amend

Although InMode has not yet been properly served in this matter, it did make a special appearance for the purpose of seeking dismissal of Wanke’s claims on timeliness grounds. Indeed, InMode asked the court to reach the service of process issue only if it did not conclude that the claims were time-barred. (Docket No. 84 at 1 (“This court should not even need to address the

issue of whether InMode was properly served since plaintiff's claims against InMode are time-barred.") The court, therefore, will treat InMode as having consented to the court's exercise of jurisdiction for the limited purpose of resolving the issues raised by the pending motions. Invasix has sought dismissal for untimeliness as well. Wanke opposes those motions but has also sought leave to amend her Complaint to plead certain facts relevant to the application of the statute of limitations.

A number of factors guide the court's decision under Rule 15(a)(2), but one factor, as a practical matter, most often takes the central place in the court's analysis of a request for leave to amend a complaint: whether the amendment would be futile. The policy of liberally allowing amendments in the interests of justice reflects the principle that, "[i]f the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Accordingly, as long as there was no undue delay, abuse of the amendment process, or bad faith, and as long as the opposing party will not be too severely prejudiced, whether an amendment will be allowed typically hinges on whether the amendment will actually solve the substantive problems it is intended to solve. By the same token, however, if an amendment would be futile, there is no benefit from allowing the amendment to go forward, even if other factors would support allowing the amendment. The court, therefore, will first consider whether Wanke's amendments, which primarily seek to establish the potential timeliness of her claims, would be futile, and then, if the court finds that they would not be, the court will turn to the remaining considerations.

1. Waiver of Statute of Limitations Defense by Invasix

As a threshold matter, Wanke argues that, by failing to file a timely answer, Invasix has waived its statute of limitations defense by failing to file a timely responsive pleading. A domestic

defendant who waives service of process is required to respond to the complaint “within 60 days after the request for a waiver was sent.” Fed. R. Civ. P. 12(a)(1)(A)(ii). The defendant’s answer must “affirmatively state any avoidance or affirmative defense,” including statute of limitations defenses. Fed. R. Civ. P. 8(c)(1). It is undisputed that Invasix failed to file an answer preserving the statute of limitations defense—or, indeed, any answer—during the applicable 60-day period. Invasix did, however—after that 60-day period had elapsed—file a Rule 12(b)(6) motion raising the issue.

Wanke does not dispute that Invasix could have preserved its affirmative defense by way of a motion to dismiss—if that motion to dismiss had been filed within the period for filing an answer. She argues, however, that Invasix’s failure to file the motion within the period for filing an answer should have the same consequences as failing to file an answer. As Wanke admits, there is no express requirement, under Rule 12, that a Rule 12(b) motion must be filed within the 60-day answer period. Some courts, however, have inferred, from the requirement that a Rule 12(b) motion must be filed *before* the answer, that a defendant cannot extend the time for filing a Rule 12(b) motion simply by missing the deadline for an answer without receiving an extension. *See Gillo v. Gary Cmty. Sch. Corp.*, No. 2:14-CV-99-JVB-JEM, 2014 WL 3767680, at *2 (N.D. Ind. July 31, 2014) (collecting cases). Wanke, however, admits that that issue presents an unsettled question, and she identifies no Sixth Circuit Court of Appeals case endorsing her position.

Moreover, even if the court accepted Wanke’s reading of the sixty-day requirement, caselaw in the circuit is clear that the rule for raising affirmative defenses can and should be applied flexibly, as long as the plaintiff is not unduly prejudiced. “Under Federal Rule of Civil Procedure 8(c), ‘a party must affirmatively state any avoidance or affirmative defense’ in the answer, Fed. R. Civ. P. 8(c), but under common law, a ‘[f]ailure to raise an affirmative defense by responsive

pleading does not always result in waiver.” *Shelbyville Hosp. Corp. v. Mosley*, No. 4:13-CV-88, 2017 WL 5586729, at *14 (E.D. Tenn. Nov. 20, 2017) (quoting *Smith v. Sushka*, 117 F.3d 965, 969 (6th Cir. 1997)). “Where the matter is raised in the trial court in a manner that does not result in unfair surprise[,] technical failure to comply precisely with Rule 8(c) is not fatal.” *Moore, Owen, Thomas & Co. v. Coffey*, 992 F.2d 1439, 1445 (6th Cir. 1993) (quoting *Allied Chem. Corp. v. Mackay*, 695 F.2d 854, 856 (5th Cir. 1983); see also *In re Cipriano*, No. 14-14826, 2015 WL 3441212, at *8 (E.D. Mich. May 28, 2015) (noting that statute of limitations defense that was apparent on the face of the complaint is “not waived simply because it was raised in a motion to dismiss rather than in the answer”) (quoting *Pierce v. Oakland Cty.*, 652 F.2d 671, 672 (6th Cir. 1981)); *Peacock v. Equifax, Inc.*, No. 3:13-CV-651-PLR-HBG, 2015 WL 1457996, at *1 (E.D. Tenn. Mar. 30, 2015) (applying rule that, where no prejudice occurs and statute of limitations defense is raised by motion, the court may hold that the defense was not waived by failure to include it in an earlier responsive pleading). Because there has been no prejudice and because Invasix raised the statute of limitations prior to filing any Answer, the court will not treat that defense as waived.

2. Accrual of Claims Under the Discovery Rule

The parties appear to agree that Tennessee’s one-year statute of limitations governing causes of action based on personal injury, Tenn. Code Ann. § 28-3-104(a)(1)(A), applies to all of Wanke’s claims.⁶ The defendants argue that Wanke’s claims are time-barred because she filed

⁶ Neither party suggests that California law of timeliness or accrual should govern any aspect of this case, despite the fact that at least two of the counts are based on California substantive law. The question of how to apply causes of action across state lines has a complicated and at times challenging history. See *McCann v. Foster Wheeler LLC*, 225 P.3d 516, 525 (Cal. 2010) (discussing application of forum state causes of action under California law); *SunTrust Bank v. Ritter*, No. E2017-01045-COA-R3-CV, 2018 WL 674000, at *4 (Tenn. Ct. App. Feb. 1, 2018) (discussing same issues in Tennessee). Because neither party suggests that any statute of limitations other than Tennessee’s one-year limit should apply here, the court will treat the issue as conceded for the purposes of the pending motions.

them well over a year after her immediately negative response to the Fractora procedure. They argue, moreover, that the Tolling Agreement cannot rescue her claims because, on its face, it explicitly disavows any agreement by the parties to affect any time-based defenses that were already available before the agreement went into an effect, and the agreement was made more than a year after Wanke's claims accrued. Wanke, relying on the facts that she wishes to allege in her proposed Second Amended Complaint, argues that a question of fact exists with regard to when she reasonably should have known about her injuries and that, therefore, her claims should not be dismissed.

The general rule is that “[s]tatute-of-limitations defenses are [more] properly raised in Rule 56 motions [for summary judgment], rather than Rule 12(b)(6) . . . motions, because ‘[a] plaintiff generally need not plead the lack of affirmative defenses to state a valid claim.’” *Munson Hardisty, LLC v. Legacy Pointe Apartments, LLC*, 359 F. Supp. 3d 546, 567 (E.D. Tenn. 2019) (quoting *Paulin v. Kroger Ltd. P’ship I*, No. 3:14-cv-669, 2015 WL 1298583, at *4 (W.D. Ky. Mar. 23, 2015)). However, if it is “‘apparent from the face of the complaint that the time limit for bringing the claim[s] has passed,’” then the plaintiff, if she wishes to avoid dismissal, has an “obligation to plead facts in avoidance of the statute of limitations defense.” *Bishop v. Lucent Techs., Inc.*, 520 F.3d 516, 520 (6th Cir. 2008) (quoting *Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 744 (6th Cir. 1992)). When “the allegations in the complaint affirmatively show that a claim is time-barred,” then “dismissing the claim under Rule 12(b)(6) is appropriate.” *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012).

For most ordinary causes of action, Tennessee courts apply the discovery rule to determine when a cause of action accrues. Under this rule, a cause of action accrues “when the plaintiff knows or in the exercise of reasonable care and diligence should know that an injury has been sustained

as a result of wrongful or tortious conduct by the defendant.” *John Kohl & Co. v. Dearborn & Ewing*, 977 S.W.2d 528, 532 (Tenn. 1998) (citations omitted). In other words, the plaintiff must have suffered “legally cognizable damage—an actual injury,” and she “must have known or in the exercise of reasonable diligence should have known that this injury was caused by the defendant’s wrongful or negligent conduct.” *Id.* (citation omitted).

As the Tennessee Supreme Court has explained:

An actual injury occurs when there is the loss of a legal right, remedy or interest, or the imposition of a liability. An actual injury may also take the form of the plaintiff being forced to take some action or otherwise suffer some actual inconvenience, such as incurring an expense, as a result of the defendant’s negligent or wrongful act However, the injury element is not met if it . . . amounts to a mere possibility.

Id. at 532 (citations omitted).

Under the discovery rule, the statute of limitations begins to run, at the latest, when the plaintiff becomes aware that such an injury has been done to her. As the Tennessee Supreme Court explained, however, “[u]nder the theory of constructive knowledge, . . . the statute may begin to run at an earlier date—whenever the plaintiff becomes aware or reasonably should have become aware of facts sufficient to put a reasonable person on notice that an injury has been sustained as a result of the defendant’s negligent or wrongful conduct.” *Id.*

The plaintiff’s knowledge or constructive knowledge, moreover, need not entail a complete understanding of the severity or legal significance of the situation:

[T]here is no requirement that the plaintiff actually know the specific type of legal claim he or she has, or that the injury constituted a breach of the appropriate legal standard. Rather, the plaintiff is deemed to have discovered the right of action if he is aware of facts sufficient to put a reasonable person on notice that he has suffered an injury *as a result of wrongful conduct*.

Id. at 533 (emphasis added). Accordingly, in this case, it is immaterial when Wanke knew or should have known how severe her injuries were or that the defendants violated any particular legal

prohibition; what matters is when she knew or should have known that some wrongful injury had occurred.

Applying the discovery rule to an injury caused by a medical procedure or treatment is often difficult, because medical intervention can involve significant pain and suffering even when performed entirely according to plan. *See, e.g., Sherrill v. Souder*, 325 S.W.3d 584, 594 (Tenn. 2010) (applying discovery rule to medication side effects); *Shadrick v. Coker*, 963 S.W.2d 726, 737 (Tenn. 1998) (applying discovery rule to effects of surgical screws); *Stanbury v. Bacardi*, 953 S.W.2d 671, 677 (Tenn. 1997) (applying discovery rule to results of foot surgery); *see also Cates v. Stryker Corp.*, No. 3:10-CV-546, 2012 WL 256199, at *3 (E.D. Tenn. Jan. 27, 2012) (applying discovery rule to effects of implanted pain pump). As Wanke points out, the very premise of her Fractora procedure was, in a sense, to injure her—to inflict controlled, planned damage to her tissue in order to cause a particular desired biological result. Accordingly, the mere fact that she, for example, took on a wounded appearance in the days following the procedure is not enough to allow the court to assume, for Rule 12(b)(6) purposes, that her claims accrued at that time. At some point, of course, her reaction to the procedure put her at least on inquiry notice of her claims, even if she did not yet know the extent of her injury or what precisely had been done wrong. However, “whether the plaintiff exercised reasonable care and diligence in discovering the injury or wrong is usually a question of fact for the jury to determine.” *Shadrick*, 963 S.W.2d at 737 (quoting *Wyatt v. A-Best, Co.*, 910 S.W.2d 851, 854 (Tenn. 1995)).

As the court has already discussed, Wanke’s original Complaint and Amended Complaint at the very least come close to admitting that she knew or should have known that she was injured by wrongful conduct more than a year before she entered into the Tolling Agreement or filed her claims. The relevant language of the complaints, however, appears not to have been drafted with

a consciousness of how determinative the issue ultimately could be. The revised language in the proposed Second Amended Complaint, in contrast, captures the uncertainties of applying the discovery rule to medical injuries persuasively. The revised language, moreover, does not seek to extend the time of accrual indefinitely. Rather, Wanke claims that she became aware that she may have been wrongfully injured when, after a year, she had not properly healed. Based on the revised language, therefore, the cause of action plausibly may not have accrued until June 15, 2018, one year after her procedure.

Applying the June 15, 2018 accrual date to Wanke's claims against Invasix is fairly straightforward. Based on that date, she originally had until June 15, 2019 to file her claims. She filed her original Complaint naming Invasix on April 17, 2019. Accordingly, her claims against Invasix would be timely based on that accrual date. It, therefore, would not be futile to amend her complaint to plead facts supporting the later date of accrual for claims against Invasix.

Applying the accrual date based on the discovery rule to InMode is more complicated. Wanke did not name InMode as a defendant until October 22, 2019, well over a year after Wanke, by her own account, knew or should have known that the procedure had improperly injured her. The Tolling Agreement, moreover, cannot preserve her claims, because it expired on April 18, 2019, after running for 86 days. Wanke did not file her claims against InMode until 130 days after the June 15, 2019 deadline. Therefore, even if one assumes that the Tolling Agreement applied to InMode as a related entity and treats the agreement as having tolled the running of the limitations period while it was in effect, that does not, alone, rescue Wanke's claims against InMode.

3. Relation Back of Claims Against InMode

Wanke argues that the court should nevertheless treat her InMode claims as timely because they relate back to the filing of the Complaint pursuant to Rule 15(c)(1)(C). Generally speaking,

an amendment that “adds a new party creates a new cause of action and there is no relation back to the original filing for purposes of limitations.” *In re Kent Holland Die Casting & Plating*, 928 F.2d 1448, 1449 (6th Cir. 1991) (quoting *Marlowe v. Fisher Body*, 489 F.2d 1057, 1064 (6th Cir. 1973)). Such an amendment “establishes a new and independent cause of action which cannot be maintained when the statute has run, for the amendment is one of substance rather than one of form and brings into being one not presently in court.” *United States ex rel. Statham Instruments, Inc. v. W. Cas. & Surety Co.*, 359 F.2d 521, 523 (6th Cir. 1966). For example, where a plaintiff attempts to add additional defendant entities that were later found to have acted in concert with the original, properly named defendants, those additions constitute new causes of action for which there is no relation back. *See Venezia v. 12th & Div. Props., LLC*, No. 3:09-cv-430, 2010 WL 3122787, at *3 (M.D. Tenn. Aug. 6, 2010) (Wiseman, J.).

Rule 15(c)(1)(C) of the Federal Rules of Civil Procedure, however, creates an exception whereby a plaintiff may amend his complaint to change the party or the naming of the party against whom a claim is asserted, and that amendment will relate back to the date of the original pleading if: (1) the claim asserted in the amended pleading arises out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading; (2) the added party received notice of the suit in the 120 days following the filing of the original complaint; (3) the notice was such that the added party will not be prejudiced in maintaining a defense on the merits; and (4) the added party knew or should have known that, but for a mistake of the identity of the proper party, the action would have been brought against him. Fed. R. Civ. P. 15(c); *Moore v. City of Harriman*, 272 F.3d 769, 774 (6th Cir. 2001).

Courts have consistently held that Rule 15(c)(1)(C) permits an amendment to relate back where a plaintiff seeks to substitute a correct party for a previously improperly named defendant

or to correct a misnomer. *See, e.g., Krupski v. Costa Crociere S.p.A.*, 560 U.S. 538, 557 (2010) (permitting relation back where a plaintiff filed suit against the wrong defendant due to a mistake and sought to substitute the proper defendant after the limitations period had expired). A “mistake,” as the term is used in Rule 15(c)(1)(C), occurs where the wrong party is blamed while the real culprit remains unknown, and also where the plaintiff has full knowledge of all relevant actors but lists the technically incorrect parties. *Pullins v. Klimley*, No. 3:054-cv-082, 2008 WL 85871, at *11 (S.D. Ohio Jan. 7, 2008).

A paradigmatic Rule 15(c)(1)(C) case is one in which the plaintiff “mistakenly sue[d] party A instead of party B” and wishes to swap one for the other as the defendant. *Venezia*, 2010 WL 3122787, at *4. Here, however, Wanke does not claim that it was entirely a mistake to sue Invasix. Rather, she wishes to keep suing Invasix but also to account for the possibility that it was a mistake to sue Invasix in its capacity as a manufacturer. In some circuits that would be unproblematic. “Many courts have liberally construed the rule to find that amendments simply adding or dropping parties, as well as amendments that actually substitute defendants, fall within the ambit of [Rule 15(c)(1)(C)].” Wright & Miller, 6A Fed. Prac. & Proc. Civ. § 1498.2 (3d ed.). The Sixth Circuit, however, has mostly been skeptical of such a reading and has typically instead applied a more categorical rule that adding a new party, without taking out the old one, creates a new cause of action. *See Ham v. Sterling Emergency Servs. of the Midwest, Inc.*, 575 F. App’x 610, 616 & n.4 (6th Cir. 2014) (rejecting approach described in Wright & Miller); *but see Lockhart v. Holiday Inn Exp. Southwind*, 531 F. App’x 544, 548 (6th Cir. 2013) (stating that Rule 15(c)(1)(C) can be used to “add a party”). At the very least, the mistake requirement and the general rule that simply adding defendants does not fall within Rule 15(c)(1)(C) suggest that the new party should be substituted

for the existing party in some way to reflect an earlier misattribution, even if other allegations and claims may keep the original defendant in the case in a more limited capacity.

Wanke's proposed amended causes of action confirm that she is not, in fact, attempting to "change[] the party or the naming of the party against whom a claim is asserted," as that provision has been interpreted in this circuit. All of the causes of action are stated against "Defendant," which Wanke defines as referring to Invasix and InMode collectively. In other words, there is no preexisting allegation against Invasix that is changed to an allegation against InMode in order to rectify a mistake. Wanke simply adds a second party against whom each claim is asserted, falling outside the bounds of Rule 15(c)(1)(C), as it has been interpreted by the Sixth Circuit. *See, e.g., Boyd v. City of Warren*, No. 16-12741, 2020 WL 1861986, at *3 (E.D. Mich. Apr. 14, 2020). That outcome may be frustrating to Wanke, who does not know and may not have a way to know who actually manufactured the Fractora. The court, however, cannot conclude that Wanke can rely on relation back to render her claims against InMode timely.

4. Equitable Estoppel/Fraudulent Concealment

Wanke argues next that, even if her claims do not relate back, equitable considerations may support concluding that the statute of limitations was tolled for long enough to preserve the claims. In Tennessee, "the doctrine of equitable estoppel tolls the running of the statute of limitations when the defendant has misled the plaintiff into failing to file suit within the statutory limitations period." *Redwing v. Catholic Bishop for Diocese of Memphis*, 363 S.W.3d 436, 460 (Tenn. 2012) (citing *Fahrner v. SW Mfg., Inc.*, 48 S.W.3d 141, 145 (Tenn. 2001); *Ingram v. Earthman*, 993 S.W.2d 611, 633 (Tenn. Ct. App. 1998)). In order to invoke equitable estoppel, "the plaintiff must demonstrate that the defendant induced him or her to put off filing suit by identifying specific promises, inducements, suggestions, representations, assurances, or other similar conduct by the

defendant that the defendant knew, or reasonably should have known, would induce the plaintiff to delay filing suit.” *Id.* (citing *Fahrner*, 48 S.W.3d at 145; *Hardcastle v. Harris*, 170 S.W.3d 67, 85 (Tenn. Ct. App. 2004)). The distinct but related doctrine of tolling based on fraudulent concealment provides that a plaintiff is entitled to tolling of the statute of limitations if she can establish the following:

(1) that the defendant affirmatively concealed the plaintiff’s injury or the identity of the wrongdoer or failed to disclose material facts regarding the injury or the wrongdoer despite a duty to do so; (2) that the plaintiff could not have discovered the injury or the identity of the wrongdoer despite reasonable care and diligence; (3) that the defendant knew that the plaintiff had been injured and the identity of the wrongdoer; and (4) that the defendant concealed material information from the plaintiff by withholding information or making use of some device to mislead’ the plaintiff in order to exclude suspicion or prevent inquiry.

Id. at 462–63 (Tenn. 2012) (internal citations and quotation marks omitted).

Wanke argues that, even if her claims against InMode do not relate back, they should not be dismissed because one or both of those doctrines may have tolled the applicable statute of limitations. Specifically, Wanke, in her proposed Second Amended Complaint, alleges that, in Texas litigation against other clients of Wanke’s counsel that took place from 2014 through 2016, Invasix judicially admitted that it, not InMode, was the manufacturer of the Fractora device. (Docket No. 80-12 at 3.) Wanke also asserts that, “[i]n March 2017 and October 2018, Invasix . . . claimed it had authority to settle and, in fact, resolved (pre-suit) identical product liability . . . claims asserted by two additional women injured by the Fractora procedure and represented by Plaintiff’s counsel.” (*Id.* at 4.) Wanke’s counsel believes, based on representations of Invasix’s counsel in those negotiations, that Invasix’s attorneys were in ongoing communication with InMode, suggesting that InMode was involved in Invasix’s earlier representations. (*Id.*) Finally, Wanke alleges that counsel for Invasix engaged in pre-suit settlement discussions with her counsel

regarding her claims, during which they gave no indication that Invasix was not, in fact, the manufacturer of the device. (*Id.*)

InMode responds that Wanke or her counsel should have been able to ascertain easily that InMode was the device's manufacturer from numerous publicly available sources, including the § 510(k) application materials. Such an inquiry, however, would represent precisely the type of factual evaluation of a contested affirmative defense that is not appropriate for a Rule 12(b)(6) motion. InMode also argues that Wanke is not entitled to tolling because InMode did not engage in wrongdoing related to InMode's identity as the manufacturer and did not induce Wanke's misunderstanding. But that issue, too, is beyond what the court can or should consider on a motion to dismiss. Because Wanke's claims are not categorically untimely based on the face of her proposed Second Amended Complaint, allowing the amendment would not be futile.

5. Weighing of Amendment Factors

Normally, if a plaintiff at this stage of litigation demonstrated a lack of futility, this court would be overwhelmingly likely to grant leave to amend. Sometimes, however, the unique circumstances of a case cause factors other than futility to take particular prominence. There is, at least, a strong argument that this should be such a case with regard to one factor: bad faith. Wanke is not seeking leave merely to add some omitted fact or correct an earlier understandable misstatement. To the contrary, Wanke seeks to substantially revise—and arguably contradict—a factual claim that she made in her two earlier complaints and could not plausibly have been innocently mistaken about. Wanke claimed twice that she knew that “something had gone terribly wrong” almost immediately following her procedure. (Docket No. 1 ¶ 55; Docket No. 58 ¶ 54.) She described tearful conversations with her physician confirming the severity of the situation. (Docket No. 1 ¶ 57; Docket No. 58 ¶ 56.). Now, however—after it has been pointed out that those

facts lend support to a statute of limitations defense against her claims—she seeks to assert that, rather than immediately knowing something had gone wrong, she spent a year reasonably believing that she needed only to wait for her injuries to heal normally and only then could she have realized she had suffered a compensable injury.

Wanke’s two versions of events are at least in tension with each other, if not outright contradiction. Some courts have concluded that a proposed amendment’s contradicting earlier claims by the moving party can be evidence of bad faith weighing strongly against allowing the amendment. *See, e.g., Airs Aromatics, LLC v. Opinion Victoria’s Secret Stores Brand Mgmt., Inc.*, 744 F.3d 595, 600 (9th Cir. 2014) (“A party cannot amend pleadings to ‘directly contradic[t] an earlier assertion made in the same proceeding.’”) (quoting *Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990)); *Ragland v. Raby*, No. CIV.A.08-15253, 2009 WL 4506422, at *2 (E.D. Mich. Nov. 25, 2009) (treating contradictory attempts to amend as evidence of bad faith). In other instances, however, courts have concluded that contradictions between a plaintiff’s statements during litigation are “more appropriately tested at the motion for summary judgment stage or at trial.” *E.g., Pendlebury v. Starbucks Coffee Co.*, No. 04-80521-CIV, 2005 WL 8156157, at *2 (S.D. Fla. Feb. 7, 2005). Therefore, insofar as Wanke has contradicted herself, it does not necessarily mandate that her motion be denied.

Also somewhat softening any appearance of bad faith is that a charitable reading of the relevant language can reconcile her statements to some degree. The belief that something has “gone wrong” during a medical procedure does not necessarily mean that one has been injured in a wrongful way. It could mean that one was simply unlucky or that the unpredictability and frailty of the human body gave rise to a bad outcome despite the best efforts of all involved. The details of Wanke’s original account are difficult to square with this reading, given that she describes

immediate, severely negative effects of her procedure far outside what she had been told to expect, as well as a response from her physician seeming to confirm the direness of the situation. Nevertheless, one could at least argue that what Wanke meant to say in her first two complaints was only that she knew immediately that her reaction to the procedure had been negative, not that she had been wrongfully injured.

The stark differences in Wanke's accounts, however, do raise serious questions about whether the interests of justice would support allowing the amendment. Twice now, Wanke has asserted facts, in signed complaints, that arguably present problems for the survival of her claims. They were facts about her own knowledge and experience and about which, therefore, she had no reason to be confused. She has, moreover, offered little by way of a persuasive explanation for why she would seemingly change her story, other than her counsel's having now realized the dangers posed by her earlier statements. If Wanke is allowed to amend her Complaint, the Second Amended Complaint will supersede the Amended Complaint, *Parry v. Mohawk Motors of Michigan, Inc.*, 236 F.3d 299, 306 (6th Cir. 2000), relieving her, at least as a legal matter, from the potentially damaging assertions she originally made and repeated.⁷ Allowing her to do so could, among other things, erode the seriousness of signed pleadings under Rule 11.

On the other hand, the factors of prejudice and delay do not strongly weigh against allowing amendment. It is still early in the litigation, and the defendants have not devoted substantial resources in reliance on Wanke's assertions—or, at least, they have devoted no more resources than an ordinary party that files a motion to dismiss that prompts a motion for leave to amend.

Despite its misgivings, the court will grant the motion for leave to amend. As the court has discussed, it is possible to explain the tension between the prior complaints and the amended

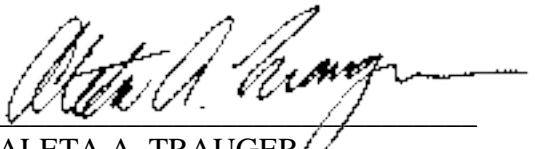
⁷ The fact that a complaint has been superseded as a legal matter, however, does not necessarily preclude a plaintiff's being questioned about its contents at trial or in a deposition.

version based on Wanke's use of imprecise language on an issue that she did not anticipate being pivotal. The Rules of Civil Procedure, moreover, favor allowing her claims to succeed or fail on the merits. Those claims may be time-barred, and any argument that they are not will have to contend to her prior characterization of the days and weeks following her procedure. The court, however, will allow that issue to be resolved at a more appropriate stage by granting leave to amend.

IV. CONCLUSION

For the foregoing reasons, Invasix's Motion to Dismiss (Docket No. 67) will be denied as moot, InMode's Motion to Dismiss will be granted in part and denied in part as moot, and Wanke's Motion for Leave to File a Second Amended Complaint (Docket No. 80) will be granted. The court will prospectively authorize service on InMode by any method not forbidden by relevant international agreements.

An appropriate order will enter.



ALETA A. TRAUGER
United States District Judge