

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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THIS DOCUMENT RELATES TO ALL CASES

**PRETRIAL ORDER # 41  
(Memorandum Opinion and Order re: Plaintiffs' Motion  
for Leave to Amend to Add Defendants [Docket 193])**

Pending is Plaintiffs' Motion for Leave to Amend Complaint to Add Defendants and Brief in Support, filed September 21, 2012 [Docket 193]. On September 28, 2012, defendant Boston Scientific Corporation ("Boston Scientific") filed a memorandum in opposition [Docket 204]. On September 28, 2012, specially appearing defendant Proxy Biomedical, Ltd. ("Proxy Ltd.") filed an objection to the plaintiffs' motion [Docket 205] and on October 5, 2012, plaintiffs filed a reply in support of their motion [Docket 213]. On October 11, 2012, Proxy Ltd. filed a Motion for Leave to file Sur-Reply to Plaintiffs' Motion for Leave to Amend Complaint [Docket 217]. I **GRANT** Proxy Ltd.'s Motion for Leave to file Sur-Reply.

Following a status conference on December 6, 2012, the court granted the parties and Proxy Ltd. time to conduct jurisdictional discovery<sup>1</sup> and directed that they file supplemental briefs if the issue could not be resolved. On February 7, 2013, Proxy Ltd. filed a supplemental objection to plaintiffs' motion [Docket 317]. On February 8, 2013, plaintiffs filed their

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<sup>1</sup> Proxy Ltd. answered interrogatories, and the plaintiffs were scheduled to depose a corporate representative of Proxy Ltd., but cancelled the deposition.

supplemental brief in support of the motion [Docket 321]. The remaining parties whom plaintiffs seek to add as defendants have not responded to the motion.

Upon consideration of the filings submitted by the parties and Proxy Ltd., I **DENY** Plaintiffs' Motion for Leave to Amend Complaint to the extent it seeks to add Proxy Ltd. Also, I **DENY** Plaintiffs' Motion for Leave to Amend Complaint to the extent it seeks to add MedVenture Technology Corporation, TEI Biosciences Inc., and LifeCell Corporation without prejudice if and until those parties consent to this court's jurisdiction and venue or if plaintiffs can establish personal jurisdiction over those defendants in West Virginia.

## **I. Background**

I have been assigned this MDL by the Judicial Panel on Multidistrict Litigation (the "Panel"), along with four MDLs involving the implantation of allegedly defective pelvic mesh products used to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Currently, there are approximately 2,813 cases in the Boston Scientific MDL. By Pretrial Order ("PTO") entered September 26, 2012, the court adopted a Master Complaint, Short Form and Amended Short Form Complaint, and Master Answer in this MDL. [Docket 196]. The Master Complaint against Boston Scientific alleges nine counts: negligence; strict liability-design defect; strict liability-manufacturing defect; strict liability-failure to warn; breach of express warranty; breach of implied warranty; loss of consortium; discovery rule, tolling and fraudulent concealment; and punitive damages. [Docket 196-1].

Plaintiffs seek to amend their Master Complaint in MDL 2326 to name (1) Proxy Ltd., (2) MedVenture Technology Corporation ("MedVenture"), (3) TEI Biosciences Inc. ("TEI") and LifeCell Corporation ("LifeCell"). Plaintiffs assert that they previously believed that Boston Scientific manufactured the pelvic mesh products it sold, but that they recently learned via

deposition of Boston Scientific's corporate representative, Edward C. Walbridge, that Boston Scientific does not manufacture any of its pelvic mesh products. Instead, Boston Scientific is responsible for and performs labeling, sales, marketing, and distribution of those products. [Docket 193, at 1]; (Walbridge Dep., [Docket 193-1], at 74: 19–22).

Proxy Ltd. is an Irish company that manufactures different forms of synthetic mesh. Plaintiffs assert that Proxy Ltd.'s product was sold as a standalone, polypropylene mesh or as a component in two of Boston Scientific's POP kits and that it manufactured a mesh used in six of Boston Scientific's SUI sling kits. [Docket 193, at 2–3]. Plaintiffs allege that MedVenture, headquartered in Jeffersonville, Indiana, is responsible for assembling the final kits incorporating Proxy Ltd.'s mesh. Plaintiffs assert that TEI, headquartered in Boston, Massachusetts manufactures fetal bovine collagen mesh used in the Xenform Soft Tissue Repair Matrix. They further allege that LifeCell is headquartered in Branchburg, New Jersey and manufactures a cadaveric allograft used in the Repliform Tissue Regeneration Matrix. [Docket 193, at 3].

Among other types of mesh, Proxy Ltd. manufactures Polyform Synthetic Mesh ("Polyform"). Polyform is a non-absorbable synthetic mesh, constructed of knitted filaments of polypropylene. (510(k), [Docket 193-3], at 1). It is supplied in sterile, sheet form to be cut to size and sutured by a surgeon to meet an individual patient's needs. (*Id.*) Section 510(k) of the Food, Drug and Cosmetic Act ("FDA") requires device manufacturers, unless exempted, to notify the FDA of their intent to market a medical device in the United States at least 90 days in advance of such marketing. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 510(k), 52 Stat. 1040 (1938), as amended 21 U.S.C. § 360(k) (2012). This application is known as a pre-market notification. 21 C.F.R. § 807.92(a)(3) (2012). If the FDA finds the device to be "substantially equivalent" to a legally marketed device that is not subject to pre-market approval, the FDA will

allow the device to be marketed. *Id.* Proxy Ltd. filed a 510(k) for Polyform in May of 2005. (510(k) Summary, [Docket 193-3], at 1). On or around June 17, 2005, the FDA approved Proxy Ltd.'s 510(k) application to market Polyform. (*Id.* at 2). Proxy Ltd. sells Polyform to Boston Scientific in Galway, Ireland pursuant to orders Boston Scientific sends to Galway, Ireland. Proxy Ltd. then ships Polyform to Boston Scientific's distribution center in Quincy, Massachusetts. (Interrogatories, [Docket 317-1], at 3).

Proxy Ltd. has no involvement in the sale or marketing of Polyform after it is shipped to Boston Scientific. (Interrogatories, [Docket 317-1], at 4). From August 2005 through November 30, 2012, there has been one adverse incident reported to the FDA from West Virginia relating to Polyform as a standalone product. (*Id.* at 5). Proxy Ltd. sponsored an "ISO Muscle Implantation Study with Sponsor Provided Control" using "polypropylene surgical mesh" in Northwood, Ohio. (ISO Study, [Docket 321-21]). It also sponsored an in vivo animal study of Polyform and another product, but the document cited by plaintiffs does not state where this was performed. (Animal Study, [Docket 321-22]). Proxy Ltd. has purchased bulk non-sterile mesh for manufacture of polypropylene mesh from Secant Medical in Perkasi, Pennsylvania. (Interrogatories, [Docket 321-26], at 23).

Proxy Inc. is a U.S. subsidiary of Proxy Ltd. located in Cleveland, Ohio. Proxy Inc. and Proxy Ltd. have attended a variety of trade shows in the U.S. both with regard to the biomaterials industry generally, and with regard to women's health. None of the trade shows were in West Virginia. (Interrogatories, [Docket 317-1], at 18–19).

It is conceded that Proxy Ltd.'s officers regularly communicate and meet with Boston Scientific in Massachusetts, and from time-to-time visit Boston Scientific in Massachusetts to address issues related to the supply and manufacture of the mesh components for Boston

Scientific's products. Also, Boston Scientific identified Proxy Ltd. employees as team members for mesh related initiatives. (Supplemental Obj., [Docket 317], at 17–18).

Boston Scientific described a former Proxy Inc. employee, Jon Rischmiller, based in Cleveland, Ohio, as “directly responsible for [its] mesh business and our key contact at Proxy.” (Email, [Docket 321-16]). Rischmiller met and communicated with Boston Scientific in Massachusetts about Polyform Mesh and Boston Scientific's women's health product business in general. (Email, [Docket 321-20]). It is conceded that he had meetings with Boston Scientific about a Polyform pre-clinical study which he was involved in procuring and was involved in the investigation of a single adverse event. He also attended field visits with Boston Scientific sales personnel to observe U.S. doctors perform implant surgeries.

Turning to the products alleged in the amended Master Complaint, in 2008 Proxy Ltd. began selling “bulk non-sterile polypropylene mesh that has physical properties equivalent to Polyform” to MedVenture to be used in the Uphold product, one of several products that is the subject of plaintiffs' motion to amend.<sup>2</sup> MedVenture is a contract manufacturer for Boston Scientific. (Interrogatories, [Docket 317-1], at 6). MedVenture places orders for the mesh with Proxy Ltd. in Galway, Ireland, based on information it receives from Boston Scientific. (*Id.*) MedVenture incorporates the mesh into Uphold in Jeffersonville, Indiana, and sells the finished product back to Boston Scientific. (*Id.*)

In 2007, Proxy Ltd. began selling “bulk non-sterile polypropylene mesh that has physical properties equivalent to Polyform” to MedVenture to be used in the Pinnacle product under the same arrangement as that of Uphold. (*Id.* at 8).

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<sup>2</sup> In its Position Statement, Boston Scientific stated that Proxy Ltd. provided a bulk, non-sterile form of Polyform to be used in Boston Scientific's Pinnacle Pelvic Floor Repair Kit and Uphold Vaginal Support System. (Boston Scientific Position Statement, [Docket 193-4], at 7).

In 2010, Proxy Ltd. began selling a bulk, non-sterile polypropylene mesh, known as Advantage, which is incorporated into the Advantage, Lynx, Obtryx, Prefyx, and Solyx devices under the same arrangement as that of Uphold and Pinnacle. (*Id.* at 10–11); (Walbridge Dep., [Docket 193-1], at 38:12–16); (Position Statement, [Docket 193-4], at 5).

Proxy Ltd. does not hold the 510(k) clearance for any of the finished products at issue in this litigation and named in the proposed amended Master Complaint, but, as noted above, it does hold the 510(k) clearance for Polyform. (*Id.* at 5–6, 8, 10–11); (510(k) Summary, [Docket 193-3]). As Peter Mulrooney, CEO of Proxy Ltd. stated by Affidavit, “[w]hile [Boston Scientific] has an exclusive licensing agreement to distribute Proxy Ltd.’s Polyform Mesh, for which Proxy Ltd. holds a 510k regulatory clearance, it is my understanding that [Boston Scientific] uses the separate bulk, non-sterile mesh supplied by Proxy Ltd. to [Boston Scientific’s] contract manufacturer, Medventure, to manufacture and finish medical device implants known generally as the Uphold[,] ... Pinnacle .... [and Advantage, Lynx, Obtryx, Prefyx and Solyx] ....” (Affidavit of Peter Mulrooney, [Docket 317-2], at 1). Proxy Ltd. “is not required to register with the Secretary of Health & Human Services (“SHHS”) in connection with the sale of bulk, non-sterile polypropylene mesh to [Boston Scientific] or their contract manufacturer.” (*Id.* ¶ 4). Finally, Proxy Ltd. does not take title to or sell the finished product of the devices at issue in this litigation. (*Id.* at ¶ 5).

In July of 2005, Proxy Ltd. entered into a Distribution Agreement with Boston Scientific in which Proxy Ltd. agreed to sell “[p]roducts[, defined as condensed monofilament propylene mesh configured in any shape or size for any use,] produced and/or sold by [Proxy Ltd.] . . . .” (Distribution Agreement, [Docket 321-3], at 1–4). Under the Distribution Agreement Boston Scientific “agree[d] that during the Term of the Agreement it shall use commercially reasonable

efforts to launch and market the Product in the Field in the United States and Europe.” (*Id.* at 5). Also, the parties agreed that Proxy Ltd. “shall be responsible, at its expense, for obtaining, maintaining and complying with all United States and foreign regulatory requirements and approvals . . . necessary or useful to promote and sell the Products in the Territory.” (*Id.* at 8). And “[Proxy Ltd.] shall, at its own expense, be responsible for conducting and managing all pre-clinical trial programs in the Territory necessary or desirable in order to fulfill [Proxy Ltd.’s] obligations . . . .” (*Id.* at 11).

## **II. Legal Standard**

### **a. Motion to Amend Complaint**

Federal Rule of Civil Procedure 15 provides that in cases when amendment would not be as a matter of course, “a party may amend its pleading only with the opposing party’s written consent or the court’s leave. The court should freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2). The United States Court of Appeals for the Fourth Circuit “reads Rule 15(a) to mean that leave to amend should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or amendment would be futile.” *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009) (citing *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006) (en banc)).

### **b. Personal Jurisdiction**

For a district court to validly assert personal jurisdiction over a non-resident defendant, two conditions must be satisfied. First, a state long-arm statute must authorize jurisdiction over the non-resident defendant. Second, the court’s exercise of personal jurisdiction over the non-resident defendant must “comport with the Due Process Clause.” *In re Celotex Corp.*, 124 F.3d

619, 627 (4th Cir. 1997); *Mylan Labs., Inc. v. Akzo, N.V.*, 2 F.3d 56, 59–60 (4th Cir. 1993). “Because the West Virginia long-arm statute is coextensive with the full reach of due process, it is unnecessary in this case to go through the normal two-step formula for determining the existence of personal jurisdiction.” *Celotex*, 124 F.3d at 627–28 (internal citations omitted). Consequently, the statutory inquiry merges with the constitutional inquiry, and the court must determine whether exercising personal jurisdiction over the defendant is consistent with the Due Process Clause. *See id.*

“A court’s exercise of personal jurisdiction over a non-resident defendant is consistent with the Due Process Clause if the defendant has sufficient ‘minimum contacts’ with the forum such that requiring the defendant to defend its interests in the forum does not ‘offend traditional notions of fair play and substantial justice.’” *Celotex*, 124 F.3d at 628 (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). The Supreme Court has recognized that this protection provided by the Due Process Clause extends to foreign corporations. *See Goodyear Dunlop Tires Ops., S.A. v. Brown*, 131 S. Ct. 2846, 2852–54 (2011).

There are two approaches to finding jurisdiction over persons outside a state’s borders: specific and general jurisdiction. *ALS Scan, Inc. v. Digital Serv. Consultants, Inc.*, 293 F.3d 707, 711 (4th Cir. 2002). If the suit does not arise out of the defendant’s contacts with the state, the defendant must have “continuous and systematic” contacts with the state to confer general jurisdiction. *Id.* at 712. On the other hand, if the defendant’s contact with the state is the basis of the suit, then specific jurisdiction applies. *Id.* The Fourth Circuit applies a three-part inquiry to determine whether specific jurisdiction exists; the inquiry looks to: “(1) the extent to which the defendant purposefully availed itself of the privilege of conducting activities in the State; (2) whether the plaintiff’s claims arise out of those activities directed at the State; and (3) whether

the exercise of personal jurisdiction would be constitutionally reasonable.” *Mitrano v. Hawes*, 377 F.3d 402, 407 (4th Cir. 2004). The “touchstone” of the specific jurisdiction analysis is whether the defendant “engaged in some activity purposefully directed toward the forum state.” *Celotex*, 124 F.3d at 628 (internal quotations omitted).

The parties have conducted discovery limited to the issue of personal jurisdiction over Proxy Ltd., but there has not been an evidentiary hearing. When a court rules on personal jurisdiction without holding an evidentiary hearing, the plaintiff must make a prima facie showing of personal jurisdiction with the court viewing the facts in the light most favorable to the plaintiff. *Mitrano*, 377 F.3d 402, 406 (4th Cir. 2004).

### **III. Analysis**

Because Proxy Ltd. does not consent to this court’s jurisdiction, I must determine whether amending the Master Complaint to add Proxy Ltd. would be futile because there is no personal jurisdiction over Proxy Ltd. in West Virginia. I also must determine whether the other proposed additional parties may be added to the Master Complaint.

#### **a. Consent in MDL Cases**

Although the MDL Panel might not be constrained by “traditional considerations of venue or personal jurisdiction” in transferring an MDL to any district in the first instance,<sup>3</sup> parties typically must consent to jurisdiction and venue in the transferee court for direct filing purposes. See *In re Denko K.K. L-Tryptophan Prods. Liab. Lit.–II*, 953 F.2d 162, 165 (4th Cir. 1992) (“The authority for consolidating cases on the order of the judicial panel on multi-district litigation, however, is merely procedural and does not expand the jurisdiction of the district court

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<sup>3</sup> 2 Newberg on Class Actions § 6:41 (5th ed.) (citing *In re Peanut Crop Ins. Lit.*, 342 F. Supp. 2d 1353, 1354 (J.P.M.L. 2004)).

to which the cases are transferred.”); *see also In re Heartland Payment Sys., Inc. Customer Data Sec. Breach Litig.*, No. H-10-171, 2011 WL 1232352, at \*4 (S.D. Tex. Mar. 31, 2011) (“In some cases, a defendant facilitates direct filing through a stipulation waiving personal jurisdiction for the pretrial proceedings under § 1407.”); *see also* 28 U.S.C. § 1404(a) (“[A] district court may transfer any civil action . . . to any district or division to which all parties have consented.”). Only “[w]here the defendant waives venue and personal jurisdiction objections for pretrial proceedings” may plaintiffs “file directly in the transferee court, thus eliminating the involvement of the Panel.” Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges* 30 (2011). Pretrial Order # 14 explicitly indicates that “the parties submit to this court’s personal jurisdiction and venue in the Southern District” for purposes of consolidated discovery and related proceedings only. (PTO # 14, [Docket 196], at 4).

My decision in the *In re Avaulta* (now *C.R. Bard, Inc.*) MDL cited by plaintiffs was not contrary to this view. (*In re C. R. Bard, Inc. Pelvic Repair Sys. Prods. Liability Lit.*, No. 2:10-md-02187, [Docket 193-7]). In that decision, the issue of personal jurisdiction over the proposed new parties was not presented. (*Id.*) Because Proxy Ltd. is not consenting to this court’s jurisdiction over it, I must find that this court has personal jurisdiction over Proxy Ltd. under the traditional analysis to grant the motion to amend. Otherwise, the amendment would be futile.

Boston Scientific argues that the other proposed parties, like Proxy Ltd., have had little to no involvement in this litigation, have not been before the MDL Panel, and have not waived personal jurisdiction or venue. MedVenture, TEI, and LifeCell have not made an appearance for the purpose of briefing the issue of this court’s jurisdiction over them. Without the consent of MedVenture, TEI, and LifeCell to exercise limited jurisdiction as expressed in Pretrial Order

# 14 or a finding of personal jurisdiction, a burden which I cannot conclude plaintiffs have met at this time, I must **DENY** Plaintiffs' Motion for Leave to Amend Complaint without prejudice as to these parties.

**b. Pretrial Order # 14**

At the outset, I will address Boston Scientific and Proxy Ltd.'s argument that Pretrial Order # 14 [Docket 196] establishes the process for handling non-Boston Scientific defendants in MDL 2326. Although I did indicate in PTO #14 that direct filing by plaintiffs who named defendants other than those named in the Master Complaint was inappropriate and must be corrected, PTO #14 did not address amendments to the Master Complaint. If I grant leave to amend, the defendants would be named in the Master Complaint and the preclusion would not apply.

**c. Personal Jurisdiction over Proxy Ltd.**

If I grant the motion to amend the complaint to add Proxy Ltd., plaintiffs could eventually direct file against Proxy Ltd. in the Southern District of West Virginia. Direct filers would not have an antecedent transferor court whose substantive law would apply. In these situations, the majority of district courts sitting in diversity have applied the substantive law of the state in which they sit.<sup>4</sup> As noted above, a defendant typically must consent to this court's jurisdiction and venue to be added to the Master Complaint. The plaintiffs have raised the

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<sup>4</sup> *In re Trasyol Prods. Liab. Litig.*, No. 1:08-MD-01928, 2011 WL 1033650, at \*3-4 (S.D. Fla. Jan. 18, 2011) (applying Florida choice-of-law rules to MDL case direct-filed in Florida even though the plaintiffs were domiciled and injured in Oklahoma); *see also Byers v. Lincoln Elec. Co.*, 607 F. Supp. 2d 840, 844 (N.D. Ohio 2009); *In re Vioxx Prods. Liability Lit.*, 522 F. Supp. 2d 799, 806 (E.D. La. 2007) ("The court previously discussed the use of direct filing in this MDL and has concluded that Louisiana's choice-of-law rules must be applied in such cases, unless, of course, the parties stipulate otherwise.").

possibility that jurisdiction would be proper over Proxy Ltd. in West Virginia, and possibly all fifty states, such that its consent would be unnecessary. Thus, I will analyze whether this court would have personal jurisdiction over Proxy Ltd. as if a plaintiff originally filed against Proxy Ltd. in the Southern District of West Virginia.

There are no allegations that Proxy Ltd. is subject to general jurisdiction in West Virginia, and there is no basis for that finding. *See Goodyear*, 131 S. Ct. at 2853–54 (stating that a corporation is subject to general jurisdiction in a forum “in which the corporation is fairly regarded as at home”). Thus, the inquiry centers on whether Proxy Ltd. is subject to specific jurisdiction in West Virginia, which Proxy Ltd. disputes. In this regard, Proxy Ltd. contends that there are no plaintiffs in this MDL that reside in West Virginia or that have alleged that their injuries occurred in West Virginia. (Supplemental Objection, [Docket 317], at 19). Proxy Ltd. does not contend that there is no jurisdiction in the United States where it is subject to jurisdiction. It fears that if I allow the motion to amend to add it to the Master Complaint (and the Short Form Complaint in turn), its due process right to only be haled into court where it is subject to personal jurisdiction would be circumvented. Of course, if I allowed the amendment it would not preclude Proxy Ltd. from challenging personal jurisdiction. But because the issue has arisen in conjunction with its futility argument, its concerns are not premature.

A recent decision of the United States Supreme Court is relevant to the personal jurisdiction analysis. In *J. McIntyre Machinery, Ltd. v. Nicastro*, the United States Supreme Court considered whether New Jersey had personal jurisdiction over a foreign manufacturer. 131 S. Ct. at 2785 (2011). The New Jersey Supreme Court found that New Jersey’s courts could exercise personal jurisdiction over a foreign manufacturer “so long as the manufacturer ‘knows or reasonably should know that its products are distributed through a nationwide distribution

system that might lead to those products being sold in any of the fifty states.” *Id.* (quoting *Nicastro v. McIntyre Mach. Am., Ltd.*, 201 N.J. 48, 76–77, 987 A.2d 575, 591–92 (2010)). Applying this logic, the New Jersey Supreme Court “concluded that a British manufacturer of scrap metal machines was subject to jurisdiction in New Jersey, even though at no time had it advertised in, sent goods to, or in any relevant sense targeted the State.” *Id.*

The United States Supreme Court reversed, finding no personal jurisdiction. *Id.* (plurality opinion); *id.* at 2791 (concurring opinion). Justice Kennedy delivered the plurality opinion with three Justices joining. *Id.* at 2783. Justice Breyer delivered an opinion, joined by Justice Alito, concurring in the judgment. *Id.* at 2791. Justice Ginsburg delivered an opinion, joined by two Justices, dissenting. *Id.* at 2794.

In *McIntyre*, Nicastro’s counsel stated several facts in support of the state’s jurisdiction; namely:

1. “[A]n independent company agreed to sell J. McIntyre’s machines in the United States. J. McIntyre itself did not sell its machines to buyers in this country beyond the U.S. distributor, and there is no allegation that the distributor was under J. McIntyre’s control.” *Id.* at 2786.
2. “J. McIntyre officials attended annual conventions for the scrap recycling industry to advertise J. McIntyre’s machines alongside the distributor. The conventions took place in various States, but never in New Jersey.” *Id.*
3. “[N]o more than four machines . . . , including the machine that caused the injuries that are the basis for this suit, ended up in New Jersey.” *Id.*
4. “J. McIntyre held both United States and European patents on its recycling technology.” *Id.* (citation omitted).

5. “[T]he U.S. distributor ‘structured [its] advertising and sales efforts in accordance with’ J. McIntyre’s ‘direction and guidance whenever possible,’ and [] ‘at least some of the machines were sold on consignment to’ the distributor.” *Id.* (citation omitted).

Justice Kennedy, in reviewing the Supreme Court’s jurisprudence on personal jurisdiction, recognized that a “defendant’s transmission of goods permits the exercise of jurisdiction only where the defendant can be said to have targeted the forum; as a general rule, it is not enough that the defendant might have predicted its goods will reach the forum State.” *Id.* at 2788. Furthermore, “personal jurisdiction requires a forum-by-forum, or sovereign-by-sovereign, analysis.” *Id.* at 2789. Justice Kennedy specifically recognized in the context of the case before the Court, “[h]ere the question concerns the authority of a New Jersey state court to exercise jurisdiction, so it is petitioner’s purposeful contacts with New Jersey, not with the United States, that alone are relevant.” *Id.* at 2790. He found that the facts recited above “reveal an intent to serve the U.S. market, but they do not show that J. McIntyre purposefully availed itself of the New Jersey market.” *Id.*

Likewise, Justice Breyer found the facts insufficient to demonstrate that it was “constitutionally proper to exercise jurisdiction over petitioner J. McIntyre . . . .” *Id.* at 2791. Justice Breyer did not find the “something more” that is required under Supreme Court precedent. *Id.* There were no regular sales in New Jersey, no “special state-related design, advertising, advice, marketing, or anything else.” *Id.* Furthermore, Justice Breyer found that J. McIntyre had not otherwise purposefully availed itself within New Jersey, and it had not “delivered its goods in the stream of commerce ‘with the expectation that they will be purchased’ by New Jersey users.” *Id.* (citing *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297–298 (1980)).

Justice Breyer did not join in the plurality opinion’s reasoning because the case could be determined by the Court’s precedents. *Id.* at 2791. Justice Breyer found it too strict to preclude jurisdiction in every case “where a defendant ‘does not inten[d] to submit to the power of a sovereign’ and cannot ‘be said to have targeted the forum,’” especially in light of the issues presented by sales over the internet. *Id.* at 2793 (quoting *id.* at 2788). And he did not agree with the New Jersey Supreme Court because its reasoning was too broad, subjecting a defendant to jurisdiction if it “knows or reasonably should know that its products are distributed through a nationwide distribution system that *might* lead to those products being sold in any of the fifty states.” *Id.* (citation omitted). Justice Breyer was concerned that such a blanket rule failed to take into account the size of the manufacturer, the distance of the forum, and the number of items that end up in the particular forum. *Id.* He continued, “the fact that the defendant is a foreign, rather than a domestic, manufacturer makes the basic fairness of an absolute rule yet more uncertain.” *Id.* at 2793–94.

The contacts in *McIntyre* largely parallel those that Proxy Ltd. has with West Virginia in this case. There are some differences, but those differences do not militate in favor of finding that Proxy Ltd. purposefully availed itself of West Virginia’s laws in particular. Proxy Ltd. differs from J. McIntyre in that it has a subsidiary (Proxy Inc.) in Ohio, at least one of its employees has visited Boston Scientific in Massachusetts, and it filed a 510(k) with the FDA indicating its intent to market Polyform in the United States. The Ohio<sup>5</sup> and Massachusetts contacts are obviously with states other than West Virginia, and the 510(k) is a contact with the United States in general. Furthermore, the contacts arising from the 510(k) are related to

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<sup>5</sup> Proxy Inc. is a separate entity from Proxy Ltd., so its activities are not necessarily imputed to Proxy Ltd. without allegations which have not been made here.

Polyform as a finished product, not the finished products at issue in this litigation that incorporate the unfinished bulk, non-sterile polypropylene mesh.

These additional facts do not suggest that Proxy Ltd. has directed activities at West Virginia in particular. The facts do not suggest anything more than the possibility that Proxy Ltd.'s products *might* be sold in West Virginia. Furthermore, there is nothing in the record indicating the extent to which the final products were sold in West Virginia. Factual allegations arising to this level were found insufficient to exert personal jurisdiction over a defendant by a majority of the Justices in *McIntyre*. 131 S. Ct. at 2788 (Kennedy, J., plurality) (“[A]s a general rule, it is not enough that the defendant might have predicted that its goods will reach the forum State.”); 131 S. Ct. at 2793 (Breyer, J., concurring in judgment) (disagreeing with the proposition that a defendant that “‘knows or reasonably should know that its products are distributed through a nationwide distribution system that *might* lead to those products being sold in any of the fifty states’” is subject to personal jurisdiction for a products-liability action (quoting *Nicastro v. McIntyre Mach. Am.*, 201 N.J. 48, 76–77, 987 A.2d 575, 592 (2010))).

*McIntyre* is in accordance with a controlling decision from the United States Court of Appeals for the Fourth Circuit. In *Lesnick v. Hollingsworth & Vose Co.*, the Fourth Circuit held that Maryland had no personal jurisdiction over Hollingsworth & Vose, a Massachusetts corporation principally operating in Massachusetts, even though there was no dispute that it sold millions of its filters to Lorillard, a U.S. cigarette manufacturer, in Kentucky and New Jersey, and Lorillard distributed its cigarettes to stores in all fifty states. 35 F.3d 939, 947 (4th Cir. 1994). The court found “no affirmative action by Hollingsworth & Vose rising to the level of purposeful availment [in Maryland].” *Id.* The instant matter is even further removed; Proxy Ltd. sold Polyform, not at issue in the proposed Amended Complaint, and unfinished bulk mesh in

Ireland to Boston Scientific and MedVenture, respectively, and shipped the products to Massachusetts and Indiana. Even if Boston Scientific distributed the finished products to all fifty states, this would not be enough, without more, for West Virginia to exert personal jurisdiction over Proxy Ltd. under *Lesnick*.

In *Estes v. Midwest Products, Inc.*, I distinguished *Lesnick* in holding that the court had jurisdiction over a defendant who sold its finished products directly to retail chains including Kmart, Wal-Mart, and others. 24 F. Supp. 2d 621, 630 (S.D. W. Va. 1998). I explained that the defendant in *Lesnick* was a component parts manufacturer that “‘relinquished’ its product into the stream of commerce, wherein a third party made it a part of a separate finished product”; therefore, it did not purposefully direct its activities toward the forum state. *Id.* The defendant in *Estes*, however, manufactured a finished product, and its “intent and purpose [were] completely revealed in its decision to sell through national retail chains.” *Id.* I reasoned that, “the defendant structure[d] its primary conduct with genuine assurance that its activities [would] render them liable to suit in West Virginia. It is the difference between shipment and setting adrift.” *Id.* Consequently, I concluded that the defendant’s sale of finished products to national retailers that have stores in West Virginia constituted a substantial connection to West Virginia that was purposefully directed toward West Virginia. *Id.* Proxy Ltd. has not directly shipped any finished product to national retailers with stores in West Virginia; rather, it ships Polyform (not named in the proposed Amended Master Complaint) to Massachusetts and unfinished bulk mesh products to either Massachusetts or Indiana to be incorporated into finished products allegedly assembled in Indiana by MedVenture for Boston Scientific. Furthermore, Proxy Ltd. has no input on the sale and marketing of its product after it is shipped to Boston Scientific. Thus, the facts favor a

finding that any contacts with West Virginia were a result of Proxy Ltd. setting its products adrift, which is not enough for this court to exercise personal jurisdiction over it.

The plaintiffs rely on *Tobin v. Astra Pharmaceutical Products, Inc.* in support of their argument that Proxy Ltd. is subject to personal jurisdiction anywhere in the United States, including West Virginia. 993 F.2d 528 (6th Cir. 1993). In *Tobin*, the plaintiff appealed the dismissal of a defendant that manufactured the drug at issue in a products-liability suit. *Id.* at 532. The Court of Appeals for the Sixth Circuit held “that dismissal was inappropriate because [the manufacturer] purposefully availed itself of the United States market.” *Id.* The court analyzed the issue of personal jurisdiction under Kentucky’s long-arm statute, which “reach[es] the limit permitted by the Constitution.” *Id.* at 542 (citing *Handley v. Indiana & Michigan Elec. Co.* 732 F.2d 1265, 1271 (6th Cir. 1984)). The court found that “[e]ven under the test set forth in the plurality opinion of *Asahi*, relied on by both [the manufacturer] and the district court, [the manufacturer] has contact that is ‘something more’ than mere awareness that the stream of commerce will sweep the product into the forum state.” *Id.* at 543 (citing *Asahi Metal Indus. Co. v. Superior Court of Calif., Solano Cty.*, 480 U.S. 102, 111–12, 107 S. Ct. 1026, 1031–32 (1987)). The court continued, “[the manufacturer] made a *deliberate decision* to market [the drug] in all 50 states, including Kentucky the forum state.” *Id.* (citations omitted). The manufacturer “did not, for example, seek a ‘New England regional distributor’ or a distributor for specific states. It sought and obtained a distributor to market its product in each and every state.” *Id.* at 544. The court reasoned that the manufacturer “did not merely sell its product on the market with no direction in mind.” *Id.* The manufacturer “directly submitted a New Drug Application to the FDA for approval, conducted clinical studies in the United States, and sought out a United States distributor to exploit the United States market.” *Id.*

The court rejected the manufacturer's argument that it did "nothing in particular to purposefully avail itself of the Kentucky market as distinguished from any other state in the union." *Id.* It stated: "If we were to accept [this argument], a foreign manufacturer could insulate itself from liability in each of the fifty states simply by using an independent national distributor to market its products . . . ." *Id.* The court went on to find the cause of action arose out of the manufacturer's purposeful availment, and personal jurisdiction did not offend "traditional notions of fair play and substantial justice." *Id.* (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316, 66 S. Ct. at 154, 158 (1945) (citations omitted)).

Addressing the main concern in *Tobin*, I initially note that a finding that there is no personal jurisdiction in West Virginia does not imply that there is no jurisdiction in any state. Furthermore, many of the contacts in the present case that align with those in *Tobin* were actions of Proxy Inc., not Proxy Ltd. The plaintiffs contend that Proxy Ltd. cannot deny that by licensing Boston Scientific to distribute Polyform in all fifty states it employed the distribution system that brought Polyform to West Virginia. Polyform, as a standalone product is not at issue in this litigation. Furthermore, similar reasoning was employed in *Tobin* in support of finding personal jurisdiction, but a similar national distribution agreement in *McIntyre* did not yield a finding of personal jurisdiction. *Tobin*, 993 F.2d at 544; *J. McIntyre*, 131 S. Ct. at 2786 ("[A]n independent company agreed to sell J. McIntyre's machines in the United States. J. McIntyre itself did not sell its machines to buyers in this country beyond the U.S. distributor, and there is no allegation that the distributor was under J. McIntyre's control."). Thus, the mere existence of a distribution agreement is not enough on its own. Furthermore, *Tobin* runs contrary to the notion that "personal jurisdiction requires a forum-by-forum, or sovereign-by-sovereign, analysis." 131 S. Ct. at 2789. The fifty states and the United States are distinct sovereigns, and a finding of

personal jurisdiction with respect to the United States is not always sufficient to find personal jurisdiction with respect to a single state. *See id.*

Further distinguishing the cases, in *Tobin*, the drug for which the defendant sought FDA approval was the drug at issue in the litigation. In the present case, FDA approval was given for Polyform as a standalone product. But it was the bulk, non-sterile version of Polyform that was incorporated into different final products, and it is those final products that are at issue in this litigation.

Justice Kennedy recognized that “[p]ersonal jurisdiction . . . restricts ‘judicial power not as a matter of sovereignty, but as a matter of individual liberty,’ for due process protects the individual’s right to be subject only to lawful power.” *J. McIntyre*, 131 S. Ct. at 2789 (quoting *Ins. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982)). “[T]he stream-of-commerce metaphor cannot supersede either the mandate of the Due Process Clause or the limits on judicial authority that Clause ensures. . . . [T]he Constitution commands restraint before discarding liberty in the name of expediency.” *Id.* 2791. In light of *McIntyre*, *Lesnick*, and the foregoing reasoning, I **FIND** *Tobin*’s reasoning unpersuasive.

#### **IV. Conclusion**

I **FIND** that this court does not have personal jurisdiction over Proxy Ltd.; and therefore, amending the Master Complaint would be futile with respect to it. Because the plaintiffs cannot fulfill the first part of the personal jurisdiction test with respect to Proxy Ltd., it is unnecessary to continue the analysis. It is also unnecessary to address the defendant’s argument with respect to the Biomaterials Access Assurance Act at this time. Thus, I **DENY** the plaintiffs’ Motion for Leave to Amend Complaint to the extent it seeks to add Proxy Ltd. Furthermore, I **DENY** the

plaintiffs' Motion for Leave to Amend Complaint to the extent it seeks to add MedVenture, TEI, and LifeCell, without prejudice. Also, I **GRANT** Proxy's Motion for Leave to file Sur-Reply.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2326 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-05785. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at [www.wvsc.uscourts.gov](http://www.wvsc.uscourts.gov).

ENTER: March 25, 2013



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JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE