IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., Plaintiff, v. KURIN, INC., Defendant.	C.A. No. 24-1124-CFC **DEMAND FOR JURY TRIAL**

DEFENDANT KURIN, INC'S
SECOND AMENDED ANSWER AND COUNTERCLAIMS

Defendant Kurin, Inc. ("Kurin") by and through its counsel, hereby files its second amended answer, affirmative defenses, and counterclaims ("Second Amended Answer") to Plaintiff Magnolia Medical Technologies, Inc.'s ("Plaintiff" or "Magnolia") Complaint for Patent Infringement, dated March 4, 2024 ("Complaint"). Kurin denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Kurin further denies that Magnolia is entitled to the relief requested in the Complaint, or to any other relief. In connection with and subject to the foregoing, Kurin responds to the Complaint as follows:

RESPONSE TO ALLEGATIONS REGARDING "SUMMARY OF THE ACTION"

1. Kurin denies each and every allegation of Paragraph 1 of the Complaint.

2. Kurin denies each and every allegation of Paragraph 2 of the Complaint.

3. Kurin admits that in a case pending in the U.S. District Court for the District of Delaware, *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), on a different product, the Kurin Lock, a jury returned a verdict that the Kurin Lock infringed claims 1 and 24 of U.S. Patent No. 10,039,483 ("the '483 Patent"). However, on May 14, 2024, the Delaware Court issued an order granting Kurin's Motion for Judgment of Non-Infringement of the '483 Patent by the Kurin Lock as a Matter of Law. D.I. 536, 537. Judgment was entered in Kurin's favor on June 10, 2024. D.I. 541. Kurin denies that the Kurin Lock infringes any valid and enforceable claim of the '483 Patent. Kurin denies the remaining allegations of Paragraph 3 of the Complaint.

4. Kurin admits that it has announced a new product called the Kurin Jet. Kurin denies the remaining allegations of Paragraph 4 of the Complaint.

5. Kurin denies each and every allegation of Paragraph 5 of the Complaint.

6. To the extent Paragraph 6 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin denies each and every allegation of Paragraph 6 of the Complaint.

7. Kurin admits the Kurin Jet has various configurations. To the extent Paragraph 7 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin denies the remaining allegations of Paragraph 7 of the Complaint.

RESPONSE TO ALLEGATIONS REGARDING "NATURE OF THE ACTION"

8. Kurin admits the Plaintiff purports to bring a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. Kurin denies the legal sufficiency of Plaintiff's claims and allegations, and further denies that Plaintiff has any viable claim thereunder.

RESPONSE TO ALLEGATIONS REGARDING "PARTIES"

9. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9 of the Complaint, and on that basis denies them.

10. Kurin admits that it is a corporation organized and existing under the laws of the state of Delaware and that it has a principal place of business in San Diego, California.

RESPONSE TO ALLEGATIONS REGARDING "JURISDICTION AND VENUE"

11. Kurin admits that Plaintiff purports to bring an action for patent infringement arising under the patent laws of the United States. Kurin denies the remaining allegations of Paragraph 11 of the Complaint.

12. Kurin admits that this Court has original jurisdiction over this patent infringement action under 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. Kurin denies the legal sufficiency of Plaintiff's claims and allegations, and further denies that Plaintiff has any viable claim thereunder. Kurin denies the remaining allegations of Paragraph 12 of the Complaint. For the reasons set forth in Kurin's motion to transfer, Kurin denies that this is the proper forum to resolve this action.

13. For the purposes of this action only, Kurin does not contest that this Court has personal jurisdiction over Kurin. Kurin denies that it has infringed, or has contributed to or induced infringement of, any valid and enforceable claim of the asserted patents. Kurin denies the remaining allegations of Paragraph 13 of the Complaint. For the reasons set forth in Kurin's motion to transfer, Kurin denies that this is the proper forum to resolve this action.

14. For the purposes of this action only, Kurin does not contest venue under 28 U.S.C. § 1400(b) in this judicial district with respect to Plaintiff's patent claims. Kurin denies that it has infringed any valid and enforceable claim of the asserted

patents. Kurin denies the remaining allegations of Paragraph 14 of the Complaint. For the reasons set forth in Kurin's motion to transfer, Kurin denies that this is the proper forum under 28 U.S.C. § 1404(a) to resolve this action.

RESPONSE TO ALLEGATIONS REGARDING "FACTUAL BACKGROUND"[1]

15. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15 of the Complaint, and on that basis denies them.

16. To the extent Paragraph 16 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin admits the allegations of Paragraph 16 of the Complaint.

17. To the extent Paragraph 17 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin admits that studies have reported a range of rates of false-positive blood cultures, and admits the remaining allegations of Paragraph 17 of the Complaint.

18. To the extent Paragraph 18 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin admits the allegations of Paragraph 18 of the Complaint.

[1] Kurin denies any allegations within Magnolia's subheadings in this section.

19. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19 of the Complaint, and on that basis denies them.

20. To the extent Paragraph 20 contains statements of opinion and legal conclusions, no response is required. To the extent a response is required, Kurin denies each and every allegation of Paragraph 20 of the Complaint.

21. To the extent Paragraph 21 contains statements of opinion and legal conclusions, no response is required. Kurin denies that the asserted patents are valid and enforceable. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 21 of the Complaint, and on that basis denies them.

22. To the extent Paragraph 22 contains statements of opinion and legal conclusions, no response is required. Kurin denies that the asserted patents are valid and enforceable. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22 of the Complaint, and on that basis denies them.

23. To the extent Paragraph 23 contains statements of opinion and legal conclusions, no response is required. Kurin denies that the asserted patents are valid and enforceable. Kurin lacks knowledge or information sufficient to form a belief as

to the truth of the remaining allegations of Paragraph 23 of the Complaint, and on that basis denies them.

24. To the extent Paragraph 24 contains statements of opinion and legal conclusions, no response is required. Kurin denies that the asserted patents are valid and enforceable. Kurin denies the remaining allegations of Paragraph 24 of the Complaint.

25. Kurin admits that Kurin, Inc. was founded after 2013, and that its founder and CEO Bobby Rogers was the former CEO of Ivera. Kurin denies the remaining allegations of paragraph 25.

26. Kurin admits that Mr. Rogers was introduced to Gregory Bullington in 2013. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26 of the Complaint, and on that basis denies them.

27. Kurin admits that Ivera was acquired in 2015. Kurin denies that Magnolia's characterization of any documents or communications is accurate. Kurin denies any remaining allegations of Paragraph 27 of the Complaint.

28. Kurin denies the allegations regarding Mr. Rogers and Kurin in Paragraph 28 of the Complaint. Kurin denies that Mr. Rogers stole anything from Magnolia. Kurin lacks knowledge or information sufficient to form a belief as to the

truth of the remaining allegations of Paragraph 28 of the Complaint, and on that basis denies them.

29. Kurin denies that Magnolia's characterization of any documents or communications is accurate. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 29 of the Complaint, and on that basis denies them.

30. Kurin denies that Magnolia's characterization of any documents or communications is accurate. Kurin denies that Mr. Rogers stole anything from Magnolia. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 30 of the Complaint, and on that basis denies them.

31. Kurin admits that Mr. Rogers and Mr. Bullington met in San Diego on or around March 26, 2015, and that Mr. Bullington brought with him the Steripath device, which at the time was already commercially available. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 of the Complaint, and on that basis denies them.

32. Kurin denies each and every allegation of Paragraph 32 of the Complaint.

33. Kurin denies each and every allegation of Paragraph 33 of the Complaint.

34. Kurin admits that Mr. Rogers left a voicemail for Tamara Johnson. Kurin denies the remaining allegations of Paragraph 34 of the Complaint.

35. Kurin admits that Magnolia filed a patent infringement action against Kurin in the United States District Court for the District of Delaware and that action is ongoing.

36. Kurin admits that it commercially launched the Kurin Lock in or around January 2017. Kurin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 36 of the Complaint, and on that basis denies them.

37. Kurin admits that on January 16, 2019, Magnolia filed a patent infringement action against Kurin in the United States District Court for the District of Delaware related to the Kurin Lock, and that action is ongoing. Kurin denies that its Kurin Lock infringes any valid claim of any patent asserted in that lawsuit. Kurin denies the remaining allegations of Paragraph 37 of the Complaint.

38. Kurin admits that in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), involving a different product, the Kurin Lock, a jury returned a verdict that the Kurin Lock device infringed claims 1 and 24 of the ’483 Patent and that verdict is currently the subject of pending post-trial motions. Kurin admits that, among other limitations, claim 1 of the ’483 Patent requires a “blood sequestration device” that is “configured to allow a subsequent

volume of blood to flow from the inlet port toward the outlet port via a sampling flow path, thereby bypassing the fluid reservoir and the initial volume of blood sequestered therein" and claim 24 of the '483 Patent requires that a "subsequent volume of blood" "flow toward the outlet port via the second fluid flow path and bypass the initial volume of blood sequestered in the first fluid flow path." Kurin admits that it argued at trial that the Kurin Lock does not infringe claims 1 and 24 of the '483 Patent because it does not meet these claim limitations. Kurin denies that the Kurin Lock infringes any valid and enforceable claim of the '483 Patent. Kurin denies the remaining allegations of Paragraph 38 of the Complaint.

39. Kurin denies each and every allegation of Paragraph 39 of the Complaint.

40. Kurin admits that Paragraph 40 of the Complaint contains a portion of text from a submission to FDA on the Kurin Lock. Kurin denies the remaining allegations of Paragraph 40 of the Complaint.

41. Kurin admits that Mr. Rogers certified that "to the best of [his] knowledge," "all data . . . submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted." Kurin denies the remaining allegations of Paragraph 41 of the Complaint.

42. Kurin admits that it had, in the past, used the word "sequester" in documents related to the Kurin Lock. Kurin denies the remaining allegations of Paragraph 42 of the Complaint.

43. Kurin admits that it argued at trial that the Kurin Lock does not meet the requirement of claim 1 of the '483 Patent of a "blood sequestration device" that is "configured to allow a subsequent volume of blood to flow from the inlet port toward the outlet port via a sampling flow path, thereby bypassing the fluid reservoir and the initial volume of blood sequestered therein." Kurin admits that it argued at trial that the Kurin Lock does not meet the requirement of claim 24 of the '483 Patent that a "subsequent volume of blood" "flow toward the outlet port via the second fluid flow path and bypass the initial volume of blood sequestered in the first fluid flow path." Kurin denies the remaining allegations of Paragraph 43 of the Complaint.

44. Kurin admits that it argued at trial that the Kurin Lock does not meet the requirement of claim 1 of the '483 Patent of a "blood sequestration device" that is "configured to allow a subsequent volume of blood to flow from the inlet port toward the outlet port via a sampling flow path, thereby bypassing the fluid reservoir and the initial volume of blood sequestered therein." Kurin admits that it argued at trial that the Kurin Lock does not meet the requirement of claim 24 of the '483 Patent that a "subsequent volume of blood" "flow toward the outlet port via the second fluid

flow path and bypass the initial volume of blood sequestered in the first fluid flow path." Kurin denies the remaining allegations of Paragraph 44 of the Complaint.

45. Kurin denies the allegations of Paragraph 45 of the Complaint.

46. Kurin admits that Mr. Rogers testified at trial in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), which related to a different patent, the '483 Patent, and a different product, the Kurin Lock. Kurin denies the remaining allegations of Paragraph 46 of the Complaint.

47. Kurin admits that Mr. Rogers testified at trial in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), which related to a different patent, the '483 Patent, and a different product, the Kurin Lock. Kurin denies the remaining allegations of Paragraph 47 of the Complaint.

48. Kurin admits that it cited the Steripath® Micro™ as a predicate device in a submission to the FDA. Kurin denies the remaining allegations of Paragraph 48 of the Complaint.

49. Kurin admits that its 510(k) submission concluded that the Kurin Lock is substantially equivalent to the Steripath® Micro™, and that Magnolia has quoted a portion of Exhibit 6. Kurin denies the remaining allegations of Paragraph 49 of the Complaint.

50. Kurin denies each and every allegation of Paragraph 50 of the Complaint.

51. Kurin admits that in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), involving a different product, the Kurin Lock, a jury returned a verdict that the Kurin Lock device infringed claims 1 and 24 of the ’483 Patent. On May 14, 2024, the Delaware Court issued an order granting Kurin’s Motion for Judgment of Non-Infringement of the ’483 Patent by the Kurin Lock as a Matter of Law. D.I. 536, 537. On June 10, 2024 the Delaware Court entered final judgment in favor of Kurin. D.I. 541. Kurin denies that it infringes any valid and enforceable claim of the ’483 Patent.

52. Kurin admits that in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), involving a different product, the Kurin Lock, a jury returned a verdict that the Kurin Lock device infringed claims 1 and 24 of the ’483 Patent. On May 14, 2024, the Delaware Court issued an order granting Kurin’s Motion for Judgment of Non-Infringement of the ’483 Patent by the Kurin Lock as a Matter of Law. D.I. 536, 537. On June 10, 2024 the Delaware Court entered final judgment in favor of Kurin. D.I. 541. Kurin admits that it announced the launch of the Kurin Jet on February 15, 2023. Kurin denies the remaining allegations of Paragraph 52 of the Complaint.

53. Kurin denies each and every allegation of Paragraph 53 of the Complaint.

54. Kurin admits that it permitted Magnolia's counsel to inspect samples of the Kurin Jet. Kurin denies the remaining allegations of Paragraph 54 of the Complaint.

55. Kurin admits that Mr. Rogers received a letter from Mr. Bullington dated February 23, 2023. Kurin denies the remaining allegations of Paragraph 55 of the Complaint.

56. Kurin denies the allegations of Paragraph 56 of the Complaint.

57. Kurin admits that in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), involving a different product, the Kurin Lock, a jury returned a verdict that the Kurin Lock device infringed claims 1 and 24 of the '483 Patent and that verdict is currently the subject of pending post-trial motions. Kurin admits that Mr. Rogers testified at trial in *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.), which related to a different patent, the '483 Patent, and a different product, the Kurin Lock. Kurin denies the remaining allegations of Paragraph 57 of the Complaint.

RESPONSE TO ALLEGATIONS REGARDING "THE ASSERTED PATENTS"

58. Kurin admits that Magnolia has attached as Exhibit 1 to the Complaint what purports to be a copy of the '002 Patent. Kurin admits that the document, on its face, bears the title "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples With Reduced Contamination," bears an issue date of January 2,

2018, and names as an inventor Richard G. Patton. Kurin lacks information sufficient to admit or deny the remaining allegations of Paragraph 58 of the Complaint and on that basis denies them.

59. Kurin admits that Magnolia has attached as Exhibit 2 to the Complaint what purports to be a copy of the ’053 Patent. Kurin admits that the document, on its face, bears the title “Systems and Methods for Parenterally Procuring Bodily-Fluid Samples With Reduced Contamination,” bears an issue date of August 21, 2018, and names as an inventor Richard G. Patton. Kurin lacks information sufficient to admit or deny the remaining allegations of Paragraph 59 of the Complaint and on that basis denies them.

60. Kurin admits that Magnolia has attached as Exhibit 3 to the Complaint what purports to be a copy of the ’081 Patent. Kurin admits that the document, on its face, bears the title “Fluid Control Devices and Methods of Using the Same,” bears an issue date of December 20, 2022, and names as inventors Gregory J. Bullington, Jay M. Miazga, Shan E. Gaw, and Timothy F. Ramsey. Kurin lacks information sufficient to admit or deny the remaining allegations of Paragraph 60 of the Complaint and on that basis denies them.

61. Kurin admits that Magnolia has attached as Exhibit 4 to the Complaint what purports to be a copy of the ’863 Patent. Kurin admits that the document, on its face, bears the title “Fluid Control Devices and Methods of Using the Same,”

bears an issue date of May 23, 2023, and names as inventors Gregory J. Bullington, Jay M. Miazga, Shan E. Gaw, and Timothy F. Ramsey. Kurin lacks information sufficient to admit or deny the remaining allegations of Paragraph 61 of the Complaint and on that basis denies them.

62. Kurin admits that Magnolia has attached as Exhibit 5 to the Complaint what purports to be a copy of the '709 Patent. Kurin admits that the document, on its face, bears the title "Fluid Control Devices and Methods of Using the Same," bears an issue date of February 20, 2024, and names as inventors Gregory J. Bullington, Jay M. Miazga, Shan E. Gaw, and Timothy F. Ramsey. Kurin lacks information sufficient to admit or deny the remaining allegations of Paragraph 62 of the Complaint and on that basis denies them.

RESPONSE TO COUNT I

63. Kurin incorporates by reference its responses made in all foregoing Paragraphs of this Answer as though fully set forth herein.

64. Paragraph 64 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 64 of the Complaint.

65. Paragraph 65 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 65 of the Complaint.

66. Kurin admits that Paragraph 66 of the Complaint contains the language of claim 17 of the ’002 Patent. Kurin denies any remaining allegations of Paragraph 66 of the Complaint.

67. Kurin denies each and every allegation of Paragraph 67 of the Complaint.

68. Kurin denies each and every allegation of Paragraph 68 of the Complaint.

69. Kurin denies each and every allegation of Paragraph 69 of the Complaint.

70. Kurin admits that Exhibit 6 contains the language quoted in Paragraph 70 of the Complaint. Kurin denies any remaining allegations of Paragraph 70 of the Complaint.

71. Kurin denies each and every allegation of Paragraph 71 of the Complaint.

72. Kurin denies each and every allegation of Paragraph 72 of the Complaint.

73. Kurin denies each and every allegation of Paragraph 73 of the Complaint.

74. Paragraph 74 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 74 of the Complaint.

75. Paragraph 75 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 75 of the Complaint.

RESPONSE TO COUNT II

76. Kurin incorporates by reference its responses made in the foregoing Paragraphs of this Answer as though fully set forth herein.

77. Paragraph 77 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 77 of the Complaint.

78. Paragraph 78 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 78 of the Complaint.

79. Kurin admits that Paragraph 79 of the Complaint contains the language of claim 1 of the ’053 Patent. Kurin denies the remaining allegations of Paragraph 79 of the Complaint.

80. Kurin denies each and every allegation of Paragraph 80 of the Complaint.

81. Kurin denies each and every allegation of Paragraph 81 of the Complaint.

82. Kurin denies each and every allegation of Paragraph 82 of the Complaint.

83. Kurin denies each and every allegation of Paragraph 83 of the Complaint.

84. Kurin denies each and every allegation of Paragraph 84 of the Complaint.

85. Paragraph 85 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 85 of the Complaint.

86. Paragraph 86 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 86 of the Complaint.

RESPONSE TO COUNT III

87. Kurin incorporates by reference its responses made in the foregoing Paragraphs of this Answer as though fully set forth herein.

88. Paragraph 88 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 88 of the Complaint.

89. Paragraph 89 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 89 of the Complaint.

90. Kurin admits that Paragraph 90 of the Complaint contains the language of claim 1 of the ’081 Patent. Kurin denies the remaining allegations of Paragraph 90 of the Complaint.

91. Kurin denies each and every allegation of Paragraph 91 of the Complaint.

92. Kurin denies each and every allegation of Paragraph 92 of the Complaint.

93. Kurin denies each and every allegation of Paragraph 93 of the Complaint.

94. Kurin denies each and every allegation of Paragraph 94 of the Complaint.

95. Kurin denies each and every allegation of Paragraph 95 of the Complaint.

96. Kurin denies each and every allegation of Paragraph 96 of the Complaint.

97. Kurin denies each and every allegation of Paragraph 97 of the Complaint.

98. Kurin denies each and every allegation of Paragraph 98 of the Complaint.

99. Paragraph 99 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 99 of the Complaint.

100. Paragraph 100 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 100 of the Complaint.

RESPONSE TO COUNT IV

101. Kurin incorporates by reference its responses made in the foregoing Paragraphs of this Answer as though fully set forth herein.

102. Paragraph 102 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 102 of the Complaint.

103. Paragraph 103 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 103 of the Complaint.

104. Kurin admits that Paragraph 104 of the Complaint contains the language of claim 1 of the ’863 Patent. Kurin denies the remaining allegations of Paragraph 104 of the Complaint.

105. Kurin denies each and every allegation of Paragraph 105 of the Complaint.

106. Kurin denies each and every allegation of Paragraph 106 of the Complaint.

107. Kurin denies each and every allegation of Paragraph 107 of the Complaint.

108. Kurin denies each and every allegation of Paragraph 108 of the Complaint.

109. Kurin denies each and every allegation of Paragraph 109 of the Complaint.

110. Kurin denies each and every allegation of Paragraph 110 of the Complaint.

111. Kurin denies each and every allegation of Paragraph 111 of the Complaint.

112. Kurin denies each and every allegation of Paragraph 112 of the Complaint.

113. Paragraph 113 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 113 of the Complaint.

114. Paragraph 114 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies Kurin denies the allegations of Paragraph 114 of the Complaint.

RESPONSE TO COUNT V

115. Kurin incorporates by reference its responses made in the foregoing Paragraphs of this Answer as though fully set forth herein.

116. Paragraph 116 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 116 of the Complaint.

117. Paragraph 117 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 117 of the Complaint.

118. Kurin admits that Paragraph 118 of the Complaint contains the language of claim 1 of the ’709 Patent. Kurin denies the remaining allegations of Paragraph 118 of the Complaint.

119. Kurin denies each and every allegation of Paragraph 119 of the Complaint.

120. Kurin denies each and every allegation of Paragraph 120 of the Complaint.

121. Kurin denies each and every allegation of Paragraph 121 of the Complaint.

122. Kurin denies each and every allegation of Paragraph 122 of the Complaint.

123. Kurin denies each and every allegation of Paragraph 123 of the Complaint.

124. Kurin denies each and every allegation of Paragraph 124 of the Complaint.

125. Kurin denies each and every allegation of Paragraph 125 of the Complaint.

126. Kurin denies each and every allegation of Paragraph 126 of the Complaint.

127. Paragraph 127 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 127 of the Complaint.

128. Paragraph 128 of the Complaint contains statements of opinions and legal conclusions to which no response is required. To the extent a response is required, Kurin denies the allegations of Paragraph 128 of the Complaint.

RESPONSE TO MAGNOLIA'S PRAYER FOR RELIEF

129. Magnolia's prayer for relief does not require a response. To the extent a response is deemed required, Kurin denies the allegations contained in Magnolia's prayer for relief and denies that Magnolia is entitled to the relief requested or to any other relief.

130. Kurin denies all remaining allegations of the Complaint not specifically admitted above.

AFFIRMATIVE DEFENSES

131. Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the Complaint, Kurin asserts the following additional defenses:

FIRST DEFENSE
(FAILURE TO STATE A CLAIM)

132. The allegations and claims in the Complaint, in whole or in part, fail to state a claim on which relief may be granted.

SECOND DEFENSE
(NON-INFRINGEMENT)

133. Kurin does not infringe and has not infringed, in any manner under 35 U.S.C. § 271, any claim of the asserted patents, literally, under the doctrine of equivalents, directly, indirectly, contributorily, by way of inducement, and/or via any other mechanism of liability.

THIRD DEFENSE
(NO WILLFUL INFRINGEMENT)

134. Kurin has not willfully infringed any claim of the asserted patents.

FOURTH DEFENSE
(INVALIDITY)

135. One or more claims of the asserted patents are invalid for failure to satisfy one or more of the requirements of the Patent Act, 35 U.S.C. § 1, *et seq.*, including, but not limited to, the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or 256. For example, one or more claims of asserted patents are invalid in view of the prior art, including references cited on the face of those patents, and articles, products, and processes that were publicly available or disclosed before their respective priority dates. In addition, one or more claims of the asserted patents are invalid because the full scope of those claims is not enabled, nor described, by their respective written descriptions, and those claims are indefinite.

FIFTH DEFENSE
(PROSECUTION LATCHES)

136. Magnolia's claims are barred, in whole or in part, by the doctrine of prosecution laches, including because of admissions, amendments, arguments, and statements made to the United States Patent and Trademark Office during prosecution of the applications leading to, or related to, the issuance of at least one

or more of the ’002, ’053, ’081, ’863, and ’709 Patents that render the claims of those patents unenforceable.

SIXTH DEFENSE
(INEQUITABLE CONDUCT)

137. Kurin hereby incorporates the allegations of Paragraphs 1 to 262 and Count XI of the Counterclaims, as if fully set forth herein.

138. All asserted claims of the ’081, ’863, and ’709 Patents are unenforceable for inequitable conduct during the prosecution of those patents, or during prosecution of their family members.

SEVENTH DEFENSE
(NO ENTITLEMENT TO INJUNCTIVE RELIEF)

139. Magnolia is not entitled to preliminary and/or permanent injunctive relief against Kurin under the principles of equity applicable to actions for patent infringement. Kurin has not infringed any valid and enforceable claim of any of the asserted patents. Any purported injury to Magnolia is not immediate and irreparable, and Magnolia will have an adequate remedy at law. The public interest and balance of hardships do not favor an injunction under the circumstances here.

EIGHTH DEFENSE
(NO EXCEPTIONAL CASE)

140. Kurin’s actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

NINTH DEFENSE
(FAILURE TO MARK)

141. On information and belief, Magnolia failed to follow the patent marking requirements set forth in 35 U.S.C. § 287.

TENTH DEFENSE
(ESTOPPEL)

142. Magnolia's claims are barred, in whole or in part, by the doctrine of estoppel.

ELEVENTH DEFENSE
(WAIVER)

143. Magnolia's claims are barred, in whole or in part, by the doctrine of waiver.

TWELFTH DEFENSE
(ADDITIONAL DEFENSES OR COUNTERCLAIMS)

144. Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Kurin, by and through its undersigned counsel, alleges the following Counterclaims against Magnolia.

THE PARTIES

1. Kurin is a Delaware corporation with its principal place of business in San Diego, California.

2. On information and belief, Magnolia is a corporation organized and existing under the laws of the state of Washington, with a principal place of business at 220 W. Mercer Street, Suite 100, Seattle, Washington 98119.

JURISDICTION AND VENUE

3. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

4. This Court has subject-matter jurisdiction over these Counterclaims pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338(a)–(b), the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has personal jurisdiction over Magnolia at least because it has availed itself of the rights and privileges of this forum by filing its Complaint in this judicial district.

6. Upon information and belief, Magnolia makes, uses, offers to sell, and/or sells its Steripath Micro products, and related configurations (hereinafter "the Accused Products") in the United States. Upon information and belief, Magnolia has committed patent infringement in Delaware.

7. Venue is proper because Magnolia has consented to this venue by asserting and filing claims of patent infringement against Kurin.

FACTUAL BACKGROUND

A. The Kurin Lock

8. Bobby Rogers is an inventor who develops simple solutions to complex problems. Prior to founding Kurin, Mr. Rogers founded Ivera Medical Corporation ("Ivera"), where he invented and designed the Curos cap, which disinfects needleless connectors that provide access to intravenous lines. This simple, innovative solution solved a major healthcare concern relating to potentially deadly bloodstream infections caused by contaminated needleless connectors.

9. In February 2015, 3M Company acquired Ivera, and Mr. Rogers moved on to a new project. Mr. Rogers had been aware of the problems with blood culture contaminations from his work at Ivera, going back to at least 2011.

10. Magnolia recognized Mr. Rogers' expertise in preventing contamination. In or about 2013, Magnolia's CEO Greg Bullington reached out to Mr. Rogers seeking his advice.

11. Mr. Bullington communicated with Mr. Rogers without any confidentiality agreements, expectations of confidentiality, or compensation.

12. In or about March 2015, Mr. Bullington reached out to Mr. Rogers to set up a meeting to discuss the possibility of Mr. Rogers joining Magnolia as an advisor or board member. Mr. Rogers informed Mr. Bullington prior to the meeting

that he was not interested in being on Magnolia's board, and Mr. Bullington maintained that he wanted to meet with Mr. Rogers.

13. While Mr. Rogers agreed with Mr. Bullington that blood culture contamination was a serious issue, he did not believe that Magnolia's Steripath product was the answer. He therefore declined to invest in Magnolia or otherwise be involved with the company.

14. Mr. Rogers' experience working in medical sales and developing medical devices including needleless connectors and disinfecting caps taught him that the key to success in reducing contamination was to ensure that the device was actually used. Mr. Rogers firmly believed that to be successful, a device must integrate seamlessly into the medical practitioner's existing workflow. Any device that alters workflow or requires additional steps would not be used as often (i.e., compliance would be low), and therefore patient outcomes would not be improved, and the company would not succeed.

15. It was plain to Mr. Rogers that Magnolia's Steripath device was overly complex and did not take into consideration the workflow of the end user. Magnolia's device would force medical practitioners to adopt a new workflow for blood draws: The medical practitioner had to hold the bulky device (where previously he or she did not have to hold anything) and squeeze it (not too fast but

not too slow), while manipulating the needle and the vacutainers. Some users would later complain that the device required three hands to operate it.

16. Magnolia's own documents state that "average customers" "[d]on't like [the] product" and there is only "60 percent compliance" with Steripath. See Exhibit 1 at 29:2–4 (7/27/2022 Trial Tr.).

17. In addition, the Steripath wastes approximately 2 mL of the patient's blood, which Mr. Rogers thought was excessive.

18. Mr. Rogers decided to develop a different solution to the blood culture contamination problem that overcame the many issues with Magnolia's approach, and the Kurin Lock was born. The Kurin Lock discards only 0.15 mL of the patient's blood, significantly less than Magnolia's Steripath device and—particularly useful for the relevant patient population—is easy to use, small, and effective.

19. The innovation of discarding just a tiny amount of blood was Mr. Rogers' alone. Magnolia was insistent that a device must discard 1–2 mL of blood to be effective, based on early studies by Dr. Richard Patton. Mr. Rogers, however, understood that if blood-culture contaminations were caused by the tiny amount of skin that might enter the needle when blood is drawn, a successful device would need only divert the volume of the needle plus a small additional volume as a precaution.

20. Mr. Rogers determined that the volume of a commonly used needle is approximately 0.004 mL and realized that setting aside 0.15 mL would be sufficient to accomplish the task.

21. Magnolia told the market for years that the Kurin Lock would not work because it did not discard a sufficiently high volume of blood. Magnolia was wrong, and in fact now touts that its Steripath Micro device—released years after the Kurin Lock—discards only 0.5–1.0 mL of blood.

22. Importantly, the Kurin Lock requires the medical practitioner to make just one change to the normal blood draw workflow: a few-second pause is added to allow the blood to travel down the U-shaped side channel and hit the porous plug.

23. As Magnolia's Chief Commercial Officer reported to Magnolia's Chief Executive Officer, "Nurses prefer Kurin." Exhibit 1 at 34:21–22 (7/27/22 Trial Tr.).

24. Contrary to Magnolia's allegations, Mr. Rogers did not "steal" anything from Mr. Bullington.

25. Mr. Rogers developed a competing product—one that was fundamentally different from and far superior to Magnolia's Steripath.

26. Magnolia has been aware of the Kurin Lock since Kurin "launched their website . . . right in the middle of January of 2017."

27. At that time, Magnolia had a large portfolio of issued patents, but it did not sue Kurin.

28. Recognizing that none of its existing patents covered the Kurin Lock, Magnolia instead began filing new patent applications with claims written specifically to read on the Kurin Lock.

29. Unsurprisingly, the Kurin Lock is popular in the marketplace because it is easy to use and improves compliance, which in turn improves patient outcomes.

30. Hospitals prefer the Kurin Lock to other available solutions, including Magnolia's Steripath and other options such as waste tubes.

31. Magnolia launched its first generation Steripath product in 2014. Yet as of July 2022, Magnolia had still never made a profit. Magnolia is and has been floundering in the marketplace because its product does not meet a hospital's needs and is difficult to use. Magnolia's Steripath product could not compete with Kurin's easy-to-use Kurin Lock, and Magnolia perceived Kurin as a threat to its business because of Kurin's superior technology and product.

32. Magnolia has been well-aware of the industry's criticisms of its products but chose not to improve them to address these concerns and compete with Kurin on the merits of its products.

33. In fact, Mr. Bullington testified that in 2018, one year after the launch of the Kurin Lock, Magnolia began working on a product that would perform automatically rather than requiring user intervention, but Magnolia "intentionally"

did not bring that automatic product to market despite knowing since 2011 that an automatic product would improve compliance.

34. Instead of competing on the merits of the products, Magnolia came up with a different plan, which it announced to Mr. Rogers at a trade show in 2017 after seeing Kurin's innovative new product. At the time Kurin launched its Kurin Lock, Magnolia's patents did not claim, let alone disclose, anything that resembled the innovations that Kurin came up with and incorporated into its Kurin Lock. Nevertheless, Mr. Bullington inexplicably vowed to Mr. Rogers at the trade show that he would sue Kurin for patent infringement. To make good on that promise, Magnolia launched a concerted scheme to prosecute patent claims that Magnolia could assert against Kurin, even though such claims were wholly untethered from anything Magnolia had invented. The patent applications for the patents Magnolia asserted in the Delaware case and that it is asserting in this case were products of this scheme. Every single one of the nine patents asserted in both cases arose from a patent application Magnolia filed ***after*** seeing Kurin's inventions embodied in the Kurin Lock and/or Kurin's later Kurin Jet product. Prosecuting patent claims on inventions that Magnolia did not invent required Magnolia to resort to the inequitable conduct described herein.

B. The Delaware Action

35. Further to Magnolia's inequitable conduct before the Patent Office, instead of making a better product to address the concerns and needs of the marketplace, Magnolia chose to try to take the better, more popular Kurin Lock off the market through litigation.

36. On January 16, 2019, Magnolia filed a patent infringement action in the United States District Court for the District of Delaware ("*Kurin I*"), alleging that the Kurin Lock infringes U.S. Patent Nos. 9,855,001 (the "'001 Patent") and 10,028,689 (the "'689 Patent"). D.I. 1.[2] On March 7, 2019, Magnolia filed an Amended Complaint alleging that the Kurin Lock infringes two additional patents, U.S. Patent Nos. 10,039,483 (the "'483 Patent") and 10,220,139 (the "'139 Patent"). D.I. 5.

37. All four of the applications that led to the patents asserted in *Kurin I* were filed after the Kurin Lock was on the market and Magnolia had viewed information about the product on Kurin's website and in Kurin's public 510(k) filing, with claims written specifically to try to capture the Kurin Lock.

38. On January 28, 2021, Magnolia dismissed ***with prejudice*** its infringement claims as to the '689 and '139 Patents. D.I. 255.

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[2] Citations to D.I. numbers refer to docket entries in the Delaware action, *Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, C.A. No. 19-97 (CFC)(CJB) (D. Del.).

39. On the eve of trial Magnolia agreed that Kurin Lock does not infringe the ’001 Patent. D.I. 406.

40. The ’001 Patent is in the same patent family as the ’002 and ’053 Patton Patents asserted against the Kurin Jet in this case. All three patents claim priority to Provisional U.S. Patent Application No. 60/870,599, have the same named inventor, and share the same specification. In fact, the ’053 Patton Patent is a continuation of the application that led to the ’001 Patton Patent.

41. The Joint Motion for Entry of Partial Judgment of Non-Infringement of U.S. Patent No. 9,855,001 was a result of the Delaware Court’s construction of the term “diverter.” D.I. 406 at 2. As stated in the Joint Motion and in the Delaware Court’s Claim Construction Memorandum, “diverter” was construed as a means-plus-function claim term because the ’001 Patton Patent’s “diverter” limitations did “not recite structure sufficient to perform” the function of “divert[ing] (or direct[ing]) fluid flow from one fluid flow path to a second fluid flow path.” D.I. 74 at 6–7.

42. Magnolia agreed that under this Court’s construction of “diverter,” the Kurin Lock did not infringe the ’001 Patent, and this Court entered judgment of non-infringement as to the ’001 Patent for the Kurin Lock.

43. In July 2022, trial proceeded in Delaware on only claims 1 and 24 of the ’483 Patent.

44. In the Delaware action, like here, Magnolia alleged that Kurin willfully infringed all four asserted patents, even though the evidence did not support that allegation. Indeed, as noted above, Magnolia dropped its infringement claims altogether as to three of those patents before trial.

45. At trial, the Court warned Magnolia about presenting its willfulness case with respect to the ’483 Patent. Magnolia nevertheless presented the evidence it alleged supported its willfulness claim to the jury, which was not relevant to any other issue in the case—the same so-called evidence it presents in its Complaint—and then promptly dropped its willfulness claim.

46. Over a year after trial, on August 4, 2023, the Court *sua sponte* issued an order in which it opined that “it seems likely that Kurin will prevail on its renewed motion for JMOL of noninfringement of at least claim 1 and perhaps claim 24 as well.” D.I. 514 at 36–37.

47. At the same time, the Court stayed all post-trial motions, including Kurin’s additional claim that the asserted claims in the Delaware action are invalid because they are indefinite under 35 U.S.C. § 112. D.I. 515; D.I. 516. Kurin filed a motion for judgment as a matter of law of noninfringement.

48. Thus, contrary to Magnolia’s suggestions in its Complaint, the Delaware Court has not issued a final decision on infringement.

49. There is no enforceable judgment of infringement in the Delaware action.

50. Instead, on May 14, 2024, the Court issued an order granting Kurin's Motion for Judgment of Non-Infringement of the '483 Patent by the Kurin Lock as a Matter of Law. D.I. 536, 537.

51. On June 10, 2024 the Court entered final judgment in favor of Kurin. D.I. 541.

C. The Patent Office Has Found Claims 1 and 24 of the '483 Patent Invalid in an *Ex Parte* Reexamination

52. On March 22, 2023, Kurin filed a request for *ex parte* reexamination of claims 1 and 24 of the '483 Patent. D.I. 517. On April 26, 2023, the Patent Office granted the request for *ex parte* reexamination of Claims 1 and 24 of the '483 Patent. *See* D.I. 517.

53. On August 9, 2023, the Patent Office issued a first Office Action in the *ex parte* reexamination proceeding, rejecting claims 1 and 24 of the '483 Patent as anticipated by the prior art, specifically, U.S. Patent No. 3,886,930 ("Ryan") and U.S. Patent No. 6,013,037 ("Brannon").

54. Magnolia responded with arguments contradicting those it made to this Court regarding the same claim terms.

55. For example, in response to the Examiner's rejection, Magnolia argued that neither Ryan nor Brannon discloses that an "initial volume of blood is

sequestered" or "bypassing...the initial volume of blood" because at least some of the first portion of blood mixes with the subsequent portion of blood.

56. This argument is wholly inconsistent with the arguments Magnolia made at trial to obtain its verdict of infringement.

57. At trial, Magnolia specifically argued that the claimed "initial volume of blood" was not all of the blood contained in the U-shaped channel and that mixing in the U-shaped channel in the Kurin Lock did not prevent a finding of infringement. Indeed, during Magnolia's closing argument on infringement, its counsel told the jury that "mixing is irrelevant . . . Mixing is nowhere in the language of the claim as we've been evaluating it."

58. Thus, at trial, where it saw benefit in this argument, Magnolia asserted that mixing was within the scope of its claims. Then, during reexamination, Magnolia repudiated this position, asserting that mixing brought the relevant art outside the scope of the claims. Magnolia did not disclose these contradictory litigation arguments to the Examiner during reexamination despite its obligation to do so.

59. In reexamination, Magnolia also argued that Brannon does not anticipate claims 1 and 24 of the '483 Patent because the subsequent volume of blood does not bypass the "initial flash of blood" in the device disclosed by Brannon.

60. Yet Magnolia argued throughout *Kurin I* that the "initial volume" of claims 1 and 24 ***was not*** the entire initial flash of blood of the Kurin Lock, and therefore that it did not matter for purposes of infringement that part of that initial flash of blood was not bypassed by the subsequent volume of blood.

61. On December 1, 2023, Patent Office issued a Final Rejection of claims 1 and 24 of the '483 Patent on the basis that they are anticipated by Brannon.

62. In response, Magnolia argued again that Brannon does not disclose each limitation of claims 1 and 24 of the '483 Patent because the entirety of the very first flash of blood is not necessarily sequestered.

63. This again contradicted the arguments it made at the Delaware trial, where it insisted that the Kurin Lock infringed claims 1 and 24 despite the undisputed fact that some of the initial flash of blood mixed with a subsequent volume of blood.

64. On February 27, 2024, the Examiner issued an Advisory Action that considered and rejected each of Magnolia's arguments. Specifically, the Examiner stated:

The examiner has weighed the evidence and determined that the evidence provided by PO with respect to non-anticipation, including the information in the affidavit by Dr. Jensen, fails to outweigh the evidence of anticipation as outlined

by the examiner, and therefore the rejections on the record have not been overcome.

65. Thus, contrary to the suggestions in Magnolia's Complaint, the Patent Office has found claims 1 and 24 of Magnolia's '483 Patent invalid because they are anticipated by the prior art.

66. The infringement verdict on which Magnolia rests its willfulness allegations stems from two patent claims that should never have been allowed and have been finally rejected by the Patent Office.

67. Magnolia's reexamination tactics are representative of its approach with the USPTO in the prosecution of its entire patent portfolio. Magnolia has repeatedly used deceptive strategies to obtain invalid patent claims to further its litigation campaign against Kurin.

D. The Kurin Jet

68. Kurin has continued to innovate and create new and better products that improve patient outcomes.

69. The Kurin Jet is the result of years of research and innovation.

70. In December 2021, Kurin began selling the Jet to a single customer for use in only one of its facilities. The test-run was successful, and the customer soon began using it across its other facilities.

71. Throughout 2022, the Jet was gradually introduced into more facilities around the country. Kurin publicly announced the launch of the Kurin Jet on February 15, 2023.

72. The Jet removes the one change in workflow required by the Kurin Lock, a short pause after venipuncture to allow blood to fill its side channel.

73. The Kurin Jet is a different product than the Kurin Lock that is at issue in the Delaware action and is a significant improvement over the Kurin Lock.

74. Unlike the Kurin Lock, the Kurin Jet requires no pause before the medical practitioner connects the vacutainer, and thus requires no change at all in workflow for the clinician drawing blood as compared to using a regular butterfly needle set.

75. The Kurin Jet has a different theory of operation than the Kurin Lock, using the vacuum of the sample bottle or syringe as an initial power source rather than the patient's own blood pressure.

76. The Kurin Jet uses a different design and has different physical components than the Kurin Lock.

77. Magnolia was again faced with a decision: compete with Kurin's new improved product in the marketplace on the merits of the Steripath or try to force Kurin off the market through litigation. Magnolia chose the latter.

78. On February 23, 2023, just days after the press release announcing Kurin's launch of the Kurin Jet, Mr. Bullington sent a letter to Mr. Rogers stating:

> Last week, on February 15, 2023, Kurin, Inc. announced to the world, via internet press release, the commercial launch of a new product called the "Kurin Jet". As you undoubtedly understand, Magnolia has serious concerns about the "Kurin Jet" announcement. Kurin's actions, at this particular point in time, are very troublesome given Magnolia's motion for permanent injunction pending before Chief Judge Connolly in the District Court of Delaware.
>
> Kurin's press release compares the new "Kurin Jet" to the Kurin Lock, which, as you know, a jury found in July 2022 infringes Magnolia's U.S. Patent No. 10,039,483.
>
> For your (and your counsel's) convenience, Addendum A attached provides a listing of all currently publicly available and published Magnolia patents and pending patent applications.
>
> I have instructed Magnolia's outside counsel to request from Kurin's outside counsel 10 samples of the "Kurin Jet" for evaluation. As you know, Magnolia intends to

> enforce its intellectual property rights to the fullest extent necessary to protect its technology and innovations.
>
> We continue to be dismayed by your on-going willful infringement and we will seek appropriate remedies for any and all additional unlawful use of our intellectual property.

79. Kurin offered Magnolia the opportunity to inspect the Kurin Jet product at the office of Kurin's counsel to alleviate Magnolia's unfounded "concerns." That inspection occurred on March 23, 2023.

80. After the inspection, Magnolia wrote to Kurin, claiming that it "has grave concerns that the Kurin Jet infringes the asserted claims of the '483 Patent" even though Magnolia admitted it was not sure whether Kurin Jet included the claimed features.

81. In response, on April 3, 2023, Kurin provided to Magnolia a detailed technical explanation of the Kurin Jet's design and operation.

82. Magnolia then went silent for almost a year, leaving Kurin to believe and rely on the fact that Magnolia had concluded that the Kurin Jet does not infringe any Magnolia patent.

83. Then, eleven months after its last communication with Kurin, Magnolia filed suit—not on the patent over which it alleged it had "grave concerns," but instead asserting five different, unrelated, patents.

84. Three of those patents stem from applications filed after Kurin began selling the Kurin Jet. And, incredibly, one of the was filed 10 days after Kurin allowed Magnolia to inspect its products.

85. In the interim, as described above, the Patent Office granted Kurin's request for reexamination of claims 1 and 24 of the '483 Patent and determined that Magnolia should not have been granted those claims because they are anticipated by the prior art. But, as explained below, Magnolia had defrauded the Patent Office into issuing the other patents asserted here, including at least the '081, '863, and '709 Patents, and those patents also claim what is in the prior art.

E. Kurin's Patents

86. Kurin has sought, and received, over thirty patents in the United States and worldwide for the innovative technology in both its Kurin Lock and Kurin Jet products. Kurin lists its patents on its website.

87. Most recently, on November 12, 2024, the United States Patent and Trademark Office ("USPTO"), recognizing Kurin's significant improvements in blood collection technology, duly and legally issued Kurin U.S. Patent No. 12,138,052 ("the '052 Patent), entitled "Blood Sample Optimization Device." The named inventors of the '052 Patent are Bobby E. Rogers, Gino Kang, and John Detloff. A true and correct copy of the '052 Patent is attached to this complaint as Exhibit 4.

88. Kurin is the owner of the ’052 Patent and has the full right to enforce, license, and seek damages for the ’052 Patent.

89. Kurin’s ’052 Patent is directed to a device for optimizing blood sample collection. Generally, this patent is directed to the collection of blood samples through multiple flow paths and a collection chamber by use of a drawing force provided by a blood sample collection device to efficiently reduce or eliminate contaminants in collected blood samples, in turn reducing or eliminating false positive readings in blood cultures or other testing of collected blood samples. Specifically, the patent solves the problem of blood culture contamination due to contaminants present in collected blood samples while subsequently increasing the efficiency, and effectiveness, of the collection process. The patented solution includes an inlet port, an outlet port, and a chamber configured to collect a first portion of the blood sample being collected that are all contained within the patented device’s housing.

F. Magnolia’s Attempts to Claim Credit for Kurin’s Technology

90. Kurin’s blood culture contamination prevention technologies have been a resounding market success due to their ease of use and seamless integration into the medical practitioner’s existing workflow.

91. These features are made possible by Kurin's innovative approach in creating passive products that effectively reduce contamination without altering clinician workflow.

92. Magnolia is a failing company offering a product that is hard to use and that healthcare professionals do not like. From the moment Kurin's superior technology arrived on the market, Magnolia has sought to impede Kurin's growth and take credit for Kurin's innovations.

93. Magnolia has engaged in fraud on the Patent Office, as well as unwarranted litigations against Kurin as part of its campaign to claim ownership over a technology that it did not invent.

94. As part of this campaign, Magnolia has engaged in extensive and unwarranted continuation practice, including filing multiple simultaneous patent applications claiming the same purported invention in different patent families, in an effort to create an impenetrable patent thicket to deter Kurin.

95. For example, in *Kurin I*, it became clear that Magnolia drafted the claims of the applications that became the four asserted patents, including the claims of the '483 Patent that went to trial by looking at Kurin's device, website, and FDA filings, and attempting—although poorly—to copy them. At trial, Magnolia did not deny that this spurious drafting tactic is how the claims of the '483 Patent came about.

96. The timeline of events leading up to the issuance of the patents asserted in *Kurin I* confirms Magnolia's strategy: Kurin launched its Kurin Lock product in or around January 2017.

97. On March 13, 2017, Magnolia filed a continuation patent, U.S. Patent Application No. 15/457,082, which claimed priority to a 2007 application and issued as the '001 Patent.

98. On December 5, 2017, Magnolia filed a continuation patent, U.S. Patent Application No. 15/832,087, which claimed priority to the same 2007 application as the '001 Patent and issued as the '689 Patent.

99. On December 5, 2017, Magnolia filed a continuation patent, U.S. Patent Application No. 15/832,091, which claimed priority to a 2012 application and issued as the '483 Patent.

100. On February 20, 2018, Magnolia filed a continuation patent, U.S. Patent Application No. 15/899,856, which claimed priority to a 2013 application and issued as the '139 Patent.

101. Each of the patents asserted in *Kurin I* claimed priority to applications filed years prior, and included claims that found no support in the specification, based on what it believed Kurin's product did. In the case of the '483 Patent, Magnolia's claims captured prior art technology in its failed attempt to cover the Kurin Lock.

102. Despite the fact that Magnolia has all but admitted that it deliberately attempted to patent Kurin's technology, Magnolia asserted during years of litigation in Delaware and again before this Court that it was Kurin that stole Magnolia's patented technology. Magnolia was only able to do so because it first defrauded the Patent Office by filing claims that it never should have filed on technology that Magnolia did not invent. The Patent Office is now in the process of correcting its mistake in issuing the '483 Patent claims through reexamination proceedings.

G. Magnolia's Patent Prosecution Playbook

103. Magnolia has developed and implemented a playbook of stretching, abusing, and/or disregarding USPTO procedures to unfairly expand the scope of its patents and to deter innovation or competition in the market.

104. Despite selling only two products, the Steripath and Steripath Micro, since its inception in 2008, Magnolia has filed over 270 patent applications and obtained over 146 patents worldwide.

105. Magnolia's patents, while extensive in number, make up just 29 patent families, with many of those families including multiple follow-on continuation applications.

106. Magnolia's continuation strategy is not one based on innovation, but is instead founded upon lawyers using aggressive procedures to overwhelm and hoodwink patent examiners. Magnolia and the lawyers prosecuting its patent

portfolio keep patent families alive so that Magnolia can leverage the priority dates from earlier applications in those families and simultaneously adapt its patent filings to claim inventions the listed inventors never invented, possessed, or disclosed, to cover Magnolia's competitors' products. Through its manipulation of the continuation process, Magnolia has kept several patent families alive for over 17 years.

107. This tactic is not about protecting any of Magnolia's innovations, it is about usurping Kurin's innovation. Magnolia has also engaged in tactics of withholding material information from the USPTO, misdirecting patent examiners, and exploiting and disregarding the USPTO's practices to obtain patents it is not entitled to.

108. Magnolia has worked from the same playbook here. Three of the patents asserted in this case were filed after the first public use of the Kurin Jet in December 2021, while claiming priority to an earlier set of patent applications.

109. For example, the '081, '863, and '709 Patents that Magnolia asserts here were all filed after July 2022. Each claims priority on its face to a September 12, 2018 non-provisional application and three prior provisional applications, the first of which was filed on September 12, 2017.

110. These patent applications are a blatant attempt to patent features of Kurin Jet technology that Magnolia did not invent, after it was already on the market.

111. Magnolia continued its concerted campaign to defraud the Patent Office and attempt to claim Kurin's technology as its own throughout and after *Kurin I*.

112. Beyond the applications of the patents asserted in this litigation, ongoing patent prosecution reveals Magnolia, through its patent prosecution team, goes to great lengths to unfairly keep its patent families alive so that it is ready to retroactively sue competitors and inhibit development of competitor products.

113. For example, U.S. Patent Application No. 18/407,010 ("'010 Application") is in the same family as the '081, '863, and '709 Patents. The '010 Application was filed as a Track One application (prioritized examination with a final disposition within about twelve months), but only with one claim that is nearly identical to the independent claims of the '709 Patent:

> A fluid control device, the device comprising:
>
> a housing having an inlet fluidically coupleable to a bodily-fluid source and an outlet fluidically coupleable to a fluid collection device, the housing defining at least a portion of each of a containment channel and a sampling channel between the inlet and the outlet;
>
> a selectively permeable blood barrier, the blood barrier defining a portion of the containment channel and

fluidically coupled to the containment channel and the outlet; and

a flow controller configured to substantially obstruct a flow path between the inlet and the outlet when in a first state,

the blood barrier configured to allow a gas to flow from the containment channel and through the blood barrier in response to a pressure differential between the inlet and the outlet, thereby allowing a volume of blood to flow into the containment channel, past the flow controller in the first state, and toward the blood barrier,

in response to the volume of the blood in the containment channel, the blood barrier configured to allow a pressure differential in at least a portion of the sampling channel between the flow controller and the outlet to build to an extent sufficient to transition the flow controller from the first state to a second state.

114. On February 26, 2024, Examiner David J. McCrosky reached out to Magnolia's patent prosecution team at Cooley LLP ("Cooley") in an Examiner-Initiated Interview, before issuing an Office Action, stating that he would be

providing a double-patenting rejection that would need a terminal disclaimer. Cooley indicated to the Examiner that they would be filing more claims in a preliminary amendment, and the Examiner graciously allowed them one week to do so before he would provide the Office Action.

115. Cooley never filed a preliminary amendment, and the Examiner mailed a Non-Final Rejection on March 13, 2024 of the one and only claim, based on non-statutory double patenting.

116. Cooley then requested another interview which took place on May 24, 2024, which the Examiner summarized as:

> Applicant proposed adding about 150 claims in response to the first office action. Examiner stated that he would likely require election by original presentation. Applicant proposed filing many divisional track one applications and prosecuting them until allowable subject matter was obtained. Then adding the claims from the divisionals into the instant pending application.

117. Cooley did, in fact, file ***five*** new continuation applications (all on the same day or within a day of each other, and after May 30th), each as Track One applications and with 30 claims each for a total of 150 simultaneously filed new claims in the same patent family.

1. Magnolia Files Its ’237 and ’239 Applications Seeking Materially Identical Claims to Each Other

118. On February 2, 2022, less than two months after Kurin began selling the Kurin Jet, Magnolia simultaneously filed two patent applications that claim priority to the same provisional application filed May 31, 2018: U.S. Patent Application Nos. 17/591237 (“the ’237 Application”) and 17/591239 (“the ’239 Application”). *See* Exhibit 2; Exhibit 3.

119. Those two applications contained materially identical claims and were assigned to the same patent examiner, Matthew Kremer.

120. On May 3, 2022, Examiner Kremer issued Office Actions rejecting the pending claims of the ’237 and ’239 Applications relying on, *inter alia*, U.S. Patent Application Publication No. 2018/0177445 (“the ’445 Rogers Publication”) as anticipatory prior art, particularly, the embodiment disclosed in Figure 24 and the related specification.

121. Rejected exemplary proposed claim 28 of the ’237 Application recites:

> A fluid control device, the device comprising:
>
> an inlet fluidically coupleable to a bodily fluid source;
>
> an outlet fluidically coupleable to a fluid collection device,
>
> a negative pressure differential being produced between the outlet and the inlet when the outlet is fluidically coupled to the fluid collection device;

a containment channel between the inlet and the outlet, the containment channel including a first flow controller, the first flow controller in a first state allowing a flow of gas but not bodily fluid from the containment channel to the outlet operable to draw an initial volume of bodily fluid from the inlet to the containment channel, the first flow controller in a second state preventing a flow of gas and bodily fluid therethrough when the initial volume of bodily fluid is in the containment channel; and

a sampling channel between the inlet and the outlet, the sampling channel in fluid communication with a second flow controller, the second flow controller in a first state obstructing a flow path through the sampling channel, the second flow controller in a second state allowing bodily fluid to flow from the inlet through the sampling channel to the outlet, the second flow controller being operable between the first state and the second state when a magnitude of the negative pressure differential exceeds a threshold pressure differential.

122. Rejected exemplary proposed claim 28 of the ’239 Application recites:

A fluid control device, the device comprising:

an inlet fluidically coupleable to a bodily fluid source; an outlet fluidically coupleable to a fluid collection device; a first flow controller disposed in a containment channel, the first flow controller in a first state allowing a flow of gas but not bodily fluid through the containment channel and to the outlet, a negative pressure differential between the inlet and the outlet generated by fluidically coupling the outlet to the fluid collection device being operable to draw an initial volume of bodily fluid from the inlet to the containment channel when the first flow controller is in the first state, the first flow controller in a second state preventing flow of the initial volume to the outlet; and

a second flow controller in fluid communication with a sampling channel, the second flow controller in a first state preventing fluid flow from the inlet and into the sampling channel, the second flow controller transitioning to a second state when a magnitude of the negative pressure differential within the sampling channel exceeds a threshold pressure differential, the second flow controller

> in the second state allowing bodily fluid to flow from the inlet through the sampling channel to the outlet.

123. Figures 24A-D of the ’445 Rogers Publication, below, “illustrate a blood sample optimization system **2400** that includes a patient needle **2402** for vascular access to a patient’s bloodstream, a blood sample collection device **2404** to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit **2406** providing a fluid connection between the patient needle **2402** and the blood sample collection device **2404**.” ’445 Rogers Publication, [0138].

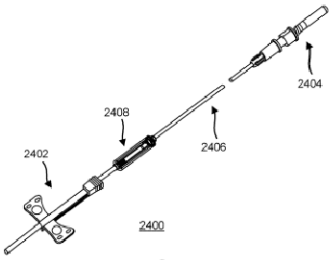


FIG. 24A

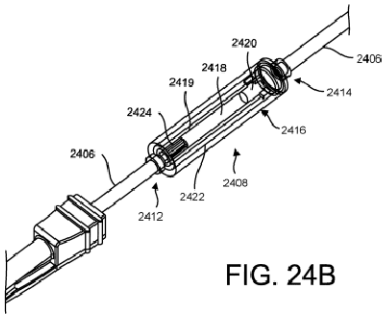


FIG. 24B

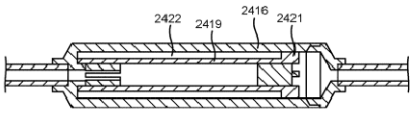


FIG. 24C

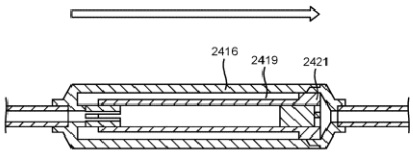


FIG. 24D

124. The ’445 Rogers Publication further teaches:

> In operation, the inner chamber housing **2419** is in the first position toward the inlet port **2412**, such that the one or more apertures **2424** are closed, and the blood

sequestration chamber **2418** is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device **2404**, the initial aliquot of blood flows into the blood sequestration chamber **2418**. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier **2420**, forcing the inner chamber housing to the second position. The inner chamber housing **2419** and/or housing **2416** can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing **2419** in the first position until the blood sequestration chamber **2418** is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing **2419** to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber **2418** and the one or more apertures **2424** are opened to create a

> pathway from the inlet port **2412** to the blood sampling channel **2422**, bypassing and/or flowing around the blood sequestration chamber **2418**.

'445 Rogers Publication, [0142]

125. The '445 Rogers Publication is the published version of a patent application that issued as U.S. Patent No. 11,311,219.

126. The '445 Rogers Publication is assigned to Kurin and lists as the first named inventor Mr. Rogers. Thus, the principal reference used to reject Magnolia's pending claims in the '237 and '239 Applications was ***Kurin's own patent***.

127. One June 9, 2022, at Magnolia's request, Examiner Kremer held an interview with Magnolia regarding both the '237 and '239 Applications, a summary of which was recorded in their file histories on June 14, 2022.

128. Magnolia submitted an agenda for the interview, in which it reproduced Figures 24B–D of the '445 Rogers Publication and argued that the "distinctions between claimed invention and cited art" included the "first and second flow controllers" and "claimed structures performing recited functional limitations in response to a negative pressure differential."

129. The "functional limitations" referenced by Magnolia referred to the change of the "second flow controller" from first state to a second state in response to a threshold negative pressure differential within the sampling channel.

130. On July 18, 2022, Magnolia amended the claims to address the anticipation rejections. For example, Magnolia amended proposed claim 28 of the ’237 Application to, *inter alia*, specify that the device must be configured to transition the second flow controller from its first state to its second state specifically when the negative pressure differential “within at least a portion of the sampling channel between the second flow controller and the outlet” exceeds a threshold pressure differential.

131. Magnolia argued that the ’445 Rogers Publication does not disclose or reasonably suggest such a transition specifically in response to the negative pressure differential in the sampling channel between the second flow controller and the outlet, and thus proposed claim 28 should be allowed.

132. On August 4, 2022, Examiner Kremer issued final rejections of the pending claims of the ’237 and ’239 Applications as anticipated by Kurin’s ’445 Rogers Publication and/or rendered obvious by Kurin’s ’445 Rogers Publication in view of U.S. Patent Publication No. 2019/0000367 (“Lundquist”).

133. Examiner Kremer pointed out the embodiments disclosed in Figures 23 and 24 of the ’445 Rogers Publication and the related portions of the specification.

134. The Examiner noted that Applicant’s arguments with respect to Kurin’s ’445 Rogers Publication were “not persuasive.”

135. As to the ’237 Application’s pending claims, Examiner Kremer did not find persuasive the Applicant’s argument that the ’445 Rogers Publication does not disclose “a flow controller configured to transition from the first state to [a] second state when a magnitude of the negative pressure differential within at least a portion of the sampling channel between the second flow controller and the outlet exceeds a threshold pressure differential” because the ’445 Rogers Publication “discloses that the apertures 2424 are exposed at the same time as when the magnitude of the negative pressure differential within at least a portion of the blood sampling channel 2422 between the apertures 2424 and the outlet port 2414 is above a threshold pressure differential (a differential so as to permit flow),” and the “claim limitation does not require a cause-and-effect relationship between the second flow controller’s transition from the first state to the second state and the negative pressure differential.”

136. As to the ’239 Application’s pending claims, Examiner Kremer did not find persuasive the Applicant’s argument that the ’445 Rogers Publication does not disclose a “housing defining each of a containment channel and sampling channel” because “[t]he inlet port 2412 of Rogers and the outlet port 2414 of Rogers and the tubing in FIGS. 24C and 24D that form the sequestration path and the blood sampling channel 2422 of Rogers are considered to be the housing.”

137. Magnolia needed to get away from Examiner Kremer to execute its strategy against Kurin.

2. Magnolia Files Two More Applications in a Different Family with Materially Identical Claims to the ’237 and ’239 Applications that Issue as the Asserted ’081 and ’863 Patents

138. Just four days later, on August 8, 2022, Magnolia simultaneously filed two new patent applications, listing the same inventors, in a different patent family with materially identical claims to those rejected in the ’237 and ’239 Applications.

139. These two new applications ultimately issued as the ’081 and ’863 Patents that Magnolia now asserts against Kurin.

140. Magnolia’s new patent applications were filed by the same prosecuting team that filed the ’237 and ’239 Applications. That same attorney, Michael D. Winternitz at Cooley, handled prosecution of the applications that would lead to the ’081, ’863, and ’709 Patents and was responsible for interactions with the USPTO throughout prosecution. The ’237 and ’239 Applications and the applications that issue as the asserted ’081, ’863 and ’709 Patents all include declarations from the same four alleged inventors: Gregory J. Bullington, Jay M. Miazga, Shan E. Gaw, and Timothy F. Ramsey.

141. The ’081 Patent was filed as U.S. Patent Application No. 17/883,339 (the ’339 Application). Original proposed claim 37 recites:

> A fluid control device, the device comprising:

a housing having an inlet fluidically coupleable to a patient and

an outlet fluidically coupleable to a fluid collection device, the housing defining at least a portion of each of a containment channel and a sampling channel between the inlet and the outlet; a selectively permeable blood barrier, the blood barrier disposed in the housing between the containment channel and the outlet; and

a moveable plug disposed in the housing and configured to obstruct a flow path between the inlet and the outlet via the sampling channel when in first position, the blood barrier configured to allow a gas to flow through the blood barrier in response to a pressure differential between the inlet and the outlet, thereby allowing a volume of blood to flow into the containment channel,

in response to contact with at least a portion of the volume of the blood in the containment channel, the blood barrier configured to allow the pressure differential in at least a portion of the sampling channel between the moveable plug and the outlet to build to an extent sufficient to move

the moveable plug from the first position to a second position in which the moveable plug allows blood to flow through the sampling channel to the outlet.

142. The ’863 Patent was filed as U.S. Patent Application No. 17/883,340 (the ’340 Application). Original proposed claim 37 recites:

A fluid control device, the device comprising:

a housing having an inlet fluidically coupleable to a patient and

an outlet fluidically coupleable to a fluid collection device, the housing at least partially defining each of a containment channel and a sampling channel between the inlet and the outlet; a selectively permeable blood barrier at a proximal end portion of the containment channel, the blood barrier configured to allow a gas to flow from the containment channel to the outlet in response to a pressure differential between the inlet and the outlet such that a volume of blood is drawn from the patient and into the containment channel; and

a moveable plug between a portion of the containment channel and sampling channel, the moveable plug

> configured to move from a first position to a second position in response to a pressure differential in at least a portion of the sampling channel between the moveable plug and the outlet exceeding a threshold pressure as a result of the volume of blood in the containment channel, the moveable plug configured to obstruct a distal end portion of the sampling channel when in the first position but not in the second position to allow blood to flow from the patient through the sampling channel to the outlet.

143. While Magnolia shuffled the order of certain elements, specified the first flow controller as a "selectively permeable blood barrier" and the second flow controller as a "movable plug," these proposed claims were materially identical to the rejected proposed claims in the '237 and '239 Applications. And to the extent these changes were intended to be material, they were not sufficiently described in the specifications because Magnolia had not invented, disclosed, or possessed any such inventions.

3. Magnolia Simultaneously Prosecutes Four Patents from Two Families with Materially Identical Claims Before Different Examiners

144. On information and belief, Magnolia intentionally pursued the strategy of filing new patent applications in a new family to avoid Examiner Kremer and the

fate of ’237 and ’239 Applications. Magnolia’s scheme worked. Magnolia’s two new applications were assigned to Examiner McCrosky.

145. After receiving several rejections during prosecution of the ’237 and ’239 Applications, Magnolia realized that Examiner Kremer was not going to allow Magnolia to expand its patents to capture overbroad scope beyond what it had invented and what Magnolia, in fact, knew was prior art work by Kurin.

146. Rather than recognizing Kurin’s prior invention, Magnolia filed continuation applications in a different patent family it had kept alive in front of Examiner McCrosky, seeking claims materially identical to those rejected by Examiner Kremer in the ‘237 and ‘239 Applications.

147. Magnolia intentionally exploited the USPTO’s practice of assigning co-pending applications (i.e. continuations) to the same examiners. Thus, to ensure it could pursue the claims it wanted, Magnolia filed the applications that would lead to the ’081 and ’863 Patents as continuations of U.S. Patent Application No. 17/390,249, a patent family pending before Examiner McCrosky.

148. Not only did Magnolia withhold material references that had already been determined to be invalidating prior art by another USPTO examiner, Magnolia doubled-down and engaged in further patent prosecution misconduct by intentionally misdirecting Examiner McCrosky away from key necessary disclosures. Specifically, Magnolia engaged in a process of selectively disclosing

inordinate numbers of irrelevant references to act as a smokescreen over material prior art and information that it knew was fatal to Magnolia's application.

149. For example, Magnolia filed 31-page Information Disclosure Statements with both applications pending before Examiner McCrosky, while intentionally withholding critical prior art references it was intimately familiar with from other pending prosecutions: the '445 Rogers Publication and Lundquist. Despite having disclosed the '445 Rogers Publication and the Lundquist references in the '237 and '239 Applications, neither reference was disclosed in these Information Disclosure Statements.

150. Magnolia was fully aware of the '445 Rogers Publication and Lundquist when it filed its applications for the '081 and '863 Patents.

151. The same Magnolia patent prosecutor that conducted the June 9, 2022 interview with Examiner Kremer to discuss his rejections of the '237 and '239 Applications based on the '445 Rogers Publication and signed the response and arguments Magnolia filed on July 18, 2022 addressing the same issues, also signed the two new applications filed just days later on August 4, 2022, that issued as the asserted '081 and '863 Patents.

152. While Lundquist was referenced in a disclosure related to the '249 application, the parent application for both the '081 and '863 Patents, Magnolia did not cite or list Lundquist in the applications for those later patents, recognizing the

validity risk it faced in the combination of Lundquist and the ’445 Rogers Publication.

153. Magnolia did disclose many other references it previously disclosed in the ’249 application, but Lundquist was selectively left off, and the combination of Lundquist with the ’445 Rogers Publication was not expressly referenced.

154. Unlike the applications that led to the ’081 and ’863 Patents, some of the claims in the ’249 application were rejected as anticipated by a different Kurin patent publication, U.S. Patent Publication No. 2017/0020427 to Rogers.

155. The Examiner did find some of the claims of the ’249 application patentable and issued a notice of allowance on March 28, 2024. Nevertheless, on information and belief, Magnolia has not yet paid its issuance fees and the ’249 Application has not issued as a patent.

156. This is not surprising as Magnolia is aware that once a patent issues from the ’249 application, it will need to rely on a different pending application to keep this family of patents alive so that it can try to claim additional content and continue trying to cover competitors’ products with claims on things that it did not invent. As the ’249 application has not yet issued as a patent, it is not asserted in this case.

157. While Magnolia disclosed the May 3 and August 4, 2022 Office Actions from the ’237 and ’239 Applications in the Information Disclosure

Statements in the applications that led to the ’081 and ’863 Patents, they were buried among 597 listed references including 411 U.S. and international patents and published patent applications, 98 U.S. and international office actions and search reports, 50 journal articles, and dozens of litigation exhibits.

158. Moreover, Magnolia’s “disclosure” of the May 3 and August 4, 2022 Office Actions from the ’237 and ’239 Applications made no mention of the references asserted therein, but were instead strewn among a list of 63 office actions spanning more than 1,000 pages in various other Magnolia patent prosecutions along with approximately 2,400 pages of documents from the *Kurin I* litigation and foreign patent prosecutions.

159. Magnolia did not provide any information regarding where material information could be found in any of the 597 references, leaving blank the column of the Information Disclosure Statement for identifying “Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear.”

160. Magnolia’s disclosure of nearly 600 references was intended to misdirect the Examiner. Magnolia’s non-specific disclosure did not include any description of the relevance of the disclosed prior art, and completely omitted prior art that Magnolia and its patent prosecution team were acutely aware was relevant.

161. Moreover, Magnolia’s practice of dumping voluminous disclosures of references was clearly an effort to misdirect the Examiner away from the prior art

and most relevant office actions contained in the disclosure. Magnolia and its lawyers knew how to game the disclosure process.

162. Then, to further ensure the effective concealment of the material prior art, its prior rejection, and its knowing efforts to mislead the USPTO and Examiner, Magnolia's prosecution team filed requests to expedite examination under Track One. They did so despite the fact that this family had been previously prosecuted for nearly four years without being expedited.

163. The only urgency facing Magnolia was a desire to avoid careful review by the USPTO and to try to improperly obtain patent claims designed to cover products actually invented and developed by Kurin. Magnolia's strategy worked in that these were issued within four and a half months and nine and a half months for the '081 and '863 Patents respectively, without a single rejection.

164. On September 12, 2022, Magnolia's Track One expedited examination requests for both applications were granted.

165. Meanwhile, the '237 and '239 Applications remained pending with all claims rejected. On September 27, 2022, at Magnolia's request, Examiner Kremer conducted another interview with Magnolia regarding the rejections in the '237 and '239 Applications.

166. The agenda provided by Magnolia reproduced Figures 24C–D and Figure 23B of the '445 Rogers Publication, and proposed discussion of alleged

distinctions between the claimed invention and these embodiments from the ’445 Rogers Publication, specifically the claimed second flow controller and its transition to a second state as a result of negative pressure differential within at least a portion of the sampling channel.

167. On October 20, 2022, Magnolia filed responses in the ’237 and ’239 Applications further amending proposed claims 28 in both applications. In the ’237 Application, for example, Magnolia amended proposed claim 28 to specify that the negative pressure differential must build between the “second side” of the second flow controller and the outlet “until a difference in pressure between the first and the second side of the second flow controller exceeds a threshold pressure differential operable to move the second flow controller from the first position the second position.” Magnolia amended proposed claim 28 of the ’239 Application to include similar limitations.

168. Magnolia falsely told the Patent Office that the ’445 Rogers Publication does not disclose this causative relationship between the magnitude of the negative pressure differential and movement of the second flow controller.

169. Eleven days later, Examiner McCrosky issued a first-action allowance of the ’081 Patent without rejection.

170. The List of References cited by applicant and considered does not indicate that Examiner McCrosky substantively considered any of the 597 references

cited by Magnolia in its initial Information Disclosure Statements for the ’081 Patent.

171. Examiner McCrosky did find the ’445 Rogers Publication in his own search, and cited it along with one other U.S. patent application and one international application.

172. In his reasons for allowance, Examiner McCrosky referred specifically to the embodiment disclosed in Figure 1 of the ’445 Rogers Publication, stating that it discloses “a moveable plug (52) and blood barrier (20) that allows gas to flow [0060]-[0062], Fig. 1),” but does not disclose other claimed features relating to movement of the plug in response to pressure differentials.

173. Examiner McCrosky specifically stated that the embodiment of Figure 1 of the ’445 Rogers Publication does not teach or suggest: “in response to contact with at least a portion of the volume of the blood in the containment channel, the blood barrier configured to allow the pressure differential in at least a portion of the sampling channel between the moveable plug and the outlet to build to an extent sufficient to move the moveable plug from the first position to a second position in which the moveable plug allows blood to flow through the sampling channel to the outlet.”

174. Examiner McCrosky, however, made no reference to any other embodiment disclosed in the ’445 Rogers Publication, ***including the embodiments***

of Figures 23 and 24 that Examiner Kremer found to disclose precisely these features.

175. This result is unsurprising given that Magnolia improperly withheld the ’445 Rogers Publication and Lundquist from the Examiner. When prosecuting the ’081 and ’863 Patents, Magnolia did not submit an IDS disclosing the ’445 Rogers Publication ***until after*** Examiner McCrosky had independently found it, and never disclosed Lundquist to the Examiner.

176. Magnolia and its patent prosecution team undoubtedly knew of the relevance of the ’455 Rogers Publication and Lundquist, but they intentionally withheld those references from the USPTO. Indeed, Lundquist was of particular relevance given Examiner McCrosky’s reasons for allowance, which relied on the movement of the moveable plug in response to a pressure differential between the sampling channel and the outlet. In the ’237 application, Examiner Kremer found that Lundquist disclosed a membrane that would respond to this type of pressure differential and accordingly rejected similar claims. Magnolia took steps, however, to make sure Examiner McCrosky would overlook Lundquist when evaluating the applications for the ’081 and ’863 Patents.

177. Examiner McCrosky was also apparently unaware of the ***combination*** of the ’445 Rogers Publication and Lundquist that was the basis for Examiner Kremer’s obviousness rejection based on their disclosures of this specific element

regarding movement of the second flow controller in response to the pressure differential in the sampling channel.

178. On November 4, 2022, Magnolia paid the issue fee and filed another Information Disclosure Statement in the application for the ’081 Patent, this time disclosing three Japanese patents and a Japanese Office Action, and requesting that the Examiner review and initial the disclosures.

179. On November 10, 2022, Examiner McCrosky issued a corrected Notice of Allowance of the ’081 Patent and, as requested by Magnolia, indicated that he reviewed the three Japanese references and Office Action.

180. On November 14, 2022, Magnolia filed a second Information Disclosure Statement in the application for the ’863 Patent disclosing the same four Japanese references as in the application for the ’081 Patent, but further disclosing six additional U.S. patents and patent applications, one additional international patent, and one additional U.S. Office Action in U.S. Patent Application No. 17/684,920.

181. On November 17, 2022, Examiner McCrosky issued a first-action allowance of the proposed claims in the application for the ’863 Patent.

182. On November 25, 2022, Examiner McCrosky issued a corrected notice of allowance of the ’863 Patent in view of Magnolia’s second Information Disclosure Statement.

183. As in the application for the ’081 Patent, the List of References cited by applicant does not indicate that Examiner McCrosky substantively considered any of the 597 references cited by Magnolia in its initial Information Disclosure Statement for the ’863 Patent, as none of the references were initialed.

184. In his reasons for allowance of the ’863 Patent, Examiner McCrosky again stated that the embodiment disclosed in Figure 1 of the ’445 Rogers Publication discloses “a moveable plug (52) and blood barrier (20) that allows gas to flow [0060][0062], Fig. 1),” but does not disclose other claimed features relating to movement of the plug in response to pressure differentials.

185. Examiner McCrosky again made no reference to any other embodiment disclosed in the ’445 Rogers Publication, including the embodiments of Figures 23 and 24 that disclose those other claimed features.

186. The ’445 Rogers Publication and Lundquist were particularly material to the claims that issued in the ’081 and ’863 Patents and would have resulted in their denial if disclosed and considered by Examiner McCrosky.

187. Examiner McCrosky’s notice of allowances for the ’081 and ’863 Patents (dated October 31, 2022 and November 17, 2022, respectively) purported to rely specifically on the ’445 Rogers Publication, but nevertheless concluded:

> The above prior art does not teach or suggest: “in response to contact with at least a portion of the volume of the blood

in the containment channel, the blood barrier configured ***to allow the pressure differential in at least a portion of the sampling channel between the moveable plug and the outlet to build*** to an extent ***sufficient to move the moveable plug from the first position to a second position*** in which the moveable plug allows blood to flow through the sampling channel to the outlet" (cl 37); "the moveable plug configured to move from the first position to a second position in response to an increase in a pressure differential between the moveable plug and the outlet as a result of the volume of blood in the containment channel such that a subsequent volume of blood is drawn from the inlet through the sampling channel and to the outlet" (cl 47); "the moveable plug in the first position configured to prevent the volume of blood from flowing from the inlet to the outlet via the sampling channel, the moveable plug in the second position configured to allow a subsequent volume of blood to flow from the inlet through the sampling channel to the outlet" (cl 57).

188. The ’445 Rogers Publication and Lundquist disclosed these limitations. For example, the ’445 Rogers Publication discloses Figure 24 and explains that:

> As the initial aliquot of blood flows into the blood sequestration chamber, ***it displaces air therein*** and eventually the blood contacts the blood barrier 2420, ***forcing the inner chamber housing to the second position***. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, ***providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position***. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.”

’445 Rogers Publication, [0142]. Similarly, Lundquist discloses:

> “In another embodiment, a membrane or pressure valve at a convenient location inside the double-ended needle, preferably close to the second needle-end, blocks the flow of blood prior to bringing the two inner volumes 101, 404 into fluid communication. This allows easier handling by not needing as careful handling and observation to ensure the blood does not run out of the second needle end prior to puncturing the self-sealing septum as well as a controlled and ***limited depressurisation as consequence of bringing the two inner volumes into fluid communication since the blood will have pushed a certain controlled, preferably high amount of the air out of the double-ended needle***. For example, this membrane or valve comprises rubber or another convenient material. ***Bringing the inner volumes into fluid communication breaks or opens the membrane or opens the valve and allows the blood to flow***.”

Lundquist, [0110].

189. This bears emphasis: On August 4, 2022, Examiner Kremer clearly told Magnolia that a particular prior art combination, the ’445 Rogers Publication in view of Lundquist, invalidated its alleged inventions including every element of the claims of the asserted ’081 and ’863 Patent.

190. Magnolia never specifically disclosed this combination in any of its other pending prosecutions and as a result (and by Magnolia’s design) therefore never had to address this combination in prosecution for the Asserted Patents.

191. Magnolia’s strategy to repackage its rejected claims in new applications in a new patent family before a different Examiner (McCrosky) is particularly probative of the materiality of the original Examiner’s (Kremer) rejections and the withheld prior art. It is further probative of Magnolia’s intent to deceive the patent Examiner in order to obtain the ’081, ’863, and ’709 Patents.

192. The rejected claims of the ’237 and ’239 Applications were patentably indistinct from the claims filed as part of the applications that led to the later three patents. The claims of the ’081, ’863, and ’709 Patents would therefore not have issued over the prior art combinations that led to the rejections in the ’237 and ’239 Applications.

193. For example, the final version of proposed claim 28 in Applicant’s August 16, 2023 Amendment of the ’239 Application required:

> 28. A fluid control device, the device comprising:

a housing having an inlet fluidically coupleable to a bodily fluid source and an outlet fluidically coupleable to a fluid collection device, the housing defining at least partially each of a containment channel and a sampling channel between the inlet and the outlet;

a first flow controller in fluid communication with the containment channel, the first flow controller in a first state configured to allow a gas but not a bodily fluid to flow through the containment channel and toward the outlet in response to a negative pressure differential between the inlet and the outlet via the containment channel that is generated by fluidically coupling the outlet to the fluid collection device such that a volume of the bodily fluid is drawn from the inlet to the containment channel, the first flow controller in a second state configured to prevent at least a portion of the volume of the bodily fluid from flowing from the containment channel to the outlet; and

a second flow controller in fluid communication with the sampling channel, the second flow controller in a first state

> configured to prevent the gas and the bodily fluid from flowing through the sampling channel to the outlet, and
>
> after the first flow controller is in the second state, the second flow controller configured to transition to a second state as a result of at least a portion of the negative pressure differential building in a portion of the sampling channel between the second flow controller and the outlet until the negative pressure differential causes an elastic deformation of the second flow controller that allows at least a portion of the second flow controller to translate from a first position to a second position, thereby allowing the bodily fluid to flow through the sampling channel to the outlet.

194. Claim 1 of the ’081 Patent required the same limitations in material respects, albeit in a slightly different order and verbiage. Claim 1 of the ’081 Patent requires:

> 1. A fluid control device, the device comprising:
>
> a housing having an inlet fluidically coupleable to a patient and an outlet fluidically coupleable to a fluid collection device, the housing defining at least a portion of each of a

containment channel and a sampling channel between the inlet and the outlet;

a selectively permeable blood barrier, the blood barrier disposed in the housing between the containment channel and the outlet; and

a moveable plug disposed in the housing and configured to obstruct a flow path between the inlet and the outlet via the sampling channel when in first position,

the blood barrier configured to allow a gas to flow through the blood barrier in response to a pressure differential between the inlet and the outlet, thereby allowing a volume of blood to flow into the containment channel,

in response to contact with at least a portion of the volume of the blood in the containment channel, the blood barrier configured to allow the pressure differential in at least a portion of the sampling channel between the moveable plug and the outlet to build to an extent sufficient to move the moveable plug from the first position to a second position in which the moveable plug allows blood to flow through the sampling channel to the outlet.

195. Independent claim 1 of the asserted ’081 Patent is patentably indistinct from the proposed claims of the ’239 Application that were repeatedly rejected by the Patent Office based on the ’445 Rogers and Lundquist references.

196. For example, comparing claim 1 of the asserted ‘081 Patent to the final version of proposed claim 28 of the ‘239 Application on an element-by-element basis shows material identity of the claim requirements.

197. The preambles of Claim 1 and Proposed Claim 28 are identical.

198. The first element of Claim 1 requiring a “housing” is identical to the first element of Proposed Claim 28.

199. The second element of claim 1 requiring “an inlet fluidically coupleable to a patient and an outlet fluidically coupleable to a fluid collection device” is patentably indistinct from the second element of Proposed Claim 28, substituting only the word “patient” for “bodily fluid source.”

200. The third element of Claim 1 requiring “the housing defining at least a portion of each of a containment channel and a sampling channel between the inlet and the outlet” is patentably indistinct from the third element of Proposed Claim 28, substituting only the words “a portion of” for “partially.”

201. The fourth element of Claim 1 substitutes the term “selectively permeable blood barrier” for the term “first flow controller” in Proposed Claim 28, but this “first flow controller” is required to “selectively allow gas but not bodily

fluid/blood to flow through the containment channel to the outlet" in response to a pressure differential between the inlet and the outlet, thereby allowing blood/bodily fluid to flow into the containment channel, thus these two elements impose the same requirements and are patentably indistinct.

202. The fifth element of Claim 1 substitutes the term "moveable plug" for the term "second flow controller" in Proposed Claim 28, but in their first state both must be configured to obstruct/prevent the flow of blood/bodily fluid between the inlet and outlet via the sampling channel, thus these two elements impose the same requirements and are patentably indistinct.

203. The sixth element of both Claim 1 and Proposed Claim 28 requires that as a result of the pressure differential in at least a portion of the sampling channel between the moveable plug/second flow controller and the outlet, the moveable plug/second flow controller must move/translate from a first position to a second position in which each must allow blood to flow through the sampling channel to the outlet, thus these two elements impose the same requirements and are patentably indistinct.

204. Claim 1 does not impose any additional limitations beyond those imposed by Proposed Claim 28 and thus is patentably indistinct from Proposed Claim 28.

205. On information and belief, Magnolia and its patent prosecution team intentionally drafted Claim 1 to have the same scope as Proposed Claim 28.

206. On information and belief, Magnolia and its patent prosecution team intentionally changed certain claim terms in Claim 1 in ways that would not materially change the scope of the claim but would make it appear different to the reader in an effort to deceive the Patent Office and obscure the identical scope of Claim 1 with Proposed Claim 28.

207. On information and belief, Magnolia and its patent prosecution team similarly intentionally changed certain terms in other asserted claims in ways that would not materially change the scope of the claims but would make them appear different to the reader in an effort to deceive the Patent Office and obscure the identical scope of the asserted claims with the scope of other claims rejected in the '237 and '239 Applications.

208. On information and belief, Magnolia and its patent prosecution team intentionally rearranged certain claim elements in Claim 1 in ways that would not materially change the scope of the claim but would make it appear different to the reader in an effort to deceive the Patent Office and obscure the identical scope of Claim 1 with Proposed Claim 28.

209. On information and belief, Magnolia and its patent prosecution team similarly intentionally rearranged certain claim elements in other asserted claims in

ways that would not materially change the scope of the claims but would make them appear different to the reader in an effort to deceive the Patent Office and obscure the identical scope of the asserted claims with the scope of other claims rejected in the '237 and '239 Applications.

210. Had Magnolia disclosed the '445 Rogers Publication and Lundquist during the prosecution of the applications for the '081 and '863, the Examiner would have recognized the full disclosure of the '445 Rogers Publication, as opposed to just Figure 1, and the combined disclosure with Lundquist, and would have rejected Magnolia's proposed patent claims.

211. Likewise, had Magnolia meaningfully disclosed to Examiner McCrosky the reasoning recited in Examiner Kremer's office actions, Examiner McCrosky would have rejected the claims.

4. Magnolia's Fraud in Prosecution of the '081 Patent

212. On December 20, 2022, the '081 Patent issued.

213. Throughout prosecution of the '081 Patent Magnolia, through its patent prosecution team, omitted material prior art, misdirected the Examiner, and repeatedly chose not to bring Examiner McCrosky's attention to the most relevant prior art and prosecution history from co-pending applications.

214. Specifically, Magnolia omitted Lundquist and the '445 Rogers Publication from its required initial disclosures entirely, and in the case of the '445

Rogers application, did not disclose the reference until the Examiner identified the reference on his own.

215. Magnolia did not bring to the attention of the examiner: (i) the embodiments of Figures 23 and 24 of the ’445 Rogers Publication, (ii) the Lundquist reference, or (iii) the combination of the ’445 Rogers Publication with Lundquist as set forth in the May 3 and August 4, 2022 Office Actions in the ’237 and ’239 Applications.

216. Magnolia chose not to bring these materials to Examiner McCrosky’s attention despite its knowledge that: (i) Examiner Kremer found that these materials disclosed the specific elements found missing from the prior art by Examiner McCrosky, (ii) these materials were the basis for repeated rejection of materially identical claims in the ’237 and ’239 Applications, and (iii) there is no indication that Examiner McCrosky substantively considered Examiner Kremer’s Office Actions in the ’237 and ’239 Applications buried in Magnolia’s first Information Disclosure Statement.

217. Magnolia intentionally buried these materials in tens of thousands of pages of undifferentiated references for which it declined to identify the relevant portions so as to allow Examiner McCrosky a reasonable opportunity to consider patentability in view of their disclosures.

5. Magnolia's Continued Strategy of Fraud on the Patent Office

218. On December 21, 2022, the day after the '081 Patent issued, after a series of technical correction filings, Magnolia filed a third Information Disclosure Statement in the application for the '863 Patent, this time disclosing an additional six U.S. patents and publications and two additional international patents.

219. Meanwhile, on February 16, 2023, Examiner Kremer again rejected the proposed claims of the '237 Application, including proposed independent claim 28, as obvious under Section 103 based on the Rogers '445 Publication in view of Lundquist.

220. In response to Applicant's attempt to distinguish the prior art, Examiner Kremer pointed out that the proposed combination of the Rogers '445 Publication, particularly the embodiment disclosed in Figure 23, combined with Lundquist, discloses the feature of the amended proposed claims requiring that the negative pressure differential must build between the "second side" of the second flow controller and the outlet "<u>until a difference in pressure between the first and the second side of the second flow controller</u> exceeds a threshold pressure differential <u>operable to move the second flow controller from the first position the second position</u>."

221. Examiner Kremer likewise rejected the proposed claims of the '239 Application on February 17, 2023, also as obvious in view of the Rogers '445

Publication and Lundquist, rejecting arguments similar to those made regarding the ’237 Application.

222. On February 23, 2023, Examiner McCrosky issued a new Notice of Allowance of the ’863 Patent setting forth the same reasons for allowance as in the prior notice.

223. Even though Examiner Kremer’s Office Action just the week prior found that the pending claims of the ’237 and ’239 Applications, which disclosed the same features as the claims of the ’863 Patent, were invalid over Figure 23 of the Rogers ’445 Publication and Lundquist, neither Magnolia nor its prosecution team disclosed the February 16 and 17 Office Actions to Examiner McCrosky.

6. Magnolia’s Fraud in Prosecution of the ’863 Patent

224. On May 23, 2023, the ’863 Patent issued.

225. Throughout prosecution of the ’863 Patent, Magnolia repeatedly chose not to bring Examiner McCrosky’s attention to the most relevant prior art and prosecution history from co-pending applications.

226. Specifically, Magnolia omitted Lundquist and the ’445 Rogers Publication from its required initial disclosures entirely, and in the case of the ’445 Rogers application, the Examiner identified the reference on his own.

227. Magnolia did not bring to the Examiner’s attention: (i) the embodiments of Figures 23 and 24 of the ’445 Roger Publication, (ii) the Lundquist

reference, or (iii) the combination of the ’445 Rogers Reference with Lundquist as set forth in the May 3, 2022, August 4, 2022, and February 16 and 17, 2023 Office Actions in the ’237 and ’239 Applications.

228. Magnolia chose not to bring these materials to Examiner McCrosky’s attention despite its knowledge that: (i) Examiner Kremer found that these materials disclosed the specific elements found missing from the prior art by Examiner McCrosky, (ii) these materials were the basis for repeated rejection of materially identical claims in the ’237 and ’239 Applications, and (iii) there is no indication that Examiner McCrosky substantively considered Examiner Kremer’s Office Actions in the ’237 and ’239 Applications buried in Magnolia’s first Information Disclosure Statement.

229. Magnolia intentionally buried these materials in tens of thousands of pages of undifferentiated references for which it declined to identify the relevant portions so as to allow Examiner McCrosky a reasonable opportunity to consider patentability in view of their disclosures.

7. Magnolia Files a New Continuation Application that Issues as the ’709 Patent

230. On April 3, 2023, less than two months after Kurin issued a press release about the launch of the Kurin Jet, Magnolia applied for ***another*** patent in the same family as the ’081 and ’863 Patents, U.S. Patent Application No. 18/130,207 (the “’207 Application). The ’207 Application ultimately issued as the ’709 Patent,

which Magnolia asserts here against Kurin. Proposed claim 37 of the ’207 Application, which issued as claim 1 of the ’709 Patent recites:

> A fluid control device, the device comprising:
>
> a housing having an inlet fluidically coupleable to a blood bodily fluid source and an outlet fluidically coupleable to a fluid collection device, the housing defining at least a portion of each of a containment channel and a sampling channel between the inlet and the outlet;
>
> a selectively permeable blood barrier, the blood barrier fluidically coupled to the containment channel and the outlet; and
>
> a valve disposed at least partially in the housing and configured to substantially obstruct a flow path between the inlet and the outlet when in a first state,
>
> the blood barrier configured to allow a gas to flow through the blood barrier in response to a pressure differential between the inlet and the outlet, thereby allowing a volume of blood to flow into the containment channel,
>
> in response to contact with at least a portion of the volume of the blood in the containment channel, the blood barrier

configured to allow the pressure differential in at least a portion of the sampling channel between the valve and the outlet to build to an extent sufficient to transition the valve from the first state to a second state in which the valve allows blood to flow through the sampling channel to the outlet.

231. Although Magnolia substitutes a "valve" for the "moveable plug" of the '081 and '863 Patents and the "second flow controller" of the '237 and '239 Applications, the proposed claims of the application for the '709 Patent are materially identical to the rejected claims of the '237 and '239 Applications and the allowed claims of the '081 and '863 Patents for purposes of Magnolia's disclosure obligations and the Examiners' analysis.

232. On May 19, 2023, Magnolia's request for expedited Track One prosecution of this application was granted.

233. On May 26, 2023, Magnolia filed an Information Disclosure Statement citing 739 prior art references.

234. In this disclosure, Magnolia buried the '445 Rogers Publication, Lundquist, and Office Actions in the '237 and '239 Applications among 426 U.S. patents, publications, and applications, 93 international patents, and 102 office actions from various U.S. and foreign applications.

235. On July 7, 2023, Examiner McCrosky issued a Notice of Allowance of the ’709 Patent, with the same reasons for allowance as the ’081 and ’863 Patents.

236. On August 23 and 25, 2023 Examiner Kremer issued Office Actions again rejecting the proposed claims in the ’237 and ’239 Applications based on the Rogers ’445 Publication in view of U.S. Patent No. 3,848,579 (“Villa-Real”).

237. Examiner Kremer explained that none of the claimed features of the pending ’237 and ’239 Applications—all of which are found in the issued claims of the ’081, ’863, and ’709 Patents, including those that Examiner McCrosky cited as reasons for allowance—rendered those pending claims patentable over the prior art, specifically Figures 23 and 24 of the ’445 Rogers Publication.

238. Specifically, Examiner Kremer noted:

> Therefore, it would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to have the predetermined pressure differential threshold of the elastically deformable component of Villa-Real be the point when the sequestration chamber is filled, i.e., there is only one pressure differential due to the penetration into the subject’s vein on one side of the membrane and only one pressure differential due to the vacuum from the vacuum

> container on the other side of the membrane since it permits an automatic operation of the device of Rogers while fulfilling its requirement that the valve prevents the sampling blood from flowing to the outlet until the sequestration chamber is filled.

239. Months later, now nearly five months after Examiner McCrosky's Notice of Allowance, recognizing the relevance of Examiner Kremer's rejections, on December 1, 2023, Magnolia filed a second Information Disclosure Statement in the application for the '709 Patent, which included those Office Actions. But Magnolia again went to its playbook to misdirect Examiner McCrosky away from those highly relevant Office Actions.

240. Instead of simply disclosing these two further Office Actions in the '237 and '239 Applications that set forth specific grounds that would also result in the rejection of the application for the '709 Patent, Magnolia again buried them in a disclosure of 106 prior art references, bringing the total references disclosed in this application to more than 840.

241. Again, Magnolia employed its strategy of misdirection, effectively obscuring the material Office Actions from the Examiner's attention. Magnolia's misdirection was done with the specific intent and goal of deceiving the Examiner. Magnolia provided no explanation for its purported discovery of ***over 100*** relevant

pieces of prior art that were for whatever reason not available to Magnolia at the time it filed its original IDS. In fact, of the 106 disclosures, all but a handful of references existed before the issuance of the August 23 and 25, 2023 Office Actions. Indeed, Magnolia's misdirection was intentional and achieved the goal of effectively withholding material prior art from the Examiner.

242. On information and belief, had the asserted claims of the '081, '836, and '709 Patents been examined by Examiner Kremer, they, too, would have been rejected as anticipated and/or rendered obvious by Kurin's '445 Rogers Publication.

243. Magnolia avoided this outcome by filing new patent applications, in a new family, that were assigned to a different Examiner and then intentionally concealed the first Examiner's rejections from the second Examiner.

244. Magnolia now takes those issued patent claims that should have been rejected based on at least Kurin's '445 Rogers Publication and asserts them against Kurin's Jet product, imposing litigation costs and causing damage to Kurin in the market.

245. Magnolia, like all patent applicants, has and had an ongoing duty of candor to the Patent Office, including to apprise the Patent Office of other applications belonging to the same applicant. For example, the Manual of Patent Examining Procedure ("MPEP") instructs applicants:

Do not rely on the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be "material to patentability" of the application the examiner is considering. *See Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365–69, 66 USPQ2d 1801, 1806–08 (Fed. Cir. 2003) (contrary decision of another examiner reviewing substantially similar claims is 'material'; copending application may be 'material' even though it cannot result in a shorter patent term, when it could affect the rights of the patentee to assign the issued patents). It is desirable to be particularly careful that prior art or other information in one application is cited to the examiner in other applications to which it would be material. Do not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining, or has examined. A "lapse on the part of the examiner does not excuse the

> applicant." *KangaROOS U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985); *see also* MPEP § 2001.06(b).

MPEP § 2004 ¶ 9.

246. Moreover, 37 C.F.R. § 1.56 imposes additional requirements on patent applicants:

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) opposing an argument of unpatentability relied on by the Office, or

(ii) asserting an argument of patentability.

247. This duty of candor is critical to the *ex parte* prosecution process to ensure that patent applications are examined with the most material information regarding patentability before the examiner.

248. Magnolia intentionally did not comply with its duty of candor to the Patent Office and as a result, its patents should be found unenforceable by this Court.

249. Magnolia's failure to comply with its duty of candor is evident in various intentional strategies it used during prosecution.

250. The Office Actions in the '237 and '239 Applications clearly establish that the '445 Rogers Publication alone and combined with Lundquist and/or Villa Real are highly material to patentability of the '081, '863, and '709 Patents.

251. Magnolia never should have filed the applications for the '081, '863, and '709 Patents in the first instance because it knew that the claims it was seeking were unpatentable over the prior art, including because they were obvious over the embodiments of Figures 23 and 24 of Kurin's '445 Rogers Publication.

252. Although Magnolia cited the Office Actions of the '237 and '239 Applications in Information Disclosure Statements, Magnolia did so in a way designed to hide those documents from the examiner by burying them among hundreds of other documents.

253. Further, on information and belief, Magnolia's decision to change the claim language in immaterial ways was intended to further induce the examiner into overlooking those Office Actions.

254. Despite having no indication that Examiner McCrosky had substantively reviewed these office actions in issuing his notices of allowance of the '081, '863, and '709 Patents, Magnolia specifically elected not to bring these office actions to his attention.

255. On information and belief, Magnolia engaged in the Patent Office equivalent of forum-shopping—as it did when filing this action in this Court rather than in Delaware.

256. Magnolia understood it could not obtain the pending claims of the ’237 and ’239 Applications with Examiner Kremer, so it filed materially identical claims in three patent applications in a different family, hoping to mislead a different Examiner to obtain a different outcome.

257. From filing and throughout prosecution, Magnolia knew that Figures 23 and 24 were the embodiments that caused materially identical claims to be found unpatentable by Examiner Kremer, yet it deliberately chose not to bring this to the attention of Examiner McCrosky.

258. As Examiner Kremer properly determined, Figures 23 and 24 disclose the features that Examiner McCrosky found missing from Figure 1 that caused him to allow the claims.

259. Like Figure 1, Figures 23 and 24 contain a moveable plug (e.g., the “Valve 2308” in Figure 23B, or the “inner chamber housing” (2419) in Figure 24B) and a blood barrier (e.g., “Hydrophobic Plug” in Figure 23B, or “air permeable blood barrier” in Figure 24B). However, in contrast to Figure 1, the moveable plug in Figures 23 and 24 prevents blood from flowing from the inlet to the outlet via the sampling channel, and as is explicitly disclosed in the description of Figure 24, the

locking mechanism "maintain[s] the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, ***providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position.*** Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and ***the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel****....*"

260. Magnolia's failure to bring Figures 23 and 24 of the '445 Rogers Publication to Examiner McCrosky's attention was but-for material to the finding of patentability of the claims that issued in the '081, '863, and '709 Patents. This is the rare situation in which there is certainty that an Examiner would and did reject materially identical claims when provided with a complete understanding of the prior art.

261. Taken together, there is a pattern of behavior by Magnolia before the Patent Office of intentional deceit and bad faith to try to claim prior art technologies that do not belong to Magnolia. For at least the reasons set forth above, the only reason that Magnolia obtained its patent claims in the '081, '863, and '709 Patents is by Magnolia misleading and misdirecting the examiner who allowed the claims, which was part of an overarching strategy by Magnolia to intentionally deceive the

Patent Office and systematically try to hide the reality of Magnolia's unpatentable claims in light of the prior art.

8. Magnolia's Fraud in Prosecution of the '709 Patent

262. On February 20, 2024, the '709 Patent issued.

263. Throughout prosecution of the '709 Patent Magnolia repeatedly chose not to bring Examiner McCrosky's attention to the most relevant prior art.

264. Specifically, Magnolia did not bring to the attention of the examiner: (i) the embodiments of Figures 23 and 24 of the '445 Rogers Publication, (ii) the Lundquist reference, or (iii) the combination of the '445 Rogers Publication with Lundquist as set forth in the May 3 and August 4, 2022 Office Actions in the '237 and '239 Applications. Instead, the '445 Rogers Publication, Lundquist and May 3 and August 4, 2022 Office Actions in the '237 and '239 Applications were submitted in an Information Disclosure Statement among 739 other references.

265. Magnolia chose not to bring these materials to Examiner McCrosky's attention despite its knowledge that: (i) Examiner Kremer found that these materials disclosed the specific elements found missing from the prior art by Examiner McCrosky, (ii) these materials were the basis for repeated rejection of materially identical claims in the '237 and '239 Applications, and (iii) there is no indication that Examiner McCrosky substantively considered Examiner Kremer's Office

Actions in the ’237 and ’239 Applications buried in Magnolia’s first Information Disclosure Statement.

266. Magnolia intentionally buried these materials in tens of thousands of pages of undifferentiated references for which it declined to identify the relevant portions so as to allow Examiner McCrosky a reasonable opportunity to consider patentability in view of their disclosures.

COUNT I
(Declaratory Judgment of Non-Infringement of the ’002 Patent)

267. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

268. Magnolia has accused Kurin of infringing at least claim 17 of the ’002 Patent.

269. Kurin does not infringe, and has not infringed, any valid and enforceable claim of the ’002 Patent literally, under the doctrine of equivalents, directly, indirectly, contributorily, or by way of inducement.

270. There is an actual, substantial, and continuing justiciable case or controversy between Magnolia and Kurin regarding whether Kurin has infringed any valid and enforceable asserted claim of the ’002 Patent.

271. Kurin is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid or enforceable asserted claim of the ’002 Patent.

272. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

273. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT II
(Declaratory Judgment of Non-Infringement of the '053 Patent)

274. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

275. Magnolia has accused Kurin of infringing at least claim 1 of the '053 Patent.

276. Kurin does not infringe, and has not infringed, any valid and enforceable claim of the '053 Patent literally, under the doctrine of equivalents, directly, indirectly, contributorily, or by way of inducement.

277. There is an actual, substantial, and continuing justiciable case or controversy between Magnolia and Kurin regarding whether Kurin has infringed any valid and enforceable asserted claim of the '053 Patent.

278. Kurin is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid or enforceable asserted claim of the '053 Patent.

279. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

280. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT III
(Declaratory Judgment of Non-Infringement of the '081 Patent)

281. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

282. Magnolia has accused Kurin of infringing at least claim 1 of the '081 Patent.

283. Kurin does not infringe, and has not infringed, any valid and enforceable claim of the '081 Patent literally, under the doctrine of equivalents, directly, indirectly, contributorily, or by way of inducement.

284. There is an actual, substantial, and continuing justiciable case or controversy between Magnolia and Kurin regarding whether Kurin has infringed any valid and enforceable asserted claim of the '081 Patent.

285. Kurin is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid or enforceable asserted claim of the '081 Patent.

286. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

287. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT IV
(Declaratory Judgment of Non-Infringement of the ’863 Patent)

288. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

289. Magnolia has accused Kurin of infringing at least claim 1 of the ’863 Patent.

290. Kurin does not infringe, and has not infringed, any valid and enforceable claim of the ’863 Patent literally, under the doctrine of equivalents, directly, indirectly, contributorily, or by way of inducement.

291. There is an actual, substantial, and continuing justiciable case or controversy between Magnolia and Kurin regarding whether Kurin has infringed any valid and enforceable asserted claim of the ’863 Patent.

292. Kurin is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid or enforceable asserted claim of the ’863 Patent.

293. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

294. Kurin is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT V
(Declaratory Judgment of Non-Infringement of the '709 Patent)

295. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

296. Magnolia has accused Kurin of infringing at least claim 1 of the '709 Patent.

297. Kurin does not infringe, and has not infringed, any valid and enforceable claim of the '709 Patent literally, under the doctrine of equivalents, directly, indirectly, contributorily, or by way of inducement.

298. There is an actual, substantial, and continuing justiciable case or controversy between Magnolia and Kurin regarding whether Kurin has infringed any valid and enforceable asserted claim of the '709 Patent.

299. Kurin is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid or enforceable asserted claim of the '709 Patent.

300. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

301. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT VI
(Declaratory Judgment of Invalidity of the ’002 Patent)

302. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

303. Magnolia has accused Kurin of infringing at least claim 17 of the ’002 Patent.

304. The claims of the ’002 Patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including but not limited to Sections 101, 102, 103, 112, 116, and/or 256. For example, the alleged invention claimed in the ’002 Patent is not directed to patentable subject matter, is taught by, suggested by, and/or is obvious in light of the prior art, is not adequately supported or enabled by the written description of the patented invention, and/or the claims of the ’002 Patent are indefinite.

305. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the invalidity of the claims of the ’002 Patent.

306. Kurin is entitled to a declaration that the claims of the ’002 Patent are invalid.

307. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

308. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT VII
(Declaratory Judgment of Invalidity of the '053 Patent)

309. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

310. Magnolia has accused Kurin of infringing at least claim 1 of the '053 Patent.

311. The claims of the '053 Patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including but not limited to Sections 101, 102, 103, 112, 116, and/or 256. For example, the alleged invention claimed in the '053 Patent is not directed to patentable subject matter, is taught by, suggested by, and/or is obvious in light of the prior art, is not adequately supported or enabled by the written description of the patented invention, and/or the claims of the '053 Patent are indefinite.

312. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the invalidity of the claims of the '053 Patent.

313. Kurin is entitled to a declaration that the claims of the '053 Patent are invalid.

314. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

315. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT VIII
(Declaratory Judgment of Invalidity of the '081 Patent)

316. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

317. Magnolia has accused Kurin of infringing at least claim 1 of the '081 Patent.

318. The claims of the '081 Patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including but not limited to Sections 101, 102, 103, 112, 116, and/or 256. For example, the alleged invention claimed in the '081 Patent is not directed to patentable subject matter, is taught by, suggested by, and/or is obvious in light of the prior art, is not adequately supported or enabled by the written description of the patented invention, and/or the claims of the '081 Patent are indefinite.

319. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the invalidity of the claims of the '081 Patent.

320. Kurin is entitled to a declaration that the claims of the ’081 Patent are invalid.

321. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

322. Kurin is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT IX
(Declaratory Judgment of Invalidity of the ’863 Patent)

323. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

324. Magnolia has accused Kurin of infringing at least claim 1 of the ’863 Patent.

325. The claims of the ’863 Patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including but not limited to Sections 101, 102, 103, 112, 116, and/or 256. For example, the alleged invention claimed in the ’863 Patent is not directed to patentable subject matter, is taught by, suggested by, and/or is obvious in light of the prior art, is not adequately supported or enabled by the written description of the patented invention, and/or the claims of the ’863 Patent are indefinite.

326. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the invalidity of the claims of the ’863 Patent.

327. Kurin is entitled to a declaration that the claims of the ’863 Patent are invalid.

328. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

329. Kurin is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT X
(Declaratory Judgment of Invalidity of the ’709 Patent)

330. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

331. Magnolia has accused Kurin of infringing at least claim 1 of the ’709 Patent.

332. The claims of the ’709 Patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including but not limited to Sections 101, 102, 103, 112, 116, and/or 256. For example, the alleged invention claimed in the ’709 Patent is not directed to patentable subject matter, is taught by, suggested by, and/or is obvious in light of the prior art, is not adequately supported

or enabled by the written description of the patented invention, and/or the claims of the ’709 Patent are indefinite.

333. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the invalidity of the claims of the ’709 Patent.

334. Kurin is entitled to a declaration that the claims of the ’709 Patent are invalid.

335. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

336. Kurin is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XI
(Declaratory Judgment of Unenforceability)

337. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

338. Magnolia asserts that the Bullington Patents, including the ’081, ’863, and ’709 Patents, are enforceable and is asserting infringement of those patents against Kurin for its Kurin Jet product.

339. Kurin asserts that its product cannot infringe the Bullington Patents, including the ’081, ’863, and ’709 Patents, because those patents are unenforceable as a result of Magnolia’s inequitable conduct.

340. There is an actual, substantial, and continuing case or controversy between Magnolia and Kurin regarding the enforceability of the claims of the ’081, ’863, and ’709 Patents.

341. Magnolia, by and through its patent prosecution team, omitted material information from the Examiner during the applications leading up to the ’081, ’863, and ’709 patents.

342. On information and belief, for at least the reasons set forth in Paragraphs 1 to 266, which are incorporated herein by reference, Magnolia intended to deceive the United States Patent and Trademark Office by and through its long-term scheme to file materially identical claims to those rejected by Examiner Kremer in multiple applications in an unrelated family in the hopes that a new Examiner would overlook the material references Magnolia concealed in its voluminous information disclosure statement.

343. On information and belief, Magnolia’s deceptive acts, including, e.g., Magnolia’s failure to specifically identify or draw attention to Examiner Kremer’s analysis and Figures 23 and 24 of the ’445 Rogers Publication, are material to the patentability of the claims that issued in the asserted ’081, ’863, and ’709 Patents. On information and belief, but for Magnolia’s deceptive acts, none of the claims in the asserted ’081, ’863, and ’709 Patents would have issued, as evidenced by

Examiner Kremer's proper rejections of materially identical claims in unrelated applications.

344. In some cases, when a Patentee commits inequitable conduct, "the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011). That is the case here, where Magnolia has engaged in a concerted effort over a number of years and across several patents families to defraud and deceive the Patent Office in an effort to obtain the '081, '863, and '709 Patents, which Magnolia knows claim prior art technologies and/or technologies that are obvious in view of the prior art. Here, Magnolia's inequitable conduct is especially egregious and intentional and has tainted the patent family of the '081, '863, and '709 Patents in its entirety.

345. Kurin is entitled to a declaration that Magnolia's inequitable conduct has rendered each of the '081, '863, and '709 Patents unenforceable.

346. Kurin is also entitled to a declaration that Magnolia's inequitable conduct as to the '081, '863, and '709 Patents has rendered unenforceable any patents that will later issue in the families of these patents, unless and until Magnolia takes the fair steps necessary to purge its misconduct.

347. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

348. Kurin is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XII
(Infringement of the '052 Patent)

349. Kurin hereby incorporates the allegations of the foregoing Paragraphs of these Counterclaims, as if fully set forth herein.

350. Magnolia is directly infringing, either literally or under the doctrine of equivalents, at least claims 1, 6, 7, 8, 9, 10, 11, 12, 13, 18, 19, 20, 21, 22, 23 and 24 of the '052 Patent under 35 U.S.C. § 271(a) by, without authority, consent, right or license, making, using, selling, and/or offering to sell the Accused Products.

351. As detailed below, the Accused Products practice all elements of at least claim 1 of the '052 Patent. Magnolia's infringement of claim 1 is representative of infringement of all Magnolia's Accused Products.

352. Claim 1 of the '052 Patent recites:

> 1. A device comprising:
>
> an inlet port for receiving a blood sample;
>
> an outlet port;
>
> a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device;

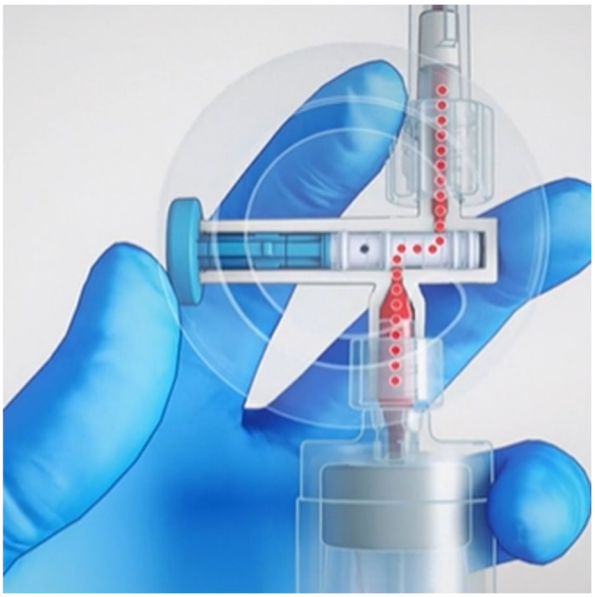
a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port; and a housing that defines the inlet port, the sampling channel, and the outlet port.

353. The Accused Products are devices for reducing blood culture contamination. For example, in an October 15, 2020 launch announcement, Magnolia described the Accused Products as "the first FDA 510(k)-cleared device indicated to reduce blood culture contamination," with "lightweight, lower diversion volume . . . with syringe-driven diversion and collection." https://magnolia-medical.com/press-release/steripathmicro/. Magnolia's website similarly advertises the Accused Products as "FDA 510(k)-cleared with a specific indication to reduce blood culture contamination." https://magnolia-medical.com/steripath/steripath-micro/. Magnolia's website goes on to describe the Accused Products as optimizing "the blood culture collection process" through the use of "an active blood culture bottle- or syringe-driven diversion method," which "diverts the initial .5 to 1.0 mL of blood into the diversion chamber, preventing contaminants from entering the culture bottle," and a push-button to "automatically sequester the contaminants and open a second, sterile pathway for blood culture collection." *Id.*

354. The Accused Products are devices comprising an inlet port for receiving a blood sample, as shown below in images from Magnolia's website:

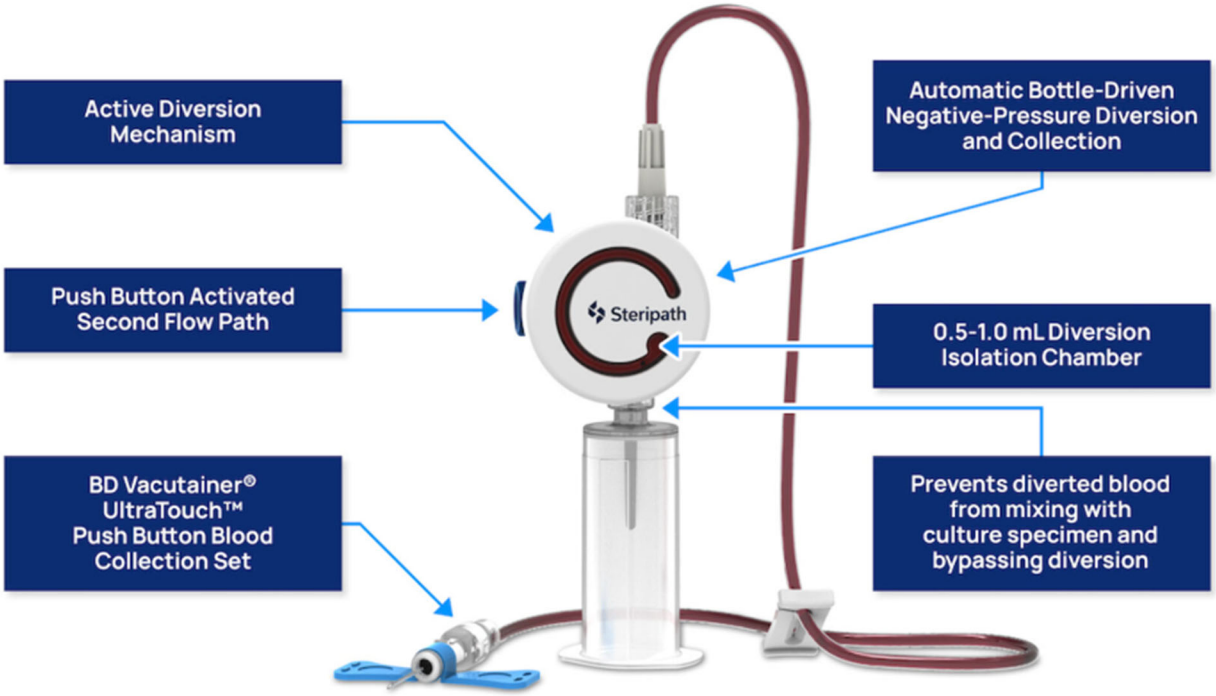
https://magnolia-medical.com/; https://magnolia-medical.com/steripath/steripath-micro/. Further, Magnolia's website describes the Accused Products as being designed to "optimize blood culture collection," and notes that the Accused Products work "after gaining vascular access" and "actively divert the initial .5 to 1.0 mL of blood" drawn from the patient and into the Accused Product's "diversion chamber." https://magnolia-medical.com/steripath/steripath-micro/.

355. The Accused Products further include an outlet, as shown below in images from Magnolia's website:



https://magnolia-medical.com/; https://magnolia-medical.com/steripath/steripath-micro/. Further, Magnolia's website describes the Accused Products as being designed to "optimize[] the blood culture collection process" through the use of "an active blood culture bottle- or syringe-driven diversion method," and notes that the Accused Products have a "collection mode," where the user opens "an independent sterile pathway for specimen collection." https://magnolia-medical.com/steripath/steripath-micro/.

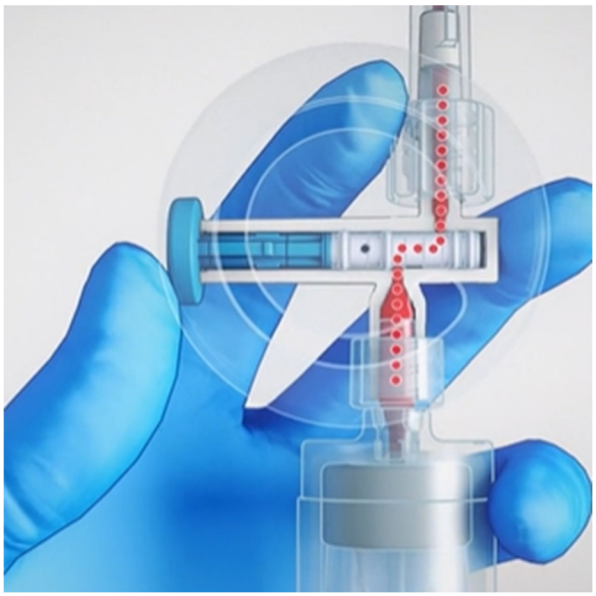
356. The Accused Products further include a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device, as shown below in images from Magnolia's website:



https://magnolia-medical.com/steripath/steripath-micro/. Magnolia's website describes the Accused Products as using "an active blood culture bottle- or syringe-driven diversion method" to "divert[] the initial 0.5 to 1.0 mL of blood into the diversion chamber, preventing potential contaminants from entering the culture

bottle," and notes that this diversion occurs after "innoculat[ing] the blood culture bottle" to the Accused Product. https://magnolia-medical.com/steripath/steripath-micro/. Magnolia's press releases further confirm that the Accused Products meet this limitation through use of "a syringe-driven negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood" in a chamber.

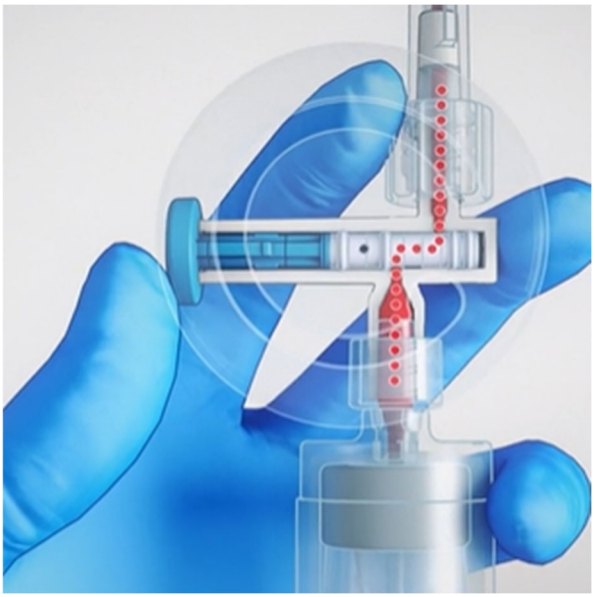
357. The Accused Products further include a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, as shown in the below image from Magnolia's website:



https://magnolia-medical.com/steripath/steripath-micro/. Magnolia's website describes the Accused Products as having a "second, sterile pathway for blood culture collection," which bypasses the "initial 0.5 to 1.0 mL of blood in the diversion chamber" to reduce the presence of contaminants in the blood culture collection. https://magnolia-medical.com/steripath/steripath-micro/. Magnolia's

press releases further confirm that the Accused Products meet this limitation, noting that the Accused Products include "a second independent blood flow pathway" which "opens to collect the blood system for culture into the syringe." https://magnolia-medical.com/press-release/steripathmicro/.

358. The Accused Products further include a housing that defines the inlet port, the sampling channel, and the outlet port, as shown in both the image below taken from Magnolia's website, as well as the below picture of the Accused Product:



https://magnolia-medical.com/steripath/steripath-micro/. Magnolia describes the Accused Products as a "Vein-to-Bottle, Closed-System Technology" that includes a "second, sterile pathway for blood culture collection" that flows from the Accused Product's inlet to its outlet and is defined by the Accused Product's housing. Magnolia further describes the Accused Product as an "all-in-one device[]" that "combines a small, highly intuitive design for optimal user-experience with the

speed of traditional blood culture collection methods." *See* https://www.prnewswire.com/news-releases/magnolia-medical-expands-steripath-micro-initial-specimen-diversion-device-isdd-product-family-with-new-fda-510k-clearance-301791990.html.

359. Unless enjoined by this Court, Magnolia will continue to infringe the '052 Patent and as a direct result Kurin will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Kurin is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

360. Magnolia's infringement of the '052 Patent has damaged and will continue to damage Kurin. Kurin is entitled to recover damages adequate to compensate for Magnolia's infringement, which cannot be less than a reasonable royalty, together with interest and costs fixed by the Court under 35 U.S.C. § 284.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Kurin hereby demands a trial by jury on all claims and issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Kurin respectfully requests that this Court enter judgment in its favor and against Magnolia as follows:

A. Dismissal of Magnolia's Complaint against Kurin, in its entirety, with prejudice, and a denial of the relief sought in its claims and prayer for relief;

B. Declaratory judgment that Kurin has not infringed and does not infringe any valid and enforceable claim of the ’002, ’053, ’081, ’863, and ’709 Patents;

C. An order denying Magnolia’s request for any injunctive relief and request for monetary damages;

D. A declaratory judgment that the ’002, ’053, ’081, ’863, and ’709 Patents, and each claim thereof, are invalid;

E. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Kurin its costs and reasonable attorneys’ fees;

F. An order that Magnolia, its agents, and all persons acting in concert or participation with Magnolia be enjoined from charging infringement, or instituting any further action for infringement of the ’002, ’053, ’081, ’863, and ’709 Patents, against Kurin and its related companies, and any actual or prospective customers;

G. A declaration that the ’081, ’863, and ’709 Patents are unenforceable;

H. A declaration that any patents that are progeny of the ’081, ’863, and ’709 Patents are unenforceable;

I. A judgment that Magnolia has infringed the ’052 Patent

J. A judgment that permanently enjoins Magnolia and their officers, agents, servants, and employees from further infringement of the ’052 Patent;

K. An award of all damages adequate to compensate Kurin for Magnolia's infringement of the '052 Patents, such damages to be determined by a jury and an accounting;

L. An award of pre-judgment and post-judgement interest at the maximum rate allowed by law;

M. Award of Kurin's attorneys' fees, costs, and expenses incurred in prosecuting this action, as provided by 35 U.S.C. § 285; and

N. Granting Kurin such other relief as this Court deems just and reasonable under the circumstances.

/s/ Kelly E. Farnan

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