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INTRODUCTION

It's rare when a single acquisition can offer insight into two different important questions in innovation. But the proposed purchase of cancer-diagnostic developer Grail — a startup with tremendous potential — by gene-sequencing leader Illumina is just that pivotal.

First, is it pro-innovation for European antitrust regulators to have the power to block a deal involving two American biotech companies that do no substantial business in Europe?

We argue that such “regulatory imperialism” by the EU has the potential to slow down biotech innovation, especially given the region’s generally lagging performance in biotech (BioNTech notwithstanding).

Second, under what conditions is vertical integration a socially beneficial strategy for accelerating innovation? Successful innovation in the biosciences often combines risk-taking by small companies with the development and regulatory resources of larger companies. We conclude that excessive antitrust focus on blocking vertical integration in the biosciences could impede the development of important new products and treatments.

These issues go far beyond Illumina and Grail. But it’s helpful to have the facts about this particular case. Grail has spent the past five years developing a diagnostic capable of screening for 50 different cancers at once — a test set to launch this year — while Illumina

makes the hardware that performs those tests. Illumina offered to buy Grail, with the idea of integrating Grail's technology with its own, to simplify the process of using gene sequencing for clinical diagnostics on a massive scale. If successful, this would dramatically reduce the cost of performing cancer screenings.

The Federal Trade Commission (FTC) intervened to block the acquisition, worried that Illumina would block potential competitors of Grail from using its gene sequencers. Illumina promised to supply these competitors with gene sequencing equipment and supplies without price increases. The FTC, through a complicated series of maneuvers that are not relevant to this paper, temporarily pulled back from its intervention to allow the European Commission to take the first swing at blocking the acquisition. The EU antitrust regulators are planning to rule by July 27 on whether to clear the merger.¹

And here's where we come to the first issue: Should the EU antitrust regulators be considering a biotech deal that by the ordinary rules would not come under their jurisdiction? As the Wall Street Journal notes, "Since the merger doesn't qualify for antitrust review under the bylaws of the European Union or any member states, the Commission asked countries to invoke Article 22 of the EU's Merger Regulations. This rarely used provision allows countries to refer transactions to the Commission when their governments lack jurisdiction."²

This fits the general EU strategy of "regulatory imperialism." Rather than focusing on innovation, the EU has tried to position itself as the global leader in regulation in a variety of areas, from artificial intelligence to chemicals to GMOs to data privacy. The European approach to regulation has been framed by the precautionary

principle, which puts less weight on the benefits of innovation and more on the potential harms.

That risk-avoiding approach is one important reason why Europe has consistently lagged in biotech. European biotech is not nonexistent — after all, Pfizer partnered with a German biotech firm, BioNTech, to develop a very successful COVID-19 vaccine. Nevertheless, data from the Organisation for Economic Co-operation and Development shows that business spending on biotech research and development (R&D) in the EU comes to roughly one-third that of the U.S.

Tacitly accepting European jurisdiction over American biotech deals has the potential to slow down commercialization of important technologies. According to the New York Times, Europe has been "a world leader in technology regulation, including privacy and antitrust."³ In a recent speech, Emmanuel Macron said that during its turn at the helm of the EU presidency, France would "try to deliver a maximum of regulation and progress."⁴ When the EU sets the global standard on regulation and companies choose to comply with it everywhere (even where standards are lower), that's known as the "Brussels effect."⁵

First, on privacy, the General Data Protection Regulation (GDPR) has become a de facto floor on policy for many large multinational companies. The problem for companies — especially in biotech and software — is that there are very high fixed costs to product development (and low marginal costs for distribution), and reworking a product for a different regulatory environment is often more trouble than it's worth. That leads to a race to the top (or bottom, depending on your perspective) in terms of regulation.

In its first few years in effect, GDPR's flaws have become manifest and EU policymakers are starting to consider reforms to the law.⁶ According to a recent joint report from three academy networks, "GDPR rules have stalled or derailed at least 40 cancer studies funded by the US National Institutes of Health (NIH)."⁷ The authors go on to note that "5,000 international health projects were affected by GDPR requirements in 2019 alone." This flawed model for privacy regulation has unfortunately been exported around the globe.

Second, mergers between globally competitive firms with a presence in multiple jurisdictions have to get clearance from multiple antitrust enforcement agencies. If a single agency in a large market objects to the merger, the deal might fall apart completely. For example, a merger between U.S.-based Honeywell and U.S.-based General Electric collapsed after the EU competition enforcement agency decided to block the deal out of concern it would create a monopoly in jet engines. Of course, the EU's investigation of the Illumina-Grail merger takes that one step further, given the fact that Grail doesn't conduct any business in the EU, and Illumina's business there isn't substantial, with revenues below the usual threshold for antitrust scrutiny for both the European Commission and individual countries.

The next important question raised by the Illumina-Grail purchase is the role of vertical integration. We start with the simple observation that innovating in complex systems is both risky and expensive. That's true in frontier industries such as electric vehicles and e-commerce, and it's especially true in the biosciences, with the high hurdle set by the need for safety and efficacy.

The cost to bring a drug to market is a huge barrier for startups to remain independent. A 2020 paper in JAMA examining 63 of the 355 new therapeutic drugs and biologic agents approved by the U.S. Food and Drug Administration between 2009 and 2018 found that the median capitalized research and development cost per medicine was \$985 million.⁸ Other studies using private data have found even higher figures. A 2019 study published in the Journal of Health Economics estimated the average cost to reach approval at \$2.6 billion (post-approval R&D costs nudge the total up to \$2.9 billion).

Should these complex systems be built by one company, which is better able to integrate all the pieces of the puzzle? (Tesla comes to mind when we are discussing electric vehicles). Or is it better to distribute the risk over multiple companies? The biotech industry has mostly followed this second strategy. Risky R&D is done by small firms with financing by high-risk capital such as venture firms. Then the resulting product, if successfully passing clinical trials, is acquired by a larger firm for commercialization.

In some cases, both strategies are important. The initial stages of research and development of a new idea are farmed out to a smaller company and financed by risk capital. And then when it comes time to build the idea into a complex system, the actual integration is done by a larger company, which has an established distribution network and marketing resources for reaching patients in a targeted fashion. This can greatly accelerate the development process.

The question, then, is whether this integration would be easier within one company or at arms-length. Illumina has made an offer to buy Grail, which was originally spun off from Illumina in

order to get funding from risk capital. The goal, obviously, is to accelerate the development of this game changing integration.

The FTC has objected to the acquisition, because the agency worries about Illumina prioritizing its internal customer over other potential cancer diagnostics systems. Certainly, it's true that some vertical mergers are anti-competitive. "Killer acquisitions" are one type of merger in biotech that is anti-competitive in nature. A recent paper from Ederer, Cunningham and Ma found that between 5% and 7% of acquisitions in the pharmaceutical industry are killer acquisitions, meaning the incumbent firm purchased the startup with the intention of shutting down one or more of its products, because the legacy company offers a competing product that is more profitable.⁹

There is increasing agreement among regulators on both sides of the Atlantic that acquisitions — especially in the pharmaceutical sector — need to be scrutinized more closely if products have the potential to be killed off post-acquisition. One heuristic a regulator might use is to look at how much overlap there is between the acquired product and the incumbent, especially in terms of benefits and use cases. If the incumbent's product is still on patent, then there is a significant incentive to acquire a competitive product that might be disruptive to an acquirer's portfolio and shut down the new product.

But there's little evidence that most vertical acquisitions are anti-competitive. Vertical mergers — or the combination of two companies at different layers of the supply chain — are less

likely than horizontal mergers — acquisition of a direct competitor — to be anticompetitive as both economic theory and empirical evidence show. Regarding the theory, firms are engaged in "make or buy" decisions all the time. If they choose to produce an input in-house instead of buying it from the market, then they have vertically integrated (either by developing the capacity on their own or by acquiring another firm with that capacity). Prohibiting firms from vertically integrating via acquisition would forgo some of the benefits of economies of scope and economies of scale. A literature review by Lafontaine and Slade showed that vertical mergers were procompetitive on average.¹⁰

One of the most common reasons vertical mergers are less suspect than horizontal mergers has to do with "double marginalization." If you assume two products are monopolies in their respective markets, then the producers of those products will each charge the monopoly price, which is higher than socially optimal. If the two products are complementary, then the companies can merge and create a positive sum scenario by lowering prices. Lower prices reduce deadweight loss, which is good for consumers, and lead to higher profits for the combined firm.

We note that if the FTC ruling stands, it will mean that developers of complex integrated systems will choose to keep their technologies in house rather than spinning them out and run the risk of having an acquisition blocked. And innovative development will be slowed rather than accelerated.

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