

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

In re Testosterone Replacement)	
Therapy Products Liability Litigation)	No. 14 C 1748
Coordinated Pretrial Proceedings)	MDL No. 2545

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

In this multidistrict litigation proceeding (MDL), over two thousand individual lawsuits, filed throughout the country, have been consolidated for coordinated pretrial proceedings in this Court. Plaintiffs in the individual cases have jointly filed a master complaint, which sets forth common allegations regarding plaintiffs' claims against the multiple defendants in the MDL. All of the plaintiffs allege that they suffered injuries caused by defendants' testosterone replacement therapy (TRT) drugs. Two of the defendants, Besins Healthcare Inc. (Besins Inc.) and Besins Healthcare, S.A. (Besins S.A.), have moved to dismiss all claims in plaintiffs' second amended master complaint. Both Besins defendants move to dismiss for failure to state a claim. Besins S.A. also moves to dismiss for lack of personal jurisdiction.

Background

For purposes of the motion to dismiss, the Court accepts as true the facts alleged in plaintiffs' master complaint. Defendant Besins S.A. is a privately held Belgian corporation headquartered in Thailand. Defendant Besins Inc., a wholly owned subsidiary of Besins S.A., is a Delaware corporation that has its principal place of business in Virginia. Plaintiffs allege that both Besins defendants "engaged in the

research, development, design, testing, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including AndroGel," one of the TRT drugs at issue in the MDL. Master Compl. ¶¶ 25(a), 26(a). Besins S.A. engaged in these activities "with knowledge and intent that AndroGel would be marketed, distributed and sold throughout the United States" *Id.* ¶ 26(a). According to plaintiffs, Besins Inc. holds the United States patent for the pharmaceutical formulation of AndroGel, whereas Besins S.A. owns unspecified "intellectual property rights" to AndroGel's pharmaceutical formulation as well as the rights to sell AndroGel in the United States. *Id.* ¶¶ 25(b), 26(b).

Besins S.A. manufactures AndroGel sold in the United States at its plant in Montrouge, France. AndroGel is an exogenous (that is, originating outside the body) form of testosterone that is delivered transdermally and applied to the skin in the form of a gel. AndroGel, like the other TRT products in this case, has been approved by the United States Food and Drug Administration (FDA) for treatment of hypogonadism, the diminished functional activity of the gonads which may involve the severely diminished production or nonproduction of testosterone. In 1995, the Besins defendants gave defendant Unimed Pharmaceuticals, LLC (Unimed) the exclusive right to market AndroGel in the United States. Unimed, a co-assignee with Besins Inc. for AndroGel's United States patent, is a wholly owned subsidiary of defendant AbbVie Inc. and a direct, wholly owned subsidiary of defendant AbbVie Products LLC (AbbVie Products). Unimed is a limited liability company organized under the laws of Delaware, AbbVie Products is organized under the laws of Georgia, and AbbVie Inc. is organized under the laws of Delaware. All three have their principal places of business in Illinois.

According to plaintiffs, Besins S.A. manufactured AndroGel "for sale in the United States. . . ." *Id.* ¶ 26(c). Sales of AndroGel in the United States have been significant; sales revenue for 2013, for example, totaled \$1.4 billion. Plaintiffs allege that the defendants in this MDL have sold and promoted the use of AndroGel and other TRT drugs to treat a condition referred to as "Low T," which is not a form of classical hypogonadism and for which, plaintiffs allege, TRT drugs confer little or no benefit. They further allege that Besins S.A. has "derived substantial revenue" from such United States sales, and it "expected or should have expected its acts to have consequences within the United States" *Id.* ¶ 26(d)–(e).

Plaintiffs aver that AndroGel is unsafe and that its design is defective because it causes those who use it serious injuries and death as the result of the formation of blood clots and other adverse cardiovascular events. Allegations in the master complaint describe how and why AndroGel and other TRT products cause these injuries:

392. Testosterone regulates the expression of platelet TXA2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

393. Use of exogenous testosterone can cause an increase in serum levels of estradiol, the primary female sex hormone, through the conversion of excess testosterone into estradiol. Increased serum levels of estradiol have been associated with the development of blood clots and with life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

Id. ¶¶ 392–93.

In the master complaint, plaintiffs assert fourteen claims for relief against all defendants. In response to the Besins defendants' motion to dismiss, plaintiffs concede that some of those claims cannot properly be asserted against the Besins defendants, and they consent to dismissal of those claims. These are claims Two, Four, Five, Six, Seven, and Nine in the second amended master complaint. Plaintiffs, however, continue to assert their strict liability claim based on design defect (Claim One), a negligence claim (Claim Three), and a redhibition claim (Claim Eight), as well as claims seeking damages pursuant to those causes of action.

In support of the three claims at issue, plaintiffs make allegations about the "Defendants" collectively. The relevant collective allegations for the purposes of this motion are as follows. In support of Claim One, plaintiffs allege that the TRT drugs' defective design made them unreasonably dangerous but that "Defendants" knowingly introduced the drugs into the market and plaintiffs sustained their injury as a direct and proximate cause of "Defendants' manufacture . . . of the defectively designed drugs." *Id.* ¶ 477. In support of Claim Three, plaintiffs allege that "Defendants" had a duty to properly manufacture and design the TRT products, they breached that duty by negligently and carelessly manufacturing and designing the TRT drugs, and this negligence was a proximate cause of plaintiffs' injuries. In support of Claim Eight, plaintiffs allege that the TRT drugs' defect rendered them useless or their use so inconvenient that buyers would not have used them had they known of the defect. In the alternative, plaintiffs allege that the TRT drugs' defect so diminished their value that buyer would have purchased them for a lesser price had they known of the defect.

Discussion

When considering a motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), a court views the complaint "in the light most favorable to the plaintiff[s], taking as true all well-pleaded factual allegations and making all possible inferences from the allegations in the plaintiff[s]' favor." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). In their complaint, the plaintiffs must provide "some specific facts to support the legal claims asserted" and cannot rely on conclusory allegations. *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011). But the "degree of specificity required is not easily quantified." *Id.* Ultimately, the Federal Rules require the complaint to contain "factual allegations that give the defendant fair notice of the claim[s] for relief and show the claim[s] ha[ve] substantive plausibility." *Runnion ex rel. Runnion v. Girl Scouts of Greater Chicago & Nw. Indiana*, 786 F.3d 510, 517 (7th Cir. 2015).

In responding to a motion to dismiss for lack of personal jurisdiction under Federal Rule of Civil Procedure 12(b)(2), plaintiffs bear the "burden of demonstrating the existence of jurisdiction." *Purdue Research Found. v. Sanofi-Synthelabo, S.A.*, 338 F.3d 773, 782 (7th Cir. 2003). Because the Court has not held a jurisdictional evidentiary hearing (and none has been requested), plaintiffs need only make out a *prima facie* case of personal jurisdiction. *Id.* In evaluating whether plaintiffs have made that case, the Court accepts the uncontroverted allegations in the complaint as true and resolves any disputes concerning relevant facts in plaintiffs' favor. *Id.* As with a Rule 12(b)(6) motion, however, plaintiffs cannot rely on "conclusory allegations unsupported by factual assertions." *Castillo v. Allegro Resort Mktg.*, 603 F. App'x 913, 916 (11th Cir.

2015) ("[C]onclusory allegations are insufficient to establish a prima facie case of jurisdiction"); see also *Genetic Technologies Ltd. v. Interleukin Genetics Inc.*, No. 10-CV-69-BBC, 2010 WL 3122304, at *2 (W.D. Wis. Aug. 9, 2010) (general allegation in complaint that defendant committed purposeful acts in forum state would not be enough to satisfy federal pleading standards, "let alone make out a prima facie showing that exercising personal jurisdiction over [the defendant] would be appropriate").

If the plaintiffs' allegations establish a "colorable" showing of personal jurisdiction, the Court has discretion to order limited discovery that would allow plaintiffs to uncover facts that might establish jurisdiction. *Cent. States, Se. & Sw. Areas Pension Fund v. Reimer Express World Corp.*, 230 F.3d 934, 946 (7th Cir. 2000); see also *Gilman Opco LLC v. Lanman Oil Co.*, No. 13-CV-7846, 2014 WL 1284499, at *6 (N.D. Ill. Mar. 28, 2014) ("Courts generally will grant jurisdictional discovery if the plaintiff can show that the factual record is at least ambiguous or unclear on the jurisdiction issue."). Before addressing the Besins defendants' Rule 12(b)(6) motions, the Court first considers whether it has personal jurisdiction over Besins S.A. or, in the alternative, whether limited discovery is necessary to answer the jurisdictional question.

A. Personal jurisdiction over Besins S.A.

A federal court sitting in diversity has personal jurisdiction over a defendant if a court of the state in which it sits would have such jurisdiction. *Citadel Grp. Ltd. v. Washington Reg'l Med. Ctr.*, 536 F.3d 757, 760 (7th Cir. 2008). In an MDL proceeding, the MDL court also has jurisdiction over cases transferred to it under 28 U.S.C. § 1407 if the originating, transferor courts would have jurisdiction. *In re FMC Corp. Patent Litig.*, 422 F. Supp. 1163, 1165 (Jud. Pan. Mult. Lit. 1976) ("Following a transfer, the

transferee judge has all the jurisdiction and powers over pretrial proceedings in the actions transferred to him that the transferor judge would have had in the absence of transfer."). Defendants do not argue that the Court lacks jurisdiction over Besins S.A. under the laws of Illinois or any of the other states in which the transferor courts sit. Rather, they argue only that the Court's exercise of jurisdiction over Besins S.A. would not comport with due process.

For a court to exercise jurisdiction over a defendant consistent with the Fourteenth Amendment's Due Process Clause, the defendant must "have certain minimum contacts with [the forum state] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. State of Wash., Office of Unemployment Comp. & Placement*, 326 U.S. 310, 316 (1945). Plaintiffs do not contend that Besins S.A. has sufficient contacts with any of the forum states involved in the MDL to allow the Court to exercise *general* jurisdiction over it; thus the question for the Court is whether Besins S.A.'s contacts with the forum states subject it to *specific* jurisdiction in those states. The specific jurisdiction inquiry "focuses on the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). The Court may exercise specific jurisdiction over a defendant who is not a resident of a given forum state if the suit "aris[es] out of or [is] related to the defendant's contacts with the forum." *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984). In other words, if a defendant "purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws," the defendant may be subject to jurisdiction in a suit arising out of such activities. *J. McIntyre Mach., Ltd. v. Nicastro*,

131 S. Ct. 2780, 2787–88 (2011).

In arguing that Besins S.A.'s contacts with the forum states are insufficient for the Court to exercise jurisdiction, defendants compare the jurisdictional facts alleged here to those in *Nicastro*, where the Supreme Court found a lack of jurisdiction over the foreign defendant. In *Nicastro*, a plaintiff who injured his hand while using a metal-shearing machine in New Jersey brought a products-liability suit in New Jersey state court against the British company that manufactured the machine. *Id.* at 2786. The manufacturer owned United States patents for its technology but contracted with an independent distributor to sell its machines in the United States. *Id.* Though officials from the manufacturing company had attended conventions to advertise the machines in various states, they never attended conventions in New Jersey, and the record revealed that no more than four machines (and possibly only one) ever ended up in New Jersey. *Id.* The Court concluded that even though the manufacturer had "directed marketing and sales efforts at the United States," the plaintiff failed to establish that the manufacturer "engaged in conduct purposefully directed *at New Jersey*." *Id.* at 2790 (emphasis added).

Defendants contend that *Nicastro* is exactly like this case. Like the foreign manufacturer in *Nicastro*, though Besins S.A. may intend to have its products sold throughout the United States, it does not itself market or sell its products in the United States, having assigned those exclusive rights to Unimed in 1995. Thus "Besins, S.A.'s involvement ends" when it delivers AndroGel to the independent distributor, Defs.' Reply Br. 9, and contacts between third parties (like Unimed or AbbVie) and the forum state cannot provide a basis for specific jurisdiction over the defendant. *Advanced Tactical*

Ordnance Sys., LLC v. Real Action Paintball, Inc., 751 F.3d 796, 801 (7th Cir. 2014).

Defendants say that like the manufacturer in *Nicastro*, Besins S.A. itself did not engage in conduct purposefully directed at any of the forum states here and therefore cannot be haled into court in any of those states.

Plaintiffs argue that this case is distinguishable from *Nicastro* in two respects and that jurisdiction over Besins S.A. is proper throughout the United States. First, they note that, unlike the metal-shearing machine industry, the prescription drug industry that Besins S.A. sought to enter is subject to a pervasive federal regulatory scheme in the United States. Because selling AndroGel in any of the fifty states requires one approval from the FDA and because the same FDA packaging must be used in each state, plaintiffs argue that Besins S.A.'s entry into the nationally regulated market, by itself, reveals the company's intention that AndroGel be sold in every state. By itself, this is unpersuasive. Obtaining FDA approval is indeed a prerequisite for selling prescription drugs in any or every state, but entry into a nationally regulated market is, at least in theory, equally consistent with targeting only a single state. If a company wishes to sell prescription drugs only in Illinois, for example, it too must obtain FDA approval, and obtaining such approval, without more, would not automatically indicate that the company intends to sell the drugs in any other state or has purposefully directed its conduct there. The second distinction plaintiffs offer may have more merit. They argue that the volume of AndroGel sales in the United States—\$1.4 billion in 2013—contrasts sharply with the four (or possibly one) metal-shearing machines that ended up in New Jersey in *Nicastro*. That level of national sales, plaintiffs contend, involves nationwide market penetration rather than the targeting of particular states.

Plaintiffs are correct that *Nicastro* does not foreclose the possibility that a United States court could exercise jurisdiction over a foreign manufacture who contracts with an independent third party to distribute its products within the United States. See *Appjigger GmbH v. Blu Prods., Inc.*, No. 14-CV-9650, 2015 WL 3463413, at *5 (N.D. Ill. May 29, 2015) ("*Nicastro* does not stand for the proposition that if a defendant places goods into the stream of commerce via a third-party distributor who causes those goods to be sold in Illinois, it can never be subject to personal jurisdiction in Illinois."). Justice Breyer's concurring opinion in *Nicastro*, which this Court treats as providing that case's holding,¹ emphasized that the British manufacturer's "single isolated sale" was not a sufficient contact with the forum state to warrant jurisdiction. *Nicastro*, 131 S. Ct. at 2792 (Breyer, J., concurring in the judgment). Justice Breyer considered it significant that the plaintiff had demonstrated neither a "regular flow" or "regular course of sales" in New Jersey nor "something more [than the isolated sale] such as special state-related design, advertising, advice, marketing, or anything else." *Id.* (internal quotation marks omitted). Justice Breyer further stated that the plaintiff could have shown other facts to support jurisdiction, such as those considered in Justice Ginsburg's dissent, noting in particular the "size and scope of New Jersey's scrap-metal business." *Id.* But based on the record before the Court, which did not include such facts, the plaintiff had failed to

¹ None of the opinions in *Nicastro* was joined by a majority of the Justices. This Court can therefore treat Justice Breyer's narrow concurrence, which avoided fashioning new jurisdictional rules and focused on the particular facts before the Court, as providing the case's holding. *Marks v. United States*, 430 U.S. 188, 193 (1977) ("When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds.").

carry the burden of establishing jurisdiction. *Id.*

Based on the general allegations in plaintiffs' master complaint, the Court cannot conclude that Besins S.A. has "purposefully availed itself of the privilege of conducting activities" within any particular forum state at issue here. *Id.* Plaintiffs have alleged that Besins S.A. has derived substantial revenue from the sale of AndroGel within the United States and that it expected or should have expected its acts to have consequences within the forum states. But determining whether Besins S.A. can be properly haled into this Court would require more information about, for example, the volume of AndroGel sales or revenue derived in particular states, or the underlying basis for Besins S.A.'s expectations about the "consequences" its acts would have in those states. See *Jennings v. AC Hydraulic A/S*, 383 F.3d 546, 551 (7th Cir. 2004) ("[S]tate lines are not 'irrelevant for jurisdictional purposes.' For this reason . . . , personal jurisdiction may not be exercised over a nonresident defendant unless 'minimum contacts' between the particular state . . . and the defendant have been established.") (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980)).

Without this sort of information, the Court cannot determine whether, to adopt Justice Breyer's terminology, there was a "regular flow" or "regular course of sales" in any (or all) of the forum states or whether there is any "something more" than isolated sales to indicate that Besins S.A. targeted any (or all) of the forum states. Of course, at this stage of the litigation, plaintiffs cannot be expected to possess such information without conducting discovery. Though the general allegations in plaintiffs' complaint are insufficient to establish jurisdiction, those allegations—coupled with the specific national

sales figures for AndroGel in one year—do establish a "colorable showing" that the Court might properly exercise personal jurisdiction over Besins S.A. At a minimum, plaintiffs have shown that the factual record on the jurisdiction issue "is at least ambiguous or unclear." *Gilman Opco*, 2014 WL 1284499, at *6. Focused jurisdictional discovery is thus warranted, and defendants' motion to dismiss for lack of personal jurisdiction is entered and continued until this discovery is conducted and the parties have engaged in further briefing.

In ordering jurisdictional discovery, the court is mindful that "[f]oreign nationals usually should not be subjected to extensive discovery in order to determine whether personal jurisdiction over them exists." *Reimer*, 230 F.3d at 946. But in their response to defendants' motion, plaintiffs have provided a list of topics about which they might inquire for jurisdictional discovery purposes, and much of the relevant information likely can be obtained from defendants in the MDL other than Besins S.A. The Court, therefore, will permit discovery on the following topics taken from plaintiffs' suggestions: (1) the volume of AndroGel sales in each state on an annual basis; (2) whether or not sales were targeted at certain geographic areas within in the United States; (3) the extent to which Besins S.A. is aware of and/or influences where AndroGel is sold in the United States; (4) whether and how Besins' knowledge of other "economic realities" influenced its agreement with Unimed or influences its relationship with Unimed regarding where AndroGel will be sold within the United States; and (5) other relevant details of the distribution agreement between Besins S.A. and Unimed.

B. Design defect and redhibition claims

Defendants have moved to dismiss all of plaintiffs' claims against the Besins

defendants on the ground that the master complaint fails to allege any specific wrongdoing on the part of either defendant and is therefore inadequate under Federal Rule of Civil Procedure 8(a). In their response, plaintiffs concede that certain of their claims against the Besins defendants must be dismissed. On this basis, the Court dismisses Claims Two, Four, Five, Six, Seven, and Nine. Plaintiffs continue to assert claims for strict liability (based on design defect), negligence, and redhibition (in addition to claims for damages resulting from those substantive claims). Thus in reply, defendants focus on the design defect and redhibition claims. Because plaintiffs have alleged adequate facts to provide fair notice to the Besins defendants of their claims and to show that those claims have "substantive plausibility," *Runnion*, 786 F.3d at 517, the Court declines to dismiss those claims.

Defendants fault plaintiffs for referring collectively to the "Defendants" in the master complaint, lumping each defendant together in violation of Federal Rule of Civil Procedure 8(a)'s requirement that plaintiffs offer a "short and plain statement" of their claims that give defendants notice of the claims against them. This dooms plaintiffs' claims, according to defendants. See *Bank of Am., N.A. v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013) ("Each defendant is entitled to know what he or she did that is asserted to be wrongful. A complaint based on a theory of collective responsibility must be dismissed.").

The Court agrees with defendants that it is somewhat sloppy to make allegations about "Defendants" when the allegations do not actually refer to all defendants. The allegations concerning the claims that plaintiffs now concede should be dismissed, for example, should not have included the Besins defendants among the "Defendants"

referenced. The master complaint's allegations, however, are not premised on a "theory of collective responsibility." *Id.* This is not like a case in which the plaintiffs charge that "the defendants looted the corporation . . . without any details about who did what." *Id.* Now that plaintiffs have agreed to dismissal of the claims based on marketing and direct sale of AndroGel, plaintiffs' specific allegations against the Besins defendants, as discussed in greater depth below, are clear from the master complaint: (1) the Besins defendants were involved in the design or manufacture of AndroGel; (2) AndroGel's unreasonably dangerous side effects rendered it defective; (3) AndroGel's defective design injured plaintiffs; and (4) the Besins defendants acted negligently in designing the drug, should be held strictly liable for the drug's defective design, and should be held liable for the price of the drugs to buyers who would not have purchased them had they known of the defects. Though the complaint could have been more carefully drafted, the notice it provides to the Besins defendants is sufficient to survive a Rule 12(b)(6) motion.

In addition to asserting this general problem with the complaint's drafting, defendants argue specifically that plaintiffs' allegations concerning AndroGel's defective design are inadequate to support their design defect claim against the Besins defendants. Defendants argue in particular that plaintiffs' design defect claim fails because they do not specify the contributions the Besins defendants made to AndroGel's design or what about AndroGel renders its defective. But defendants do not cite any authority for the proposition that plaintiffs must allege the precise contribution a defendant makes to an allegedly defective product's design. At this stage, plaintiffs' allegations that each Besins defendant was "engaged in the research, development,

design, [and] testing" of AndroGel—supported by the allegation that each defendant holds intellectual property rights to AndroGel's pharmaceutical formulation—are sufficient to permit a reasonable inference that both defendants contributed in such a way to AndroGel's design that they could be held liable under a design defect theory.

Defendants' additional argument that the complaint "lacks even the most basic information regarding what, if any, supposed defect . . . exists," Defs.' Reply Br. at 9, is simply untrue. The master complaint contains detailed allegations about the health hazards and risks of TRT drugs (including the formation of blood clots and other cardiovascular injuries), as well as the mechanism by which TRT drugs create those risks. Plaintiffs' complaint thus provides much more than "bare allegation[s] that the [product] suffered from a 'design defect'," *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010), or allegations that "never even identif[y] what the supposed defect" is, *Ball v. Takeda Pharm. Am., Inc.*, 963 F. Supp. 2d 497, 505 (E.D. Va. 2013).

Defendants also argue that the design defect claims against the Besins defendants should be dismissed because plaintiffs fail to allege the existence of a safer alternative design and because they have not indicated that AndroGel is so risky that it lacks medical usefulness. With one exception, however, the cases defendants cite in support of their alternative-design argument all stand for the proposition that a plaintiff must *prove* the existence of a safer alternative design to survive summary judgment—not that the plaintiff must allege the existence of such a design in the complaint. See, e.g., *Piltch v. Ford Motor Co.*, 778 F.3d 628, 634 (7th Cir. 2015) (affirming grant of summary judgment under Indiana law); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 679 (5th Cir. 2014) (noting Texas state law requirement that plaintiff prove

existence of safer alternative to prove a strict liability design defect claim). In *Mendez v. Shah*, 28 F. Supp. 3d 282 (D.N.J. 2014), which defendants cite and which *did* involve a motion to dismiss, the court stated that "there is no per se rule that Plaintiffs must, under all circumstances, provide a reasonable alternative design . . ." *Id.* at 297.

The Court's own research reveals that some federal district courts have ruled that plaintiffs must allege the existence of a safer alternative design to support a design defect claim under certain states' laws. See, e.g., *Kennedy v. Pfizer, Inc.*, No. CIV.A. 13-3132, 2014 WL 4093065, at *4 (W.D. La. Aug. 15, 2014) ("Because [the plaintiff] failed to allege that an alternative design existed, it is impossible for the complaint to have sufficiently alleged . . . a design defect claim [under Louisiana law.]; *S.F. v. Archer-Daniels-Midland Co.*, No. 13-CV-634S, 2014 WL 1600414, at *8 (W.D.N.Y. Apr. 21, 2014) (dismissing plaintiff's defective design claim under New York law for failure to allege safer alternative design). *But see*, e.g., *Show v. Ford Motor Co.*, 697 F. Supp. 2d 975, 981 (N.D. Ill. 2010), *aff'd*, 659 F.3d 584 (7th Cir. 2011) ("While the existence of an alternative design and the balancing of risks and benefits are relevant in a products liability case under Illinois law, they are not elements of the claim that the plaintiff is required to plead and prove in every case."). But even if this shortcoming in the complaint would be fatal for some plaintiffs' design defect claims, it would not provide a reason to dismiss entirely the master complaint's design defect claims against the Besins defendants. In addition, defendants first raised the alternative-design argument in their reply, and plaintiffs have not had the opportunity to respond. Defendants have thus "forfeited the point for purposes of their motion to dismiss." See *Sumling v. Vill. of E. Dundee*, No. 14 C 3794, 2015 WL 5545294, at *5 (N.D. Ill. Sept. 18, 2015) (citing

Darif v. Holder, 739 F.3d 329, 336 (7th Cir. 2014)).

Similarly, defendants' argument that plaintiffs' claim must be dismissed for failing to allege that AndroGel lacks medical usefulness was first raised in their reply and is therefore forfeited for purposes of the present motion. That argument is based on the Third Restatement of Torts, under which a prescription drug will only be considered "not reasonably safe due to defective design" if a fully informed, reasonable health-care provider would not prescribe the drug for "any class of patients." Restatement (Third) of Torts: Prod. Liab. § 6(c) (1998). Defendants argue that because plaintiffs have not alleged that AndroGel's risks render it medically useless for the treatment of classical hypogonadism, their design defect claim cannot succeed. Not all states, however, have adopted the position of the Third Restatement. Indeed, a number of state courts have expressly rejected it. See, e.g., *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 567, 618 N.W.2d 827, 840 (2000) ("We conclude that § 6(c) has no basis in the case law. We view § 6(c) as too strict of a rule, under which recovery would be nearly impossible. Accordingly, we do not adopt § 6(c) of the Third Restatement."). In addition, plaintiffs have alleged that the TRT drugs' defects made them "unreasonably dangerous," and the Court's only role at the motion to dismiss stage is to determine whether such a claim is plausible, not to determine how plaintiffs must go about proving their claim or to assess the probability of their success. See, e.g., *Small v. Amgen, Inc.*, 2 F. Supp. 3d 1292, 1297 (M.D. Fla. 2014) ("At this stage of the proceedings, the Court finds that the allegations of an unreasonably dangerous defect are sufficient to plausibly state a strict liability claim based on a design defect.").

In their reply, defendants do not distinguish between their arguments against

plaintiffs' negligence and strict liability design defect claims. For the reasons just discussed, the Court denies defendants' motion to dismiss the strict liability design defect claim against the Besins defendants. Because plaintiffs have alleged the necessary additional elements for a negligence claim (the Besins defendants' duty of care owed to plaintiffs and the breach of that duty), plaintiffs' negligence claim survives as well.

The Court also denies the motion to dismiss as to plaintiffs' redhibition claim. Redhibition is a cause of action under Louisiana law that allows a purchaser of a defective product to rescind the sale and recover a refund—or, alternatively, a reduction—of the purchase price. *Alexander v. GlaxoSmithKline, LLC*, No. CIV.A. 15-2323, 2015 WL 5440994, at *5 (E.D. La. Sept. 14, 2015). A plaintiff bringing a redhibition claim must prove that the product's defect "renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." La. Civ. Code Ann. art. 2520. Plaintiffs have alleged that the TRT products at issue in the MDL contain such a defect. Master Compl. ¶ 567. Under Louisiana law, buyers may recover directly from the products' manufacturers despite a lack of privity between them. *Aucoin v. S. Quality Homes, LLC*, 984 So. 2d 685, 692 (La. 2008).

Defendants' arguments supporting dismissal of plaintiffs' redhibition claim, like some of the design-defect arguments, were first raised in defendants' reply and are thus also forfeited. But even if they were properly raised, the Court does not believe they have merit. Defendants, for example, argue that plaintiffs' redhibition claim must be dismissed because they failed to contact either AbbVie or the Besins defendants to give

them an opportunity to cure the alleged defect prior to filing the suit. The obligation to provide an opportunity to correct or cure the alleged defect, however, "applies only to a good-faith seller [and] not to a manufacturer, who is presumed to have knowledge of the defects." *Live Oak Homes Corp. v. Carrier Sales & Distribution, LLC*, 140 So. 3d 362, 368 (La. Ct. App. 2014). Plaintiffs thus were not required to contact the Besins defendants to give them an opportunity to cure the alleged defect.

Defendants also argue that plaintiffs' allegation that AndroGel is "useless for its intended purpose" is inconsistent with their failure to claim that AndroGel is ineffective for the treatment of hypogonadism. But treatment of hypogonadism may not have been the "intended purpose" of the AndroGel sold to those plaintiffs seeking redhibition if, as plaintiffs allege, AndroGel was marketed and sold to those plaintiffs for the treatment of a condition other than hypogonadism. Plaintiffs have plausibly alleged that if they had known of the alleged defects prior to such sales, they would not have purchased the product. In this situation, it is possible for the product to have been useless for its "intended purpose" even if the product served some use for other buyers.

Finally, defendants argue that even if a redhibition claim were cognizable against Besins S.A. as the "manufacturer" of AndroGel, no such claim is available against Besins Inc., as the complaint did not allege that Besins Inc. manufactured AndroGel for sale in the United States. Plaintiffs, however, have alleged that Besins Inc. holds the intellectual property rights to AndroGel's pharmaceutical formulation and that it was "engaged in the research, development, design, testing, manufacture, sales, marketing, and/or distribution of . . . AndroGel." Master Compl. ¶ 25(a). It is therefore unclear why Besins Inc., who holds intellectual property rights in AndroGel and allegedly played

some role in its design or manufacture, would not be considered a "manufacturer" under Louisiana law. "[T]he Louisiana Supreme Court . . . has interpreted the [redhibition] statute liberally." *Howard Pardue/Pardue's Auto Repair, Inc. v. Cummins, Inc.*, No. CIV. A. 08-1677, 2009 WL 5171462, at *2 (E.D. La. Dec. 17, 2009). "[O]ne does not need to be the actual manufacturer to be considered a manufacturer under the [Louisiana products liability statute] or Louisiana redhibition law." *Performance Contractors, Inc. v. Great Plains Stainless, Inc.*, No. CIV.A. 11-485-JJB, 2012 WL 5398534, at *3 (M.D. La. Nov. 2, 2012). Indeed, the Louisiana products liability statute defines "manufacturing a product" to include "designing" a product. La. Rev. Stat. Ann. 9:2800.53. At this stage, based on the allegations against Besins Inc. in the master complaint, the Court concludes that Besins Inc. would be considered a "manufacturer" against whom a redhibition action could proceed under Louisiana law.

Conclusion

For the foregoing reasons, the Court grants defendants' motion to dismiss in part [dkt. no. 876] and defers ruling in part. Claims Two, Four, Five, Six, Seven, and Nine of the Master Complaint are dismissed for failure to state a claim insofar as they are asserted against defendants Besins S.A. and Besins Inc. The Court declines to dismiss Claims One, Three, Eight, Ten, Eleven, Twelve, Thirteen, and Fourteen for failure to state a claim. Ruling on the motion to dismiss for lack of personal jurisdiction is otherwise deferred pending discovery as described in the body of this decision. Prior to the October case management conference, counsel are to confer and attempt to agree upon a discovery schedule regarding the motion. The parties' proposal or proposals are

to be included in the status report filed in advance of that conference.



MATTHEW F. KENNELLY
United States District Judge

Date: September 30, 2015