In The Supreme Court Of Pennsylvania

No. 7 EAP 2019

PATRICIA L. HAMMONS,
Plaintiff-Appellee,
v.
ETHICON, INC.; and JOHNSON & JOHNSON,
Defendants-Appellants,
and
GYNECARE; SECANT MEDICAL; SECANT MEDICAL INC.; PRODESCO, INC.; and SECANT MEDICAL, LLC,
Defendants.

REPLY BRIEF FOR DEFENDANTS-APPELLANTS

Appeal by allowance granted April 10, 2019, from the Panel Decision of the Superior Court in 1526 EDA 2016 and 1522 EDA 2016 (190 A.3d 1248), dated June 19, 2018, En Banc *Reargument Denied, August 29, 2018; affirming the Order of the Court of Common Pleas of Philadelphia County, May Term 2013, No. 3913 (Bernstein, J.), dated April 14, 2016, Entering Judgment Following a Jury Verdict and Denial of Post-Trial Motions*

D. Alicia Hickok (PA ID No. 87604)
William L. Carr (PA ID No. 200274)
Mark D. Taticchi (PA ID No. 323436)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700 (telephone)
(215) 988-2757 (facsimile)
alicia.hickok@dbr.com
william.carr@dbr.com
mark.taticchi@dbr.com

Julie A. Callsen (PA ID No. 323883)
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113
(216) 592-5000 (telephone)
(216) 592-5009 (facsimile)
julie.callsen@tuckerellis.com

Robert C. Heim (PA ID No. 15758)
Judy L. Leone (PA ID No. 41165)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
(215) 994-2015 (telephone)
robert.heim@dechert.com
judy.leone@dechert.com

Attorneys for Defendants-Appellants Ethicon, Inc.; and Johnson & Johnson

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

STATUTES, RULES & REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

Plaintiff Patricia Hammons's Brief in Opposition ("Opp'n") confirms the case for reversal. Plaintiff is an Indiana resident who was implanted with a Prolift device in Indiana. She brought design-defect and failure-to-warn claims under Indiana law based on injuries she sustained in Indiana. Nothing about those claims relates in any way to Pennsylvania, other than Plaintiff's choice to file suit here.

The Prolift device consisted of pieces of specially-shaped, non-absorbable mesh implants and instruments to facilitate placement of the mesh. In Plaintiff's telling, her claims focus on the "physical properties" of the mesh Ethicon chose to use in Prolift (called Gynemesh Prolene Soft or Gynemesh PS), but she offered no evidence showing that the conduct she challenges—the choice to use that mesh in the Prolift device or the design of the device itself—occurred in Pennsylvania. Specific jurisdiction exists only where the conduct giving rise to the Plaintiff's substantive claims occurred in-state. The conduct at issue here did not, so personal jurisdiction is lacking.

In advocating a different outcome, Plaintiff answers a question other than the one on which this Court granted *allocatur*—indeed, she wrote and answered an entirely different question. *Compare* 206 A.3d 495, *with* Opp'n 2. She also derives the wrong rule from the relevant Supreme Court precedent, including the

Court's recent decision in *Bristol-Myers Squibb Co. v. Superior Court of California* [hereinafter *BMS*], 137 S. Ct. 1773 (2017).

According to Plaintiff, the question posed by *BMS* is whether Plaintiff's "lawsuit is related to or affiliated with the defendant's activities in the forum." Opp'n 14. That is doubly wrong. *BMS* makes clear that the relevant nexus is between Plaintiff's ***claims*** and the defendant's in-state conduct. *BMS*, 137 S. Ct. at 1781 (focusing on "the conduct giving rise to the nonresidents' claims" and the "connection between the forum and the specific claims at issue"). And that nexus must be "substantial," *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985); the in-state conduct forming the basis for jurisdiction must also form the basis of the plaintiff's claims. *BMS*, 137 S. Ct. at 1781; *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011).

The loose "affiliation" test advanced by Plaintiff and inappropriately adopted by the Superior Court, by contrast, is no different than the test rejected in *BMS*. The presence of a component supplier in the Commonwealth, when the finished product was made out of state, does not change that result. Rather, Plaintiff's effort to make it a jurisdictional hook only emphasizes the extent to which her position is at odds with the Supreme Court's holding.

Properly applied, *BMS*, the decisions that preceded it, and Pennsylvania law all foreclose Plaintiff's arguments. Plaintiff asserts that Ethicon's contract with its

in-state component supplier Secant to knit unfinished mesh is sufficient to ground jurisdiction because this is a mesh-related lawsuit and Secant engaged in mesh-related activity. The problem for Plaintiff is that Secant's conduct does not form the basis for her claims. Plaintiff did not show that Secant designed the mesh for Prolift, had any role in choosing its pre-cut shapes, had any role in the development of the instruments needed to implant that mesh, or made the choice to use the mesh in Prolift—all activity that took place outside Pennsylvania. Plaintiff has not even offered evidence that the knitted mesh, when it left Secant, was in a form to be used in Prolift without further out-of-state activity by Ethicon. That Secant did not feature in Plaintiff's trial presentation confirms its irrelevance to the substance of her claims. Plaintiff's reliance on the conduct of Allentown physician Dr. Vincent Lucente is likewise unavailing. Dr. Lucente's participation in clinical trials—as one of numerous doctors across the globe—does not form the basis for Plaintiff's claims, nor does any other conduct by Dr. Lucente.

The decision below should be reversed.

ARGUMENT

I. THE TRIAL COURT LACKED PERSONAL JURISDICTION OVER DEFENDANTS FOR PLAINTIFF'S CLAIMS.

A. Settled Principles Foreclose Specific Personal Jurisdiction.

Specific jurisdiction exists only when the plaintiff's claims "arise out of or relate to the foreign corporation's activities in the forum State." *Helicopteros*

Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414 (1984). It is not enough, as Plaintiff repeatedly contends, for there to be a loose "'connection' between Ethicon, Pennsylvania, and [her] lawsuit." Opp'n 31. The Supreme Court has been unmistakably clear that there must be a "connection between the forum and the ***specific claims at issue***." *BMS*, 137 S. Ct. at 1781 (emphasis added). As explained at length in Defendants' Principal Brief ("Br."), that connection is entirely lacking. *See* Br. 29-33.

The relevant facts are not disputed. Plaintiff is an Indiana resident who suffered from pelvic organ prolapse. To treat her condition, Plaintiff received a Prolift device. Plaintiff received warnings about the device in Indiana or Kentucky, was implanted with the device in Indiana, received follow-up medical care in Indiana and Kentucky, and suffered her injuries in Indiana. In other words, Plaintiff has no relationship to Pennsylvania, other than her choice to file suit here.

Nor do her claims. Plaintiff tried two claims under Indiana's Product Liability Act: design defect and failure to warn. Ind. Code § 34-20-20-2; *see* Opp'n 8 (acknowledging design-defect and failure-to-warn liability findings). In support of her failure-to-warn claim, Plaintiff argued that Prolift did not contain adequate warnings under Indiana law because the package insert allegedly omitted a number of risks. Opp'n 39. But Plaintiff does not and cannot contend that

Prolift's warnings were in any way developed here, making the jurisdictional analysis especially simple: There is none. *See* Br. 28.

Looking at Plaintiff's design-defect claim leads to the same conclusion. Plaintiff now asserts that her claim "focused entirely on the physical properties of the mesh." *E.g.*, Opp'n 39. The mesh in Prolift, Gynemesh PS, was developed initially for hernia repair and was later used in gynecologic applications, as Plaintiff herself acknowledges. Opp'n 5. According to Plaintiff, the mesh was "toxic, dense, inelastic," had pores that were "too small," and "degraded and shed particles after implantation." *Id*. at 3. But none of this would have mattered if Ethicon had not chosen to use that mesh, rather than some other mesh, in Prolift.

Plaintiff identifies no evidence that Gynemesh PS was designed in Pennsylvania and has never asserted that the decision to use Gynemesh PS in Prolift was made in the Commonwealth. That is because it was not. The decision to use that mesh as part of the Prolift device was made in France and New Jersey. *See* Br. 8-9. As in *BMS* and the myriad other cases cited in Defendants' Brief, "what is needed—and what is missing here—is a connection between the forum" and Plaintiff's actual design-defect claim. *BMS*, 137 S. Ct. at 1781.

Not only does settled law foreclose Plaintiff's assertion of specific jurisdiction, but so do the first principles that animate it. The Constitution's limits on the exercise of personal jurisdiction derive from the Due Process Clause.

Burger King Corp., 471 U.S. at 471-72. The Supreme Court has identified several "legitimate[]" state interests that support the exercise of personal jurisdiction consistent with due process. *Id*. at 473; *see BMS*, 137 S. Ct. at 1780. A state has a strong interest in providing a forum to vindicate the rights of in-state plaintiffs or plaintiffs who sustained their injuries in state. *Burger King*, 471 U.S. at 473.[1] A state also has a legitimate interest in regulating in-state conduct, but only when that in-state conduct forms the basis for the plaintiff's claims. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 884 (2011) (plurality op.) ("question is whether" a defendant has directed conduct at the forum state "so that the sovereign has the power to subject the defendant to judgment concerning that conduct"). Neither interest is present here. Adjudicating this controversy does not protect Pennsylvania plaintiffs—Plaintiff is an Indiana resident who sustained her injuries in Indiana. And it does not regulate Pennsylvania conduct—all of the decisions that Plaintiff challenges occurred elsewhere.

Because the relevant conduct took place elsewhere, the exercise of personal jurisdiction also threatens principles of federalism. *See BMS*, 137 S. Ct. at 1780-81; Br. 25-26. To the extent she addresses federalism at all, Plaintiff casually dismisses it by declaring that personal jurisdiction does not involve "a choice-of-

[1] That Ethicon did not object to personal jurisdiction in ***other*** cases involving non-Pennsylvania plaintiffs who were implanted in Pennsylvania, *see* Opp'n 42, obviously says nothing about whether personal jurisdiction exists ***here***.

law analysis." Opp'n 42. But the question presented obviously is not one of choice of law—it is whether the Constitution and the Pennsylvania statute permit Commonwealth courts to adjudicate disputes arising from conduct that took place entirely in other states, whether or not Pennsylvania law applies.

Of course, there is immense practical significance to the choice-of-law issue Plaintiff flagged—and it too defeats Plaintiff's position. Authorizing jurisdiction in circumstances like these will almost always require courts of this Commonwealth to apply the unfamiliar substantive law of another state. Disputes about foreign law will inevitably slow down protracted proceedings and proliferate appeals, as they have here.[2] And they do not develop the Commonwealth's law or the law of the state with an actual connection to the plaintiff's claims (here Indiana and New Jersey). That these practical consequences militate strongly against the exercise of jurisdiction is further proof that her jurisdictional position must be incorrect.

These are not the only principles that compel rejecting Plaintiff's position. For a number of reasons, jurisdictional rules should be straightforward. *See Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980). Plaintiff's rule is anything but. Under

[2] Of the cases tried and yet to be tried in this mass-tort proceeding, only approximately 10% involve Pennsylvania law.

Plaintiff's rule it is entirely unclear what type of "connection" is sufficient for jurisdiction, other than the type of generalized, sliding-scale contacts explicitly rejected in *BMS*. *Compare* Opp'n 53 ("Ethicon produced its mesh for a national market. Obviously Ethicon was on notice that it could be sued anywhere."), *with BMS*, 137 S. Ct. at 1781 (rejecting sliding-scale approach like Plaintiff's that would have resulted in near-Nationwide jurisdiction). Defendants' rule (also the Supreme Court's rule), by contrast, is both easy to administer and legally correct: Specific jurisdiction exists when the conduct giving rise to the plaintiff's claims had a meaningful connection to the forum state. *See* Br. 21-26. That is absent here.

Not only is Plaintiff wrong about the law, but she is also wrong about the principles at issue. Her sole argument is that jurisdiction is proper because "there is no surprise." Opp'n 34; *id*. at 31-32. Even if Plaintiff were correct, the absence of "surprise" is not itself sufficient to ground jurisdiction. *See J. McIntyre Mach., Ltd.*, 564 U.S. at 883 (plurality op.). Indeed, the Supreme Court has explicitly held that the foreseeability of injury in a forum state (which is also lacking in this case) is insufficient, explaining that jurisdiction exists when the defendant purposefully avails itself of the benefits of the forum such that the plaintiff's claims result from alleged injuries that "arise out of or relate to" the defendant's in-state activities.

Burger King, 471 U.S. at 472-74 (citation omitted). Plaintiff's claims do not, and the decision below should be reversed.

B. Secant's Pennsylvania Contacts Cannot Ground Personal Jurisdiction.

Plaintiff's principal theory on appeal concerns Ethicon's contract with Secant, a third-party component supplier with whom Ethicon contracted to manufacture mesh for Ethicon's pelvic-mesh devices. Secant cannot support specific jurisdiction, and Plaintiff's effort to cast it as a viable jurisdictional hook rests not only on misstatements of the law but also on mischaracterizations of the factual record. *See* Br. 29-33.

1. Secant's role in the manufacturing process cannot support jurisdiction over Defendants for Plaintiff's design-defect and failure-to-warn claims.

Secant's role in the "production" of Prolift was a limited one.[3] As explained, Secant ***manufactured*** unfinished, bulk rolls of mesh pursuant to specifications set by Ethicon. That much is clear from the three affidavits on

[3] Plaintiff's brief contains numerous factual inaccuracies, underscoring the importance of consulting the source material. Plaintiff asserts, for example, that "Ethicon ... produced 100% of the mesh at the Secant facility" in Bucks County, Opp'n 11, and that "[w]orking with Secant, Ethicon developed and produced virtually all of the mesh used in its pelvic mesh products, including the mesh implanted into" Plaintiff, *id.* at 22. But Ethicon did not produce anything in Pennsylvania. *See, e.g.*, R.267b–R.271b. As explained, *infra* at 10-12, Secant knit unfinished rolls of mesh and then shipped them out of state for further processing and for the production of medical devices. Plaintiff also incorrectly suggests that Ethicon "purchased" mesh from Secant. Opp'n 43. Ethicon purchased services from Secant (knitting), but retained ownership of the bulk rolls.

which Plaintiff relies. *See* Opp'n 22-23. Because factual accuracy is of paramount importance,[4] Defendants provide the following recap of the manufacturing process as described in those affidavits:

Ethicon first "creates polypropylene resin pellets referred to as PROLENE® using a proprietary formula and procedure." R.266b. Ethicon next "transforms the pelletized pigmented or unpigmented polypropylene resin into spools of PROLENE® filament (a thin yarn) through an extrusion process." *Id*. All of this occurs out of state.

Ethicon then "sends the PROLENE® filament to Secant," R.267b, a third-party contractor in Bucks County, Pennsylvania. "Secant knits the polypropylene PROLENE® filament into large rolls of PROLENE® mesh pursuant to Ethicon's specifications." *Id*. And then it "returns the bulk rolls to Ethicon for further processing" out of state. *Id*. That out-of-state processing includes "cutting individual units of implantable mesh from the large mesh rolls, assembly of those individual units with other component parts such as surgical tools, sterilization of

[4] Plaintiff repeatedly misstates the standard of review (and the facts), urging this Court to construe the evidence in her favor. *See, e.g.*, Opp'n 1, 14, 25, 34-35. This case arises out of factual findings after a hearing, Pa.R.C.P. No. 1028(c)(2), and thus "it is the actual ***proof*** that counts." *C.G. v. J.H.*, 172 A.3d 43, 55 (Pa. Super. 2017). "[O]n preliminary objections that require a factual hearing, … there is no longer any need to give the plaintiff the benefit of any doubt about its case." *Id*. Regardless, under any view of the facts, Plaintiff's claims fail. *See Allstate Life Ins. Co. v. Commonwealth*, 52 A.3d 1077, 1080 (Pa. 2012) (whether the facts the trial court found support jurisdiction is a question of statutory and constitutional construction, reviewed *de novo*).

the unit, [and] finished product testing." R.268b. Indeed, "[w]ithout further [out-of-state] processing performed by Ethicon, the mesh component knitted by Secant has no implant value or purpose." R.267b. Thus, the ***only*** part of the process that occurs in Pennsylvania is the knitting of polypropylene threads into bulk rolls of unfinished mesh that could be used in any number of Ethicon's products.

Secant's bulk-roll knitting process is governed entirely by designs and specifications set by Ethicon out of state. Ethicon, not Secant, determines the specifications governing the "characteristics of the mesh"—in Plaintiff's words, "its physical properties"—"including its elasticity, density, mass, and areal density." *Id*. And "Ethicon establishes the specifications for the knitting of the mesh component of Ethicon's pelvic mesh devices and imposes these specifications on Secant." *Id*. To be sure, Secant tests samples of the raw mesh, but only "to ensure that Secant has knit the mesh per Ethicon's specifications." R.271b. As explained, the trial court found that Secant complied with Ethicon's specifications ***as a matter of law***. Br. 2, 31.

Other than Secant's limited role as the component supplier knitting polypropylene filament into bulk rolls of mesh, it "plays no role in the final manufacture, marketing, promotion, sale, packaging and/or distribution of Ethicon's implantable pelvic mesh devices." R.267b; *see also* Opp'n 51 (conceding that Secant's knitting of mesh was only "one step in a long chain" that

led to Ethicon's devices, all but one of which occurred out of state). "Ethicon, and not Secant, is responsible for conducting any preclinical testing or clinical trials on its pelvic mesh products, in compliance with applicable regulations." R.268b. And "Ethicon, and not Secant, is responsible for developing the packaging inserts, labels and marketing materials for its pelvic mesh products." *Id*.[5]

These undisputed facts show that Secant's role was limited to ***manufacturing*** unfinished mesh pursuant to design specifications set by Ethicon out of state. But again, Plaintiff's claims did not take issue with the manufacturing of Prolift's mesh. Her design-defect claim took issue with the decision to use Prolene Soft as the mesh for Prolift—a decision that was made entirely out of state and, indeed, out of the country.[6] Because "specific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction," Secant provides no basis to exercise personal jurisdiction here. *BMS*, 137 S. Ct. at 1780; *see* Br. 29-33.

Put differently, while Secant's "activities in Pennsylvania" might relate tangentially to the broad subject of "Ms. Hammons' ***lawsuit***," Opp'n 21-22 (emphasis added), insofar as Secant knit the unfinished mesh that was ultimately

[5] The emails cited by Plaintiff, Opp'n 24, tell exactly the same story. They show only that Ethicon supervised Secant's ***manufacture*** of rolls of polypropylene mesh. *See* Br. 14, 31-32.

[6] Plaintiff's failure-to-warn claim took issue with Ethicon's alleged omission of certain risks from Prolift's Instructions for Use. *Supra* at 4. Secant played no part in the creation of those warnings. R.268b.

incorporated into her implant, Secant's activities do not relate to ***Plaintiff's claims***. Those claims are not based on any conduct that occurred, or any decision that was made, during the in-state knitting process. Indeed, Plaintiff's studied efforts to avoid using the word "design," and her focus instead on the "physical properties" of mesh and "mesh production," unmoored form the claims she tried, speaks volumes.

The absence of a meaningful connection between ***Plaintiff's claims*** and Secant forecloses jurisdiction. *See BMS*, 137 S. Ct. at 1781 (finding no jurisdiction because "the conduct giving rise to the nonresidents' claims occurred elsewhere" and focusing on the "connection between the forum and the specific claims at issue"); *Goodyear*, 564 U.S. at 919; *see also* 42 Pa.C.S. § 5322(c); *Slota v. Moorings, Ltd.*, 494 A.2d 1, 5 (Pa. Super. 1985).[7] This is a bedrock jurisdictional rule. *See, e.g.*, *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945) (a state court may exercise specific jurisdiction over an out-of-state defendant only when the defendant's in-state conduct "give[s] rise to the liabilities sued on"); *see also id*. at 320.

[7] Even the Superior Court recognized this rule, *Hammons v. Ethicon, Inc.*, 190 A.3d 1248, 1262 (Pa. Super. 2018) ("Specific jurisdiction enables a court to adjudicate ***claims arising from activity that occurs within the forum state's borders*** and is therefore 'subject to the State's regulation.'" (emphasis added) (quoting *BMS*, 137 S. Ct. at 1780), though it failed to apply that rule and inexplicably ignored Plaintiff's failure-to-warn claim.

At most, Ethicon's relationship with Secant might have established jurisdiction for a manufacturing-defect claim arising from some failure by Secant to knit the mesh to Ethicon's specifications.[8] But Plaintiff made no such allegations, let alone pursued a manufacturing-defect claim at trial, *see* Br. 24 n.7, and she does not assert that jurisdiction was proper with respect to her design-defect and failure-to-warn claims by piggy-backing on the long-dismissed manufacturing-defect claim. For good reason. As explained at length, specific jurisdiction must be determined on a claim-by-claim basis, Br. 22-23, so even if Plaintiff argued that there was jurisdiction with respect to her manufacturing-defect claim, that could not as a matter of law establish jurisdiction for the design-defect and failure-to-warn claims she actually tried.

Plaintiff disagrees that due process prescribes a claim-by-claim analysis, Opp'n 37-40, but offers no support for her position. She observes that the federal cases cited by Defendants are "not binding," *id*. at 39, but identifies no Pennsylvania case—indeed, no case from any jurisdiction, state or federal—adopting her approach. That is unsurprising, because a claim-by-claim analysis is the generally recognized rule. Br. 22-23; *see also*, *e.g.*, *Seifarth v. Helicopteros*

[8] Plaintiff notes that Secant was dismissed as a defendant under the Biomaterials Access Assurance Act, Opp'n 32, but omits to mention that the basis for that dismissal was the trial court's unchallenged finding that Secant satisfied Ethicon's specifications and was not a manufacturer of any pelvic-mesh device, Br. 2 (citing 21 U.S.C. § 1604(c), (d)).

Atuneros, Inc., 472 F.3d 266, 274 & n.5 (5th Cir. 2006) ("Is specific personal jurisdiction a claim-specific inquiry? We conclude that it is."); *Phillips Exeter Academy v. Howard Phillips Fund*, 196 F.3d 284, 289 (1st Cir. 1999).

And under *BMS*, the claim-by-claim analysis eschewed by Plaintiff is required. The Supreme Court expressly held that "[w]hat is needed … is a connection between the forum and the specific claims at issue." *BMS*, 137 S. Ct. at 1781. The reason the Court did not segment out its analysis is because there was no reason to: none of the plaintiffs' claims gave rise to jurisdiction. *Id*. at 1782 ("[A]ll the conduct giving rise to the non-residents' claims occurred elsewhere. It follows that the California courts cannot claim specific jurisdiction."). The same is true here.

Even if federal law were as Plaintiff imagines it, her claims would still fail as a matter of Pennsylvania law.[9] As Ethicon explained in its opening brief, 42

[9] Section 5322(c), which requires an "arising from" relationship, is also narrower than the "arising from or related to" formulation in *Burger King*. *See, e.g.*, *Black's Law Dictionary* (11th ed. 2019) (to "arise" means "to stem (from)" or to "result (from)"). It is doubtful that this distinction matters because Plaintiff cannot satisfy the federal Due Process standard, but if it does, jurisdiction clearly does not exist as a matter solely of Pennsylvania law. *See* Br. 26-27. Plaintiff, by contrast, devotes a significant portion of her brief to arguing that she satisfied § 5322(a) and (b). *See, e.g.*, Opp'n 29-30. Whether she satisfied the prerequisites of Pennsylvania's long-arm statute is not the question—the question is whether the exercise of personal jurisdiction is consistent with Due Process and with the limitation on the scope of jurisdiction imposed by § 5322(c). To the extent Plaintiff asserts that the Court can affirm without reaching the Due Process question and § 5322(c), Opp'n 29, she is obviously mistaken. The Due Process Clause imposes an independent limit on the exercise of jurisdiction and § 5322(c) limits the reach of § 5322(a) and (b).

Pa.C.S. § 5322(c) limits the "scope of jurisdiction" "only" to a "cause of action or other matter arising from" the conduct giving rise to the basis for jurisdiction. Br. 26-27. Plaintiff offers no response—in fact, she does not address § 5322(c) at all, despite the fact that this Court's grant of *allocator* expressly concerned that provision.

In the end, Plaintiff did not assert ***any*** claim with a sufficient nexus to Secant. In Plaintiff's words, "the *sin*[*e*] *qua non*" of her "lawsuit" is Prolift's mesh. Opp'n 32; *id*. at 39. But under the Due Process Clause, "attenuated contacts" between Prolift's "mesh" and her "lawsuit" are not enough; there must be a "substantial connection" between Plaintiff's claims and conduct in the forum state. *Burger King*, 471 U.S. at 475 (citations omitted); *see BMS*, 137 S. Ct. at 1370-71. For all the reasons just described, there is no connection between Secant's role as a component manufacturer/supplier and Plaintiff's claims in this case.

Indeed, while Plaintiff struggles unsuccessfully to distinguish the mountain of case law foreclosing jurisdiction, *see* Opp'n 44-51, Plaintiff cites ***no case*** finding jurisdiction on remotely similar facts. Neither did the Superior Court. *See Hammons*, 190 A.3d at 1263. That, too, is unsurprising. The Supreme Court has in recent years rejected grasping notions of jurisdiction. *BMS*, 137 S. Ct. at 1781; *Goodyear*, 564 U.S. at 919; *Daimler AG v. Bauman*, 571 U.S. 117, 137-38 (2014).

Yet the rule Plaintiff advocates would permit jurisdiction over not just all claims brought by mesh plaintiffs whose devices contained Secant-knit mesh, but also those of any plaintiff who could point to ***some*** conduct by a component supplier, however meaningless to that plaintiff's actual claims, in Pennsylvania. That is precisely the type of "loose and spurious" jurisdiction the Supreme Court has specifically rejected. *BMS*, 137 S. Ct. at 1776.

Estate of Vaughan v. Olympus America, Inc., 208 A.3d 66, 72 (Pa. Super. 2019), the sole case cited by Plaintiff, Opp'n 33-34, is not to the contrary. In fact, to the extent the Superior Court's opinion is correct, it supports Defendants. There, the defendant redesigned a medical scope that could be used with multiple patients, but allegedly failed to update the protocol for reprocessing (or disinfecting) the scope. *Vaughan*, 208 A.3d at 69. All of the plaintiff's causes of action "center[ed] on the claim that the reprocessing protocol was inadequate," and the complaint alleged that if the defendant "wanted or needed to disseminate information about changes to the reprocessing protocol, it allegedly would do so through [its Pennsylvania agent]." *Id*. at 70. That relationship sufficed to establish jurisdiction, the Superior Court held, because that agent's in-state conduct was closely related to the plaintiff's "***substantive claims***." *Id*. at 74-75 (emphasis added).

Vaughan thus rejects Plaintiff's assertion that all that matters is the relationship between her ***lawsuit***, writ large, and Secant. As *Vaughan* explains, "specific jurisdiction is narrowly 'confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction.'" *Id*. at 73 (quoting *Goodyear*, 564 U.S. at 919). And here, unlike in *Vaughan*, there is no nexus between Secant's in-state conduct and Plaintiff's substantive claims.

2. Secant's alleged role in the patent for Prolene Soft cannot ground jurisdiction.

Recognizing that the argument she presented to the trial court and to the Superior Court is likely to fail, Plaintiff advances a completely new argument before this Court—namely, that Secant's predecessor company, Prodesco, "contribut[ed]" to the patent for Prolene Soft, the hernia mesh that was later selected by surgeons in France to be used in Prolift. Opp'n 25 (citing R.908c-R.909c).[10] Not only is this eleventh-hour argument waived by Plaintiff's failure to advance it at ***any point*** below, *see, e.g.*, *Samuel-Bassett v. Kia Motors Am., Inc.*, 34 A.3d 1, 45 (Pa. 2011) (argument not properly raised in the trial court is waived); *Wirth v. Commonwealth*, 95 A.3d 822, 837 (Pa. 2014) (issue not meaningfully

[10] Plaintiff cites a PowerPoint slide purportedly showing that a Prodesco employee was listed on four Ethicon patents. R.908c. Ethicon markets many different types of meshes; not all of its meshes are the same. And only Gynemesh PS (patented as Prolene Soft, #6,638,284) is used in Prolift. Obviously, Prodesco's involvement in other patents for other meshes used in other devices cannot ground jurisdiction here. The patent is available on the U.S. Patent and Trademark Office website and is judicially noticeable. Pa.R.E. 201.

developed in appellate brief is waived), it also rests on facts that were not even before the trial court when it overruled Defendants' preliminary objections, *infra* at 26-28.[11]

Regardless, Plaintiff's argument is specious. To start, Plaintiff never explains what Prodesco's specific contribution to the Prolene Soft patent was—or how those contributions relate to her claimed defects. For instance, there is no evidence in the record that Prodesco's contributions to Prolene Soft were to the conception of the invention, i.e., the idea for the mesh, as opposed to reducing the practice of the invention, i.e., the process of making that idea into something actionable or practical. The relative contributions to the claims covered by the patent are not shown or recorded in the patent or identified anywhere else in the record—likely because this theory is beyond an afterthought. So even if Plaintiff's claim focused on the design of Prolene Soft mesh, Plaintiff would not have carried her burden to prove jurisdiction, especially not at the preliminary-objection stage.

But Plaintiff's claim does not in fact take issue with the original design of Prolene Soft for hernia repair. This is a case about Prolift, not Prolene Soft. At most, the design decision at issue here is the decision to use pre-existing Prolene Soft mesh designed to treat hernias in the Prolift device to treat prolapse. *See, e.g.*,

[11] Over Defendants' strenuous objection, Plaintiff filed a supplemental certified record containing these documents on December 12, 2017, ***after*** briefing was closed in the Superior Court and ***after*** that court heard oral argument.

Opp'n 5. That decision was not made by anyone at Prodesco or Secant—it was made by surgeons in France and Ethicon in New Jersey. *See* Br. 8-9.

Plaintiff's argument, by contrast, would confer jurisdiction on any state in which any person contributed to the patent for a component part—even when (as here) that component part was itself a standalone product designed and patented for a different application. Consider, for example, a claim challenging the design of a car that alleges the steel used in the car's frame was too weak. Jurisdiction would not lie where the steel was patented because the claim is not that the steel itself is defective, it is that the decision to use this particular type of steel in the car rendered ***the car*** defective. And jurisdiction certainly would not lie simply because the steelmaking process was invented in the forum state. Yet Plaintiff's position is essentially the opposite.

What Plaintiff fails to appreciate—and what is dispositive here—is that jurisdiction requires a "substantial connection" between the plaintiff's claims and the forum state. *Burger King*, 471 U.S. at 475 (citations omitted). "[S]pecific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction." *Goodyear*, 564 U.S. at 919 (citations omitted); *see BMS*, 137 S. Ct. at 1781. And even putting aside Plaintiff's failure to offer evidence of Prodesco's contribution to the Prolene Soft patent, the controversy here is about the decision to take pre-existing Prolene Soft mesh and

use it in Prolift—a decision made entirely out of state. Whatever Prodesco's contribution to the Prolene Soft patent[12] might be, it is not enough to establish jurisdiction over a claim for the design of Prolift—a device that consists in relevant part of the choice of mesh, the shape of that mesh, and the insertion tools.

C. Dr. Lucente's Pennsylvania Contacts Cannot Ground Personal Jurisdiction.

Plaintiff's argument concerning Dr. Lucente likewise fails to address the need to connect Dr. Lucente's Pennsylvania conduct to her specific claims. As explained, Dr. Lucente was ***not*** an Ethicon employee; he was a contractor, like many contractors throughout the world, who participated in clinical trials for Ethicon, among other activities. *See* Br. 14-15, 35-39. Plaintiff offered no evidence that any conduct by Dr. Lucente—whether his participation in clinical trials or "marketing" activities post-dating Prolift's launch—in any way affected the "physical properties" of Prolift's mesh or gave rise to Plaintiff's claims in this case. *Id*. at 35-39. Plaintiff identifies no such evidence on appeal.

[12]It bears noting that Ethicon's pelvic-mesh devices use different meshes. While the Prolift device uses Prolene Soft/Gynemesh PS mesh, Ethicon's devices for the treatment of stress urinary incontinence ("SUI"), including the device in *Carlino v. Ethicon Inc*., Nos. 360 and 361 EAL 2019, which is currently pending before this Court, do not. That case also does not involve Dr. Lucente's clinical trial work. *Carlino v. Ethicon, Inc.*, 208 A.3d 92, 102 (Pa. Super. 2019). And the majority of out-of-state plaintiffs in the mass-tort proceeding have SUI devices, and thus do not concern Prodesco or Prolene Soft mesh.

Instead of responding to Defendants' arguments, Plaintiff simply asserts that Dr. Lucente engaged in "mesh-related" activities in Pennsylvania, doubling down on her position that any conduct that relates to mesh, whether or not it meaningfully relates to ***her claims***, is sufficient to establish jurisdiction. Opp'n 25-28. That position mirrors almost precisely the type of general jurisdiction arguments rejected by the Supreme Court in *BMS*. But as that decision makes clear, specific jurisdiction exists only when there is a meaningful connection between the defendant's conduct and the "specific claims at issue." *BMS*, 137 S. Ct. at 1781; *Goodyear*, 564 U.S. at 919; *supra* at 3-9. None of Dr. Lucente's in-state conduct comes close to satisfying that standard.

Indeed, by definition, most of the evidence Plaintiff cited cannot relate to her claims. Plaintiff cites, for example, the fact that Dr. Lucente trained "other" surgeons to implant Ethicon-pelvic mesh devices, arguing that Dr. Lucente's "activity is related to the pelvic-mesh lawsuits filed by injured women such as [Plaintiff]." Opp'n 28. But Dr. Lucente's conduct with respect to ***other*** plaintiffs cannot establish jurisdiction over Defendants with respect to ***this Plaintiff***. That is the very argument the Supreme Court rejected in *BMS*, holding "[t]he mere fact that ***other*** plaintiffs were prescribed, obtained, and ingested Plavix in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents' claims." 137 S. Ct. at

1781. Plaintiff would have Pennsylvania courts cast this holding aside. And it bears repeating that the relevant question is not whether Dr. Lucente's conduct relates to the subject matter challenged in Plaintiff's ***lawsuit***; it is whether Dr. Lucente's in-state conduct gave rise to Plaintiff's ***claims*** (it did not).

For similar reasons, Plaintiff's observation that Dr. Lucente performed clinical studies (the dates of which Plaintiff does not specify) on ***other*** Ethicon products, Opp'n 26-27, cannot establish jurisdiction with respect to claims about the design of ***Prolift***, absent some explanation how those studies influenced the actual Prolift design decisions that Plaintiff challenges. *See BMS*, 137 S. Ct. at 1781 ("Nor is it sufficient—or even relevant—that BMS conducted research in California on matters unrelated to Plavix."). Plaintiff offers no such explanation.[13]

Plaintiff also cannot establish jurisdiction based on conduct post-dating the launch of Prolift in 2005. *See* Br. 33-34. Again, that is because the conduct she challenges—the decision to use Gynemesh PS in Prolift (or even the design of Prolene Soft)—pre-dated Prolift's launch. *Id.*[14] If Plaintiff's claims challenged

[13] Plaintiff incorrectly claims that all Ethicon products apart from Prolift+M use "the same mesh." Opp'n 3. While all of Ethicon's meshes are made from knitted filaments of Prolene polypropylene, the mesh in Ethicon's Prolapse devices (Gynemesh PS) is not the same as the mesh in its SUI devices, as explained.

[14] Setting aside this temporal problem, Plaintiff's claims also do not arise out of any of the post-2005 conduct she identifies, *see* Br. 38-39, and thus it cannot support the exercise of jurisdiction.

post-launch conduct, then perhaps post-launch conduct might be relevant—but she does not. And certainly, conduct post-dating ***2009***, has no bearing on her claims.

That leaves Dr. Lucente's participation in two clinical studies. *See* Br. 34. But as Defendants explained in their opening brief, Dr. Lucente was but one of many investigators working in locales across the globe, and Plaintiff still has not identified any evidence that the studies would have been materially different without Dr. Lucente's participation. More importantly, there is no evidence that Dr. Lucente's participation in those studies somehow influenced Ethicon's design decisions. In other words, Plaintiff's claims do not arise out of, or even meaningfully relate to, Dr. Lucente's participation in those studies.

Worse, if Dr. Lucente's participation in those studies were sufficient to ground jurisdiction, then jurisdiction would exist in any state in which a clinical study was conducted. The Supreme Court has not adopted such an expansive view of specific jurisdiction—which would resemble "a loose and spurious form of general jurisdiction," *BMS*, 137 S. Ct. at 1781—as multiple courts have concluded, *see* Br. 36-38.

Neither of the two unpublished California trial court decisions cited by Plaintiff—*Cortina v. Bristol-Myers Squibb Co.*, Case No. 17-cv-00247-JST, 2017 WL 2793808 (N.D. Cal. June 27, 2017), and *Dubose v. Bristol-Myers Squibb Co.*, Case No. 17-cv-00244-JST, 2017 WL 2775034 (N.D. Cal. June 27, 2017)—

supports a different result. Both cases, decided by the same judge on the same day, Br. 38 n.9, applied "a 'but for' test to determine whether a claim arises out of the defendant's forum-related activities." *Cortina*, 2017 WL 2893808, at *3; *Dubose*, 2017 WL 2775034, at *3. In both, the court held that the plaintiffs' "injuries would not have occurred but for Bristol-Myers's and AstraZeneca's contacts with California because the Saxagliptin clinical trials conducted here were part of the unbroken chain of events leading to Plaintiff's alleged injury." *Cortina*, 2017 WL 2793808, at *3; *Dubose*, 2017 WL 2775034, at *3.

For two reasons, *Cortina* and *Dubose* do not help Plaintiff. First, the "but for" test misapplies Supreme Court precedent, which perhaps explains why this Court has never adopted it. *See* Br. 36. Plaintiff does not actually disagree. On the contrary, she explicitly disclaims any reliance on "but-for" causation, arguing that she "has not advanced an argument concerning but-for causation in the trial or appellate courts." Opp'n 53-54.[15] If Plaintiff cannot even bring herself to embrace the reasoning in the cases she cites, those cases obviously cannot support affirmance. Second, even assuming a "but for" test applied, Plaintiff would not meet it. Br. 36-38; *see, e.g.*, *Dyson v. Bayer Corp.*, No. 4:17CV2584 SNLJ, 2018 WL 534375, at *5 (E.D. Mo. Jan. 24, 2018). Plaintiff does not argue otherwise.

[15] In truth, Plaintiff's position appears to be that ***no*** causal nexus is required between the in-state conduct and the Plaintiff's claims. None of the cases cited by Plaintiff supports that extreme view of the law, which was rejected in *BMS*.

Of course, this Court need not even consider Dr. Lucente's conduct because his Pennsylvania contacts are not properly before the Court. This case is on appeal from the trial court's denial of Defendants' motion to dismiss and preliminary objections. When those matters were before the trial court, Plaintiff did not advance the argument that Dr. Lucente's contacts were sufficient to ground jurisdiction. *See, e.g.*, Opp'n 4, 36. Instead, Plaintiff raised Dr. Lucente as a jurisdictional hook for the first time on appeal, based on videotaped testimony that became part of the record for the first time when played before the jury at trial. And even then, Plaintiff did not argue Dr. Lucente in her initial briefing to the Superior Court; she raised Dr. Lucente only after the Superior Court called for supplemental briefing on the impact of *BMS*. Not only did Plaintiff waive her reliance on Dr. Lucente by failing to raise the issue at the appropriate time, but also facts adduced for the first time at trial cannot logically or legally establish that Plaintiff carried ***her burden*** to prove jurisdiction ***at the preliminary-objection stage***.

Plaintiff responds that this Court can affirm, as the Superior Court did, based on the "right for any reason" doctrine. Opp'n 36. But the lone case cited by the Superior Court, *see Hammons*, 190 A.3d at 1263 n.6 (citing *Wilson v. Plumstead Twp. Zoning Hr'g Bd.*, 936 A.2d 1061, 1065 n.3 (Pa. 2007)), does not support the principle that a court's decision may be affirmed based on facts adduced at a later

stage in the case—i.e., based on facts that were ***unavailable*** to the court when ruling on the motion in question. Nor does the case Plaintiff cited. Opp'n 37 (citing *Commonwealth v. Shaffer*, 209 A.3d 957 (Pa. 2019)).[16] Indeed, elsewhere in her brief (literally on the same page), Plaintiff undermines her position by asserting that a trial court decision cannot be evaluated "by considering subsequent case developments of which the trial court could not have been aware at the time of its decision." *Id*. at 36 (citing *Samuel-Bassett*, 34 A.3d at 22).

That rule makes perfect sense, especially in the context of a foundational issue like personal jurisdiction. It is the Plaintiff's burden to support her claims through each stage of the case. If the plaintiff does not advance an argument at the preliminary-objection stage, then later-developed evidence cannot help—it cannot establish that the plaintiff carried her earlier burden to overcome a preliminary objection. Moreover, "[t]he rationale behind the 'right for any reason' doctrine is that appellate review is of the judgment or order before the appellate court, rather than any particular reasoning or rationale employed by the lower tribunal." *In re A.J.R.-H.*, 188 A.3d 1157, 1176 (Pa. 2018) (citations omitted). But the question being reviewed here is the trial court's denial of Defendants' motion to dismiss and preliminary objections, *see Hammons*, 190 A.3d at 1259, and in evaluating the

[16] Plaintiff inexplicably cites to Justice Wecht's partial dissent in *Shaffer*, but neither the dissent nor the majority supports the notion that later-developed facts can be used to hold that the plaintiff carried her burden of proof at an earlier stage of the case.

correctness of the trial court's order, this Court must evaluate the record as it existed at the time the trial court issued that order. This type of judicial restraint is particularly appropriate here, because the trial court made factual findings to support its jurisdictional ruling, but obviously made no findings with respect to Dr. Lucente. *In re A.J.R.-H.*, 188 A.3d at 1176 (doctrine does not apply when appellate court must act as factfinder).

Either way, Dr. Lucente's Pennsylvania contacts cannot establish jurisdiction.

II. DEFENDANTS DID NOT WAIVE THEIR OBJECTIONS TO JURISDICTION.

Finally, Plaintiff halfheartedly asserts that Ethicon waived its jurisdictional challenge. Opp'n 15-16. Her argument lacks merit for the reasons described by the Superior Court: "the case management order for pelvic mesh cases did not require Ethicon to contest personal jurisdiction in preliminary objections to the Long Form Complaint." *Hammons*, 190 A.3d at 1260. And they then did exactly what was required by the trial court's procedures: They timely filed preliminary objections to ***Plaintiff's claims*** once Plaintiff filed ***her*** Short-Form Complaint, *see* R.277a, as both the Court of Common Pleas (which created the procedure at issue) and the Superior Court correctly concluded. There was no waiver.

CONCLUSION

For the foregoing reasons, and for the reasons in Defendants' principal brief, the judgment of the Superior Court should be reversed.

Dated: September 19, 2019

Respectfully submitted,

/s/ D. Alicia Hickok

D. Alicia Hickok (PA ID No. 87604)
William L. Carr (PA ID. No. 200274)
Mark D. Taticchi (PA ID No. 323436)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700 (telephone)
(215) 988-2757 (facsimile)
alicia.hickok@dbr.com
william.carr@dbr.com
mark.taticchi@dbr.com

Julie A. Callsen (PA ID No. 323883)
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113
(216) 592-5000 (telephone)
(216) 592-5009 (facsimile)
julie.callsen@tuckerellis.com

Robert C. Heim (PA ID No. 15758)
Judy L. Leone (PA ID No. 41165)
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104-2808
(215) 994-2015 (telephone)
robert.heim@dechert.com
judy.leone@dechert.com

Counsel for Defendants-Appellants Ethicon, Inc.; and Johnson & Johnson

CERTIFICATE OF COMPLIANCE

Counsel for Defendants-Appellants hereby certifies that, pursuant to Pa.R.A.P. 2135(b), the preceding Brief for Appellant is produced using 14-point font in the text and 12-point font in the footnotes and contains no more than 7,000 words. This word count relies on the word court of the computer program used to prepare this brief. The word count is less than the total words permitted under Pa.R.A.P. 2135(a)(1).

Dated: September 19, 2019

/s/ D. Alicia Hickok

D. Alicia Hickok (PA ID No. 87604)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700 (telephone)
(215) 988-2757 (facsimile)
alicia.hickok@dbr.com

Counsel for Defendants-Appellants Ethicon, Inc.; and Johnson & Johnson

CERTIFICATE OF COMPLIANCE WITH THE PUBLIC ACCESS POLICY OF THE UNIFIED JUDICIAL SYSTEM

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Dated: September 19, 2019

/s/ D. Alicia Hickok

D. Alicia Hickok (PA ID No. 87604)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700 (telephone)
(215) 988-2757 (facsimile)
alicia.hickok@dbr.com

Counsel for Defendants-Appellants Ethicon, Inc.; and Johnson & Johnson

PROOF OF SERVICE

I, D. Alicia Hickok, hereby certify that, on this day, I caused two true and correct copies of the foregoing Reply Brief for Defendants-Appellants Ethicon, Inc.; and Johnson & Johnson, to be served on counsel of record by United States First Class Mail, postage prepaid, which service satisfies the requirements of Pa.R.A.P. 121:

Shanin Specter
Lee Barry Balefsky
Charles Lyman Becker
Kila Briget Baldwin
Ruxandra Maniu Laidacker
KLINE & SPECTER PC
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000 (telephone)
Shanin.Specter@KlineSpecter.com
Lee.Balefsky@KlineSpecter.com
Charles.Becker@KlineSpecter.com
Kila.Baldwin@KlineSpecter.com
Andra.Laidacker@KlineSpecter.com

Counsel for Plaintiff-Appellee
Patricia L. Hammons

Dated: September 19, 2019

/s/ D. Alicia Hickok
D. Alicia Hickok