UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION, CINCINNATI

INNOVATIVE HEALTH, LLC, *Plaintiff*, v. VEIN360, LLC, *Defendant*.	Case No. 1:24-cv-0068 **JURY DEMAND**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Innovative Health, LLC (Innovative Health) files this complaint for patent infringement against Defendant Vein360, LLC (Vein360) and states as follows:

I. NATURE OF THE ACTION

1. This is an original complaint for patent infringement pursuant to 35 U.S.C. §§ 100 *et seq*. As further stated herein, Innovative Health alleges that Vein360 infringes one or more claims of U.S. Patent No. 11,896,730 ('730 patent) owned by Innovative Health.

II. THE PARTIES

2. Innovative Health is an Arizona limited liability company having an address of 1435 N. Hayden Rd., Ste. 100, Scottsdale, AZ 85257.

3. Upon information and belief, Vein360 is a limited liability company organized under the laws of Wyoming, having a principal place of business of 4460 Lake Forest Dr., Ste 230, Blue Ash, OH 45242.

III. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Vein360 because it has conducted and continues to regularly conduct business within the State of Ohio and this District. Vein360 has purposefully and voluntarily availed itself of the privileges of conducting business in the United States, the State of Ohio, and this District by continuously and systematically placing goods into the stream of commerce through an established distribution channel with the expectation that they will be purchased by consumers in this District. Vein360 directly and/or through intermediaries (including distributors, sales agents, and others), ships, distributes, sells, offers to sell, imports, advertises, makes, and/or uses its products (including but not limited to the products accused of infringement herein) in the United States, the State of Ohio, and this District.

6. Upon information and belief, Vein360 has sold and offered for sale products in this District, including products manufactured using the methods accused of infringement herein, and practiced the methods accused of infringement herein, in this District. Vein360 has committed infringing acts in this District by, *inter alia*, directly and/or indirectly making, using, selling, offering to sell or importing products manufactured using methods that infringe one or more claims of the ’730 patent. Innovative Health’s infringing acts within this District have established minimum contacts with the State of Ohio and this District.

7. Innovative Health’s causes of action arise directly from Vein360’s business contacts and other activities in the State of Ohio and this District.

8. Vein360 has derived substantial revenues from its infringing acts within the State of Ohio and this District.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) because Vein360 has committed acts of infringement in this District and has a regular and established place of business in this District.

10. Vein360 has committed acts of infringement in this District and does business in this District, including making sales and/or providing service and support for customers and/or end-users in this District. Vein360 purposefully and voluntarily sold one or more products manufactured using the infringing methods with the expectation they would be purchased in this District. The products manufactured using the infringing methods have been and continue to be purchased in this District. Thus, Vein360 has committed acts of infringement within the United States, the State of Ohio, and this District.

11. Vein360 has established minimum contacts with this District such that the exercise of jurisdiction over Vein360 would not offend traditional notions of fair play and substantial justice.

IV. THE ASSERTED PATENT

12. On February 13, 2024, the United States Patent and Trademark Office (USPTO) duly and legally issued United States Patent No. 11,896,730 entitled "Reprocessing a Single-Use Medical Device," and naming Blessan C. Joseph, Rafal Chudzik, and Haley C. Ellis as inventors. A copy of the '730 patent is submitted herewith as Exhibit A.

13. Innovative Health asserts and alleges that Vein360 has infringed and continues to infringe at least one claim of the '730 patent.

V. FACTUAL ALLEGATIONS

Overview of the Patented Technology

14. Innovative Health was founded in 2014. At the time, safe, effective, and precise methods for reprocessing single-use medical devices were unknown. These methods are highly important for medical devices that are to be used in a patient, particularly for reprocessed medical devices.

15. Innovative Health recognized the challenges of the medical device industry. For example, Innovative Health recognized that many medical devices were single-use medical devices that could be reprocessed and used again. Many single-use medical devices, such as catheters, have coatings that provide a lubricous surface allowing better maneuverability, increased patient comfort, and more precise control. However, these coatings can trap biological contaminants and can be difficult to remove during a reprocessing method. Biological contaminants must be removed from the single-use medical device in order for the device to be safely used in a patient.

16. In view of these challenges, Innovative Health developed and implemented a coating removal and reapplication processing method. For example, Innovative Health's technology completely removes coatings from a single-use medical device after use in a patient or after discovery of a non-compliant coating. Specifically, Innovative Health discovered coatings can be effectively removed utilizing solvents, such as denatured ethyl alcohol. The single-use medical device is then prepared for a new coating and a new coating is applied. The single-use medical device is reprocessed in a Food and Drug Administration (FDA) approved condition for use in a patient. The methods can be used on Eagle Eye Catheters and other similar medical devices.

17. All applicable rights have been assigned to Innovative Health, and Innovative Health is the owner of the '730 patent and the patented inventions relating to its methods for reprocessing single-use medical devices.

The Accused Products and Methods

18. Vein360 has practice and continues to practice Innovative Health's patented coating removal and application methods, and has sold and continues to sell devices manufactured using Innovative Health's patented coating removal and application methods, including the Vein360 Reprocessed Visions PV .035 Catheter, Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter (collectively, the Accused Products).

19. The Accused Products all have hydrophilic coatings on an outer surface of the catheters. The Accused Products have been approved by the FDA under the FDA's 510(k) clearance program.

20. A copy of the FDA's publication entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" is submitted herewith as Exhibit B.

21. According to the FDA's 510(k) program, medical devices are required to be evaluated for substantial equivalence before being approved for commercial sale.[1] The FDA bases its approval of a device on whether the device is substantially equivalent to a legally marketed (predicate) device.[2]

22. "Substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device (originally manufactured device), that the device

[1] (Ex. B, at p. 2-3.)

[2] (Ex. B, at p. 3.)

has the same intended use as the predicate device and that the device has (i) the same technological characteristics as the predicate device, or (ii) different technological characteristics, and that the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary, that demonstrates the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness from those of the predicate device.[3]

23. A copy of the FDA's publication "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" is submitted herewith as Exhibit C.

24. As set forth therein, Coating integrity testing is recommended for all coated catheters.[4]

25. To fully reprocess the Accused Products, the hydrophilic coating must be removed due to biological contamination from previous use in a patient and to ensure uniform surface for coating reapplication. A catheter that has been used in a patient does not have a coating that can be reused in another patient due to, amongst other issues, biological contamination. Further, when a catheter with a hydrophilic coating is used in a patient, the properties of the coating change. Hydrophilic coatings expand when they contact fluids such as blood or water. The hydrophilic coating does not return to its same form after use. Therefore, in order to reprocess a catheter, the hydrophilic coating must be removed and reapplied.

[3] (Ex. B, at p. 6-7.)

[4] (Ex. C, at p. 33-34.)

26. Upon information and belief, without removing the hydrophilic coatings from the Accused Products and reapplying the coatings, the Accused Products would not have been determined to be substantially equivalent to a predicate device as required by the FDA's 510(k) clearance program. Further, in order to obtain substantial equivalence, the new coating must have the same properties as the original coating. Therefore, the surface of the catheter must be cleaned and validated for coating removal, such that the surface is substantially equivalent to the originally manufactured surface.

27. The Vein360 Reprocessed Visions PV .035 Catheter is depicted below:

28. The Vein360 Reprocessed Visions PV .035 Catheter has a hydrophilic coating on an exterior surface of the catheter.

29. Since the FDA requires substantial equivalence between the reprocessed device and a predicate device, upon information and belief the FDA would not approve the Vein360 Reprocessed Visions PV .035 Catheter unless the hydrophilic coating was removed, the coating removal was validated for any residual coating, the surface was prepared by removing any soil, and a new hydrophilic coating was applied, to ensure substantial equivalence to predicate device, safety, and efficacy for reuse.

30. On June 6, 2023, Vein360 received a first FDA Section 510(k) clearance letter to make, use, and sell the Vein360 Reprocessed Visions PV .035 Catheter. A copy of the first FDA Section 510(k) clearance letter is submitted herewith as Exhibit D.

31. The first FDA 510(k) clearance letter states "[t]he Vein360 Reprocessed Visions PV .035 Catheter is substantially equivalent to the new, unused device of the same product currently marketed by the device's original equipment manufacturer (OEM)."[5]

32. The Vein360 Reprocessed Visions PV .035 Catheter predicate device is for "single patient use."[6] Therefore, the Vein360 Reprocessed Visions PV .035 Catheter is a reprocessed single-use medical device.

33. The first FDA 510(k) clearance letter further states "[u]pon receipt, the Visions PV .035 Digital IVUS catheter is cleaned, inspected, functionally tested, hydrophilic coated, packaged, and sterilized using (EO) gas."[7]

34. "The cleaning operation was validated with a high degree of confidence by objectively demonstrating removal of all soil under minimum operating conditions."[8] Vein360 cleans the Vein360 Reprocessed Visions PV .035 Catheter by removing the coating and any soil or biological contaminates from the Vein360 Reprocessed Visions PV .035 Catheter. Vein360 also inspects the Vein360 Reprocessed Visions PV .035 Catheter for removal of the coating and any soil. After cleaning, the Vein360 Reprocessed Visions PV .035 Catheter is dried. As stated in the first FDA 510(k) clearance letter, Vein360 performs a drying validation.[9]

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[5] (Ex. D, at 5-3.)

[6] (*Id*.)

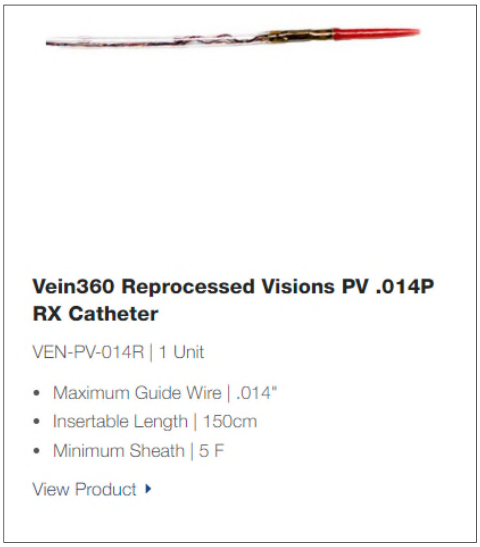
[7] (*Id*., at 5-2.)

[8] (*Id*., at 5-3.)

[9] (*Id*., at 5-4.)

35. After all soil has been removed, thereby preparing the surface of the Vein360 Reprocessed Visions PV .035 Catheter, a new hydrophilic coating is applied. As stated in the first FDA 510(k) clearance letter, "[a] hydrophilic coating is applied externally to the distal end of the catheter."[10] Vein360 also validates the hydrophilic coating. As stated in the first FDA 510(k) clearance letter, Vein360 performs "hydrophilic coating integrity" testing.[11] Furthermore, Vein360 sterilizes the Visions PV .035 Digital Catheter.[12]

36. The Vein360 Reprocessed Visions PV .014P RX Catheter is depicted below:



37. The Vein360 Reprocessed Visions PV .014P RX Catheter provides similar functionality to the Eagle Eye Platinum Catheters.[13]

38. The Vein360 Reprocessed Eagle Eye Platinum Catheter is depicted below:

[10] (*Id.*, at 5-2.)

[11] (*Id.*, at 5-4.)

[12] (*Id.*)

[13] *See* https://vein360.com/product/reprocessed-visions-pv-014p-rx-catheter/.

39. The Vein360 Reprocessed Eagle Eye Platinum Catheter has "plug-and-play simplicity and efficiency . . . [and] an enhanced hydrophilic coating."[14]

40. The Vein360 Reprocessed Eagle Eye Platinum ST Catheter is depicted below:

[14] *See* https://vein360.com/product/reprocessed-eagle-eye-platinum-catheter/.

41. The Vein360 Reprocessed Eagle Eye Platinum ST Catheter "retains all the features in the Vein360 Reprocessed Eagle Eye Platinum model, including . . . hydrophilic coating."[15]

42. The Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter all have a hydrophilic coating on the exterior surface. Upon information and belief, to fully reprocess the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter and Vein360 Reprocessed Eagle Eye Platinum ST Catheter, the hydrophilic coating must be removed, and a new coating must be applied.

43. Upon information and belief, since the FDA requires substantial equivalence between the reprocessed device and a predicate device, the FDA would not approve the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter unless the hydrophilic coatings were removed, the coating removal was validated for any residual coating, the surface was prepared by removing any soil, and a new coating was applied to ensure substantial equivalence to a predicate device.

44. On October 24, 2023, Vein360 received a second FDA Section 510(k) clearance letter to make, use, and sell the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter. A copy of the second FDA Section 510(k) clearance letter is submitted herewith as Exhibit E.

[15] *See* https://vein360.com/product/reprocessed-eagle-eye-platinum-st-catheter/.

45. The second FDA 510(k) clearance letter states "[t]he subject devices are substantially equivalent to the predicate devices of the same product currently marketed by the device's original equipment manufacturer (OEM)."[16]

46. The Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter are for "single patient use."[17] Therefore, the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter are reprocessed single-use medical devices.

47. The second FDA 510(k) clearance letter further states that "[u]pon receipt, the subject devices are cleaned, inspected, functionally tested, hydrophilic coated, packaged, and sterilized using (EO) gas."[18]

48. "The cleaning operation was validated with a high degree of confidence by objectively demonstrating removal of all physical soil under minimum operating conditions."[19] Vein360 cleans the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter by removing the coating and any soil or biological contaminates from the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter.

49. Vein360 also inspects the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye

[16] (Ex. E, at 5-3.)

[17] (*Id.*)

[18] (*Id.*, at 5-1.)

[19] (*Id.*, at 5-3.)

Platinum ST Catheter for removal of the coating and soil. After cleaning, the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter are dried. As stated in the second FDA 510(k) clearance letter, Vein360 performs a drying validation.[20]

50. After all soil has been removed and the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter and Vein360 Reprocessed Eagle Eye Platinum ST Catheter have been dried, a new hydrophilic coating is applied. As stated in the second FDA 510(k) clearance letter, the devices are "hydrophilic coated" as part of the Vein360 reprocessing method.[21]

51. Vein360 also validates the hydrophilic coating. As stated in the second FDA 510(k) clearance letter, Vein360 performs "hydrophilic coating integrity" testing.[22]

52. Furthermore, Vein360 sterilizes the Vein360 Reprocessed Visions PV .014P RX Catheter, Vein360 Reprocessed Eagle Eye Platinum Catheter, and Vein360 Reprocessed Eagle Eye Platinum ST Catheter.[23]

53. Vein360 specifically marketed and continues to market the Accused Products having removed and applied coatings using the methods of the '730 patent to manufacture the Accused Products.

[20] (*Id*., at 5-4.)

[21] (*Id*., at 5-1.)

[22] (*Id*., at 5-4.)

[23] (*Id*.)

Vein360's Acts of Infringement

54. Vein360 has made, used, sold, offered to sell and/or imported products manufactured using infringing methods, and continues to do so, including the Accused Products.

55. By doing so, Vein360 has directly infringed the '730 patent.

56. There is an actual, substantial, and continuing justiciable controversy between Innovative Health and Vein360 regarding Vein360's infringement of the '730 patent. Absent a judgment and injunction from this Court, Vein360 will continue to infringe the '730 patent and cause damage and irreparable harm to Innovative Health.

57. Despite being aware and having knowledge of Innovative Health's '730 patent, and recognizing the value and benefits of Innovative Health's patented technology, Vein360 has elected to infringe the '730 patent, including incorporating Innovative Health's technology into at least the Accused Products and using Innovative Health's technology to manufacture the Accused Products.

58. In accordance with 35 U.S.C. § 287, Vein360 has had actual notice and knowledge of the '730 patent since at least as early as the '730 patent's priority date, and otherwise had such actual notice and knowledge at all relevant times, and no later than the filing of this complaint for patent infringement and/or the date this complaint for patent infringement was provided to/served on Vein360.

59. Vein360 cannot avail itself of any defense pursuant to 35 U.S.C. § 287 as Innovative Health is under no obligation to mark a patented product or the performance of a patented method with respect to the '730 patent, and at no time was Innovative Health or any predecessor-in-interest to Innovative Health subject to an obligation to mark a patented product or the performance of a patented method with respect to the '730 patent.

VI. COUNT ONE
(Infringement of U.S. Patent No. 11,896,730)

60. Innovative Health incorporates the preceding paragraphs by reference as if fully set forth.

61. Innovative Health owns all right, title and interest in and to the '730 patent, and holds all substantial rights pertinent thereto, including the right to sue and recover for all past, current, and future damages for Vein360's infringement.

62. The '730 patent is valid and enforceable and directed to patentable subject matter.

63. Through at least the manufacturing of the Accused Products, Vein360 infringes at least claim 1 of the '730 patent.

64. Claim 1 of the '730 patent claims a method for reprocessing a single-use medical device.

65. The Accused Products are reprocessed single-use medical devices.

66. Claim 1 of the '730 patent recites: removing one or more coatings on a surface of the single-use medical device by contacting the one or more coatings on the surface of a single-use medical device to denatured ethyl alcohol, wherein the denatured ethyl alcohol removes the one or more coatings.

67. In accordance with the '730 patent, to remove a coating from a single-use medical device the single-use medical device is contacted to a solution operable to remove the coating. Vein360 cleans the Accused Products, which, upon information and belief includes removing the coating, since Vein360 applies a new coating to the Accused Products during its reprocessing method. Upon information and belief Vein360 would not be able to apply a new coating without removing the old coating. Upon information and belief, Vein360 removes coatings from

Accused Products by contacting the Accused Products with denatured ethyl alcohol, or equivalents thereof.

68. Claim 1 of the ’730 patent recites: validating the surface of the single-use medical device for the coating removal by visually inspecting the single-use medical device for any residual coating or using other detection methods.

69. Vein360 validates the cleaning of single-use medical devices by inspecting the Accused Products after cleaning (i.e., coating removal). Upon information and belief, Vein360 visually inspects or utilizes other detection methods to validate coating removal.

70. Claim 1 of the ’730 patent recites: preparing the surface of the single-use medical device for coating to form a prepared surface on the single-use medical device.

71. Upon information and belief, Vein360 prepares the surface of the single-use medical device for coating to form a prepared surface on the single-use medical device. Vein360 applies a new hydrophilic coating to the Accused Products, therefore, upon information and belief Vein360 prepares the surface of the single-use medical device for coating.

72. Claim 1 of the ’730 patent recites: wherein preparing the surface of the single-use medical device comprises: (i) contacting the single-use medical device to hydrogen peroxide or an enzymatic solution; (ii) rinsing the single-use medical device with water; and (iii) drying the single-use medical device.

73. Upon information and belief, Vein360 prepares the surface of the single-use medical device by contacting the single-use medical device to hydrogen peroxide, enzymatic solution, or equivalent thereof. In the FDA clearance letters, Vein360 states the cleaning operation was validated with a high degree of confidence by objectively demonstrating removal of all physical soil under minimum operating conditions. Hydrogen peroxide and enzymatic

solutions are used to remove physical soil and clean medical devices. Upon information and belief, Vein360 utilizes hydrogen peroxide, enzymatic solution, or an equivalent thereof to prepare the surface of the Accused Products for coating.

74. Water is used to rinse the Accused Products.

75. As stated in the FDA 510(k) clearance letters, Vein360 dries the Accused Products.

76. Vein360 has infringed and continues to infringe the ’730 patent under 35 U.S.C. § 271(g), directly, literally and/or under the doctrine of equivalents, by making, using, selling and/or offering to sell in the United States and/or importing into the United States, the Accused Products, during the term of the ’730 patent.

77. Vein360 has actual knowledge of the ’730 patent, and has had knowledge of the ’730 patent at all relevant times, and knows the above-described actions, if taken, would constitute infringement of the ’730 patent.

78. Vein360’s actions and infringement of the ’730 patent are without license or authorization from Innovative Health.

79. Vein360’s acts of infringement have caused Innovative Health to suffer damages. Innovative Health is entitled to and seeks to recover from Vein360 pursuant to 35 U.S.C. § 284 the damages it has sustained as a result of Vein360’s wrongful actions in an amount subject to proof at trial, and in no event less than a reasonable royalty, together with interest and costs.

80. Additionally, Vein360’s acts of infringement have caused and continue to cause immediate and irreparable harm to Innovative Health. Unless such acts of infringement are permanently enjoined by the Court, Vein360 will continue to cause immediate and irreparable

harm to Innovative Health for which there is no adequate remedy at law. Innovative Health is entitled to and seeks injunctive relief pursuant to 35 U.S.C. § 283.

VII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Innovative Health demands a trial by jury on all issues so triable.

VIII. PRAYER FOR RELIEF

Innovative Health prays that the Court enter judgment in its favor and against Vein360 as follows:

a) a judgment and order that Vein360 has infringed, either literally and/or under the doctrine of equivalents, the '730 patent;

b) a permanent injunction prohibiting Vein360 from further acts of infringement;

c) a judgment and order requiring Vein360 to pay Innovative Health its damages, costs, expenses, and any enhanced damages to which Innovative Health is entitled due to Vein360's infringement;

d) a judgment and order requiring Vein360 to provide an accounting and to pay Innovative Health supplemental damages, including without limitation, pre-judgment and post-judgment interest; and

e) such other and further relief to which it may be entitled.

Dated: February 13, 2024

Respectfully submitted,

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