Simpson Thacher & Bartlett LLP

900 G STREET, NW
WASHINGTON, D.C. 20001

TELEPHONE: +1-202-636-5500
FACSIMILE: +1-202-636-5502

Direct Dial Number
+1-202-636-5582

E-mail Address
sara.razi@stblaw.com

BY ELECTRONIC DELIVERY

January 5, 2021

Re: Request for COVID-19-Related Business Review Letter

The Honorable Makan Delrahim
Assistant Attorney General
U.S. Department of Justice
Main Justice Building, Room 3109
950 Pennsylvania Avenue NW
Washington, DC 20530

Dear Mr. Delrahim:

On behalf of Baxalta US Inc., Emergent BioSolutions Inc., Grifols Therapeutics LLC, and CSL Plasma Inc., and each of those companies' respective subsidiaries and affiliates (altogether, the "**Requesting Parties**" and each independently, a "**Party**"), we write to request that the Antitrust Division issue an expedited business review letter concerning certain efforts of the companies to assist in the U.S. Government's response to the COVID-19 crisis.[1]

Each Party is engaged in various initiatives directed at responding to the ongoing COVID-19 health crisis. More specifically for the purposes of this request letter, each Party is engaged in some capacity in the development of hyperimmune globulin ("**HIg**") therapies targeting COVID-19 (or SARS-CoV-2 or mutated strains of SARS-CoV-2) through clinical trials sponsored by the National Institutes of Health ("**NIH**").[2] The HIg therapies under development are derived from plasma collected from individuals who have contracted and recovered from COVID-19, which is referred to as "COVID-19 convalescent plasma." COVID-19 convalescent plasma itself has been authorized for clinical use by the U.S. Food

[1] Simpson Thacher & Bartlett represents CSL Plasma Inc. in this matter and has been authorized to submit this request letter on behalf of all of the Requesting Parties.

[2] Specifically, the Requesting Parties are contributing to a Phase III clinical trial called the Inpatient Treatment with Anti-Coronavirus Immunoglobulin, also known as INSIGHT 013. The National Institute of Allergy and Infectious Diseases, part of NIH, is sponsoring and funding INSIGHT 013.

and Drug Administration ("**FDA**") pursuant to an Emergency Use Authorization ("**EUA**") as a treatment for COVID-19 in hospitalized patients via direct transfusion.

As detailed further below, the Biomedical Advanced Research and Development Authority ("**BARDA**"), an office of the U.S. Department of Health and Human Services, has engaged the Requesting Parties to contribute to the development of Quality Assurance standards concerning the collection of COVID-19 convalescent plasma by certain blood collection centers. BARDA seeks to develop and implement Quality Assurance standards aimed at ensuring that COVID-19 convalescent plasma collected by BARDA under its existing supply contracts with the blood collection centers can be repurposed for use by the Requesting Parties for the manufacture of their HIg therapies in the event that BARDA determines there are excess supplies of COVID-19 convalescent plasma not needed for direct transfusion, and/or if clinical data support the use of HIg as a therapeutic.

The development of the Quality Assurance standards will involve narrowly tailored discussions, led by BARDA, focused on technical specifications in connection with the collection, labeling, testing, and storage of COVID-19 convalescent plasma. There will be no disclosure or discussion by the Requesting Parties of competitively sensitive information concerning pricing, volumes of source plasma collected, or volumes of HIg expected to be produced. That said, the Requesting Parties recognize that they would traditionally be considered competitors in the commercial areas of plasma collection and development of plasma-derived therapies. The Requesting Parties therefore seek to confirm that the limited collaborative conduct contemplated in this proposal does not in any way transgress the antitrust laws.

I. BACKGROUND

In an effort to respond to the current global pandemic, each Party is contributing to an NIH-sponsored clinical trial to develop and expedite the manufacturing of their respective HIg therapy targeting COVID-19.[3] HIg therapies are being developed for use in the cure, mitigation, treatment, or prevention of COVID-19. Development and manufacture of HIg therapies requires the collection of convalescent plasma from individuals who have recovered from COVID-19. Convalescent plasma cannot be developed by artificial methods.

The U.S. Government through Operation Warp Speed is currently supporting the collection of COVID-19 convalescent plasma through BARDA's contracts with America's Blood Centers, American Red Cross, and potentially other COVID-19 convalescent plasma collection blood banks (altogether, the "**Blood Banks**"). The primary intent is to use this plasma for direct transfusion. However, the U.S. Government is also supporting the development of HIg products and has engaged the Requesting Parties to ensure that the collected COVID-19 convalescent plasma, and specifically excess stores of convalescent plasma collected by the Blood Banks under contract with BARDA but not needed or

[3] Each Party would manufacture an HIg therapy using its own platform. Thus, if clinical trials prove successful, it is the Requesting Parties' hope that four independent, albeit similar HIg therapies would enter the market.

appropriate for direct transfusion, can be repurposed for use in the Parties' HIg therapies targeting COVID-19.

Thus, in order for BARDA to maximize flexibility in its ability to put collected COVID-19 convalescent plasma to productive use, BARDA proposes to develop, in coordination with the Requesting Parties, a single set of Quality Assurance parameters to be implemented by the Blood Banks, as an addendum to BARDA's existing convalescent plasma supply agreements with the Blood Banks (the "**Quality Assurance Addendum**"). The express aim of the Quality Assurance Addendum would be to ensure that COVID-19 convalescent plasma collected by the Blood Banks under contract with BARDA would meet the requirements of each participating Party as a manufacturer of HIg therapies targeting COVID-19, as well as all requirements for the manufacture of HIg therapies targeting COVID-19 as set by FDA.[4]

In order to facilitate the development of the Quality Assurance Addendum, BARDA has proposed that one or more representatives of each of the Requesting Parties participate in at least one phone call or meeting about the appropriate technical parameters that would (i) satisfy the needs of each of the four Requesting Parties for their manufacture of their respective HIg, (ii) be agreeable to the Blood Banks, and (iii) be acceptable to FDA.

II. THE PROPOSED CONDUCT

The Requesting Parties understand that representatives of BARDA would first develop a template Quality Assurance Addendum that provides technical standards for the Blood Banks in order to ensure that excess COVID-19 convalescent plasma collected for direct transfusion can be repurposed for use in the manufacture of each Party's HIg product. BARDA would then share that draft with each Party on a bilateral basis for individual review and comment by that Party. Each Requesting Party would comment on the template individually and provide its comments only to BARDA and not to any other Requesting Party. The Requesting Parties would then jointly convene with BARDA on at least one occasion, to discuss and finalize the parameters of the proposed Quality Assurance Addendum. It is possible that additional joint meetings would be required to incorporate additional suggestions. BARDA would then coordinate with the Blood Banks and then FDA to confirm that the Quality Assurance Addendum is agreeable to all stakeholders. BARDA may request that representatives of the Requesting Parties be present for and engage in those discussions with the Blood Banks and/or FDA. The Requesting Parties understand that BARDA aims to limit the frequency of direct joint discussions as much as possible, and that live discussions involving the Requesting Parties would only be held on an as-needed basis with counsel present.

[4] The Requesting Parties are unaware of how BARDA contemplates allocating collected COVID-19 convalescent plasma. The Requesting Parties understand at this time that such distribution would likely be done on an equitable, as-needed basis; however, any such conversations are beyond the scope of the collaborative conduct contemplated in this request letter. The Requesting Parties have not engaged, and currently have no plans to engage, with BARDA on allocation or distribution arrangements, and expect that any such discussions would be bilateral as between BARDA and the relevant Party.

On November 19th, 2020, the Requesting Parties entered into a Confidential Disclosure Agreement, attached as Confidential Attachment 1, outlining the narrow scope of technical information that the Requesting Parties would provide to BARDA and potentially also discuss jointly in discussions that would include BARDA, the Requesting Parties, the Blood Banks, and/or FDA. The categories of information to be provided to BARDA and potentially discussed among the Requesting Parties would be technical in nature and focused on the quality requirements for the Blood Banks' collection processes under BARDA's existing supply contracts, including parameters concerning:

- Sampling: Requirements for sampling methodology to ensure consistency with FDA approved methods.
- Testing: Requirements for the testing of collected COVID-19 convalescent plasma, and specifically what forms of testing shall be conducted by the Blood Banks.
- Labeling: Potential requirements for updated labeling practices to the extent required by FDA.
- Titering: Establishment of a minimum titer threshold for release by the Blood Banks.
- Anticoagulants: Guidance concerning the Blood Banks' use of additive anticoagulants (i.e., the type and concentration of anticoagulant solution used by the Blood Banks).
- Storage Specifications: Requirements concerning the acceptable range of temperatures for storing COVID-19 convalescent plasma, and establishment of a timeframe within which the plasma must be frozen, and shelf-life requirements (each as consistent with FDA requirements).

III. ANALYSIS

As the Antitrust Division recognizes, "many types of collaborative activities designed to improve the health and safety response to the pandemic would be consistent with the antitrust laws."[5] However, certain collaborations among competitors may "limit independent decision making or combine the control of or financial interests in production, key assets, or decisions regarding price, output, or other competitively sensitive variables, or may otherwise reduce the participants' ability or incentive to compete independently."[6]

The limited interaction contemplated by BARDA and the Requesting Parties does not involve competitor collaboration around resource allocation, pricing, or output arrangements. Rather, it is effectively limited to a proposal to have the Requesting Parties assist BARDA in developing comprehensive and effective Quality Assurance protocols for convalescent plasma collection by the Blood Banks that will provide the U.S. Government

[5] U.S . Dep't of Justice & Federal Trade Comm'n, *Joint Antitrust Statement Regarding COVID-19* (Mar. 2020).

[6] Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* 6 (2000).

with additional flexibility in promoting the productive use of COVID-19 convalescent plasma. As BARDA would serve as the central authority and decision-maker in presenting the final Quality Assurance Addendum to the Blood Banks and FDA for their respective approvals, there is no risk of tacit or explicit collusion among the Requesting Parties that would create any potential for a reduction in competition.

BARDA has already established pricing and other commercial terms with the Blood Banks under existing U.S. Government supply contracts. The Requesting Parties are not currently aware of the terms of those U.S. government supply contracts, and such terms will not be made available to or otherwise discussed with the Requesting Parties as a result of the proposed conduct. The Requesting Parties would be assisting BARDA solely in developing BARDA's Quality Assurance Addendum by offering input and expertise strictly to the extent that such feedback concerns the adequacy of technical protocols employed by the Blood Banks in their collection and storage of COVID-19 convalescent plasma so that the plasma can be repurposed for use by each Requesting Party for their respective HIg manufacturing. BARDA, rather than the Requesting Parties, is the relevant authority contracting with the Blood Banks.

Moreover, as any resulting Quality Assurance Addendum would be implemented as a component of BARDA's existing supply contracts with the Blood Banks, the Quality Assurance Addendum and the technical parameters set forth therein would naturally terminate when BARDA's supply contracts with the Blood Banks terminate.

In sum, we believe that the conduct contemplated by BARDA and in which the Requesting Parties would participate is not a competitor collaboration of the type that would create even a remote prospect of anticompetitive outcomes. Critically, the proposed collaborative conduct in no way contemplates the exchange of categories of information that the Antitrust Division would typically consider to be competitively sensitive in nature.[7] Indeed, none of the Requesting Parties would discuss or disclose commercial information related to their individual ordinary course supply contracts with blood centers. Further, there will be no disclosure or discussion by the Requesting Parties of information regarding pricing, volumes of source plasma collected, volumes of their respective HIg products expected to be produced, or any other data that would traditionally be considered competitively sensitive.

The Requesting Parties and BARDA agree that the establishment of a single set of Quality Assurance protocols for the Blood Banks concerning the collection of COVID-19 convalescent plasma is inherently procompetitive and efficiency-enhancing. Such protocols assure that any COVID-19 convalescent plasma distributed by BARDA to a Requesting Party for HIg use in the future, whether directly in the NIH clinical trials or for subsequent

[7] As set forth in Confidential Attachment 1, each Requesting Party would agree to share information with respect to its plasma collection processes "solely for the development of uniform standards for the collection by Blood Banks of apheresis plasma for fractionation and manufacturing of their respective anti-SARS-CoV-2 hyperimmune globulin and for such information to be used and submitted to regulatory authorities for purposes of seeking regulatory approval of their anti-SARS-CoV-2 hyperimmune globulin . . . using such apheresis plasma collected by Blood Banks."

manufacturing of HIg therapies, would satisfy the requirements of FDA and the recipient Requesting Party. This in turn would facilitate the more efficient and accelerated manufacture of several HIg therapies targeting COVID-19, as opposed to a process whereby BARDA would have to pre-allocate COVID-19 convalescent plasma collections by the Blood Banks to specific companies, and each company would independently need to certify compliance with FDA's requirements or expectations.[8]

IV. CONCLUSION

In sum, BARDA's proposed collaborative engagement with the Requesting Parties is a narrowly tailored approach to achieving the efficient and productive use of COVID-19 convalescent plasma, collected by the U.S. Government from the Blood Banks under existing supply contracts, for production of HIg. With the proposed Quality Assurance Addendum in place, in the event that BARDA's stores of convalescent plasma are not needed for direct transfusion, the Requesting Parties would be well-positioned to utilize this critical input in production of HIg therapies targeting COVID-19, with the added confidence that collection and storage was accomplished in a manner consistent with FDA and company requirements. Given the very limited extent of collaboration and discussion between the Requesting Parties, the central involvement of BARDA in the process, and the promise of real and substantial efficiencies resulting from the protocols, the Requesting Parties submit that anticompetitive effects are extremely unlikely.

We therefore respectfully request a business review letter confirming that the Antitrust Division views the proposed collaborative conduct described herein as consistent with the antitrust laws and that it has no present intention to bring an enforcement action against the Requesting Parties for that proposed conduct.

Sincerely,

Sara Y. Razi

Sara Y. Razi

Enclosures

cc: Brian Tse, Ph.D., Health Scientist at the Biomedical Advanced Research & Development Authority

[8] As the Antitrust Division recognizes, "a competitor collaboration may enable participants to offer goods or services that are . . . brought to market faster than would be possible absent the collaboration." Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* 6 (2000).

CONFIDENTIAL ATTACHMENT 1