UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

TELA BIO, INC., Plaintiff, v. BECTON, DICKINSON AND COMPANY; C. R. BARD, INC.; and DAVOL, INC., Defendants.	Case No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

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INTRODUCTION

Monopolies aren't illegal, but abusing them is. Antitrust laws forbid firms from leveraging their monopoly power to exclude competitors, such as by tying their products across markets, entering exclusive-dealing arrangements, or using conditional pricing to punish consumers for buying better, less expensive products from their rivals. Antitrust laws forbid that behavior because it harms competition, and competition brings lower prices, higher quality, and greater choice. Competition matters in every industry, but especially in healthcare, where better access, choice, and prices can make the difference between life and death for a vulnerable patient.

This case is about Defendants exploiting their monopoly power in relevant markets for hernia mesh—surgical mesh that is used to repair and reinforce weakened internal tissue—to reduce choices for patients and care providers, while raising their costs and blocking better and less expensive products from the market.

Defendants are the sprawling medical device conglomerate Becton, Dickinson & Company and its two wholly owned subsidiaries C. R. Bard, Inc. and Davol, Inc. (collectively, "BD"). BD is a monopolist. It dominates the U.S. market for Permanent hernia mesh—the cheap, decades-old plastic mesh used in the vast majority of hernia repairs—with a dollar share of 65%. And it dominates the U.S. market for Resorbable hernia mesh—a modern mesh made

with material that the body can naturally absorb or integrate and that surgeons prefer for more complex hernia repairs—with a dollar share of 77%.

After building a dominant business in Permanent mesh, BD launched a line of Resorbable mesh under the brand name Phasix in 2012. Within a few years, BD controlled almost three-quarters of the Permanent and Resorbable mesh markets. But then in July 2016, TELA Bio, Inc., based in Malvern, Pennsylvania, released OviTex in the United States. Made with a non-dermal sourced ovine (*i.e.*, sheep-derived) extracellular matrix paired with synthetic fibers for added strength, TELA Bio's OviTex is a groundbreaking Resorbable mesh that combines the best features of synthetic and tissue-based materials while costing 15–45% less than BD's Phasix products. Because of OviTex's better price, clinical performance, and patient outcomes, many physicians prefer TELA Bio's OviTex over BD's Phasix.

Once TELA Bio entered the market and began winning business, BD had a choice. It could compete on the merits, by offering a lower price for or improving its Resorbable mesh. Or it could instead abuse its dominant market position and exploit care providers' need for its Permanent mesh and other products that TELA Bio does not sell, to exclude TELA Bio from the Resorbable mesh market.

BD chose to abuse its monopoly. Using a complex scheme of overlapping, multiyear contracts across group purchasing organizations ("GPOs"),

integrated delivery networks ("IDNs"), and individual hospital facilities, BD abuses its monopoly power in the markets for Permanent and Resorbable hernia mesh to block TELA Bio's OviTex from hospital shelves in the United States. Those efforts have succeeded, limiting TELA Bio to a fractional share of the Resorbable mesh market and entrenching BD's costlier and clinically inferior Phasix mesh in healthcare facilities across the country, despite physicians' and care providers' desire to use OviTex instead.

BD's conduct takes a heavy toll on patients, care providers, and competition. In fact, one surgeon was repeatedly denied approval to use OviTex with a vulnerable patient because of BD's contract with the hospital. Ultimately, the patient's family elected to pay for OviTex on their own. But in the meantime, the patient's condition had worsened, and the patient died after coding on the operating table.

By depriving patients and care providers of choice, BD's anticompetitive conduct impairs TELA Bio's ability to compete and has substantially injured its business. To end BD's unlawful conduct, restore competition, and protect the right of patients and care providers to choose TELA Bio's better and less costly OviTex product, TELA Bio now brings this action for damages, injunctive relief, and all other relief this Court may find just and proper.

PARTIES

1. Plaintiff TELA Bio, Inc. ("TELA Bio") is a publicly traded medical technology company with about 200 employees. Incorporated in Delaware and with its headquarters and principal place of business in Malvern, Pennsylvania, TELA Bio (stock ticker: TELA) designs and manufactures hernia mesh products that preserve and restore a patient's own anatomy. TELA Bio engineers its products to leverage the patient's natural healing response, optimize durability of the repaired site, and minimize patient exposure to synthetic materials. TELA Bio's advanced technologies—including its marquee hernia mesh OviTex—also offer lower prices and expand choice for patients.

2. Defendant Becton, Dickinson & Company ("Becton Dickinson") is a New Jersey corporation with its headquarters and principal place of business located at 1 Becton Drive, Franklin Lakes, New Jersey 07417. Becton Dickinson (stock ticker: BDX) is a publicly traded, Fortune 500, global medical technology company engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including Phasix, a line of Resorbable mesh for hernia repair and soft tissue reconstruction. Becton Dickinson's annual revenue for the fiscal year ending

September 30, 2025, was $21.84 billion, an 8.24% increase from the year prior. The average market capitalization for Becton Dickinson in November 2024 was approximately $55.24 billion.

3. Defendant C. R. Bard, Inc. ("Bard") is a New Jersey corporation with its headquarters and principal place of business located at 730 Central Avenue, Murray Hill, New Jersey 07974. Bard is a wholly owned subsidiary of Becton Dickinson. Bard is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including Phasix, a line of Resorbable mesh for hernia repair and soft tissue reconstruction.

4. Defendant Davol, Inc. ("Davol") is a Delaware corporation with its headquarters and principal place of business located at 100 Crossings Boulevard, Warwick, Rhode Island 02886. Davol is a wholly owned subsidiary of Bard and/or Becton Dickinson. Davol is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including Phasix, a line of Resorbable mesh for hernia repair and soft tissue reconstruction.

JURISDICTION AND VENUE

5. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1–2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

6. The Court has subject-matter jurisdiction under 15 U.S.C. §§ 4 and 15(a), and 28 U.S.C. §§ 1331 and 1337(a).

7. The Court has personal jurisdiction over BD because BD does extensive business within the Eastern District of Pennsylvania—including by marketing, transacting business, maintaining substantial contacts, and providing monopolized products like Phasix under the terms alleged in the Complaint and in this District—and because this action arises out of BD's contacts within this District. BD contracts for the sale of its hernia mesh products with many hospitals and hospital systems in this District, including the Jefferson Health, Penn Medicine, and Temple Health systems, as well as Universal Health Services—the largest IDN in Pennsylvania and second largest IDN in the country by number of affiliate hospitals, with its corporate headquarters located within this District—through a large GPO, Premier. BD also contracts for the sale of its hernia mesh products with several of the country's other leading GPOs, including Vizient and HealthTrust, both of which have member hospitals throughout Pennsylvania and this District. And

BD has at least six supply distributors for its products located within this District.

8. The violations of law alleged in this Complaint took place, in substantial part, in the Eastern District of Pennsylvania and have foreseeably and intentionally caused harm to TELA Bio in this District. BD sells Phasix and other products to customers located in this District and realizes profit thereby, and BD's Phasix and other products have flowed in interstate commerce through this District.

9. Venue is appropriate in the Eastern District of Pennsylvania under Sections 4 and 12 of the Clayton Act, 15 U.S.C. §§ 15 and 22, and under 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to TELA Bio's claims occurred in this District, and because BD transacts substantial business within this District.

10. The manufacture, marketing, sale, and distribution of the products at issue, and the actions complained of in this Complaint, occur in and substantially affect interstate commerce.

FACTUAL ALLEGATIONS

I. BACKGROUND

11. A hernia is an abnormal protrusion of an organ or tissue through the surrounding muscle or connective tissue. Hernias typically present as visible or palpable bulges under the skin. They do not go away on their own;

anyone can get them; and they are very common. Approximately one in five Americans will develop a hernia of some kind during their lifetime. There are many types of hernias, but most hernias are either ventral (in the abdomen) or inguinal (in the groin). Of those two types, ventral hernias tend to be larger and more complex. One reason is that the abdomen is flexible, mobile, and under greater pressure and torsion.

12. Although many hernias are benign, an untreated hernia can be dangerous. The protrusion can trap important tissue or block blood flow, causing pain, illness, bowel obstructions, infection, or even death.

13. To treat a hernia, a surgeon will push the bulging organ or tissue back into place and then reinforce the surrounding tissue, usually with surgical mesh, so that the hernia is less likely to recur.

14. Hernia repairs are one of the most common surgeries in the United States. Surgeons in the United States perform more than 1.5 million hernia repairs each year, at a total procedure cost of about $12 billion annually.

15. Because hernia mesh greatly reduces the risk that the hernia will recur, surgeons use it for most hernia repairs, and surgeons' reliance on mesh continues to grow. According to one report, mesh is used in more than 80% of all hernia surgeries, and about one million meshes are consumed each year during hernia surgery.

16. Demand for hernia mesh is separate and distinct from the demand for surgical mesh more generally. Other types of surgical mesh, such as the mesh used in breast reconstruction, cannot be put to the same uses as hernia mesh. And market participants recognize hernia mesh as a separate and distinct mesh product. Sellers differentiate hernia mesh from other types of surgical mesh, including in their marketing materials and clinical instructions. For example, TELA Bio's hernia mesh product, OviTex, is indicated for "the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome." Physicians would not use a mesh that was not indicated for hernia repair to repair a hernia. And when seeking regulatory approval to market hernia mesh, sellers classify it as suitable for hernia repairs, and regulators endorse that classification when approving hernia meshes. The Food and Drug Administration ("FDA"), for example, has approved Section 510(k) applications that classify the approved devices as hernia mesh. Healthcare payers, like Medicare and private insurers, also distinguish hernia repair from other uses of surgical mesh for purposes of billing and reimbursement. And in their purchasing contracts, buyers of hernia mesh treat it as a separate product category. Accordingly, a small but significant increase in the price of hernia mesh would not cause enough buyers to switch to other types of surgical mesh to render the price increase unprofitable.

17. The buyers of hernia mesh are care providers, like hospitals and hospital systems. Though they sometimes buy hernia mesh directly from their manufacturers, care providers typically contract for or buy hernia mesh through entities that aggregate the purchases of many care providers to negotiate for lower prices. Those entities fall into two main categories: GPOs and IDNs.

18. GPOs are third parties that negotiate contracts with suppliers on behalf of their care-provider members. GPOs help care providers screen suppliers and establish base-level pricing and contract terms. By negotiating on behalf of their network of care providers, GPOs aggregate the purchasing volume of their members to obtain better prices. Hospitals and other care providers join GPOs to outsource their contracting and to access the GPOs' negotiated prices. About 98% of U.S. hospitals and the vast majority of other care providers use GPOs to help them with procurement, with each using an average of two to four GPOs. Major GPOs in the United States include Vizient, Premier, and HealthTrust.

19. IDNs, also known as health systems, are combinations of care providers like hospital or healthcare systems that purchase directly from suppliers at scale. Though they often contract with suppliers through GPOs, IDNs also deal directly with suppliers on behalf of their constituent care providers. Today, IDNs, along with GPOs, are the main point of contact for

suppliers seeking to sell hernia mesh and other medical devices to U.S. care providers. There are about 1,000 IDNs in the United States today, with more than 70% of U.S. hospitals affiliating with an IDN. HCA Healthcare, Universal Health Services, CommonSpirit Health, Jefferson Health, Advocate Health, Kaiser Permanente, and Penn Medicine are among the largest IDNs in the United States by number of in-network care providers. In nearly half of metropolitan areas in the United States, one or two IDNs provide all general inpatient hospital care, while in 82% of metropolitan areas, one or two IDNs comprise at least three-fourths of all inpatient hospital discharges.

20. BD is the dominant seller of hernia mesh in the United States. It gets 65 cents of every dollar spent on hernia mesh, and BD has maintained its dominance for years because of its anticompetitive conduct. In fact, from 2017 to 2024, its monopoly share of Permanent and Resorbable hernia mesh sales increased—from 67% to 70% of dollar share. That dominance cannot be explained by product innovation. BD has not introduced a new line of hernia mesh since Phasix in 2012.

21. This case centers on the surgical mesh used to repair hernias—and BD's illegal exclusion of TELA Bio's better and less costly OviTex hernia mesh from the market.

II. RELEVANT MARKETS

A. The Markets for Permanent and Resorbable Hernia Mesh

22. There are two types of hernia mesh that each comprise distinct relevant antitrust markets: Permanent and Resorbable.

23. **Permanent** hernia mesh is synthetic mesh that remains inside the body indefinitely, permanently reinforcing the tissue after a hernia repair. It is usually made with plastic or filaments like polypropylene or polyester. Permanent hernia mesh has been used since 1958, is by far the cheapest mesh product available, and is the default standard of care for straightforward hernias. In 2024, Permanent mesh comprised 90% of the mesh (by unit share) used to repair hernias. But Permanent mesh carries significant safety and liability risks like infection, inflammation, erosion, shrinkage, organ damage, chronic pain, and foreign-body sensations.

24. **Resorbable** hernia mesh, unlike Permanent mesh, does not stay intact in the body permanently. Resorbable mesh is made either: (1) entirely from synthetic absorbable polymers that degrade over time after being inserted into the body (*i.e.*, "synthetic resorbable" mesh), such as BD's Phasix; or (2) from a combination of synthetic polymers and animal tissue that the body remodels and reforms into its own tissue over time (*i.e.*, "hybrid" mesh), such as TELA Bio's OviTex.

25. Resorbable mesh debuted in the United States in 2007 and made up 8% of the hernia mesh market by unit share in 2024. Resorbable mesh costs much more than Permanent mesh—usually five to twelve times more. And because it weakens over time, Resorbable mesh generally requires patients to seek a second hernia repair more often than Permanent mesh. But Resorbable mesh has significant clinical advantages over Permanent mesh. For example, because the body naturally resorbs it over time, or integrates it, in the case of OviTex, Resorbable mesh presents a lower risk of downstream complications like inflammation, infection, pain or foreign-body sensations, and mesh erosion. Physicians also turn to Resorbable mesh much more often when repairing ventral hernias, which tend to be larger and more complex than inguinal hernias.

26. The U.S. Permanent and Resorbable hernia mesh markets comprised more than $1 billion in annual sales in 2024. While Permanent mesh makes up 90% of the hernia mesh market by unit share, it generated only $590 million in sales for 2024 because it is considerably less expensive than Resorbable mesh. Conversely, while Resorbable mesh accounts for a mere 8% of the hernia mesh market by unit share, it generated more than $450 million in sales for 2024.

27. The markets for Permanent and Resorbable hernia mesh are separate and distinct. The average prices for each type of mesh differ

dramatically, and changes in average price over time for each type are uncorrelated.

28. Demand for each type of mesh is distinct. Although both types of mesh are used to repair hernias, Resorbable mesh is seen as superior for complex repairs and higher-risk patients, while Permanent mesh is preferred for standard hernias in low-risk patients without comorbidities. Resorbable mesh is also more appropriate for patients with contaminated wounds. In short, different types of hernia mesh are appropriate for different patients. Surgeons choose the best option for each patient based on that patient's risk profile, the patient's own preferences (such as to reduce the amount of permanent foreign material or synthetics used in the repair), how the patient's hernia presents, and other factors.

29. In fact, within the healthcare industry, each type of hernia mesh is considered a Physician Preference Item. Unlike products that are standardized and commoditized, like gauze or intravenous tubes, Physician Preference Items are medical products whose selection is heavily influenced by physician choice and preference regarding product type or supplier. The Physician Preference Item label reflects that physicians tend to have strong preferences, informed by their training and experience, regarding the types (and brands) of hernia mesh and when each should be used. Physician preference for hernia mesh is a substantial switching cost, because it is

extremely difficult to persuade a significant number of surgeons across a hospital or hospital system to switch to a different brand of mesh. And unlike trying a different dose or brand of drug with a patient, which a physician may tailor as a patient's needs evolve, the choice of which hernia mesh to implant inside the patient has long-term consequences for that patient and is difficult and costly—physically for the patient, financially for the payor, and reputationally for the surgeon—to reverse. Even surgeons who want to switch to a new brand of Resorbable mesh face other significant switching costs. For example, they must learn how and when to use the new Resorbable mesh effectively, and they face risks of damage to their professional reputation if the new mesh underperforms or harms patients.

30. Buyers and sellers of hernia mesh, as well as the medical and scientific literature, recognize Permanent and Resorbable mesh as separate and distinct categories of hernia mesh. In their contracts with manufacturers, GPOs and IDNs typically delineate Permanent and Resorbable hernia mesh as different purchasing categories, with different value propositions. Sellers of each type of mesh market them separately and advertise different features. Sellers of Resorbable mesh, for example, stress that their mesh is non-permanent and reduces the risk of complications for vulnerable patients. Sellers also treat both categories of hernia mesh, Permanent and Resorbable,

as separate economic categories, such as when tracking their competition, market shares, and sales.

31. For all these reasons, a small but significant increase in the price of Permanent or Resorbable hernia mesh would not cause enough buyers to switch to the other type of hernia mesh to render the price increase unprofitable. In fact, significant price increases on Resorbable hernia mesh have not resulted in significant switching to Permanent hernia mesh, and vice versa.

B. Barriers to Entry in the Relevant Markets

32. Barriers to entry are significant in the markets for Permanent and Resorbable hernia mesh.

33. Regulatory barriers to entry in these markets are enormous. Any firm seeking to sell hernia mesh in the United States must navigate an extensive, expensive, and time-consuming U.S. regulatory regime, including product-specific regulatory clearances from the FDA and ongoing reporting obligations. These U.S.-specific regulatory and legal requirements limit the ability of firms that sell mesh elsewhere in the world to enter or expand in the United States, and they prevent care providers from sourcing hernia mesh from outside the United States unless it is also approved specifically for sale within the United States.

34. Significant innovation, research, and development costs further impede entry and expansion. Developing hernia mesh products requires years of costly research, specialized materials and manufacturing capabilities, extensive testing, and credible safety and efficacy data that satisfies regulators and care providers. And even after the FDA clears a new hernia mesh for marketing and selling in the United States, the manufacturer must train clinicians on how to use it and hire a skilled sales team that can navigate the complex and burdensome procurement processes for healthcare providers approving the purchase and use of new medical devices, especially Physician Preference Items, in their U.S. facilities. These significant expenditures do not guarantee success and cannot be recovered if a putative entrant fails.

35. Patent and other intellectual-property rights are another barrier to entry. Incumbent hernia mesh manufacturers hold extensive portfolios of patents and proprietary know-how covering materials, coatings, manufacturing processes, and device designs. Accordingly, entering the market with a new product risks infringement litigation, especially from dominant incumbents eager to protect their market position, and unexpected research and development costs necessary to avoid infringement.

36. Care providers' complex procurement processes also impede entry and entrench established firms at the expense of new rivals. Even if many physicians want to use a new, innovative product, getting approval from their

hospital or hospital system to stock it will require expending substantial time and energy to complete paperwork and overcome internal bureaucracy, such as procurement committees. Using an established brand is the path of least resistance.

37. TELA Bio has overcome all these barriers to entering the Resorbable hernia mesh market. TELA Bio developed its own innovative hernia mesh, OviTex; secured regulatory clearance; and then won over a coalition of patients, physicians, and care providers who wanted to use OviTex, which is better and costs less than BD's Phasix. But TELA Bio still couldn't sell OviTex, because BD violated, and continues to violate, antitrust laws to exclude it from the Resorbable hernia mesh market.

III. BD'S UNLAWFUL AND ANTICOMPETITIVE CONDUCT

38. BD has monopoly power in the markets for Permanent and Resorbable hernia mesh. BD abuses its monopoly power in those markets to foreclose competition from TELA Bio in the market for Resorbable hernia mesh.

A. BD Monopolizes the Relevant Markets

i. BD's Dominance

39. BD is, and has been for decades, the dominant manufacturer of hernia mesh in the United States. Its dominance runs deep: in the 1970s, Defendant Davol, later acquired by Defendant Bard in 1980, launched several

Permanent hernia mesh products, which were among the first hernia meshes to gain widespread commercial adoption. By acquiring Bard and Davol in 2017, Becton Dickinson captured their extensive portfolios of Permanent and Resorbable mesh products, solidifying BD's dominant position in the hernia mesh market.

40. BD has a history of anticompetitive conduct. In 2017, Becton Dickinson's acquisition of Bard (and its subsidiary Davol) prompted the Federal Trade Commission ("FTC") to sue Becton Dickinson and Bard for antitrust violations. The FTC alleged that the proposed $24 billion acquisition of Bard would negatively impact competition by combining the top two suppliers in the U.S. markets for tunneled home drainage catheter systems and soft tissue core needle biopsy devices. To settle the FTC's charges, Becton Dickinson and Bard agreed to divest the two medical device product lines. But BD's dominance in the Permanent and Resorbable hernia mesh markets went unchecked.

41. BD makes and sells a variety of Permanent mesh products, including Bard Mesh and Ventralight ST Mesh. BD's Permanent mesh sales accounted for roughly 65% of the dollar share for Permanent mesh products in 2024 and 60% of all Permanent mesh units sold that year. BD can charge supracompetitive prices for Permanent mesh and is doing so. For example,

BD's average sales price for one subcategory of Permanent mesh (Coated) is 100% higher than its closest competitor Covidien.

42. BD also makes and sells three types of Resorbable hernia mesh under the brand name Phasix: Phasix Mesh, Phasix ST Mesh, and Phasix Umbilical Hernia Mesh. BD's Resorbable mesh sales accounted for roughly 77% of all Resorbable hernia mesh sales by dollar share in 2024 and 58% of all Resorbable mesh units sold that year. BD can charge supracompetitive prices for Resorbable mesh and is doing so. BD's average sales price for Resorbable mesh is about 50% higher than its closest competitor, TELA Bio.

43. BD also makes and sells a suite of other hernia repair products.

44. The top three hernia mesh products in the United States by units sold are all BD products: Phasix ST (Resorbable), Ventralight ST (Permanent), and Bard Mesh (Permanent).

45. BD's large product portfolio belies the company's lack of innovation. BD has not meaningfully improved its hernia mesh products in more than a decade. Instead, BD has focused on pushing its thirteen-year-old Resorbable mesh line, Phasix, to dominate the lucrative and growing market for Resorbable hernia mesh. For instance, BD recently launched the Phasix ST Umbilical Hernia Patch, which markets BD's old Phasix technology as a "new" fit-for-purpose mesh for umbilical hernias (a type of ventral hernia).

46. And numerous clinical studies have revealed problems with Phasix. Several studies have found significant rates of hernia recurrence and surgical site infection among patients who used Phasix. One study reported a 31.3% hernia recurrence rate within five years for patients that used Phasix for mesh repair that was applied using an onlay technique. Other studies have reported complications associated with Phasix, including the development of seromas (a buildup of fluid) caused by inflammatory responses to the mesh. Yet others have found that Phasix causes foreign-body inflammatory responses that persist until the mesh has been fully absorbed—a process that BD says can take 12 to 18 months.

47. Phasix Mesh and Phasix ST also rank among the most expensive Resorbable hernia mesh products on the market today. Despite being nearly a decade older and, according to most medical studies, an inferior product, BD's Phasix meshes cost on average about $1,500 more per unit than TELA Bio's OviTex, which had an average selling price of $2,957 in 2024.

48. BD has faced legal troubles in recent years because of its suboptimal hernia mesh products, with tens of thousands of private lawsuits filed against it in state and federal courts alleging injuries caused by BD's mesh. Several of those cases went to trial, resulting in verdicts between $255,000 and $4.8 million. In October 2024, BD agreed to settle about 38,000 hernia mesh lawsuits filed against it in both state and federal courts. Although

the specific terms of the settlement were not disclosed, BD shared that it agreed to pay its victims a "large majority" of the $1.7 billion it had set aside for product liability litigation. Tens of thousands of other hernia mesh lawsuits remain pending against BD.

ii. TELA Bio's Entry

49. TELA Bio first entered the hernia mesh market in mid-2016 with the commercial launch of OviTex.

50. OviTex is a next-generation soft tissue repair mesh intended for hernia repairs and abdominal wall reconstruction. OviTex is a hybrid mesh option comprising 87–95% ovine material (*i.e.*, from sheep) and 5–13% synthetic suture fibers. Patients' bodies can remodel the natural ovine material into a functional collagen layer to regenerate tissue, while the synthetic suture fibers hold the ovine layers together to ensure structural integrity over time.

51. Today, there are five products in the OviTex product portfolio that are used for hernia repairs: CORE, 1S, 2S, LPR, and IHR. OviTex is designed to leverage a patient's natural healing response, facilitate tissue remodeling, optimize strength, and minimize the foreign-body footprint of the synthetic polymer. OviTex comes in various shapes, sizes, and configurations to suit surgeon preference and meet each patient's needs, and can also be trimmed to

different shapes and sizes if desired. OviTex works with all surgical hernia repair techniques: open, laparoscopic, and robotic approaches.

52. OviTex is a significant advancement in mesh technology and a promising alternative to traditional hernia mesh products. TELA Bio developed OviTex with the aim of combining the best features of synthetic and biologic materials while negating their downsides. Its unique hybrid composition, which TELA Bio calls the "Reinforced Tissue Matrix," enhances mesh performance and strength, improves integration with the patient's tissue, and reduces the risk of infection and inflammation. This design also significantly reduces the rate of hernia recurrence as compared to traditional synthetic Resorbable mesh such as Phasix, and minimizes the downstream complications usually associated with Permanent mesh. Many care providers also report that OviTex is easier to handle, particularly in complex hernia repairs with high risk factors.

53. All those benefits come at a lower price, too. OviTex is less expensive than other Resorbable mesh products on the market. In 2024, OviTex's average selling price was $2,957, making it 15–45% cheaper than BD's Resorbable Phasix products.

54. BD itself takes the position that OviTex hernia mesh counts against a customer's contractual commitments for purchasing Resorbable mesh from BD. And more generally, market participants, from care providers

to BD itself, recognize that BD's Phasix and TELA Bio's OviTex directly compete for the same customers seeking Resorbable mesh.

55. TELA Bio specializes in developing OviTex variants for use in an array of abdominal wall defect and hernia repair applications. TELA Bio does not make any Permanent hernia mesh.

56. Despite OviTex's considerable clinical benefits and competitive pricing, OviTex had roughly an 8% dollar share and a 9% unit share of the $450 million U.S. Resorbable mesh market in 2024, while BD controlled 77% and 58% shares by dollars and units, respectively.

57. By contrast, TELA Bio has achieved far higher market penetration in direct sales of its OviTex hernia mesh overseas, where it also competes against BD's Phasix. TELA Bio's sales of OviTex in the United Kingdom have steadily increased, and it has a significantly greater dollar share of the U.K. Resorbable hernia mesh market than in the United States. The key difference between OviTex's success in the U.K. market and its limited penetration of the U.S. market: BD cannot contract through GPOs and IDNs in the same way in the U.K. because hospitals there use formal tender processes.

B. BD's Illegal Foreclosure of Competition

58. In a few short years, BD—despite having lower-quality and higher-priced products—has monopolized the Resorbable hernia mesh market to foreclose competition from TELA Bio.

59. BD has illegally excluded TELA Bio from the Resorbable mesh market through engaging at least in the following anticompetitive conduct throughout the United States: (*i*) charging hospitals and other healthcare systems a large contractual penalty for disloyalty to BD's products, by retroactively imposing much higher prices for Permanent and Resorbable mesh unless care providers buy virtually all their Permanent and/or Resorbable mesh and, sometimes, other medical devices, from BD; and (*ii*) contractually imposing threshold purchasing requirements with similar contractual penalties that amount to exclusive dealing arrangements.

60. This anticompetitive conduct has succeeded. BD's steep retroactive penalties and market share requirements have prevented rivals from achieving sufficient market penetration to constrain BD's exercise of monopoly power. Despite selling worse and more costly Resorbable mesh, BD has consistently maintained (and slightly increased) its dominant dollar-based market share across the combined Permanent and Resorbable mesh markets, with shares of 67% in 2017 and 70% in 2024, whereas TELA Bio's share across those markets has hit a ceiling in the last two years, reaching just about 4%.

i. BD's Bundling Arrangements

61. BD has been a key player in the hernia mesh market for more than fifty years. In 2017, Becton Dickinson acquired Bard and Davol to add Phasix to its already expansive product portfolio and dominate the fast-growing

Resorbable mesh market. With that acquisition, BD now controls 65% of the Permanent and 77% of the Resorbable hernia mesh markets in the United States by dollar share. BD also has a sizable portfolio of other medical devices: it is the world's largest syringe manufacturer and sells IV catheters, rapid diagnostic instruments, surgical instruments, home-healthcare products such as elastic bandages, ports, and drainage devices, and a variety of products that help collect blood. BD reported total revenues of more than $20 billion in 2024.

62. By contrast, TELA Bio sells only one hernia mesh product: OviTex. OviTex directly competes with BD's Phasix in the Resorbable hernia mesh market. TELA Bio specializes in developing clinical applications for OviTex and derives roughly 99% of its annual revenue from its use in hernia repair and plastic reconstructive surgery. TELA Bio reported total revenues of $69 million in 2024.

63. Despite TELA Bio's nearly exclusive focus on, and substantial investment into, its OviTex mesh products—better and cheaper substitutes for BD's Resorbable mesh products—it has managed to capture only an 8% share of the Resorbable mesh market by dollar share. Why? Because BD has leveraged its monopoly power over the Permanent and Resorbable hernia mesh markets, its diverse portfolio of products, and its wide contractual network to block TELA Bio from penetrating the Resorbable mesh market.

64. BD has entered into long-term, multi-year contracts with most of the country's largest GPOs, IDNs, and care providers to supply a variety of its products. These contracts condition the pricing of a wide variety of BD's products—including its Permanent and Resorbable hernia mesh—on buyers agreeing to buy virtually all their Resorbable hernia mesh from BD and not from BD's rivals, like TELA Bio. BD's conditional pricing works on a tiered pricing system. When the contract starts, the buyer commits to a particular pricing tier. That price is conditioned on the buyer purchasing a certain amount of BD products—the more BD products, the lower the average unit price. BD measures the buyer's compliance (the percentage of products the buyer buys from BD instead of from its rivals) on a quarterly basis. If the buyer meets the threshold, BD pays the buyer the difference between its list price and its conditional tier-based price. If the buyer fails to meet the threshold, it loses its tier pricing and must pay a higher per-unit price for every covered BD product that it bought that quarter.

65. BD's pricing tiers are not tethered to its costs of production or logistical efficiency. Instead, they are set near the buyer's total needs (usually 80% to 90% market share) so that the buyer cannot feasibly source from multiple suppliers. In practice, BD's pricing tiers create a penalty so steep—doubling or even tripling the average unit price if the buyer slips below the

market share requirements—that the buyer cannot switch even part of its volume to a rival with a better and less costly product.

66. For example, a care provider could begin at an entry-level market access tier after it contracts with BD, which would require the lowest purchasing commitment but also result in a per-unit conditional price that is often more than double the per-unit lowest available price. For a lower price, the care provider could then move up to an intermediate tier that requires buying even more (usually between 80–90%) of BD's products within one category of hernia mesh, such as Resorbable mesh, to obtain the conditional price. But the lowest conditional pricing is available only to care providers who are almost entirely loyal to BD—who meet the target purchasing percentage in both the Permanent *and* Resorbable mesh categories as well as for other categories of BD products. The penalty for failing to meet the market share requirements for the Resorbable mesh category is stark: the care provider likely faces roughly double the price for Resorbable *and* significantly higher prices for its (typically larger) purchases of Permanent mesh. In economic substance, then, the true price of Resorbable mesh for that care provider far exceeds even the new penalty price that the care provider must pay per unit of Resorbable mesh. This penalty makes it almost impossible for the buyer to switch to a different supplier for even ***part*** of its Resorbable mesh purchases.

67. Below are the terms of the tiered conditional pricing that BD has in place with Vizient, one of the largest GPOs in the United States:

VIZIENT CONTRACT (July 1, 2023 - June 30, 2025)

Tier	Type	Synthetic surgical mesh (ms9002) Includes synthetic mesh, mesh fixation, and absorbable mesh	Hemostasis (RX0045) Arista and Avitene	CHG Skin Prep (MS9200) through August 31, 2026
1	Individual ASC	Access	Access	Access
2	Individual ASC	50%	60%	90% + $50k-$249k
3	Individual ASC	80%	85%	90% + $250k-$499k
4	AMC (academic med ctr)	70%	IDN 90%	90% + $500k-$999k

68. To achieve the lowest per-unit pricing, BD's contract with Vizient imposes an 80% compliance requirement across a bundle of three products—BD's Permanent mesh (here, "synthetic mesh"), Resorbable mesh (here, "absorbable mesh"), ***and*** mesh fixation devices.

69. And these compliance requirements are going up, not down. As recently as October 2025, BD renewed its contract with another major GPO, Premier Inc., that imposes compliance requirements of 90% in both the Permanent and Resorbable hernia mesh categories for members of its Premier Surpass program.

70. BD explicitly conditions its pricing on its buyers hitting 80–90% compliance requirements across two or more distinct product lines. Through this scheme, a buyer can only be eligible for the lower, conditional pricing if it achieves 80–90% compliance in both Permanent ***and*** Resorbable categories—two markets that BD dominates. This bundling tactic enables BD to leverage

its monopoly power over Permanent mesh—a legacy product that has been on the market for more than 50 years but accounts for 90% of all hernia mesh procedures—to block an innovative competitor in the Resorbable mesh market. As a result, even though OviTex is 15–45% less expensive than Phasix (and by all accounts superior), buyers are unwilling to risk the contractual penalties (which likely amount to more than one million dollars per year for each of the top 75 IDNs) that BD imposes by more than doubling the effective prices for Resorbable mesh when those buyers don't buy 80–90% of their mesh in both categories from BD. And because TELA Bio does not make or sell Permanent mesh, it cannot replace BD as a provider across both hernia mesh categories.

71. BD conditions even lower pricing—up to 10% lower across all purchases—on a buyer achieving the target purchasing threshold across all hernia mesh categories, hernia-mesh related products, and even other categories of BD products. In other words, BD has conditioned its pricing on buyers accepting long-term agreements that cut out BD's competitors. And as the dominant manufacturer of hernia mesh, BD is the only firm that can condition pricing on bundling purchases across its multiple mesh (and other) product lines that a "best of breed" producer in any single product category (like TELA Bio in the Resorbable mesh category) cannot match. And TELA Bio's portfolio of other products is too small to support a comparable arrangement. BD's conditional pricing scheme thus excludes equally efficient

mesh producers that compete in one of the mesh product categories in BD's bundle.

72. BD's tiered conditional pricing has succeeded at excluding competition from TELA Bio. BD forces its buyers not to conduct business with its competitors, like TELA Bio, using the threat of significant pricing penalties from BD across multiple product lines as leverage. If a buyer refuses to meet BD's exclusionary conditions, BD imposes higher prices on that buyer for hernia mesh. So even if a hospital is interested in sourcing and offering TELA Bio's OviTex products, which directly compete with BD's Resorbable Phasix products, that hospital could not do so without jeopardizing its conditional pricing from BD in every other hernia mesh category.

73. BD has further insulated its contracts from competitors by conditioning pricing for its hernia mesh products *and* other products in its extensive portfolio on care providers not buying any significant amount of hernia mesh from BD's competitors. So, for example, if a hospital meets BD's condition that 80% or more of its overall hernia mesh usage and its usage of other product categories must comprise BD products, it will receive BD's promised pricing; but if it doesn't meet that condition, it will pay much higher prices.

74. The net effect of BD's anticompetitive bundling practices is to deprive buyers of product choice. By bundling conditional prices across

different hernia mesh categories and across its broader product portfolio, BD blocks TELA Bio from competing because care providers cannot buy TELA Bio's OviTex without risking the loss of the conditional pricing on BD's expensive hernia mesh products like Phasix and on other medical devices and healthcare products that the buyer cannot get from TELA Bio. TELA Bio cannot feasibly make up the penalty that BD imposes—in many cases, more than one million dollars—on care providers who decline BD's conditions.

75. Conditioning prices for BD's Permanent and Resorbable hernia mesh on loyalty to BD's Permanent and Resorbable hernia mesh products is anticompetitive because it forecloses a substantial portion of the Resorbable hernia mesh market to BD's potential competitors, including TELA Bio, that do not manufacture an equally diverse group of products and therefore cannot make a comparable offer to buyers. BD imposes its conditional pricing—across hernia mesh and all other product offerings—on nearly all hospitals across the country by imposing it on the major GPOs. BD has agreements with all major GPOs. Vizient and Premier alone represent hospitals accounting for more than 80% of all staffed hospital beds in the United States, and BD has conditioned its prices for Resorbable and Permanent hernia mesh on its buyers' reaching commitments of 80–90% of purchases across all hernia mesh with these GPOs. BD also has additional "wrap-around" conditional pricing based on total purchases from BD with these GPOs.

76. BD has also imposed a second layer of restraints through contracts directly with most hospital systems across the United States: BD contracts directly with IDNs (including more than 80% of the Top 75 IDNs) covering an estimated 60–90% of the Resorbable hernia mesh purchases in the United States. BD also has imposed a third layer of restraints through contracts with many individual facilities. As a result, BD's conditional pricing reaches nearly every customer in the market through a contract with a GPO, IDN, or facility—and often through a contract with a GPO *and* a contract with an IDN or facility. With its 80–90% purchasing commitments spread across such a wide swath of the market, BD has guaranteed its monopoly foothold everywhere but the most remote corners of the hernia mesh market.

77. BD has tried to keep these exclusionary contract terms secret. It requires buyers of its hernia mesh products to agree to keep the nature and terms of their agreements confidential, which hampers BD's rivals from asserting their legal right to fair and free competition.

78. There is no legitimate business justification for BD's bundling arrangements. The only purpose of BD's anticompetitive bundling scheme is to foreclose lower-priced competition by TELA Bio in the Resorbable mesh market and maintain BD's supracompetitive prices.

ii. BD's De Facto Exclusive Dealing

79. In addition to BD's cross-product bundling scheme, BD utilizes its conditional tier-based pricing to foreclose TELA Bio's competition in the Resorbable hernia mesh market. BD effectuates this scheme though its long-term, *de facto* exclusionary contracts with the major buyers across the United States.

80. Within the Resorbable hernia mesh category alone, buyers qualify for BD's conditional pricing only if they buy 80–90% of all their Resorbable mesh from BD. If the buyer fails to meet that threshold, BD punishes them with much higher prices—often 100% higher—on all the BD Resorbable mesh they have bought, by taking away the promised conditional pricing. For example, suppose that a hospital needs 100 units of Resorbable hernia mesh each year. Even if half of the hospital's surgeons would prefer to use OviTex, the hospital cannot switch some or even all of those surgeons to OviTex; if the hospital falls below BD's market share requirement (80–90 units), it will pay double (or more) per unit of Phasix, which will eliminate the entire economic benefit of buying 50 units of TELA Bio's better and less expensive Resorbable mesh.

81. Like the bundling, this extreme pricing structure based on very high market shares creates a penalty so steep that the buyer cannot switch even part of its volume to a rival. The top 75 IDNs alone likely comprise more

than half of the Resorbable mesh market. Given their size, they likely face penalties of more than $1 million per year for missing BD's market share requirements under BD's tiered pricing structure for Resorbable mesh. Moreover, the cost of switching ***entirely*** to a rival like TELA Bio, to avoid the conditional pricing altogether, is far too high. A typical hospital system would have to persuade dozens of general surgeons, across multiple facilities, to agree to switch to a rival brand of Resorbable mesh in a short period of time. Many surgeons would refuse to switch to a rival brand of Resorbable hernia mesh based on, for example, a lack of familiarity with and experience using the new brand. And just as many physicians prefer OviTex, some will stick with Phasix, the old brand they know well already. But unlike BD, TELA Bio lacks the market power necessary to profitably impose on care providers market share requirements that exclude its competitors.

82. BD knows and intends these penalties to foreclose rival sellers of Resorbable mesh by making it prohibitively costly for care providers to allow rival Resorbable meshes like OviTex into their facilities. In effect, BD says to each buyer, "if you want to buy our Resorbable mesh, Phasix, at a price that won't require you to bankrupt yourself to meet your physicians' demand, you cannot risk that your physicians will use a Resorbable mesh from our rivals in more than 10% (or 20%) of your cases." Although TELA Bio offers OviTex at a lower cost than Phasix, buyers must forgo purchasing OviTex to protect

themselves from the risk that BD will hike their prices so much that they cannot meet the demand of their physicians who use Phasix for hernia repairs.

83. Although BD's contracts purport to allow care providers to use a trivial amount of Resorbable mesh made by its competitors, in practice they require buyers to deal exclusively with BD by harshly punishing buyers for failing to meet their purchasing thresholds. Even *stocking* OviTex is too risky, according to several hospital sources, because physicians like it and may use too much of it, causing hospitals to fall short of BD's purchasing threshold and suffer a crushing financial penalty that wipes out the per-unit savings they achieve from buying OviTex. In other words, to comply with their multi-year contracts with BD, buyers typically stock only Phasix and place OviTex on consignment, meaning that they only pay for what is used in one-off, by-request cases. Other buyers will refuse to buy OviTex at all, while other buyers strictly limit their OviTex purchases to ensure they do not exceed a trivial quantity. These consequences—which also result from BD's bundling practices—combine to exclude TELA Bio from the Resorbable mesh market, where it competes directly with BD's Phasix.

84. BD's monopolistic behavior deprives physicians and patients alike of the ability to make a meaningful choice among hernia mesh products. Although hernia mesh is considered a Physician Preference Item, BD's conduct renders the physician's "choice" meaningless. Because of BD's exclusionary

contracts, OviTex is largely unavailable to surgeons. And although a surgeon may request OviTex on a case-by-case basis for a particular surgery, care providers will regularly deny those requests for fear of BD's massive economic reprisal.

85. BD's large contractual penalties for failing to meet its 80–90% purchasing requirements, which, as explained above, likely cover upwards of 90% of the market, firmly entrench BD's monopoly and foreclose competition in nearly the entire market for Resorbable hernia mesh. They are designed to make even partial switching unprofitable and lock in customers even if rivals offer lower prices. Such a dramatic, substantial foreclosure of competition from a rival like TELA Bio—despite its better and less expensive Resorbable mesh—is possible only because of BD's market power in the Resorbable hernia mesh market.

86. There is no legitimate business justification for BD to condition its pricing for Permanent and Resorbable hernia mesh on the purchase of its Resorbable hernia mesh so long as the purchasers agree not to buy more than a *de minimis* amount of products from BD's competitors, like TELA Bio. The only purpose of BD's anticompetitive exclusionary scheme is to foreclose lower-priced competition by TELA Bio and maintain its supracompetitive prices.

87. As a result, TELA Bio cannot constrain BD's exercise of monopoly power. If left unchecked, BD will continue depriving patients and care

providers of choices that they want and deserve by exploiting its monopoly power and its web of exclusionary contracts, conditional pricing, and penalties.

IV. ANTICOMPETITIVE EFFECTS

88. As a result of BD's exclusionary scheme, customers—including most of the largest care providers, GPOs, and IDNs in the country—are effectively precluded from buying hernia mesh from BD's rivals like TELA Bio. Instead, they are forced to buy hernia mesh of lower quality at higher prices regardless of physician and patient preference. In other words, because BD's contracting practices exclude TELA Bio from a significant portion—likely 60% to 90%—of the Resorbable hernia mesh market, those who want to use OviTex cannot, even though it offers benefits and cost savings that BD cannot match.

89. Care providers confirm that BD's conditional pricing and exclusive contracting tactics spanning across many product lines are the reason why they cannot buy or stock TELA Bio's OviTex. One hospital system's vice president of supply chain explained that BD's contractual penalties are too extreme to source from multiple suppliers: "Falling short of complete conversions means any dollars left with BD triple in price and wipe away any savings." In response to an inquiry from a TELA Bio sales representative offering OviTex, a director for clinical resources for a GPO simply wrote: "We cannot use your mesh instead of Davol due to tier pricing." Or, as another

healthcare administrator explained to a physician asking that his hospital system approve the use of OviTex:



RE: new mesh request

Hi [redacted]

Thank you for your email.
At this time, BD (Bard) remains our preferred vendor in the mesh space, with an 85% compliance requirement that we are currently just meeting. The TelaBio product falls within the same contract category and is therefore considered a direct competitor.
Previously, a limited conditional approval was granted for TelaBio to be used only in the event of a product issue or recall with BD. While I am open to ordering TelaBio for a specific patient case when clinically necessary, it is not approved to be carried as part of our regular stock.
Please note that usage will be closely monitored. If our compliance with BD falls below 85%, we face significant pricing penalties that would negatively impact our financial performance.

90. BD has designed its exclusionary contracts to foreclose market participation by any of its direct competitors, like TELA Bio, in the Resorbable mesh market. As a Vice President of Supply Chain Management for a large IDN explained to a TELA Bio employee:

Unfortunately on a business level, [redacted] cannot afford to consider the TeleBio contract due to the award structure of the [redacted] agreement. To boil it down simply, when they split the category into two, they actually made it worse for [redacted]. Not doing business with BD highly in both Synthetic and Absorbable categories makes the pricing in the category remaining significantly punitive. While the TeleBio pricing would save us around $120k on Absorbable, it would force us to Access Tier with BD on Synthetics or require a 100% conversion to Medtronic, which won't happen. The access tier is effectively a doubling in price, or about $880k in price increases.

We cannot afford any increases, let alone a net increase north of $700k on mesh.

91. In another email to a TELA Bio sales director, a purchasing service line manager for a large healthcare network explained the significant financial implications of BD's conditional pricing across its surgical mesh, xenograph mesh, and endomechanical fixation product lines on that hospital's supply chain procurement process:

[redacted] is currently at a 25% Telabio/75% BD/Davol market share which puts [redacted] at a financial risk with our contract compliance. [redacted] needs to be >80% of total product purchases in all the categories, surgical mesh (synthetic) bioabsorbable mesh, xenograph mesh (ab wall), endomechanical fixation and this 5% gap represents significant financial implications. Therefore, we are continuing to monitor our mesh compliance to ensure we meet our BD/Davol contractual obligations and have communicated to our key internal clinical stakeholders the at-risk financial issue.

If you have any additional questions, please let me know.

Regards,
[redacted]

92. Yet another supply chain employee for a large regional IDN wrote:

> Right now I'm looking at the analytics of contract compliance. It looks like some of our phasix use would or could be potentially impacted by this consignment, which would put us out of compliance.
>
> I have to get the full financial impact before presenting to my VP. Your cost per item is cheaper, however market share compliance is at risk with potential higher structure on the davol/bard products.

93. As these emails show, TELA Bio cannot overcome BD's exclusionary contracting scheme even though OviTex is *cheaper* per unit than Phasix. TELA Bio cannot offer any comparable conditional price given its small product portfolio. So it cannot compete on the merits, even though OviTex costs less and works better than BD's Phasix.

94. By threatening buyers with the loss of their conditional pricing across hernia mesh and other product categories, BD can effectively prevent buyers from purchasing TELA Bio's less expensive OviTex product even if there is significant interest in doing so. For example, in response to an email from one of TELA Bio's sales managers inquiring about a potential contract to purchase TELA Bio's OviTex products, the Vice President of Supply Chain for a major IDN stated:

Hi [redacted],

I have looked at this nine ways to Sunday and there is no wiggle room with where we are today. The compliance calculation is not a simple average as in your hypothetical below. It is total dollars spent with BD in both categories divided by total spent with all vendors. We are barely at 80% right now and are actively converting non-BD mesh to get our combined average to the required 85%. I have literally built about 9 scenarios where I have tried to carve out niches that we can play within, while still allowing some choice. There are only two answers that come up with us not costing ourselves more than $200k on net. Option 1: get to combined 85% with BD and pretty much break even…maybe $75k savings on $1.8M. Option 2: 100% conversion to both Medtronic and Telebio. Falling short of complete conversions means any dollars left with BD triple in price and wipe away any savings. With our lack of physician alignment, there is no way option 2 is realistic. Thus, option 1 is the only alternative. We went ahead and made our LOC selections based on my scenarios and will remain with BD for this cycle. I wish there was space to entertain what you've suggested, but just won't work out.

Thank You!
[redacted]

95. Buyers also report that the terms of BD's contracts effectively impose exclusive purchasing requirements. By offering surgeons hernia mesh options from BD's competitors, buyers risk inadvertently falling out of compliance with the terms of BD's contracts. So, to ensure compliance with its multi-year contractual commitments to BD, these buyers take a number of measures, including refusing to contract with BD's competitors like TELA Bio, standardizing their product stock across the hernia mesh supply chain to one manufacturer like BD, or declining to place orders for inventory stock from BD's competitors like TELA Bio. As a supply chain manager for a large healthcare system that uses a GPO to negotiate its supplier contracts explained:

> Hi [redacted],
> Sorry for the late response. I had to do some digging, as I have not received any requests for Ovitex from our sites. However, I did find out we are currently under a highly committed GPO agreement with BD for synthetic mesh, which is why the sites are most likely not submitting a request for this product.

96. BD's anticompetitive scheme also has the practical effect of physically excluding TELA Bio from marketing to these contracted entities. For instance, one supply chain manager for a major IDN wrote to tell a TELA Bio sales representative to not even contact surgeons and staff at their affiliate hospitals about their interest in OviTex because the IDN—to avoid falling out

of compliance with its contractual commitment—had decided to standardize its Resorbable hernia mesh to BD products:

> A couple of months ago, I shared with [redacted] that [redacted] would not be able to bring in OVITEX. [redacted] has standardized to Phasix. Since this time, I have heard you in our OR and meeting with staff and surgeons. I need to ask you starting today, not visit our facility during the next few years unless you have been specifically invited by the supply chain. This contract is in effect for several years so please remain on the sidelines and respect this decision for the [redacted] facilities.

97. Not only has BD taken affirmative steps to exclude TELA Bio from the hernia mesh market through its complex contractual scheme, it has also undertaken a targeted campaign to exclude TELA Bio by leveraging its market power in the United States. There are numerous instances where, at BD's request, TELA Bio sales representatives were banned from particular hospitals, and at least one or two instances where TELA Bio has been excluded from healthcare events or conferences at BD's request. Moreover, on at least one occasion, a BD sales representative walked into an operating room to inform the surgeon that he was not "allowed to use OviTex" because it was "not compliant" with the hospital's contract with BD.

98. TELA Bio has tried many strategies to circumvent BD's bundling arrangements—including by marketing OviTex as falling into a new category outside of the bundled categories—but each time TELA Bio has pivoted, BD has shut it out.

99. The same is true for physician-led efforts to advocate for OviTex: they are consistently met with roadblocks and resistance from their affiliated care providers because of BD's contracts and pressure from BD itself. For example, after one surgeon at a hospital that contracts with BD received conditional, one-time approval to use TELA Bio's OviTex product for a complex ventral hernia repair, TELA Bio wrote to the hospital's contracts analyst to ask about entering into a contract for OviTex to be made available without the need for case-by-case approval. In response, that contract analyst wrote:

Hi [redacted],

Things have been quite busy here, so I apologize for the delay in response. It's nice to digitally meet you.

While I appreciate your interest and enthusiasm for trying to win the business, that one usage generated a lot of concern among our vendors and staff and lead to a day of me having to put out fires. Right now bringing Ovitex on board is still not something we are interested in doing. Since it was declined by the Executive Steering Committee, it is not eligible for review for 12 months. After those 12 months, Dr. [redacted] is welcome to submit it again with your revised proposal.

In other news, I will be leaving the organization after next week. Even without the cooling off period on requests, there is not much I could get done for you in the next few days.

Thanks,

[redacted]

Contract Analyst

100. In another instance, a surgeon who had been using Phasix requested to use OviTex for an upcoming hernia repair case instead. The Clinical Resources Director for that hospital responded to a TELA Bio sales representative's email inquiring how the company could provide the surgeon with its product, to which the hospital employee responded:

> The issue that I anticipate is that we are right in the middle of a Bard mesh conversion at the facility, as this is a benchmarking initiative, and several other facilities within the division are looking to do the same. Phasix is a Bard mesh, and by converting to Ovitex, we would be working AGAINST the initiative we have already initiated.

101. By limiting physician choice, BD's conduct reduces access to care and harms vulnerable patients. For example, in March 2025, a surgeon at an Arizona hospital that contracts with BD for hernia mesh products asked to use OviTex for a complicated case where the patient had multiple previous failed hernia repairs and required immediate surgery. Despite many requests by the surgeon and by the patient's family for approval to use OviTex, the hospital's supply chain management team refused to approve OviTex for the case, citing its contract with BD as the reason. After weeks of delay, the patient's family paid for OviTex out of pocket so they wouldn't have to use Phasix. But by then, the patient's condition had considerably worsened. The patient coded on the operating table and died later that day.

* * *

102. Even though TELA Bio offers a better and less expensive product, and despite vigorous efforts to compete, TELA Bio has been foreclosed from gaining a competitive foothold as a direct result of BD's scheme. Over the last few years, TELA Bio's OviTex sales were just 8% of the Resorbable mesh market in the United States by dollar share and 9% by unit share in 2024. If not for BD's exclusionary and anticompetitive practices, TELA Bio's growth in the Resorbable hernia mesh market would be much greater than it has been and would be substantially larger in the future. In contrast to its limited success in the U.S. market, TELA Bio's direct sales of OviTex in the U.K. market have increased at a steady pace, and its dollar share of the U.K. Resorbable hernia mesh market is significantly greater than in the United States. The key difference? The anticompetitive arrangements BD has used to put a ceiling on OviTex's growth are unavailable in the U.K.

103. BD's conduct has deprived TELA Bio of: (1) past profits, (2) future profits, and (3) the value of invested capital from unrealized efforts to enter and expand in the relevant Resorbable hernia mesh market. Further, TELA Bio's current and prospective customer relationships and goodwill have been, and will continue to be, impaired. BD's conduct, if allowed to continue, will also dampen the incentives of TELA Bio and other competing hernia mesh manufacturers to invest the substantial resources needed to bring new, innovative, and better mesh products to the market.

104. BD's anticompetitive conduct has not only harmed TELA Bio; it has caused substantial harm to the competitive process as well as to members of the public and the healthcare community at large, who have been deprived of the principal benefit of competition—more choices and lower prices. This leads to consistently worse health outcomes, as evidenced by the patient who died waiting to use OviTex after the hospital refused to provide it based on BD's restrictive contract terms. And as evidenced by the many surgeons who have asked to use OviTex and been denied, there is significant unmet demand for OviTex among U.S. care providers. TELA Bio would achieve far greater success, benefiting consumers and care providers, but for BD's anticompetitive conduct.

105. The anticompetitive effects of BD's conduct are also evident in the pricing of its hernia mesh products like Phasix. Despite the fact that TELA Bio has offered discounts and a lower average selling price on its OviTex products to compete for business, BD has been able to increase the price of its products without losing any significant share or volume of sales to TELA Bio (or any other competitor): BD's prices for Phasix have been increasing by every measure over the last several years. And Phasix's average selling price has also increased since OviTex's entry—negating any claim that BD's conditional prices qualify as meaningful price competition.

CLAIMS FOR RELIEF

COUNT 1: MONOPOLIZATION OF THE RESORBABLE HERNIA MESH MARKET IN VIOLATION OF THE SHERMAN ACT, 15 U.S.C. § 2

106. Plaintiff TELA Bio repeats and incorporates by reference each of the foregoing allegations of this Complaint.

107. Defendant BD has monopolized the Resorbable hernia mesh market in violation of Section 2 of the Sherman Act.

108. BD possesses monopoly power in the Permanent and Resorbable hernia mesh markets.

109. Through the anticompetitive and exclusionary scheme and actions described above, and other conduct likely to be revealed in discovery, BD has willfully and unlawfully acquired, maintained, and enhanced its monopoly power in the Resorbable hernia mesh market in violation of Section 2 of the Sherman Act. BD's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act. BD's conduct includes exclusive dealing, illegal bundling arrangements, monopoly leveraging, and/or other anticompetitive conduct. BD has leveraged, and continues to leverage, its monopoly power in the Permanent and Resorbable hernia mesh markets by imposing contractual terms on purchasers of its hernia mesh that penalizes purchasers for buying hernia mesh products from rivals such as TELA Bio.

110. Defendant BD's scheme has stifled competition in the Resorbable hernia mesh market.

111. By engaging in this exclusionary conduct as alleged herein, BD has gained an artificial and unlawful advantage in the Resorbable hernia mesh market from its monopoly power. As a result, BD has unfairly impeded, and continues to unfairly impede, competition in the Resorbable hernia mesh market. The purpose and effect of BD's conduct has been, and continues to be, to suppress competition rather than promote it.

112. There are no procompetitive justifications for BD's conduct.

113. As a result of BD's unlawful conduct, TELA Bio has suffered, and continues to suffer, monetary harm in an amount to be proved at trial.

COUNT 2: ATTEMPTED MONOPOLIZATION OF THE RESORBABLE HERNIA MESH MARKET IN VIOLATION OF THE SHERMAN ACT, 15 U.S.C. § 2

114. Plaintiff TELA Bio repeats and incorporates by reference each of the foregoing allegations of this Complaint.

115. Defendant BD has intentionally and unlawfully attempted to monopolize the Resorbable hernia mesh market in violation of Section 2 of the Sherman Act.

116. BD is violating Section 2 of the Sherman Act by attempting to implement the anticompetitive scheme set forth herein.

117. The anticompetitive conduct set forth herein evinces a specific intent to monopolize and a dangerous probability of BD monopolizing the Resorbable hernia mesh market. BD's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

118. The anticompetitive conduct set forth herein has been directed at accomplishing the unlawful objective of controlling prices and/or destroying competition in the Resorbable hernia mesh market.

119. There is a dangerous probability that BD will succeed in monopolizing the Resorbable hernia mesh market through its anticompetitive scheme.

120. BD's scheme has stifled competition in the Resorbable hernia mesh market.

121. As a direct and proximate result of BD's wrongdoing alleged herein, TELA Bio has been injured in its business, having suffered, among other things, substantial lost revenue, and will likely be driven from the Resorbable hernia mesh market altogether if BD is not enjoined from engaging in its anticompetitive conduct.

COUNT 3: UNLAWFUL RESTRAINT OF TRADE IN VIOLATION OF THE SHERMAN ACT, 15 U.S.C. § 1

122. Plaintiff TELA Bio repeats and incorporates by reference each of the foregoing allegations of this Complaint.

123. By reason of the agreements and understandings reached with its customers to purchase its hernia mesh products under the terms and conditions of those sales, Defendant BD has acted in concert with its customers to unreasonably restrain trade in the Resorbable hernia mesh market in violation of Section 1 of the Sherman Act.

124. As a consequence of this concerted action, TELA Bio has been injured in its business.

125. As a consequence of this concerted action, competition in the Resorbable hernia mesh market has been harmed.

COUNT 4: ANTICOMPETITIVE EXCLUSIVE DEALING IN VIOLATION OF THE CLAYTON ACT, 15 U.S.C. § 14

126. Plaintiff TELA Bio repeats and incorporates by reference each of the foregoing allegations of this Complaint.

127. Defendant BD sells and has sold hernia mesh, and it conditions its pricing for those sales on each buyer not substantially dealing in TELA Bio's hernia mesh products. BD's agreements function as per se exclusive dealing agreements that are, for all practical purposes, sole-source contracts, the effect of which is to substantially foreclose competition from BD's rivals, such as TELA Bio.

128. BD's exclusive dealing violates Section 3 of the Clayton Act because it has foreclosed TELA Bio from substantial portions of the Resorbable

hernia mesh market, has substantially lessened competition in that market, and tends to create a BD monopoly over that market.

129. The intent and effect of the buyers' performance of these contracts is to cause care providers to forego alternatives to BD's Resorbable hernia mesh and drive all sales of Resorbable hernia mesh to BD. The result of BD's contracts thus is the amplification of foreclosure, such that TELA Bio is denied access to a substantial portion—likely upwards of 90%—of sales in the Resorbable hernia mesh market and foreclosed from competition in that market.

130. These *de facto* exclusive arrangements are in effect durable long-term agreements because the incentives BD has exploited are not likely to change. So long as BD's contracts remain in place, TELA Bio and other competitors cannot penetrate BD's extensive web of exclusionary contracts, and the incentives underlying BD's contracts will remain. No buyer can practically walk away from and cease performing BD's contracts due to the above-discussed financial penalties.

131. The effect of each such contractual agreement is, and has been, to substantially lessen competition in the Resorbable hernia mesh market. The aggregate impact of such contracts is, and has been, to substantially lessen competition or tend to create a monopoly in the Resorbable hernia mesh market.

132. BD's conduct has had anticompetitive effects in the Resorbable hernia mesh market, including, without limitation, the effects described above.

133. TELA Bio has been damaged by the loss of sales and profits resulting from buyers' unwillingness and inability to resist BD's exclusive dealing arrangements. As a result of BD's conduct, and the harm to competition caused by that conduct, TELA Bio has suffered substantial and continuing injuries.

PRAYER FOR RELIEF

134. WHEREFORE, TELA Bio requests the Court to enter judgment in its favor against Defendants, awarding all such relief as the Court deems appropriate and just.

135. TELA Bio requests the following relief:

a. That the Court enter an order declaring that Defendants' actions, as alleged herein, violate the Sherman Act and Clayton Act;

b. That the Court enjoin Defendants from continuing to violate the Sherman Act and Clayton Act and enter relief to restore competition;

c. That the Court enjoin Defendants from taking additional actions that will further harm competition;

d. That the Court award Plaintiff TELA Bio damages, treble damages, punitive damages, and/or restitution in an amount to be determined at trial;

e. That the Court award Plaintiff TELA Bio pre- and post-judgment interest;

f. That the Court award Plaintiff TELA Bio its costs of suit, including reasonable attorneys' fees and expenses; and

g. That the Court award any and all such other relief as the Court may deem proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, TELA Bio demands a jury trial of all issues so triable.

Dated: December 19, 2025

Respectfully submitted,

/s/ *Steven Maniloff*

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**Pro hac vice* motions forthcoming

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