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Antitrust and patent law have complementary objectives: both are "aimed at encouraging innovation, industry and competition."[2] Abraham Lincoln once observed that an inventor would gain "no special advantage from his own invention" if others could instantly use it.[3] By securing the exclusive use of an invention for a limited time, a patent "adds the fuel of interest to the fire of genius" and thus promotes the creation of "new and useful things."[4] The prospective reward of a limited monopoly similarly incentivizes competition among innovators.

The single inventors of Abraham Lincoln's time have given way to teams of researchers capable of tackling today's increasingly complex problems. Breakthrough discoveries often result from collaborations, including in the life-science sector where new treatments are expensive to research and even more costly to bring to market. A recent joint workshop hosted by the U.S. Department of Justice and the U.S. Patent and Trademark Office[5] emphasized that collaborations play an important procompetitive role so long as their structure and scope safeguard against possible anticompetitive effects.

Hallmarks of Procompetitive Collaborations

The proliferation of biotechnology has transformed the life-science industry over the past decades. Until the late 1990s, the pharmaceutical industry was focused on antibiotics and small-molecule drugs.[6] Large pharmaceutical companies exhibited a high degree of vertical integration, and their business model was rooted in maintaining an R&D pipeline capable of generating "blockbuster" drugs that would eventually fund follow-on research.[7]

Advances in biotechnology, such as cell and gene therapies as well as monoclonal-antibody technology, have not only led to scientific breakthroughs but have also paved the way for new business models.[8] For example, instead of being fully integrated, some biotechnology companies focus on specific diseases while others specialize in

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[2] *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 988 (9th. Cir. 2020).
[3] See Opening Remarks of Makan Delrahim, Assistant Att'y Gen., Antitrust Division, U.S. Dep't of Just., *Workshop on Promoting Innovation in Life Science Sector* (Sept. 24, 2020), https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-opening-remarks-2020-life-sciences (quoting Second Lecture on Discoveries and Inventions, 363 (Feb. 11, 1859), in COLLECTED WORKS OF ABRAHAM LINCOLN, VOL. 3 (1809-1865)).
[4] See *id.*
[5] See Press Release, U.S. Dep't of Just., *Workshop on Promoting Innovation in Life Science Sector* (Sept. 24, 2020), https://www.justice.gov/atr/promoting-innovation-life-science-sector-and-supporting-pro-competitive-collaborations-role.
[6] Mark G. Edwards, *Biotechnology and Pharmaceutical Commercialization Alliances: Their Structure and Implications for University Technology Transfer Offices, in* INTELL. PROP. MGMT. IN HEALTH & AGRIC. INNOVATION 1227 (A. Krattiger et al. eds., 2007).
[7] Jim Gilbert, Preston Henske & Ashish Singh, *Rebuilding Big Pharma's Business Model*, 21 IN VIVO 10 (2003) (emphasizing that a "greater reliance on partnerships [can help] manage risk and return").
[8] E.g. Roy Berggren et al., *R&D in the "Age of Agile,"* MCKINSEY & CO. (Oct. 5, 2018), http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/r-and-d-in-the-age-of-agile# (reporting that "innovation has diversified" and shifted from small molecules to a "plethora of new technologies").

certain platform technologies that can be used across a wide range of candidate treatments.[9] Today, biotechnology startups and university laboratories play a significant role in early-stage innovation but often lack the funding and resources to engage in complex and risky clinical trials.[10]

In spite of scientific progress, drug development remains a risky endeavor and many promising candidate treatments fail during pre-clinical and clinical development.[11] An increasing degree of specialization has also made it difficult and undesirable for large pharmaceutical companies to do all their research and development in house. Instead, large pharmaceutical and biotechnology companies increasingly embrace collaborations with startups and university labs as a means for balancing risk and maintaining a diversified research pipeline across industry segments.[12]

Collaborations between large pharmaceutical companies and early-stage startups are generally procompetitive and benefit consumers and patients alike. In fact, each partner in such a collaboration contributes unique expertise at different points of the value chain. Startups and university labs, on one hand, lack the funding and expertise to run the clinical trials needed to bring drugs to market. "Big pharma," on the other hand, relies on collaborations with biotech startups to keep its research pipeline balanced. Procompetitive effects usually dominate because, absent the collaboration, the parties would not compete. Moreover, collaborations benefit patients because they can bring new treatments to market faster.

Although procompetitive effects tend to dominate, collaborations can have anticompetitive effects. For example, parties should not be permitted to end-run merger guidelines by disguising a de facto merger as a collaboration. Another concern relates to a collaboration's potential of eliminating competing research efforts. For instance, if collaborators engaged in competing research efforts directed at a certain treatment prior to the collaboration, a partnership between them may extinguish competition in this "innovation market"— assuming third parties are not engaged in competing research efforts. In their April 2000 antitrust guidelines for collaborations among competitors, the Antitrust Division and Federal Trade Commission specifically recognized this risk and provided for a "safety zone."[13] R&D collaborations in "innovation markets" would not be challenged so long as at least three independently controlled research efforts remained in addition to the proposed collaboration. Proposed collaborations where fewer than three independent research efforts remained were not per se illegal but faced the risk of being challenged.

While the existing guidelines raise valid concerns about the possibility of foreclosing research, the requirement of "three

[9] Edwards, *supra* note 6, at 1227–28.
[10] Toby AuWerter, Jeff Smith & Lydia The, *Biopharma Portfolio Strategy in the Era of Cell and Gene Therapy*, McKinsey & Co. (Apr. 8, 2020), https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/biopharma-portfolio-strategy-in-the-era-of-cell-and-gene-therapy.
[11] Gilbert, *supra* note 7, at 4 (noting that the number of compounds in clinical trials that reaches the market has decreased from one in eight to one in thirteen).
[12] Auwerter, *supra* note 10, at 6–7.
[13] Fed. Trade Comm'n & U.S. Dep't of Just., Antitrust Guidelines for Collaborations Among Competitors 26–27 (2000) [hereinafter *Competitor Collaboration Guidelines*].

independently-controlled research efforts" may need to be adapted to today's circumstances. In fact, the increased degree of specialization suggests the scope of innovation markets has narrowed and, as a result, the existing safety zones may need to be adjusted to account for new business realities. Moreover, as detailed below, recent business review letters suggest that safeguards on information sharing can mitigate anticompetitive concerns.

Safeguards Can Mitigate Anticompetitive Risks

The Antitrust Division affords parties the opportunity to mitigate antitrust risk by requesting that the government review proposed business conduct ahead of time.[14] This business-review process assures parties that, at least at the time of issuance, the Division does not intend to challenge proposed conduct. In addition, recent business-review letters provide valuable guidance as to the Antitrust Division's enforcement intentions along with factors it considers helpful for mitigating anticompetitive concerns. These safeguards generally fall into two categories: (1) restrictions that limit the scope of partnerships to areas where the parties do not compete and (2) limitations as to the types of information and know-how shared between the parties.

The scope of a proposed collaboration can be limited at the outset by putting in place temporal, geographical, or field-of-use restrictions. For example, temporal restrictions might limit a proposed collaboration to the discovery phase of drug development but require parties to compete at the commercialization stage. Similarly, collaborators may propose to exchange information about platform technologies capable of leading to the identification of promising treatments while competing with respect to any actual candidate treatments identified through this process. Field-of-use restrictions are another means for narrowing the scope of proposed collaborations. For example, collaborations can be limited to a certain disease type while preserving competition as to the compound's potential application to other indications.

In addition to a collaboration's scope, antitrust authorities are also concerned about the exchange of competitively sensitive information. For example, price and cost information, market shares, or information about commercial terms should never be exchanged among collaborators because of their inherent risk of leading to collusion. On the other hand, the exchange of technical information and know-how that is germane to the collaboration does not raise the same level of concern. Nonetheless, even technical information can give rise to anticompetitive risk if it is shared beyond the confines of the collaboration. To prevent improper dissemination, collaboration agreements should consider the formation of steering or oversight committees and official guidelines on the handling of information to ensure that data is used on a need-to-know basis. For instance, ethical walls between researchers engaged in a collaborative project can be an effective way of mitigating "spillover" risk.

[14] 28 C.F.R. § 50.6 (noting the Antitrust Division's longstanding practice of reviewing proposed business conduct and stating its enforcement intentions).

Applying Collaborative Principles to the COVID Pandemic

The ongoing COVID-19 pandemic highlights the potential of collaborative research to speed up the quest for treatments and vaccines. In March 2020, the Antitrust Division and the Federal Trade Commission issued a joint statement encouraging procompetitive collaborations and offering an expedited business-review process for COVID-19 to evaluate and resolve concerns.[15] The joint statement also recognized that "sharing technical know-how" may be needed to achieve the "procompetitive benefits of certain collaborations."[16]

A recent business-review letter serves as a helpful case in point. In a July 2020 decision, the Division confirmed its intention not to challenge a proposed collaboration among six pharma companies aimed at identifying ways to expand production of any approved COVID-related treatments or vaccines based on monoclonal antibodies.[17] The six collaborators were all pharmaceutical companies engaged in independently researching, developing, and manufacturing biologic products that target a range of diseases, such as asthma, cervical cancer, or leukemia.[18] Although the collaborators compete with each other as to these biologic products, they envisioned that demand for any effective COVID treatments rooted in monoclonal-antibody technology will dwarf the capacity available to any one manufacturer.[19] To speed up production, the collaborators proposed to exchange technical information concerning "manufacturing facilities," "manufacturing processes/platforms," and the "amount of available raw materials and supplies" that each independently decides to devote to COVID-19 treatments instead of other non-COVID applications.[20] Exchanging this information was aimed at bringing COVID treatments to the market faster by enabling companies to reduce the lead-time needed to prepare their facilities for the eventual production of treatments.

In reaching its favorable decision, the Division emphasized the limited "scope and duration" of the collaboration and highlighted that safeguards on information sharing further reduced anticompetitive concerns.[21] In particular, the Division emphasized the parties' upfront agreement to limit the duration of the collaboration to the ongoing "COVID-19 crisis" and to focus on the manufacturing of an approved treatment rather than the treatment's initial development.[22] Moreover, the business review letter stressed that each of the collaborators agreed to continue making independent decisions as to key elements of the collaboration, including the amount of manufacturing capacity each party intended to devote to COVID treatments. In doing so, the

[15] U.S. DEP'T OF JUST. & FED. TRADE COMM'N, JOINT ANTITRUST STATEMENT REGARDING COVID-19 (Mar 2000), https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19 (announcing that the expedited business-review process would aim to resolve COVID-19-related requests within seven calendar days).
[16] *Id.* (citing *Competitor Collaboration Guidelines*, *supra* note 13, at 15).
[17] Letter from Makan Delrahim, Assistant Att'y Gen., Antitrust Division, U.S. Dep't of Just., to Thomas O. Barnett (July 23, 2020) [hereinafter *Eli Lilly Business Review Letter*].
[18] *Id.* at 4.
[19] *Id.*
[20] *Id.* at 5.
[21] *Id.*
[22] *Id.* at 10.

Division reasoned, the parties will continue to compete as to the production of non-COVID treatments based on similar monoclonal antibody technology. The decision also stressed the highly technical nature of the information to be disclosed and the lack of competitively sensitive information.

Since its issuance, this favorable business review letter has given rise to a manufacturing collaboration aimed at increasing the supply capacity of the neutralizing antibody treatment bamlanivimab (LY-CoV-555).[23] In September 2020, Eli Lilly and Amgen announced that, "should one or more of Lilly's antibody treatments prove successful," both companies would collaborate to "quickly scale up production and serve more patients around the world."[24] Indeed, on November 9, 2020, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the monoclonal antibody therapy bamlanivimab "for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients"[25] suggesting that the manufacturing collaboration will become a reality soon.

Collaboration in Other Technology Areas

While the joint workshop organized by the Antitrust Division and the Federal Trade Commission focused on collaborations in the life-science sector, similar principles apply to other technology areas as well. For example, standard development in the high-tech industry involves collaboration among numerous technology companies competing in various segments of the industry. Similar to the discussion above, limitations on the scope of the collaboration and information-sharing safeguards play an important role in balancing procompetitive benefits with potential antitrust risk.

As a general rule, standard-development organizations carefully limit the scope of standardization activities to technical features that must be agreed-upon to ensure compatibility across vendors.[26] For example, a cellular industry standard necessarily needs to define signal types and message formats exchanged wirelessly between cell phones and base stations. Otherwise, the system will not work. But the same standard need not define features unrelated to communication functions, such as the phone's display or cameras. Those features are intentionally left open for vendors to compete.

In connection with the information-sharing safeguards discussed above, standardization proposals exchanged among members of a standardization group are highly technical in nature and thus do not give rise to the same level of concern that the sharing of commercial information would. To further mitigate anticompetitive risk, some standardization groups automatically publish all exchanged information, including technical contributions

[23] Press Release, Eli Lilly & Co. & Amgen, Inc., *Lilly and Amgen Announce Manufacturing Collaboration for COVID-19 Antibody Therapies* (Sept. 17, 2020), https://investor.lilly.com/news-releases/news-release-details/lilly-and-amgen-announce-manufacturing-collaboration-covid-19.
[24] *Id.*
[25] Press Release, U.S. Food & Drug Admin., *Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19* (Nov. 9, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19.
[26] See, e.g. EUR. TELECOMM. STANDARDIZATION INST., ETSI INTELLECTUAL PROPERTY RIGHTS POLICY § 15.6 (Feb. 2, 2020), https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf (defining "essential" technology as technical solutions that are necessary to practice the standard "on technical (but not commercial) grounds").

and meeting minutes.[27] This transparency not only ensures that there is a record of what was exchanged but also requires contributors to carefully consider what to disclose to its collaborators and the public and what to keep proprietary. Moreover, contractual commitments to license on fair, reasonable, and non-discriminatory ("FRAND") terms ensure that the standard, once finalized, will be available on terms that fairly reward innovators while ensuring the technology's rapid adoption in the marketplace.

Conclusion

In sum, the September 2020 joint DOJ Antitrust Division and USPTO workshop highlighted the procompetitive role of collaborations in today's innovation economy and emphasized that structural limitations as to the scope of proposed collaborations, along with information-sharing safeguards, can effectively limit anticompetitive risks.

[27] Justus Baron et al., *Unpacking 3GPP Standards* 26–27 (Nw. Law & Econ. Rsch. Paper No. 18-09, 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3119112.