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# US deal watchdog's bark could be worse than its bite

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## Chills in the biopharma M&A market are frequently blamed on the FTC. But is the agency really stopping deals from happening?

The last few years have been quiet for biopharma M&A, and an increasingly muscular US Federal Trade Commission is regularly cited as a reason. The agency's scrutiny of proposed deals has certainly stepped up, but to what extent can the antitrust regulator be blamed for this apparent dip in activity?

Lawyers and advisors insist that their clients are not being dissuaded from pursuing acquisitions, although they do admit that executive teams are "thinking very carefully" about any move. The due diligence process has become more complex and lengthy, they say, and the risk of a protracted review period is real.

The FTC's stance is "causing a sense of caution", as Monica Chmielewski, partner at Foley & Lardner, describes it. "Companies are engaging in additional planning and review, pre-merger, and really trying to anticipate what the FTC may look at."

Companies are having to factor in longer FTC review times, of up to a year for some larger deals, she tells *Evaluate Vantage*.

Heather Meade, principal at Washington Council Ernst & Young, agrees. "The FTC is forcing drug makers to think more creatively about the types of deals they're going to pursue," she says. A lengthy review period is very undesirable, and "is very costly from a legal perspective".

**From products to pipelines**

The FTC laid bare its intention to dig deeper into biopharma deals in 2021, when the US agency announced an international collaboration on the matter. Evidence had been building for some time, however, that the sector was in its sights.

In 2019 Bristol Myers Squibb's $73bn Celgene buy only narrowly scraped through, with the FTC's commissioners voting 3-2 in favour, even with the proposed divestment of Otezla to Amgen on the table. That year the agency also spent 10 months scrutinising Roche's acquisition of Spark Therapeutics, which was working on a very early haemophilia project.

Before this it was almost unheard of for the watchdog to concern itself with deals involving assets such a long way from the market.

“We now have to plan for a focus not only on an [approved] product-by-product basis, but for an expanded FTC review that asks: is the potential acquisition going to have an anticompetitive effect on the development of drugs that are in the pipeline, and is the acquisition going to seek to eliminate a competitive threat?” says Ms Chmielewski.

Even proposed divestments are receiving much greater scrutiny, she adds.

“Is the acquirer capable of further developing it and bringing it to market? Or will the divestiture further an anticompetitive environment? The FTC has really come out and said they want to make sure that, in terms of pipeline development, manufacturers have a motive and an incentive to bring products to market,” she says.

Ernst & Young’s Ms Meade stresses that the FTC is looking for very specific types of transactions before engaging.

“They're interested in transactions that they view as limiting competition and growth and opportunity. So to the extent that we're seeing a lot of bolt-ons [in biopharma], those aren't the types of market-limiting activities that I think they're particularly concerned with,” she says.

Still, in the pharma world some huge transactions can be described as bolt-on deals: Astrazeneca’s $39bn acquisition of Alexion, for example, which took the FTC just four months to clear. The agency also chose not to intervene in Pfizer’s $6.7bn move on Arena, despite the two companies having a much more obvious therapy overlap.

Both examples raise hopes for a similarly smooth path for the deal that the sector is currently watching: Amgen’s $28bn Horizon buy, announced in December. Earlier this month the companies received a second request for information, which is a step in the FTC clearance process that allows the agency more time to consider a proposed deal.

It is worth nothing that the FTC could soon have only three commissioners in place, all of whom are Democrat appointees who have pushed the agency’s more hawkish antitrust stance. The final Republican commissioner, Christine Wilson, said this month she would resign in protest against some recent actions.

**Cause and effect**

Given the new lengths that developers must go to, to satisfy the breadth of the FTC’s enquiries, it is easy to see why large deals have become less appealing.

“If the key [to an FTC review] is going to be looking at the entire portfolio in relation to a potential acquisition, it's a bit of a daunting project to think about,” Ms Chmielewski says.

“If the acquisition in question is of a smaller pharmaceutical company, and they have a much smaller pipeline that's only focused on one therapeutic area, that is a little bit easier to predict what the FTC may be asking for.”

If the Horizon takeover goes through, particularly after vocal political pressure to intervene, perhaps this would embolden other developers to decide that the effort of thinking big could pay off, in terms of FTC clearance.

Of course it is not solely the FTC that has been putting a dampener on biopharma dealmaking. Uncertainties created by rising interest rates and geopolitical and economic concerns have also helped create an environment where smaller, bolt-on deals are a more agreeable prospect. Few expect the bolt-on trend to change any time soon.

It is also worth remembering that it does not take much to transform a disappointing M&A year into one worth talking about. Last year was a perfect example: had Amgen not announced its move on Horizon 2022 would have been the slowest year since 2012, according to *Evaluate Pharma*.

In all likelihood, the prospect of a protracted and expensive review period is scuttling some moves, but surely only at very early stages of the deal process. Presumably, these are also exactly the transactions that the FTC would clamp down on anyway.

“When we have the new election cycle, depending on who ends up in office, things could change,” Ms Chmielewski says. “But I think that for the next few years the FTC’s going to follow on the path that we're on right now.”

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