CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

See Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

81 FR 7106 (Feb. 10, 2016); 85 FR 43654, 43675 (July 21, 2020).

[FR Doc. 2021–24712 Filed 11–17–21; 8:45 am]

BILLING CODE 6760–01–P

FEDERAL TRADE COMMISSION

[File No. 191 0082; Docket No. C–4710]

Petition for Prior Approval of Sartorius Stedim Biotech S.A.'s Proposed Acquisition of Novasep Process SAS's Chromatography Equipment Business

AGENCY: Federal Trade Commission.

ACTION: Announcement of petition; request for comment.

SUMMARY: Sartorius Stedim Biotech S.A. (''Sartorius'') has petitioned the Federal Trade Commission (''FTC'' or ''Commission'') for approval of its acquisition of the chromatography equipment business of Novasep Process SAS. Sartorius was the FTC-approved divestiture buyer in 2020, when the FTC required Danaher Corporation to divest assets as a condition of acquiring General Electric's biopharmaceutical business, which included chromatography assets. Sartorius agreed to obtain the Commission's prior approval if it proposed to acquire Novasep's chromatography business.

DATES: Comments must be received on or before December 20, 2021.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment, and file your comment online at *www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Lisa De Marchi Sleigh (202–326–2535), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to FTC Rule 2.41(f), 16 CFR 2.41(f), notice is hereby given that the public [redacted] version of the above-captioned petition has been filed with the Secretary of the Commission and is being placed on the public record for a period of thirty (30) days. After the period for public comments has expired, the Commission shall determine whether to approve the petition. In making its determination, the Commission will consider, among other information, all timely and responsive comments submitted in connection with this document.

The text of the public [redacted] version of the petition is provided below. An electronic copy of the text of the public [redacted] version of the petition can be obtained from the FTC website at this web address: *https://www.ftc.gov/enforcement/cases-proceedings/191-0082/danaher-corporation-matter.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 20, 2021. Write ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *www.regulations.gov* website.

Due to protective actions in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Sartorius Petition for Prior Approval; Docket No. C–4710'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this document and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 20, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see

https://www.ftc.gov/site-information/privacy-policy.

Joel Christie,

Acting Secretary.

Petition for Prior Approval of Sartorius Stedim Biotech S.A.'s Proposed Acquisition of Novasep Process SAS's Chromatography Equipment Business

I. Introduction

Pursuant to Section 2.41(f) of the Federal Trade Commission (the ''FTC'' or the ''Commission'') Rules of Practice and Procedure [1] and Section X(B) of the May 28, 2020 final decision and order in *In the Matter of Danaher Corporation and General Electric Company* (the ''Danaher Order'' or ''Order''),[2] Sartorius Stedim Biotech S.A. (''Sartorius'') hereby petitions the Commission to approve its proposed acquisition of the chromatography equipment business of Novasep Process SAS (''Novasep'' and, together with Sartorius, the ''Parties'') (the ''Proposed Transaction'').

The Commission's Order was entered to resolve competition concerns arising from Danaher Corporation's (''Danaher'') $21.4 billion acquisition of General Electric Company's (''GE'') biopharma business. Danaher and GE have been leading suppliers of manufacturing equipment and related products to the biopharma industry for many years. The FTC was concerned that combining Danaher's Pall Biotech and GE's Cytiva chromatography equipment product lines would create or reinforce dominant market positions in: (1) Conventional low pressure liquid chromatography (''LPLC'') columns; [3] (2) conventional LPLC skids; [4] (3) single-use (''SU'') LPLC chromatography skids; and (4) LPLC continuous chromatography systems.[5] By requiring Danaher to divest to Sartorius the overlapping Pall Biotech products in these segments (collectively, the ''Pall Assets''), the FTC facilitated a new entrant in this important area of downstream biopharmaceutical manufacturing.[6] In support of its determination that Sartorius would be a suitable purchaser of the Pall Assets and other Danaher divested assets, the Commission explained: ''Sartorius's existing biopharma business includes products that are highly complementary to the divestiture assets. Sartorius has the expertise, worldwide sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.'' [7] Sartorius completed the acquisition on April 30, 2020.[8]

As a new entrant in the chromatography equipment business, Sartorius is playing ''catch up'' with incumbent chromatography suppliers that have long dominated the industry, including Danaher/GE, Merck Millipore, and Thermo Fisher. To compete with these incumbent suppliers, which benefit from an extensive installed base of chromatography equipment, Sartorius must offer customers a range of innovative products and disruptive technologies that generate significant productivity gains and cost savings to justify customers replacing their existing legacy equipment.[9]

By bringing together the Parties' largely complementary chromatography equipment businesses and technologies, the Proposed Transaction will accelerate Sartorius's efforts to commercialize disruptive technologies needed to achieve a more efficient, more productive, and lower cost drug and vaccine production infrastructure that will improve healthcare outcomes and benefit consumers throughout the U.S. and around the world.

a. Background to the Proposed Transaction

Through the Proposed Transaction, the Parties will be able to achieve innovations in biopharma manufacturing that are necessary to bring new drugs and vaccines to market more quickly, cost-effectively, and equitably. The COVID–19 pandemic has underscored the critical importance of having a robust biopharma infrastructure to combat new viruses and diseases. There is a need for innovative manufacturing processes that are capable of developing and mass-producing new drugs and vaccines rapidly and cost-effectively. Although the biopharma industry quickly rose to the challenge of developing biologic therapies and vaccines to ameliorate the severity of COVID–19, those medical breakthroughs were not available on a large scale to populations in the U.S. and around the world in time to avoid significant loss of human life. New COVID–19 variants and novel diseases will remain an ongoing public health concern, and the biopharma industry needs to be able to respond quickly, equitably, and efficiently to address these threats to public health and economic security around the world.

To ensure that all members of the population have timely access to life saving drugs and vaccines at reasonable cost, disruptive technologies are needed to remove bottlenecks in biopharma drug and vaccine development and manufacturing. One of the primary roadblocks to achieving this goal with protein-based therapies is that ''downstream'' biopharma production—the purification of cell mass to eliminate contaminants and unwanted viruses that occurs after the ''upstream'' process of discovery, development, and growth of therapeutic cell mass—is still a relatively inefficient process. These inefficiencies inhibit the biopharma industry from being able to provide patients with rapid access to life saving therapies and provide new vaccines to entire populations on a large scale. For decades, downstream chromatography has been performed using conventional ''batch'' LPLC equipment packed with specialized, costly resins (such as Protein A resins) to purify the product. This process does not utilize resins efficiently, and significant volumes are

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[1] 16 CFR 2.41(f).

[2] *In the Matter of Danaher Corp. and General Electric Co.,* Decision and Order, Docket No. C–4710, (F.T.C. May 28, 2020), *https://www.ftc.gov/system/files/documents/cases/191_0082_c4710_danaher_do_0.pdf* (hereinafter, the ''Danaher Order''), at § X(B).

[3] ''Conventional LPLC columns are containers that hold chromatography resins used as the adsorbent during the stationary phase. Columns are made of glass, stainless steel, acrylic glass, or plastic[.]'' *In the Matter of Danaher Corp. and General Electric Co.,* Complaint at ¶ III(5)(b), Docket No. C–4710 (F.T.C. Mar. 19, 2020), *https://www.ftc.gov/system/files/documents/cases/191_0082_c4710_danaher_ge_complaint.pdf* (hereinafter, the ''Danaher Complaint'').

[4] ''Conventional LPLC skids control the flow of liquid in the chromatography process. Conventional LPLC skids contain a system of pumps, valves, sensors, tubing, electronic components, software, and flow paths composed of multi-use components[.]'' Danaher Complaint, at ¶ III(5)(c).

[5] ''LPLC continuous chromatography systems allow for the simultaneous processing of multiple columns in LPLC. LPLC continuous chromatography systems consist of pumps, valves, sensors, tubing, electronic components, software, and flow paths composed of either multi-use or single-use components[.]'' Danaher Complaint, at ¶ III(5)(f). ''While continuous chromatography has for some time been an accepted practice by small-molecule manufacturers, it is not yet [as] widely used in larger bio-manufacturing processes.'' European Commission: DG Competition, *Danaher/GE Healthcare Life Sciences Biopharma,* Case M.9331, Commission Decision, at ¶ 367, *https://ec.europa.eu/competition/mergers/cases/decisions/m9331_3668_3.pdf* (last visited Oct. 22, 2021) (hereinafter, ''European Commission Decision'').

[6] *See* Danaher Order at § I(N); Danaher Complaint, at ¶ 5.

[7] *In the Matter of Danaher Corp. and General Electric Co.,* Analysis of Agreement Containing Consent Orders to Aid Public Comment. at 5, Docket No. C–4710, File No. 191–0082 (F.T.C.), *https://www.ftc.gov/system/files/documents/cases/191_0082_danaher-ge_aapc.pdf* (last visited Oct. 22, 2021).

[8] *Sartorius closes acquisition of selected assets of Danaher Life Sciences,* Sartorius (Apr. 30, 2020), *https://www.sartorius.com/en/company/newsroom/corporate-news/483898-483898.*

[9] *See* SART_0002159—SART_0002187, at SART_0002173 (comparing projected customer cost savings of the Parties' jointly developed BioSC–RCC system to GE/Cytiva's conventional LPLC batch equipment).

wasted in the process.[10] Furthermore, each of the up to four downstream chromatography steps are performed using separate equipment, which results in additional inefficiencies and bottlenecks.[11]

The leading incumbent suppliers of conventional LPLC systems—including Danaher/GE, Merck Millipore, and Thermo Fisher—also have resin supply businesses (including the costly Protein A resin) that are highly profitable and generate very significant recurring revenues. These incumbent suppliers are incentivized to maintain the status quo to protect their installed base of conventional LPLC equipment and the significant recurring resin revenues they generate. As a result, they have not aggressively pursued innovations in downstream chromatography that are necessary to address the bottlenecks that inhibit the rapid and cost-effective development and production of biologic drugs and vaccines. New disruptive technologies are required to replace this installed base of resin-dependent legacy chromatography equipment with innovative equipment and technologies that reduce (and ultimately will eliminate) bottlenecks.

The acquisition will allow Sartorius to accelerate the development and commercialization of ''intensified'' LPLC chromatography systems as platforms for innovation to support the biopharma industry's need to develop and commercialize lifesaving vaccines and biologic drugs faster and at lower cost.

b. The Sartorius-Novasep Collaboration

Sartorius is a disruptor to the resin industry and a new entrant in the chromatography equipment business that must continue to innovate to successfully compete with larger incumbent suppliers. For the past several years, Sartorius has been pursuing a strategic collaboration with Novasep that utilizes Sartorius's disruptive membrane technology, Sartobind (which eliminates the need for costly resins), with Novasep's innovative LPLC continuous chromatography system, BioSC (which combines several downstream processing steps in one platform). The innovative product development that Sartorius and Novasep have been pursuing through their collaboration offers the potential for significant productivity gains and cost savings in the development and production of biopharma drugs and vaccines. Notably, the Parties have developed a unique new product, BioSC–RCC, an intensified chromatography system that eliminates the need for resin, which is currently in customer trials.

After the collaboration was already well advanced, Novasep made a strategic decision to exit the chromatography equipment business for reasons that are further explained in Section II below.[12] Novasep viewed Sartorius as the natural acquirer of the business because Sartorius was already utilizing Novasep's LPLC continuous chromatography system (BioSC) as a platform for its innovative membrane technology.[13] Since Novasep had decided to exit and sell the business, both Parties concluded that acquiring the business was the only way to preserve the fruits of the collaboration, and achieve further innovations utilizing a combination of Novasep and Sartorius technologies, know-how, and equipment.

Due to the accelerated timing of the Pall Asset divestitures, Sartorius acquired the Pall Assets before finalizing its agreement to acquire Novasep's chromatography equipment business. The Pall Assets include BioSMB, a LPLC continuous chromatography system that offers some of the same process intensification capabilities as BioSC. Because the Novasep acquisition was not reportable under the Hart-Scott-Rodino Act, Sartorius agreed to provide the FTC an opportunity to review the transaction and not to close without the Commission's prior approval.[14]

c. The Proposed Transaction

On March 2, 2021, following approval by Novasep's French Works Council, the Parties executed a share and asset purchase agreement (''SAPA'') to sell Novasep's chromatography equipment business to Sartorius.[15] To effectuate the Proposed Transaction, Novasep has contributed the assets that comprise its chromatography business in France to a NewCo that Sartorius will acquire in a stock purchase transaction, in addition to assets that comprise Novasep's U.S. and Chinese chromatography businesses. Both Parties have received uniformly positive feedback from customers who view Sartorius as an innovative supplier that will be able to overcome the challenges that Novasep has experienced with its LPLC business.[16]

d. The PharmaZell-Novasep Transaction

On September 16, 2021, Novasep announced it had entered into exclusive negotiations to create a common platform in the contract development and manufacturing organization (''CDMO'') space through a proposed merger with PharmaZell.[17] The transaction excludes Novasep's chromatography equipment business, which is not a strategic fit with PharmaZell's or Novasep's CDMO businesses.[18] PharmaZell has no interest in acquiring Novasep's chromatography equipment business if the sale to Sartorius does not proceed. In that event, the chromatography equipment business (the French portion of which has already been transferred to a NewCo in preparation for the sale to Sartorius) would be transferred to NVHL S.A., a non-operating holding company owned by Novasep's private investors, which include funds focused on credit and special situations investments.

e. Procompetitive Effects of the Proposed Transaction

As described further in Section III below, as a result of the Proposed Transaction:

- Novasep's high pressure liquid chromatography (''HPLC'') equipment, which is used for the production of small molecules, and LPLC equipment will be supported by a manufacturer with a reputation for producing high quality innovative products and a global marketing, sales and service infrastructure. As part of Sartorius's broader product portfolio and global sales and service infrastructure, Novasep's chromatography business will have a stronger platform for commercial success.

[10] *See* SART_0016472, at 19 (indicating customers' most significant chromatography challenges include the high cost associated with the inefficient use of resins, the relatively slow speed of conventional batch chromatography, and the large spaces within manufacturing facilities required to house conventional batch chromatography equipment).

[11] *See infra* Section III(c)(i).

[12] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021 (regarding Novasep's decision to exit the chromatography equipment business).

[13] *Id.* at 6–7; *see also* NOVA–002147, at NOVA–002147 (containing Novasep Holding Meeting Minutes from November 20, 2020).

[14] Danaher Order at §§ II(A), X(B).

[15] SART_0001673—SART_0002117.

[16] *See, e.g.,* SART_0171028 (customer letter in support of transaction); NOVA–002483—NOVA–002484; NOVA–002485; NOVA–002486 (customer declarations in support of transaction).

[17] *See PharmaZell and Novasep enter into exclusive negotiations in new drive to create a technology-driven leader for complex small molecules and ADCs of global scale,* PharmaZell (Sept. 16, 2021), *https://pharmazell-group.com/blog/2021/09/16/pharmazell-and-novasep-enter-into-exclusive-negotiations-in-new-drive-to-create-a-technology-driven-leader-for-complex-small-molecules-and-adcs-of-global-scale/.*

[18] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 7, 2021 (regarding proposed PharmaZell-Novasep transaction).

○ The benefits will be particularly pronounced in the U.S. where Sartorius has a robust sales and service infrastructure and Novasep has very limited presence.

• All of Novasep's chromatography equipment product lines will benefit from Sartorius's more efficient manufacturing and distribution, greater security of supply, and accelerated delivery times, which will increase their competitiveness and penetration with new customers and in new applications.

• The Parties' LPLC continuous chromatography systems are differentiated products that virtually never compete directly.

○ Sartorius's BioSMB system and Novasep's BioSC system are based on different technologies that provide process intensification in different ways and meet distinct customer needs and manufacturing strategies.

• As a disruptor and new entrant in a space with strong incumbents and increasing competition, Sartorius has a strong incentive to continue to invest in and innovate with both of the differentiated process intensification platforms it will be offering to biopharma customers: BioSC and BioSMB.

○ Sartorius's product roadmap and research and development plans demonstrate that Sartorius will continue to support, enhance, and innovate with both of these platforms.

○ Sartorius also has made specific commitments to the French government to maintain and invest in Novasep's chromatography equipment business and retain its employees.[19]

• The transaction poses no risk to competition in HPLC columns or skids as Sartorius has no HPLC product offering.

• The transaction similarly poses no risk to competition in conventional LPLC columns or skids because Novasep has *de minimis* sales and market shares in these products.

II. The Parties and the Transaction Rationale

a. The Parties

i. Sartorius

Sartorius is a supplier of innovative, cost-effective technologies and products that accelerate biopharma development and increase the speed, efficiency, and safety of biopharma production. Sartorius's Bioprocessing Solutions Division (''BPS'') supports all phases of biopharmaceutical product development, from early phase development to commercial manufacturing, from cell line development to process development, including upstream and downstream processing. Sartorius's innovative membrane technology (Sartobind) eliminates the use of resins in certain downstream chromatography processing steps—a significant advance that holds the promise of improving the efficiency and reducing the cost of developing and manufacturing biologic drugs and vaccines, compared to traditional batch chromatography systems.[20]

Sartorius has a worldwide presence with manufacturing, sales, and research and development (''R&D'') sites in more than 20 countries in Europe, North America, and Asia. Sartorius also has expertise in SU bioprocessing technologies, including LPLC equipment, as well as in value-added automation technology and software, which it uses to meet the evolving technology needs of its large molecule biopharma customers.

ii. Novasep

Novasep is a provider of services, equipment, and ingredients to the pharmaceutical, chemical, and food industries. Novasep's core focus and competency is its CDMO business, which accounts for over [REDACTED] of its overall revenues. Novasep's much smaller chromatography equipment business is focused on supporting the development and production of smaller molecule drugs and applications.

From its historic roots in food production, Novasep has developed expertise in multi-use (''MU'') HPLC equipment, which is used in the production of small molecule drugs. Novasep derives a high proportion (75–85%) of its chromatography equipment revenue and profits from the sale of HPLC equipment.[21] Novasep's LPLC equipment business, by contrast, is very small, as Novasep has struggled to penetrate biopharma customers. Novasep's equipment utilizes MU technology, which is cleaned and then re-used in different bioprocessing production runs. Many biopharma customers increasingly require equipment that uses SU flow-paths for manufacturing at commercial scale. Novasep has no expertise in the plastics technologies required to produce SU (*i.e.,* disposable) flow-paths and has been unable to develop a SU flow-path for BioSC or its other LPLC equipment.[22] Novasep's LPLC business is not profitable on a standalone basis, and has declined over the last several years.[23]

b. The Transaction Rationale

In 2019, Novasep made a strategic decision to exit the chromatography equipment business. Novasep has had significant financial and operational challenges with the business,[24] which is highly capital intensive and lacks synergies with its core CDMO business. As mentioned above, Novasep's chromatography equipment business generates 75–85% of its revenues from sales of HPLC equipment used in small molecule drug production.[25] To address the increasing importance of biopharmaceutical medicine, Novasep also has developed LPLC equipment for larger molecule biopharma drug and vaccine production. However, Novasep has been unable to gain traction with larger biomolecule customers and applications. Thus, its LPLC business remains very small. Novasep's lack of SU technology, which many biopharma customers (particularly in North America) prefer for drug and vaccine manufacturing at clinical and commercial scales, also has hampered

[19] *See* Andrew S. Wellin Letter to Lisa DeMarchi Sleigh, dated July 1, 2021 (regarding Sartorius's commitments in connection with French foreign investment approval of the Proposed Transaction).

[20] SART_0006206, at 5, 12 (indicating that Sartobind Rapid A membranes have significantly higher productivity than Protein A resins and can be easily scaled up for commercial production). Sartorius's membrane innovations have the potential to be a significant disrupter to traditional resin suppliers, led by Danaher (Cytiva), which has an estimated 75% market share in Protein A resin.

[21] *See* NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147.

[22] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 5–6 (regarding Novasep's decision to exit the chromatography equipment business); Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 4, 2021 (regarding Novasep's inability to develop a SU flow-path); NOVA–000872, at NOVA–000875, NOVA–000881 (Budget 2020 BU Process Solutions, October 30, 2019); NOVA–000691, at NOVA–000703 (Budget 2021 Equipment Solutions, December 22, 2020); NOVA–000783, at NOVA–000796 (Novasep Business Review, April 2020); SART_0000526—SART_0000538, at SART_0000533 (stating Novasep's ''[i]nability to develop SU flowpath has challenged business growth especially in North America.''); NOVA–001091—NOVA–001097, at NOVA–001095.

[23] *See* NOVA–Appendix 13–00000001, at NOVA–Appendix 13–00000004; NOVA–Appendix 13–00000048, at NOVA–Appendix 13–00000051; NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147; *see also* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 8, 2021 (regarding Novasep's financial condition).

[24] *See e.g.,* NOVA–VAL–0028970 at 2; NOVA–VAL–0028981, at 2; NOVA–VAL–0039971, at 3; *see generally* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021 (regarding Novasep's decision to exit the chromatography equipment business).

[25] *See* NOVA–Appendix 13–00000095, at NOVA–Appendix 13–00000098; NOVA–Appendix 13–00000143, at NOVA–Appendix 13–00000147.

its efforts to develop the LPLC business.[26]

In sum, Novasep concluded that it did not have the infrastructure,[27] reputation, or SU technology to grow its LPLC business successfully on its own. Furthermore, because Novasep is dependent on equipment sales, which are lumpy and unpredictable, and Novasep lacks a consumables business that would generate regular recurring revenues, Novasep has been unable to make the necessary investments to update its LPLC product line or develop next generation chromatography technologies, despite customer needs and requests for SU technology.[28] Given these challenging financial dynamics and the significant ongoing capital needs of its chromatography equipment business, Novasep realized that it would continue to lose competitive ground in an increasingly competitive space if it held on to this business.[29] In contrast, selling the equipment business to Sartorius would allow Novasep to focus resources on its core CDMO business.

i. The Proposed Transaction is Necessary To Protect the Fruits of the Parties' Collaboration

Sartorius's acquisition of Novasep's chromatography equipment business was a natural evolution of the Parties' multi-year collaboration to develop innovative alternatives to the legacy batch chromatography equipment that is dependent on the use of resin, which is often supplied by incumbent chromatography equipment suppliers. These incumbent suppliers, including Danaher/GE, Merck Millipore, and Thermo Fisher, generate significant revenues and profits from the sale of costly resins, such as Protein A, required for the batch chromatography process. Protein A, which is required for the production of monoclonal antibody (''mAb'') drug therapies (*e.g.,* COVID antibody ''cocktails''), can cost anywhere from $5,000 to $16,000 per liter.

Sartorius's collaboration with Novasep already has produced a new product—BioSC–RCC—that utilizes Novasep's BioSC LPLC continuous chromatography system as a platform for Sartorius's innovative membrane technology. BioSC–RCC provides an alternative to resin-based chromatography, and promises to accelerate the speed and efficiency of large molecule discovery and production, while greatly reducing process risk and cost.

To accelerate access to this disruptive new product, the Parties initially developed and launched BioSC–RCC MU, which utilizes BioSC's existing BioSC platform and MU technology. BioSC–RCC MU is currently being tested by potential customers, who have shown strong interest in this unique new product that eliminates the need for costly resin and offers productivity gains, and cost and process risk reductions. However, to convert customer interest to actual sales, many of these potential customers will need to be assured that Sartorius will develop a BioSC–RCC version with a SU flow-path that they can use at larger scales. Once the transaction closes, Sartorius will be able to move forward with the development of a SU flow-path for the BioSC–RCC system and launch a SU version (BioSC–RCC SU) in 2022.[30]

Although Sartorius was willing to make the investments to develop a prototype of BioSC–RCC MU pursuant to the collaboration, transforming the BioSC–RCC prototype into a commercially viable product has been (and will continue to be) challenging absent the Proposed Transaction due, in part, to Novasep's high cost of manufacturing BioSC, which limits the return on investment required to launch and maintain a new product long term.[31]

Furthermore, the BioSC platform needs substantial upgrades and enhancements before any BioSC system (BioSC or BioSC–RCC) can be successfully commercialized. While BioSC utilizes an innovative continuous chromatography process and its integrated architecture works well with Sartorius's rapid cycling chromatography (''RCC'') process and membrane technology, it has suffered from years of underinvestment. In addition to its lack of a SU flow-path, there have been ongoing challenges with its software (which is supplied by GE/Cytiva), the lab scale version of the system does not easily ''scale up'' to clinical and commercial scale versions of the system, and its engineered-to-order design and manufacturing process does not meet biopharma customer preferences for off-the-shelf systems with accelerated delivery times. The investments required to address these problems with the BioSC platform are beyond Sartorius's ability to address in the context of the Parties' collaboration because Sartorius does not own the platform, and in the case of BioSC–RCC MU has limited, short-term marketing rights and, for a potential BioSC–RCC SU version, no rights at all.[32]

While Sartorius believes that the development of a SU flow-path, redesign of BioSC lab to easily scale up, standardization of the platform and manufacturing process, and software improvements will allow BioSC and BioSC–RCC to be commercially successful,[33] these investments only make sense if Sartorius has the ability to achieve the necessary innovations and recoup its investment. Sartorius cannot achieve these innovations or recoup its investment in a system it does not own and, therefore, has no ability to redesign, manufacture, market or sell.

The acquisition of Novasep's chromatography equipment business is critical to successfully commercializing those innovations. Unless the acquisition is approved, the innovations the Parties have already developed (and plan to pursue after the acquisition) very likely will be lost. The ''winners'' will be incumbent suppliers, who will remain immune from disruptive technologies that would erode their installed base of outdated and inefficient equipment. The biggest ''losers'' will be biopharma producers and consumers who need new and improved biopharma manufacturing infrastructure to provide timely, efficient, and cost-effective access to new drugs and vaccines to address

[26] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 5–6 (regarding Novasep's decision to exit the chromatography equipment business); *see also* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated October 4, 2021 (regarding Novasep's inability to develop a SU flow-path); NOVA–000691—NOVA–000748, at NOVA–000708 (Budget 2021 Equipment Solutions).

[27] For example, Novasep has limited customer service and support. *See, e.g.,* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029 (documents discussing software challenges, December 22, 2020).

[28] *See* NOVA–000001, at NOVA–000039 (Novasep Strategy Discussions and Options, July 2019). *See also, e.g.,* NOVA–001208, at NOVA–001208, NOVA–001209; NOVA–VAL–0027941; NOVA–VAL–0038766; NOVA–VAL–0040141.

[29] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated August 9, 2021, at 2–3 (regarding Novasep's decision to exit the chromatography equipment business).

[30] *See* SART_0000487—SART_0000498, at SART_0000498; SART_0001130—SART_1177, at SART_0001151 (Sartorius's acquisition business case assumes a multiyear investment in the development of a SU flow-path for BioSC RCC); *id.* at SART_0001171 (Sartorius's acquisition business plan assumptions include sales projections for SU BioSC–RCC systems).

[31] *See* SART_0063502 (Sartorius BioSC–RCC margin calculations).

[32] *See generally* SART_0002268—SART_0002303 (Collaboration Interim Manufacturing and Marketing Agreement).

[33] *See* SART_0000539, at ''EUR Summary'' tab (Sartorius discounted cash flow analysis prepared for transaction valuation purposes indicating accelerating BioSC/BioSC–RCC growth due to investments).

public health risks and keep economies functioning well.

ii. The Proposed Transaction Will Enhance Sartorius's Competitiveness as a New Entrant That Competes Through Innovation

Sartorius's acquisition of Novasep's chromatography equipment business will provide complementary technologies and expertise to ''fill in the gaps'' in Sartorius's newly acquired downstream LPLC bioprocessing equipment portfolio.[34]

The acquisition of Novasep's HPLC equipment will enable Sartorius to offer customers a complete range of technologies for the purification of smaller molecules, complementing Sartorius's LPLC equipment that serves larger molecule biopharma manufacturing. Historically, Novasep's HPLC equipment was predominantly used to purify smaller molecule active ingredients and insulin. Recently, Novasep's HPLC equipment has played a critical role in the purification of key components of mRNA and recombinant protein COVID vaccines. Through its extensive sales and service network, Sartorius will be able to expand the reach and availability of Novasep's HPLC equipment across the globe, offer a full line of LPLC and HPLC equipment for customers who prefer to purchase from one source, and provide more choices in equipment and services for producers of life-saving drug therapies and vaccines.

In addition to supporting and enhancing Novasep's HPLC business, the acquisition will enable Sartorius to successfully commercialize BioSC, Novasep's LPLC ''multistep'' intensified chromatography system, an innovative technology that Novasep has struggled to commercialize, particularly in North America, for reasons that include its limited sales presence, lack of SU technology, and inability to invest in necessary improvements and innovations (see further Section III(c)(ii) below). BioSC has achieved very few sales at the clinical or commercial scale, and sales have stagnated. Biopharma customers are making decisions today about investments in their manufacturing infrastructure for decades to come. Absent the Proposed Transaction and the investment and innovation Sartorius is uniquely placed to make to transform BioSC into a commercially attractive option, customers will miss a critical window to realize BioSC's potential to improve the downstream biopharma manufacturing process.

c. FTC Procedural History

The FTC has conducted an extensive investigation of Sartorius's proposed acquisition of Novasep's chromatography equipment business. Sartorius provided an initial briefing on the Proposed Transaction in July 2020 and formally notified the transaction on January 21, 2021. The Parties have voluntarily produced numerous documents, data and submissions to the FTC, and regularly addressed staff questions as they arose in their investigation of the Proposed Transaction. In addition, Sartorius and Novasep management presented to, and were interviewed by, FTC staff. Both before and in response to the FTC's Voluntary Access Letters (''VALs'') issued in June 2021, Sartorius and Novasep each produced thousands of ordinary course business documents and data, and, at the FTC's request, both parties certified substantial compliance with the VALs.

Now that the FTC staff have completed their investigation, the Parties submit this petition requesting the Commission's approval to permit the transaction to close before year end. In addition to enabling the Parties to meet their contractual obligations and transaction timetable, permitting closing before year end will eliminate the state of uncertainty that has hung over the Novasep chromatography equipment business for the past year, further business deterioration, and the ongoing challenge of retaining critical employees while the business is in limbo. Furthermore, essential innovation, including the completion of the development of the SU flow-path for BioSC–RCC and BioSC, along with necessary software improvements[35] and innovative product development for the BioSC system and other projects cannot be achieved until the transaction has closed. In the event that approval is not obtained by mid-December, Novasep likely will be forced to transfer the business back to its private investor shareholders, in which case the business will operate with even fewer financial and organizational resources than it has today.

Permitting the transaction to close before year end will enable the Novasep and Sartorius product development engineers to integrate and work together as a single team to move forward with product development and other innovations that cannot be achieved in the Parties' collaboration. Most importantly, approving the transaction before year end will ensure that customers and consumers benefit from the innovation resulting from new product launches and necessary improvements to existing products, which will be further delayed if the deal does not close by year end (and very likely will be lost altogether if the transaction is not approved).

III. The Transaction Is Procompetitive and Will Not Lessen Competition in Any Relevant Chromatography Market

As the Commission alleged in the Danaher Complaint, ''[t]he relevant geographic area in which to assess the competitive effects of the Acquisition [of chromatography equipment] is no narrower than the United States and may be as broad as the entire world.''[36]

As described further below, the acquisition of Novasep's HPLC column and skid assets will not lessen competition because Sartorius does not manufacture or sell HPLC equipment. Similarly, although Sartorius and Novasep each manufacture and sell conventional LPLC columns and skids, Novasep's sales and market share in each of these products is very small. Finally, the addition of Novasep's LPLC intensified chromatography system (BioSC) to Sartorius's product portfolio will be procompetitive because BioSC and Sartorius's BioSMB systems are complementary, highly differentiated products that meet distinct customer needs.[37]

a. HPLC Columns and Skids

Sartorius's acquisition of Novasep's HPLC equipment fills a gap in its chromatography equipment portfolio and enhances Sartorius's ability to compete with incumbent chromatography equipment suppliers

[34] *See* SART_0160423, at 2 (explaining how Sartorius is positioning itself to provide customers with more options in intensified downstream processing in a highly competitive environment of large, established players, where technology progress is already pointing towards continuous manufacturing); SART_0115519, at 12 (July 2021 BioSMB Business Plan projecting distinct growth rates for BioSC, BioSMB, and BioSC RCC).

[35] *See* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029 (documents discussing software challenges). *See also* Rebecca H. Farrington Letters to Lisa DeMarchi Sleigh, dated September 15, 2021 and October 5, 2021.

[36] Danaher Complaint at ¶ III(6).

[37] The segmentation of approaches to intensified/continuous LPLC chromatography between single-step and multistep solutions, demonstrates that customer demand exists for both intensification approaches, which will incentivize Sartorius to continue innovating with both BioSC and BioSMB platforms following the transaction. [REDACTED]. *See* SART_0000601—SART_0000605 (regarding Sartorius's plans to continue to support both systems).

that offer a full range of HPLC and LPLC equipment. By expanding its product portfolio, Sartorius will be able to serve customers who prefer to source their HPLC and LPLC equipment needs from a single supplier and give them more competitive choices.

Novasep's HPLC equipment will allow Sartorius to offer a complete range of technologies for both the needs of the biopharma industry and adjacent pharmaceutical segments. The availability of Novasep's HPLC offerings alongside LPLC solutions from a single source also will allow Sartorius to achieve economies of scale and conform control systems across platforms.

Following the acquisition, Sartorius will have every incentive to support and enhance Novasep's HPLC equipment. In addition to purification of small molecule active ingredients and insulin, Novasep's HPLC equipment is increasingly being used in COVID–19 vaccine development. For example, Novasep's Hipersep Pilot skid is being used to purify COVID–19 vaccine components, including the mRNA strands and lipid nanoparticles that are critical to the vaccines' efficacy. With its robust global marketing, sales and service infrastructure, Sartorius will be able to increase sales and penetration of Novasep's HPLC product lines with new customers and in new applications, including supporting vaccine producers' efforts to combat the COVID–19 pandemic.

b. Conventional LPLC Columns and Skids

As alleged in the FTC's Danaher Complaint, conventional LPLC column and skid markets have ''only three significant suppliers'': Danaher, GE and Merck Millipore.[38]

In the case of columns, the FTC ''estimate[d] the combined firm [*i.e.,* Danaher/GE] would have a market share of greater than 45 percent'' with ''[s]everal fringe firms.'' [39] In the case of skids, the FTC estimated that GE was ''the leading supplier of conventional LPLC skids with over 30 percent market share [and that combined] Danaher and GE would have an even larger share of the market.'' [40]

Novasep is one of the ''fringe'' firms that the FTC concluded in its GE/Danaher investigation had an insufficient market presence to competitively constrain GE/Danaher in these product areas. Novasep estimates that its global market share in conventional LPLC columns and conventional LPLC skids is de minimis (less than [REDACTED] globally and in the U.S.).[41] Accordingly, the acquisition by Sartorius would not risk substantially lessening competition in those products in any relevant geographic market.

c. LPLC Intensified/Continuous Chromatography Systems

Different technologies have been developed to address biopharma customers' needs for faster, more efficient downstream bioprocessing at lower cost and bioprocess risk. Sartorius's BioSMB and Novasep's BioSC systems each provide a form of ''intensified'' chromatography using distinct technologies that addresses different customer needs.[42] Customers have different manufacturing strategies and equipment preferences that, in turn, depend on a number of factors, including the configuration of their facilities, available and desired footprint, type of products (*e.g.,* innovator or biosimilar), stage of production (development, clinical or commercial scale), volumes and mix of products, efficiencies desired from affinity capture step intensification versus other chromatography steps, and labor costs.[43]

i. BioSMB and BioSC Product Differentiation

BioSMB and BioSC exemplify two distinct approaches to bioprocessing intensification that have evolved over the past decade:

- ''Single-step'' intensification of the affinity capture chromatography step alone.
  - Other steps in the chromatography process (the virus inactivation step and two polishing steps) are achieved using separate LPLC batch chromatography equipment.
  - Commercially available systems using ''single step'' intensification include BioSMB, Cytiva's PCC (now owned by Danaher), YMC/ChromaCon Contichrom Twin, and Tosoh/Semba ProGMP).
- ''Multistep'' intensification of all chromatography steps by integrating each chromatography step in a single system and continuous process.
  - Commercially available systems include BioSC, PAK BioSolutions, and Sepragen QuantaSep).[44]

BioSMB (and other single step systems) are designed to maximize the productivity of resin at the affinity capture step using a sequential multi-column chromatography (''S–MCC'') process. BioSMB offers the greatest efficiencies for customers that make biologic drugs such as mAbs, which require expensive Protein A resin for purification. Because BioSMB only performs the affinity capture step, it may be more attractive to customers who are looking to reduce costs and improve productivity without replacing their entire downstream bioprocessing production line. Customers can still generate significant resin savings and increase productivity by replacing their existing batch LPLC equipment with BioSMB to perform the affinity capture step without having to invest in an entirely new production line (and securing the extensive regulatory approvals that are required to do so).

With its SU flow path technology, BioSMB also is attractive to customers who prefer not to undertake intensive cleaning and sterilization of MU equipment between process runs. In particular, innovator biopharma customers in North America and Europe increasingly prefer to use disposable SU flow-kits so that they can quickly switch between process runs for different biologic products without time-consuming cleaning and sterilization, or risk cross-contamination between process runs for different drugs.[45] Some customers explicitly make SU technology a requirement in their ''request for proposal'' specifications.[46]

[38] *See* Danaher Complaint at ¶ IV(9); European Commission Decision at ¶¶ 388, 401.

[39] Danaher Complaint at ¶ IV(9).

[40] *Id.* ¶ IV(10).

[41] Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated July 15, 2021 (regarding MU LPLC columns); *see also* NOVA–000296—NOVA–000303, at NOVA–000300.

[42] SART_0016281, at 2 (illustrating the different customer applications for BioSMB and the Parties' recently launched BioSC–RCC system based on customer consumable usage strategy, product development stage, and risk tolerance); SART_0145766 (indicating that BioSC–RCC is for customers with different preferences or needs than multi-column chromatography (''MCC'') systems like BioSMB).

[43] *See* SART_0000606—SART_0000607, at SART_0000606; SART_0170114 (illustrating the distinct applications for resin-based MCC and membrane-based RCC systems based on customer consumable usage strategies, product development status, and customer risk tolerance); SART_0115519, at 12 (projecting distinct growth rates for BioSC, BioSMB, and BioSC–RCC in Sartorius's July 2021 BioSMB Business Plan).

[44] Suppliers of multistep systems also include various in-house systems developed by biopharma companies such as Fujifilm, Bayer, Boehringer Ingelheim, and Novartis.

[45] *See* NOVA–001242—NOVA–001755, at NOVA0001572 (''With single-use equipment now in routine common use, [biopharma survey] respondents may be viewing disposable options from more of an economic vs. technological perspective, particularly eliminating weeks of manual labor-intensive cleaning and sterilizing stainless steel equipment.'').

[46] When intensified chromatography systems were first introduced to customers as a nascent technology, customers purchased benchtop/lab scale models for equipment testing and

Continued

Because BioSC lacks a SU option,[47] it cannot compete with BioSMB for these opportunities.

In contrast, BioSC's greatest value to customers is its ability to continuously perform multi-step, multi-column chromatography (''MS–MCC'').[48] Although it is technically capable of performing S–MCC alone, most customers have placed orders without the S–MCC configuration because this would eliminate the system's ability to continuously perform multiple chromatography steps in an MS–MCC process.[49] To perform the affinity capture step, MS–MCC typically uses a simplified, less efficient form of multi-column intensification or a conventional batch process, which is not as efficient as BioSMB. BioSC's productivity benefits are largely achieved through the integration of the entire downstream chromatography process in a single system using an onboard software suite to coordinate each chromatography step.[50] BioSC's integrated system also eliminates time consuming (and productivity reducing) intermediate steps such as product storage in holding tanks between chromatography processes that are required for single-step, standalone systems such as BioSMB.[51]

BioSC is an attractive option for customers who have the flexibility to implement a new downstream production line or are building a new manufacturing facility. BioSC's integrated system reduces manufacturing footprint by reducing the size (and associated operational costs) of the sterile ''clean rooms'' required to produce biologics.[52] In addition, certain customers may prefer BioSC's MU technology if, for example, they are producing larger product runs (*e.g.,* biosimilars), switching between products infrequently, and/or are located in regions where labor costs for cleaning and sterilization of MU equipment are lower (*e.g.,* Southeast Asia).[53]

Because BioSMB and Novasep BioSC are highly differentiated products that provide process intensification in different ways, customers generally do not view them as close substitutes, particularly at clinical and manufacturing scales.

ii. BioSC Has Failed To Penetrate the U.S. and Its Global Sales Are Declining

Since BioSC's launch in 2015, Novasep has sold only a few lab scale units in the U.S.[54] To the extent that BioSC Lab sales are viewed as an indication of potential future BioSC sales at commercial scale, Novasep lacks an installed base of lab scale equipment to generate future sales. Novasep has faced challenges convincing customers to scale up to BioSC's larger (clinical or manufacturing scale systems), in part because Novasep's product family does not have a simple scale-up pathway.[55]

BioSC's lack of sales in the U.S. is attributable to several challenges that Sartorius is uniquely placed to overcome and to do so quickly, given its extensive experience working with the BioSC platform.[56] First, Novasep does not have an established reputation as an LPLC supplier and is relatively unknown to the North American biopharma industry for LPLC. Second, unlike BioSMB, Novasep's BioSC product family does not provide customers an easily achievable scale-up pathway because the system architecture of the BioSC lab scale model, which biopharma customers can use to test the BioSC proof of concept, differs significantly from that of BioSC Pilot and BioSC M, which are used for drug development and manufacture.[57] Third, innovator biotechnology companies in North America prefer to purchase from longstanding suppliers that have significant local sales and support infrastructure. Novasep has only [REDACTED] salespeople and [REDACTED] service technicians in the U.S. to support all of its HPLC and LPLC product lines.[58] In contrast, Sartorius's specialized chromatography sales and service ''task force'' already includes 11 individuals in the U.S. supporting its LPLC chromatography products alone, and Sartorius is planning to expand the team. Fourth, there is an increasing customer preference in the U.S., particularly at commercial scale, to use SU flow-path technology (which Novasep does not have).[59] Fifth, BioSC's software, which controls and coordinates the MS–MCC process, has experienced challenges and the system will benefit from Sartorius's expertise in software and process automation.[60]

Despite the potential benefits of the system, the trajectory of Novasep's BioSC sales over the past several years has been declining and its sales prospects are unlikely to improve without necessary investment and improvements that Sartorius is uniquely placed to provide.[61] In order to achieve commercial adoption and deliver its potential benefits to customers, BioSC requires the investment and innovations that Sartorius is planning to provide once it owns the platform including, *inter alia,* updating and redesigning the systems to a more ''off the shelf'' design and streamlined manufacturing process at a lower cost, the development of a SU flow-path and software improvements, as well as the support of Sartorius's U.S. and global sales and service infrastructure.

experimentation. Given the small scale of production and the corresponding relative ease of changing tubing for SU systems or cleaning the tubing for MU systems, customers did not necessarily have a strong preference for SU versus MU flow path technology because there is not necessarily a significant difference in cost or contamination risks at this scale. This was the competitive environment the Commission analyzed in its review of the Danaher-GE transaction. Now that large molecule innovators are advancing to pilot/process development stage production, their preference for SU technology has become more pronounced.

[47] NOVA–000691—NOVA–000748, at NOVA–000703, NOVA–000707, NOVA–000730 (''No Single Use skills'').

[48] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated April 26, 2021, at 3–4 (regarding BioSC chromatography processes).

[49] *Id.* at 3. A BioSC system configured for MS–MCC in Novasep's factory cannot be ''switched'' to the S–MCC process that BioSMB uses by a customer. Customers must ship the equipment back to the Novasep factory for modification and, in practice, they have not done so. *Id.*

[50] *See* SART_0002159—SART_0002187, at SART_0002171.

[51] *See* Sartorius BioSMB Technical Discussion Presentation: Meeting with FTC (Apr. 22, 2021), at 9.

[52] *See* Rebecca H. Farrington Letter to Lisa DeMarchi Sleigh, dated April 26, 2021, at 2 (regarding BioSC chromatography processes).

[53] *See, e.g.,* NOVA–001210—NOVA–001241; NOVA–001759—NOVA–001800; NOVA–001756—NOVA001758; NOVA–001191—NOVA–001207.

[54] Novasep manufactures the BioSC system at three different scales: Lab, pilot/clinical, and manufacturing. Bioprocesses that are investigated on BioSC Lab are ''scaled up'' (*i.e.,* increased in size/volume) to the larger BioSC Pilot system for clinical development (although BioSC faces challenges when scaling up that Sartorius plans to address in its redesign of the three scales of the system), and ultimately to BioSC Manufacturing system for commercial production.

[55] *See* Bates White's CRM Data Analysis Presentation and exhibits, dated May 26, 2021, at 8.

[56] *See* NOVA–000691—NOVA–000748, at NOVA–000738 (Novasep's customer sales, service, and support infrastructure is underdeveloped.).

[57] *See* NOVA–001208—NOVA–001209 (explaining that BioSC Lab does not scale up to BioSC Pilot).

[58] *See* Novasep's Voluntary Access Letter Response dated September 17, 2021, at 25.

[59] *See* SART_0001180—SART_0001181, at SART_0001180; SART_0003306 (providing Sartorius' projections of customer preference for the SU version of BioSC RCC); SART_0168117, at 17 (June 2021 Business Review indicating ''Growth to achieve 2025 driven by steady-increased Multi-Use System and explosive-increased Single-Use System''); *see also* NOVA–000872, NOVA–000881 (Budget 2020 BU Process Solutions).

[60] *See, e.g.,* NOVA–VAL–0000079; NOVA–VAL–0014556; NOVA–VAL–0018504; NOVA–VAL–0025513; NOVA–VAL–0027911; NOVA–VAL–0063924; NOVA–VAL–0063984; NOVA–VAL–0073282; NOVA–VAL–0073557; NOVA–VAL–0075029.

[61] *See* F. Schaeffer Letter to Lisa DeMarchi Sleigh, dated July 9, 2021, at 3 (regarding BioSC scale up and sales).

iii. BioSMB and BioSC Virtually Never Compete Head-to-Head

Because BioSMB and BioSC utilize different technologies and approaches that meet different customer needs, there has been very little head-to-head competition between them since their lab scale systems were launched. Indeed, the Parties have identified only one instance of BioSMB and BioSC pursuing the same opportunity at commercial (*i.e.,* clinical or manufacturing) scale. This was an opportunity to sell to a potential customer located outside of the U.S., which neither company won.

Because BioSMB and BioSC are highly differentiated products that are very rarely in direct competition in new sales opportunities,[62] there is no practical risk of unilateral price effects from the acquisition.[63] The Parties' win/loss data confirms that BioSMB and BioSC virtually never compete directly[64] and that any attempted unilateral price increase for either product post-merger would be unprofitable.[65]

iv. Sartorius Must Continue To Offer Multiple Platforms and Innovate To Displace Incumbent Batch LPLC Suppliers and Meet Increasing Process Intensification Competition

Sartorius views the acquisition of the multistep BioSC system as filling a gap in its chromatography portfolio to meet customer demand for an integrated continuous chromatography system that BioSMB's single-step system does not provide. Sartorius has forecast distinct customer demand (and growth rates) for both BioSMB and BioSC platforms.[66]

Sartorius has already made investments in the BioSC–RCC and BioSMB platforms.[67] Once the transaction is approved, Sartorius will be able to make necessary investments in BioSC to make it a commercially attractive option for customers. As a new entrant in the chromatography equipment business, Sartorius needs to overcome the incumbency advantages of the dominant batch LPLC chromatography equipment suppliers by convincing customers that it is worth replacing their legacy batch systems with superior Sartorius equipment. Sartorius has a better prospect of convincing customers across the board to make the switch if it can offer multiple options for intensification in a range of systems and approaches that meet different customer priorities and needs.

The Proposed Transaction also will combine Sartorius's and Novasep's complementary technologies, know-how, and engineering expertise that will accelerate the development of next generation systems and innovations, and meet escalating competition in intensified chromatography processing.[68] Intensification of downstream processing is a strategic focus of biopharma companies, which have an increasing number of competitive options through their own product development efforts, as well as strategic combinations and investments by their supplier base:

Tosoh/Semba: In January 2019, Tosoh Corporation increased its investment in U.S.-based Semba Biosciences, Inc. in pursuit of its goal to become a full range solutions provider for biopharma purification.[69] The investment enhanced Semba's ability to market and innovate with its SU lab and process development scale LPLC continuous chromatography systems, and Tosoh's scale and resources, which include a significant resins business, allowed it to commercialize its first commercial scale SU LPLC continuous chromatography system this year.[70]

YMC/ChromaCon: In April 2019, YMC Co., Ltd. acquired ChromaCon AG, a manufacturer of LPLC continuous chromatography systems.[71] As a result, ChromaCon has been able to leverage YMC's expertise in resin and packed columns to enhance its lab, pilot, and commercial scale LPLC continuous chromatography systems.[72] In July 2020, the U.S. Food and Drug Administration purchased a ChromaCon LPLC continuous chromatography system for evaluation, signaling its interest and confidence in ChromaCon's equipment.[73]

Sepragen: Sepragen, a U.S.-based firm, offers a complete product portfolio including resins, columns, and MU and SU chromatography systems at lab, pilot, and commercial scales.[74] Sepragen has developed and sold MU LPLC continuous chromatography systems and recently added a lab scale chromatography system with a SU flow path to its product portfolio.[75]

Repligen/ARTeSYN: In October 2020, Repligen Corporation announced its acquisition of ARTeSYN Biosolutions.[76] ARTeSYN produces engineered-to-order (''ETO'') SU continuous chromatography systems at different

[62] ''In differentiated product industries, some products can be very close substitutes and compete strongly with each other, while other products are more distant substitutes and compete less strongly. . . . The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects.'' Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.1 (2010) [hereinafter Horizontal Merger Guidelines].

[63] ''Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice. The Agencies consider any reasonably available and reliable information to evaluate the extent of direct competition between the products sold by the merging firms. This includes documentary and testimonial evidence, win/loss reports and evidence from discount approval processes, customer switching patterns, and customer surveys.'' *Id.*

[64] *See* Bates White's CRM Data Analysis Presentation and exhibits, dated May 26, 2021, at 8.

[65] ''A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level. Some of the sales lost due to the price rise will merely be diverted to the product of the merger partner and, depending on relative margins, capturing such sales loss through merger may make the price increase profitable even though it would not have been profitable prior to the merger.'' Horizontal Merger Guidelines at § 6.1.

[66] *See* SART_0115519, at 12 (projecting distinct growth rates for BioSC, BioSMB, and BioSC–RCC in Sartorius's July 2021 BioSMB Business Plan); SART_0000601—SART_0000605 (regarding Sartorius's plans to continue to support both platforms).

[67] Sartorius also completed an extensive, in-house sales training program and launched a marketing campaign in March 2021 to promote the BioSMB system to prospective customers whom it had identified might be interested in moving from conventional batch processing to a continuous chromatography system. *See generally* SART_0016472.

[68] *See* Horizontal Merger Guidelines § 6.4 (''The Agencies also consider whether the merger is likely to enable innovation that would not otherwise take place, by bringing together complementary capabilities that cannot be otherwise combined or for some other merger-specific reason.'').

[69] *Tosoh Corporation Invests in Semba Biosciences, Inc.,* Tosoh (Jan. 10, 2019), *https://www.tosoh.com/news-press/news-releases/2019/tosoh-corporation-invests-in-semba-biosciences-inc.*

[70] *New ProGMP 150 System,* Semba Biosciences, *https://sembabio.com/progmp-150-system/#1617729557380-f5d67fe8-6d6a* (last visited Oct. 22, 2021).

[71] *YMC Acquires Chromacon,* ChromaCon (Apr. 9, 2019), *https://www.chromacon.com/en/news/ymc-acquires-chromacon.*

[72] *Contichrom TWIN—GMP Scale-up equipment,* ChromaCon, *https://www.chromacon.com/en/products/gmp-scale-up-equipment* (last visited Oct. 22, 2021).

[73] *FDA selects twin-column chromatography system by YMC ChromaCon for evaluation,* ChromaCon (July 2020), *https://www.chromacon.com/resources/public/lava3/media/kcfinder/files/FDA%20orders%20Twin%20Column%20Chromatography%20of%20YMC%20Press%20Release%2007F2020.pdf.*

[74] *Products Overview,* Sepragen, *https://www.sepragen.com/Products.html* (last visited Oct. 22, 2021).

[75] *QuantaSep Single Use,* Sepragen, *https://www.sepragen.com/Products-Chromatography-Systems-Single-Use.html* (last visited Oct. 22, 2021).

[76] *Repligen Corporation Announces Agreement to Acquire Bioprocess Systems Innovator ARTeSYN Biosolutions and Completes Acquisition of Non-Metallic Solutions,* Repligen (Oct. 27, 2020), *https://repligen.q4ir.com/news/news-details/2020/Repligen-Corporation-Announces-Agreement-to-Acquire-Bioprocess-Systems-Innovator-ARTeSYN-Biosolutions-and-Completes-Acquisition-of-Non-Metallic-Solutions/default.aspx.*

scales, which Repligen is now actively marketing.[77] As a leading resin supplier to biopharma companies in the U.S. and globally, Repligen has the financial resources and customer relationships to commercialize and improve ARTeSYN's continuous chromatography technology. For example, Repligen produces pre-packed columns, which are well suited to ARTeSYN systems. Repligen plans to continue developing ARTeSYN's single-use solutions as part of its portfolio.

Merck Millipore: Merck Millipore is leveraging a platform called BioContinuum to provide a form of intensified processing using chromatography equipment based on the company's ''Mobius'' concept. Merck Millipore has announced a collaboration in intensified downstream processing with Transcenta (formerly Just Bio).[78]

PAK BioSolutions: PAK BioSolutions is a new, U.S.-based, chromatography equipment entrant that was founded in 2018. In 2021, PAK introduced a SU pilot scale multistep intensified chromatography system that can perform MS–MCC in a manner similar to BioSC.[79]

In sum, competition in LPLC continuous chromatography systems and intensified processing approaches has significantly increased since the Danaher-GE transaction.[80] Larger players are investing in smaller competitors and developing their own products, and customers continue to develop their own in-house solutions.[81]

Following the transaction, Sartorius will continue to face competition from a range of intensified LPLC system suppliers including:

- At least six, well-capitalized suppliers that are actively marketing products in the chromatography intensification space: Danaher (Cytiva), Tosoh/Semba, YMC/ChromaCon, Sepragen, Repligen/ARTeSYN, and PAK BioSolutions;
- incumbent batch LPLC equipment suppliers, such as Merck Millipore, which are entering the space;
- emerging Chinese suppliers, such as Lisure Science; and
- customers who are continuing to develop their own intensification technologies in-house.

Intensified/continuous chromatography is an emerging area with a range of technologies. No single approach has achieved broad adoption at this time. To achieve commercial success, Sartorius will need to continue to innovate and demonstrate greater efficiencies to convince a critical mass of customers to adopt its products in place of incumbent conventional LPLC batch systems and other competing intensification solutions. The proposed acquisition will enhance Sartorius's ability to continue to successfully innovate in this growing and increasingly competitive field and to develop next generation solutions to meet industry needs for cost-effective, biologic drug development and large-scale production.

IV. If the Proposed Acquisition Is Not Approved, the Parties' Existing and Future Innovations Will Be Lost and Customers and Consumers Will Be Harmed

In developing BioSC–RCC, the Parties have created a unique new product—a membrane-based intensified chromatography system that employs RCC as an alternative to resin-based systems.[82] The product is still in the testing phase and no sales have been made as yet. Sartorius has concluded that it needs to develop and launch a BioSC–RCC system with a SU flow-path option for the BioSC–RCC concept to achieve commercial success. A SU option would be preferred by many customers who are concerned about maintaining purity and low bioburden risk, while achieving quick turnaround times between batches.[83] However, Sartorius has no incentive to invest in this innovation without any right to manufacture or market the system. Developing and launching BioSC–RCC with a SU option will not be feasible unless Sartorius is able to acquire the Novasep equipment business.

If Sartorius were unable to acquire Novasep's chromatography equipment business, the innovations achieved by the collaboration are unlikely to be successfully commercialized and planned innovations, such as the BioSC–RCC SU version, will not be achieved. If the sale of the business to Sartorius is not approved, it would be transferred to Novasep's private investor shareholder until it could be divested. Uncertainty over the future ownership of the business would stall further investment and development by both Sartorius and the Novasep chromatography equipment team (which already is operating with significant resource constraints). The fruits of the Parties' collaboration would be lost and ultimately the collaboration would end.

Furthermore, if the Proposed Transaction does not close before year end, the business would be transferred to NVHL S.A., which would risk business deterioration and attrition of critical employees. The further uncertainty that would result from a transfer of the business to NVHL S.A. would risk employee attrition with further adverse business impacts. It would also undermine customers' confidence in the Novasep equipment business and its ability to support long-term investments in its equipment. In particular, biopharma customers, who prioritize security of supply and long-term business continuity when making equipment purchasing decisions, understandably would be reluctant to invest in Novasep equipment while the business' ownership and future remains uncertain. Thus, in addition to depriving the business of the resources needed to invest in, market, and sell its products that its acquisition by Sartorius would provide, this standalone scenario would likely lead to a reduction of revenue further undermining the competitiveness and prospects for the business.

Once the transaction is approved, Sartorius will be able to progress its planned investments in BioSC, including development of a SU flow-path, redesign of the BioSC family so that it scales up easily and without extensive and costly revalidation studies, redesign of the current ETO BioSC M system as an off-the-shelf system to improve customer delivery

[77] *ARTeSYN Chromatography Systems,* Repligen, *https://www.repligen.com/technologies/engineered-systems/chromatography-systems#collapse1-2* (last visited Oct. 22, 2021).

[78] *MilliporeSigma and Transcenta Collaborate to Advance Continuous Biomanufacturing, Make the 'Facility of the Future' a Reality,* MilliporeSigma (Nov. 7, 2020), *https://www.emdmillipore.com/US/en/20201106_153338?bd=1.*

[79] *The PAK System,* PAK BioSolutions, *https://www.pakbiosolutions.com/the-pak-system/* (last visited Oct. 22, 2021).

[80] SART_0009787—SART_0009826, at pp. 11–12 (comparing BioSC to PAK BioSolutions, a ''[n]ew entrant . . . offering SU equivalent to BioSC,'' and identifying biopharma companies developing systems in-house and noting that more biopharma companies are utilizing multistep processes).

[81] *MilliporeSigma and Transcenta Collaborate to Advance Continuous Biomanufacturing, Make the 'Facility of the Future' a Reality,* (Nov. 7, 2020), MilliporeSigma, *https://www.emdmillipore.com/US/en/20201106_153338?bd=1.*

[82] Membrane capsules and cassettes are an emerging technology that offer the potential for greater production efficiencies than conventional resin-based chromatography systems. *See* SART_0002159—SART_0002187, at SART_0002173 (comparing projected customer cost savings of BioSC–RCC to GE/Cytiva's conventional LPLC batch equipment).

[83] *See* SART_0000487—SART_0000498, at SART_000498; SART_0003206 (indicating Sartorius's expectation that BioSC–RCC would displace less-efficient, traditional batch equipment, notably GE/Cytiva's dominant conventional LPLC batch equipment and providing Sartorius' projections, showing sales of the SU version of BioSC–RCC exceeding the MU version over time); *see also* SART_0003306; SART_0168117, at 17.

times,[84] and redesign of BioSC's software, which has been unreliable and rendered some systems inoperable.[85] The Proposed Transaction will allow these innovations to be achieved and will accelerate product development by enabling each company's engineering personnel to work together under one roof[86] with a unified and stronger strategic focus on developing these products more quickly and cost-effectively.[87]

Combining Sartorius and Novasep technologies, IP, engineering personnel, and know-how also will accelerate innovation in the BioSMB product line. Planned innovations include value-engineering BioSMB's SU flow-kits to reduce their cost, developing BioSMB-specific applications data for additional types of therapies, and line extensions, such as the planned, [REDACTED].[88]

The Proposed Transaction will ensure that Novasep's products are effectively manufactured, marketed, and supported by an innovative supplier with the infrastructure that biopharma customers rely on to make long-term capital investments in these products. With the support of Sartorius's global manufacturing, supply chain, sales, and service infrastructure,[89] customers will have the confidence to purchase Novasep equipment as a long-term capital investment. All of these benefits will be particularly pronounced in the U.S., where Novasep has been unable to successfully commercialize BioSC or its other LPLC product lines.

V. Request for Confidential Treatment

This petition, including its related documents, contains certain confidential and competitively sensitive business information relating to Sartorius, Novasep, and the Proposed Transaction. Disclosure of such confidential information may prejudice Sartorius and Novasep, and cause harm to the ongoing competitiveness of both companies. Pursuant to Sections 2.41(f)(4) and 4.9(c) of the FTC's Rules of Practice and Procedure,[90] Sartorius has redacted such information from the public version of this application, and requests confidential treatment for such redacted information under Section 4.10(a)(2) of the FTC's Rules of Practice and Procedure [91] and Sections 552(b)(4) and (b)(7) of the Freedom of Information Act.[92] In the event that a determination is made that any material marked as confidential is not subject to confidential treatment, Sartorius requests that the FTC provide prompt notice of that determination and adequate opportunity to appeal such a decision.

Respectfully submitted,

/s/Fiona A. Schaeffer

Fiona A. Schaeffer,
Andrew S. Wellin,
MILBANK, LLP, 55 Hudson Yards, New York, NY 10001.

Counsel for Sartorius Stedim Biotech, S.A.

Dated: October 28, 2021.

[FR Doc. 2021–25150 Filed 11–17–21; 8:45 am]

BILLING CODE 6750–01–P

[84] The average time from order to delivery for a BioSC system is significantly longer than for a BioSMB system, in part because Sartorius has a superior manufacturing process and efficiencies, and many of Novasep's products are manufactured on an ETO basis, which is more costly and time-consuming. SART_0000464—SART0000471, at SART0000468; *see also* SART_0001130—SART_1177, at SART_0001142 (regarding Sartorius's plans for significant additional investment in product development); *id.* at SART_0001151 (regarding Sartorius's acquisition business case, which includes a multiyear investment in the development of BioSC M).

[85] *See Why Novasep is Not a Competitive Constraint—White Paper Prepared for the U.S. Federal Trade Commission,* dated June 4, 2021, at 17, n.25 (regarding BioSC software challenges).

[86] *See* SART_0001130—SART_0001177, at SART_0001136; SART_0002571—SART_0002591, at SART_0002576 (outlining Sartorius' integration plans, including highlighting the creation of a centralized research and development site as ''priority #1'' as it will benefit from ''automation expertise for [the] full chromatography portfolio,'' the ''use of existing supplier network/cooperation partner—short distances (250km radius) to established suppliers/sub-contractors of BioSMB/Allegro systems,'' ''[c]lose collaboration with French [Sartorius] colleagues in Aubagne for single-use systems,'' and the ''[o]pportunity to hire former Pall people because of close proximity to Dreieich'').

[87] Although Sartorius's research and development plans confirm that it intends to do much more than maintain the status quo for Novasep's products, Sartorius also made specific guarantees to maintain and invest in Novasep at least at current levels for a three-year period in connection with French foreign investment approval, which demonstrates its commitment to Novasep's technologies and employees. *See* Andrew S. Wellin Letter to Lisa DeMarchi Sleigh, dated July 1, 2021 (regarding Sartorius's commitments in connection with French foreign investment approval of the Proposed Transaction).

[88] *See* SART_0000487—SART_0000498, at SART_0000496; SART_0009752, at SART_0009754–55 (illustrating Sartorius' development plans for BioSMB); SART_0153310, at 14 (listing ongoing BioSMB PD improvement projects).

[89] Currently, Sartorius has 306 sales and service employees in the BPS organization. Following the closing of the Danaher/Pall divestiture, Sartorius created a 20-person chromatography ''task force'' dedicated solely to chromatography sales with a special focus on intensified/continuous chromatography equipment. Over half of Sartorius's chromatography task force is located in the U.S.

[90] 16 CFR 2.41(f)(4) and 4.9(c).

[91] 16 CFR 4.10(a)(2).

[92] 5 U.S.C. 552(b)(4), 552(b)(7).

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for comment.

SUMMARY: The FTC requests that the Office of Management and Budget (OMB) extend for three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the rules and regulations under the Pay-Per-Call Rule (Rule). That clearance expires on November 30, 2021.

DATES: Comments must be received by December 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. The *reginfo.gov* web link is a United States Government website produced by OMB and the General Services Administration (GSA). Under PRA requirements, OMB's Office of Information and Regulatory Affairs (OIRA) reviews Federal information collections.

FOR FURTHER INFORMATION CONTACT: P. Connell McNulty, Attorney, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Mail Code CC–5201, 600 Pennsylvania Ave. NW, Washington, DC 20580, (202) 326–2061.

SUPPLEMENTARY INFORMATION:

Title: Trade Regulation Rule Pursuant to the Telephone Disclosure and Dispute Resolution Act of 1992 (''Pay-Per-Call Rule''), 16 CFR part 308.

OMB Control Number: 3084–0102.

Type of Review: Extension of a currently approved collection.

Abstract: The existing reporting and disclosure requirements of the Pay-Per-Call Rule are mandated by the Telephone Disclosure and Dispute Resolution Act of 1992 (TDDRA) to help prevent unfair and deceptive acts and practices in the advertising and operation of pay-per-call services and in the collection of charges for telephone-billed purchases. The information obtained by the Commission pursuant to the reporting requirement is used for law enforcement purposes. The disclosure requirements ensure that consumers are told about the costs of