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FTC Antitrust Enforcement in Life Sciences Reveals Fissures Among Commissioners

December 3, 2019

The Federal Trade Commission has promised vigorous antitrust enforcement in life sciences industries, with Chairman Joe Simons promising a "robust program to identify and stop anticompetitive conduct, especially in the nation's critical markets for healthcare." Simons committed that the “agency will continue to monitor this space carefully, and … will not hesitate to take vigorous action to protect the integrity of US pharmaceutical markets where warranted."

Two recent enforcement actions show that while the five FTC commissioners continue to stand together in enforcing traditional theories of life sciences deals, there appears to be an emerging split along party lines regarding how far to push the boundaries of merger enforcement on newer theories of harm in FTC's life sciences antitrust program.

In a 5-0 vote in the matter of *Otto Bock*, the full commission affirmed an administrative law judge's ruling that a consummated acquisition, which was not reportable under the Hart-Scott-Rodino Act, reduced competition in a market of prosthetic knees equipped with microprocessors, ordering Otto Bock to divest the acquired firm’s entire business with limited exceptions.

In a 3-2 vote, a majority of the commissioners allowed Bristol-Myers Squibb to proceed with its $74 billion acquisition of Celgene, after the parties agreed to divest Celgene's psoriasis blockbuster Otezla for $13.4 billion to resolve an overlap with a BMS drug under development. Democratic commissioners Rohit Chopra and Rebecca Slaughter, however, each filed dissents arguing that the agency should examine alternative theories of harm before approving pharmaceutical mergers given rising drug prices and alleged anticompetitive conduct in the industry.

Full commission stands united in requiring divestitures to resolve consummated Otto Bock/Freedom acquisition

The FTC opened an investigation into Otto Bock's acquisition of FIH Group Holdings (Freedom) in September 2017, shortly after the acquisition was consummated, in response to customer complaints.

Within three months, the commission filed an administrative complaint, alleging that Otto Bock was the leading supplier of microprocessor prosthetic knees and that Freedom was Otto Bock's closest competitor, with the combined firm holding more than 80% of the microprocessor-equipped prosthetic knees (MPK) market.

The FTC contended that direct, head-to-head competition, between the companies had resulted in lower prices to prosthetic clinics and was driving significant product improvements, including the development and planned launch of next-generation offerings. The FTC rejected Otto Bock's argument that other types of prosthetic knees should be included in the market.

The FTC also rejected Otto Bock's affirmative defenses, including that Freedom was a failing firm. The commission reasoned that to satisfy that defense, Otto Bock was required to show that the target (i) was in imminent danger of failure, (ii) would not be able to reorganize successfully in bankruptcy and (iii) had made a reasonable, good faith attempt to locate an alternative buyer, and so the acquisition was the only way to ensure the assets would remain in the market. While acknowledging that Freedom had some financial difficulties, the FTC noted recent improved financial performance. It also took issue with the process Freedom employed to identify potential buyers, noting that there were interested buyers that Freedom rejected in favor of Otto Bock's

more lucrative offer.

The commission also rejected Otto Bock's argument that its offer to divest Freedom's MPK assets was sufficient to remedy any potential harm and that mandating divestiture of additional assets, including foot products, was "punitive." The commission concluded that it was not required to consider the divestiture offer as part of its competitive effects analysis, since (i) competitive harm had already occurred and (ii) the divestiture agreement was not offered close in time to the filing of the complaint. The commission said that including Freedom's foot products in the divestiture order was aimed "to avoid placing the risk of a failed remedy on consumers" by depriving the divestiture buyer of tools Freedom used to compete effectively.

Otto Bock demonstrates the common ground that the commissioners share in vigorous enforcement against life sciences deals that involve traditional theories of harm, i.e., where the firms are close competitors in a highly concentrated market earmarked by high barriers to entry.

On the flip side, the divide within the FTC arises where pharma mergers meet next-generation antitrust concerns.

Divided FTC accepts divestiture of Otezla in BMS/Celgene merger, while Democratic commissioners push agenda for closer scrutiny for pharma mergers

In *BMS/Celgene*, the FTC required BMS to divest Celgene's Otezla after concluding that BMS's Phase 3 oral product to treat psoriasis would likely be the next entrant into the market and would compete directly with Otezla. Requiring that BMS divest the on-market product is itself quite significant and consistent with recent FTC staff pronouncements that the commission would insist upon divestiture of the marketed product, rather than the pipeline product, when firms merge. The decision resulted in a $13.4 billion divestiture, the largest ever in a merger enforcement matter.

The FTC had foreshadowed that it would start requiring the divestiture of the currently marketed product in cases involving one marketed drug and one pipeline drug in February 2018. The FTC's Bureau of Competition director, Bruce Hoffman, said divestitures of pipeline products in certain pharmaceutical mergers likely would be insufficient to cure enforcers' concerns of anticompetitive harm. Consistent with the full commission's reasoning in *Otto Bock* and pointing to the FTC's remedies study, which found that divestitures of drugs in development failed more often than marketed drugs, he argued that "in the context of merger remedies … it is entirely proper that the risk of failure be placed on the parties to the merger."

In announcing the settlement of *BMS/Celgene* on November 15, Simons said the divestiture of Otezla would "preserve BMS's incentive to continue developing its own oral product for treating moderate-to-severe psoriasis," asserting the antitrust laws "protect not only competition today, but competition in the future, especially when it comes to the development of new treatments for chronic conditions."

This significant development, however, is somewhat overshadowed by the dissents of the two Democratic commissioners. Chopra's and Slaughter's dissents took aim at the FTC's current analytical framework.

Chopra expressed skepticism that the "status quo" or "routine" analysis would "unearth the full set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today's pharmaceutical industry when it comes to innovation." He challenged the agency to move away from the "routine" analysis and further towards "rigor," including inquiries that have historically not been included in the FTC's analysis, such as:

- Will the merger facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property?
- Will the merger deter formation of biotechnology firms that fuel much of the industry's innovation?

Regarding the proposed BMS acquisition of Celgene, Chopra expressed concern that BMS's "incentives might

… be distorted given overlaps in ownership" with Celgene.

Slaughter similarly called for consideration of how a merger would facilitate anticompetitive conduct, including reverse payment settlements of patent litigation, sham litigation and anticompetitive product hopping. Slaughter said she supported the agency's efforts to remedy the psoriasis drug-level overlap involving Otezla, but said she "remain[ed] concerned that [the commission's] analytical approach is too narrow." In particular, she noted that "the [c]ommission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation."

The Chopra and Slaughter dissents reflect political pressure on the FTC to broaden the scope of antitrust enforcement to help address healthcare costs and, in particular, perceived high pharmaceutical prices. The Democratic commissioners are pushing for expanded antitrust enforcement.

The split between the Democratic and Republican parties applies beyond the merger context. It was also on display this past summer when the FTC issued a statement to Congress regarding the use of its Section 5 authority, which makes illegal "unfair methods of competition," to address high drug prices. The commission majority advised that "the attempted use of standalone Section 5 to address high prices, untethered from accepted theories of antitrust liability under the Sherman Act, is unlikely to find success in the courts." Chopra and Slaughter, however, in a separate statement, advocated that the commission "carefully examine and aggressively employ new ways to utilize our enforcement tools that restore competition and eliminate unfair or deceptive acts or practices in the pharmaceutical industry."

Key takeaways

Understanding the unique issues that drive antitrust enforcement in life sciences mergers – from the importance of innovation and intellectual property to FDA regulations and life cycle management strategies and specialty distribution – is essential to achieving merger clearance in close cases. These recent enforcement actions show that understanding these issues will become even more critical as Democrats continue to push the boundaries on the FTC's approach to merger enforcement actions in life sciences mergers.

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