FTC Secures Record $12 Million Penalty for HSR Violation

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FTC takes aim at deal structures that avoid HSR filing obligations

On July 13, 2026, the Federal Trade Commission (FTC) announced that Edwards Lifesciences and Genesis MedTech Group agreed to pay a combined civil penalty of $12 million to settle allegations that they intentionally structured Edwards' acquisition of JC Medical, a subsidiary of Genesis, to avoid premerger reporting requirements under the Hart-Scott-Rodino (HSR) Act, a "device in avoidance." The settlement is the largest civil penalty ever imposed for failure to file an HSR notification.

This enforcement action appears to have grown out of the FTC's earlier substantive investigation into Edwards' proposed acquisition of JenaValve Technology, which the FTC alleged was the only other company besides JC Medical that was, at the time, conducting US clinical trials for transcatheter aortic valve replacement for aortic regurgitation (TAVR-AR) devices. Edwards announced the JenaValve acquisition the day after closing the JC Medical acquisition. The FTC successfully sought a preliminary injunction blocking the JenaValve deal in January 2026, shortly after which Edwards abandoned the deal.

The Edwards/Genesis complaint centered on two contemporaneous transactions between Edwards and Genesis: a $115 million acquisition for JC Medical voting securities and a $25 million investment in nonvoting securities of Genesis, which, if both counted toward the size of transaction, would have been over the then-applicable threshold. The FTC alleged that the parties' internal documents "made clear that both [payments] were part of a single transaction." The complaint also cited an email in which Edwards reportedly described such two-tiered deal structure as "below the threshold! Intentional[.]"

While device-in-avoidance enforcement actions are rare (only two in this century), the Edwards/Genesis settlement may be part of a larger agency push to rein in deal structures that result in transactions not requiring filings, especially acquihires, which have become more common in the AI space.

FTC alleged payment for nonvoting securities of Genesis was really consideration for acquisition of JC Medical

On July 22, 2024, Edwards acquired JC Medical from Genesis by purchasing all voting shares of JC Medical for $115 million, plus contingent milestone payments. Concurrently, Edwards committed to a separate $25 million investment in nonvoting shares of the parent company, Genesis, which closed on August 9, 2024. Taken individually, the $115 million subsidiary purchase fell below the then-applicable $119.5 million HSR size-of-transaction threshold, and the $25 million parent investment involved nonvoting equity. Under standard HSR aggregation rules, two purchases from the same ultimate parent entity are aggregated if the acquiring person is purchasing voting securities or assets in both instances. However, because the $25 million investment in Genesis involved nonvoting securities, the consideration paid for such shares was excluded from the size-of-transaction calculation under the HSR Act. Consequently, the transactions closed without premerger HSR notifications.

The FTC alleged that the $25 million nonvoting investment in Genesis was "intended […] to be additional compensation to Genesis for the sale of JC Medical to Edwards," and, when combined with the $115 million acquisition price, would have resulted in total consideration of $140 million, exceeding the then-applicable $119.5 million threshold and triggering an HSR filing obligation. The FTC pointed to the parties' internal documents indicating that the split payment structure was not reached for independent commercial reasons. Per the preliminary injunction opinion from the related JenaValve litigation, after Edwards internally flagged an "H[SR] concern" with its offer, JC Medical's then-CEO proposed that "'[if] the HSR component [wa]s a no-go for the deal structure,' Edwards could close the valuation gap by making a separate investment in Genesis" rather than by increasing the stated acquisition price.

The FTC challenged the transaction as a "device in avoidance" under 16 CFR § 801.90 (Rule 801.90), which provides that "[a]ny transaction(s) or other device(s) entered into or employed for the purpose of avoiding the obligation to comply with the requirements of the [HSR Act] shall be disregarded, and the obligation to comply shall be determined by applying the [HSR Act] and these rules to the substance of the transaction."

Edwards/Genesis is particularly noteworthy because the antitrust agencies rarely invoke Rule 801.90 in enforcement actions. Indeed, before Edwards/Genesis, the enforcement action against Canon/Toshiba, settled on June 10, 2019, was the only civil penalty case in the 21st century invoking the anti-evasion rule.

In Canon/Toshiba, Toshiba transferred all voting shares in Toshiba Medical Systems Corporation (TMSC), a subsidiary of Toshiba, to a newly created special purpose vehicle (SPV) for nominal consideration. Simultaneously, Canon purchased the only nonvoting share in TMSC – coupled with options to purchase all voting shares from the SPV for nominal consideration – for $6.1 billion. The complaint alleged that, despite the nonvoting nature of the share acquired by Canon, the terms of this single-share-plus-options package effectively transferred full beneficial ownership and economic interest in TMSC to Canon. The FTC alleged that such structure was designed to allow Toshiba to recognize the $6.1 billion sale proceeds before its fiscal year-end without observing the HSR waiting period. To settle the allegations, Canon and Toshiba each paid a $2.5 million civil penalty ($5 million combined).

Edwards/Genesis is also notable because the allegations involve consideration attributed to nonvoting securities, which is a feature of recent acquihire structures, often involving an acquisition of nonvoting securities and a nonexclusive license to intellectual property, both of which are traditionally considered not reportable.

Record fine levied against buyer and seller, plus five-year notice requirement

The proposed settlement requires Edwards to pay $10 million and Genesis to pay $2 million. The combined $12 million is the largest civil penalty ever imposed for failure to make an HSR filing. The penalty is notable in part because civil penalties are more commonly imposed on acquirers; requiring a seller to pay is less common, though not unprecedented (e.g., Canon/Toshiba split the $5 million penalty equally between buyer and seller).

The $12 million penalty is a relatively small fraction of the theoretical maximum exposure. The government alleged that the parties were in violation of the HSR Act for 721 days beginning July 22, 2024. At the current maximum penalty of $53,088 per day per defendant, the government could have sought approximately $38 million from each party, or roughly $77 million combined. The $12 million settlement thus represents approximately 16% of the maximum.

In addition to the monetary penalty, the proposed judgment requires Edwards, for a period of five years, to provide at least 30 days' advance written notice to the FTC before acquiring any interest in any firm that commercially sells, is conducting US clinical trials for, or holds a US Food and Drug Administration Investigational Device Exemption for a TAVR-AR device, regardless of whether such an acquisition would otherwise require an HSR filing. Edwards must also implement an antitrust compliance program, including designation of a compliance officer and annual certifications from relevant personnel. The five-year term is two years longer than the three-year term imposed in the Canon/Toshiba judgment.

What this means for dealmakers

- **The HSR rules elevate substance over form, and fewer bright lines remain.** Edwards/Genesis shows that the antitrust agencies are prepared to look past the formal structure of related payments – including payments characterized as a nonvoting equity investment in the seller parent – to assess whether, in substance, they constitute integrated consideration for one acquisition.
- **Internal documents and deal communications carry significant weight.** The FTC's complaint relied heavily on how the transaction was discussed internally and in negotiations, not only on how it was documented in the final agreements. Emails, board presentations and deal correspondence that reference the HSR threshold in connection with pricing decisions, including discussions about structuring around the threshold, may be used to establish the purpose of a transaction structure under Rule 801.90.
- **The FTC's skepticism of nonvoting securities as consideration may have implications for acquihires and other nontraditional structures.** The FTC under the Trump administration has expressed concerns about transactions being structured to avoid HSR filings. For example, Chairman Andrew Ferguson has said that the agency is examining acquihires, particularly in AI, for potential HSR evasion and substantive antitrust concerns, and may issue additional guidance. Similarly, Commissioner Mark Meador has warned companies against acquihire structures that are deliberately "designed to fall below premerger notification thresholds" to "limit[] the opportunity for advance [agency] review," emphasizing the importance for the agency to "look past formal transaction labels and assess whether a deal, however packaged, forecloses competition and constrains access to the specialized talent on which dynamic markets depend." To address these concerns, the FTC issued a Request for Public Comment, seeking input on whether to formally extend HSR coverage to "non-traditional transaction structures," including acquihires and convertible security transactions. Edwards/Genesis may be part of this initiative, offering a real-time example of how parties have allegedly attempted to structure transactions to avoid HSR filings.
- **Buyers and sellers can each be on the hook for civil penalties.** Both buyers and sellers have independent HSR filing obligations and can each face civil penalties for structures that the government deems to violate the HSR Act. The $2 million penalty against Genesis illustrates that sell-side exposure is real. Sell-side counsel should conduct an independent HSR analysis and should not rely solely on the buyer's threshold determination, particularly where the deal structure involves payments to the seller or its affiliates that are structured separately from the stated acquisition price.

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