PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Andrew N. Ferguson, Chairman**
Melissa Holyoak
Mark R. Meador

In the Matter of **GTCR, LLC,** **a corporation;** **GTCR BC HOLDINGS, LLC,** **a corporation;** **and** **SURMODICS, INC.,** **a corporation.**	**Docket No. 9440**

AMENDED COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents GTCR, LLC, GTCR BC Holdings, LLC (collectively, "GTCR") and Surmodics, Inc. ("Surmodics") (together with GTCR, "Respondents") have executed an acquisition agreement pursuant to which GTCR and its affiliates and subsidiaries will acquire substantially all the assets of Surmodics (the "Proposed Acquisition") in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and which if consummated would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

NATURE OF THE CASE

1. GTCR, LLC is a private equity firm based in Chicago, Illinois, which in late 2022 acquired a majority stake in Biocoat, Inc. ("Biocoat"), the second-largest provider of hydrophilic coatings in the United States. GTCR, LLC, through its affiliate, GTCR BC Holdings, LLC, now proposes to acquire Surmodics, the largest provider of hydrophilic coatings in the United States. The Proposed Acquisition, if consummated, would result in a combined company that controls over 50 percent of the market for outsourced hydrophilic coatings, which are critical inputs into lifesaving medical devices. The Proposed Acquisition may therefore lead to a substantial lessening of competition in an already concentrated market, as well as a loss of head-to-head competition,

resulting in lower quality and service levels, diminished innovation, and higher prices for hydrophilic coatings sold to U.S. medical device customers.

2. Hydrophilic coatings are applied to a wide range of interventional medical devices used inside the human body, such as catheters and guidewires, to perform high-stakes neurological, cardiovascular, and peripheral vascular procedures. These medical devices require hydrophilic coatings to reduce friction during use so that the devices function as intended. The coatings allow physicians to maneuver medical devices within the tight confines of the body—for example, within a blood vessel in the brain—without damaging sensitive tissue or vital structures.

3. Hydrophilic coatings are primarily purchased by original equipment manufacturers ("OEMs") that design, develop, and manufacture medical devices. OEMs range from large, established companies with numerous commercialized devices to smaller startup companies with new and innovative devices in development. Though hydrophilic coatings can be manufactured by an OEM in-house, the vast majority of OEMs opt to purchase hydrophilic coatings produced by specialized third-party manufacturers, such as Surmodics and Biocoat.

4. The Proposed Acquisition may be analyzed in a relevant market that is no broader than outsourced hydrophilic coatings. Specialized third-party hydrophilic coating providers are a distinct, critical, and growing part of the medical device ecosystem.

5. Surmodics and Biocoat are the two leading providers in the outsourced hydrophilic coatings market. Surmodics describes itself as the [redacted] Biocoat likewise describes Surmodics as the [redacted] and the [redacted] while Biocoat's CEO has described Biocoat as the second-largest player in the [redacted] OEMs also recognize Surmodics and Biocoat as the two most significant players in the market, noting that both companies have longstanding reputations for producing high performance coatings on FDA-approved medical devices.

6. The Proposed Acquisition is presumptively illegal because it would significantly increase concentration in the already highly concentrated outsourced hydrophilic coatings market. The Proposed Acquisition would result in GTCR controlling more than 50 percent of the outsourced hydrophilic coatings market in the United States, well above the threshold to establish a prima facie case that the Proposed Acquisition is unlawful. Ordinary course documents, witness testimony, and economic analysis further confirm this strong presumption of illegality.

7. This increase in market concentration is especially concerning because [redacted]

8. Moreover, the Proposed Acquisition is unlawful because it would eliminate significant head-to-head competition between Biocoat and Surmodics. Biocoat and Surmodics target the same OEM customers and compete aggressively for their business. Biocoat has

identified Surmodics as [redacted] Biocoat executives have discussed [redacted] Surmodics likewise views Biocoat as a [redacted] and has sought to win customers from Biocoat, including [redacted] The head of Surmodics' coatings business, upon learning of GTCR's purchase of Biocoat, declared [redacted] competition has led both Surmodics and Biocoat to offer higher quality coatings and service, better pricing terms, and more innovative products. The Proposed Acquisition is unlawful because it will eliminate this competition and its attendant benefits, harming OEM customers and, ultimately, patients.

9. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. The merging parties cannot demonstrate that new entry in the market would be timely, likely, or sufficient to offset these anticompetitive effects. Nor can they show cognizable, verifiable, or merger-specific efficiencies sufficient to offset the likely and substantial competitive harm from the Proposed Acquisition.

JURISDICTION

10. Respondents and each of their relevant operating affiliates and subsidiaries are, and at all relevant times have been, engaged in commerce or activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

11. The Proposed Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

RESPONDENTS AND THE PROPOSED ACQUISITION

12. Respondent GTCR BC Holdings, LLC, is an affiliate of GTCR, LLC, which is a private equity firm founded in 1980 and headquartered in Chicago, Illinois [redacted] GTCR owns a portfolio of companies in the medical technology, pharmaceutical, financial services, media, and telecommunications industries. Since 2000, GTCR has invested in approximately 125 portfolio companies and currently manages $40 billion in equity capital.

13. On November 2, 2022, GTCR announced that it had made a majority investment in Biocoat. GTCR gained a controlling interest in Biocoat, and GTCR and its affiliate, Regatta Medical [redacted]

14. Biocoat, founded in 1991, is a hydrophilic coating provider headquartered in Horsham, Pennsylvania. Biocoat operates two different business segments: coating products and coating services. Biocoat's coating products unit formulates and sells hydrophilic coatings directly to customers under the brand name "Hydak." Biocoat's coating services unit provides two distinct services: (1) application development, which assists medical device companies in optimizing Biocoat's coating chemistry for their products; and (2) commercial coating services, which coats customers' devices with the optimized coating.

15. Surmodics, founded in 1979 and headquartered in Eden Prairie, Minnesota, is a publicly traded company that sells medical devices, in-vitro diagnostics, and hydrophilic coatings. Like Biocoat, Surmodics offers both hydrophilic coating products and related services, such as application development, regulatory and commercialization support, and commercial coating services. Surmodics' hydrophilic coatings are generally marketed under the brand names "Serene" and "Preside." Surmodics also develops and markets its own interventional medical devices under the brand names "Pounce" and "Sublime."

16. Pursuant to a merger agreement dated May 28, 2024, GTCR through its corporate affiliates and their subsidiaries, agreed to acquire Surmodics for $43 per share, for a total valuation of approximately $627 million.

INDUSTRY BACKGROUND

17. Hydrophilic coatings are applied to interventional medical devices such as catheters, guidewires, sheaths, and stents, that are inserted into confined spaces in the human body. These coated devices are used in a range of interventional procedures such as neurovascular, structural heart, coronary, and peripheral vascular procedures.

18. Although they are a relatively small part of the overall cost of a medical device, hydrophilic coatings are critical to a device's safety and performance. They increase the lubricity of the device, enabling physicians to navigate the device through small, sensitive structures, such as blood vessels, without causing abrasions. Without a hydrophilic coating, excessive friction created by the medical device's movement could damage vital structures within the patient.

19. A hydrophilic coating's performance primarily turns on three criteria:

a. lubricity, a measure of the reduction in friction that occurs when a medical device has a hydrophilic coating;

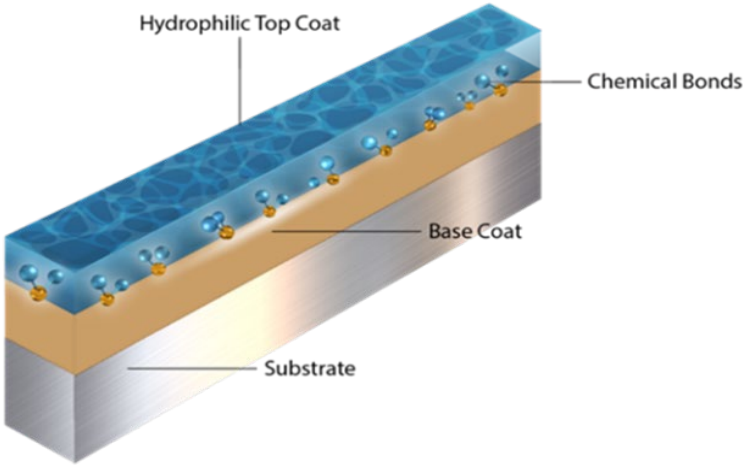
b. particulate count, which measures the amount of hydrophilic coating particles that are shed from the medical device during use; and

c. durability, which measures the hydrophilic coating's ability to maintain its quality of performance, including its high lubricity and low particulate count, over time.

20. The FDA tests the performance and safety of hydrophilic coatings during its review of the medical devices that use them. An OEM with a medical device that is rejected by the FDA due to poor hydrophilic coating performance can be set back by millions of dollars and multiple years. OEMs typically hedge against that risk by relying on hydrophilic coating providers with a reputation for high performance, good service, and a history of FDA approvals.

21. Most hydrophilic coatings consist of both a base coat and a top coat. Like paint primer, the base coat is used to normalize and prepare the surface (referred to as the "substrate") of the medical device for coating. Typically, the base coat can better chemically bind to a wider range of substrates (e.g., different polymers, metals, and other surface materials) than the top coat

and is itself a superior substrate for the top coat to bind to as well. The top coat is then applied onto the base coat, and it is the top coat which gives the medical device its lubricity.



[Fig. 1]

22. Hydrophilic coatings are typically applied by either dipping the medical device in the coating liquid or by spraying the coating on. After the coating has been applied, it must then be cured. The method for curing will depend on the chemistry of the specific hydrophilic coating. The two most common ways to cure hydrophilic coatings are either by heating them in an oven (thermal curing) or by exposing them to UV light (UV curing).

23. Competitors and OEMs that participate in the outsourced hydrophilic coatings market consistently report that *both* thermal and UV curing are suitable for the vast majority of medical devices. One hydrophilic coating competitor estimated that [redacted] OEMs typically select a hydrophilic coating supplier based on overall performance and track record of FDA approval rather than the method of curing. For a small subset of devices, however, only one method is suitable: *either* thermal curing *or* UV curing. Thermal curing is generally required, for example, to coat the inner diameter of medical devices, where UV light may not be able to reach, and UV curing may be required for devices that react poorly to very high temperatures.

24. OEMs often engage with hydrophilic coating providers very early in the process of developing a medical device—either a new device or the next generation of an existing product—to determine which hydrophilic coating might best serve their needs. First, the OEM conducts initial testing, also referred to as a feasibility study. As part of the feasibility study, the OEM sends samples and design specifications of their product to the hydrophilic coating provider, which then adjusts its hydrophilic coating formula and process based on the device substrate and the OEM's performance goals. As part of this process, OEMs may test each coating sequentially or conduct feasibility studies with multiple coating providers at the same time before selecting the provider and coating that offers the best mix of performance, service, and price.

25. The next step in the coating selection process is optimization. Once an OEM has identified its preferred coating formulation, the OEM will continue to work with the coating provider to make further adjustments to the coating's formulation and application process. This

iterative process occurs while the OEM continues to adjust the design of the medical device itself, as both the OEM and hydrophilic coating provider strive to achieve an optimal dynamic between the coating and device substrate.

26. Once a hydrophilic coating is finally "locked in," the coating provider may also offer development and commercialization support, which includes a range of services to help prepare the OEM to launch the medical device. For example, the coating provider may itself apply the coating to the medical devices for pre-clinical or early commercial use. The coating provider may also work with the OEM on technology transfer issues to prepare the OEM to take over the coating application process. If the OEM plans to coat the devices itself, the coating provider will work out an arrangement to supply the proprietary reagents needed to do so. Finally, the coating provider may provide regulatory support to the OEM as it seeks FDA approval for its device. Although the FDA does not require hydrophilic coatings on medical devices, if an OEM submits a device for review with a hydrophilic coating, the FDA will examine the safety and efficacy of the coating along with the rest of the medical device.

27. Hydrophilic coating providers derive the vast majority of their revenue from sales of commercialized medical devices. Although hydrophilic coating providers typically do not start earning any revenue related to the sale of a commercialized medical device until two to four years after the beginning of feasibility testing, successful medical devices may be sold on the market with the same hydrophilic coating for over a decade. The coating provider generates some revenue by selling coating reagents to the OEM for the entire lifecycle of the device but typically earns more revenue from a licensing agreement between the coating provider and the OEM for continued use of the proprietary coating, under which the coating provider may receive various licensing fees and milestone payments and, more importantly, an additional payment for each unit of the medical device sold. This additional payment can take the form of a fixed amount per unit sold or a royalty (i.e., a percentage of the average sale price).

THE RELEVANT ANTITRUST MARKET, MARKET STRUCTURE, AND THE PROPOSED ACQUISITION'S PRESUMPTIVE ILLEGALITY

28. The Proposed Acquisition would significantly increase concentration in the already highly concentrated market for outsourced hydrophilic coatings in the United States. Surmodics and Biocoat are the top two competitors, and should the Proposed Acquisition be consummated, the merged entity would control over 50 percent of the market. The resulting level of market concentration and the increase in market concentration due to the merger make the Proposed Acquisition presumptively unlawful under the 2023 U.S. Department of Justice and Federal Trade Commission Merger Guidelines (the "Merger Guidelines") and controlling case law.

A. The Relevant Product Market

29. The relevant product market is no broader than outsourced hydrophilic coatings. Outsourced hydrophilic coatings have unique characteristics and serve specific customer needs. There are no reasonably interchangeable substitutes for hydrophilic coatings. Although other types of coatings, such as hydrophobic coatings—which repel water rather than attract it—can also provide some lubricity to a medical device, they have a much lower level of performance compared to hydrophilic coatings. Moreover, the most common hydrophobic coating material,

polytetrafluoroethylene ("PTFE"), cannot be used to coat the outer diameter of certain medical devices (such as catheters) because PTFE can only be shaped and formed at extremely high temperatures. Coating the outer diameter of a medical device with PTFE at the end of the manufacturing process may damage the rest of the device. Safety and performance concerns related to the use of PTFE on medical devices have recently led some OEMs to switch from PTFE to hydrophilic coatings, but, for the same reasons, OEMs would not switch from hydrophilic coatings to PTFE, even if prices of hydrophilic coatings increased significantly.

30. Industry participants—including competitors, customers, and Respondents themselves—all recognize that the outsourced hydrophilic coatings market is a distinct market in which Surmodics and Biocoat are the largest players and frequent head-to-head competitors. Surmodics and Biocoat target many of the same large, small, and startup OEMs for business development.

31. Hydrophilic coatings are complicated products that require specialized expertise, years of research, and millions of dollars to develop. As such, small and startup OEMs generally do not have the capabilities to produce their own in-house hydrophilic coatings and must therefore rely on the outsourced market for their coating needs. Moreover, because hydrophilic coatings are a relatively small line item on the total cost of manufacturing a medical device, most larger OEMs also choose not to invest the time or resources into developing an in-house coating.

32. Outsourced hydrophilic coatings from the market leaders, Surmodics and Biocoat, have meaningfully better performance than in-house solutions. They are more lubricious, shed fewer particulates, and have greater durability. Thus, large and small OEMs alike depend on outsourced hydrophilic coatings when their devices have coating performance requirements above and beyond what in-house coatings can offer. Indeed, demand for outsourced hydrophilic coatings is expected to grow as the FDA implements increasingly stringent coating performance requirements, especially with regard to particulate count.

33. Outsourced hydrophilic coating providers also offer important development and commercialization support and services that many OEMs do not have the expertise, time, or resources to perform themselves. Simply having access to a base hydrophilic coating is insufficient; OEMs depend on feasibility testing and optimization services from hydrophilic coating providers to customize the coating so that it best fits their products. OEMs also depend on the product expertise and technical know-how from hydrophilic coating providers to get their manufacturing started and working smoothly. And OEMs may even depend on outsourced hydrophilic coating providers for contract coating services for their medical devices at all stages of the product's lifecycle, including pre-clinical, clinical, and commercialization.

34. For all these reasons, OEMs are unlikely to switch from outsourced hydrophilic coatings to in-house solutions in response to a small but significant price increase.

B. The Relevant Geographic Market

35. The relevant geographic area in which to analyze the effects of the Proposed Acquisition is the United States.

36. Hydrophilic coatings are a key component of medical devices. The FDA regulates the production, development, testing, manufacture, marketing, and promotion of medical devices in the United States. A company must perform testing and obtain 510(k) clearance from the FDA, which requires demonstrating substantial equivalence to another legally U.S. marketed medical device, before marketing a medical device in the United States. Accordingly, hydrophilic coatings sold exclusively outside the United States, and not used on devices approved for sale in the United States, are not viable alternatives for U.S. medical device customers, even if the prices for hydrophilic coatings currently available in the United States increase significantly.

C. The Relevant Market is Highly Concentrated

37. The Proposed Acquisition is presumptively illegal because it significantly increases concentration and results in a highly concentrated market for outsourced hydrophilic coatings. The impact of the Proposed Acquisition on market concentration is sufficient to establish a prima facie case that the Proposed Acquisition violates the antitrust laws.

38. The market for outsourced hydrophilic coatings manufacturers is highly concentrated. Surmodics and Biocoat together account for over 50 percent of the outsourced hydrophilic coatings market. The remainder of the market is comprised of smaller hydrophilic coating providers that lack Surmodics' and Biocoat's reputation for high quality coatings and service and track record of coating successful FDA-approved medical devices.

a. #1: Surmodics

39. Surmodics is the acknowledged market leader, generating roughly [redacted] million in annual revenue from its U.S. hydrophilic coatings business in 2023. [redacted] Its customers include large and small OEMs that make devices for neurovascular, peripheral vascular, coronary, and structural heart procedures.

40. Surmodics' hydrophilic coatings are UV-cured, and its products are sold under the brand names Serene and Preside. Surmodics launched Preside in October 2023, [redacted]

b. #2: Biocoat

41. Biocoat is the second-largest competitor in the outsourced hydrophilic coatings market and earned approximately [redacted] million in U.S. coatings revenue in 2023. Like Surmodics, Biocoat's revenue is primarily driven by the provision of coatings and coating-related services to OEMs that manufacture neurovascular, coronary, peripheral vascular, and structural heart devices. [redacted]

42. Historically, Biocoat specialized in thermal-cured hydrophilic coatings sold under the brand name Hydak. In 2017, Biocoat hired Robert Hergenrother, Surmodics' former Senior Director of Hydrophilic Technologies, as its Senior Director of Research and Development. Under the direction of Dr. Hergenrother, Biocoat developed and launched its own UV-cured hydrophilic coating, called "Hydak UV," in 2020. This development allowed Biocoat to more closely compete

with Surmodics for OEMs that had already invested exclusively in UV-curing equipment to apply coatings to their medical devices.

c. #3: Harland

43. Harland is the third-largest player in the market, generating approximately [redacted] million in coatings-related revenue in 2023. Harland only sells UV-cured hydrophilic coatings, under the brand names Lubricent and Tylicent, which were launched in 2016. Before 2016, Harland contracted with a smaller hydrophilic coating provider, Innovative Surface Technologies, Inc. (also known as "ISurTec"), to bundle ISurTec's coatings with Harland's equipment.

d. #4: DSM

44. DSM, which also exclusively sells UV-cured hydrophilic coatings, is the fourth-largest competitor in the market for outsourced hydrophilic coatings, generating approximately [redacted] million in coatings-related revenue in 2023. DSM is a division of dsm-firmenich, a Dutch company focused on health and nutrition.

e. Fringe Competitors

45. Several smaller market participants, including Hydromer and ISurTec, collectively comprise the remainder of the outsourced hydrophilic coatings market. These companies do not offer the same level of performance, track record of success, or suite of services as Surmodics and Biocoat.

D. The Proposed Acquisition Would Lead to a Presumptively Illegal Level of Market Concentration

46. Courts, federal and state agencies, and economists commonly employ market shares and a metric known as the Herfindahl-Hirschman Index ("HHI") to measure market concentration. The HHI for a given market is calculated by summing the squares of the individual firms' market shares. A perfectly competitive market has an HHI approaching zero, whereas a market consisting of a single monopolist (i.e., a pure monopoly) has an HHI of 10,000. A market is considered highly concentrated if it has an HHI of more than 1,800.

47. An acquisition is presumptively illegal under the Merger Guidelines and controlling case law if it increases the HHI of a relevant market by more than 100 points and either (a) produces a post-acquisition HHI greater than 1,800 points or (b) creates a combined firm with a market share greater than 30 percent.

48. Preliminary information indicates that the outsourced hydrophilic coatings market is already highly concentrated, with an HHI in excess of 1,800. The Proposed Acquisition would result in a merged entity with control of over 50 percent of the relevant market, a post-merger HHI exceeding 3,500 and a change in HHI of over 1,000—levels that substantially surpass the threshold for presumptive illegality. The Proposed Acquisition is therefore presumptively illegal under the Merger Guidelines and controlling case law.

E. GTCR's Plan to Consolidate the Outsourced Hydrophilic Coatings Market

49. The Proposed Acquisition is consistent with GTCR's acquisition strategy, dating back to its original Biocoat investment, for an [redacted] in the outsourced hydrophilic coatings market. In a presentation to its investment committee in August 2022, GTCR explained [redacted] and described the outsourced hydrophilic coatings market as having [redacted]

50. To that end, GTCR [redacted] A January 2023 Biocoat board of directors presentation noted that [redacted]

51. Before pursuing Surmodics, GTCR and Biocoat [redacted] In January 2023, Biocoat's Executive Chairman wrote [redacted] An initial draft of this letter [redacted] in the medical biomaterials sector, though [redacted] GTCR and Biocoat circled back in January 2024 [redacted] GTCR began exploring an acquisition of the #1 player, Surmodics.

52. [redacted] On June 3, 2024, after the Proposed Acquisition was announced, GTCR [redacted]

ANTICOMPETITIVE EFFECTS OF THE PROPOSED ACQUISITION

53. Internal documents from both companies, as well as competitor and customer testimony, recognize Surmodics and Biocoat as head-to-head competitors in the outsourced hydrophilic coatings industry. The Proposed Acquisition will eliminate this competition, removing a key driver of quality, competitive pricing, and innovation to the detriment of OEMs and patients that rely on interventional medical devices.

A. Surmodics and Biocoat Compete Head-to-Head

54. Surmodics and Biocoat compete head-to-head for customers. The companies target many of the same OEM customers for business development, including both well-established and startup manufacturers.

55. Surmodics and Biocoat consistently identify each other as key competitors in the outsourced hydrophilic coatings market. This mutual recognition is evident in numerous internal communications and strategic planning documents from both companies. [redacted] In a July 2022 internal email, [redacted]

56. Indeed, head-to-head competition between Surmodics and Biocoat accelerated after GTCR acquired Biocoat. For example, [redacted] shortly after the Proposed Acquisition was announced, [redacted]

57. Biocoat similarly views Surmodics as its primary competition. In an email from May 30, 2024, Biocoat's CFO [redacted] and Biocoat's CEO [redacted] in a July 2022 email. A May 2024 Biocoat presentation to its board of directors [redacted] Based on Surmodics' stature in the market, Biocoat CEO Jim Moran [redacted] Mr. Moran also [redacted] In another email from July 2022, Mr. Moran [redacted] And in February 2024, [redacted]

58. Consistent with Respondents' internal communications, customers and competitors of Surmodics and Biocoat describe the two companies as regularly competing head-to-head for new opportunities. OEM customers consistently cite Surmodics and Biocoat as the top two coating providers they considered during medical device development. OEM customers further report that curing method is not a significant factor in choosing a coating provider and that Surmodics and Biocoat compete for their business based on performance, service, and price.

59. Even for the small share of customers that prefer UV-cured coatings, Surmodics and Biocoat have become increasingly close competitors in recent years. As Biocoat's UV-cured hydrophilic coating, Hydak UV, has gained traction in the market, a significant number of OEMs have benefitted from competition between Hydak UV and Surmodics' hydrophilic coatings.

Today, [redacted] Hydak UV, and Biocoat [redacted] Indeed, Biocoat has estimated that Hydak UV [redacted]

60. Surmodics and Biocoat have repeatedly competed head-to-head over the last several years for the same customers and devices, including competition for the following OEMs:

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

[redacted]

g. [redacted]

B. The Benefits of Current Competition Between Surmodics and Biocoat Will Likely Be Eliminated Post-Acquisition

61. Respondents' internal documents show that Surmodics and Biocoat closely monitor each other's business strategy and routinely respond to each other's competitive decision-making. This fierce competition has driven Surmodics and Biocoat to improve coating quality and services, lower prices, and increase innovation. If the Proposed Acquisition is allowed to proceed, current competition between Surmodics and Biocoat will be eliminated, and the benefits of this competition will likely be lost.

a. Better Quality and Services

62. Current head-to-head competition between Surmodics and Biocoat incentivizes the companies to offer better quality and services than they would absent that competition. Unlike some of their competitors, both Surmodics and Biocoat offer full-service support, including testing, assistance with regulatory approval, and contract coating services, differentiating them from other coating providers. The breadth and quality of their service offerings further differentiates them from other outsourced hydrophilic coating manufacturers in the market.

63. For example, when [redacted] became concerned with the performance of Surmodics' hydrophilic coating [redacted] testified that the competition between Surmodics and Biocoat ultimately helped produce a higher quality product offering from Surmodics at better terms.

64. [redacted] indicated that Surmodics and Biocoat were the two best options [redacted] and expressed concern that, if the companies merge and the new company reduces choices or service [redacted]

b. Competitive Pricing

65. Surmodics and Biocoat compete aggressively on price and pricing structure. [redacted] This price competition benefits customers and drives down costs.

66. Price competition can occur in the early stages of development, feasibility testing, optimization, or pre-commercial services. For example, [redacted] Price competition may also occur later in the development process, including in licensing and royalty rates. [redacted]

67. Surmodics and Biocoat also compete on pricing structure. In a presentation to Surmodics' board of directors, Surmodics executives [redacted] Biocoat [redacted] To that end, Biocoat has tried to win business [redacted]

68. Examples of competition for price and pricing structure between Surmodics and Biocoat include:

a. [redacted]

b. [redacted]

[redacted]

c. [redacted]

d. [redacted]

c. Increased Innovation

69. Surmodics and Biocoat have historically utilized different curing methods for their most popular hydrophilic coatings: Surmodics' Serene coating is UV-cured, while Biocoat's Hydak coating is thermal-cured. More recently, the keen competition between Surmodics and Biocoat has driven both companies to release innovative new products. Biocoat utilized the expertise of Surmodics' former Senior Director of Hydrophilic Technologies, Bob Hergenrother, to develop Hydak UV in 2020. Hydak UV allows Biocoat the opportunity to convert Surmodics customers that are reluctant to use thermal-cured coatings because they have already invested in UV-curing infrastructure. Hydak UV also enables Biocoat to compete for heat-sensitive medical devices that would not withstand thermal curing. Biocoat [redacted]

70. Surmodics has similarly developed innovative new coatings to better compete with Biocoat. In late 2023, Surmodics released Preside, its next-generation hydrophilic coating, which was developed in part as a response to performance gains made by Biocoat's product offerings in

recent years. Surmodics believes that Preside will enable it to more effectively compete with Biocoat [redacted]

71. The time and expense Surmodics and Biocoat have invested to develop and market these new and improved coatings demonstrates the ongoing competitive pressure driving innovation in the outsourced hydrophilic coatings market.

COUNTERVAILING FACTORS DO NOT OFFSET THE PROPOSED ACQUISITION'S THREAT TO COMPETITION

A. Entry And Expansion

72. The Proposed Acquisition raises significant competitive concerns in the outsourced hydrophilic coatings market. Barriers to entry and expansion in the outsourced hydrophilic coatings market are high, and Respondents cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition.

73. As an initial matter, there has not been meaningful new entry into the hydrophilic coatings market in at least five years, and expansion in the industry is slow. [redacted]

74. For a new entrant, the timeline from product development to revenue generation can average between four to seven years. Even for an established player, the development timeline for a new product is at least two years. This is because developing a new hydrophilic coating is a multi-year R&D effort, and once developed and launched, the sales cycle for hydrophilic coatings averages between one to two years and involves multiple rounds of feasibility testing and optimization. In addition, once the OEM has completed feasibility testing and selected a hydrophilic coating for its medical device, it can take at least several more months, if not years, depending on the novelty of the device, for the device to receive FDA approval and begin generating commercial revenue. As such, the average timeline from the launch of a new hydrophilic coating product to the point at which it is ordered on a regular basis for a device is approximately two to five years. Biocoat estimates that reaching minimum viable scale could take an average of [redacted] years.

75. Two recent examples illustrate the difficulty of launching a new hydrophilic coating product, even for the largest and most sophisticated suppliers. Surmodics began developing its latest generation hydrophilic coating, Preside, [redacted]

76. Likewise, Biocoat [redacted] launch the product in March 2020. Three years later, in March 2023, Biocoat announced that Hydak UV was being used on two FDA-cleared medical devices. Biocoat's May 2024 presentation to its board of directors [redacted]

77. The complexity of developing a hydrophilic coating is compounded by the stringent regulatory requirements of the FDA. For medium-risk (Class II) devices, such as catheters and guidewires, the FDA requires a 510(k) Premarket Notification, which involves testing to compare a submitted device to one or more legally marketed medical devices to support a claim of substantial equivalence. Higher-risk (Class III) novel or implantable devices require a Premarket Approval (PMA) application, which involves extensive clinical trials and additional rigorous testing. Critically, both 510(k) and PMA applications must specify the exact hydrophilic coating used in testing. FDA approval is granted for the complete medical device, not individual components, effectively "locking in" the hydrophilic coating for the medical device's lifespan.

78. Changing a hydrophilic coating after a device receives FDA approval requires a new round of development, testing, and FDA application. As a result, OEMs are unlikely to switch to another hydrophilic coating on existing devices unless they are already developing a next-generation version that requires new FDA approval. This "lock-in" effect means that new and existing hydrophilic coatings cannot readily displace existing coatings on commercialized devices.

79. New coating providers, especially those without existing reputations or relationships, face additional challenges in gaining market traction because OEMs are hesitant to adopt coatings without a proven track record. OEMs prioritize the stability and longevity of their coating providers because they rely on them for extended periods. Many customers are unwilling to be the first to use a new coating that has not previously received FDA approval on another device. Rather, large OEMs typically prefer to partner with full-service coating providers with a proven history of coating FDA-approved devices. Small medical device manufacturers likewise tend to rely on established hydrophilic coating providers because they do not have the resources or time to develop an in-house solution and do not want to jeopardize the launch of the device (and, by extension, the success of the company) by partnering with an unproven coating supplier.

C. Efficiencies

80. Respondents cannot demonstrate merger-specific, verifiable, and cognizable efficiencies sufficient to overcome the structural presumption of illegality or show that the Proposed Acquisition does not threaten to substantially lessen competition.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

81. The allegations of Paragraphs 1 through 80 above are incorporated by reference.

82. The Proposed Acquisition, if fully consummated, may substantially lessen competition in outsourced hydrophilic coatings market throughout the country in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the sixth day of August, 2025, at 10:00 a.m. ET, is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that this administrative proceeding shall be conducted as though the Commission, in an ancillary proceeding, has also filed a complaint in a United States District Court, seeking relief pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. 53(b), as provided by Commission Rule 3.11(b)(4), 16 CFR 3.11(b)(4). You are also notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the Respondents' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Proposed Acquisition challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Proposed Transaction is consummated, full divestiture or reconstitution of all associated and necessary assets, in a manner that fully restores competition, eliminates the effects of the Proposed Transaction, and replaces the lost competitive intensity.

2. A prohibition against any transaction between Respondents that combines their businesses in the relevant market, except as may be approved by the Commission.

3. A requirement that, for a period of time, Respondents provide prior notice to and obtain prior approval of the Commission before all Proposed Acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant market.

4. A requirement to file periodic compliance reports with the Commission.

5. A requirement that Respondents' compliance with the order be monitored at Respondents expense and by an independent monitor for a term to be determined by the Commission.

6. Any other relief appropriate to correct or remedy the anticompetitive effects of the Proposed Acquisition or to restore Surmodics as a viable, independent competitor in the relevant market.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this 14th day of May, 2025.

By the Commission.

_____
April Tabor
Secretary

SEAL:

PUBLIC

CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2025, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Secretary
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Washington, D.C. 20580
ElectronicFilings@ftc.gov

The Honorable Jay L. Himes
Office of Administrative Law Judges
Federal Trade Commission
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I also certify that I caused the foregoing document to be served via email to:

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