How Biotech Deals May Help Competition, Despite FTC View

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A wave of consolidations among pharmaceutical companies in recent years has prompted increased scrutiny from antitrust agencies.[1]

Some commentators have observed that the so-called third wave of mergers in the pharmaceutical industry — which began around 2010 — has been marked primarily by larger companies acquiring startups with innovative products.[2]

In this landscape, antitrust agencies under the Biden administration have raised novel concerns about future competition and incentives to innovate, which have served as the basis for challenging some of these deals.

Among the rationales for their interventions is the killer acquisition theory — the idea that a larger incumbent acquires a smaller company or startup with an innovative asset solely for the purpose of eliminating or avoiding future competition.[3] One well-known study of killer acquisitions in the pharmaceutical industry found that such acquisitions may represent approximately 5% to 7% of mergers in the sector.[4]

Over the past few years, the Federal Trade Commission has challenged multiple deals in the pharmaceutical industry, alleging that the proposed merger would harm current or future innovation — for instance, in Illumina/Pacific Biosciences, Illumina/Grail, and Bristol-Myers Squibb/Celgene.[5]

On Dec. 11, 2023, the FTC sought to block Sanofi's proposed acquisition of an exclusive license from Maze Therapeutics for its recombinant protein therapy, MZE001, for the treatment of Pompe disease, a rare genetic condition that causes progressive weakness to the heart and skeletal muscles.[6]

The FTC's complaint alleged that the deal would "eliminate a nascent competitor poised to challenge Sanofi's monopoly in the Pompe disease therapy market."[7]

On the same day, Sanofi announced its intention to abandon the deal, given the anticipated litigation costs and delays. In a statement, the company noted that, in contrast to the FTC's allegations, the partnership was "designed to apply Sanofi's resources, knowledge, and expertise to accelerate the development of MZE001."[8]

That the FTC is now willing to challenge a relatively narrow licensing deal involving an early- stage asset — a "Phase 1 investigational medicine,"[9] as described by Maze's CEO Jason Coloma — as a killer acquisition signals both the agency's increasing skepticism of licensing deals in the pharmaceutical industry and its willingness to challenge life sciences deals based on concerns about their impact on potential competition.

But perhaps the procompetitive rationale offered by Sanofi in defense of the acquisition should be given more consideration.

Could the reason behind some acquisitions of startups or other early-stage pharmaceutical firms be to accelerate development of technologies directly or indirectly related to the acquired asset?

Put differently, do the theories of competitive harm on which the agencies have relied make sense in the pharmaceutical industry, given the unique process by which new therapies are developed and come to market? And how, if at all, does the rise of biologics and novel therapeutics affect the application of the killer acquisition theory?

We attempt to shed some light on these questions in this article.

First, we examine the process of drug development and the acquisition of assets in life sciences. Second, we investigate potential scientific reasons why an incumbent may decide to delay or abandon entirely the development of a particular product.

A deeper familiarity with these factors may help regulators objectively assess the parties' rationales for future transactions and evaluate potential impacts on innovation and competition.

The Drug Development Process and its Complexity

The discovery and development of a new medicine is a complex process that often requires the work of hundreds or even thousands of scientists, billions of dollars,[10] and an average of more than 10 years of clinical investigation.[11] It is also a highly risky endeavor.

Overall, a small fraction of drugs that enter the clinical trial phase will ultimately receive approval from the U.S. Food and Drug Administration, although there is

substantial variation in these probabilities across technologies and indications and many different factors can affect the likelihood of success.[12]

Moreover, the process of developing an individual drug is a process of trial and error. A potentially promising clinical candidate is subjected to waves of testing, alterations and refinements.

These iterative changes all center on the need to optimize the so-called big three scientific features of a drug: its safety; its efficacy; and development activities that include the ability to manufacture, store and administer the drug.

Further complications are introduced by the need to create, access or design around key intellectual property that may be needed to construct a successful biopharmaceutical product. For example, a particular experimental medicine might deploy IP in a different or novel way from what is stated in its patent claims.

There are two important points to draw from this sketch of drug development. First, drug development entails an iterative process that builds on prior knowledge — both successes and failures — and that often may benefit from advances from sources outside the company — for example, already existing IP. Second, bringing a new therapeutic product to market requires significant investments in time, money and knowledge.

An important consequence of these points is that not every company is able to ideate and execute the myriad activities necessary to bring a drug through the research and development process to the patient.

Consequently, the biotech industry has grown ever more reliant upon mergers, acquisitions and licensing agreements among both large and small companies. It follows that not only are these activities not necessarily harmful to competition, but also that they may well be procompetitive, as they are often necessary for a product to travel the great distance from concept to approval.

Scientific Reasons Why a Pharmaceutical Company May Choose to Discontinue the Development of an Acquired Asset

As mentioned above, the killer acquisition theory envisions only one reason for an incumbent to acquire an upstart firm: to ultimately delay or shutdown the development of the acquired target, thereby eliminating or reducing competition.

However, given the complexity and uncertainty in the drug development process, there may be other scientific reasons why a pharmaceutical company may choose to abandon the development of an acquired asset.

In particular, the delay or discontinuation of the development of an acquired asset could be the result of an acquiring company reaching a different assessment of the asset's big three features from that of the product's originator. A careful assessment of these features based on objective scientific data can lead to important insights.

Safety

Additional investigation by the acquirer might identify potential concerns not known to the product's originator. Safety concerns have become more common in the current era of industry consolidation, where smaller companies tend to initiate the early stages of discovery before handing off the process to larger and more experienced developers.

The originator, for example, may have satisfied the minimal regulatory requirements to initiate clinical investigation but may not have addressed other emergent issues that might change the safety profile of the intended product.

This concern is especially relevant when dealing with complex therapeutics such as biologics and cell- and gene-based therapies that entail the modification of DNA and additional challenges in manufacturing.[13]

Efficacy

Because the drug discovery process can last a decade or more, what might have been perceived as an innovative new product earlier in its clinical investigation could be rendered ordinary or outdated by the time the product is under FDA review.

Consider, for example, the dramatic advances in immune oncology over the past two decades,[14] or the revolutionary impact of mRNA-based products over a handful of months during the COVID-19 pandemic.[15] Such innovative shifts may alter the efficacy standards for therapies, which can affect the acquiring firm's decision on continued development.

Development Activities

Considerations about a product's ability to be manufactured, formulated and administered may also lead to a pharmaceutical company sidelining or terminating a development program. In particular, a company might choose not to further pursue the development of an acquired asset if it is determined to be inconsistent with its internal IP, trade secrets or know-how.

Many companies have preferred formulation and/or manufacturing capabilities that might be inconsistent with the procedures used for the production of the acquired asset.

For example, a biologic manufacturer might have a standard production cell system that would require conversion of the acquired product to the new platform. Were this system deemed to be incompatible — perhaps reducing yields or introducing potential post- translational modifications — then a decision might have to be made either to reengineer the product or terminate the development program altogether.

In the latter case, the technologies gained during discovery and development may be reengineered and adopted to create an entirely new product.

In other cases, a company may acquire a smaller firm simply to gain access to key know- how — including IP, trade secrets and experimental data — with the intention of applying it to a different product.

This scenario is particularly common and valuable when the acquired and acquiring firm have overlapping projects in development. In such a case, the acquired IP and

know-how might provide a breakthrough to develop a therapy that is entirely different from the assets initially acquired.

Conclusion

Failure to consider these realities in pharmaceutical research and development may lead to a merger being labeled as a killer acquisition when its actual intention is to spur innovation.

The difference between procompetitive and anticompetitive acquisitions in the pharmaceutical sphere may well lie in the scientific and technological rationales informing a firm's decision making.

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Endnotes

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