

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

W. H. WALL FAMILY
HOLDINGS, LLLP

Plaintiff,

v.

CELONOVA BIOSCIENCES, INC.

Defendant.

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Civil Action No. 1:18-cv-303

JURY DEMAND

PLAINTIFF’S COMPLAINT

1. Plaintiff W. H. Wall Family Holdings, LLLP (“Plaintiff” or “Wall”) files this Complaint asserting claims for patent infringement of U.S. Patent No. 6,974,475 (“the ‘475 Patent”), a copy of which is attached hereto as Exhibit “A” against Defendant CeloNova BioSciences, Inc. (collectively “Defendant” or “CeloNova”), under 35 U.S.C. § 271, *et seq.* In support thereof, Wall would respectfully show the Court the following:

PARTIES

2. Wall is a Georgia limited liability limited partnership, with its principal place of business located at 4485 Commerce Drive, Suite 106, Buford, Georgia 30518. The limited partners in Wall consist of Dr. W. Henry Wall, the inventor of the ‘475 Patent, and members of his family.

3. CeloNova is a Delaware corporation with its principal executive offices and corporate headquarters located at 8023 Vantage Drive, Suite 1500, San Antonio, Texas, 78230. CeloNova conducts business in Texas through its offices at this location. CeloNova may be served

through its registered agent for service of process, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This Court has exclusive subject matter jurisdiction over this case for patent infringement under 28 U.S.C. §§1331 and 1338(a).

5. This Court has personal jurisdiction over Defendant CeloNova. CeloNova is headquartered in the State of Texas and the Western District of Texas. CeloNova, makes, ships, distributes, offers for sale, sells, and advertises its products in the United States, the State of Texas, and the Western District of Texas. CeloNova has committed the tort of patent infringement within the State of Texas and this District.

6. Venue is proper in the Western District of Texas under 28 U.S.C. § 1400. CeloNova has committed acts of infringement and has a regular and established place of business located in the Western District of Texas by virtue of its offices located at 8023 Vantage Drive, Suite 1500, San Antonio, Texas 78230.

BACKGROUND

7. According to the Centers for Disease Control, coronary artery disease (“CAD”) is the most common type of heart disease in the United States. CAD is caused by plaque buildup in the walls of the arteries that supply blood to the heart and other parts of the body. Plaque buildup causes the inside of the arteries to narrow over time, which could partially or totally block the blood flow, leading to a heart attack. More than 600,000 people die of heart disease in the United States every year, with heart disease being the leading cause of death for both men and women.

8. In 1974, German-born physician-scientist Andreas Gruntzig first used a balloon-tipped catheter to re-open a severely blocked artery. Balloon angioplasty became a leading therapy for treating cardiovascular diseases.

9. In 1981, while he was working as a visiting clinical professor at Emory Dental School, Dr. Wall became acquainted with Dr. Gruntzig, who had recently joined the Emory faculty. Dr. Wall studied the balloon angioplasty therapy pioneered by Dr. Gruntzig, and concluded that arterial blockage would likely return in patients, requiring balloon angioplasty to have to be repeated over time. Dr. Wall considered this issue and began working on ideas to address this problem. Initially, he tried to develop an ultrasound method to remove the blockage. After experimenting with this idea, Dr. Wall concluded that this method was not a viable solution. On or about October 15, 1984, he conceived the invention of inserting a sleeve into an artery following an angioplasty procedure. The sleeve would then effectively hold open the artery and prevent restenosis. Dr. Wall filed a disclosure document with the USPTO in December 1984, and then filed a formal patent application on December 8, 1987.

10. Due to a number of issues that arose during the prosecution of Dr. Wall's patent, including the litigation and appeal of an interference action, and the misplacing of the application by the USPTO, the '475 Patent finally issued on December 13, 2005. Because of the lengthy delays in the prosecution process, the USPTO extended the term of the '475 Patent by 903 days.

11. Over time, doctors have moved from treating coronary heart disease with angioplasty alone to using stents in conjunction with angioplasty. The National Institutes of Health has described how stents are commonly used as part of a procedure known as percutaneous coronary intervention, or "PCI." A stent is generally a small mesh tube that is placed in an artery as part of the PCI procedure. PCI restores blood flow through a narrowed or blocked artery. The

stent helps support the inner wall of the artery following the PCI procedure. Stents are typically made of metal mesh, although they can be made from other materials as well. Some stents are coated with medicine that is slowly and continuously released into the artery.

12. During a PCI procedure, a doctor threads through a blood vessel a thin, flexible tube, or catheter, with a balloon or other device on the end to the place in the artery that is narrowed or blocked. Once in place, the balloon is inflated to compress against the wall of the artery the plaque that has built up inside the artery. The stent, which was carried on the deflated balloon, expands when the balloon expands, and is pushed into place in the artery. The balloon is then deflated and pulled out along with the catheter. The stent remains in place in the artery and, over time, cells in the artery grow through the mesh of the stent.

PATENT INFRINGEMENT

13. On December 13, 2005, the United States Patent and Trademark Office (“PTO”) issued the ‘475 Patent to Dr. Wall, entitled “Angioplasty Stent” after a full and fair examination. The PTO extended the term of the ‘475 Patent by 903 days. All rights in the ‘475 Patent have been assigned to Wall. The patent relates generally to a prosthesis that can be inserted into a bodily lumen while in a collapsed position, and then expanded in order to prevent restenosis in the lumen. Wall has the right to enforce the ‘475 Patent and to recover all damages available under law.

14. The ‘475 Patent contains a total of forty-two claims, including ten independent claims and thirty-two dependent claims. By way of example, Claim 39 states:

A stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen, said stent comprising:

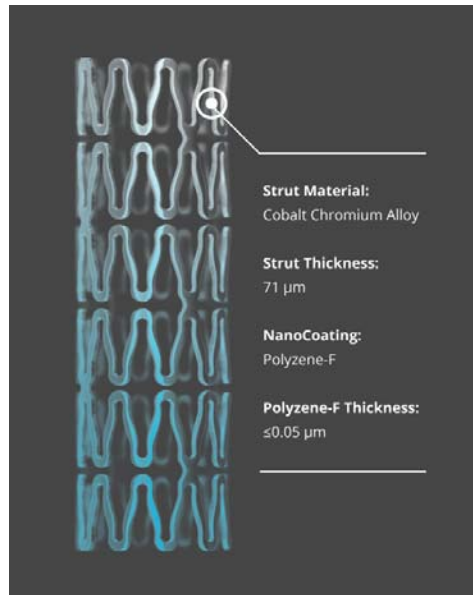
a radially collapsible sleeve formed in a mesh and a coating applied thereto, said sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and
said mesh being biased toward either its collapsed position or its expanded position.

Infringement of the '475 Patent

15. CeloNova manufactures, sells, and/or offers for sale to customers within the United States a stent device known as the COBRA PzF NanoCoated Coronary Stent System ("Accused Product"), which infringes one or more of the claims of the '475 Patent. On February 21, 2017, CeloNova received authorization from the United States Food and Drug Administration to begin commercial distribution of the Accused Product in the United States. CeloNova also manufactures the Accused Product in the United States which it has been selling to customers located outside the United States since at least 2012.

16. The Accused Product is intended for use in patients in connection with percutaneous transluminal coronary angioplasty.

17. The Accused Product is a sleeve formed in a mesh. The Accused Product is made from cobalt chromium (CoCr) alloy that is coated with Polyzene-F nanocoating.



18. The Accused Product is radially collapsible. The COBRA PzF Stent System is shipped with the stent premounted, in a crimped, unexpanded state, on the delivery balloon.

19. The Accused Product contains openings that allow tissue to grow through the stent.

20. Finally, before being used in the body, the Accused Product is biased toward its closed position. After it is inserted and expanded, the Accused Product is biased toward its expanded position.

COUNT ONE: INFRINGEMENT OF '475 PATENT

21. Wall realleges paragraphs 1 through 20 herein.

22. CeloNova has been making the Accused Product in the United States and distributing it to users located outside the United States since it received a CE Mark in December 2012. CeloNova received FDA approval to distribute the Accused Product within the United States on February 21, 2017.

23. By making, selling and/or offering for sale in the United States the Accused Products, CeloNova has been and is now infringing directly, and/or actively inducing and/or

contributing to the infringement of at least Claims 30, 34, and 39 of the '475 patent, either literally or through the doctrine of equivalents, pursuant to 35 U.S.C. § 271.

24. The Accused Products have no suitable non-infringing use, and they are not staples of commerce.

25. CeloNova has had knowledge of the '475 Patent at least since Wall informed it of the '475 Patent through a letter dated October 26, 2017 and addressed to Nicole Barber.

MISCELLANEOUS

26. Wall has satisfied all conditions precedent to filing this action, or any such conditions that have not been satisfied have been waived.

27. Through this pleading, Wall has not elected any one remedy to which it may be entitled, separately or collectively, over any other remedy.

RELIEF

Plaintiff W. H. Wall Family Holdings, LLLP respectfully requests the following relief:

- A. That the Court award damages to Plaintiff W. H. Wall Family Holdings, LLLP;
- B. That the Court find that Defendant CeloNova Biosciences, Inc. has willfully infringed the '475 Patent;
- C. That the Court award to Plaintiff W. H. Wall Family Holdings, LLLP enhanced damages of up to three times the amount of their actual damages;
- D. That the Court declare this to be an "exceptional" case under 35 U.S.C. § 285;
- E. That the Court award pre-judgment and post-judgment interest on such damages at the highest rates allowed by law;
- F. That the Court award Plaintiff W. H. Wall Family Holdings, LLLP its costs and attorneys' fees incurred in this action; and

G. That the Court award such other and further relief, at law or in equity, as the Court deems just and proper.

A JURY TRIAL IS DEMANDED BY PLAINTIFF W. H. WALL FAMILY HOLDINGS, LLLP.

Respectfully submitted,

By: /s/ Steven N. Williams

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