

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re:)
)
Sorin 3T Heater-Cooler Litigation) MDL DOCKET NO. _____
_____)

**MEMORANDUM IN SUPPORT OF MOTION OF PLAINTIFFS
WEST AND AUSTIN FOR TRANSFER AND COORDINATION OR
CONSOLIDATION UNDER 28 U.S.C. §1407**

I. INTRODUCTION

The individual and representative Plaintiffs in the *West, et al. v. Sorin Group Deutschland GmbH, et al.* action respectfully request that the Judicial Panel on Multidistrict Litigation (“the Panel”) select an appropriate transferee district and judge for the coordination and consolidation of the Sorin 3T Heater-Cooler litigation in order to promote the just and efficient conduct of all federal actions under the comprehensive jurisdiction of a single court. Plaintiffs specifically request that the Panel transfer the actions to the United States District Court for the District of South Carolina, Greenville Division, and assign the Honorable Bruce H. Hendricks as the transferee judge. The District of South Carolina, Greenville Division, is an appropriate place to consolidate the litigation because the majority of the pending cases are filed in the District of South Carolina and assigned to Judge Hendricks, with the majority of plaintiffs’ witnesses and much of the documentary evidence located there. Further, it is a convenient location for the parties and counsel because there are adequate hotels and an international airport.

II. BACKGROUND

The plaintiffs in all of the actions subject to the pending motion bring claims arising from exposure to Mycobacterium Chimera (“*M. chimaera*”) or Mycobacterium abscessus (*M. abscessus*) from Defendants’ Sorin 3T Heater-Cooler System, a device used to regulate blood temperature during

surgical procedures. This type of bacteria occurs naturally in the environment and in only rare circumstances causes illness. Because the Sorin 3T Heater-Cooler System aerosolized bacteria into the operating room during open chest surgeries, patients were exposed to a greater amount of bacteria than naturally occurring background levels. Exposure to *M. chimaera* or *M. abscessus* is extremely risky to individuals with compromised immune systems, especially individuals who have undergone surgical procedures.

This type of bacteria is slow growing and can take anywhere from a few weeks to more than a year to present or manifest. Symptoms are non-specific and may include fever, pain, heat or pus around a surgical incision, night sweats, joint and muscle pain, weight loss, and fatigue. An infection diagnosed early may be successfully treated with a series of antibiotics. Notably, there is a significant risk of death in cases with a late diagnosis and/or when individuals have a more weakened immune system.

The Sorin 3T Heater-Cooler System regulates blood temperature by circulating water through tubes into a heat exchanger (for example, cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) where blood is pumped into separate chambers during surgery. The water in the tanks is aerosolized through the exhaust system, which may contain *M. chimaera* or *M. abscessus*. Either of these two mycobacteria can then be released out of the device into the ambient air of the operating room through the Sorin 3T Heater-Cooler System's exhaust fan. Thus, if the device is placed in the operating room, the device's contaminated vapor is released into the sterile surgical space and comes in direct contact with the patient's open body.

In 2006, Defendants submitted a 510K premarket notification of intent to the FDA in order to market the device in the United States. The FDA determined the device was equivalent to legally

marketed predicate devices, and thus did not require approval. This finding by the FDA allowed Defendants to commercially distribute the Sorin 3T Heater-Cooler System. Significantly, Defendants were still required to comply with the Federal Food, Drug, and Cosmetic Act (“the Act”).

In early 2014, patients began testing positive for *M. chimaera* or *M. abscessus*. A majority of those infected were patients who underwent procedures that utilized cardiopulmonary surgical equipment. Based on this discovery, hospitals began sending letters to patients alerting them to their possible exposure to *M. chimaera* and the associated risks. By June 2015, the FDA issued a Class II recall of the Sorin 3T Heater-Cooler System due to potential bacterial issues, including *M. chimaera* or *M. abscessus*, if the device was not properly disinfected and maintained. As a result of and in conjunction with the recall, Sorin issued a Field Safety Notice Letter in June 2015 to the European Union and a second letter in August 2015 to the United States in which Sorin provided new Instructions for Use and stressed the importance of proper use. At the time of these letters, Defendants knew or should have known that neither proper maintenance nor new instructions would substantially reduce the risk of *M. chimaera* or *M. abscessus*.

In December 2015, the FDA issued a Warning Letter to Defendants, which indicated that its inspection of Sorin’s facilities in Germany and Colorado revealed the Sorin 3T Heater-Cooler System devices were not in compliance with federal regulations. The Warning Letter set forth several other violations.

III. PENDING ACTIONS

In addition to their pending case, Plaintiffs are aware of the fourteen (14) other federal cases listed in the accompanying Schedule of Actions. Of the fifteen (15) total actions subject to this pending MDL petition, ten (10) are currently pending in the District of South Carolina and

assigned to the Honorable Bruce H. Hendricks. As noted below, all of these actions involve common factual issues, claims against the same Defendants, and common legal theories and requests for relief.

IV. ARGUMENTS

A. **TRANSFER TO ONE DISTRICT FOR COORDINATION OR CONSOLIDATED PRETRIAL PROCEEDINGS WILL ENSURE THE JUST AND EFFICIENT CONDUCT OF THE ACTIONS AND AVOID INCONSISTENT OR CONFLICTING SUBSTANTIVE AND PROCEDURAL DETERMINATIONS**

The purpose of 28 U.S.C. §1407 is to provide centralized management, under a single court's supervision, of pretrial proceedings of litigation arising in various districts to ensure the just and efficient conduct of such actions. *In Re New York City Mun. Sec. Litig.*, 572 F.2d 49 (2d. Cir. 1978). The transfer of actions to a single forum under §1407 is appropriate where it will prevent duplication of discovery, and most importantly, in the instant case, where it will eliminate the possibility of overlapping or inconsistent determinations by courts of coordinate jurisdiction. *In re Litig. Arising From Termination of Retirement Plan for Employees of Fireman Fund Ins. Co.*, 422 F. Supp. 859 (Jud. Pan. Mult. Lit. 1978).

The litmus test of transferability and coordination under §1407 is in the presence of common questions of fact. *In re Fed. Election Campaign Act Litigation*, 511 F. Supp. 821 (Jud. Pan. Mult. Lit. 1981). In ten (10) of the fifteen (15) pending actions, the respective plaintiffs assert nearly *identical* claims for negligence, strict products liability, breach of express warranty, breach of implied warranty, negligent misrepresentation, misrepresentation by omission, and unfair trade practices against Defendants. The remaining actions assert similar claims for negligence and strict liability through design defect, warning defect, and manufacturing defect, along with claims for declaratory relief and medical monitoring.

At the heart of each of the Scheduled Actions are common factual questions, which include:

- Whether Defendants were negligent in the design of the Sorin 3T Heater-Cooler System;
- Whether Defendants were negligent in the manufacturing of the Sorin 3T Heater-Cooler System;
- Whether Defendants knew or reasonably should have known that their device produced *M. chimaera* or *M. abscessus*;
- Whether Defendants' device caused illness and/or death;
- Whether Defendants concealed evidence of the device releasing *M. chimaera* or *M. abscessus*;
- Whether Defendants concealed evidence of potential risk;
- When Defendants became aware of the defect;
- Whether Defendants made misrepresentations or omissions to the FDA; and
- The time period in which Defendants placed patients at risk for *M. chimaera* or *M. abscessus*.

Determination of these factual issues is essential to all claims arising from Defendants' actions in all pending cases and future cases that may arise throughout the country.

Moreover, transfer and coordination under §1407 before a multiplicity of lawsuits have begun to generate their repetitive administrative burden on the federal court system will promote judicial economy, efficiency, consistency, and fairness. Early entry of a Transfer Order governing all future filings will minimize unnecessary filings in other districts, prompt original filings in the transferee district, and may eliminate other filings entirely.

B. THE FORUM SELECTION CRITERIA UNDER § 1407 FAVOR TRANSFER TO THE DISTRICT OF SOUTH CAROLINA, CHARLESTON DIVISION.

Plaintiffs respectfully request that the Panel transfer the individual cases arising out of Defendants' negligence and misrepresentation to the District of South Carolina, Greenville Division, because it is the location most likely to serve the convenience of the parties, witnesses,

and counsel in the numerous actions. A majority of the cases are pending in the District of South Carolina. The potential claims arising from patients whose surgical procedures involved a Sorin 3T Heater-Cooling System could conceivably be filed in a number of additional federal jurisdictions. Consequently, consolidation in the District of South Carolina, where witnesses and documents are available, the first substantial outbreak involving this medical device occurred, and the CDC has inspected the devices, and which is a location convenient for the majority of parties and counsel, would serve the interests of all parties in ensuring the just and efficient conduct of all actions and the greatest convenience to witnesses, parties, and counsel. Moreover, the Honorable Bruce H. Hendricks should be assigned as the transferee judge because she is currently presiding over ten (10) of the fifteen (15) filed cases, she is familiar with the factual and legal background of the cases, and she has experience as a MDL transferee judge.

Respectfully submitted,

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al.*, Civil Action No. 3:17-cv-00218 (D.S.C.)