IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

In Re: Pelvic Mesh Litigation	:	**FEBRUARY TERM, 2014** **NO. 829**
Master Docket	:	**652 EDA 2018**

OPINION

New, J. **May 18th, 2018**

For the reasons set forth below, this Court respectfully requests the Superior Court affirm its Order dated December 4, 2017, and docketed December 5, 2017, sustaining personal jurisdiction in these actions.

FACTUAL HISTORY

By Order dated February 11, 2014, this Court created the In Re Pelvic Mesh Litigation mass tort program for the coordination of all cases in which a plaintiff alleged she suffered injuries as a result of the implementation of a pelvic mesh medical device. Pursuant to Case Management Order 1, a "Master Docket," February Term 2014 No. 829, was created to serve as a depository for the filing of pleadings, motions, orders, and other documents common to all pelvic mesh cases; once a document or order has been filed on the Master Docket, it could be incorporated by reference in any other properly filed Motion or Pleading. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Case Management Order No. 1 at § I (March 31, 2014). Case Management Order 1 also required the filing of a Master Long-Form Complaint which made allegations common to all plaintiffs in the litigation; the filing of the Master Long-Form

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Complaint superseded the pleadings in each individual case. Id. at §§ III(A)(1), III(B)(1). Each individual plaintiff was then required to file a case-specific short-form complaint, which incorporated the Master Long-Form Complaint by reference and set forth the factual circumstances unique to that individual plaintiff. Id. at §§ III(B)(3), III(C)(I).

Various defendants[1] stated their intention to file preliminary objections based on lack of personal jurisdiction in all cases involving plaintiffs who did not reside, or have their pelvic mesh implanted, in Pennsylvania (hereinafter referred to as "non-Pennsylvania plaintiffs"). At the direction of this Court, the defendants filed on the Master Docket a Motion to Dismiss on the grounds of lack of personal jurisdiction, which encompassed all cases filed by non-Pennsylvania plaintiffs. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Motion to Dismiss (September 29, 2014). The Court permitted extensive discovery, briefing, and oral argument on the issue of personal jurisdiction. By Order dated March 30, 2015, this Court sustained personal jurisdiction over cases involving non-Pennsylvania plaintiffs, and denied the Motion to Dismiss. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Order of March 30, 2015.

In late May 2017 and early June 2017, the United States Supreme Court decided two cases involving personal jurisdiction, BNSF Ry. Co. v. Tyrell, 137 S.Ct. 1549 (2017) and Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County, 137 S.Ct. 1773 (2017). On June 30, 2017, Defendants Ethicon, Inc., and Johnson & Johnson (herein after referred to as "Moving Defendants") filed a Motion for Reconsideration in which they argued the U.S. Supreme Court's decisions in Tyrell and Bristol-Myers required this Court to dismiss the claims of non-Pennsylvania plaintiffs due to lack of personal jurisdiction.[2] See In Re Pelvic

[1] The Master Long-Form Complaint named ten defendants including, Ethicon, Inc., Johnson & Johnson, and Boston Scientific Corp.

[2] Defendant Boston Scientific Corp filed a similar Motion for Reconsideration; however, this

Mesh Litigation, February Term 2014 No. 829, Motion for Reconsideration (June 30, 2017). By Order dated August 1, 2017, and docketed August 2, 2017, this Court granted the Motion for Reconsideration, vacated the March 30, 2015 Order denying the Motion to Dismiss, and ordered further briefing on the issue of personal jurisdiction in light of Tyrell and Bristol-Myers Squibb.

In their brief, the non-Pennsylvania plaintiffs conceded this court lacked general jurisdiction, but argued this Court had specific personal jurisdiction over all cases, including those filed by non-Pennsylvania plaintiffs. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Supplemental Response in Opposition to Motion to Dismiss, at p. 2 (September 7, 2017). The non-Pennsylvania plaintiffs made two arguments in support of specific jurisdiction – 1) the involvement of a Pennsylvania based company, Secant Medical Inc.,[3] in the manufacturing process permitted this Court to exercise specific jurisdiction in cases involving non-Pennsylvania plaintiffs, Id. at pp. 6-9, and 2) this Court has specific personal jurisdiction over the cases of all non-Pennsylvania plaintiffs because Moving Defendants conducted clinical tests and safety studies in and around Allentown, Pennsylvania.[4] Id. at pp. 9-15.

With respect to the first argument, the non-Pennsylvania plaintiffs produced evidence showing a portion of the manufacturing process for eight pelvic mesh medical devices - Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur - occurred at Secant Medical, Inc.'s Bucks County facility. In the manufacturing process for these eight pelvic mesh medical devices, Moving Defendants use an extrusion

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Court limits its focus to Moving Defendants.

[3] Secant Medical Inc. was originally named as a defendant in the Master Long-Form Complaint; however, for reasons unrelated to the issue of jurisdiction, see *infra* at pp. 10-11, this Court dismissed Secant Medical Inc. by Order dated August 25, 2014.

[4] Since this Court sustained specific personal jurisdiction under the first argument, the second argument advanced by the non-Pennsylvania plaintiffs will not be addressed.

process at their facility in Georgia to transform polypropylene resin pellets, known as PROLENE®, into spools of filament. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Supplemental Response in Opposition to Motion to Dismiss, Ex. "A" (Affidavit of James O. Williams), at ¶¶ 6-8. Moving Defendants send the spools of PROLENE® filament to Secant's facility in Perskasie, Bucks County, where Secant knits the filament into mesh according to specifications set forth by Moving Defendants. Id. at ¶¶ 12-17. Secant then returns the knitted mesh to Moving Defendants, who engage in further steps of the manufacturing process. Id. at ¶¶ 17-18.

At oral argument, this Court enquired whether Secant knitted the mesh used in every pelvic mesh medical device produced by Moving Defendants; the parties provided conflicting responses. Accordingly, the Court issued an Order, dated September 15, 2017, and docketed September 18, 2017, requesting post-argument briefing focused on two questions: 1) whether Secant Medical, Inc., was the exclusive provider of mesh used in the pelvic mesh medical devices, and 2) if not, whether it was possible to discern if a particular pelvic mesh medical device contained Secant-provided mesh. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Order docketed September 18, 2017. The parties conducted discovery relevant to the issues presented in the September 18th Order and filed post-argument briefs in support of their respective positions.

The post-argument discovery revealed two classes of non-Pennsylvania plaintiffs –1) women implanted with the Prolift+M pelvic mesh medical device, and 2) women implanted with one of eight other pelvic mesh medical devices, Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur, manufactured by Moving Defendants. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Second Supplemental Response in Opposition to Motion to Dismiss, at p. 3 (November 6, 2017). James

Williams, the strategic sourcing manager for Ethicon, testified that between 2001 and 2015, Secant knitted the mesh used in all of the Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur pelvic mesh medical devices. Id. at Ex. "D" (Deposition of James O. Williams), at 31:5-32:4, 35:21-36:12, 62:11-69:9, 72:2-73:2 (October 25, 2017). Secant was not involved in the manufacturing of the Prolift+M. See Id. at p. 3 (citations omitted).

By Order dated December 4, 2017, and docketed December 5, 2017 on the Master Docket, this Court granted the Motion to Dismiss in part and denied the Motion to Dismiss in part. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Order docketed December 5, 2017. This Court sustained personal jurisdiction over cases involving non-Pennsylvania plaintiffs implanted with the Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, or TVT-Secur pelvic mesh medical devices, but found a lack of personal jurisdiction over cases in which the non-Pennsylvania plaintiff was implanted with the Prolift+M pelvic mesh medical device. Id.

Moving Defendants filed a Motion to Amend in which they requested this Court amend its December 4th Order to include the language prescribed by Pa.R.A.P. 311(b)(2). See Pa.R.A.P. 311(b)(2) (providing an interlocutory appeal as of right in cases in which the trial court sustained personal jurisdiction if "the court states in the order that a substantial issue of venue or jurisdiction is presented"). On January 2, 2018, a non-Pennsylvania plaintiff who had been implanted with the Prolift+M pelvic mesh medical device, Ronna Moore, appealed the dismissal of her case for lack of personal jurisdiction. See Moore v. Ethicon, Inc., et al., July Term 2013 No. 1485. In light of the fact a portion of the December 4th Order was subject to appellate review by virtue of Ms. Moore's appeal, this Court believed judicial economy would best be served if an appellate court reviewed the December 4th Order in its entirety. Accordingly, by

Order dated February 9, 2018, this Court granted Moving Defendants' Motion to Amend, and added the necessary language from Rule 311(b)(2), thereby granting Moving Defendants an appeal as of right.[5] For the reasons set forth below, this Court respectfully requests the Superior Court affirm its December 4th Order sustaining jurisdiction over Moving Defendants as it relates to the non-Pennsylvania plaintiffs.

ANALYSIS

Pennsylvania courts may exercise personal jurisdiction over an out-of-state resident if jurisdiction is conferred by the long-arm statute and the exercise of jurisdiction does not offend the Due Process Clause of the Fourteenth Amendment to the United States Constitution. Nutrition Management Services Co. v. Hinchcliff, 926 A.2d 531, 537 (Pa. Super. 2007). The long-arm statute sets forth a list of ten activities that may serve as the basis for the exercise of personal jurisdiction. See 42 Pa. C.S. § 5322(a). Here, the long-arm statute permits the exercise of jurisdiction over Moving Defendants because there is no dispute Moving Defendants transact business in this Commonwealth. See 42 Pa. C.S. § 5322(a)(1) (permitting the exercise of jurisdiction over a defendant who "transact[s] any business in this Commonwealth."). Accordingly, this Court may exercise jurisdiction over Moving Defendants so long as the exercise of jurisdiction comports with the Due Process Clause.

The Due Process Clause limits the authority of a state to exercise personal jurisdiction over non-resident defendants. Mendel v. Williams, 53 A.3d 810, 817 (Pa. Super. 2012)(citing Burger King Corp. v. Rudzewicz, 471 U.S. 462, 105 S.Ct. 2174 (1985)). "The extent to which jurisdiction is proscribed by the Due Process Clause is dependent upon the nature and quality of the defendant's contacts with the forum state." Id. (citations omitted). A court may exercise

[5] By Order dated February 13, 2018, the Superior Court quashed Ms. Moore's appeal. See Moore v. Ethicon, Inc., et al., 175 EDA 2018.

personal jurisdiction over an out-of-state defendant who has "certain minimum contacts with [the State] such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" International Shoe Co. v. Washington, 326 U.S. 310, 66 S.Ct. 154, 158 (1945) (citations omitted). "Where a defendant 'has established no meaningful contacts, ties or relations' with the forum, the Due Process Clause prohibits the exercise of personal jurisdiction." Mendel, 53 A.3d at 817 (citations omitted). "A defendant's activities in the forum State may give rise to either specific jurisdiction or general jurisdiction." Id. (citations omitted).

Here, the non-Pennsylvania plaintiffs conceded this Court lacks general jurisdiction over Moving Defendants. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Supplemental Response in Opposition to Motion to Dismiss, filed September 7, 2017, at p. 2 ("Initially, Plaintiffs agree that [Ethicon, Inc., and Johnson & Johnson are] not subject to general jurisdiction in Pennsylvania."). Accordingly, for this Court to exercise jurisdiction over Moving Defendants, there must be specific jurisdiction.

In order for a state court to exercise specific personal jurisdiction, "the suit must arise out of or relate to the defendant's contacts with the forum." Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County, 137 S.Ct. 1773, 1780 (2017) (internal quotes and citations omitted). "[T]here must be an affiliation between the forum and the underlying controversy, principally, [an] activity or occurrence that takes place in the forum State and is therefore subject to the State's regulation." Id. (internal quotes and citations omitted). Additionally, a plaintiff must show 1) there are sufficient pre-litigation connections between the non-resident defendant and the forum and 2) the non-resident defendant purposefully availed itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws. Burger King, 105 S.Ct. at 2182-84. Specific jurisdiction analysis requires an examination of the unique facts of each case; however, "the inquiry distills to whether the defendant has availed itself of the minimum contacts necessary to vest the Commonwealth with jurisdiction such that it comports with fair play and substantial justice." Haas v. Four Seasons Campground, Inc., 952 A.2d 688, 693 (Pa. Super. 2008).

In Bristol-Myers, more than 600 plaintiffs, most of whom were not California residents, filed suit in California state court against Bristol–Myers Squibb Company alleging they were injured as a result of taking Plavix. Bristol-Myers, 137 S.Ct. at 1777. The non-California residents were not prescribed Plavix in California, did not purchase Plavix in California, did not ingest Plavix in California, and were not injured by Plavix in California; nevertheless, the California Supreme Court held California's trial courts had specific personal jurisdiction over Bristol-Myers Squibb. Id. at 1781. Utilizing a "sliding-scale" approach, the California Supreme Court reasoned it had specific personal jurisdiction over the nonresidents' claims because of Bristol-Myers Squibb's extensive contacts in California and the fact the nonresidents' claims were similar to the claims of California residents. Id. The United States Supreme Court reversed, holding the "sliding-scale" method used by the California Supreme Court conflicted with U.S. Supreme Court precedent. Id. at 1782. Applying their own precedent, the U.S. Supreme Court held the California courts lacked specific jurisdiction over nonresidents' claims because the nonresidents were not injured in California and none of Bristol-Myers' conduct occurred in California. Id.

Furthermore, the United States Supreme Court held Bristol-Myers' decision to contract with a California company, McKesson, to be its national distributor of Plavix was insufficient to grant California courts specific personal jurisdiction because a relationship with a third party, standing alone, is an insufficient basis for jurisdiction. Bristol-Myers, 137 S.Ct. at 1783. In reaching this conclusion, the Court noted there were no allegations Bristol-Myers engaged in relevant acts together with McKesson in California, or a nonresident took a Plavix pill distributed by McKesson. Id.

In the case *sub judice*, the non-Pennsylvania plaintiffs established Moving Defendants have sufficient minimum contacts with Pennsylvania such that this Court's exercise of personal jurisdiction comports with the notion of fair play and substantial justice. Moving Defendants purposefully availed themselves of the privilege of doing business in Pennsylvania by reaching out to a Pennsylvania-based corporation, Secant Medical, Inc., to fulfill its manufacturing needs. As demonstrated by the affidavit and deposition of James Williams, an integral portion of the manufacturing process of the Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur pelvic mesh medical devices occurs in Perkasie, Bucks County, Pennsylvania. Specifically, for each of these devices, Secant Medical, Inc. knits the Prolene® filament into mesh according to specifications set forth by Moving Defendants at its Bucks County facility before returning the knitted mesh to Moving Defendants for further processing. See Williams Affidavit at ¶¶ 12-18, Williams Deposition at 31:5-32:4, 35:21-36:12, 62:11-69:9, 72:2-73:2. Since a portion of the manufacturing process of the Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur pelvic mesh medical devices occurs in Pennsylvania, this Court's exercise of specific personal jurisdiction comports with traditional notions of fair play and substantial justice.

Furthermore, unlike in Bristol-Myers, where the United States Supreme Court observed there were no allegations Bristol-Myers engaged in relevant acts with McKesson in California, Moving Defendants in the case *sub judice* are alleged to have engaged in relevant acts with Secant Medical, Inc. in Pennsylvania by contracting with Secant for the manufacture of eight of the pelvic mesh medical devices at issue. In Bristol-Myers, the United States Supreme Court focused on the fact none of the non-California residents alleged they ingested a Plavix pill distributed by McKesson. In this case, the allegations and the evidence show the opposite –

every plaintiff who was implanted with a Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur pelvic mesh medical device received a medical device that was manufactured, in part, in Bucks County, Pennsylvania. Based on these connections with Pennsylvania, this Court has specific jurisdiction over any non-Pennsylvania plaintiff's case which involved the implant of a Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, or TVT-Secur pelvic mesh medical device. Contra Bristol-Myers, 137 S.Ct. at 1783.

Moving Defendants make three arguments as to why this Court lacks specific jurisdiction; none of Moving Defendants' arguments are persuasive. First, Moving Defendants argue Secant's involvement in the manufacturing process cannot serve as the basis for specific jurisdiction because Secant's role is *de minimus*. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Moving Defendants' Supplemental Response in Support to Motion to Dismiss, at pp. 2-8 (November 6, 2017). The factual record, as set forth above, undermines Moving Defendants' argument that Secant's role is *de minimus*. While Moving Defendants correctly point out the process of manufacturing a pelvic mesh medical device involves multiple steps – including the extrusion of polypropylene pellets into filament, knitting the filament into a mesh, testing the mesh, cutting the mesh, sterilizing the mesh, and adding other component parts – Secant's role is far from *de minimus*. Indeed, Secant's job is to knit filament into the mesh used in pelvic *mesh* medical devices. In light of this crucial role Secant Medical, Inc., plays in the manufacturing process for pelvic mesh medical devices, Moving Defendants' first argument fails.

Next, Moving Defendants argue Secant is not a manufacturer as defined by the Biomaterials Access Assurance Act (BAAA), 21 U.S.C. § 1601, *et seq*. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Moving Defendants' Supplemental Response in

Support to Motion to Dismiss, at pp. 2-8. This argument is misplaced. Congress adopted the BAAA as a policy initiative to ensure the continued availability of raw materials and component parts for medical devices by insulating suppliers of raw materials and component parts from liability. 21 U.S.C. § 1601. The BAAA achieves this policy goal by limiting liability to "manufacturers" of medical devices and defining "manufacturer" in such a way that suppliers of raw materials and component parts fall outside of the definition of "manufacturer." See 21 U.S.C. § 1604(b)(1); 21 U.S.C. § 1602(6). The BAAA does not address the issue of personal jurisdiction. Therefore, the fact this Court previously dismissed Secant pursuant to the BAAA is wholly irrelevant to the issue of personal jurisdiction.

Finally, Moving Defendants argue Secant's knitting of the mesh cannot serve as the basis for jurisdiction because Secant's activities do not serve as the basis for the non-Pennsylvania plaintiff's claims. See In Re Pelvic Mesh Litigation, February Term 2014 No. 829, Moving Defendants' Supplemental Response in Support to Motion to Dismiss, at pp. 9-11. Specifically, Moving Defendants argue the non-Pennsylvania plaintiffs' theories of liability focus on the design of the pelvic mesh medical devices, the manner in which the mesh is cut, and implementation techniques, none of which is controlled by Secant. Id (citing the arguments made in Hammons v. Ethicon, Inc., May Term 2013 No. 3913, Carlino v. Ethicon, Inc., June Term 2013 No. 3470, and Engleman v. Ethicon, Inc., March Term 2014 No. 5384). The argument fails. The Master Long Form Complaint is the operative pleading in this litigation. A review of the Master Long Form Complaint reveals it contains a manufacturing defect claim. See Master Long Form Complaint at ¶¶ 117-122. At the time the Master Long Form Complaint was filed, Secant was a named Defendant. Id. at ¶¶ 15-19, 41-42. Indeed, the manufacturing defect claim alleges Secant, together with other named defendants, "deviated materially from their design and manufacturing specifications ...." Id. at ¶¶ 18-19, 118. The existence of this manufacturing defect claim grants this Court specific personal jurisdiction because, as detailed above, Secant is involved in the manufacturing process. The fact other non-Pennsylvania plaintiffs have subsequently abandoned their manufacturing defect claim at the summary judgment stage or at trial is irrelevant.

At this stage of the proceedings, the non-Pennsylvania plaintiffs have alleged manufacturing defect claims, and a portion of the manufacturing process occurred at Secant's Pennsylvania facility; accordingly, this Court has specific personal jurisdiction. See Bristol-Meyers, 137 S.Ct at 1780 ("In order for a state court to exercise specific jurisdiction, the *suit* must arise out of or relate to the defendant's contacts with the *forum*") (emphasis in original) (internal quotations and citations omitted). Every non-Pennsylvania plaintiff who was implanted with a Gynemesh/Gynemesh PS, Prolene, Prolift, Prosima, TVT, TVT-Exact, TVT-Obturator, and TVT-Secur pelvic mesh medical device received a medical device manufactured, in part, at Secant's Bucks County facility. Furthermore, the exercise of personal jurisdiction over Moving Defendants comports with the notion of fair play and substantial justice because for at least the past seventeen years, Moving Defendants purposefully availed themselves of the privilege of conducting activities in the Commonwealth by contracting with a Pennsylvania manufacturers, Secant Medical Inc., to perform a portion of the manufacturing process. See Burger King, 105 S.Ct. at 2182-84. Accordingly, under International Shoe and its progeny, this Court sustained specific personal jurisdiction over Moving Defendants' for the non-Pennsylvania residents' claims.

WHEREFORE, for the reasons set forth above, this Court respectfully requests the Superior Court affirm its Order dated December 5, 2017 dismissing this matter for lack of personal jurisdiction.

BY THE COURT:

ARNOLD L. NEW, J.