

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

_____)	
PHARMGATE LLC)	Civil Action No. 17-cv-1899
and PROTATEK INTERNATIONAL)	
INC.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
ZOETIS INC. and ZOETIS)	
SERVICES LLC,)	
)	
Defendants.)	
_____)	

FIRST AMENDED COMPLAINT

Plaintiffs Pharmgate LLC and ProtaTek International Inc. (collectively “Plaintiffs”) for their Complaint against Defendants Zoetis Inc. and Zoetis Services LLC (collectively “Defendants”) hereby allege as follows:

THE PARTIES

1. Plaintiff Pharmgate LLC (“Pharmgate”) is a Delaware limited liability corporation with its principal place of business at 1015 Ashes Drive #102, Wilmington, North Carolina 28401.

2. Plaintiff ProtaTek International Inc. (“ProtaTek”) is a Minnesota corporation with its principal place of business at 2635 University Avenue West #140, Saint Paul, Minnesota 55114. ProtaTek is a wholly-owned subsidiary of Pharmgate.

3. Upon information and belief, Defendant Zoetis Inc. is a Delaware corporation with its principal place of business at 10 Sylvan Way, Parsippany, New Jersey 07054.

4. Upon information and belief, Defendant Zoetis Services LLC is a Delaware limited liability company with its principal place of business at 10 Sylvan Way, Parsippany, New Jersey 07054. Upon information and belief, Zoetis Services LLC is a wholly-owned subsidiary of Zoetis Inc.

BACKGROUND

5. Plaintiffs develop and market high quality medicines for the control of disease in livestock and poultry in North America. They market and support innovative new products and differentiated generics.

6. ProtaTek operates a research and manufacturing facility in the state of Minnesota. That facility develops and manufactures Plaintiffs' vaccines, including CircogardTM and Circo/MycogardTM. These vaccines are used by swine producers to immunize pigs against diseases associated with porcine circovirus type 2 and *Mycoplasma hyopneumoniae*.

7. Upon information and belief, Defendants also develop animal health medicines and vaccines, as well as diagnostic products, genetic tests, and biodevices, for use by veterinarians and animal owners.

8. Plaintiffs and Defendants directly compete in the marketplace for animal medicines and vaccines.

9. Zoetis Services LLC purports to own eleven patents relating to porcine circovirus vaccines and vectors. Those eleven patents are U.S. Patent Nos. 6,703,023 (the "'023 patent"); 7,223,407 (the "'407 patent"); 7,223,594 (the "'594 patent"); 7,407,803 (the "'803 patent"); 7,604,808 (the "'808 patent"); 7,722,883 (the "'883 patent"); 7,740,866 (the "'866 patent"); 7,758,865 (the "'865 patent"); 7,951,907 (the "'907 patent"); 8,715,690 (the "'690 patent"); and

8,124,723 (the “723 patent”) (collectively the “Asserted Patents”). The Asserted Patents are attached hereto as Exhibits A-K.

10. Upon information and belief, Defendants contend that their Fostera® PCV MH product is a commercial embodiment of at least one claim of the Asserted Patents. Upon information and belief, Zoetis Inc. manufactures and markets Fostera® PCV MH.

11. On or about May 20, 2017, Plaintiffs’ President and Chief Executive Officer Colin Gray was playing golf in Dublin, Ireland with, among others, Zoetis Inc.’s Executive Vice President/President of International Operations, Clinton Lewis. Mr. Lewis notified Mr. Gray that Plaintiffs could expect a letter in the near future from Zoetis’s legal team regarding patent infringement by Plaintiffs.

12. On or about May 25, 2017, Defendants’ V.P. and Chief Patent Counsel, Dr. Sally K. Mannion, sent a letter by email on behalf of Defendants to Plaintiffs alleging infringement of the Asserted Patents (the “Letter”). The email and the Letter are attached hereto as Exhibit L.

13. The Letter carbon copied by email John Martin and Mr. Lewis. On information and belief, Mr. Martin is Vice President and Chief Counsel – U.S., Chief Litigation Counsel and Chief Compliance Officer for Zoetis Inc. Mr. Lewis is the individual that played golf with Mr. Gray and notified him of the impending Letter. The email from Dr. Mannion acknowledges this prior conversation. It states: “Further to your discussion with Clint Lewis . . .”

14. The Letter alleges that Pharmgate Animal Health has recently launched new porcine circovirus vaccines called Circogard™ and Circo/Mycogard™ (“the Accused Vaccines”).

15. The Letter further asserts that the Accused Vaccines are manufactured by ProtaTek International Inc.

16. The Letter states that a patent application published in the name of ProtaTek International Inc. (WO 2014/182872) describes a single nucleotide sequence of a PCV2 ORF2 capsid antigen. The Letter alleges that the ProtaTek sequence has “a 99% sequence identity” with SEQ. ID. No. 25 claimed in the Asserted Patents.

17. The Letter asserts that the sequence used in Plaintiffs’ Circogard™ and Circo/Mycogard™ vaccines “would appear to infringe one or more of [the Asserted Patents].”

18. The Letter demands that Plaintiffs provide additional information to disprove Defendants’ infringement allegations and requests a response from Plaintiffs by no later than June 7, 2017.

19. The Letter specifically indicates that ProtaTek is the manufacturer of the Accused Vaccines. The letter further indicates that ProtaTek was recently acquired by Pharmgate Animal Health and alleges infringement of the Asserted Patents. These allegations, the threats made by Mr. Lewis to Mr. Gray, and the competitive relationship of the parties, establish that the parties have adverse interests in relation to the Asserted Patents, and a substantial controversy exists between the two parties.

JURISDICTION AND VENUE

20. This is a declaratory judgment action arising under 28 U.S.C. § 2201 and the patent laws of the United States, 35 U.S.C. § 1, *et seq.* As described above, Plaintiffs and Defendants have adverse legal interests presenting a concrete, real and substantial, justiciable controversy between them. Plaintiffs seek judicial declarations that the Asserted Patents are invalid and not infringed by Plaintiffs.

21. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over Defendants. On information and belief, Defendants regularly conduct business throughout the U.S., including within the State of Minnesota, and derive substantial revenue from their activities within the State of Minnesota. Moreover, upon information and belief, Zoetis Inc. and related entities are registered to do business in Minnesota.

23. The Defendants have also specifically directed activities to the state of Minnesota by sending a letter to Plaintiffs accusing ProtaTek, a Minnesota company with a principal place of business in Minnesota, of infringing its patents.

24. Venue is proper pursuant to 28 U.S.C. § 1391(b).

THE ASSERTED PATENTS

25. The Asserted Patents are all entitled “Circovirus Sequences Associated with Piglet Weight Loss Disease (PWD)” and have the same inventors, Andre Jestin et al.

26. The patents are all related to the asserted ’023 patent, which is a continuation-in-part of application No. PCT/FR98/02364, filed on December 4, 1998.

27. The Asserted Patents relate to “vaccines comprising a nucleotide sequence of the genome of Porcine circovirus type B, or a homologue or fragment thereof, and an acceptable pharmaceutical or veterinary vehicle.” (*See* Ex. A at 3:40-44.) For example, claim 1 of the ’023 patent covers:

1. A vaccine comprising a nucleic acid having a nucleotide sequence with at least 90% sequence identity to SEQ. ID. No. 25 and an acceptable pharmaceutical vehicle, wherein said nucleic acid encodes an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus.

28. The claims of the Asserted Patents are directed to patent ineligible subject matter, namely laws of nature or natural phenomena. In addition to claiming patent ineligible laws of

nature or natural phenomena, the Asserted Patents merely add well-understood, routine, and/or conventional components that were previously used by those of skill in the art and that do not transform the unpatentable laws of nature and natural phenomena into patent eligible subject matter. For example, the above claim 1 of the '023 patent claims the natural phenomena of a particular nucleic acid and the well-understood, routine, and conventional use of an acceptable pharmaceutical vehicle. The above claim 1 does not amount to significantly more than a product of nature. The same conclusion applies to all the remaining claims in the Asserted Patents.

29. In addition, the claims of the Asserted Patents are also at least invalid as obvious under 35 U.S.C. §103. Specifically, the claims are invalid as obvious over the prior art isolation and characterization of the virus that came to be known as “PCV2” or “PCVB”, which necessarily would have contained a sequence including ORF'2 of PCVB. One of ordinary skill in the art would have been motivated to make vectors to express proteins from the ORFs of this virus in order to prepare both diagnostic and vaccine products. In addition, the methods described and claimed in the Asserted Patents for preparing vaccine compositions are well-known and conventional.

COUNT 1 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '023 PATENT

30. Plaintiffs incorporate all previous allegations by reference.

31. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '023 patent.

32. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '023 patent.

COUNT 2 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '023 PATENT

33. Plaintiffs incorporate all previous allegations by reference.

34. The claims of the '023 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

35. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '023 patent are invalid.

COUNT 3 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '407 PATENT

36. Plaintiffs incorporate all previous allegations by reference.

37. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '407 patent.

38. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '407 patent.

COUNT 4 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '407 PATENT

39. Plaintiffs incorporate all previous allegations by reference.

40. The claims of the '407 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

41. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '407 patent are invalid.

COUNT 5 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '594 PATENT

42. Plaintiffs incorporate all previous allegations by reference.

43. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '594 patent.

44. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '594 patent.

COUNT 6 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '594 PATENT

45. Plaintiffs incorporate all previous allegations by reference.

46. The claims of the '594 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

47. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '594 patent are invalid.

COUNT 7 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '803 PATENT

48. Plaintiffs incorporate all previous allegations by reference.

49. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '803 patent.

50. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '803 patent.

COUNT 8 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '803 PATENT

51. Plaintiffs incorporate all previous allegations by reference.

52. The claims of the '803 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

53. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '803 patent are invalid.

COUNT 9 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '808 PATENT

54. Plaintiffs incorporate all previous allegations by reference.

55. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '808 patent.

56. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '808 patent.

COUNT 10 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '808 PATENT

57. Plaintiffs incorporate all previous allegations by reference.

58. The claims of the '808 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

59. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '808 patent are invalid.

COUNT 11 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '883 PATENT

60. Plaintiffs incorporate all previous allegations by reference.

61. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '883 patent.

62. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '883 patent.

COUNT 12 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '883 PATENT

63. Plaintiffs incorporate all previous allegations by reference.

64. The claims of the '883 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

65. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '883 patent are invalid.

COUNT 13 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '866 PATENT

66. Plaintiffs incorporate all previous allegations by reference.

67. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '866 patent.

68. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '866 patent.

COUNT 14 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '866 PATENT

69. Plaintiffs incorporate all previous allegations by reference.

70. The claims of the '866 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

71. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '866 patent are invalid.

COUNT 15 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '865 PATENT

72. Plaintiffs incorporate all previous allegations by reference.

73. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '865 patent.

74. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '865 patent.

COUNT 16 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '865 PATENT

75. Plaintiffs incorporate all previous allegations by reference.

76. The claims of the '865 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

77. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '865 patent are invalid.

COUNT 17 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '907 PATENT

78. Plaintiffs incorporate all previous allegations by reference.

79. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '907 patent.

80. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '907 patent.

COUNT 18 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '907 PATENT

81. Plaintiffs incorporate all previous allegations by reference.

82. The claims of the '907 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

83. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '907 patent are invalid.

COUNT 19 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '690 PATENT

84. Plaintiffs incorporate all previous allegations by reference.

85. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '690 patent.

86. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '690 patent.

COUNT 20 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '690 PATENT

87. Plaintiffs incorporate all previous allegations by reference.

88. The claims of the '690 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

89. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '690 patent are invalid.

COUNT 21 – DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '723 PATENT

90. Plaintiffs incorporate all previous allegations by reference.

91. Plaintiffs' Circogard™ and Circo/Mycogard™ vaccines do not and will not infringe the claims '723 patent.

92. Accordingly, Plaintiffs are entitled to a judicial declaration that they have not infringed, literally or under the doctrine of equivalents, directly or indirectly, any claim of the '723 patent.

COUNT 22 – DECLARATORY JUDGMENT OF INVALIDITY OF THE CLAIMS OF THE '723 PATENT

93. Plaintiffs incorporate all previous allegations by reference.

94. The claims of the '723 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

95. Accordingly, Plaintiffs are entitled to a judicial declaration that the claims of the '723 patent are invalid.

PRAYER FOR RELIEF

Wherefore, Plaintiffs request that judgment be entered in their favor and against Defendants as follows:

A. A declaration that Plaintiffs have not infringed, and do not infringe, the Asserted Patents;

B. A declaration that the claims of the Asserted Patents are invalid;

C. A declaration that this is an exceptional case;

D. A declaration that Plaintiffs are entitled to their fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285 and any other applicable statute, and awarding such fees, costs, and expenses; and

E. An award of such other relief as deemed appropriate.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: June 5, 2017

Respectfully submitted,

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