

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

BIOTRONIK, INC.,	)	
	)	
Plaintiff,	)	Civil Action File
	)	
v.	)	No. _____
	)	
W.H. WALL FAMILY HOLDINGS LLLP,	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendant.	)	

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**COMPLAINT FOR DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT, INVALIDITY, AND UNENFORCEABILITY**

Plaintiff Biotronik, Inc., for its Complaint against W.H. Wall Family Holdings LLLP (“Wall”), hereby alleges as follows:

**NATURE OF THE ACTION**

1. Biotronik, Inc. seeks a declaration that U.S. Patent No. 6,974,475 entitled “Angioplasty Stent” (the “’475 patent”) is not infringed by Biotronik, Inc.’s Pro-Kinetic<sup>®</sup> Energy Stent System, Astron<sup>®</sup> Stent System, Astron<sup>®</sup> Pulsar<sup>®</sup> Stent System, Pulsar<sup>®</sup>-18 Stent System, and Osiro<sup>®</sup> Sirolimus Eluting Coronary Stent System products (hereinafter together Biotronik, Inc.’s “Stent System Products”), is invalid, and is unenforceable. A true and correct copy of the ’475 patent is attached as **Exhibit A**.

## THE PARTIES

2. Plaintiff Biotronik, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business located at 6024 Jean Road, Lake Oswego, Oregon, 97035.

3. On information and belief, Defendant Wall is a limited liability limited partnership organized and existing under the laws of Georgia, having its principal place of business at 5590 Militia Drive, Stone Mountain, Georgia, 30087.

## JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over Biotronik, Inc.'s claims for Declaratory Judgment (Counts One-Three) that arise under the patent laws of the United States (*see* 35 U.S.C. § 1, *et seq.*; 28 U.S.C. §§ 1331 and 1338(a)), and under the Declaratory Judgment Act (*see* 28 U.S.C. §§ 2201 and 2202). As demonstrated by, *inter alia*, Wall's filing of patent infringement claims based on the '475 patent against Biotronik, Inc.'s Stent System Products, *W.H. Wall Family Holdings, LLLP v. Biotronik SE & Co. KG*, No. 6:21-cv-00019 (W.D. Tex. Jan. 11, 2021), a substantial controversy of sufficient immediacy and reality exists between the parties to warrant the issuance of a declaratory judgment of noninfringement, invalidity, and unenforceability of the '475 patent.

5. Wall did not sue Biotronik, Inc. in the pending Western District of Texas case but instead, improperly sued a non-U.S. Biotronik, Inc. affiliate, Biotronik SE & Co. KG. Biotronik SE & Co. KG has no contacts within that district and does not make, use, sell, or import the accused products within the United States. Wall sued this entity despite previously corresponding with Biotronik, Inc. concerning the '475 patent. On information and belief, Wall did not file a lawsuit against Biotronik, Inc. because Wall knew that venue for such a case would not be proper in the Western District of Texas.

6. This Court has personal jurisdiction over Wall because, *inter alia*, Wall resides in the State of Georgia, and is organized and existing under the laws of the State of Georgia. Wall has its principal place of business in Stone Mountain, Georgia, which is located in DeKalb County within the jurisdiction of the Northern District of Georgia. Dr. W. Henry Wall, the named inventor of the '475 patent, is the registered agent of Wall in the State of Georgia, with a physical address at 5590 Militia Drive, Stone Mountain, GA, 30087. Moreover, this Court has personal jurisdiction over Wall because Wall has conducted business in Georgia, at least in DeKalb County where Wall's principal place of business is located. Wall submitted annual registration statements to the State of Georgia every year since its formation in the State of Georgia and as recently as April 5, 2020 (Filing No.

18946328). As Wall was formed under the laws of the State of Georgia in 2005, and Wall is actively registered to do business in the State of Georgia (Control No. 0526321), it has thus availed itself of the rights and benefits of Georgia law such that it should reasonably anticipate being brought into court in this judicial district.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(c) at least because Defendant resides in this judicial district and, on information and belief, does business in this District and is subject to personal jurisdiction in this District for the claims asserted herein.

#### **BIOTRONIK AND ITS INNOVATIVE STENT SYSTEM PRODUCTS**

8. Biotronik, Inc. is a leading medical device and technology enterprise, focusing on innovation and development in the areas of cardiac rhythm management, electrophysiology, and vascular intervention solutions. Biotronik, Inc. has been doing business in the United States for forty-two years.

9. Among Biotronik, Inc.'s products is a portfolio of coronary and peripheral vascular intervention products, which includes a line of stent system products available in the United States.

10. The Pro-Kinetic<sup>®</sup> Energy Stent System is a bare metal coronary stent used for improving the diameter of coronary arteries and indicated for use in patients with vessels that either have lesions which have not been previously

treated with angioplasty or stenting, or in patients with vessels that have restenotic lesions. The Pro-Kinetic<sup>®</sup> Energy Stent System first received Pre-Market Approval (“PMA”) in the U.S. in February 2017 and has been commercially offered for sale by Biotronik, Inc. since its approval.

11. The Astron<sup>®</sup> Stent System is a peripheral self-expanding nitinol stent system and is used for improving the diameter of vessels that have diameters between 4.3mm and 9.5mm in patients with total blockages in the arteries leading to the legs, specifically in the pelvis. The Astron<sup>®</sup> Stent System first received PMA in the U.S. in December 2015 and has been commercially offered for sale by Biotronik, Inc. since its approval.

12. The Astron<sup>®</sup> Pulsar<sup>®</sup> Stent System is a peripheral self-expanding stent used to improve the diameter of vessels with diameters between 3.0mm and 6.0mm that have complete or partial blockages, specifically in arteries located in the legs that either have lesions not previously treated with angioplasty or stenting, or have restenotic lesions. The Astron<sup>®</sup> Pulsar<sup>®</sup> Stent System first received its PMA in the U.S. in March 2017 and has been commercially offered for sale by Biotronik, Inc. since its approval.

13. The Pulsar<sup>®</sup>-18 Stent System is a peripheral self-expanding stent used to improve the diameter of vessels with diameters between 3.0mm and 6.0mm that

have complete or partial blockages, specifically in arteries located in the legs that either have lesions not previously treated with angioplasty or stenting, or have restenotic lesions. The Pulsar<sup>®</sup>-18 Stent System first received PMA in the U.S. in March 2017 and has been commercially offered for sale by Biotronik, Inc. since its approval.

14. The Osiro<sup>®</sup> Sirolimus Eluting Coronary Stent System is a coronary drug-eluting stent system used for improving the diameter of vessels with a diameter of 2.25mm to 4.0mm, in patients that have conditions including diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation myocardial infarction or documented silent ischemia with certain types of atherosclerotic lesions in the coronary arteries. The Osiro<sup>®</sup> Sirolimus Eluting Coronary Stent System first received its PMA in the U.S. in February 2019 and has been commercially offered for sale by Biotronik, Inc. since its approval.

### **THE PATENT-IN-SUIT**

15. The United States Patent and Trademark Office (“USPTO”) issued the ’475 patent on December 13, 2005. The ’475 patent identifies W. Henry Wall (“Dr. Wall”) as sole inventor.

16. On information and belief, W. H. Wall Family Holdings, LLLP purports to be the current sole assignee of the ’475 patent.

17. The patent application that eventually issued as the '475 Patent, U.S. Pat. Appl. No. 07/129,834 ("834 application"), was filed well over thirty years ago, on December 8, 1987.

18. Early in the '834 application's pendency before the USPTO, the examiner rejected the claims, concluding that they were anticipated by U.S. Patent No. 4,740,207 to Kreamer ("Kreamer").

19. Unable to distinguish his purported invention from Kreamer, Dr. Wall sought instead to establish an invention date prior to Kreamer. To that end, Dr. Wall and his patent counsel provoked a so-called "interference" – a contest over priority of invention – by amending his claims in response to a June 20, 1988 office action during the prosecution of the '834 application. An interference proceeding was declared in January 1993, which deferred the prosecution of the '834 application.

20. In the interference, Dr. Wall relied on a sworn declaration in which he alleged conception of the claimed subject matter on or about October 15, 1984, pointing to a drawing, purportedly of the alleged invention, said to have been made on that date. In an effort to pre-date Kreamer, Dr. Wall submitted documents, which he contended showed a date of invention prior to 1986. Under the rules governing interference practice, Dr. Wall was required to testify under oath in a

deposition on December 7, 1993. His testimony was recorded in a sworn, written transcript.

21. The Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (“BPAI”) rejected Dr. Wall’s claims in a decision dated June 28, 1995, nearly eight years after the ’834 application filing date. It determined that Dr. Wall’s claims were not confirmed or supported by any witness, as is required to establish prior invention, and that his uncorroborated testimony alone was therefore “unavailing.” The BPAI also concluded that, even if Dr. Wall’s uncorroborated testimony were true at face value, which the BPAI did not find evidence to support, the “earliest possible date with which Wall could be credited as showing a conception of the invention” was September 8, 1987. With Dr. Wall’s priority case rejected in its entirety, the BPAI confirmed that Kreamer was the first in time to invent the subject matter of the claims, meaning Dr. Wall was not the inventor of the claimed subject matter.

22. Subsequently, Dr. Wall appealed the BPAI’s decision to the U.S. Court of Appeals for the Federal Circuit, but in February of 1997, his appeal was dismissed for his failure to timely file his brief.

23. Several claims in the ’834 application had been directed to “non-interfering” subject matter, that is, subject matter that fell outside of that



proceeding, and remained pending in the application after the final resolution of the interference. Even after the Federal Circuit dismissed his appeal, Dr. Wall was not diligent or active in prosecuting the remaining '834 application claims to ensure they were promptly examined and placed in a condition for allowance.

24. For the next seven and a half years, Dr. Wall's patent application—already pending for roughly a decade—was not prosecuted further by him. Importantly, Dr. Wall, who is a dentist by training, had not been the first to develop the stent devices he sought to claim ownership of via the '834 application. Instead, others, like Dr. Julio Palmaz, a vascular radiologist, and Dr. Richard Schatz, an interventional cardiologist, developed and disclosed stent technology prior to Dr. Wall's submission of the '834 application. So, while Dr. Wall claimed priority over Kreamer, lost that priority contest, and then neglected to prosecute the '834 application, the stent technology invented and developed by others before Dr. Wall was actually commercialized. In particular, Johnson & Johnson did so in 1994, “fueling a transformation in treating coronary artery disease.” In fact, Dr. Wall admitted that not only was he aware of Dr. Palmaz's work, but also acknowledged that the work of Dr. Palmaz had “sparked” his own interest. And while others commercialized their stent technology, on information and belief, Dr. Wall did not develop any products of his own.

25. While allowing the '834 application to languish unexamined, Dr. Wall and his counsel Mr. George M. Thomas nevertheless filed U.S. Pat. Appl. No. 10/293,122 (“’122 application”) as a division of the '834 application in November 13, 2002—acknowledging their awareness that the '834 application remained pending, yet unexamined, at that time.

26. The USPTO rejected all claims of the '122 application on December 17, 2003, finding claims 1, 3-7 and 10 anticipated by Kreamer, and claims 2, 8, 9, 11-24 obvious over the same reference. The claims were again rejected on April 19, 2004 as “anticipated by Palmaz (4733665 or 4739762)” and as “unpatentable over Palmaz (4733665 or 4739762) in view of Kreamer (4740207) and further in view of Garza et al (4665918),” and on September 9, 2004 as being “anticipated by Maass et al (4553545),” and “unpatentable over Kreamer (4740207) in view of Palmaz (4733665 or 4739762) and in further view of Garza et al (4665918).”

27. In an attempt to avoid the prior art, Dr. Wall sought to swear behind it to establish an earlier date. *See* 37 C.F.R. § 1.131. As noted, the applied prior art references included the Kreamer reference, which the BPAI had already determined benefitted from an earlier invention date than Wall’s '834 application.

28. Dr. Wall and his representative, Mr. Thomas, rehashed the same uncorroborated story Dr. Wall had told the BPAI and which the BPAI had rejected.

Tellingly, however, Dr. Wall and Mr. Thomas omitted any mention in the Statement of Prior Invention that this same allegation had been fully adjudicated and rejected, and that it had not been reversed on appeal.

29. The USPTO then withdrew its rejections and allowed the '122 application on January 25, 2005.

30. During prosecution by Dr. Wall of his '122 application, the USPTO on August 20, 2004 issued an office action concerning the '834 application. The USPTO officially concluded that Dr. Wall "is not entitled to his application claims 1, 2, 12, 13, and 19-26, which claims correspond to the count in interference." In other words, having lost on priority on that subject matter in the interference, Dr. Wall could not go back and try again to reclaim the same subject matter via prosecution based on claims that had been designated as not "corresponding to the count" in interference. These claims were therefore "finally disposed of." The USPTO also noted that "remaining claims 3-11, 14-18, *which did not correspond to the count* are allowable." (emphasis added). Dr. Wall did not respond to the communication. As a result, the '834 application went abandoned as of September 21, 2004.

31. The subsequent year, on February 14, 2005, Dr. Wall sought to revive the abandoned '834 application. In doing so, Dr. Wall contended that he was

unaware that an office action would issue on the '834 application, even though, based on the patent examiner's August 2004 action, he was well aware that certain other claims, not corresponding to the subject matter of the interference, were "allowable" and therefore remained pending.

32. On March 14, 2005, the USPTO in response to Dr. Wall's submission, revived the '834 application and prosecution continued.

33. After seeking to revive the '834 application, Dr. Wall and Mr. Thomas then sought to transplant the allowable '122 application claims into the '834 application, apparently to gain the benefit of its far earlier filing date. The '834 application had a priority filing date that preceded a change in the law that ended the practice of computing patent terms based on issue date. Thus, a patent issuing from the '834 application would be entitled to a term of 17 years from issuance (approximately 2022). By contrast, the '122 application was filed *after* the change in the law, such that a patent that would have issued from the '122 application would have expired 20 years from earliest filing date (approximately 2007). Without the requested combination of the '122 application's claims with the pending '834 application claims, on information and belief, any claims of a patent issuing from the '122 application would have expired on December 8, 2007.

34. In an apparent attempt to leverage the delay that arose from failing to prosecute his '834 application, in June 2005, Dr. Wall and Mr. Thomas expressly abandoned the '122 application “subject to the transfer of claims to co-pending parent application 07/129,834.” The claims of the '122 application were added to the then co-pending '834 application, and the patent examiner allowed the combination.

35. When Dr. Wall and Mr. Thomas added the '122 application claims to the '834 application, they were added as 19 “new” claims, which Dr. Wall and Mr. Thomas represented as claims which had been transferred from the '122 application.

36. A few weeks after adding the claims from the '122 application, Dr. Wall and Mr. Thomas further amended the application to add nine entirely new claims, which Dr. Wall and his counsel claimed were “based upon the Examiner’s statement of reasons for allowance in co-pending divisional application 10/293,122.” In so doing, they stated that since “the claims in the co-pending divisional application are method claims, . . . apparatus claims based on the same information as recited by the Examiner’s statement should be allowable in [the '834] application.” Significantly, the Examiner’s statement expressly noted, among other things, the following claim limitation: “the mesh being biased toward

its collapsed position.” Contrary to what Dr. Wall and his counsel represented, the new claims added to the ’834 application were *not* solely based on the Examiner’s statement, but instead recited a markedly different approach of broader scope: “said mesh being biased toward either its collapsed position *or its expanded position*.” (Emphasis added).

37. When Dr. Wall and Mr. Thomas added the ’122 application claims to the ’834 application, they failed to disclose several key prior art references that had been of record in connection with the ’122 application.

38. After 18 years of pendency the ’475 patent passed to issue in December 2005.

39. On its face the ’475 patent acknowledges that placing a stent in a lumen of the human body after angioplasty to prevent restenosis and maintain a minimum opening of the lumen was known in the art. *See* ’475 patent, col. 1, ll. 5-14; col. 1, ll. 20-33. The ’475 patent purports to disclose a particular type of stent technology, specifically a “prosthesis in the form of a stent” that is “in the form of a sleeve having a *discontinuity* so the sleeve has a collapsed position to be assumed during placement of the stent, and an expanded position for use in its final location for maintaining the desired opening.” *See* ’475 patent, col. 1, ll. 38-47. (Emphasis added). The sleeve’s discontinuity means that the shape of the stent is

not that of a cylinder – instead, the stent is a sheet of metal that curls up upon itself like a scroll. *See* '475 patent, Fig. 2. Embodiments of the purported invention, according to the patent, are either “biased outwardly and [] forced inwardly and retained by means of a pin,” or stents that “when . . . expanded so far that the ends . . . are released from engagement, the end 29 will move inwardly and the end 30 will move outwardly . . . As a result, the stent will collapse to its minimum external diameter.” '475 patent, col. 3, ll. 20-37, 64-67. The purported invention must be “lockable,” either “selectively biased toward a closed position and lockable in an open position, or biased in an open position and lockable in a closed position.” *Id.* at col. 1, ll. 59-62.

### **THE PRESENCE OF AN ACTUAL CONTROVERSY**

40. Upon information and belief, Wall does not make, market, or sell products of any kind. It sells no products that are covered by the '475 patent or any other products, and never has, instead focusing on filing lawsuits or otherwise extracting settlements.

41. An actual case or controversy has arisen over the non-infringement of Biotronik, Inc.'s Stent System Products and the validity of the '475 patent, as demonstrated by, *inter alia*, Wall's filing of patent infringement claims based on the '475 patent against Biotronik, Inc.'s Stent System Products, *W.H. Wall Family*

*Holdings, LLLP v. Biotronik SE & Co. KG*, No. 6:21-cv-00019 (W.D. Tex. Jan. 11, 2021).

42. In recent years, Wall has asserted the '475 patent against several manufacturers and/or developers in the stent technology market, including Merit Medical Systems, Inc., Stryker Corp., and Terumo Corp., among others. *See, e.g., W.H. Wall Family Holdings, LLLP v. Stryker Corp.*, No. 6:21-cv-00127 (W.D. Tex. Feb. 5, 2021); *W.H. Wall Family Holdings, LLLP v. Philips Image Guided Therapy Corp.*, No. 6:21-cv-00020 (W.D. Tex. Jan. 11, 2021); *W.H. Wall Family Holdings, LLLP, v. Merit Med. Sys., Inc.*, No. 4:20-cv-02990 (S.D. Tex. Aug. 26, 2020); *W.H. Wall Family Holdings, LLLP v. Terumo Corp.*, No. 6:20-cv-00713 (W.D. Tex. Aug. 4, 2020); *W.H. Wall Family Holdings, LLLP v. Veryan Med. Ltd.*, No. 6:20-cv-00715 (W.D. Tex. Aug. 4, 2020); *W.H. Wall Family Holdings, LLLP v. CeloNova Biosciences, Inc.*, No. 1:18-cv-00303 (W.D. Tex. Apr. 11, 2018); *W.H. Wall Family Holdings, LLLP v. B Braun Med. Inc. et. al*, No. 3:18-cv-00866 (N.D. Tex. Apr. 9, 2018); *W.H. Wall Family Holdings, LLLP v. Integer Holdings Corp.*, No. 2:18-cv-00122 (E.D. Tex. Mar. 30, 2018). In each of these actions, all filed in Texas, Wall has accused stent products of infringing the claims of the '475 patent.



43. On October 26, 2017, Wall sent a letter, attaching the '475 patent, to Biotronik, Inc. alleging that it had conducted an investigation into Biotronik, Inc.'s Stent System Products and contending that one or more of the claims of the '475 patent were "relevant" to Biotronik, Inc.'s products. Wall identified Biotronik, Inc.'s Pro-Kinetic<sup>®</sup> Energy System Stent as meeting the limitations of claim 39 of the '475 patent. Wall then further stated that it was in Biotronik, Inc.'s interest to obtain a license to the '475 patent from Wall, which would allow Biotronik, Inc. to continue to sell its products, such as Biotronik, Inc.'s Pro-Kinetic<sup>®</sup> Energy System Stent, "Astron and Astron Pulsar" Stent Systems, and any other similar future products. A true and correct copy of Wall's October 26, 2017 letter is attached as **Exhibit B.**

44. Biotronik, Inc. promptly denied Wall's claims in writing, making clear that Wall had no basis for its assertions that Biotronik, Inc. required a license to practice one or more claims of the '475 patent, nor any basis to contend that components of Biotronik, Inc.'s Stent System Products met the limitations of the '475 patent claims.

45. Wall responded in an email on April 24, 2018, attaching a claim chart purporting to add detail in support of its allegation of infringement by Biotronik,

Inc.'s Pro-Kinetic<sup>®</sup> Stent System Product as against Claims 30, 34, and 39 of the '475 patent.

46. In response, Biotronik, Inc. stated that it failed to see how the Pro-Kinetic<sup>®</sup> Stent System purportedly met claim limitations such as “minimum opening in the lumen” and “mesh,” and failed to understand Wall’s further assertions that the term “collapsible” implicated the Pro-Kinetic<sup>®</sup> Stent System.

47. Shortly after the FDA’s approval of Biotronik, Inc.’s Osiro<sup>®</sup> Sirolimus Eluting Coronary Stent System in February 2019, Wall sent another email claiming that in light of this approval, the parties should continue their discussions of a potential license to the '475 patent.

48. Biotronik, Inc. again responded, noting once again that despite Wall’s allegations and appended claim chart, it failed to see any “basis for an assertion of rights against [Biotronik, Inc.].”

49. On March 27, 2019, Wall sent another letter to Biotronik, Inc., indicating that its positions set forth in its correspondence would not limit or restrict any position it may advance “at some later point should the parties be unable to reach a business resolution concerning the '475 patent.”

50. Wall fell silent for nearly two years and never contacted Biotronik, Inc. again. Then, without warning, it filed a lawsuit – but not against Biotronik,

Inc. Instead, it sued a non-U.S. company that does not conduct the alleged conduct in the complaint, is not the manufacturer of the allegedly infringed products, has no U.S. presence, and does not commercialize in the U.S., or import into the country, any of the accused products. That entity, Biotronik SE & Co. KG, is a non-U.S. affiliate of Biotronik, Inc.

51. Notably, Wall brought its action against the non-U.S. affiliate not in its own judicial district or in the district in which Biotronik, Inc. is located, but instead in the United States District Court for the Western District of Texas, where neither entity has contacts. Despite having corresponded previously with Biotronik, Inc.—the U.S. entity—Biotronik, Inc. is ***not a named party*** in the Western District of Texas suit. Biotronik, Inc. has no place of business in that forum. Upon information and belief, Wall brought suit nearly a thousand miles from its home court and against the incorrect entity in an effort to select a forum, since the patent venue provisions do not apply to non-U.S. entities, even though venue would not be proper for Biotronik, Inc. in that forum and the entity it did name is not subject to personal jurisdiction in that court.

52. In that separate case, Wall accuses, *inter alia*, Biotronik, Inc.’s Pro-Kinetic<sup>®</sup> Energy Stent System, Orsiro<sup>®</sup> Sirolimus Eluting Coronary Stent System, Astron<sup>®</sup> Stent System, Astron<sup>®</sup> Pulsar<sup>®</sup> Stent System, and the Pulsar<sup>®</sup>-18 Stent

System products of infringing the '475 patent, alleging they meet literally, or under the doctrine of equivalents, each limitation of at least Claim 39 of the '475 patent. *See W.H. Wall Family Holdings, LLLP v. Biotronik SE & Co. KG*, No. 6:21-cv-00019 (W.D. Tex. Jan. 11, 2021) (Dkt. No. 1), ¶¶ 66-76. In its complaint, Wall further alleges that the supply of these named products in the United States and use of these products by customers in the United States directly infringes the '475 patent under 35 U.S.C. § 271.

53. At no point did Biotronik, Inc. or its affiliates agree to obtain a license to the '475 patent or agree to pay any royalties or fees to Wall or to any of its affiliates for the use of the '475 patent. Biotronik, Inc. maintains that such a license is unnecessary in view of the '475 patent's narrow scope, and resulting absence of infringement, and because the claims are invalid and unenforceable.

54. Wall's conduct described in the foregoing paragraphs demonstrates that there is an actual and justiciable controversy between Wall and Biotronik, Inc. with respect to whether Biotronik, Inc.'s commercialization of its Stent System Products in the United States infringes any valid and enforceable claim of the '475 patent.

55. This dispute and Wall's actions entitle Biotronik, Inc. to bring this action because the controversy is of sufficient immediacy and reality to warrant

declaratory relief, at least because the threat of litigation is immediate and concrete in light of Wall's recent litigation activity. Wall's written demands to Biotronik, Inc. and Wall's lawsuit against non-U.S. entity Biotronik SE & Co. KG, targeting the products Biotronik, Inc. is responsible for marketing and distributing in the U.S., have created an actual and substantial controversy as to whether Biotronik, Inc. and Biotronik, Inc.'s Stent System Products infringe any valid claim of the '475 patent. As a result, Biotronik, Inc. faces a real and reasonable apprehension that Wall will sue Biotronik on the '475 patent, and that Biotronik, Inc.'s current marketing and distributing, offering for sale, selling, and/or importing of its Stent System Products could subject Biotronik, Inc. to suit for patent infringement.

56. Absent a declaration from this Court that Biotronik, Inc. does not infringe the '475 patent, Wall threatens to cause foreseeable and irreparable harm and injury to Biotronik, Inc. should it seek to enforce the '475 patent such that Biotronik, Inc. will be restrained from freely marketing, distributing, offering for sale, selling, and/or importing in/into the United States its Stent System Products.

### **COUNT ONE**

#### **(Declaratory Judgment of Non-infringement of the '475 patent)**

57. Biotronik, Inc. incorporates the allegations of paragraphs 8 through 56 as if fully set forth herein.

58. Wall purports to be the sole assignee of the '475 patent, which purports to describe a particular type of stent technology.

59. Biotronik, Inc. has commercialized a series of stent systems including the Pro-Kinetic<sup>®</sup> Energy Stent System, Astron<sup>®</sup> Stent System, Astron<sup>®</sup> Pulsar<sup>®</sup> Stent System, Pulsar<sup>®</sup>-18 Stent System, and Osiro<sup>®</sup> Sirolimus Eluting Coronary Stent System products ("Stent System Products") in the United States.

60. Wall has alleged that one or more claims of the '475 patent are infringed by Biotronik, Inc.'s Stent System Products. For example, Wall has previously alleged, both in prior correspondence addressed to Biotronik, Inc. and its counsel, as well as in Wall's January 11, 2021 complaint for patent infringement filed against non-U.S. affiliate Biotronik SE & Co. KG, that Biotronik, Inc.'s Stent System Products infringe at least Claims 30, 34, and 39 of the '475 patent.

61. Biotronik, Inc. contends that its Stent System Products do not infringe and have not infringed, directly or indirectly, either literally or under the doctrine of equivalents any valid and enforceable claim of the '475 patent.

62. By way of example only, and without limitation, Biotronik, Inc. does not and has not infringed Claim 30, 34, or 39 of the '475 patent. Biotronik, Inc.'s Stent System Products do not infringe because, among other reasons, Biotronik,

Inc.’s Stent System Products do not meet every limitation of at least Claims 30, 34, or 39 either literally or under the doctrine of equivalents. The Stent System Products do not possess or use “a sleeve” as required by claims 30, 34 and 39 of the ’475 patent. *See* ’475 patent, col. 9, ll. 46—col. 10, ll.6; *id.* col. 10, ll. 24-32; *id.* col. 10, ll. 46-55. The Stent System Products lack a discontinuity and instead are a continuous cylinder. *See, e.g.,* ’475 patent, col. 1, ll. 42-47. Moreover, Biotronik, Inc.’s Stent System Products do not possess a “sleeve in a radially collapsed position” as required in claim 30, or a “radially collapsible sleeve formed in a mesh” as required in claims 34 and 39. *See* ’475 patent, col. 9, ll. 46—col. 10, ll. 6; *id.* col. 10, ll. 24-32; *id.* col. 10, ll. 46-55. The products contain structures that are deformable, and are expanded to an expanded diameter but do not collapse from that expanded diameter to an initial, minimum diameter. During the prosecution of the ’475 patent, Wall repeatedly distinguished the invention purportedly claimed in the ’475 patent from prior art devices that were deformable. *See* File History of U.S. Patent Appl. No.10/293,122, at 161-65, 195-96, 198 (distinguishing *Palmaz* as a stent made of “deformable material” that was not “radially collapsible”). Moreover, Biotronik, Inc.’s Stent System Products lack a “mesh,” as required by Claims 30, 34, and Claim 39. *See* ’475 patent, col. 9, ll. 46-53; *id.* col. 10, ll. 24-28, 46-50 (requiring a “sleeve formed in mesh”). For

example, the Astron<sup>®</sup> and Astron<sup>®</sup>-Pulsar<sup>®</sup> Stent Systems comprise a “laser-cut from a Nitinol tube.”

63. An actual controversy has arisen and exists between Wall and Biotronik, Inc. concerning whether Biotronik, Inc.’s commercialization of its Stent System Products in the United States infringes any valid and enforceable claim of the ’475 patent.

64. Declaratory relief is appropriate and necessary to establish that Biotronik, Inc.’s Stent System Products do not infringe and have not infringed, directly or indirectly, either literally or under the doctrine of equivalents any valid and enforceable claim of the ’475 patent.

65. Absent declaratory relief, Wall threatens to cause foreseeable and irreparable harm and injury to Biotronik, Inc. should it seek to enforce the ’475 patent such that Biotronik, Inc. will be restrained from freely marketing, distributing, offering for sale, selling, and/or importing in/into the United States its Stent System Products.

66. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Biotronik, Inc. is entitled to a declaratory judgment and seeks a declaratory judgment that the making, using, offering to sell, selling, and/or importing its Stent System Products in/into the United States, does not and has not infringed, directly or indirectly, either literally



or under the doctrine of equivalents any valid and enforceable claim of the '475 patent under 35 U.S.C. §271(a), (b), (c), (f), or (g).

## **COUNT TWO**

### **(Declaratory Judgment of Invalidity of the '475 patent)**

67. Biotronik, Inc. incorporates the allegations of paragraphs 8 through 56 as if fully set forth herein.

68. Wall purports to be the sole assignee of the '475 patent, which purports to describe a particular type of stent technology.

69. The '475 patent issued from the U.S. Pat. Appl. No. 07/129,834 ("'834 application"), filed on December 8, 1987, and issued nearly twenty years later on December 13, 2005 as the '475 patent.

70. Wall alleges that the claims of the '475 patent are valid.

71. Biotronik, Inc. contends that its Stent System Products do not infringe and have not infringed any valid and enforceable claim of the '475 patent.

72. The claims of the '475 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including but not limited to 35 U.S.C. §§ 101, *et seq.* and under the judicially created doctrine of obviousness-type double patenting.

73. The claims of the '475 patent are invalid under at least 35 U.S.C. §§ 102 and 103 because the claimed subject matter was described, expressly or inherently, in a printed publication prior to the alleged invention by the inventor; the claimed subject matter was known or used by others in the United States prior to the alleged invention by the inventor; and/or the invention would have been obvious at the time of its conception to a person having ordinary skill in the art. By way of example, the claims of the '475 patent are anticipated and/or obvious at least in light of the following references, either alone or in combination: WO 83/03752 ("Wallsten"); U.S. Patent No. 4,739,762 ("Palmaz '762 Patent"); WO 83/00997 ("Maas"); EP 0183372A1 ("Raychem"); U.S. Patent No. 4,740,207 ("Kreamer"); U.S. Patent No. 4,674,506 ("Alcond"); U.S. Patent No. 6,436,135 ("Goldfarb"); U.S. Patent No. 4,878,906 ("Lindemann"); Sigwart et al., *Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty*, NEW ENG. J. MED. ("Sigwart"); U.S. Patent No. 5,059,211 ("Stack"); U.S. Patent No. 4,733,665 ("Palmaz '665 Patent"); U.S. Patent No. 4,776,337 ("Palmaz '337 Patent"); "What's New: New Way to Open Clogged Arteries," THE WALL STREET JOURNAL (Aug. 19, 1987) ("Palmaz WSJ Article"); Palmaz et. al, *Expandable Intraluminal Graft: A Preliminary Study*, RADIOLOGY (1985) ("Palmaz 1985 Paper"); abstract of Julio C. Palmaz, et al, Expandable Intraluminal

Graft: A Preliminary Study, Radiology, Nov. 1984, vol. 153 (P) (“Palmaz 1984 Abstract”); Palmaz, *Expandable Vascular Endoprosthesis* (May 18, 1983) (“Palmaz 1983 Monograph”); and Palmaz, Untitled Paper (“Palmaz 1980 Monograph”).

74. Additionally, the ’475 patent names Dr. W. Henry Wall as the sole inventor. However, in a letter dated December 18, 1984 addressed to Dr. Wall, Dr. Robert Guyton contributed the idea that the “inner wall of the sleeve could be treated with a heparinized surface or one of the new thrombogenic surfaces and a better patency could be achieved.” See File History of U.S. Pat. App. No. 10/293,122, Statement of Prior Invention dated September 9, 2004, Ex. 10. The claims of the ’475 patent recite the elements Dr. Guyton contributed, specifically a sleeve “formed in a mesh” where there is “a *coating of material applied* to [said/the] mesh” or “a *coating applied* to [said/the] mesh” in Claims 15, 22, 25, 28, 30, and 34, and “a radially collapsible sleeve formed in a mesh and a *coating applied* thereto” in Claim 39. See ’475 patent, col. 7, ll. 23-24; *id.* col. 8, ll. 18-20; *id.* col. 8, ll. 47-50; *id.* col. 9, ll. 19-22; *id.* col. 9, ll. 50-51; *id.* col. 10, ll. 28-29; *id.*, col. 10, ll. 49-51 (emphasis added). Thus, the ’475 patent fails intentionally to name the correct inventor with respect to at least this claim element, and its claims are invalid as a result. See 35 U.S.C. §§ 102(f), 116.

75. Moreover, the claims of the '475 patent are invalid under 35 U.S.C. § 112 for failing to enable a person skilled in the art to make and use the claimed invention without undue experimentation.

76. The claims of the '475 patent are invalid under 35 U.S.C. § 112 for failing to satisfy the written description requirement. Specifically, the specification of the '475 patent, to one of skill in the art at the time of filing, would not demonstrate that the inventor had possession of the full scope of the claimed invention.

77. Thus, an actual controversy has arisen and exists between Wall and Biotronik, Inc. as to whether or not any of the claims of the '475 patent are valid.

78. Declaratory relief is appropriate and necessary to establish that the claims of the '475 patent are invalid.

79. Absent declaratory relief, Wall threatens to cause foreseeable and irreparable harm and injury to Biotronik, Inc. should it seek to enforce the '475 patent such that Biotronik, Inc. will be restrained from freely marketing, distributing, offering for sale, selling, and/or importing in/into the United States its Stent System Products.

80. Pursuant to 28 U.S.C. §§ 2201, *et seq.* Biotronik, Inc. is entitled to a declaratory judgment and hereby seeks a declaratory judgment that the '475 patent is invalid under 35 U.S.C. § 101, *et seq.*

### **COUNT THREE**

#### **(Declaratory Judgment of Unenforceability Due To Inequitable Conduct)**

81. Biotronik, Inc. incorporates the allegations of paragraphs 8 through 56 as if fully set forth herein.

82. Wall purports to be the sole assignee of U.S. Patent No. 6,974,475 ("475 patent"), which purports to describe a particular type of stent technology.

83. The '475 patent issued from U.S. Pat. Appl. No. 07/129,834 ("834 application"), filed on December 8, 1987.

84. Dr. Wall and his counsel Mr. George M. Thomas filed U.S. Pat. Appl. No. 10/293,122 ("122 application) as a division of the '834 application in November 13, 2002. Its claims were transferred to the '834 application which eventually issued as the '475 patent.

85. The '475 patent issued on December 13, 2005.

86. Wall alleges that the claims of the '475 patent are valid and enforceable.

87. The '475 patent is unenforceable due to inequitable conduct in procuring the '475 patent. To obtain issuance of the '475 patent, Wall, through the alleged inventor, Dr. Wall, and the prosecution agents, George M. Thomas and James B. Middleton, and other individuals working in concert with them, withheld and misrepresented information material to patentability from the U.S. Patent and Trademark Office ("USPTO") with the specific intent to do so. Specifically, Dr. Wall sought to secure patent protection for subject matter that was already known and that he did not invent and for a term that he was not entitled to.

88. To achieve this, Dr. Wall, Mr. Thomas, and Mr. Middleton made a series of misrepresentations and omissions of material facts that would have precluded Wall from securing this patent had this information been properly disclosed. While delaying the prosecution of the '834 application, Dr. Wall, Mr. Thomas, and Mr. Middleton at the same time worked diligently to conceal the significant amount of prior art that rendered the '834 application invalid. They did so not only by concealing the relevant prior art that they were aware of, but also by misleading the USPTO as to Dr. Wall's date of invention. For this scheme to succeed, Dr. Wall, Mr. Thomas, and Mr. Middleton also needed to misrepresent the inventorship of the '834 application as well as feign ignorance about the continued prosecution of the '834 application. Dr. Wall, Mr. Thomas, and Mr.

Middleton did so with the specific intent to deceive the USPTO regarding material issues of patentability to secure the issuance of the '475 patent.

89. In so doing, Dr. Wall, Mr. Thomas, and Mr. Middleton violated their duties of candor, good faith, and disclosure of all material information before the USPTO. *See* 37 CFR § 1.56. 37 CFR § 1.56 requires that “[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in [§ 1.56].”

90. The gains to Dr. Wall from this scheme were substantial. First, rather than denying Dr. Wall’s claims as would have been required had Dr. Wall, Mr. Thomas, and Mr. Middleton properly apprised the USPTO of the material facts, the USPTO granted Dr. Wall a patent. Second, Dr. Wall unfairly benefited from his own substantial delay in prosecuting the '834 application.

91. For example, Dr. Wall delayed prosecution not only to extend the life of the patent, but also to conceal material prior art and Dr. Wall’s actual invention date. While the '834 application was pending, unexamined, due to Dr. Wall’s failure to prosecute it, he was studiously prosecuting separate claims in the related '122 application as well as other related applications. During prosecution of the

'122 application, Dr. Wall and Mr. Thomas misrepresented to the examiner, to avoid prior art, that the claims were entitled to an earlier invention date even though the BPAI had already concluded that there was no such entitlement. Then, once Dr. Wall and Mr. Thomas had misled the Examiner into allowing the '122 application claims, they grafted those claims into the '834 application in an improper effort to secure an extra *15 years* of term on those claims, excluding the effect of any terminal disclaimer, compounded by the material misrepresentation as to entitlement to an earlier date, when the BPAI — unbeknownst to the Examiner due to Wall's omission — had previously concluded otherwise. To consummate this bait-and-switch, Dr. Wall and Mr. Thomas concealed material prior art references. Throughout this multi-year campaign, Dr. Wall, Mr. Thomas, and Mr. Middleton violated their duties of candor, good faith, and disclosure to the USPTO, committing inequitable conduct. The substantial repeated misrepresentations and omissions, sustained over the course of months and years, leave in their wake the only reasonable inference: that Dr. Wall, Mr. Thomas, and Mr. Middleton intended to mislead the USPTO to secure the '475 patent.

92. Thus, an actual controversy has arisen and exists between Wall and Biotronik, Inc. as to whether or not any of the claims of the '475 patent are enforceable.



93. As demonstrated in the following paragraphs detailing Dr. Wall, Mr. Thomas, and Mr. Middleton's campaign of misrepresentation and omission, declaratory relief is appropriate and necessary to establish that the claims of the '475 patent are unenforceable.

94. Absent declaratory relief, Wall threatens to cause foreseeable and irreparable harm and injury to Biotronik, Inc. should it seek to enforce the '475 patent such that Biotronik, Inc. will be restrained from freely marketing, distributing, offering for sale, selling, and/or importing in/into the United States its Stent System Products.

95. Pursuant to 28 U.S.C. §§ 2201, *et seq.* Biotronik, Inc. is entitled to a declaratory judgment and hereby seeks a declaratory judgment that the '475 patent is unenforceable due to inequitable conduct.

**A. Dr. Wall and His Representatives Misrepresented and Omitted Material Facts Concerning the Invention Date of the Subject Matter in the '475 Patent**

96. Dr. Wall and Mr. Thomas repeatedly misrepresented and omitted material information from the USPTO concerning the invention date of the subject matter claimed in the '475 patent. Dr. Wall and Mr. Thomas made these misrepresentations and omissions in declaring that the '122 application (whose

claims were eventually added to the '475 patent) was entitled to an earlier invention date.

97. Dr. Wall and Mr. Thomas did so in a scheme to improperly evade certain prior art that the Examiner had concluded rendered claims sought by Dr. Wall and Mr. Thomas unpatentable. Dr. Wall and Mr. Thomas did so because an earlier invention date would avoid the cited references as prior art. Crucially, Dr. Wall had already tried and failed to establish that earlier invention date in connection with the '834 application. Specifically, the BPAI, the tribunal charged with determinations of priority of invention, after considering Dr. Wall's evidence, concluded in a decision dated June 28, 1995 that "[t]aking the uncorroborated testimony of Wall at face value" would only establish an "earliest possible date" of invention by Dr. Wall on September 8, 1987. This 1987 date would not have eliminated the cited references as prior art. Despite his failure in the 1990s to establish an earlier invention date, Dr. Wall tried doing so again in 2004 in connection with the '122 application. Specifically, he attempted to establish that his invention pre-dated *the same prior art* that he was unable to pre-date in the 1990s. Aware that the BPAI's 1995 decision would preclude securing the then-pending patent claims, Dr. Wall and Mr. Thomas not only hid the BPAI's prior conclusion, but also submitted plainly false statements in Dr. Wall's declaration for

an earlier invention date, statements that they were on notice were untrue. Dr. Wall and Mr. Thomas thus made a series of misrepresentations and omissions to the USPTO in attempting to establish an earlier invention date.

98. The Examiner rejected all of the pending claims in the '122 application in a September 9, 2004 Office Action. The Examiner's explanation included that the '122 claims were rendered obvious by U.S. Patent No. 4,740,207 ("Kreamer") in combination with either the U.S. Patent No. 4,733,665 ("Palmaz '665 Patent") or U.S. Patent No. 4,739,762 ("Palmaz '762 Patent"), and U.S. Pat. No. 4,665,918 ("Garza et al"). Kreamer is a U.S. patent that was filed on September 10, 1986, the Palmaz '665 Patent was filed on November 7, 1985, and the Palmaz '762 Patent was filed on November 3, 1986. Each of these patents benefitted from dates of U.S. filing prior to September 8, 1987, which is Wall's "earliest possible date" of invention as determined by the BPAI. Accordingly, each of these references qualifies as prior art to the '475 patent under 35 U.S.C. § 102(e).

99. In connection with his response, Dr. Wall submitted a Statement of Prior Invention (37 C.F.R. § 1.131) in an "effort to pre-date certain references that are dated prior to the earliest effective filing date of [his] patent application." Dr. Wall's Statement specifically asserted that he "began the development of [his]

invention before the earliest filing dates of either [Palmaz '762] and Kreamer ["] and he submitted materials to demonstrate this.

100. Dr. Wall signed a Statement of Prior Invention, declaring "under penalty of perjury . . . that all statements made herein of my own knowledge are true and correct" and "these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both." This was submitted to the USPTO on Dr. Wall's behalf on September 9, 2004.

101. The prior art references specifically addressed by the Statement of Prior Invention included: the Kreamer patent, which the BPAI had already determined that Dr. Wall did not pre-date, as well as the Palmaz '762 patent invented by Dr. Julio Palmaz, the vascular radiologist who, as discussed below, was the author and inventor on a variety of additional prior art that Dr. Wall and Mr. Thomas intentionally withheld from the USPTO.

102. Moreover, these efforts to antedate would also have applied to the Palmaz '665 patent, which as discussed below, Dr. Wall and Mr. Thomas withheld from the Examiner in connection with the prosecution of the '834 application.

103. After Dr. Wall submitted his Statement of Prior Invention, Dr. Wall, Mr. Thomas, and the Examiner engaged in an interview, during which "a

discussion was conducted concerning the Statement of Prior Invention and the accompanying Statement of Robert A. Guyton, M.D. Also discussed were Patent Office procedures as to how the statements would be reviewed by the Office. The references of record were not specifically discussed . . . .” U.S. Patent Appl. No. 10/293,122 File History, Amendment and Response dated September 27, 2004, at 1-2. After that interview, the Examiner withdrew his rejection over the Kreamer, and Palmaz ’665 and ’762 patents, and allowed the claims.

104. Even beyond the misrepresentation that Dr. Wall’s claims were entitled to an invention date pre-dating the Palmaz ’762 and Kreamer patents, Dr. Wall and Mr. Thomas made a series of additional misrepresentations and omissions in support of this earlier invention date.

105. First, Dr. Wall and Mr. Thomas not only failed to inform the Examiner that the BPAI had already determined that Dr. Wall had already failed to establish an earlier invention date, but also that that the “earliest possible date” of his invention was September 8, 1987, which would not have eliminated the Kreamer patent or the Palmaz ’665 or ’762 patents as prior art. Dr. Wall and Mr. Thomas also failed to tell the Examiner that Dr. Wall had appealed the BPAI’s decision, that the appeal was dismissed, and that the decision was therefore final. Instead of apprising the Examiner of these facts, Dr. Wall and Mr. Thomas instead

told the Examiner only that there had been an interference in connection with the '834 application. They withheld from the Examiner that the same arguments they were now raising, had already been rejected.

106. This information was not only critical for the Examiner to properly evaluate the prior art relevant to the '122 application, but the interference specifically concluded that Dr. Wall's alleged invention did *not* predate Kreamer. Despite having decisively lost that issue before the very USPTO tribunal charged with such determinations, Dr. Wall and Mr. Thomas asserted that Kreamer was not prior art to the '122 application, even though it was.

107. Second, Dr. Wall and Mr. Thomas knowingly submitted false evidence to support his alleged earlier invention date. Specifically, in Dr. Wall's September 9, 2004 Statement of Prior Invention, Dr. Wall submitted a drawing, attached as Exhibit 9, that he swore he had completed by October 15, 1984. That statement to the USPTO was false.

108. Dr. Wall admitted under oath that he altered the drawing after October 15, 1984, stating he had "modified [the drawing] with the addition of some material" between the dates of October 15, 1984 and December 5, 1984. According to Dr. Wall, these additions included specifying "the sleeve is being placed with a coaxial catheter," "an expansible sleeve dilated by balloon catheter,"

“a ratchet device, ratcheting the sleeve open,” and “another side view of a modification showing retention ridges on the outside of the sleeve.” On information and belief, these additions included drawings and text describing an “Expandable Sleeve” and aspects of that expandable sleeve, including “retention ridges” and “sleeve overlap,” and the “combination” of fabric, plastic, or metal. These additions relate to various claim limitations of the ’475 patent. For example, the “wall defining a discontinuity longitudinally thereof . . . providing a first edge and a second edge of said wall” are recited in claims 1, 7, and 10, and the “circumferential ribs” limitation is recited in claim 28. *See* ’475 patent, col. 5, ll. 38-42; *id.* col. 6, ll. 28-32, 62-65; *id.* col. 9, ll. 34-36.

109. Worse, Dr. Wall admitted that this drawing had been altered after October 15, 1984, *before* he submitted his Statement of Prior Invention. Upon information and belief, Dr. Wall had submitted the same drawing in connection with the Kreamer Interference on November 17, 1993. Dr. Wall’s admission that he had altered the drawing after October 15, 1984 came during his deposition during the Kreamer Interference on December 7, 1993. That was nearly 11 years before he made the misrepresentation to the USPTO in his September 9, 2004 Statement of Prior Invention that the same drawing (Exhibit 9) was completed by October 15, 1984. Dr. Wall did not provide the transcript of his deposition for the

interference to the Examiner in the course of prosecuting the '834 or '122 applications. Upon information and belief, Dr. Wall has also confirmed these representations during a 2010 deposition.

110. Third, Dr. Wall, Mr. Thomas, and Mr. Middleton omitted a variety of material information that contradicted his alleged earlier invention date.

111. For example, Dr. Wall, Mr. Thomas, and Mr. Middleton failed to inform the USPTO that the “coating” for the sleeve in his invention had been invented by or derived from another. As discussed below, upon information and belief, this subject matter was developed by Dr. Robert A. Guyton. However, Dr. Wall failed to identify Dr. Guyton as an inventor of the subject matter in the '122 application or the eventual '475 patent. Dr. Wall, Mr. Thomas, and Mr. Middleton likewise failed to identify Dr. Guyton's work as prior art.

112. As a further example, Dr. Wall, Mr. Thomas, and Mr. Middleton failed to inform the USPTO that Dr. Wall developed additional subject matter related to his invention in October 1987, not the earlier date he represented in his September 9, 2004 Statement of Prior Invention. Specifically, during his deposition in the interference, Dr. Wall admitted that a Wall Street Journal article published on Aug. 19, 1987 “sparked” his renewed interest in pursuing his idea. Dr. Wall's Statement of Prior Invention further included two letters dated Aug. 21,



1987 (Exhibits 31, 32), stating in each that Dr. Palmaz's implant discussed in the Wall Street Journal article is "strikingly similar" to his idea.

113. As a further example, Dr. Wall and Mr. Thomas failed to notify the USPTO that Dr. Wall had abandoned his alleged invention prior to reading the Palmaz WSJ Article. This abandonment would legally preclude Dr. Wall from securing an earlier invention date. Upon information and belief, Dr. Wall ceased developing his alleged invention in March 1986, after he failed to attract any interest in the approach he had initially developed. Seventeen months went by. Only when he saw the Wall Street Journal article lauding the work of Dr. Palmaz was Dr. Wall "sparked" into action. Upon information and belief, Dr. Wall shared the Palmaz WSJ Article with contacts at W. L. Gore & Associates, Inc. and C. R. Bard, Inc. In letters to his contacts at both companies, Dr. Wall stated that his idea was "strikingly similar" to Dr. Palmaz's implant as described in the Palmaz WSJ Article. Only thereafter did Dr. Wall begin to pursue his idea.

114. These misrepresentations and omissions by Dr. Wall and Mr. Thomas violated their duties of candor, good faith, and disclosure before the USPTO. For example, Dr. Wall and Mr. Thomas knew that the earliest possible invention date had already been decided by the BPAI and that his appeal to the Federal Circuit of that decision had been dismissed. Dr. Wall and Mr. Thomas also knew that the

2004 Statement of Prior Invention contained false information – both misrepresentations and omissions. Yet Dr. Wall and Mr. Thomas nevertheless submitted it. Dr. Wall and Mr. Thomas never corrected these misrepresentations at any time during the prosecution of the '122 and '834 applications, despite affirmative duties of candor, good faith, and disclosure of this material information to the Examiner. *See* 37 CFR § 1.56.

115. Had the USPTO been accurately informed of this information, Dr. Wall's assertion of an earlier invention date would have been rejected and his pending claims rejected. No doubt aware of this, Dr. Wall and Mr. Thomas omitted critical information concerning the result of the interference, submitted false evidence of a prior invention date, and selectively presented Dr. Wall's development story in his September 9, 2004 Statement of Prior Invention. For example, upon information and belief, had Dr. Wall and Mr. Thomas apprised the Examiner that the BPAI had already rejected Dr. Wall's alleged earlier invention date, the '122 application claims would not have been allowed.

116. The single most reasonable inference in light of the facts is that Dr. Wall and Mr. Thomas had the specific intent to deceive the USPTO regarding the material issue of invention date for the '122 application in order to evade the cited prior art, and secure the issuance of the '475 patent (which included allowed

claims from the '122 application). Dr. Wall and Mr. Thomas at all appearances did so intentionally to improperly secure the enormously longer patent term that the '834 application was to receive. Dr. Wall and Mr. Thomas's intent was underscored when they submitted a non-compliant disclosure of prior art after having paid the issue fee for the '834 application. In so doing they said: "submission of the [prior art] with a request for continued examination would forfeit the benefit of the early filing date under the old law that provides a 17 year patent from its issue date." The violation by Dr. Wall and Mr. Thomas of their duties of candor, good faith, and disclosure to avoid prior art with a discredited invention story that was material to patentability of the '475 Patent rises to the level of inequitable conduct.

**B. Dr. Wall and His Representatives Misrepresented and Omitted Material Facts Concerning the Inventorship of the Subject Matter in the '475 Patent**

117. Dr. Wall, Mr. Thomas, and Mr. Middleton also misrepresented and omitted information to the USPTO concerning the correct inventorship of the '475 patent. Specifically, Dr. Wall and Mr. Thomas repeatedly represented that Dr. Wall was the sole inventor of the subject matter claimed in the '475 patent. But these representations were belied in connection with prosecution of the '122 application, when Dr. Wall and Mr. Thomas submitted evidence revealing that

aspects of the claimed subject matter were contributed not by Dr. Wall, but by Dr. Robert A. Guyton, a cardiothoracic surgeon. This evidence was not only omitted from the prosecution of the '475 patent, but Dr. Wall affirmatively misrepresented that he developed the subject matter that had instead been contributed by Dr. Guyton and omitted Dr. Guyton as a named inventor on the '475 Patent.

118. In Dr. Wall's September 9, 2004 Statement of Prior Invention, which allegedly detailed the development of the claimed invention, Dr. Wall included a December 18, 1984 letter from Dr. Robert A. Guyton to Dr. Wall. In that letter, Dr. Guyton stated:

I think that placing a prosthetic sleeve on the inside of the coronary artery would be very likely to lead to atherosclerosis. It is possible, however, that the inner wall of the sleeve could be treated with a heparinized surface or one of the new thrombogenic surfaces and a better patency could be achieved.

119. Dr. Wall's September 9, 2004 Statement of Prior Invention was submitted to antedate prior art that had been cited against the then-pending '122 application. This disclosure was intended to demonstrate how the subject matter was developed prior to 1987.

120. Dr. Wall's Statement of Prior Invention sets forth no evidence that Dr. Wall developed a sleeve with a coating before Dr. Guyton's letter. In fact, Dr. Wall submitted no evidence during prosecution of either the '834 or '122

applications that suggests he conceived of adding a coating on a sleeve before Dr. Guyton's letter.

121. On information and belief, a reasonable patent examiner would have considered Dr. Guyton's letter and contributions material to the inventorship and patentability of the '475 patent. Claims 15-42 of the '475 patent recite a coating applied to a sleeve's mesh. As a result, Dr. Guyton's letter was material in deciding whether Dr. Wall was the sole inventor of the subject matter recited in the claims of the '834 application, as Dr. Wall, Mr. Middleton, and Mr. Thomas represented during prosecution of the '834 application. Nonetheless, Dr. Wall, Mr. Middleton, and Mr. Thomas failed to disclose the 1984 Guyton Letter during the prosecution of the '834 application.

122. Moreover, despite using this information to argue for an earlier invention date, Dr. Wall never listed Dr. Guyton as an inventor to the '475 patent, even though the claims included the "coating" that Dr. Guyton contributed. Instead, Dr. Wall submitted a declaration to the USPTO that "I verily believe I am the original, first, and sole inventor of the invention in 'Angioplasty stent' described and claimed therein." Upon information and belief, this was a knowingly false statement as Dr. Wall knew that he had derived this subject matter from Dr. Guyton in 1984, years before the statement was made. Upon information

and belief, Dr. Wall derived the concept of applying a coating to the sleeve from Dr. Guyton. Because Dr. Wall did not himself invent this subject matter that is claimed in the '475 patent, the patent is invalid under 35 U.S.C. § 102(f). Once again, Dr. Wall, Mr. Middleton, and Mr. Thomas did not disclose this information regarding the derivation to the USPTO.

123. Dr. Wall, Mr. Middleton, and Mr. Thomas's misrepresentations and omissions concerning inventorship were material. *See PerSeptive Biosys., Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000) (intentional "misrepresentations, omissions and half-truths to the PTO" made as a "persistent course of conduct" regarding inventorship were "highly material" and "calculated to obfuscate [] the threshold issue of inventorship") (internal quotations omitted). Inventorship is a bedrock requirement of U.S. patent law, and §§ 102(f) and 116 of the Patent Act make the provision of correct inventorship information a condition of patentability, and failure to comply with this requirement is grounds to invalidate a patent. Without correct inventorship information, the '475 patent is invalid.

124. Moreover, Mr. Thomas would have known that if Dr. Guyton contributed to at least one claim in the amended '834 application, then Dr. Guyton is required to be identified as an inventor. *See* 37 C.F.R. § 1.41. Dr. Wall and Mr.

Thomas had all the information necessary to determine that Dr. Guyton had developed the coating on the sleeve. Including Dr. Guyton as a co-inventor for the '834 application would mean that Dr. Guyton would have ownership rights in the '475 patent, and could separately license and use those rights without consulting Dr. Wall. Nevertheless, Dr. Wall and Mr. Thomas represented to the USPTO that only Dr. Wall was the inventor to the coating subject matter and withheld the 1984 Guyton Letter from the prosecution of the '834 application.

125. The most reasonable inference in light of the facts is that Dr. Wall, Mr. Middleton, and Mr. Thomas had the specific intent to deceive the USPTO regarding the material issue of inventorship in order to secure the issuance of the '475 patent.

**C. Dr. Wall and His Representatives Concealed and Misrepresented Material Prior Art**

126. Dr. Wall, Mr. Middleton, and Mr. Thomas also intentionally withheld material prior art from the USPTO during the prosecution of the '834 application. Consistent with their misleading and improper representations to antedate his invention, Dr. Wall, Mr. Middleton, and Mr. Thomas omitted material prior art that they were aware of during the pendency of the '834 application. These references included at least: (1) Palmaz, *Expandable Vascular Endoprosthesis* (May 18, 1983) ("Palmaz 1983 Monograph") and Palmaz, *Untitled Paper* ("Palmaz 1980

Monograph”) (collectively, “Palmaz Monographs”); (2) “What’s New: New Way to Open Clogged Arteries,” THE WALL STREET JOURNAL (Aug. 19, 1987) (“Palmaz WSJ Article”); (3) abstract of Julio C. Palmaz, et al, *Expandable Intraluminal Graft: A Preliminary Study*, RADIOLOGY (Nov. 1984), vol. 153 (P) (“Palmaz 1984 Abstract”); (4) Palmaz ’665 patent; (5) U.S. Patent No. 4,776,337 (“Palmaz ’337 patent”); and (6) U.S. Patent No. 5,059,211 (“Stack ’211 patent”). Both individually and in combination, these references demonstrate that Dr. Wall was not the first to develop the subject matter claimed in the ’475 patent.

127. Dr. Wall, Mr. Middleton, and Mr. Thomas omitted these references with the intent to deceive the USPTO into believing that the claimed invention was patentable. The examples of the omissions of this prior art made during the prosecution of the ’834 application described below demonstrate a pattern of misconduct as well as an intent to deceive the USPTO. Dr. Wall, Mr. Middleton and Mr. Thomas did so as part of a scheme to secure patent rights that Dr. Wall was not entitled to receive and would not have received had Dr. Wall, Mr. Middleton, and Mr. Thomas not omitted this material prior art.

128. As a result, Dr. Wall, Mr. Middleton, and Mr. Thomas breached their duties of candor, good faith, and disclosure before the USPTO by concealing these references and their conduct renders the ’475 patent unenforceable.



Dr. Wall and His Representatives Concealed the Palmaz Monographs During the '834 Application Prosecution

129. Dr. Wall and Mr. Thomas concealed the Palmaz Monographs (the Palmaz 1980 and 1983 Monographs) from the USPTO during the prosecution of the '475 patent, despite having known of these references and their materiality. Dr. Wall and Mr. Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

130. Dr. Wall and Mr. Thomas were in possession of the Palmaz Monographs prior to the issuance of the '475 patent. On information and belief, Dr. Wall and Mr. Thomas were in possession of the Palmaz Monographs by no later than on or about October 25, 2005.

131. The Palmaz Monographs are material because they at minimum disclose an intraluminal tubular structure made of a deformable wire mesh mounted in a collapsed state on a balloon catheter, inserted into a vessel, and expanded by inflation of the balloon, and having memory properties to oppose elastic recoil of the vessel wall and coated with vascular prosthetic material, which correspond to at least limitations of all claims of the '475 patent. The Palmaz Monographs are prior art at least under 35 U.S.C. §102(g) as evidence that Dr. Palmaz conceived of his invention and completed the monographs prior to Dr. Wall's invention. As a result, for at least these reasons, a reasonable examiner

would have considered the Palmaz Monographs material to patentability of the '475 patent. On information and belief, a reasonable examiner, having the opportunity to consider the Palmaz Monographs in relation to the claims as allowed in the '834 application, would have required a narrowing of the scope of those claims or would have precluded their issuance.

132. Moreover, Dr. Wall and Mr. Thomas conceded the materiality of the Palmaz Monographs by later and improperly disclosing them to the USPTO.

133. Despite having known of the materiality of the Palmaz Monographs before issuance, Dr. Wall and Mr. Thomas delayed its disclosure. They disclosed them to the USPTO *after* having already paid the issue fee for the '834 application. As a result, the disclosure did not comply with the requirements of 37 C.F.R. §1.97. They did so to avoid the USPTO from reviewing and considering the Palmaz Monographs in connection with the '834 application. In order to have the USPTO consider additional information that could be material to patentability after the issue fee has already been paid, it is customary for the applicant to petition for withdrawal from issue and file a request for continued examination. But as Dr. Wall and Mr. Thomas themselves explained to the USPTO, filing such a petition with a request for continued examination would “forfeit the benefit ... provid[ing] a 17 year patent from its issue date.”

134. As a result, Dr. Wall and Mr. Thomas made clear that their desire in disclosing the Palmaz Monographs in this defective manner was to prevent the Examiner from considering them in view of the claims and interfering with the issuance of the '475 patent. As Dr. Wall and Mr. Thomas explained:

“[S]ubmission of the monographs with a request for continued examination would forfeit the benefit of the early filing date under the old law that provides a 17 year patent from its issue date.”

135. Dr. Wall and Mr. Thomas withheld the Palmaz Monographs from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall and Mr. Thomas had the specific intent to withhold the Palmaz Monographs to deceive the USPTO. In so doing, Dr. Wall and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

Dr. Wall and His Representatives Concealed the Palmaz WSJ Article During the '834 Application Prosecution

136. Dr. Wall, Mr. Middleton, and Mr. Thomas concealed the Palmaz WSJ Article from the USPTO during the prosecution of the '475 patent, despite having known of this reference and its materiality. Dr. Wall, Mr. Middleton, and Mr. Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

137. Dr. Wall, Mr. Middleton, and Mr. Thomas were aware of the Palmaz WSJ Article and its materiality prior to the issuance of the '475 patent. However, at no point during the prosecution of the '834 application did Dr. Wall, Mr. Middleton, or Mr. Thomas identify the Palmaz WSJ Article.

138. For example, Dr. Wall, Mr. Thomas, and Mr. Middleton failed to disclose the Palmaz WSJ Article in connection with the '834 application, despite having known about this article since before Dr. Wall submitted the '834 application. For example, on August 21, 1987 Dr. Wall sent a letter to C. R. Bard, Inc. concerning the Palmaz WSJ Article. In that letter, Dr. Wall acknowledged the materiality of the Palmaz WSJ Article to the later '834 application, describing Dr. Palmaz's stent discussed in the article as "strikingly similar" to his purported invention. Importantly, this letter memorializing his awareness of Palmaz WSJ Article and its materiality predates the filing of the '834 application by several months. Despite this clear awareness, Dr. Wall and his prosecuting attorneys failed to disclose the Palmaz WSJ Article throughout the entire prosecution of the '834 application.

139. Moreover, Dr. Wall and Mr. Thomas included the 1987 letter to C.R. Bard, Inc. in Dr. Wall's 2004 Statement of Prior Invention submitted in connection with prosecution of the '122 application. However, Dr. Wall and Mr. Thomas

again failed to disclose that the Palmaz WSJ Article was prior art in connection with the '834 application (or even the '122 application). Instead, Dr. Wall used the 1987 letter describing the Palmaz WSJ Article to represent that his claims were entitled to an earlier invention date. In so doing, Dr. Wall and Mr. Thomas relied on the aforementioned series of misrepresentations and omissions concerning the invention date of the '834 application. In particular, Dr. Wall and Mr. Thomas not only concealed that the Palmaz WSJ Article was prior art, but also that Dr. Wall's purported invention had been triggered by reviewing this article.

140. The Palmaz WSJ Article is material because it at minimum discloses Dr. Palmaz's intraluminal stents, made of steel mesh that spring open against the artery walls and hold the vessel open to the desired diameter and were implanted in human patients, which correspond to at least limitations of all claims of the '475 patent. The Palmaz WSJ Article is prior art at least under 35 U.S.C. §102(a) and is evidence demonstrating Dr. Palmaz's prior invention under 35 U.S.C. §102(g). Moreover, the context and Dr. Wall's familiarity with, and reliance on, the Palmaz WSJ Article was material to Dr. Wall's purported invention of the subject matter in the '834 application. As a result, for at least these reasons, a reasonable examiner would have considered the Palmaz WSJ Article material to patentability of the '475 patent.

141. Nonetheless, Dr. Wall, Mr. Middleton, and Mr. Thomas withheld the Palmaz WSJ Article from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall, Mr. Middleton, and Mr. Thomas had the specific intent to withhold the Palmaz WSJ Article to deceive the USPTO. In so doing, Dr. Wall, Mr. Middleton, and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

Dr. Wall and His Representatives Concealed the Palmaz Abstract During the '834 Application Prosecution

142. Dr. Wall, Mr. Middleton, and Mr. Thomas concealed the Palmaz Abstract from the USPTO during the prosecution of the '475 patent, despite having known of this reference and its materiality. Dr. Wall, Mr. Middleton, and Mr. Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

143. On information and belief, Dr. Wall, Mr. Middleton, and Mr. Thomas were aware of the Palmaz Abstract and its materiality prior to the issuance of the '475 patent. On information and belief, the Medical College of Georgia sent the Palmaz Abstract to Dr. Wall. Moreover, on information and belief, Dr. Wall referenced the Palmaz Abstract in a communication to Cordis in 2002. Moreover,

upon information and belief, Dr. Wall, Mr. Middleton, and Mr. Thomas were very familiar with Dr. Palmaz's work and prior inventions related to the '834 application. Neither Dr. Wall nor Mr. Middleton or Mr. Thomas could have reasonably overlooked the single paragraph disclosure of the Palmaz Abstract.

144. The Palmaz Abstract is material because it at minimum discloses an expandable, intraluminal graft made of a continuous, woven, stainless steel wire forming a tubular mesh, mounted on an angioplasty catheter, which correspond to at least limitations of all claims of the '475 patent. The Palmaz Abstract is prior art at least under 35 U.S.C. §102(b). As a result, for at least these reasons, a reasonable examiner would have considered the Palmaz Abstract material to patentability of the '475 patent.

145. Nonetheless, Dr. Wall, Mr. Middleton, and Mr. Thomas withheld the Palmaz Abstract from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall, Mr. Middleton, and Mr. Thomas had the specific intent to withhold the Palmaz Abstract to deceive the USPTO. In so doing, Dr. Wall, Mr. Middleton, and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

Dr. Wall and His Representatives Concealed the Palmaz '665 Patent During the  
'834 Application Prosecution

146. Dr. Wall, Mr. Middleton, and Mr. Thomas concealed the Palmaz '665 patent from the USPTO during the prosecution of the '475 patent, despite having known of this reference and its materiality. Dr. Wall, Mr. Middleton, and Mr. Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

147. Dr. Wall, Mr. Middleton, and Mr. Thomas were aware of the Palmaz '665 patent and its materiality prior to the issuance of the '475 patent. However, at no point during the prosecution of the '834 application did Dr. Wall, Mr. Middleton, or Mr. Thomas identify the Palmaz '665 patent.

148. For example, Dr. Wall and Mr. Thomas failed to disclose the Palmaz '665 patent in connection with the '834 application, despite disclosing the Palmaz '665 patent in November 2002 to the USPTO in connection with the related '122 application. Specifically, Dr. Wall and Mr. Thomas identified the Palmaz '665 patent in a November 13, 2002 information disclosure form that was considered by the Examiner in a December 17, 2003 list of references. Not only was the '834 application pending at this time, but the claims of the '122 application had significant overlap with the claims in the '834 application.



149. Moreover, in December 2003, the USPTO relied on the Palmaz '665 patent in rejecting the claims of the '122 application. In their January 2004 response, Dr. Wall and Mr. Thomas sought to distinguish the claims from the Palmaz '665 patent. Again the '834 application remained pending at that time, but Dr. Wall and Mr. Thomas did not disclose the Palmaz '665 patent in connection with the '834 application.

150. In April 2004, the Examiner again relied on the Palmaz '665 patent to reject the pending claims of the '122 application. Again, in their July 2004 response, Dr. Wall and Mr. Thomas sought to distinguish the Palmaz '665 patent. However, the Palmaz '665 patent was still not disclosed in connection with the '834 application.

151. In September 2004, the Examiner again relied on the Palmaz '665 patent to reject the pending claims of the '122 application. Again, in their September 2004 response, Dr. Wall and Mr. Thomas sought to distinguish the Palmaz '665 patent. However, the Palmaz '665 patent was still not disclosed in connection with the '834 application.

152. Importantly, in connection with this September 2004 attempt to distinguish the Palmaz '665 patent, Dr. Wall submitted the aforementioned misleading and omission-ridden Statement of Prior Invention. As a result, not only

did Dr. Wall, Mr. Middleton, and Mr. Thomas avoid disclosing the Palmaz '665 patent in connection with the '834 application, but they benefited from the misrepresentations and omissions about an alleged earlier invention date to set aside the Palmaz '665 patent.

153. On information and belief, Dr. Wall conceded the materiality of the Palmaz '665 patent to third parties prior to the issuance of the '475 patent. Specifically, Dr. Wall's company prepared a business plan before the issuance of the '475 patent that specifically discussed the Palmaz '665 patent. Thus, Dr. Wall, Mr. Middleton, and Mr. Thomas had direct knowledge of the Palmaz '665 patent and its materiality to the '834 application.

154. The Palmaz '665 patent is material because it at minimum discloses an expandable intraluminal graft and method and apparatus for implanting an expandable intraluminal graft, where the graft is a wire mesh tube that is expanded within a blood vessel by an angioplasty balloon on a catheter, which correspond to at least limitations of all claims of the '475 patent. The Palmaz '665 patent is prior art at least under 35 U.S.C. §102(e)(2). As a result, for at least these reasons, a reasonable examiner would have considered the Palmaz '665 patent material to patentability of the '475 patent.

155. Nonetheless, Dr. Wall, Mr. Middleton, and Mr. Thomas withheld the Palmaz '665 patent from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall, Mr. Middleton, and Mr. Thomas had the specific intent to withhold the Palmaz '665 patent to deceive the USPTO. In so doing, Dr. Wall, Mr. Middleton, and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

Dr. Wall and His Representatives Concealed the Palmaz '337 Patent During the '834 Application Prosecution

156. Dr. Wall and Mr. Thomas concealed the Palmaz '337 patent from the USPTO during the prosecution of the '475 patent, despite having known of this reference and its materiality. Dr. Wall and Mr. Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

157. Dr. Wall and Mr. Thomas were aware of the Palmaz '337 patent and its materiality prior to the issuance of the '475 patent. However, at no point in the prosecution of the '834 application did Dr. Wall or Mr. Thomas identify the Palmaz '337 patent. For example, on information and belief, Dr. Wall and his company prepared a business plan during prosecution of the '122 application, and that business plan discussed the Palmaz '337 patent.

158. The Palmaz '337 patent is material because it at minimum discloses an expandable intraluminal graft and method and apparatus for implanting an expandable intraluminal graft, where the graft is a wire mesh tube having a coating and that is expanded within a blood vessel by an angioplasty balloon on a catheter, which correspond to at least limitations of all claims of the '475 patent. The Palmaz '337 patent is prior art at least under 35 U.S.C. §102(e)(2). As a result, for at least these reasons, a reasonable examiner would have considered the Palmaz '337 patent material to patentability of the '475 patent.

159. Nonetheless, Dr. Wall and Mr. Thomas withheld the Palmaz '337 patent from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall and Mr. Thomas had the specific intent to withhold the Palmaz '337 patent to deceive the USPTO. In so doing, Dr. Wall and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

Dr. Wall and His Representatives Concealed the Stack '211 Patent During the '834 Application Prosecution

160. Dr. Wall, Mr. Middleton, and Mr. Thomas concealed the Stack '211 patent from the USPTO during the prosecution of the '475 patent, despite having known of this reference and its materiality. Dr. Wall, Mr. Middleton, and Mr.

Thomas did so with the specific intent to mislead the USPTO to secure the issuance of the '475 patent.

161. Dr. Wall, Mr. Middleton, and Mr. Thomas were aware of the Stack '211 patent and its materiality prior to the issuance of the '475 patent. However, at no point during the prosecution of the '834 application did Dr. Wall, Mr. Middleton, or Mr. Thomas identify the Stack '211 patent.

162. For example, on December 11, 1996, the USPTO cited the Stack '211 patent against another co-pending application owned by Dr. Wall (U.S. Application No. 08/578,504). The claims of the '504 application had significant overlap with the claims in the '834 application. However, Dr. Wall did not disclose the Stack '211 patent in connection with the '834 application which was then pending.

163. Dr. Wall, Mr. Middleton, and Mr. Thomas likewise failed to disclose the Stack '211 patent in connection with the '834 application, despite disclosing the Stack '211 patent to the USPTO in connection with the '122 application in November 2002. Specifically, Dr. Wall identified the Stack '211 patent in his November 13, 2002 information disclosure form that was considered by the Examiner in a list of references dated December 17, 2003. By identifying the Stack '211 patent in that filing, Dr. Wall and Mr. Thomas indicated their belief that

the Stack '211 patent was necessary to disclose to the USPTO because it was material to the '122 application claims. Not only was the '834 application pending at this time, but the claims of the '122 application had significant overlap with the claims in the '834 application.

164. The Stack '211 patent is material because it at minimum discloses a stent that is carried to a treatment site on a catheter having an inflatable balloon, where the stent has two longitudinal edges and holes to facilitate tissue ingrowth, which correspond to at least limitations of all claims of the '475 patent. The Stack '211 patent is prior art at least under 35 U.S.C. §102(e)(2). As a result, for at least these reasons, a reasonable examiner would have considered the Stack '211 patent material to patentability of the '475 patent.

165. Nonetheless, Dr. Wall, Mr. Middleton, and Mr. Thomas withheld the Stack '211 patent from being considered by the USPTO in connection with the '834 application. The single most reasonable inference in light of the facts is that Dr. Wall, Mr. Middleton, and Mr. Thomas had the specific intent to withhold the Stack '211 patent to deceive the USPTO. In so doing, Dr. Wall, Mr. Middleton, and Mr. Thomas intentionally breached their duties of candor, good faith, and disclosure before the USPTO and committed inequitable conduct in procuring the '475 patent.

**D. Dr. Wall and His Representatives Made False Statements in Petitioning to Revive the Abandoned '834 Application**

166. Dr. Wall and Mr. Thomas also committed inequitable conduct by making knowingly false statements to the USPTO when reviving the '834 application. Dr. Wall and Mr. Thomas represented that they had not known that the USPTO would issue an office action concerning the '834 application. Dr. Wall and Mr. Thomas made these representations to revive the '834 application, which had been abandoned on September 21, 2004 because of Dr. Wall's failure to respond to an office action.

167. However, Dr. Wall and Mr. Thomas were not only aware that the '834 application remained pending, and benefited from that fact, but upon information and belief, Dr. Wall also knew an office action would eventually issue. Had the USPTO known the truth, it would not have permitted the '834 application to be revived and the '475 patent would never have issued.

168. On June 28, 1995, the BPAI ruled against Dr. Wall on the interference between the '834 application and Kreamer. Dr. Wall's appeal to the Federal Circuit was dismissed on February 19, 1997 for failure to file a brief within the time permitted by the rules.

169. On August 20, 2004, the USPTO resumed prosecution on the '834 application claims that were not subject to the interference by issuing an office

action. On September 21, 2004, the '834 application was abandoned because of Dr. Wall's failure to respond to the office action.

170. On February 14, 2005, Dr. Wall and Mr. Thomas filed a Petition for Revival and a Request To Withdraw and Re-Mail Office Action dated August 20, 2004. To support that petition, Dr. Wall and Mr. Thomas stated:

The Office Action that was issued by the Office was the first Office Action issued in this file for several years. Applicant and his attorney were not aware of a likelihood that an Office Action would be issued in this application file and did not anticipate that an Office Action would be issued.

171. These statements were false and, upon information and belief, Dr. Wall and Mr. Thomas knew they were false. Upon information and belief, Dr. Wall and Mr. Thomas made these misrepresentations with the specific intent to deceive the USPTO into reviving the '834 application. Without these material misrepresentations, the '475 patent would not have issued.

172. On information and belief, at a deposition in 2010, Dr. Wall twice admitted that he had expected the August 20, 2004 office action.

173. Moreover, Dr. Wall and his attorneys have repeatedly represented that they were aware that the claims in the '834 application remained pending.

174. For example, in a November 14, 1996 letter from the USPTO in connection with the interference proceeding, the USPTO informed Dr. Wall and



Mr. Thomas that the “files [in the ’834 application will be] returned to the examiner for Ex parte prosecution.” In a November 20, 1996 letter to the USPTO, Dr. Wall, through his attorney, acknowledged receipt of the USPTO’s letter.

175. Dr. Wall again acknowledged the pending ’834 application claims in August 12, 1999, when he submitted a terminal disclaimer in connection with U.S. Application No. 08/667,604. This terminal disclaimer stated:

[t]he applicant disclaims the terminal portion of any patent that may issue to the above captioned U.S. patent application that extends beyond the expiration of any patent that may issue to U.S. patent application No. 07/129,834.

Again this acknowledged that Dr. Wall was aware of the pending ’834 application claims.

176. Then, on November 13, 2002, Dr. Wall and Mr. Thomas filed the ’122 application. Mr. Thomas filed the ’122 application as a divisional application of the ’834 application. To do so, the ’834 application must have still been pending. As a result, on November 13, 2002, Dr. Wall and Mr. Thomas knew the ’834 application was still pending.

177. Dr. Wall and Mr. Thomas again confirmed their understanding that the ’834 application remained pending after the interference in a March 17, 2005 communication with the USPTO in connection with the ’834 application. In that letter, they stated for “an application received back from the Court of Appeals of

the Federal Circuit, when some claims have been allowed,” “the proceedings are considered terminated only as to any claims which still stand rejected” and cited MPEP § 1216.01, which concerns the results of appeals on pending applications.

178. Dr. Wall and Mr. Thomas knew that the '834 application claims remained pending, as Dr. Wall has admitted he is “very familiar with the patent process,” and therefore understood that the '834 application was pending after the conclusion of the interference proceeding. Likewise, Mr. Thomas’s statements to the USPTO confirm that he was aware of the pending '834 application claims. Dr. Wall benefited from those pending claims in prosecuting additional patent applications.

179. A reasonable Examiner would have considered Dr. Wall’s and Mr. Thomas’s awareness that the '834 application was still active after the 1997 Federal Circuit dismissal to be material to patentability to the claims of the '834 application. This would have been material in determining whether to grant Dr. Wall’s February 14, 2005 Petition For Revival and Request to Withdraw and Re-Mail Office Action Dated August 20, 2004, in which Mr. Thomas stated “the failure to respond to the Office Action was unintentional.” Upon information and belief, had the Petition's Examiner known that Dr. Wall and Mr. Thomas were aware of the pending '834 application claims between 1997 and 2004, the Petitions

Examiner would have considered that to be material information in determining whether to grant Dr. Wall's Petition for Revival. Upon information and belief, Dr. Wall and Mr. Thomas understood that if they disclosed their awareness of the pending '834 application and knowledge that an office action was likely to issue in the '834 application, then their Petition for Revival would be denied, and the '475 patent would not have issued.

180. As a result, Dr. Wall and Mr. Thomas violated their duties of candor, good faith, and disclosure before the USPTO. Not only did Dr. Wall and Mr. Thomas fail to disclose their awareness of the pending '834 application, but they knowingly misrepresented that they did not know an office action would issue. Dr. Wall and Mr. Thomas never corrected these misrepresentations at any time during the prosecution of the '122 and '834 applications, despite affirmative duties of candor, good faith, and disclosure of this material information to the Examiner. *See* 37 CFR § 1.56. Upon information and belief, Dr. Wall and Mr. Thomas made these misrepresentations because, had the USPTO been accurately informed of this information, the '834 application would have remained abandoned and the '475 patent would not have issued.

181. Because both Dr. Wall and Mr. Thomas were well-versed with the U.S. patent system, and based on the statements demonstrating their awareness of

the pending '834 application, the most reasonable inference in light of the facts is that Dr. Wall and Mr. Thomas had the specific intent to deceive the USPTO to revive the '834 application.

**E. Dr. Wall and His Representatives Made False Statements in Prosecuting the '834 Application**

182. Dr. Wall and Mr. Thomas also committed inequitable conduct by making knowingly false statements to the USPTO when prosecuting the '834 application. Dr. Wall and Mr. Thomas represented that they were adding claims to the '834 application that covered subject matter deemed allowable by the examiner in the '122 application. Dr. Wall and Mr. Thomas made these representations to obtain an allowance in the '834 application.

183. However, the claims that were actually added to the '834 application when Dr. Wall and Mr. Thomas made that statement were not limited to the allowable subject matter in the '122 application. To the contrary, Dr. Wall and Mr. Thomas added claims that were broader in scope, while representing precisely the opposite to the Examiner.

184. In the Examiner's statement of reasons for allowance in the '122 application, the Examiner referred to the limitation "the mesh being biased toward its collapsed position," in combination with other limitations, as a feature not disclosed in the prior art. When Dr. Wall and Mr. Thomas amended the '834

application to add nine entirely new claims on March 17, 2005, they stated these new claims were “based upon the Examiner’s statement of reasons for allowance in co-pending divisional application 10/293,122” and asserted that since they were “apparatus claims based on the same information as recited by the Examiner’s statement [they] should be allowable in [the ’834] application.”

185. Contrary to what Dr. Wall and his counsel represented, the new claims added to the ’834 application were not solely based on the Examiner’s statement, but instead recited a markedly different approach to cover the exact opposite of what the Examiner deemed allowable: “said mesh being biased toward either its collapsed position or its expanded position.” The allowed claims in the ’122 application did not recite that the mesh is biased toward its expanded position. None of the pending claims in the ’122 application ever recited that the mesh is biased towards its expanded position, nor was this feature ever discussed in the ’122 application file history. The Examiner’s statement of reasons for allowance in the ’122 application did not indicate that any limitation regarding a mesh being biased toward its expanded position was allowable.

186. Dr. Wall and Mr. Thomas’s representation that the new claims were apparatus claims based on the same information as recited by the Examiner’s statement was false. Upon information and belief, Dr. Wall and Mr. Thomas knew

their representation was false. Upon information and belief, Dr. Wall and Mr. Thomas made these misrepresentations with the specific intent to deceive the USPTO into allowing the '834 application.

187. Without these material misrepresentations, the '475 patent would not have issued. Upon information and belief, a reasonable examiner would have considered the introduction of subject matter that was broader than what was previously deemed allowable to be material and would have implicated teachings in the prior art.

188. As a result, Dr. Wall and Mr. Thomas violated their duties of candor, good faith, and disclosure before the USPTO. Dr. Wall and Mr. Thomas knowingly made misrepresentations to the USPTO when they stated that the new claims were based on the allowable subject matter. Dr. Wall and Mr. Thomas never corrected these misrepresentations at any time during the prosecution of the '834 application, despite affirmative duties of candor, good faith, and disclosure of this material information to the Examiner. *See* 37 CFR § 1.56. Upon information and belief, Dr. Wall and Mr. Thomas made these misrepresentations because, had the USPTO been accurately informed of this information, the '834 application would not have issued as the '475 patent.

189. Because both Dr. Wall and Mr. Thomas were well-versed with the U.S. patent system, the most reasonable inference in light of the facts is that Dr. Wall and Mr. Thomas had the specific intent to deceive the USPTO to allow the '834 application.

### **JURY DEMAND**

190. Pursuant to Fed. R. Civ. P. 38, Biotronik, Inc. hereby demands a trial by jury of all issues so triable.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff requests that judgment be entered in favor of Biotronik, Inc. and against Defendant Wall:

- A. Declaring that Biotronik, Inc.'s Stent System Products have not and do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '475 patent;
- B. Declaring that the '475 patent is invalid;
- C. Declaring that the '475 patent is not enforceable;
- D. Enjoining Wall from enforcing the '475 patent;
- E. Finding that this is an exceptional case under 35 U.S.C. § 285;
- F. Awarding Biotronik, Inc. its costs and attorneys' fees; and

G. Awarding Biotronik, Inc. such other relief as the Court may deem just and proper under the circumstances.

Dated: March 18, 2021

Respectfully submitted,

/s/ Jeremy U. Littlefield

Jeremy U. Littlefield

Georgia Bar No. 141539

jlittlefield@robbinsfirm.com

Robbins Ross Alloy Belinfante Littlefield LLC

500 14th Street, N.W.

Atlanta, Georgia 30318

(678) 701-9381

*Attorney for Plaintiff Biotronik, Inc.*

*Of Counsel for Plaintiff  
Biotronik, Inc.  
(pro hac vice forthcoming)*

Scott T. Weingaertner  
John P. Padro  
Grace Wang  
Lauren Kuehn Pelletier  
WHITE & CASE LLP  
1221 Avenue of the Americas  
New York, NY 10036-2787  
(212) 819-8200