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Mr. Jason R. Kraus
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1600 Utica Avenue South
Suite 600
Minneapolis, MN 55416

In re: Patent Term Extension
Application for
U.S. Patent No. 6,929,639

December 6, 2023

REQUIREMENT FOR INFORMATION PURSUANT TO 37 CFR 1.750

Boston Scientific Scimed, Inc. (BSSI), the patent owner of record, filed a patent term extension (PTE) application for U.S. Patent No. 6,929,639 under 35 U.S.C. 156 in the United States Patent and Trademark Office (USPTO) on October 5, 2023. BSSI seeks an extension of 823 days based upon the premarket review under § 515 of the Federal Food, Drug, and Cosmetic Act of

> Boston Scientific Cardiac Cryoablation System (POLARx® Short Tip (ST) Cryoablation Balloon Catheter, POLARx® Long Tip (LT) Cryoablation Balloon Catheter, POLARx FIT™ Short Tip (ST) Cryoablation Balloon Catheter, POLARx FIT™ Long Tip (LT) Cryoablation Balloon Catheter, SMARTFREEZE® Cryo-Console, SMARTFREEZE® Remote Control, SMARTFREEZE® Cryo-Console Foot Switch, SMARTFREEZE® Inter- Connection Box, SMARTFREEZE® Diaphragm Movement Sensor, SMARTFREEZE® Cryo-Cable, and SMARTFREEZE® Catheter Extension Cable)

(hereinafter Cryoablation Catheter), which was approved for commercial use and sale by the Food and Drug Administration (FDA) on August 8, 2023. The pre-market approval (PMA) application number is P220032.[1]

BSSI is required to provide evidence of authorization for its reliance on marketing applicant Boston Scientific Corporation's activities before the FDA.

In accordance with 35 U.S.C. 156(d)(1) and 37 CFR 1.740, MPEP 2752 provides as follows:

> If the applicant for patent term extension was not the marketing applicant before the regulatory agency, then there must be an agency relationship between the patent owner and the marketing applicant during the regulatory review period. To show that such an applicant is authorized to rely upon the activities of the marketing applicant before the Food and Drug Administration or the Department of Agriculture, it is advisable for the applicant for patent term extension to obtain a letter from the marketing applicant specifically authorizing such reliance.

[1] Concurrently, BSSI filed a PTE application for U.S. Patent No. 8,187,261 based on the FDA's premarket review of the same product.

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The last sentence of the paragraph bridging pages 1-2 of the PTE application states, "BSSI is a wholly-owned subsidiary of Boston Scientific Corporation." Even if BSSI is a wholly-owned subsidiary of Boston Scientific Corporation as stated, it is not clear on the record of this PTE application that BSSI is entitled to rely on the activities of Boston Scientific Corporation before the FDA in connection with the filing of the PTE application for U.S. Patent No. 6,929,639.

PTE applicant BSSI is required, pursuant to 37 CFR 1.750, to establish on the record of this PTE application that it is entitled to rely on marketing applicant Boston Scientific Corporation's activities before the FDA. An authorization letter from an appropriate representative of Boston Scientific Corporation would satisfy this Requirement for Information.

BSSI must submit a response to this Requirement for Information within **TWO MONTHS** from the date of this letter. Extensions of time under 37 CFR 1.136 are available. Failure to respond will result in the application for patent term extension being withdrawn.

Any correspondence from the PTE applicant with respect to this matter should be submitted via the USPTO patent electronic filing system using the appropriate document description.

Inquiries related to this determination should be directed to the undersigned at 571-272-7754 or kathleen.fonda@uspto.gov.

*/Kathleen Kahler Fonda /*_____
Kathleen Kahler Fonda
Senior Legal Advisor
Office of Patent Legal Administration

cc: FDA, CDER, Office of Regulatory Policy
10903 New Hampshire Avenue
Bldg. 51, Room 6250
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

re: Boston Scientific Cardiac Cryoablation System