

**UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE**

PRYTIME MEDICAL DEVICES, INC.)	
)	
<i>Plaintiff,</i>)	Civil Action No. _____
)	
v.)	
CERTUS CRITICAL CARE, INC.)	JURY TRIAL DEMANDED
)	
<i>Defendant.</i>)	

COMPLAINT

Plaintiff Prytime Medical Devices, Inc. (“Prytime”), by and through its undersigned counsel, files this Complaint against Defendant Certus Critical Care, Inc. (“Certus” or “Defendant”), and alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement against Defendant for declaratory judgment regarding its anticipated infringement of U.S. Patent No. 11,253,264 (“the ’264 Patent” or “the Asserted Patent”).

PARTIES

2. Plaintiff Prytime is a Delaware corporation having a principal place of business at 229 North Main Street, Boerne, Texas 78006.

3. On information and belief, Defendant Certus is a Delaware corporation with a principal place of business at 4505 Wasatch Boulevard, Suite 150, Salt Lake City, Utah 84124.

JURISDICTION AND VENUE

4. This action arises under the United States Patent Act, codified at 35 U.S.C. § 1 *et seq.*, and in particular, 35 U.S.C. §§ 271 and 281-285.

5. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Certus because, on information and belief, Certus is incorporated in this Judicial District.

7. Venue in this District is proper over Certus under 28 U.S.C. §§ 1400(b) and 1391(b) and (c) because, on information and belief, Certus has committed acts of infringement and has a regular and established place of business in this District.

FACTS

8. Plaintiff Prytime is an innovative medical supply company specializing in novel occlusion catheters used to halt blood loss in emergency situations. Prytime owns numerous patents protecting this technology around the world.

9. On June 24, 2019, Curtis J. Franklin, Todd J. Krummenacher, Jeremy Reynolds, David Spencer, and Luke William Fisher (“the Inventors”) filed U.S. Patent Application No. 16/450,067 (“the ‘067 Application”) entitled “System and Method for Low Profile Occlusion Balloon Catheter.”

10. The ‘067 Application claims priority to U.S. Patent Application No. 15/573,054, filed June 2, 2017; U.S. Provisional Patent Application No. 62/375,472, filed August 16, 2016; U.S. Provisional Patent Application No. 62/353,388, filed June 22, 2016; and U.S. Provisional Patent Application No. 62/344,699, filed June 2, 2016.

11. In November 2017, the Inventors assigned their interest in and to Application No. 15/573,054 and all divisionals, continuations, substitutes, renewals, reissues, and reexaminations thereof and any patents that issued therefrom (including the ‘067 Application) to Prytime and the assignment was recorded in the United States Patent and Trademark Office (“PTO”) on January 11, 2022 at Reel 058614, beginning at Frame 0564.

12. On February 22, 2022, the '264 Patent was issued by the PTO based on the '067 Application. A true and correct copy of the '264 Patent is attached hereto as Exhibit A and is incorporated by reference as if fully set forth herein.

13. The '264 Patent is valid and enforceable. The term of the '264 Patent will expire on or about April 22, 2038.

14. Plaintiff Prytime possesses all rights of recovery under the '264 Patent, including the right to sue for infringement, recourse for damages, and to seek injunctive relief.

15. Certus has publicly announced that it is actively seeking approval from the United States Food and Drug Administration for its Endovascular Aortic Control ("EVAC") System with a balloon catheter. Certus has also publicly announced that, assuming it receives regulatory approval, it plans to launch the EVAC System with a balloon catheter for commercial sale in the United States for at least certain applications beginning in 2023. (*See Exhibit B*). Upon its launch in the United States, the EVAC System with a balloon catheter will be directly infringing at least claim 1 of the '264 Patent and will compete directly with Prytime's Resuscitative Endovascular Balloon Occlusion of the Aorta ("REBOA") catheters, reducing Prytime's market share and causing irreparable harm to Prytime.

16. Prytime has spent considerable time and resources developing its minimally invasive REBOA catheters, especially the balloons used within such catheters. These balloons require a very specific combination of strength, rigidity, and elasticity, which was developed only after years of research.

17. Upon information and belief, Certus's infringement of Prytime's technology resulted in Certus receiving over \$5 million in research grants from the U.S. Department of Defense for its EVAC System.

18. Certus has had notice of the '264 Patent since at least July 27, 2022, when it received a letter from Prytime's counsel demanding Certus cease and desist any potentially infringing activity.

19. Certus's announced intention to sell the EVAC System upon FDA approval has created a present actual and substantial controversy between Prytime and Certus concerning the threatened infringement of the '264 Patent.

COUNT I – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '264 PATENT

20. Plaintiff Prytime realleges and incorporates by reference paragraphs 1 through 19 of this Complaint as if fully set forth herein.

21. The claims of the '264 Patent are presumed valid pursuant to 35 U.S.C. § 282.

22. Upon selling or offering for sale the EVAC System in the United States, Certus will be directly infringing the '264 Patent in violation of 35 U.S.C. § 271. As shown in Exhibit C (Claim Chart of the '264 Patent).

23. Certus has engaged in concrete steps taken with the intent to conduct infringing activity. An actual and justiciable controversy exists between Prytime and Certus regarding infringement of the '264 Patent.

24. Certus has and had actual notice of the '264 Patent. Upon selling or offering for sale the EVAC System in the United States, Certus will be infringing the '264 Patent with knowledge of Prytime's patent rights. Certus's actions are willful and deliberate.

25. As a result of Defendant's anticipated infringement of the '264 Patent, Plaintiff Prytime will be damaged to an extent not yet determined.

JURY DEMAND

26. Plaintiff hereby demands a jury trial on all issues triable by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Prytime prays for judgment in its favor and against Defendant Certus for the following:

- (a) A declaratory judgment in favor of Plaintiff that, upon sale or offering for sale the EVAC System in the United States, Certus will be directly infringing the '264 Patent;
- (b) A declaratory judgment in favor of Plaintiff that the '264 Patent is not invalid;
- (c) An award of damages for Certus's infringement of the '264 Patent, including for all grant money received by Certus for development of its EVAC System, together with interest (both pre- and post-judgment), costs, and disbursements pursuant to 35 U.S.C. § 284;
- (d) An injunction pursuant to 35 U.S.C. § 283 prohibiting Certus from making, using, selling, importing or offering for sale the EVAC System in the United States;
- (e) A determination that this is an exceptional case within the meaning of 35 U.S.C. § 285, and an award to Plaintiff of its reasonable attorneys' fees; and
- (f) An award of such other and further relief, at law or in equity, as the Court may deem just and proper.

PANITCH SCHWARZE BELISARIO & NADEL, LLP

Dated: October 13, 2022

By: /s/ John D. Simmons
John D. Simmons (Bar No. 5996)
Wells Fargo Tower
2200 Concord Pike, Suite 201
Wilmington, DE 19803
Telephone: (302) 394-6030
Facsimile: (215) 965-1331
jsimmons@panitchlaw.com

Attorneys for Plaintiff Prytime Medical Devices, Inc.