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By Electronic Delivery

July 15, 2020

The Honorable Makan Delrahim
Assistant Attorney General
U.S. Department of Justice
Main Justice Building, Room 3109
950 Pennsylvania Avenue NW
Washington, DC 20530
ATR.COVID19@USDOJ.GOV

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

Dear Mr. Delrahim:

I am writing to respectfully request that the Antitrust Division issue a business review letter related to efforts of the companies identified below to combat the continuing COVID-19 crisis through the development and large-scale production of potential monoclonal antibody treatments.

The COVID-19 pandemic has created an extraordinarily severe health crisis that is taking both a human and an economic toll on a global scale. More than half a million people have died, over 10 million people have been confirmed with the illness, and hundreds of millions of people have had their daily lives disrupted from the pandemic and the efforts to contain it. The disruption to economic activity has been unprecedented in the post-war period. Accordingly, there is a compelling need to develop effective treatments for COVID-19 and to produce them in as large amounts as possible in the shortest amount of time.

Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca PLC, Genentech, and GSK (collectively, the "Parties") are each investigating monoclonal antibody agents that may be used to treat COVID-19 and are each making necessary arrangements for the mass production of those agents if they are approved as safe and effective treatments.[1] The Parties believe that certain limited exchanges of information regarding manufacturing facilities and related issues could enable them to expedite the production of COVID-19 mAb treatments once they are approved. Accordingly, the Parties request a business review letter that provides the Antitrust Division's analysis of the more detailed information exchanges described in this letter regarding

[1] We represent Eli Lilly and Company in this matter and have been authorized to submit this request letter on behalf of all of the Parties.

manufacturing facilities, raw materials, and supplies that will be necessary to produce COVID-19 mAb treatments. These efforts would be limited only to potential COVID-19 mAb treatments and would last only as long as necessary to accelerate production of treatments that can combat the detrimental effects of COVID-19 on the health and welfare of our country.

I. Background

The development, production, and distribution of monoclonal-antibody-based therapeutic agents that can safely and effectively treat COVID-19 is an urgent priority for the Parties. As the past several months have made clear, the COVID-19 pandemic is unprecedented in not only its direct impact on the health of millions of Americans, but also the dislocation it has caused across all sectors of American industry and society. The successful development and mass production of COVID-19 Treatments will help alleviate not only COVID-19's first-order toll on Americans' health, but also its second-order effects on the economy and public welfare more broadly.

Under less extraordinary circumstances, manufacturers ramp up production capacity for a given drug only towards the end of an extensive years-long approval process. "Companies typically wait until a drug or vaccine is in the advanced stages of testing, and looks like it will succeed, before starting to make large quantities."[2] But "[i]n a pandemic, '[manufacturers] can't wait to start making [their] investment in the manufacturing until [they're] sure [they] have a product.'"[3] Rather, "[t]o be ready to make large volumes of the products, companies must begin preparing their plants now. They need to secure supply chains for key ingredients[,] install new equipment, and find contract manufacturers who can help."[4]

As a result, manufacturers are committing production capacity to treatments currently under development. This advance commitment is likely to "create complications in matching limited available supply with the particular [treatments] that demonstrate clinical effectiveness,"[5] and particularly so given the many such potential treatments under development: As of May 11, 2020, the Food and Drug Administration identified 144 active trials of therapeutic agents and hundreds more under development.[6] The treatment landscape remains highly uncertain at this

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[2] Peter Loftus & Joseph Walker, *Drugmakers Scale Up for Virus Treatments*, Wall St. J. (Apr. 24, 2020).

[3] *Id.* (quoting Bruce Gellin of the Sabin Vaccine Institute).

[4] *Id.*

[5] Isha Sharma, Marta Wosinska, et al., *COVID-19 Manufacturing of Monoclonal Antibodies* at 4, Duke Univ. Margolis Ctr. for Health Pol'y (June 2020), https://healthpolicy.duke.edu/sites/default/files/2020-06/Issue%20Brief%20-%20COVID-19%20Manufacturing%20of%20Monoclonal%20Antibodies.pdf.

[6] *Coronavirus Treatment Acceleration Program (CTAP)*, U.S. Food & Drug Admin. (May 12, 2020), https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap.

point, given all that remains unknown about the virus causing COVID-19 and the relatively few clinical results to date.[7] But "[i]f one or more of these treatments prove safe and effective, it will be imperative to be able to manufacture these therapies at scale, to meet extensive . . . demand."[8]

Production capacity will present a significant constraint on the delivery of treatments shown to be safe and effective. "[S]caling up production of these treatments will be challenging because existing manufacturing capacity for a number of the most promising treatments (e.g., monoclonal antibodies. . .) is already limited."[9] One report observes that current production capacity "largely reflects only the ongoing demand for non-COVID-19 [monoclonal antibodies]" and conservatively estimates that domestic demand for monoclonal antibody COVID-19 treatments to be approximately half of all monoclonal antibody doses administered in the United States in all of 2019.[10] Prophylactic use of any such therapeutic agents would only increase this already heightened demand.

In sum, potential COVID-19 mAb treatments are characterized by limited manufacturing capacity, potentially significant demand that greatly exceeds this capacity, and significant lead times necessary to prepare manufacturing facilities. Finding ways to use this limited manufacturing capacity to produce as much as possible of the treatments that are approved as safe and effective is critical to saving lives and otherwise to reduce COVID-19's deleterious health and economic consequences.

II. The Proposed Conduct

The Parties foresee that they may wish to exchange information in the future among themselves and potentially other manufacturers regarding manufacturing facilities, raw materials, and supplies that could be used to produce COVID-19 mAb treatments, specifically global capacity that has been reserved internally or through third parties for the potential production of COVID-19 mAb treatments. A key purpose of the information exchanges would be to enable companies currently developing COVID-19 mAb treatments to identify ways to expand production of any approved treatments beyond the level that each could achieve on its own. This information will enable each company to identify additional biological production facilities and materials that could be used to expand production of its treatment beyond the level the company could produce

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[7] *See generally COVID-19: Developing Drugs and Biological Products for Treatment or Prevention: Guidance for Industry*, U.S. Dep't of Health & Human Servs., Food & Drug Admin. (May 2020), https://www.fda.gov/media/137926/download.

[8] *Ensuring Sufficient Manufacturing Capacity for COVID-19 Therapeutics*, Duke Univ. Margolis Ctr. for Health Pol'y, https://healthpolicy.duke.edu/events/webinar-ensuring-sufficient-manufacturing-capacity-covid-19-therapeutics.

[9] *Id.*

[10] Sharma, Wosniska, et al., *supra* note 5, at 1-2.

on its own or under any existing arrangements (subject to capacity constraints from production of non-COVID-19 medically critical and medically necessary supply). If the Parties obtain this information reasonably far in advance of receiving regulatory approval for agents under development, each company could develop plans for using some of this additional manufacturing capacity if and when it becomes clear that its product will obtain regulatory approval. This advance planning could significantly reduce the lead time necessary to identify and to prepare a facility to produce a particular biological treatment, which could lead to greater quantities of treatments being available more quickly.

To achieve this goal, the Parties foresee that they may wish to exchange the following relevant categories of information (the "Proposed Conduct"):

- Technical details regarding a company's relevant manufacturing facilities, including total potential capacity, technical specifications (such as the type of bioreactors), time period(s) during which the facilities would be available, and whether the facility is owned by the company or by a third party.

- Technical information regarding a company's manufacturing processes/platforms and/or the manufacturing processes/platforms of their contract manufacturers or their other manufacturing partners.

- Information regarding the source and amount of available raw materials and supplies that are necessary for the manufacture of COVID-19 mAb treatments. For purposes of clarity, the Parties would not exchange any information regarding prices or commercial terms of any arrangements for raw materials and supplies.

The Parties also commit to adhere to the following safeguards in order to ensure antitrust compliance:

1. Information exchanges will be limited to the categories of information described above;

2. The Parties will not exchange information relating to costs of inputs, costs of production, or prices of the treatments;

3. The Parties will not exchange information relating to whether or not to deal (or the terms for dealing) with customers;

4. Decisions regarding development of and investment in additional manufacturing capacity will be made by each company independently of any information exchanges covered by the business review letter;

5. The Proposed Conduct will be limited in duration and extend only as long as necessary to address the COVID-19 crisis; and

6. Any collaboration beyond the information exchanges set forth in this letter would be outside the scope of the business review letter.

III. Analysis

We believe that the exchange of information between manufacturers as described in this letter to identify and plan for ways to expand and expedite production of greater quantities of COVID-19 mAb treatments is procompetitive and would not violate any antitrust law enforced by the Division.

As the Division has recognized, "when firms collaborate on research and development this 'efficiency-enhancing integration of economic activity' is typically procompetitive."[11] In particular, collaboration on research and development "may enable participants more quickly or more efficiently to research and develop new or improved goods, services, or production processes," as here.[12] While agencies have indicated that research and development collaborations are "more likely to raise competitive concerns when the collaboration or its participants already possess a secure source of market power over an existing product,"[13] such circumstances are not present here given the unmet need for safe and effective COVID-19 treatments.

More specifically, the Proposed Conduct is procompetitive in that it seeks to maximize the overall production capacity of those treatments that are approved in the shortest possible time. As the Agencies note, some businesses "may need to temporarily combine production, distribution, or service networks to facilitate production and distribution of COVID-19-related supplies they may not have traditionally manufactured or distributed."[14] The Proposed Conduct, limited to the exchange of information regarding production, does not go so far. Rather, the Proposed Conduct seeks to ensure that the Parties sufficiently understand current production capabilities and availability of raw materials and supplies so that the Parties can make plans that will enable them to move quickly at the appropriate time.

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[11] U.S. Dep't of Justice & Federal Trade Comm'n, *Joint Antitrust Statement Regarding COVID-19* (Mar. 2020) [hereinafter "DOJ/FTC Joint Statement"] (quoting Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* 31 (2000) [hereinafter "Competitor Collaboration Guidelines"]).

[12] Competitor Collaboration Guidelines, *supra* note 11, at 14.

[13] *Id.* at 15.

[14] DOJ/FTC Joint Statement, *supra* note 11.

In sum, the Proposed Conduct would be "a necessary response to exigent circumstances that provide Americans with products or services that might not be available otherwise"[15] and/or provide Americans with larger quantities of safe and effective COVID-19 treatments than would otherwise be available in a shorter period of time.

IV. Conclusion

The proposed collaboration among the Parties would expedite the production of safe and effective treatments for COVID-19. We therefore request a business review letter confirming that the Division views the Proposed Conduct as consistent with the antitrust laws and that it has no present intention to bring an enforcement action against the Parties for the Proposed Conduct.

Sincerely,

Thomas O. Barnett

cc: James Ford, SVP & General Counsel, GSK
Jonathan Graham, EVP, General Counsel & Secretary, Amgen
Anat Hakim, SVP and General Counsel, Eli Lilly and Company
Sean Johnston, SVP, General Counsel, Genentech
Jeff Pott, General Counsel, AstraZeneca
Tryn Stimart, General Counsel, AbCellera Biologics

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[15] *Id.*