

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVANOS MEDICAL, INC.,
Petitioner,

v.

STRATUS MEDICAL, LLC,
Patent Owner.

Case IPR2024-01209
Patent 10,966,782

Case IPR2024-01210
Patent 10,736,688

Case IPR2024-01211
Patent 10,736,688

Case IPR2024-01212
Patent 10,952,664

DECLARATION OF MARK A. KONNO

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I. INTRODUCTION

A. My Background and Experience.

1. My name is Mark A. Konno. I have been retained by counsel for Avanos Medical, Inc. (“Avanos”) as an expert in the above-referenced IPR proceedings. A detailed description of my professional qualifications, including a listing of my specialties, expertise, and professional activities, is contained in my curriculum vitae, a copy of which is attached as Appendix A. Below is a short summary of my professional qualifications.

2. In 1980, I earned my Bachelor of Science with a major in Applied Mechanics and Engineering Sciences, with a specialization in Bioengineering, from the University of California, San Diego. I have also completed the Stanford BioDesign Executive Program, which is a course in managing health technology and medical device innovation and commercialization designed for executives with 10+ years of management experience.

3. I have extensive experience in the commercialization of medical devices. From 2000 through 2022, I served as the R&D leader (VP) for both Critical Care and Surgical Heart Valve businesses at Edwards Lifesciences. In this role, I was responsible for producing double digit growth for these divisions through the implementation of internal and external technical programs aligning with targeted business development strategies. I also oversaw venture acquisitions,

technology licensing, and joint research and development partnerships for these businesses, including the acquisition of BMEye, CASMED, and PVT. At BMEye I served as the on-site COO/GM for 2 years while living in the Netherlands.

4. Prior to my role at Edwards Lifesciences, I served similar roles at Baxter International – Baxter Edwards Laboratories from 1986 through 2000 and at American Hospital Supply – American Edwards Laboratories from 1980 through 1986. In these roles, I oversaw the development and integration of medical device research programs. Notably, my technical decision on the acquisition of InterFlo by Baxter Edwards Laboratories led to \$122 million in sales and gain of 30 market share points over 4 years, and my development of a new hemodynamic monitoring system at American Edwards Laboratories led to an increase of 25 market share points.

5. Since 2022, I have served as a board member of multiple medical device startups and consulted for several medical device companies. Through these positions, I was able to help complete funding to execute a first in man trial, submit preclinical validation studies for FDA clinical protocol approval, and review clinical and regulatory evaluations for optimal next generation commercial designs.

6. I have authored multiple peer-reviewed scientific publications on assorted topics including ventricular performance and cardiac output. These works

have been published in well-respected publications, including the American Society of Anesthesiology, the Journal of Clinical Monitoring, and Critical Care Medicine. I am also a named inventor on multiple patents. A sample of the related topics include transport catheters, prosthetic heart valves, and cardiac implants.

7. I have received multiple awards and honors for excellence in my profession. I have been awarded Baxter Outstanding Technical Contribution, Baxter Special Accomplishment in Science and Technology, and Baxter Distinguished Technical Achievement. I have also been awarded a Six Sigma Black Belt, and I have been named as both the winner and runner up of the E3 annual award for Edwards R&D Technical Achievement. I am a two-time recipient of the Edwards 3-fer CREDO Awards, and I have been listed on Strathmore's Who's Who.

8. In view of this experience, I regard myself as an expert in evaluating medical device companies. I am especially skilled at evaluating small to medium-sized medical device companies attempting to penetrate existing medical device markets.

9. I am being compensated at the rate of \$375/hour for my work on this matter. My compensation does not depend on the outcome of the IPR proceedings.

B. Materials considered

10. In forming my opinions expressed in this declaration, I have reviewed and considered the Declaration of Cody Jorgensen dated May 22, 2025 and marked “Stratus Ex. 2015,” which I will refer to herein as the “Jorgensen Declaration.” This document was provided to me by counsel for Avanos at Meunier Carlin & Curfman LLC. To the extent I am provided with additional documents and information in this proceeding, I may offer further opinions. In forming my opinions expressed herein, I have relied on my education, my extensive professional experience, and the facts asserted in the Jorgensen Declaration.

II. ASSUMPTIONS AND ANALYTICAL FRAMEWORK

11. I was asked by counsel for Avanos to first review the Jorgensen Declaration in its entirety, which I have done in forming the opinions expressed below. I was also asked by counsel for Avanos to assume that all the financial and commercial data provided in the Jorgensen Declaration is accurate. I was also asked by counsel for Avanos to assume that everything asserted as fact in the Jorgensen Declaration is true. In contrast, I have not assumed that all of Mr. Jorgensen’s inferences, conclusions, or opinions are true.

12. Applying these assumptions, I was then asked by counsel for Avanos to consider whether the information provided in the Jorgensen Declaration shows commercial success of the Stratus “Nimbus” device in the U.S. “RFA cannula

market.” *See* Ex-1015, ¶16. In answering this question, I was asked to consider whether the information in the Jorgensen Declaration shows significant sales levels, significant sales growth, substitution towards the Nimbus device and away from alternative products, persistent price premiums for the Nimbus device, the absence of substantial discounting for the Nimbus device, and any other indicators of commercial success that I would deem relevant based on my experience in the medical device industry.

III. ANALYSIS

A. The Jorgensen Declaration does not show significant sales or significant sales growth for the Nimbus device.

13. I refer now to the information provided in the “U.S. Historical Revenue” chart in paragraph 15 of the Jorgensen Declaration. Ex-2015, ¶15. According to Mr. Jorgensen, this chart depicts “Stratus’s total U.S. revenue by quarter from 2020 through 2024.” Ex-2015, ¶15. Mr. Jorgensen also indicates that “[REDACTED] of Stratus’s revenue is from sales of the Nimbus device and associated RF probes.” Ex-2015, ¶14.

14. As an initial matter, I note that the Jorgensen Declaration appears to have some inconsistencies with respect to Stratus’ relevant sales. First, Stratus’ total sales in 2024 are indicated as being [REDACTED], of which I assume [REDACTED] are attributable to “sales of the Nimbus device and associated RF probes” as stated by Mr. Jorgensen. *See* Ex-1015, ¶14. However, the Jorgensen

Declaration also indicates that the total RFA cannula market is sized at about [REDACTED] (Ex-2015, ¶16) and that Stratus has a [REDACTED] market share as of 2024. This would suggest Stratus’ relevant sales are about [REDACTED]. I also note that the “U.S. RFA Cannula Market” chart seems to suggest the total RFA cannula market was closer to \$ [REDACTED] in 2024—higher than what the Jorgensen Declaration suggests in paragraph 16. If this metric were used, Stratus’ [REDACTED] market share would reflect about [REDACTED]. It is unclear to me which number is correct or which number Mr. Jorgensen deems to be relevant.

15. Even assuming the highest of these figures ([REDACTED]), I disagree that Stratus’ revenue figures reflect “remarkable commercial success” as concluded by Mr. Jorgensen. *See* Ex-1015, ¶13. After five full years on the U.S. market, I would not regard the magnitude of revenue for the Nimbus device to be significant. At best, these revenue figures show that Stratus has captured a small and relatively insignificant portion of an existing device market. In the medical device world, sales of [REDACTED] are almost categorically insignificant. This is especially true here, where the total market opportunity appears to be at least [REDACTED]. Ex-2015, ¶16.

16. I also observe that, after five years on the U.S. market, Stratus sales are [REDACTED]. This is the opposite of what I would expect from a product showing “remarkable commercial success” as Mr. Jorgensen states. Based

[REDACTED]

on the information in the “U.S. Historical Revenue” chart (Ex-2015, ¶15), I have summarized Stratus’ annual revenue, Stratus’ year-over-year (YoY) revenue growth, and Stratus’ YoY revenue growth expressed as a percentage in the table below.

FY	Stratus US Revenue	Revenue Growth Over Prior Year	Percent Revenue Growth	Growth Trend
2020	[REDACTED]			
2021				
2022				
2023				
2024				

17. In 2021, Stratus demonstrated [REDACTED] growth over its first year, [REDACTED]. However, this pace almost immediately [REDACTED] with Stratus posting [REDACTED] growth in 2022 (compared to its 2021 U.S. revenue). The following year (2023), Stratus’ rate of growth for U.S. revenue [REDACTED] to [REDACTED]. In 2024, Stratus’s rate of growth [REDACTED] In other words, Stratus’ rate of growth has [REDACTED] with 2024 being [REDACTED] for U.S. revenue growth since Stratus began selling the Nimbus device in the U.S. The same is true for the magnitude of Stratus’ growth. In 2024, Stratus’ revenue grew by [REDACTED]—the [REDACTED] annual revenue growth since Stratus began selling the Nimbus device in the U.S.

18. Based on my extensive experience evaluating emerging medical device companies, it is my opinion that the Stratus revenue and revenue growth figures show a lack of significant commercial success for the Nimbus device. According to Mr. Jorgensen, the RFA cannula market is a “ [REDACTED] market.” Ex-2015, ¶16. A small medical device company attempting to penetrate this market should be posting [REDACTED] growth figures if it were truly “successful.” In other words, the product should be showing that the rate of adoption in the marketplace is [REDACTED]. The data in the Jorgensen Declaration shows the opposite of this. In the five years since its U.S. sales began, Stratus is showing a [REDACTED] rate of growth for Nimbus device. This is not the hallmark of a product enjoying significant commercial success.

19. For at least these reasons, it is my opinion that the Jorgensen Declaration does not show significant sales or significant sales growth for the Nimbus device.

B. The Jorgensen Declaration does not show that Stratus has achieved significant market share in the U.S. RFA cannula market through sales of the Nimbus device.

20. I next refer to paragraphs 17 to 26 of the Jorgensen Declaration and the charts provided with those paragraphs. These portions of the Jorgensen Declaration purport to characterize the relative market shares and performance of the market participants in the “RFA Cannula Market.” Ex-1015, ¶17-26.

21. First, I note that Mr. Jorgensen asserts that Stratus has “[REDACTED]” its share of the RFA cannula market to [REDACTED].” Ex-2015, ¶17. Based on the chart entitled “U.S. RFA Cannula Market ([REDACTED])” in paragraph 17, it appears that Stratus’ market share in 2020 was [REDACTED]

22. With respect to the other market participants, Mr. Jorgensen notes that Stryker and Abbott have “have historically [REDACTED].” Ex-1015, ¶17. This is reflected in the Jorgensen Declaration data, which indicates that Stryker’s market share [REDACTED] from about [REDACTED] in 2020 to about [REDACTED] in 2024, while’s [REDACTED] market share [REDACTED] [REDACTED]. Ex-1015, ¶19 (chart entitled “U.S. RFA Cannula Market: 2020 vs. 2024”). Thus, based on the Jorgensen Declaration, [REDACTED] combined market share [REDACTED] from about [REDACTED] in 2020 to [REDACTED] in 2024.

23. Factoring in the combined market share of [REDACTED] and Stratus’ alleged market share, I can deduce that the remaining RFA cannula market participants would necessarily have accounted for about [REDACTED] of the market in 2020 and about [REDACTED] of the market in 2024. According to the Jorgensen Declaration, these remaining market participants include [REDACTED], and “other” unspecified entities. Ex-1015, ¶17 (chart entitled “U.S. RFA Cannula Market ([REDACTED])”) and ¶19 (chart entitled “U.S. RFA Cannula Market: 2020 vs. 2024”). Based on this information, I have provided the table

[REDACTED]

below that shows the market increase (or decrease) for (i) the market leaders ([REDACTED]), (ii) Stratus, and (iii) the remaining market participants ([REDACTED], and the “other” unspecified entities).

Entities	Combined Market Share (2020)	Combined Market Share (2024)	Change From 2020 to 2024
Market Leaders: [REDACTED]	[REDACTED]		
Stratus Medical			
Other Market Participants: [REDACTED] [REDACTED] and “others”			

24. In my opinion, the chart above demonstrates that—since Stratus began selling the Nimbus device in the U.S.—the control of the market [REDACTED] [REDACTED] has only [REDACTED] From 2020 to 2024, the market [REDACTED] their combined market share [REDACTED]. Stratus’ [REDACTED] market share—which [REDACTED] by only [REDACTED] in the same time period—appears to have been obtained from the [REDACTED] market participants. In other words, the Nimbus device has not resulted in a meaningful change within the RFA cannula market. The market [REDACTED] appear to have [REDACTED] of the market (again, based solely on what is shown in the Jorgensen Declaration).

25. Once again, in my opinion, the foregoing data does not reflect “remarkable commercial success” for the Nimbus device. Stratus appears to, at

[REDACTED]

most, achieved the capture of [REDACTED] market share from the [REDACTED] market participants. Moreover, there is nothing in the Jorgensen Declaration that would suggest this [REDACTED] of sales is due to demand for the Nimbus device features. Indeed, it is possible that these [REDACTED] market participants are simply [REDACTED] their focus or investment in the RFA cannula market.

26. I also note the Jorgensen Declaration's chart showing the "CAGR of U.S. RFA Cannula Market Participants 2020 through 2024." Ex-2015, ¶21. The Jorgensen Declaration suggests that this chart shows that "Stratus is [REDACTED] [REDACTED]." Ex-2015, ¶22. In my opinion, this statement is highly misleading.

27. In short, Stratus' compound annual growth rate (CAGR) is [REDACTED] the remaining market participants because the CAGR is being measured starting in 2020—the year Stratus' sales of the Nimbus device in the U.S. began. Because sales of the Nimbus device during this first year (2020) were [REDACTED] [REDACTED], the CAGR for Stratus is [REDACTED]. See Ex-1015, ¶15 (Stratus U.S. Revenue chart). For example, measuring the CAGR from 2020 allows Stratus to [REDACTED]." Ex-1015, ¶22. But during this period, Stratus' market share [REDACTED] in 2020 to [REDACTED] in 2024. Meanwhile, during the same period, [REDACTED] market share [REDACTED] by about [REDACTED] [REDACTED] in 2024). Thus, despite [REDACTED] market

share than [REDACTED] during the same period, the CAGR chart shows Stratus [REDACTED] in terms of growth. For this reason, it is my opinion that the data included in the chart entitled “CAGR of U.S. RFA Cannula Market Participants 2020 through 2024” does not reflect any significant degree of commercial success for the Nimbus device.

28. For at least the foregoing reasons, it is my opinion that the Jorgensen Declaration does not show that Stratus has achieved significant market share in the U.S. RFA cannula market through sales of the Nimbus device.

C. The Jorgensen Declaration does not show that the Nimbus device is sold at a price premium or without substantial discounting.

29. The Jorgensen Declaration is devoid of any information regarding the Nimbus device’s price. When a supposedly “superior” product is brought to market, my experience is that the purveyor can charge a price premium because customers in the market value those features. That would be particularly true if the product allowed the buyers to reduce their costs, as Mr. Jorgensen seems to suggest the Nimbus does. Ex-2015, ¶10 and 54. But there is no evidence in the Jorgensen Declaration that shows Stratus is able to sell the Nimbus device at a price premium (or without substantial discounting) relative to other devices in the “U.S. RFA cannula market.”

D. The Jorgensen Declaration does not show meaningful customer substitution towards the Nimbus device and away from alternative products.

30. The Jorgensen Declaration indicates that “Avanos sells a product called COOLIEF* that provides large-volume lesions similar in volume to those created by the Nimbus device.” Ex-2015, ¶48. The Jorgensen Declaration indicates further that “since it first began marketing the Nimbus device in the U.S., Stratus has seen [REDACTED] [REDACTED].” Ex-2015, ¶49. However, the Jorgensen Declaration is devoid of any information that allows me to determine how many COOLIEF* accounts [REDACTED] [REDACTED] to Nimbus accounts, or any information that would allow me to determine whether any meaningful customer substitution has occurred with respect to COOLIEF* and the Nimbus device. Indeed, even the Avanos market share information included elsewhere in the Jorgensen Declaration does not indicate the portion of sales attributable to COOLIEF* (if any). Ex-2015, ¶17-24.

31. I also note an allegation in the Jorgensen Declaration that a company called Diros Technology Inc. (“Diros”) has copied the Nimbus device with a product called the “Trident.” Ex-2015, ¶28-42. While I have not been asked to evaluate whether the Diros Trident device is in fact a copy of the Nimbus device, I do note a peculiarity in the data provided in the Jorgensen Declaration regarding the alleged Stratus commercial success.

[REDACTED]

32. As I noted above, the Jorgensen Declaration asserts that “Stratus has enjoyed remarkable commercial success with the Nimbus device” (Ex-2015, ¶13), that the Diros Trident product “copied” the Nimbus device (Ex-2015, ¶31-32), and that “[t]he Nimbus and Trident devices are marketed and sold to the same consumers” (Ex-2015, ¶37). Assuming this is all true, I would then expect Diros to have achieved some degree of commercial success. Yet, none of the sales or other commercial information in the Jorgensen Declaration references sales by Diros or for the Trident device. If the features of the Nimbus device are driving its allegedly “remarkable commercial success” and the Trident is truly a “copy,” it makes little sense that Diros would not be enjoying similarly “remarkable” success in the time frame discussed in the Jorgensen Declaration.

33. Likewise, I note that the Jorgensen Declaration indicates that Avanos acquired Diros in 2023. Ex-2015, ¶50-52. Yet, the Jorgensen Declaration’s market share information indicates that Avanos’ market share [REDACTED] in 2024 ([REDACTED]). Ex-2015, ¶17 (“U.S. RFA Cannula Market” chart). Once again, if the features of the Nimbus device are driving its allegedly “remarkable commercial success” and the Trident is truly a “copy,” it makes little sense that Avanos—having acquired Diros in 2023—would not have enjoyed “remarkable” success in 2024. To the contrary, Avanos’ acquisition of Diros and its allegedly

[REDACTED]

“copied” Trident product appears to have resulted in [REDACTED] of Avanos’ market share.

34. For the foregoing reasons, it is my opinion that the Jorgensen Declaration does not show meaningful customer substitution towards the Nimbus device and away from alternative products.

IV. CONCLUSION

35. For all the reasons discussed herein, it is my opinion that the Jorgensen Declaration does not show that the Nimbus device has achieved significant or otherwise meaningful commercial success.

36. I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code

Executed on: September 2, 2025

Signature:  _____
Signed by:
Mark Konno
CE79451863814AD...

By: Mark Konno