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DOJ Provides Further Guidance to Competitor Collaborations Related to COVID-19 Response

In response to the COVID-19 pandemic, the Antitrust Division of the Department of Justice (DOJ) committed to issuing expedited "Business Review Letters" (BRLs) to provide requested guidance concerning permissible types of cooperation among actual or potential competitors relating to business initiatives focused on addressing the COVID-19 pandemic. The DOJ issued its first BRL related to coronavirus response efforts on April 4, 2020, and a second communication on April 20, 2020. These first two BRLs concerned the sourcing and production of Personal Protective Equipment (PPE) and certain other medicine and medical supplies and involved collaborations between the competitors and certain government agencies.

The DOJ recently issued another of these expedited letters concerning sourcing and production of COVID-19-related treatments. This BRL provides additional insights regarding the DOJ's philosophy and approach to competitor collaborations during the health crisis and, notably, does not involve direct government collaboration (unlike the proposals in the first two BRLs). Above all, the letter reaffirms the Antitrust Division's support of joint public health initiatives between potential competitors to facilitate pandemic-related solutions so long as the parties implement appropriate safeguards to mitigate the risks of anticompetitive behavior.

The Proposed Collaboration

The Requesting Parties (Parties) for the letter — Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca, Genentech and GSK — are leading distributors and suppliers of pharmaceuticals and other health care products throughout the global economy. Similar to the parties that received the DOJ's first two expedited BRLs concerning PPE production and medical supply distribution efforts, the Parties for the third health care-related BRL are focused on sourcing, producing and supplying vaccines and other therapeutics to respond to the ongoing pandemic. In this Request, the Parties sought guidance regarding their intention "to exchange

limited information about the manufacture of monoclonal antibodies that may be developed to treat COVID-19" in order to "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 on its own or under any existing arrangements."

Specifically, the Parties emphasized that the sharing of information will benefit the public by allowing collaboration "to advance planning [that] 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." The proposed collaboration includes the following types of information sharing:

- 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" (treatments that incorporate monoclonal antibodies, which are used to treat COVID-19-related symptoms). For purposes of clarity, the Parties would not exchange any information regarding prices or commercial terms of any arrangements for raw materials and supplies.

Unlike the activities described in the previous Requests, this conduct does not involve direct collaboration with the government and includes more significant collaboration between and among private businesses. However, the Antitrust Division clearly has signaled that the requested actions are still consistent with the spirit and guidance of an initiative called Operation Warp Speed, which the "federal government is leading to accelerate and support the development, manufacture, and distribution of these therapeutic tools." Significantly, the DOJ has previously stated that "[a] competitor collaboration may enable firms to offer goods or services that are cheaper, more valuable to consumers, or brought to market faster than would otherwise be possible." The DOJ believes that these types of collaborations "involving information sharing can be procompetitive and necessary to generating efficiencies," particularly in light of the ongoing pandemic.

In deciding that the proposed conduct would not likely violate the antitrust laws, the DOJ pointed to the following factors:

- The DOJ finds that exchanging this information in this context is unlikely to harm competition "because the likely result is that the information exchange will expand output of these critical treatments," rather than

restrict them.

- The Parties agreed to certain safeguards that will mitigate concerns regarding the potential for anticompetitive effects, including:
  - Limiting information exchanges to the categories of information described above.
  - Prohibiting the exchange of information relating to costs of inputs, costs of production, or prices of the treatments.
  - Prohibiting the exchange of information relating to whether or not to deal (or the terms for dealing) with customers.
  - Assuring that any 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.
  - Limiting the duration of the Proposed Conduct to only as long as necessary to address the COVID-19 crisis.
  - Specifying that any collaboration beyond the information exchanges set forth in this letter would be outside the scope of the business review letter.
- The Proposed Conduct is unlikely to lessen incentives to invest or develop critical COVID-19 mAb treatment protocols.
- The purpose of the information exchange is to "expedite production of greater quantities of COVID-19 mAb treatments" once they are deemed safe and effective.
- The collaborations are "a necessary response to exigent circumstances that provide Americans with products or services that might not be available otherwise 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."

As the DOJ and FTC continue to publish guidance to address COVID-19 and the numerous challenges caused by the global pandemic, it is important to remember that the antitrust laws are nuanced and complex, and their application to particular circumstances is highly fact sensitive. The DOJ has repeatedly said that any guidance issued under this program is narrowly limited to responses to COVID-19 and will only be effective for one year.

We strongly recommend that businesses consult with antitrust counsel before engaging in any collaborative conduct with a competitor that might implicate federal, state or international competition laws.

Faegre Drinker's Coronavirus Resource Center is available to help you understand and assess the legal, regulatory and commercial implications of COVID-19.

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