BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: **SORIN 3T HEATER-COOLER LITIGATION** **This Document Relates To:** *Brackenbury v. Sorin Group Deutschland, et al.* *Garver v. Sorin Group Deutschland, et al.*	**MDL No. 2816**

INTERESTED PARTIES' RESPONSE IN OPPOSITION TO MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407

INTRODUCTION

Sorin's motion for transfer and consolidation omits more useful information than it provides, leaving a trail of false impressions. There are compelling factual and legal reasons to **not** consolidate any of the Stockert 3T lawsuits. Even more compelling are the arguments for **not** consolidating the "signature" Stockert 3T cases – those involving an *M. chimaera* infection. Accordingly, Plaintiffs Brackenbury and Garver (the [redacted] Plaintiffs) respectfully submit this opposition to transfer and consolidation pursuant to JPML Rule of Procedure 6.2(e).

Consolidation should be denied here for several reasons, some of which apply to all Stockert 3T cases, and one which applies specifically to the *M. chimaera* lawsuits. First, Sorin has long since admitted that the important investigative work needed in these cases is *localized* discovery from the hospitals and medical providers that used the Stockert 3T during a Plaintiff's open-heart surgery, rather than *common* discovery from Sorin that would be useful to all Plaintiffs. The need for substantial localized discovery in every lawsuit predominates over common discovery issues in this litigation, which weighs strongly against consolidation.

Second, a new "sharing agreement" enables all law firms representing Plaintiffs to secure access to the *common* discovery obtained from Sorin by Anapol Weiss, which filed some of the first cases. The fact that this key discovery from Sorin is readily available to Plaintiffs' counsel in all Stockert 3T cases makes it highly unlikely that Sorin will be burdened by unreasonable requests for additional discovery, and again argues strongly against consolidation.

Third, Sorin's proposal that *every* Stockert 3T case (except *Baker*) be consolidated in *one* MDL is a recipe for years of needless delay. Many different types of Stockert 3T lawsuits have been filed: medical monitoring; three different *identified* bacterial species; seven cases of *unidentified* bacterial species; and one unspecified "infection." These cases will require different discovery and different experts, and those differences are important. If a "one-size-fits-all" Stockert 3T MDL were created today, the transferee judge would have to deal with at least five distinct "buckets" of claims. Sorting through all of those buckets would take a long, long time.

Finally, the *M. chimaera* cases are unique and must be treated as such to avoid undue prejudice to the *M. chimaera* Plaintiffs. The *M. chimaera* cases are the only ones in which the *source* of the bacteria that caused the Plaintiff's infection is known (the *M. chimaera* bacteria was imported from Sorin's factory in Germany). The *M. chimaera* cases are also unique because *M. chimaera* victims have a disturbingly high 50% mortality rate. Time is of the essence for every *M. chimaera* victim lucky enough to still be alive. Unlike the cases where the source of the bacteria causing the infection is unknown, the *M. chimaera* cases can be fast-tracked to trial because few if any causation facts are subject to dispute. Consolidation would immediately derail every case, even those approaching trial. The delay would likely sound the death knell for the *M. chimaera* Plaintiffs who are still living. Putting the brakes on those cases would unduly prejudice the *M. chimaera* victims, who should be allowed to seek justice from Sorin while they are still alive.

Under these facts, the consolidation of all Stockert 3T cases would not be convenient for the parties and witnesses, nor would it promote the just and efficient conduct of these lawsuits. *See* 28 U.S.C. § 1407(a). Consolidation of the *M. chimaera* cases would not only fail to meet the statutory goals, but would also derail the schedules already in place, unnecessarily and unjustly prejudicing the Plaintiffs who most desperately need the earliest possible trial dates.

For the reasons explained more fully below, the [redacted] Plaintiffs respectfully request that the Panel deny consolidation as to all Stockert 3T cases. They further request that if any consolidation is ordered, it specifically exclude the *M. chimaera* cases. Alternatively, if the *M. chimaera* cases are consolidated, Plaintiffs ask that those cases be consolidated in a *separate* MDL, set apart from all other Stockert 3T cases, in the District of Minnesota before the Honorable Judge Wilhelmina M. Wright. As further alternatives, Plaintiffs ask that the consolidation of *M. chimaera* cases occur, again in an entirely separate MDL that can facilitate prompt trial settings, in the Middle District of Pennsylvania before the Honorable Judge John E. Jones, III, or in the Southern District of Iowa before the Honorable John A. Jarvey.

FACTUAL BACKGROUND

A. WHAT IS THE STOCKERT 3T?

The Stockert 3T Heater-Cooler is used to regulate a patient's body temperature during open-heart surgeries. It has separate circuits of circulating water. The Stockert 3T pumps *warm* water to control the patient's blood and body temperature. It also pumps *cold* water to keep the "cardioplegia" (heart-stopping) solution cold so the patient's heart can be temporarily stopped during the open-heart surgery.[1] Unfortunately, the Stockert 3T was not designed to prevent the spread of infection-causing bacteria to patients in the operating room. As stated by the FDA:

[1] *See, e.g.*, LivaNova/Sorin webpage for the 3T: http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t; *see also* Exhibit 1 (Haller S, et al., *Contamination during production of*

> Although the water in the circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device or to aerosolize, transmitting bacteria through the air and through the device's exhaust vent into the environment and to the patient.

Exhibit 2 (Updated FDA Safety Communication, October 13, 2016).

B. THE LINK BETWEEN THE STOCKERT 3T AND *M. CHIMAERA* INFECTIONS.

The FDA, CDC, European authorities and medical scientists have linked the use of the Stockert 3T in open-heart surgeries to an outbreak of *M. chimaera* infections. The *M. chimaera* bacteria causing the infections has also been traced directly to Sorin's manufacturing plant in Germany. These matters only recently came to light, but have now been carefully studied.[2]

Researchers worldwide have found *M. chimaera* bacteria in Stockert 3Ts used in area hospitals. *See, e.g.*, Exhibit 1, p. 1. *M. chimaera* was also found in brand-new Stockert 3Ts at Sorin's production facility in Germany, and in the pump assembly area at its manufacturing site. *Id.*, p. 3 and Table 2. Extensive environmental testing showed that the *M. chimaera* bacteria was rising to the top of the Stockert 3T's water tank, being aerosolized, and spread to patients:

> The hydrophobic nature of cell membrane of mycobacteria results in exceedingly high concentration of *M. chimaera* at water surfaces and consequently, in bioaerosols. A feature of [Stockert] 3T HCUs [Heater Cooler Units] is the presence of several fans, a large one for heat dissipation in the lower part and smaller fans in the upper part of the device to cool electronic components. One study located aerosolization leakage and dissipation by an upper fan. Aerosol release has been traced to leakage at the edge of the tank's roof. Experiments using particle counters and smoke showed that airflow and emitted bioaerosols of [Stockert 3T] HCUs can disrupt the ultraclean air system designed to protect the operating field.

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heater-cooler units by Mycobacterium chimaera potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016, Euro Surveill. 2016, http://dx.doi.org/10.2807/1560-7917.ES.2016.21.17.30215).

[2] *See, e.g.*, Exhibit 3 (European Centre for Disease Prevention and Control, *Invasive cardiovascular infection by Mycobacterium chimaera associated with the 3T heater-cooler system used during open-heart surgery, 18 November 2016* (noting that 52 cases of *M. chimaera* infection following open-heart surgery have been detected since 2011).

Exhibit 4, p. 3 (Schreiber, et al., *Mycobacterium chimaera infections associated with heater-cooler units in cardiac surgery,* Current Opinion in Infectious Diseases: Aug. 2017, Vol. 30, Issue 4) (footnotes omitted).

Scientists using sophisticated gene sequencing technologies have also shown that the strain of *M. chimaera* found in the Stockert 3T is the same strain being found in infected patients. The CDC recently provided a useful summary of those studies and others directed to the link between *M. chimaera* infections and the Stockert 3T:

> CDC in collaboration with National Jewish Health completed a whole-genome sequencing analysis and results demonstrate that *M. chimaera* isolates from patients with heater-cooler associated infections and from the [Stockert] 3T heater-cooler devices from several U.S. hospitals (in Pennsylvania and Iowa) are all highly related to each other. This evidence for likely point-source contamination of the [Stockert] 3T heater-cooler devices is consistent with recent reports from Europe [hyperlink omitted] that describe matching of *M. chimaera* sequences from environmental isolates at the device production site in Germany and isolates from patients and devices in Europe.

Exhibit 5 (CDC Health Advisory, *CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used During Cardiac Surgery*, Oct. 13, 2016).

For Plaintiffs with *M. chimaera* infections, the source of those infections is clear: *M. chimaera* was present in the Stockert 3T at the time it was manufactured, imported to the U.S., and sold. The *M. chimaera* Plaintiffs were infected when the bacteria was aerosolized while the Stockert 3T was being used during their open-heart surgeries.

C. THE STOCKERT 3T LAWSUITS FALL INTO MARKEDLY DIFFERENT "BUCKETS."

Sorin is asking this Panel to consolidate virtually every lawsuit that names the Stockert 3T, whether the claims involved in those lawsuits are similar or not, and whether consolidation would unduly prejudice any of the Plaintiffs. The table below illustrates the various buckets that a transferee judge would be forced to deal with if all cases were consolidated:

Alleged Infection Type	Plaintiffs (by last name of first-named Plaintiff)
M. chimaera (16)	Garver; Green; Sheely; Adams; Crawford; Prescott; Reed; Smith, Terrance; Thomas; Kuhnmuench; Brackenbury; Diaz; Whipkey; Eisenberg; Cantrell; Susco
M. abscessus (14)	Dezenski; Ramierez; Blevins; Colson; Bagwell; Fowler; Gilstrap; Johnson; Mattison; Smith, De Young; Thomason; Waddell; Weinacker; Lamar
M. fortuitum (1)	Faeth
MAC (non-specific) (4)	Poole; Jenkins; Stewart; Hershey
NTM (non-specific) (3)	Goree; Sykes; Kmak
Non-specific Infection (1)	Abplnalp
N/A (medical monitoring) (2)	Pickrell; Sawvel

An understanding of the basic characteristics of each type of claim helps show why consolidation is not appropriate.

1. *M. chimaera* infections (16 cases).

Sorin has identified 16 mycobacterium chimaera (*M. chimaera*) lawsuits. An *M. chimaera* infection is the "signature" injury caused by the Stockert 3T. The *M. chimaera* cases are unique because they are the only Stockert 3T lawsuits for which the *source* of the bacteria that caused the infection is known. As discussed above in Part B, the Stockert 3Ts were contaminated with *M. chimaera* when they were built at Sorin's factory in Germany.

M. chimaera also differs greatly from other NTM (nontuberculosis mycobacterium) infections in its effect on the body. Unlike *M. abscessus* and *M. fortuitum* – the other two NTM species specifically identified in the Stockert 3T lawsuits – *M. chimaera* is a slow-growing

bacterium. *See, e.g.*, Exhibit 1, p. 1. It may take months or years before symptoms of an *M. chimaera* infection begin to appear.[3] The scientific literature describes the *M. chimaera* cases as involving "invasive" or "disseminated" infections that affect much or all of the body, rather than just one organ or the site where the infection first developed. *See generally*, Exhibits 1, 3. Patients with *M. chimaera* infections have a very high mortality rate.[4]

2. *M. abscessus* infections (14 cases).

M. abscessus is a rapid-growing NTM commonly found in soil and water, and is most closely identified with the southeastern United States.[5] It is the most common of the rapid-growing NTMs, and one of the leading causes of lung disease. *Id.*

The [redacted] Plaintiffs are not aware of any evidence linking the source of the *M. abscessus* bacteria to the Stockert 3T at the time of its manufacture, or to Sorin's manufacturing plant in Germany. This means the *M. abscessus* cases will require extensive and detailed discovery of potential sources of *M. abscessus* bacteria at the hospital where each Plaintiff's open-heart surgery took place, as well as detailed discovery regarding the bacteria monitoring and infection protocols in effect at each hospital. All of that discovery will be largely or entirely irrelevant to the *M. chimaera* cases, where the source of the bacteria and the means of its transmission to the patient are already known.

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[3] *See, e.g.*, Complaint for Plaintiff Garver, alleging open-heart surgery on September 10, 2014, and development of *M. chimaera* infection in February 2017; compared to Complaint for Plaintiff Bagwell, alleging open-heart surgery on March 20, 2014, and development of *M. abscessus* infection in April 2014.

[4] *See, e.g.*, Exhibit 4, p. 1 ("Mycobacterium chimaera infections following cardiac surgery have been reported from an increasing number of countries. These infections are characterized by a poor prognosis with a case fatality rate around 50% despite treatment.").

[5] *See, e.g.*, Exhibit 6 (Johnson, Margaret M., and Odell, John A., *Nontuberculous Mycobacterial Pulmonary Infections*, Journal of Thoracic Disease, Vol. 6, No. 3, March 2014).

3. *M. fortuitum* infections (1 case).

M. fortuitum is another fast-growing species of NTM, and is found in water, sewage, and soil. *M. fortuitum* infections can lead to lung disease, but more commonly lead to skin disease, bone inflammation, joint infections, or eye disease.[6]

The [redacted] Plaintiffs are again unaware of any evidence linking the source of the *M. fortuitum* bacteria to the Stockert 3T at the time of its manufacture, or to Sorin's manufacturing plant in Germany. Like the *M. abscessus* cases, the *M. fortuitum* lawsuit will require extensive local discovery regarding potential sources of the bacteria, and the protocols used at the hospital where the Plaintiff's open-heart surgery was done.

4. Mycobacterium avium complex (MAC) (4 cases).

Some of the tests used for the identification of bacterial infections go only to a group or "family" level rather than the species level.[7] The mycobacterium avium complex (MAC) is comprised of several different NTM species, including *M. chimaera*, *M. intracellulare*, and *M. avium*. Sophisticated genetic testing is required to narrow an MAC diagnosis to the exact species (e.g., to determine if the MAC infection is *M. chimaera* or some other species). *See* Exhibit 8.

If an MAC infection is ultimately determined to be *M. chimaera*, the source of the infection will be traceable back to the Sorin factory. Otherwise, these four cases will again require extensive localized discovery from the Plaintiff's hospital and medical providers.

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[6] *See* Exhibit 7 (Hemmersbach-Miller, et al., *Cardiac Device Infections due to Mycobacterium Fortuitum*, The Canadian Journal of Infectious Diseases & Medical Microbiology, 2005 May-June; 16(3);183-185).

[7] *See* Exhibit 8 (CDC: *Interim guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units*, May 13, 2016 (noting that the acid-fast bacilli (AFB) test can narrow the species involved in an NTM infection down to the MAC (mycobacterium avium complex) level).

5. Nontuberculous mycobacterium (NTM) (3 cases).

Nontuberculosis mycobacterium (NTM) is a broad category including over 150 known species. NTM are found in many places, and can cause a wide range of ailments, ranging in severity from skin disorders to systemic organ failure. As with the MAC cases discussed above, unless further testing determines that the bacteria species involved was *M. chimaera*, extensive discovery from the Plaintiff's hospital and medical providers will be required.

6. Unspecified infections (1 case).

One case involves an unspecified infection. Whether that turns out to be a *bacterial* infection or a *viral* infection, the situation will be similar to that described above for MAC and NTM cases. Unless further testing determines that the infection was caused by *M. chimaera*, extensive localized discovery will be required from the Plaintiff's hospital and medical providers to the determine potential sources for the bacteria or virus, and the applicable protocols.

7. Medical monitoring (2 cases).

Sorin has asked that two medical monitoring cases in Iowa be consolidated with all of the other Stockert 3T lawsuits. By definition, these are not personal injury cases. These two lawsuits have essentially nothing in common with the other "buckets" discussed above. The discovery necessary to show that the Stockert 3T is capable of spreading infection-causing bacteria in the operating room – and therefor that there is a need to monitor whether a patient develops an infection – is very minimal. It has already been scientifically demonstrated that the Stockert 3T can aerosolize *M. chimaera* and spread it to open-heart surgery patients, some of whom later develop infections.

D. THE PARTIES' NEW DISCOVERY SHARING AGREEMENT.

When this matter was before the Panel earlier this year and Sorin *opposed* consolidation, Sorin had a limited discovery sharing agreement with the Anapol Weiss firm. The agreement

allowed Anapol Weiss to use Sorin's confidential documents in other cases where the firm was counsel of record. *See* Exhibit 9, p. 4 (*Baker* Protective Order).

On August 14, 2017, Sorin agreed to a new and much broader sharing agreement. This new agreement gives all law firms representing Plaintiffs in the Stockert 3T litigation access to the confidential discovery documents Anapol Weiss has obtained from Sorin, provided the Plaintiff's firm has a protective order in place in their own lawsuit. *See* Exhibit 10, pp. 3-4 (*Baker* First Amended Protective Order). Accordingly, Plaintiffs' firms no longer need to individually approach Sorin to obtain copies of its confidential documents.

E. THE ONLY MATERIAL CHANGE SINCE SORIN OPPOSED CONSOLIDATION EARLIER THIS YEAR IS AN INCREASE IN THE NUMBER OF CASES – ALL OF THE OTHER FACTORS WEIGHING AGAINST CONSOLIDATION REMAIN THE SAME.

As alluded to in the Introduction, Sorin omitted a great deal of information from its motion for transfer and consolidation. Chief among those omissions was any acknowledgement of the many factors Sorin cited earlier this year as weighing heavily *against* consolidation, and an acknowledgment that those factors remain unchanged today. A close runner-up was the lack of even the most basic explanation of why an increase in the number of cases – in what all Parties agree appears to be a small litigation – can't be dealt with by other means.

ARGUMENT

Consolidating cases is not the usual practice in our justice system, and should be regarded as "the last solution after considered review of all other options." *In re Best Buy Co., Inc., Cal. Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011).

In the matter before this Panel, centralizing the Stockert 3T lawsuits is certainly not "the last solution" that would accommodate the Parties. Consolidation would not make this litigation more convenient for the parties or witnesses, and would not promote the ends of justice and

efficiency. Sorin's request for transfer and consolidation pursuant to 28 U.S.C. § 1407(a) should therefore be denied.

A. CONSOLIDATION IS NOT WARRANTED FOR ANY OF THE STOCKERT 3T CASES.

1. The Need for Extensive Localized Discovery Overwhelms any Need for Common Discovery.

Sorin appears to have forgotten that when it *opposed* consolidation in February 2017, it argued vigorously that highly localized **"hospital-specific, bacteria-specific, and plaintiff-specific questions of fact"** would **"overwhelm any common background issues."** Sorin Resp. in Opp'n, pp. 1, 6, Feb. 17, 2017, MDL 2772, Dkt. 18 (bolding added) (hereinafter, "Sorin Opp'n"). Sorin also correctly noted in February that the obvious need for **"significant localized discovery … weighs heavily against centralization."** *Id*., p. 9 (bolding added), citing *In re Boehringer Ingelheim Pharms., Inc. Fair Labor Standards Act Litig.*, 763 F. Supp. 2d 1377 (2011).

The need for extensive local discovery has not changed over the last few months, nor has the fact that cases are *not* good candidates for coordination when significant localized discovery predominates over common issues. *See, e.g., In re Electrolux Dryer*, 978 F. Supp. 2d 1376, 1377 (J.P.M.L. 2013) (denying consolidation when individualized issues regarding allegedly defective dryers would predominate over shared issue of alleged design defect); *see also In re American Manufactured Drywall Prods. Liab. Litig.*, 716 F. Supp. 2d 1367, 1368 (J.P.M.L. 2010) ("The proponents of centralization have not convinced us that any efficiencies from centralization would outweigh the multiple individualized issues, including ones of liability and causation, that these actions appear to present.").

The Stockert 3T cases also have very few common issues. As Sorin aptly noted in its brief opposing consolidation back in February:

> [T]he Pending Cases involve two ***different types of alleged bacterial infection***: *M. chimaera* and *M. abscessus*. These allegations implicate bacteria-specific and hospital-specific issues that preclude the treatment of these bacterial infections as "common."

Sorin Opp'n at 8 (bolding and italics in original). Sorin also correctly noted that **"these two bacteria exhibit distinct profiles that will affect the analysis of liability, product defect, causation, and damages, as well as the corresponding discovery needed to address those issues."** *Id*. (bolding added). There is now a lawsuit with a third bacterial species, *M. fortuitum*, which makes it harder still to find any material common issues. It is also worth noting that Sorin is alleging the fault of third parties, presumably the Plaintiffs' medical providers, in its Answers to Plaintiffs' Complaints. *See, e.g.*, Exhibit 11 (Sorin Answer to Brackenbury Compl., Defenses 2, 4, 6, 8, 10, 11, 22 and 28). This confirms that localized discovery will predominate, as Sorin tries to deflect fault onto the local medical providers.

Finally, Plaintiffs ask that the Panel consider how unusual these lawsuits are with respect to the liability case against Sorin. In a typical drug or medical device case where consolidation is under discussion, a great deal remains unknown about exactly how the drug or device caused injury. A key "common issue" in such cases is obtaining the discovery from the Defendant that will help develop the liability story. Here, thanks to the efforts of the researchers who first became aware of the issues with the Stockert 3T, we already have a wealth of scientific literature on the device, and much of the liability story has already been written:

> [O]nly an elegant and painstakingly thorough outbreak investigation by several international groups revealed and identified the aspects of [the Stockert 3T] that led to patient harm.

Exhibit 4, p. 5. Discovery from Sorin of course remains a "common issue," but it pales in comparison to the localized discovery issues, and it is not "complex." When common issues of fact lack sufficient complexity, centralization is inappropriate. *See In re Air Crash near*

Canadaigua, N.Y. on Sept. 16, 2002, 427 F. Supp. 2d, 1365, 1365 (J.P.M.L. 2006). Also, as discussed below, voluntary coordination of discovery from Sorin has made it possible for all Plaintiffs' firms to obtain Sorin's confidential documents, which again weighs against the consolidation of the Stockert 3T lawsuits.

2. The Parties' Expansive Sharing Agreement Gives Sorin Ample Protection on Any Common Discovery Issues.

When this case was argued before the Panel on March 30, 2017, concern was expressed about Sorin's refusal to agree to share its discovery with all Plaintiffs' firms. Judge Kaplan, after learning of Sorin's reluctance to enter into a broad-based sharing agreement, addressed the following to Sorin's counsel:

> Your client's position about making the discovery available under a common protective order, no fuss, no muss, to whoever's got a case, is **the strongest argument I've heard for granting consolidation.**

Oral Arg. Tr., Mar. 30, 2017, MDL No. 2772, Dkt 30, p. 15:7-10 (bolding added). Several months later, Sorin changed its position and executed an amended protective order that allows its confidential discovery documents to be shared with all firms. *See* Exhibit 10, pp. 3-4. Accordingly, the "strongest argument for granting consolidation" no longer exists.

The sharing agreement is also important for another reason. The six Anapol Weiss *M. chimaera* cases (Adams, Crawford, Prescott, Smith (Terrance), Thomas and Whipkey) are already being informally coordinated for discovery purposes. Recent filings show that three more *M. chimaera* Plaintiffs (Eisenberg, Reed, and Sheely) also plan to informally coordinate on discovery. *See* Dkt. 33, 23 and 30. The two [redacted] Plaintiffs (Brackenbury and Garver) have *M. chimaera* cases, and also intend to participate in the informal coordination. This means at least 11 of the 16 *M. chimaera* Plaintiffs approve of the informal coordination. There can be – at most –

only *five* cases in which informal coordination is *not* being pursued, and that number is likely closer to zero than five.

In view of the above, there is no reason to believe that Sorin will be subject to unreasonable requests for additional discovery when its documents are now available to all Plaintiffs' firms. Given the very low number of *M. chimaera* cases in particular, "informal cooperation among the involved attorneys is both practicable and preferable to centralization." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014).

3. Consolidating the Many Different Types of Stockert 3T Lawsuits, with Different Liability Theories, Discovery Needs and Expert Witness Needs, would Cause Needless Delay and Inefficiency.

The Stockert 3T claims differ significantly from each other. Putting all of them together under one roof would not be helpful. Sorin argued persuasively – and correctly – when it *opposed* consolidation in February 2017 that the multiple categories of Stockert 3T cases are very different from each other and should *not* be combined. *See, e.g.*, Sorin Opp'n at 6 (medical monitoring and personal injury claims are ***"fundamentally different claims"***) (bolding and italics in original), and pp. 8-9 (differences in bacterial infection outbreaks "implicat[e] different alternative causation issues"). These "fundamental" differences have not gone away since February.

a. Different Liability Theories.

The different case types discussed above have different liability theories. For example, Plaintiffs with *M. chimaera* cases have strong manufacturing defect claims. The Stockert 3Ts involved in those cases were not just regular Stockert 3Ts. They came from the Sorin factory "pre-loaded" with the *M. chimaera* bacteria that caused the *M. chimaera* infections. No other Plaintiffs who developed infections appear to have a claim that the infection-causing agent was incorporated into the Stockert 3T involved in their case when it was manufactured. The other Plaintiffs will rely primarily on design defect claims, on the theory that regardless of how or when an infection-

causing agent entered the Stockert 3T, only a design defect caused that agent to be aerosolized and spread to patients in the operating room. These types of differences in liability theories lead to substantial differences in discovery and experts.

b. Different Discovery Needs.

As described above in Argument A(1), Sorin has admitted that the discovery needs of these cases are vastly different. The infection cases would require very localized discovery of – in Sorin's words – "hospital-specific, bacteria-specific, and plaintiff-specific questions of fact." Sorin Opp'n, p. 1, Feb. 17, 2017, MDL 2772, Dkt. 18. No such discovery would be required for any medical monitoring claims.

Also, because of the manufacturing defect claim, the *M. chimaera* Plaintiffs will require extensive discovery from Sorin about the conditions at its manufacturing facility and how the Stockert 3Ts were contaminated with *M. chimaera* when they were built. It is easy to imagine 80% of a Sorin employee's deposition being spent on those topics when *M. chimaera* Plaintiffs are asking the questions. However, since those issues are of little concern to Plaintiffs who developed *other* types of infections, little or no time is likely to be spent on those topics when counsel for non-*M.-chimaera* Plaintiffs are taking a deposition. Conversely, Plaintiffs with non-*M.-chimaera* infections will want extensive discovery on how the Stockert 3T was cleaned and what sources of bacteria it was exposed to, while that will be of far less interest to the *M. chimaera* Plaintiffs.

c. Different Expert Witness Needs.

The different groups of Plaintiffs will need different sets of experts to cover the topics described above. For instance, the *M. chimaera* Plaintiffs will need experts on safe manufacturing practices and quality control techniques that other Plaintiffs will not require. All Plaintiffs who

suffered infections will likely retain experts on product design. There are many types of infections at issue in the Stockert litigation, and each type of infection is likely to require its own expert.

d. Consolidation Will Not Help, and Will Only Cause Delay.

Consolidation can be helpful with common issues, but the issues common to all Plaintiffs in these cases are few and far between. The most important common issue is "Can the Stockert 3T spread aerosolized bacteria throughout the operating room during open-heart surgery?" That question was answered years ago by medical scientists. *See* Part B of the Factual Background section. Moreover, Sorin has entered into a sharing agreement that allows Plaintiffs to obtain the confidential documents Sorin has already produced. Consolidation can do nothing further to meaningfully address common issues, and would only disrupt discovery and trial schedules, forcing substantial delays.

There is ample precedent for denying centralization under facts like these. For instance, consolidation requests have been refused when different injuries have arisen from the same product. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013) (declining to centralize cases alleging autoimmune disorders with cases alleging the product caused perforation or tearing); *see also In re Abbott Labs., Inc., Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376, 1376 (J.P.M.L. 2011) (denying centralization where individual facts predominated, including whether the product was contaminated, whether the contamination was the cause of the alleged injury, and what the alleged injuries were). That is clearly the situation here.

There are also ways for Sorin to effectively deal with these lawsuits without consolidation. The shoulder pain pump litigation provides an example. In that case, centralization was denied, partly because of slight differences in the products and partly because of the individual plaintiff's varying medical histories. *See In re Ambulatory Pain Pump-Chrondrolysis Prods. Liab. Litig.*, 709

F. Supp. 2d 1375 (J.P.M.L. 2010). The Panel may recall that hundreds of pain pump cases were pursued without consolidation. It became commonplace for a Defendant to prepare and offer to the Plaintiff a discovery package consisting of its confidential internal documents, employee depositions and similar materials that had been produced to Plaintiffs in prior cases.

The instant case is similar to the pain pump litigation. There are slight differences in the products (the Stockert 3Ts in the *M. chimaera* cases had manufacturing defects; the other units did not), and the Plaintiff's medical histories are different. Sorin can adopt the same type of approach taken by the pain pump Defendants and prepare discovery packages for the Plaintiffs, or can continue with the informal cooperation and discovery sharing agreements already in place. Sorin already has to make accommodations like that anyway, to deal with the 31 *state court* actions.

It is also important to remember that the infections involved here are very rare (*see, e.g.*, Exhibits 2, 5), and that steps have been taken by hospitals to greatly reduce or eliminate the risk of further infections, such as moving the Stockert 3Ts outside the operating room. *See, e.g.*, Exhibit 4. Consequently, there is no reason to expect this litigation to grow substantially. There is no need for consolidation, particularly when the cases at issue have such stark differences and Sorin has informal means to deal with any discovery issues.

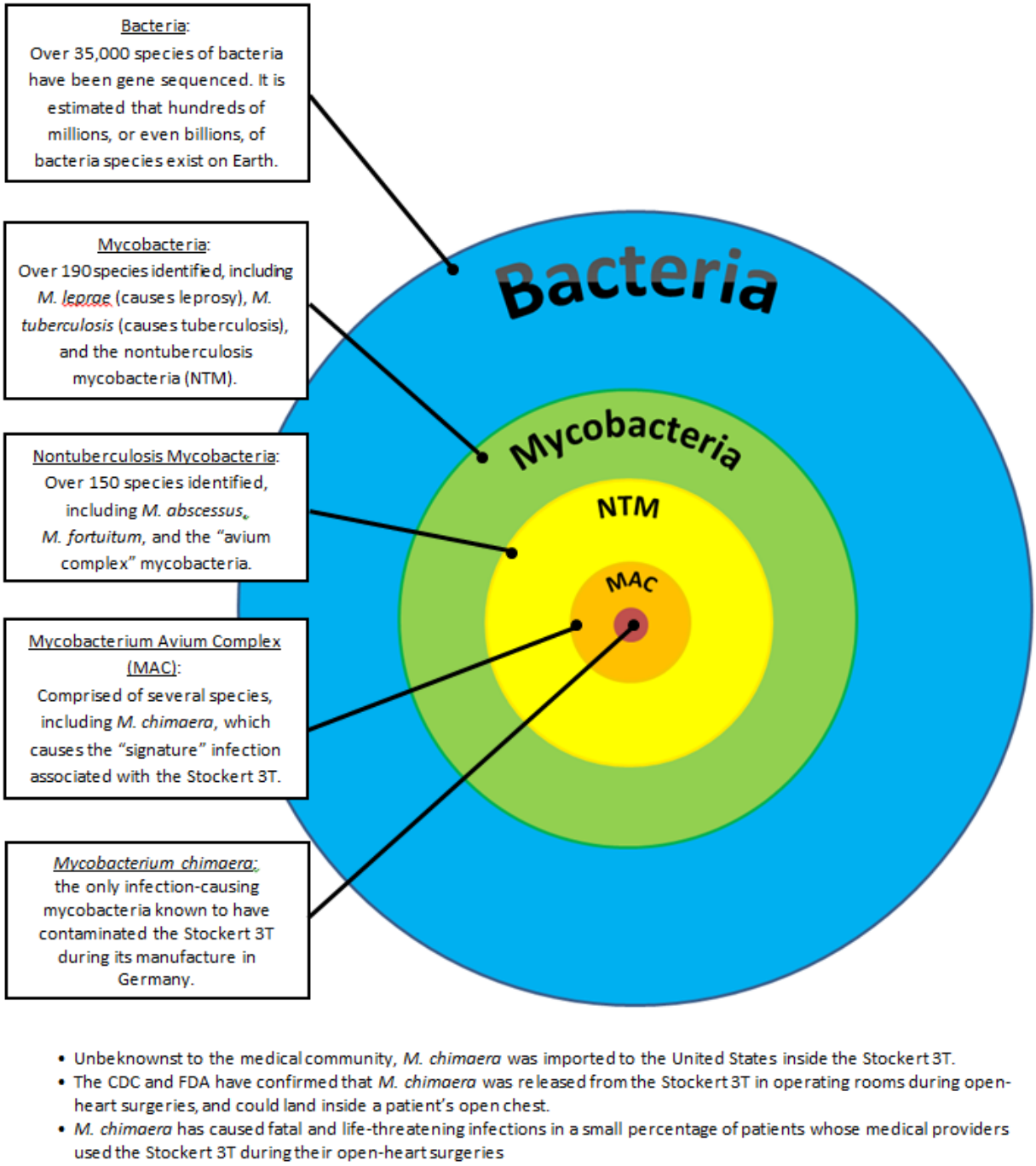
Sorin has not met its burden of showing that centralization will meet the objectives of 28 U.S.C. § 1407(a). *See In re Brandywine Comm. Tech., LLC*, 959 F. Supp. 2d 1377, 1379 (J.P.M.L. 2013). These cases should not be consolidated.

B. CONSOLIDATION OF THE *M. CHIMAERA* CASES IS UNNECESSARY AND WOULD BE PARTICULARLY INAPPROPRIATE BECAUSE THE RESULTING DELAY WOULD BE HIGHLY PREJUDICIAL TO THE *M. CHIMAERA* PLAINTIFFS.

The *M. chimaera* cases are unique in the context of this litigation. They are the only cases in which the source of the bacteria causing the Plaintiff's infection is known. The issues regarding

how the *M. chimaera* contamination occurred and how it was later spread to patients in the operating room by aerosolized water vapor have been thoroughly researched and documented.

To put this in context, a chart has been inserted below showing *M. chimaera* – one specific *species* of bacteria – against the greater world of the bacteria referenced in this litigation:



- Unbeknownst to the medical community, *M. chimaera* was imported to the United States inside the Stockert 3T.
- The CDC and FDA have confirmed that *M. chimaera* was released from the Stockert 3T in operating rooms during open-heart surgeries, and could land inside a patient's open chest.
- *M. chimaera* has caused fatal and life-threatening infections in a small percentage of patients whose medical providers used the Stockert 3T during their open-heart surgeries

Against this background, Plaintiffs respectfully submit that it would not be reasonable or appropriate to take the one specific species of bacteria *known* have come to the U.S. in the Stockert 3T, and *known* to have been disseminated to patients by the Stockert 3T, and consolidate it with all other species of bacteria. Such consolidation would halt every *M. chimaera* case and cause highly prejudicial delays, given the 50% mortality rate that afflicts the *M. chimaera* Plaintiffs. *See* Exhibit 4. There are only 16 *M. chimaera* cases. Since few of the causation facts in those cases are subject to any meaningful dispute, the cases can and should can be put on a fast track to trial, particularly for those *M. chimaera* Plaintiffs who are still alive.

Consolidating the tiny universe of unique *M. chimaera* cases with dozens of different cases whose bacteria have not been directly linked to the Stockert production facility would be highly prejudicial and simply is not necessary. The motion for centralization should therefore be denied.

C. THE DISTRICT OF MINNESOTA OR, ALTERNATIVELY, THE MIDDLE DISTRICT OF PENNSYLVANIA OR THE SOUTHERN DISTRICT OF IOWA ARE THE BEST SUITED FORUMS IF CONSOLIDATION OF THE *M. CHIMAERA* LAWSUITS IS GRANTED.

The [redacted] Plaintiffs believe consolidation is not warranted here, but if the Panel decides to consolidate the *M. chimaera* cases, Plaintiffs respectfully request that an entirely separate MDL be established for those lawsuits, and that they be sent to Judge Wilhelmina Wright in the District of Minnesota. Judge Wright is a highly accomplished jurist who has not yet overseen an MDL. The Panel regularly takes advantage of opportunities to send MDLs to judges who have not had an opportunity to preside over one. *See, e.g.*, *In re Roundup Prods. Liab. Litig.*, 214 F. Supp. 3d 1346, 1348 (J.P.M.L. 2016). Despite being relatively new to the federal bench, Judge Wright has presided at all levels of Minnesota's State Court system during her seventeen years as a judge. Judge Wright brings ample skill and experience to the federal bench. She currently has

one Stockert 3T case in her court, *Brackenbury*, no. 17-cv-4186, where it has been pending since September 2017.

The District of Minnesota would be an excellent venue for the *M. chimaera* cases. While the *M. abscessus* lawsuits have been concentrated in the southeastern United States where the *M. abscessus* bacteria is prevalent, *M. chimaera* cases have been reported across the country. Minnesota is centrally located and has a world-class airport, which makes the city convenient for parties, expert witnesses, and counsel. This venue would also be particularly convenient for Defendant Sorin, since its counsel, the Faegre Baker Daniels firm, are based in Minneapolis.

In the alternative, if the *M. chimaera* cases are consolidated outside Minnesota, Plaintiffs again ask that they be consolidated in an entirely separate MDL that can facilitate prompt trial settings. They further request that the MDL be established in the Middle District of Pennsylvania before the Honorable Judge John E. Jones, III, or in the Southern District of Iowa before the Honorable John A. Jarvey.

CONCLUSION

For the reasons stated above, the [redacted] Plaintiffs do not believe transfer and consolidation will serve the convenience of the parties and witnesses, or promote the just and efficient conduct of this litigation. Plaintiffs respectfully request that the Panel deny consolidation as to all cases, or in the alternative establish an MDL for *M. chimaera* cases only, in the District of Minnesota, or in the Middle District of Pennsylvania or the Southern District of Iowa.

Dated: November 28, 2017

[redacted]

CERTIFICATE OF SERVICE

I, [redacted], hereby certify that, on November 28, 2017, The [redacted] Plaintiffs' Interested Party Opposition to Motion for Transfer and Coordination or Consolidation under 28 U.S.C. §1407 was filed and made available via CMF/ECF to all counsel of record.

[redacted]