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Biden's FTC increased large pharma deal scrutiny, but approval remains possible – Analytics

Analysis

09:36 EDT, July 24 2023

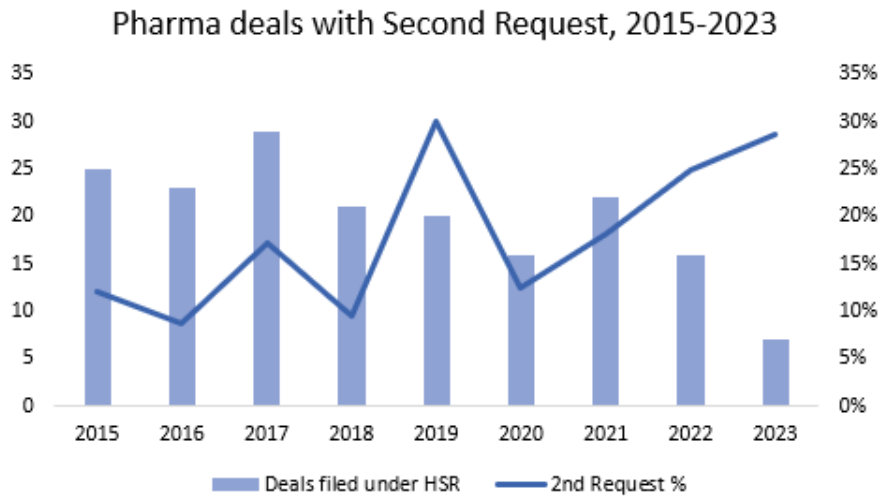
- More second requests, but also more approvals after in-depth review
- Horizon/Amgen ruling eagerly awaited by practitioners
- Other pharma deals have traditional playbook of overlap drug divestiture

Scrutiny of pharma and biotech mergers has gone up under the Biden administration's Federal Trade Commission (FTC), but unconditional clearance is a very possible outcome, according to an analysis by this news service.

Attorneys told this news service that the FTC's recent complaint against Amgen's [NASDAQ:AMGN] USD 28bn acquisition of Horizon Therapeutics [NASDAQ:HZNP] is consistent with the agency's recent approach and that it may have a chilling effect until the court rules on the case.

The share of deals receiving a second request has gone up to 24% since 2021, compared to 15% of cases in 2015-2020, an analysis of data parsed from SEC filings shows.

At the same time, six of the eight large deals that received a second request since 2021 (except pending cases) were approved without remedies. In 2015-2020, only one of 20 deals (*Spark/Roche*) was cleared unconditionally following an in-depth investigation. Then again, maybe the higher number of post-second request approvals is possible because the real problematic deals do not leave the boardroom.



Source: SEC filings, based on deal announcement year

This news service analysed 179 deals involving listed firms that were announced since 2015 with a target in the medical, pharmaceutical or biotechnology sector, where deal value was higher than USD 200m and which were notified under the Hart-Scott-Rodino (HSR) Act.

The FTC announced 11 interventions in other healthcare deals over the same period, with most recently the abandonment of Boston Scientific Corporation's acquisition of South Korean MI Tech. These cases are not included in the dataset.

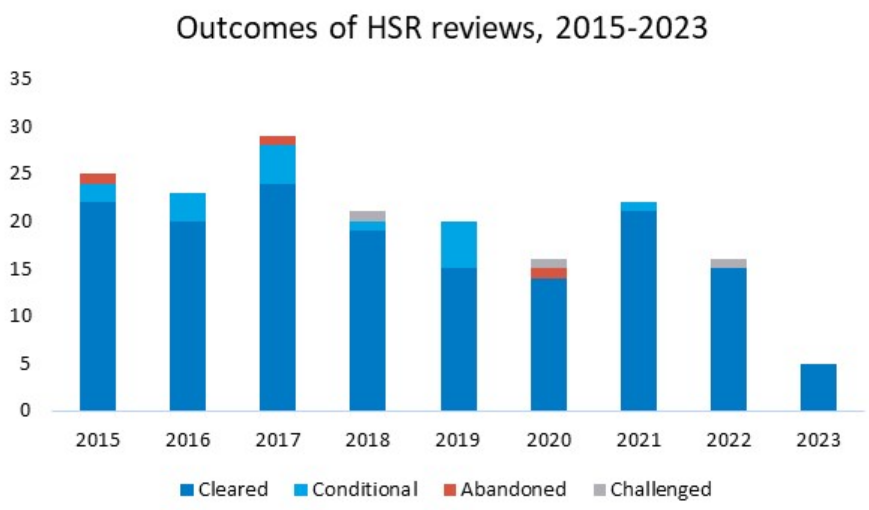
The dataset covers an average of 21 transactions per year, with a high of 29 in 2017 and low of 16 in 2020 and in 2022. This year so far, seven large pharma and biotech deals were announced and filed, including Pfizer's [NYSE:PFE] USD 43bn acquisition of Seagen [NASDAQ:SGEN] and Globus Medical's [NYSE:GMED] takeover of NuVasive [NASDAQ:NUVA], both of which are answering second requests.

The uptick in second requests in pharma and biotech deals is not a surprise, said Jeny Maier, a partner in the antitrust practice at Axinn. "The agencies have noted for the last several years that pharmaceuticals, in particular, and healthcare more broadly, is a priority area of enforcement."

The pharma cases are part of the broader effort by the FTC to slow things down, run the clock and see if parties walk away from deals they might not have walked away from in the past, said Jonathan Lewis, an antitrust partner at Lowenstein Sandler.

"There is less likelihood to resolve a transaction today than there was two or three years ago," according to Lewis, emphasizing it is really deal-specific. Many deals are still getting through, he noted, including transactions with obvious overlaps for which divestitures can resolve competition concerns.

The large majority of mergers (87.5% of the dataset) do get cleared unconditionally. Some 9% (16) were cleared with a divestment remedy – generally of overlap drugs or products – with the last conditional approval announced last year (*Intersect ENT/Medtronic*).



Source: SEC filings, FTC press releases, based on deal announcement year

Challenges and abandonments are rare, and despite an uptick in FTC lawsuits to block mergers, the only pharma deal with such a complaint is Amgen's acquisition of Horizon Therapeutics. In May, the FTC filed a lawsuit to block the transaction saying it would enable Amgen to use rebates on its existing blockbuster drugs to pressure insurance companies and pharmacy benefit managers (PBMs) into favoring Horizon's two monopoly products Tepezza and Krystexxa.

The FTC's lawsuit against Amgen's acquisition of Horizon Therapeutics is consistent with the agency's more aggressive posture, said Lewis. The theory of harm in that case was among topics discussed during the agency's June 2022 workshop on pharmaceutical mergers, he added.

Maier echoed this, noting it is consistent with the topics and issues that the agency's leadership has been vocal about over the last years.

In pharma deals, the FTC generally follows a traditional playbook where it looks at product overlaps and requires divestitures for products where there are few competitors. Commissioner Rebecca Slaughter's dissent in the 2021 approval of Celgene/Bristol Myers Squibb – which followed that playbook – already suggested that a broader look would be warranted.

Noah Brumfield of Allen & Overy said that the FTC's challenge in Horizon Therapeutics/Amgen is likely to make pharma companies more wary as they approach transactions.

This is a specific case with a novel theory of harm, and "ordinarily I would be cautious in basing future decisions on the fact that the FTC brought this complaint", he said.

The agencies' newly proposed frameworks for reviewing mergers, released on 18 July, have caused him to be less sanguine.

"Combine this with the FTC having just announced some really novel and far-reaching antitrust theories in their new merger guidelines, I think we can expect more unpredictability in merger review involving this industry," Brumfield said.

The case does raise uncertainty and is likely to have a chilling effect, at least until a court ruling on the complaint, said Maier. Another question surrounds whether it hampers the prospect of Pfizer's acquisition of Seagen getting approved, as that might also fit into the FTC's narrative on rebate walls, she said.

All eyes are now on the court to see how the Horizon/Amgen challenge is assessed. The overall picture, however, shows that pharma and biotech mergers can still cross the regulatory hurdle.

by Luuk de Klein and Aldrin Brown

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Grade

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