Health Care Antitrust Alert

FTC Settles Radioactive Allegations Against Cardinal Health with a Near Record-Breaking Disgorgement Agreement

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In a 3-2 decision, as part of its aggressive antitrust enforcement in health care industries, the Federal Trade Commission (FTC or the Commission) announced that Cardinal Health, Inc. (Cardinal) agreed to pay $26.8 million to resolve the FTC's allegations that Cardinal illegally monopolized the sale of low-energy radiopharmaceutical drugs in 25 geographic markets and inflated prices charged to hospitals and clinics for the drugs. The figure represents the second highest disgorgement settlement for the agency and the FTC's first disgorgement victory in over a decade. This case is an important reminder that the FTC can and will seek to use disgorgement as an equitable remedy when challenging certain conduct.

Cardinal, the country's largest owner and operator of radiopharmacies, sells and distributes low-energy radiopharmaceuticals, which are used by hospitals and clinics to perform diagnostic imaging procedures. Low-energy radiopharmaceuticals contain a radioactive isotope combined with a chemical agent; the ingredients, particularly the short half-life of the radioactive isotopes, require providers to use closely geographically located radiopharmacies, resulting in highly localized markets.

The FTC alleged that Cardinal began its scheme in 2003 by obtaining the de facto exclusive right to distribute radiopharmaceuticals containing heart perfusion agents (HPAs) from Bristol-Myers Squibb Co. (BMS) and General Electric Co. (GE), who were at the time the sole U.S. producers of HPAs. HPAs, used to perform heart stress tests, can represent up to 60% of a radiopharmacy's revenue. Around the same time, in 2003 and 2004, Cardinal acquired a dominant position in the marketplace by acquiring rival radiopharmacies Syncor International (Syncor) and Geodax Technology, Inc. (Geodax). The FTC claimed that these actions were designed to prevent competitors from entering the market, noting that the Syncor and Geodax acquisitions made Cardinal the only radiopharmacy in 24 markets.

According to the FTC, Cardinal continued to use anticompetitive tactics to maintain its distribution exclusivity by using its leverage as the largest (and in some markets, only) radiopharmacy to coerce BMS and GE. In some instances, Cardinal:

1. used the companies against each other to pressure BMS to abandon plans to license products to new competitors;
2. threatened to compete against BMS as a generic HPA manufacturer;
3. threatened to withhold business if the companies granted distribution rights to new competitors in the relevant markets; and
4. conditioned Cardinal's future relationship with GE in the radiopharmaceutical industry on GE's refusal to grant Myoview distribution rights in the relevant markets.

In addition to the disgorgement penalty, the FTC order prevents Cardinal from entering into exclusive deals with more than one manufacturer of the same radiopharmaceutical product at the same time or from using coercion or retaliation to obtain de facto exclusivity. Cardinal must also notify the FTC before entering into new exclusive distribution agreements or buying radiopharmacy assets, even those generally not reportable under the Hart

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Scott Rodino Act. Cardinal must also give customers in six relevant markets the option to terminate their contracts with Cardinal, a process that will be overseen by a monitor. Finally, Cardinal is also required to establish and maintain an antitrust compliance program for its radiopharmacy division.

The vote to accept the Consent Agreement split along partisan lines with Commissioners Ohlausen and Wright dissenting. The majority Commission statement defended its use of disgorgement as a remedy against assertions by Commissioners Ohlhausen and Wright, who argued that disgorgement was not appropriate and questioned more broadly the propriety of the Commission's use of disgorgement as a remedy in competition cases. The majority, noting that "an injunction against future violations is not adequate to protect the public interest," stated that a remedy consisting merely of injunctive relief would be insufficient for the following reasons:

First, countering Commissioner Olhausen's claim that the case presented no clear violation of the antitrust laws since the FTC failed to challenge Cardinal's 2003 and 2004 acquisitions of Syntax and Geodax and because Cardinal's monopolies were the result of "insufficient demand," the majority found that Cardinal's scheme relied on an anticompetitive combination of acquiring existing competitors in the relevant markets and then raising artificial barriers to new entry that would have created competition in these markets. Moreover, Cardinal's exclusionary conduct allowed it to unlawfully maintain its monopoly status. The majority pointed to evidence that Cardinal's conduct caused BMS and GE-Amersham to deny potential entrants HPA distribution rights and prevented entry that would have occurred in the relevant markets between 2003 and 2008.

Second, while agreeing with Commissioner Wright that exclusive dealing can have efficiency justifications, the majority found that where Cardinal simultaneously maintained exclusive distribution rights to the only two HPAs then available in the relevant markets, the company's exclusive dealing lacked any legitimate business or efficiency justification. In fact, the majority stated that Cardinal went a step further in locking up both manufacturers of HPAs in the relevant markets, suppressing interbrand competition.

Finally, the majority found significant evidence of anticompetitive effects, declaring that a price analysis showed that Cardinal charged higher prices in its monopoly markets.

This decision, coupled with the FTC's recent win in the Eastern District of Pennsylvania solidifying the agency's authority to seek disgorgement,[1] reflects the view that even where the unlawful conduct has ceased years ago, the FTC can and will seek disgorgement if "until that time [the company] suppressed competition in the relevant markets through its exclusionary tactics and charged its customers significantly higher prices." Injunctive relief alone, the majority argued, would fail to adequately remedy the harm caused by the company's past conduct and would have insufficient deterrent effect. Moreover, given statute of limitations issues present in private follow-on lawsuits, disgorgement could be the only avenue of relief for private plaintiffs.

As the majority noted, in 2012, the Commission withdrew its 2003 Policy Statement on Monetary Equitable Remedies in Competition Cases to dispel the notion that the FTC would seek disgorgement and restitution remedies only in "exceptional" cases. In that 2012 statement, the Commission emphasized that "[a]lthough our decisions and orders generally focus on structural or behavioral remedies intended to curb future competitive harm, the agency's mission to protect consumers and competition also includes, where appropriate, taking action to remedy the actual, realized effects of antitrust violations."[2] Our view is wholly consistent with that of the Supreme Court, which has observed that the Commission's cease-and-desist authority to prevent future competitive harm emanates from the FTC Act's prophylactic objective — that "attempts to bring about complete monopolization of an industry might be stopped in their incipiency."[3] Even over strenuous objections, the current majority is willing to resort to the disgorgement remedy.

If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.

Endnotes

[1]*Federal Trade Comm'n v. Cephalon, Inc*., No. 08-cv-2141 (E.D. Pa. Apr. 15, 2015) (Cephalon had challenged the FTC's ability to seek disgorgement on several grounds, including that the FTC Act did not permit it and that the FTC did not request disgorgement in its complaint, effectively waiving its right to seek it. The Eastern District of Pennsylvania found in the FTC's favor on both counts. Not only did the agency have the inherent authority under the FTC Act, but the agency did also plead possible disgorgement when it sought all other available equitable remedies in its prayer for relief.).

[2]Withdrawal of the Commission Policy Statement on Monetary Equitable Remedies in Competition Cases, 77 Fed. Reg. 47,070, 47,070−71 (July 31, 2012), *available at* https://www.ftc.gov/policy/federal-register-notices/federalregister-notice-withdrawal-commission-policy-statement (Commissioner Olhausen dissented from that action as well.)

[3]*Fashion Originators' Guild, Inc. v. FTC*, 312 U.S. 457, 466 (1941).

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