UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matters of	)	
CIVIL INVESTIGATIVE DEMAND TO JOHNSON & JOHNSON, DATED AUGUEST 19, 2019,	)	**File No. 191-0152**
and	)	
SUBPOENA DUCES TECUM TO JOHNSON & JOHNSON, DATED AUGUEST 19, 2019.	)	

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ORDER DENYING PETITION TO LIMIT
CIVIL INVESTIGATIVE DEMAND AND SUBPOENA DUCES TECUM

By WILSON, Commissioner:

Johnson & Johnson (J&J) petitions the Commission to limit a Civil Investigative Demand (CID) and *Subpoena Duces Tecum* (SDT), issued on August 19, 2019, in connection with the Commission's investigation into J&J's proposed acquisition from Takeda Pharmaceuticals International AG of the worldwide rights to "TachoSil," a product used to arrest serious surgical bleeding (hereinafter, the "Transaction").

Specifically, J&J requests that the return date of the CID and SDT both be extended until November 5, 2019. *Petition*, at 8. J&J also asks that the Commission narrow the CID's and SDT's definitions of "Relevant Product," and to strike their definitions of "Relevant Product Bundle" entirely. *Id*. at 10. For the reasons set below, we deny J&J's petition.

I. Background

The Commission began an investigation to consider whether the Transaction, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended. *See Resolution to Authorize Use of Compulsory Process in Nonpublic Investigation*, File No. 191-0152 (Aug. 15, 2019). The Commission seeks to determine, among other things, whether the effect of the proposed

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] 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]. 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]. We disagree. Competitive harm in the United States may occur [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 CID and SDT to November 5, 2019.

B. The Information and Documents Sought Are Relevant to the Investigation

J&J contends that the Transaction implicates only one of its hemostat products, Evarrest, and therefore, J&J argues that the Commission's demand for "information regarding *all* hemostats is unnecessary, overbroad, and unduly burdensome." *Petition*, at 11. In *Morton Salt*, the Supreme Court confirmed that the FTC's demand for information and documents is permissible "if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." 338 U.S. at 652. The scope of the Commission's CID and SDT meets those standards. The CID and SDT were issued pursuant to a duly authorized Commission resolution. J&J does not challenge the authority of the agency to investigate the Transaction or whether the demand is too indefinite.

J&J does challenge the relevance of seeking information regarding all of its hemostat products. We disagree with J&J's claim that only Evarrest is relevant to the Commission's investigation. Courts have long confirmed that the purpose of an FTC investigation is to learn whether there is reason to believe that the law has been or, in the case of a proposed acquisition under the Clayton Act, would be violated and, if so, to ascertain whether issuance of a complaint would be in the public interest. *See FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (*en banc*) (citing *Morton Salt Co.*, 338 U.S. at 642-43). During a Commission investigation, the standard for relevance in administrative compulsory process is broader and more "relaxed" than would be in an adjudication. *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992). Indeed, the Commission's demands need not be limited to that information which would be necessary to prove specific charges; instead, it can call for any documents or information relevant "to the investigation," whose boundaries may be broadly defined by the Commission. *Id*.

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 [redacted] 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 [redacted] *Id*. at 3. It claimed that [redacted] *Id*. Given J&J's position that [redacted] it is inconsistent to claim that only Evarrest is relevant to the Commission's investigation. Because J&J claims that [redacted], 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 [redacted]

J&J's arguments on [redacted] render many more documents and information essential to the investigation, and thus increases its production burden. Yet, as the D.C. Circuit has noted, "[s]ome burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest." *Texaco*, 555 F.2d at 882. "Thus courts have refused to modify investigative subpoenas unless compliance threatens to unduly disrupt or seriously hinder normal operations of a business." *Id*. J&J does not make such a claim. Accordingly, J&J's request to modify the scopes of the CID and SDT will also be denied.

III. CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED THAT Johnson & Johnson's Petition to Limit Civil Investigative Demand and Subpoena Duces Tecum be, and hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Johnson & Johnson shall comply in full with the Commission's Civil Investigative Demand and Subpoena Duces Tecum no later than October 25, 2019 at 9:30 a.m., or at such other date, time, and location as the Commission staff may determine.

By the Commission.

April J. Tabor
Acting Secretary

SEAL:
ISSUED: October 18, 2019