

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL**

Transaction “may be substantially to lessen competition, or to tend to create a monopoly.” 15 U.S.C. § 18.

J&J currently markets a product called Evarrest and, under the proposed Transaction, would acquire the rights to TachoSil. Both Evarrest and TachoSil belong to a class of hemostat devices known as “active hemostats,” which employ agents such as thrombin—an enzyme with a direct clotting effect when exposed to blood—to control serious bleeding during surgical procedures. Active hemostats come in various forms, including flowable products, stand-alone thrombin, non-patch fibrin sealants, and biosurgical fibrin sealant patches. Biosurgical fibrin sealant patches are left in situ after surgery to be absorbed by the body over time. TachoSil and Evarrest are the only biosurgical fibrin sealant patches approved by the U.S. Food and Drug Administration (FDA), and therefore are the only hemostats of that type sold in the United States. TachoSil has an FDA-approved indication for use in heart and liver surgeries, while Evarrest has a broader indication for general surgical use.

Currently, TachoSil is marketed in the United States by Baxter International, [REDACTED] The proposed Transaction under investigation grants J&J [REDACTED]

As part of its investigation of whether J&J’s proposed control of the only two biosurgical fibrin sealant patches sold in the United States would result in competitive concerns, the Commission, pursuant to a resolution authorizing the use of compulsory process, issued the demands for information and documents that J&J now seeks to limit.

II. Analysis

A. The Return Date of the Requests Is Reasonable Under the Circumstances of This Investigation

J&J objects to the CID’s and SDT’s return date of September 13, 2019, which was approximately three and a half weeks after they were served, as “unreasonable and unduly burdensome considering the breadth and scope of the Requests.” *Petition*, at 8. J&J requests instead that the date be extended to November 5, 2019. Because the timely filing of a petition to quash or limit Commission compulsory process “shall stay the remaining amount of time permitted for compliance,” 16 C.F.R. § 2.10(b), the original return date has been effectively extended by J&J’s filing of its petition. To date, J&J has produced only preliminary material such as organizational charts to negotiate limitations on the scope of custodial searches. *See, e.g.*, Commission Staff Letter to J&J Counsel, dated September 20, 2019 (modifying CID and SDT).

The proposed Transaction is not subject to the premerger notification requirements of the Hart-Scott-Rodino Act, 15 U.S.C. § 18a (“HSR”). *See* *Petition* at 2. Consequently, the return dates for compliance with the CID and SDT are not governed by the HSR Act’s process that would provide greater control to Respondent over the timing for production. But, because the

Transaction is exempt from the HSR Act, there is no legal impediment in the United States to the parties' consummating their proposed Transaction at any time.

The original return date of the CID and SDT was September 13, 2019. J&J is correct that, ordinarily, requests for documents and information in a Second Request under the HSR Act may take months for full compliance. *Petition* at 8-9. Yet, because the Transaction is not subject to the premerger notification process that ordinarily affords the Commission sufficient time to review the Transaction's possible effect on competition, the parties are free to consummate their agreement at any time. [REDACTED]

[REDACTED] Under these circumstances, the original return date was calculated to permit the Commission to review the Transaction as expeditiously as practicable and, accordingly, we conclude that the very short return date is reasonable.

[REDACTED] In contrast, J&J has not

[REDACTED] J&J's argument might have been more persuasive if J&J demonstrated a willingness to comply [REDACTED] in a timely manner by, for example, beginning a rolling production of the responsive materials. It also could have negotiated a more relaxed production schedule with staff had it [REDACTED]

[REDACTED] As it stands now, however, only J&J's prompt compliance with the CID and SDT will enable the Commission to make a meaningful judgment about the potential effects of the Transaction.

J&J argues that there is no urgency for the Commission to obtain the demanded documents and information because [REDACTED]

[REDACTED] We disagree. Competitive harm in the United States may occur [REDACTED]

[REDACTED] to the detriment of consumers. For example,

[REDACTED] Thus, contrary to J&J's claim, prompt compliance with the CID and SDT is necessary to enable the Commission to complete its investigation prior to consummation of the Transaction.

Finally, the cases that J&J cites to support its petition are unpersuasive. *United States v. Morton Salt Co.*, 338 U.S. 632 (1950), held only that agency compulsory process "shall not be unreasonable." *Id.* at 653. As we discussed above, the circumstances of this investigation render the original return date reasonable. Similarly, *D.R. Horton v. Leibowitz*, No. 4:10-cv-547-A, 2010 WL 4630210 (N.D. Tex. Nov. 3, 2010) is unavailing. The court dismissed a declaratory judgment action for lack of jurisdiction, but nonetheless addressed the scope of a CID without much substantive discussion. Those statements—at most, dicta—have no bearing on the different factual circumstances here. As we explained, prompt compliance is necessary for a meaningful

review of the Transaction. Accordingly, we deny J&J's request to reset the return dates of the

Applying these standards, we conclude that the scopes of the CID and SDT, as already modified, are appropriate. We note that through earlier discussions with FTC investigative staff, J&J has already secured significant modifications to the scopes of the CID and SDT, including the narrowing of the definition of "Relevant Product"—sometimes to only "Evarrest"—in certain specifications. *Petition*, at 4-5. Yet, J&J petitions to further limit that definition across all the specifications of the CID and SDT. J&J's argument is unconvincing because J&J has argued in assessing the competitive impact of the Transaction. In J&J's letter to the Commission's investigative staff, dated August 19, 2019, J&J claimed that

Id. at 3.

It claimed that

Id. Given J&J's position that

it is inconsistent to claim that only Evarrest is relevant to the Commission's investigation. Because J&J claims that , the Commission is entitled to documents and information related to the wider range of products.

Similarly, J&J's request that the Commission strike the definition of "Relevant Product Bundle" on relevance grounds is inconsistent with its claim that

J&J's arguments on

render many more