PUBLIC

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of

GTCR LLC,

a limited liability corporation,

Docket No. 9440

GTCR BC HOLDINGS, LLC, a limited liability corporation, and

SURMODICS, INC., a corporation

Respondents

RESPONDENT GTCR BC HOLDINGS, LLC'S ANSWER AND DEFENSES

Pursuant to Rule 3.12, Respondent GTCR BC Holdings, LLC ("BC Holdings") hereby answers the Commission's Amended Complaint. BC Holdings answers only for itself and not any other Respondent.

Response to the Amended Complaint's Specific Allegations

All allegations not expressly admitted herein are denied. The Amended Complaint uses a defined term ("GTCR") that lumps together several legal entities, and then makes allegations using that defined term. Because the term applies to multiple separate entities, the allegations using that term are so vague as to not reasonably be susceptible to an answer. On that basis, BC Holdings denies those allegations. Further, any allegation relying on the term "outsourced hydrophilic coatings market" is denied on the ground that term is vague and intertwined with legal conclusions. BC Holdings does not interpret the introduction, headings, subheadings, Notice, or Notice of Contemplated Relief in the Amended Complaint as well-pled allegations to which any response is

required. To the extent such a response is required, they are denied. BC Holdings reserves the right to amend and/or supplement this Answer.

Each paragraph below corresponds to the same-numbered paragraph in the Amended Complaint:

- 1. BC Holdings admits that in 2022, BC Holdings acquired a majority stake in Biocoat, Inc. and that Biocoat provides hydrophilic coatings in the United States. BC Holdings admits that it has proposed to acquire Surmodics, Inc., and that Surmodics provides hydrophilic coatings in the United States. BC Holdings otherwise denies the allegations in this paragraph.
- 2. BC Holdings admits that hydrophilic coatings are applied to interventional devices, that catheters and guidewires are examples of interventional devices, and that interventional devices may be used in certain procedures. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.
- 3. BC Holdings admits the allegations in the first and second sentence. The term "vast majority" is vague, and BC Holdings denies the allegations in the third sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.
 - 4. Denied.
- 5. BC Holdings admits that Surmodics and Biocoat provide hydrophilic coatings. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings admits that the quoted statement in the third sentence was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings denies the existence of an "outsourced hydrophilic coatings market" and otherwise denies the allegations in this paragraph.
 - 6. Denied.

- 7. BC Holdings admits that the quoted statement in the second sentence was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings otherwise denies the allegations in this paragraph.
- 8. BC Holdings admits the quoted statement in the third sentence was made but only insofar as Surmodics is the only UV-cured hydrophilic coating supplier with public financial information. BC Holdings admits the quoted statements in the fourth sentence were made with respect to Biocoat's UV-cured hydrophilic coatings. BC Holdings respectfully refers the Court to the full documents referenced by the Amended Complaint in the third and fourth sentences for a full and accurate view of the statements. BC Holdings lacks knowledge or information to form a belief as to the truth of the allegations in the fifth and sixth sentences. BC Holdings denies the allegations in the seventh sentence with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.
 - 9. Denied.
- 10. This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.
- 11. This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.
 - 12. Denied.
- 13. BC Holdings admits that it announced a majority investment in Biocoat on November 2, 2022. BC Holdings otherwise denies the allegations in this paragraph.

- 14. BC Holdings admits the allegations in the first, third, and fourth sentences. BC Holdings admits that Biocoat has coating products and coating services segments. BC Holdings otherwise denies the allegations in this paragraph.
- 15. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 16. Denied.
 - 17. Admitted.
- 18. BC Holdings admits that hydrophilic coatings are a small part of the overall cost of a medical device and the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.
- 19. BC Holdings admits that lubricity, particulate count, and durability may be relevant criteria for assessing a hydrophilic coating's performance. BC Holdings otherwise denies the allegations in this paragraph.
- 20. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.
- 21. BC Holdings admits the allegations only as to Biocoat's hydrophilic coatings. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph with respect to other persons. BC Holdings otherwise denies the allegations in this paragraph.
- 22. BC Holdings admits the allegations in this paragraph and further acknowledges that the significant variation in hydrophilic coating chemistries both impacts curing methodology and requires medical-device-level testing.

- 23. BC Holdings admits that some medical devices are only suitable for one method of curing and the allegations in the fifth sentence. BC Holdings denies the existence of an "outsourced hydrophilic coatings market." The term "vast majority" is vague, and BC Holdings separately denies the allegations in the first sentence on that ground. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence. BC Holdings otherwise denies the allegations in this paragraph.
- 24. BC Holdings admits the allegations in the first and second sentences. BC Holdings otherwise denies the allegations in this paragraph.
- 25. BC Holdings admits the allegation in the first sentence as to Biocoat. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence with respect to other persons. BC Holdings otherwise denies the allegations in this paragraph.
- 26. BC Holdings admits the allegations in sentences two, three, four, and six of this paragraph. The terms "development and commercialization support" and "range of services" are vague and unspecified, and BC Holdings denies the allegations in the first sentence on those grounds. The term "regulatory support" is vague, and BC Holdings denies the allegation in the fifth sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.
- 27. BC Holdings denies the allegation in the first sentence as to Biocoat. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence with respect to other persons. BC Holdings admits that successful medical devices may be sold on the market with the same hydrophilic coating for over a decade as alleged in the second sentence. BC Holdings admits that royalty structures can vary. BC Holdings otherwise denies the allegations in this paragraph.

- 28. Denied.
- 29. BC Holdings admits that, as is true of thermally-cured hydrophilic coatings, coating the outer diameter of a medical device with PTFE at the end of the manufacturing process may damage the rest of the device. BC Holdings otherwise denies the allegations in this paragraph.
 - 30. Denied.
- 31. BC Holdings admits that hydrophilic coatings require specialized expertise and that hydrophilic coatings are a relatively small line item on the total cost of manufacturing a medical device. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.
 - 32. Denied.
- 33. BC Holdings admits that some OEMs may use contract coating services in the preclinical, clinical, and commercialization stages. BC Holdings otherwise denies the allegations in this paragraph.
 - 34. Denied.
 - 35. Denied.
- 36. BC Holdings admits the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.
 - 37. Denied.
 - 38. Denied.
- 39. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings admits the allegations in the third sentence. BC Holdings otherwise denies the allegations in this paragraph.

- 40. BC Holdings admits that Surmodics's hydrophilic coatings are UV-cured hydrophilic coatings and that Serene and Preside are both brand names for Surmodics's coatings. BC Holdings otherwise denies the allegations in this paragraph.
- 41. BC Holdings admits that Biocoat earned approximately \$20 million in U.S. coating revenue in 2023. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in the first sentence. BC Holdings admits that some of Biocoat's customers pay royalties and others do not. BC Holdings otherwise denies the allegations in this paragraph, including the existence of an "outsourced hydrophilic coatings market."
- 42. BC Holdings admits the allegations in the first, second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.
- 43. BC Holdings denies the existence of an "outsourced hydrophilic coatings" market. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 44. BC Holdings denies the existence of an "outsourced hydrophilic coatings" market. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.
 - 45. Denied.
- 46. The first sentence contains a legal assertion to which no response is required. To the extent a response is required, BC Holdings denies the allegations. BC Holdings admits the allegations in the second and third sentences. BC Holdings otherwise denies the allegations in this paragraph.
- 47. This paragraph contains a legal argument to which no response is required. To the extent a response is required, BC Holdings denies the allegations.

- 48. Denied.
- 49. BC Holdings admits that the quoted statements in this paragraph were made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings denies the existence of an "outsourced hydrophilic coatings market" and otherwise denies the allegations in this paragraph.
- 50. BC Holdings admits that the quoted statement in sentence two of this paragraph was made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statements. BC Holdings otherwise denies the allegations in this paragraph.
- 51. BC Holdings admits that the quoted statements in sentences two and three were made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statements. BC Holdings admits the allegations in sentences four and five. BC Holdings otherwise denies the allegations in this paragraph.
- 52. BC Holdings admits that the quoted statement in sentence two was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings otherwise denies the allegations in this paragraph.
 - 53. Denied.
- 54. The term "compete head-to-head" is vague, and BC Holdings denies the allegations in the first sentence on that ground. BC Holdings otherwise denies the allegations in this paragraph.
- 55. BC Holdings denies the allegations in the first sentence with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings lacks knowledge or information sufficient to form a belief as

to the truth of the allegations in sentences three, four, five, and six. BC Holdings otherwise denies the allegations in this paragraph.

- 56. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences two, three, four, and five. BC Holdings otherwise denies the allegations in this paragraph.
- 57. BC Holdings admits that the quoted statements in sentences five, six, and seven were made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statements. BC Holdings otherwise denies the allegations in this paragraph.
- 58. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 59. Denied.
 - 60. Denied.
 - a. BC Holdings denies that Biocoat conducted thermal coating testing in 2020 for the manufacturer referenced in this paragraph but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - b. BC Holdings denies that Biocoat was engaged in testing with the manufacturer referenced in this paragraph from 2020 to 2021 but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

- c. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.
- d. Denied.
- e. BC Holdings admits that the quoted statement was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
- f. BC Holdings admits that the manufacturer referenced in this paragraph selected Biocoat's thermal coating for a medical device as alleged in sentence nine. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in sentence nine, as well as the allegations in sentences one, two, three, four, seven, and eight. BC Holdings otherwise denies the allegations in this paragraph.
- g. BC Holdings admits the allegations in sentence two. BC Holdings admits that the quoted statement in sentence four was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in sentence four. BC Holdings otherwise denies the allegations in this paragraph.

- 61. BC Holdings denies the allegations in sentence one with respect to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.
 - 62. Denied.
- 63. BC Holdings admits that Biocoat was contacted by the manufacturer referenced in this paragraph regarding a UV coating opportunity on a new guidewire. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the other allegations in this paragraph.
- 64. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
- 65. BC Holdings denies the allegations in the second sentence as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings otherwise denies the allegations in this paragraph.
- 66. BC Holdings admits that the quoted statement in the second sentence was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings denies the other allegations in sentence two. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentence four. BC Holdings otherwise denies the allegations in this paragraph.
- 67. BC Holdings denies the allegations in the first sentence as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.

- 68. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - a. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - b. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - c. BC Holdings admits that the quoted statements in sentences two, three, and four were made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statements. BC Holdings otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - d. BC Holdings admits that the quoted statements in sentences three, four, and five were made and respectfully refers the Court to the full documents referenced by the Amended Complaint for a complete and accurate view of the statements. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentence two. BC Holdings otherwise denies the allegations in this paragraph.
- 69. BC Holdings admits the allegations in sentences one and five. BC Holdings denies the allegations in sentence two as to Biocoat but lacks knowledge or information sufficient to form a belief as to the truth of the allegations with respect to Surmodics. BC Holdings admits that Bob Hergenrother worked on the development of Hydak UV but otherwise denies the allegations in sentence three. BC Holdings otherwise denies the allegations in this paragraph.

- 70. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.
 - 71. Denied.
 - 72. Denied.
- 73. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.
- 74. BC Holdings admits the allegations in sentences four and six. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences one, three, and five. BC Holdings otherwise denies the allegations in this paragraph.
- 75. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. BC Holdings otherwise denies the allegations in this paragraph.
- 76. BC Holdings admits the allegations in sentences two and three. BC Holdings admits that the quoted statement in sentence four was made and respectfully refers the Court to the full document referenced by the Amended Complaint for a complete and accurate view of the statement. BC Holdings otherwise denies the allegations in this paragraph.
- 77. BC Holdings admits the allegations in sentences two, three, and five. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegation in the fourth sentence. BC Holdings otherwise denies the allegations in this paragraph.
 - 78. Admitted.

- 79. BC Holdings lacks knowledge or information sufficient to form a belief as to the truth of the allegations in sentences two, three, four, and five. BC Holdings otherwise denies the allegations in this paragraph.
 - 80. Denied.
- 81. This paragraph consists of a legal claim to which no response is required. To the extent a response is required, BC Holdings denies the allegations in this paragraph.
 - 82. Denied.

Defenses

- 1. The FTC cannot show that it is entitled to a preliminary injunction, which is "an extraordinary equitable remedy that is never awarded as of right." *Starbucks Corp. v. McKinney ex rel. NLRB*, 144 S. Ct. 1570, 1576 (2024).
- 2. The FTC cannot clearly establish a likelihood of ultimate success (*i.e.*, that the proposed transaction is likely to substantially harm competition under Section 7 of the Clayton Act), including because:
 - A. The Amended Complaint fails to allege a valid product market, including because the Amended Complaint improperly excludes in-house hydrophilic coatings and other lubricious coatings from the alleged market.
 - B. The Amended Complaint fails to allege a valid geographic market, including because the Amended Complaint fails to adequately account for imported hydrophilic coatings sold in the United States.
 - C. The FTC cannot show that the proposed transaction will plausibly harm consumers or competition, including because the Amended Complaint fails to plausibly allege

- that Respondents exercise market power, and fails to account for the fact that new entry and expansion by competitors can be timely, likely, and sufficient.
- 3. The FTC cannot show that the public interest favors a preliminary injunction, including because the proposed transaction is not likely to substantially harm competition and instead will benefit competition and customers.
- 4. The equities do not favor a preliminary injunction, including because the proposed transaction will benefit competition and customers and because granting a preliminary injunction would seriously injure Respondents.
- 5. The FTC seeks relief through an administrative process that violates Article I of the Constitution, which provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. Among other things, Congress delegated to the FTC the power to decide whether to bring antitrust enforcement actions in administrative proceedings or in federal court, but did not provide the FTC with an intelligible principle by which to exercise that discretion. The FTC therefore has total, unguided discretion to decide whether to bring an antitrust enforcement action in an administrative proceeding rather than in an Article III court, in violation of the Non-Delegation Doctrine under Article I.
- 6. The FTC seeks relief through an administrative process that violates Article II of the Constitution and separation of powers principles because, among other things, the FTC's Commissioners and Administrative Law Judges can only be removed for cause, and for-cause removal restrictions impermissibly restrict the President's removal powers—especially where, as here, an agency exercises substantial executive power. Indeed, the government itself has conceded that "the for-cause removal protections for the Commissioners of the Federal Trade Commission in 15 U.S.C. § 41 . . . do not comport with the separation of powers and Article II." Defs.' Notice

of Change in Position at 1, *Express Scripts, Inc. v. FTC*, No. 4:24-cv-1549 (E.D. Mo. Feb. 15, 2025), ECF No. 57; *see also* Letter from Sarah M. Harris, Acting Solicitor General, to Richard J. Durbin, United States Senator (Feb. 12, 2025) (reporting under 28 U.S.C. § 530D that the Department of Justice "will no longer defend" the constitutionality of the "statutory tenure protections for members of the Federal Trade Commission").

- 7. The FTC seeks relief through an administrative process that violates Article III of the Constitution by, for example, adjudicating private rights before a non-Article III body without meaningful review of the FTC's factual findings by an Article III court.
- 8. The FTC seeks relief through an administrative process that violates BC Holdings's right to Due Process under the Fifth Amendment by, among other things, depriving BC Holdings of its right to adjudication before a neutral arbiter. Combining investigative, prosecutorial, and adjudicative functions violates the Due Process Clause where "the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable." *Withrow v. Larkin*, 421 U.S. 35, 47, 58 (1975). That is the case here, where the FTC Commissioners vote out the complaint, mandate its prosecution, and pass judgment on its merits; where the FTC Commissioners rely on evidence that would not be admissible in an Article III court; and where the FTC wins roughly 90% of its cases, a statistic that "reveal[s] just how tilted this game is." *Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 917 (2023) (Gorsuch, J., concurring).
- 9. The FTC seeks relief through an administrative process that violates BC Holdings's right to Equal Protection under the Fifth Amendment. For example, the FTC and the Department of Justice ("DOJ") arbitrarily decide between them which agency will review a transaction through a black box "clearance" process. As a result of that arbitrary decision, this transaction was reviewed by the FTC, which has the ability to judge the merits of its own case through an in-house

proceeding that lacks the protections of an Article III court, that permits the same decision-makers to initiate, prosecute, and decide the merits of the case, and that permits the decision-makers to rely on evidence that is inadmissible under the Federal Rules of Evidence. By contrast, if the DOJ had reviewed the transaction and decided to challenge it, that challenge could *only* be brought in an Article III court with all the attendant protections.

BC Holdings reserves the right to amend this answer and assert any other available defenses.

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Dated: May 28, 2025 Respectfully submitted,

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Certificate of Service

I hereby certify that on May 28, 2025, I caused the foregoing document to be filed electronically using the Federal Trade Commission's e-filing system, which will send notification of such filing to:

April Tabor Secretary Federal Trade Commission 600 Pennsylvania Ave., NW, Rm H-113 Washington, D.C. 20580 electronicfilings@ftc.gov

Office of Administrative Law Judges Federal Trade Commission 600 Pennsylvania Ave., NW, Rm H-110 Washington, D.C. 20580

I also certify that I caused the foregoing document to be served via email to:

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