IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: 1:25-cv-01409-RMR-SBP

HAEMONETICS CORPORATION,
a Massachusetts Corporation,

Plaintiff,

v.

TERUMO BCT, INC.,
a Colorado Corporation,

Defendant.

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT
AND JURY DEMAND

Haemonetics Corporation ("Haemonetics" or "Plaintiff"), by way of this Second Amended Complaint against Terumo BCT, Inc. ("Terumo BCT" or "Defendant"), alleges upon information and belief as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 10,758,652 (the "'652 Patent"), 10,792,416 (the "'416 Patent"), 10,980,926 (the "'926 Patent"), 10,980,934 (the "'934 Patent"), 11,738,124 (the "'124 Patent"), 12,171,916 (the "'916 Patent") 12,186,474 (the "'474 Patent"), 12,324,873 (the "'873 Patent"), and 12,377,204 (the "'204 Patent") (collectively, the "Asserted Patents"). This action arises under the United States patent laws, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. §§ 271 and 281.

THE PARTIES

2. Haemonetics is a Massachusetts corporation with its principal place of business at 125 Summer Street, Boston, MA 02110.

3. On information and belief, Terumo BCT is a corporation organized and existing under the laws of Colorado with its principal place of business at 10810 West Collins Avenue, Lakewood, CO 80215.

4. On information and belief, Terumo BCT manufactures and distributes plasma collection systems, including the Rika Plasma Donation System™ with Nomogram A and B and the Rika Plasma Donation System™ with iNomi™ Nomogram (or Individualized Nomogram) (collectively, the "Accused Products").

5. On information and belief, Terumo BCT sells and offers to sell products and services throughout the United States, including in this judicial district, and introduces products and services into the stream of commerce that incorporate infringing technology knowing that they would be sold and or used in this judicial district and elsewhere in the United States.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code.

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because Terumo BCT resides in this District, has a regular and established place of business in this District, and has committed acts of infringement in this District.

9. Terumo BCT is subject to this Court's general and specific personal jurisdiction because it is headquartered within this District and, on information and belief, is registered to do

business in the state of Colorado. Terumo BCT has purposefully availed itself of the privileges and benefits of the laws of the state of Colorado. And, on information and belief, Terumo BCT has sufficient minimum contacts with the state of Colorado, regularly conducts and solicits business within the state of Colorado, and Haemonetics' causes of action arise directly from Terumo BCT's business contacts and other activities in the state of Colorado. Additionally, Terumo BCT, either directly or through its related entities, has purposefully and voluntarily placed its infringing products into the stream of commerce with the intention and expectation that they will be acquired and used by customers in this District.

10. Terumo BCT engages in activities within this judicial district that infringe (directly or indirectly) the Asserted Patents, either literally or under the doctrine of equivalents, including the provision of, use, operation, sales, offering for sale, installation, and advertising of the Accused Products. Terumo BCT also infringes the Asserted Patents by making, using, offering for sale, selling, installing, maintaining, providing instructions, and/or advertising the Accused Products within this District, either literally or under the doctrine of equivalents.

11. End-users and partner customers infringe the Asserted Patents by at least using and operating the Accused Products in this District.

12. Terumo BCT encourages and induces third parties, including partners and customers, to use the Accused Products in an infringing way at least by advertising and distributing the Accused Products and providing instructions, materials, training, and services regarding the Accused Products.

BACKGROUND

13. Haemonetics is a global medical technology company dedicated to improving the quality, effectiveness, safety, and efficiency of healthcare. Haemonetics' innovative solutions address critical medical needs, including end-to-end plasma collection technologies to optimize operations for plasma centers; products to enable blood centers to collect blood components in the greatest demand; and a suite of hospital technologies designed to help enhance clinical outcomes and advance standards of care. Haemonetics Corporation was formed in 1971 by Jack Latham to develop and market apheresis and transfusion systems. Mr. Latham created the revolutionary Latham Bowl, an integral component for separating blood into its various components so that desired components can be collected while unneeded components can be returned to the donor, improving efficiency of donation while decreasing the time the donor must wait to make another donation. Mr. Latham's technology formed a foundation for the apheresis and transfusion systems used today. Haemonetics has been improving upon Mr. Latham's concepts and continuing to innovate in these areas ever since.

14. Haemonetics invests significant resources into these improvements. For example, for the fiscal year that ended March 30, 2024, Haemonetics invested over $64 million in research and development of its products, which is directed out of its laboratory in Boston, Massachusetts.

15. Through its research and development efforts, Haemonetics has become an industry leader in plasma solutions, providing integrated plasma collection systems. Plasma donation centers utilize Haemonetics' systems to collect blood plasma from donors. Haemonetics' systems collect physical characteristic information from a donor, collect the donor's blood, utilize the revolutionary centrifugation bowl technology and method to separate plasma from the donor blood, and then return the blood components, without the plasma, back to the donor. Haemonetics'

systems are approved by the United States Food and Drug Administration (the "U.S. FDA") and actively and commercially used to efficiently collect donated plasma. Human plasma is the indispensable source material for drugs that are known as plasma-derived medicinal products. Most of the plasma intended for fractionation into plasma-derived medicinal products is collected by plasmapheresis and is known as "source plasma." The frequency and volume of source plasma donations are strictly regulated by national regulatory authorities, for example by the U.S. FDA.

16. After more than 20 years commercializing its market-leading PCS®2 plasmapheresis device, in 2017, Haemonetics announced its next generation NexSys PCS® plasmapheresis system, which today is used throughout the United States for plasma donation collection. Haemonetics' NexSys PCS® with YES® Technology, introduced in 2018, provides higher plasma collection volumes per donation by stopping the blood collection volume only when the correct volume of actual plasma, excluding the anticoagulant added during the procedure, has been reached. In 2020, Haemonetics introduced the NexSys PCS® with PERSONA® Technology, a proprietary plasma collection system that yields more plasma per donation on average, resulting in a more efficient donation and more efficient device functionality. Both technologies were significant leaps forward in the plasma collection field when released by Haemonetics, providing a way to collect more plasma per donation on average, thereby optimizing the donation volume for each donor and improving collection efficiency.

17. Haemonetics designs, manufactures, and sells its NexSys PCS® systems to plasma collection companies that use them in the collection of plasma at donation centers around the country. Individual donors are then able to donate plasma utilizing Haemonetics' systems when visiting a donation center.

18. Haemonetics has long been the industry leader in plasma collection systems, with five decades of industry experience and over 75 million collections to date on NexSys PCS®, including over 30 million collections using PERSONA® Technology. The NexSys PCS® is the industry's most advanced, completely integrated system designed to streamline plasma collections and improve yield, productivity, safety, quality, compliance, and donor satisfaction.

19. Haemonetics has invested millions of dollars into research and development of the NexSys PCS® with YES® Technology and NexSys PCS® with PERSONA® Technology.

ASSERTED PATENTS

20. During the research and development of its NexSys PCS® systems, Haemonetics recognized that other plasma collection systems were inefficient and not optimized for plasma collection. Plasma collection amounts were primarily based on the U.S. FDA's "simplified nomogram" ("Volume Limits - Automated Collection of Source Plasma," November 1992), which prescribed the amount of blood plasma that could be collected based on three categories of donor weight. Because donors were classified into one of just three weight ranges, however, and because physiology of individual donors varies even within a particular weight category, collections were inefficient and did not tailor the amount of plasma that could safely be taken from an individual donor. At the time Haemonetics developed the NexSys PCS® system, plasma collection systems on the market utilized the U.S. FDA's simplified nomogram. Prior collection systems also only focused on the full collection volume of a donation procedure—which includes both anticoagulant and blood plasma—instead of homing in on the actual blood plasma-only volume. So, plasma collections which fell into the U.S. FDA-prescribed ranges indeed included less plasma than allowed because some of the counted volume was merely anticoagulant.

21. Recognizing these deficiencies in prior collection systems, Haemonetics created innovative approaches to plasma collection systems, embodied in their NexSys PCS® with YES® Technology and PERSONA® Technology. These technologies optimized plasma collections on an individual basis by focusing on accuracy of each collection—based on a donor's individual characteristics—and still ensuring the safety of the donor. The NexSys PCS® with PERSONA® Technology is configured to utilize an individual donor's actual height, weight, and hematocrit to calculate the correct volume of plasma to be collected, within the guidelines the U.S. FDA cleared for YES® (2018) and PERSONA® (2020). This individually tailored approach typically yields an increased amount of plasma collected during one donation, on average, while still ensuring the safety and comfort of the individual donor. In 2020, in a prospective, multicenter, double-blinded, randomized, controlled trial the NexSys PCS® with PERSONA® Technology was used with 3,443 donors in over 23,000 donations to demonstrate a plasma collection yield improvement, on average of 8% per donation as compared to the NexSys PCS® with YES® Technology alone. Additionally, Haemonetics' NexSys PCS® with YES® Technology is configured to calculate the volume of actual plasma within the collection container, instead of utilizing the plasma and anticoagulant volume as a base for determining when to stop the collection. Collections performed with the NexSys PCS® system with YES® Technology achieve an average increase in yield of 18-26 mL of plasma per donation over the same system without YES® Technology implemented. Again, this approach and these specially-configured systems allow for increased plasma collection during a single donation without impacting the safety or comfort of the donor. The increases in plasma collected in each procedure offered by Haemonetics' innovations revolutionized the industry. The increases, multiplied by the tens of millions of collections each year, offered hundreds of thousands

of liters of additional plasma available to be collected from the same pool of donors, having a value of hundreds of million dollars for the plasma collection/fractionation industry.

22. Haemonetics patented these novel approaches and systems beginning in 2017. The patents acknowledged the issues in the prior art and created novel systems to overcome the existing shortcomings. For example, as explained in the '652 Patent: "Prior art plasma collection systems are unable to determine the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant) and, therefore collect based on the total collection volume, even if the total volume of plasma that has been collected is below the limit prescribed by the FDA." **Exhibit A** at 1:38-44. Haemonetics recognized the inefficiencies in existing approaches and patented its systems which optimized the collection process by more efficiently collecting an optimized volume of plasma per-patient with increased accuracy pursuant to U.S. FDA guidelines. The '652 Patent, which is exemplary of the Asserted Patents, discussed the problems inherent in the preexisting prior art plasma collection systems that the patent improves upon:

> Various embodiment[s] of the present invention provide numerous benefits over prior art plasma collection systems. In particular, as noted above, prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant). Although this is the easiest method because it requires only that the product collection container be weighed, the amount of true product—the pure plasma—is dependent on the donor's hematocrit. In other words, **prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors because of the variation of the percentage of anticoagulant in the product**.

Id. at 9:53-64 (emphasis added). The plasma collection systems claimed in the Asserted Patents "address the issues of prior art systems by collecting a standard volume (e.g., a target volume) of pure plasma from each donor." *Id.* at 9:65-67. The claimed systems improve upon the accuracy of prior art systems by "using knowledge of the donor's hematocrit and the amount of anticoagulant

collected within the plasma collection container 216 (e.g., by counting pump rotations and/or using scale/weight sensors, etc.) to determine the percentage of anticoagulant in the product." *Id.* at 10:2-6. This allows the blood processing system to optimize plasma collection by tailoring the appropriate amount to each donor based on individualized donor information. Moreover, "by stopping the plasma collection process based on a volume of pure plasma collected, embodiments of the present invention are able to collect a greater volume of plasma as compared to prior art systems that stop based on a plasma/anticoagulant mixture." *Id.* at 10:6-11.

23. As such, the Asserted Patents are directed to a "blood processing system that collects plasma" which is tailored to the individual donor and which is capable of determining the actual plasma volume within a collection container with accuracy not seen before in this industry. *Id.* at 10:12-13. The claims of the Asserted Patents recite an improved blood processing system that optimizes plasma collection in a manner that improves upon the prior art. The claimed system is not merely focused on a computerized process via the controller; rather, the claims recite mechanical improvements and other hardware improvements (e.g., optical sensors and weight sensors) that result in an accurate, efficient blood processing system to optimize the amount of plasma collected per donor, while ensuring the safety of the donor.

24. The elements claimed by the Asserted Patents, taken alone or in combination, were not well-understood, routine, or conventional to one of ordinary skill in the art at the time of invention. Rather, the Asserted Patents teach unconventional methods and systems, utilizing the novel approaches described above and embodied in Haemonetics' NexSys PCS® YES® and PERSONA® systems. As explained in the specifications of the Asserted Patents, these unconventional approaches increase efficiency of the claimed plasma collection systems, resulting in more plasma collected, on average, per-donation, increasing the amount of donated plasma and

availability of its components for life saving therapies, ensuring accuracy in the volume of plasma that is collected, without requiring an increase in the number of donations. The claims of the Asserted Patents accordingly describe technological solutions to the problems persistent in prior art collection systems and methods of how to collect the maximum allowable plasma volume from each donor. And these novel methods and systems result in maximum plasma collection volume without sacrificing a donor's comfort level or safety.

25. The systems and methods covered by the Asserted Patents, therefore, differ from prior art collection systems and methods in use at the time of invention. The prior art systems lacked the novel features of the Asserted Patents, including, for example, tailoring collection volumes based on an individual donor's physical characteristics, determining the volume of actual plasma within a collection container, utilizing plasma weighers and optical sensors, and/or configuring an all-in-one plasma collection system capable of carrying out these methods. By enabling a plasma collection system to perform these calculations and determinations resulting in a more efficient and accurate machine, the claims are directed to specific, unconventional improvements to the way plasma collection systems operate. Moreover, the claimed standalone plasma collection system can collect blood, provide anticoagulant, separate plasma, return blood components, and utilize a controller to make determinations about the correct volume of plasma and calculate that volume. The claimed invention constitutes an unconventional and novel approach and system that optimizes plasma collection.

26. The dependent claims are further directed to specific, unconventional improvements to the way plasma collection systems operate. They claim nuances in the specific ways in which target collection volume is calculated, which individual characteristics are used in performing calculation determinations, and different ways to configure the controller using

identified ratios. The written description of the Asserted Patents provides details regarding these different calculations and ways of configuring the collection device to carry out the claimed methods.

27. The specific combination of claim elements recite systems and methods for a continuous nomogram for an individual donor in a way that had never been done before. This individualized nomogram created a new solution in the plasma donation industry. The inventive combinations of claim elements, whether previously known or unknown, constitute inventive concepts.

28. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’652 Patent, including the right to assert all causes of action arising under the ’652 Patent and the right to any remedies for infringement thereof.

29. The ’652 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on September 1, 2020 to Michael Ragusa. The ’652 Patent issued from United States Patent Application No. 15/608,183 which was filed on May 30, 2017. A copy of the ’652 Patent is attached as **Exhibit A**.

30. The ’652 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

31. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’416 Patent, including the right to assert all causes of action arising under the ’416 Patent and the right to any remedies for infringement thereof.

32. The ’416 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on October 6, 2020 to Michael Ragusa.

The ’416 Patent issued from United States Patent Application No. 15/793,339 which was filed on October 25, 2017. A copy of the ’416 Patent is attached as **Exhibit B**.

33. The ’416 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

34. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’926 Patent, including the right to assert all causes of action arising under the ’926 Patent and the right to any remedies for infringement thereof.

35. The ’926 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on April 20, 2021 to Michael Ragusa. The ’926 Patent issued from United States Patent Application No. 16/866,078 which was filed on May 4, 2020. A copy of the ’926 Patent is attached as **Exhibit C**.

36. The ’926 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

37. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’934 Patent, including the right to assert all causes of action arising under the ’934 Patent and the right to any remedies for infringement thereof.

38. The ’934 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on April 20, 2021 to Michael Ragusa. The ’934 Patent issued from United States Patent Application No. 16/931,333 which was filed on July 16, 2020. A copy of the ’934 Patent is attached as **Exhibit D**.

39. The ’934 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

40. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’124 Patent, including the right to assert all causes of action arising under the ’124 Patent and the right to any remedies for infringement thereof.

41. The ’124 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on August 29, 2023 to Michael Ragusa. The ’124 Patent issued from United States Patent Application No. 17/943,410 which was filed on September 13, 2022. A copy of the ’124 Patent is attached as **Exhibit E**.

42. The ’124 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

43. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’916 Patent, including the right to assert all causes of action arising under the ’916 Patent and the right to any remedies for infringement thereof.

44. The ’916 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on December 24, 2024 to Michael Ragusa. The ’916 Patent issued from United States Patent Application No. 17/205,374 which was filed on March 18, 2021. A copy of the ’916 Patent is attached as **Exhibit F**.

45. The ’916 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

46. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’474 Patent, including the right to assert all causes of action arising under the ’474 Patent and the right to any remedies for infringement thereof.

47. The ’474 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on January 7, 2025 to Michael Ragusa.

The ’474 Patent issued from United States Patent Application No. 17/205,400 which was filed on March 18, 2021. A copy of the ’474 Patent is attached as **Exhibit G**.

48. The ’474 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

49. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’873 Patent, including the right to assert all causes of action arising under the ’873 Patent and the right to any remedies for infringement thereof.

50. The ’873 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on June 10, 2025 to Michael Ragusa. The ’873 Patent issued from United States Patent Application No. 18/955,269 which was filed on November 21, 2024. A copy of the ’873 Patent is attached as **Exhibit H**.

51. The ’873 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

52. Haemonetics is the assignee and owner of the right, title, and interest in and to the ’204 Patent, including the right to assert all causes of action arising under the ’204 Patent and the right to any remedies for infringement thereof.

53. The ’204 Patent, entitled “System and Method for Collecting Plasma,” was duly issued by the United States Patent and Trademark Office on August 5, 2025 to Michael Ragusa. The ’204 Patent issued from United States Patent Application No. 19/077,384 which was filed on March 12, 2025. A copy of the ’204 Patent is attached as **Exhibit I**.

54. The ’204 Patent is valid, enforceable, and duly issued in full compliance with Title 35 of the United States Code.

55. Terumo BCT had knowledge of the ’652 Patent, ’416 Patent, ’926 Patent, ’934 Patent, and ’124 Patent at least as early as October 1, 2024, when Haemonetics’ counsel sent a letter to Terumo BCT, detailing its infringement allegations with respect to each of the ’652 Patent, ’416 Patent, ’926 Patent, ’934 Patent, and ’124 Patent. Terumo BCT has had knowledge of the ’916 Patent and the ’474 Patent at least since the filing of the original Complaint on May 5, 2025. Terumo BCT has had knowledge of the ’873 Patent at least since the filing of the First Amended Complaint. Terumo BCT has had knowledge of the ’204 Patent at least since the filing of this Second Amended Complaint.

ACCUSED PRODUCTS

56. Terumo BCT’s Rika Plasma Donation System™ is used to collect blood, process and remove plasma, and return blood to a donor. The Rika Plasma Donation System™ with Nomogram A and B received U.S. FDA approval in March 2022, and on August 4, 2022, Terumo Global (Terumo BCT’s parent entity) announced it used the system to collect plasma from its first donor. *See* https://www.terumo.com/newsrelease/detail/20220805/5421. On May 9, 2024, Terumo BCT received approval from the U.S. FDA for its Rika Plasma Donation System™ with the iNomi™ Nomogram. According to Terumo Global, among the iNomi™ Nomogram’s innovative features is “that plasma collection volume can be determined by an individual donor’s height, weight and hematocrit level on the day they donate plasma.” https://www.terumo.com/newsrelease/detail/20240509/6161.

57. On information and belief, Terumo BCT has made the Accused Products available to a third-party customer, CSL Plasma, to use in CSL Plasma’s laboratories and plasma donation centers. On information and belief, CSL Plasma currently uses the Rika Plasma Donation System™ with iNomi™ Nomogram in its plasma donation centers. *See*

https://www.prnewswire.com/news-releases/csl-plasma-reimagines-donor-experience-with-first-donations-completed-on-innovative-plasma-collection-technology-301600361.html; https://www.cslplasma.com/faster-plasma-donation-system. On information and belief, CSL Plasma has also used the Rika Plasma Donation System™ with Nomogram A and B in its plasma donation centers.

58. CSL Plasma was a customer of Haemonetics but was lured away by Terumo BCT with the promise of improved plasma collection predicated on the very technology Haemonetics created and for which it obtained the Asserted Patents.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 10,758,652

59. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

60. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claims 11, 13, 14, 15, 16, 17, and 18 of the ’652 Patent by making, using, selling, and/or offering for sale the Accused Products.

61. Claim 11 of the ’652 Patent covers a novel plasma collection system and recites:

A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a subject and returning blood components to the subject;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the blood draw pump, the controller configured to calculate (1) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

62. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

63. The Accused Products are systems for collecting plasma.

64. The Accused Products have a venous-access device for drawing whole blood from a subject and returning blood components to the subject.

65. The Accused Products have a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container.

66. The Accused Products have a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump.

67. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

68. The Accused Products have a controller configured to control the operation of the blood component separation device and the blood draw pump.

69. The controllers of the Accused Products are configured to calculate a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container.

70. The controllers of the Accused Products are also configured to calculate a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component.

71. The controllers of the Accused Products are configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

72. Claim 13 of the ’652 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source,

the controller further configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

73. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

74. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

75. The Accused Products have an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source.

76. The Accused Products have a controller configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source.

77. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

78. Claim 14 of the ’652 Patent depends from claim 11 and recites:

A system according to claim 11,

wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

79. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

80. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

81. The Accused Products have a controller configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood.

82. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

83. Claim 15 of the '652 Patent depends from claim 11 and recites:

A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

84. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

85. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

86. The Accused Products have a controller configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood.

87. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

88. Claim 16 of the '652 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma component based, at least in part, on the monitored volume of collected plasma component.

89. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

90. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

91. The Accused Products have a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container.

92. The Accused Products calculate the volume of pure plasma collected within the plasma component based, at least in part, on the monitored volume of collected plasma component.

93. Claim 17 of the ’652 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma component based, at least in part, on the monitored weight of collected plasma component.

94. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

95. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

96. The Accused Products have a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container.

97. The Accused Products calculate the volume of pure plasma collected within the plasma component based, at least in part, on the monitored weight of collected plasma component.

98. Claim 18 of the ’652 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device,

the controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject.

99. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

100. The Accused Products are a system according to claim 11. *See* ¶¶ 61-71, *supra*.

101. The Accused Products have an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device.

102. The Accused Products have a controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject.

103. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

104. On information and belief, at least as of its receipt of the October 1, 2024 notice letter, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’652 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT’s partners, clients, customers, and/or end users, including CSL Plasma, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’652 Patent.

105. In particular, on information and belief, Terumo BCT’s actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

106. On information and belief, Terumo BCT is liable for contributory infringement of the ’652 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the ’652 Patent. The Accused Products are a material component for use in practicing the ’652 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the ’652 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are plasma collection systems, containing all the structural elements claimed in the ’652 Patent, specifically designed for plasma collection.

107. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the ’652 Patent. For example, the Accused Products constitute a material part of the invention claimed because they contain each and every element of the claimed system, including a venous-access device, blood component separation device, plasma container, blood draw line, blood drawn pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

108. On information and belief, the infringing acts of each partner or customer regarding the Accused Product are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring

customers to provide, information and instructions to end users of the Accused Product which, when followed and used, result in infringement.

109. As a consequence of Terumo BCT's direct and indirect infringement of the '652 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be irreparably harmed.

110. On information and belief, Terumo BCT's infringement of the '652 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 10,792,416

111. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

112. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claims 17, 25, 26, 27, 28, 29, and 30 of the '416 Patent by making, using, selling, and/or offering for sale the Accused Products.

113. Claim 17 of the '416 Patent covers a novel plasma collection system and recites:

A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, (3) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (4) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component, the controller configured to stop the first pump when the calculated volume of pure plasma collected within the plasma container equals the target plasma collection volume.

114. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

115. The Accused Products are a system for collecting plasma.

116. The Accused Products have a venous-access device for drawing whole blood from a donor and returning blood components to the donor.

117. The Accused Products have a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container.

118. The Accused Products have a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump.

119. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

120. The Accused Products have a controller configured to control the operation of the blood component separation device and the first pump.

121. The controllers of the Accused Products are configured to calculate a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor.

122. The controllers of the Accused Products are also configured to calculate a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma.

123. The controllers of the Accused Products are also configured to calculate a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container.

124. The controllers of the Accused Products are also configured to calculate a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component.

125. The controllers of the Accused Products are configured to stop the first pump when the calculated volume of pure plasma collected within the plasma container equals the target plasma collection volume.

126. Claim 25 of the ’416 Patent depends from claim 17 and recites:

A system according to claim 17, further comprising:

an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source,

the controller further configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

127. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

128. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

129. The Accused Products have an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source.

130. The Accused Products have a controller configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source.

131. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

132. Claim 26 of the '416 Patent depends from claim 17 and recites:

A system according to claim 17,

wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

133. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

134. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

135. The Accused Products have a controller configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood.

136. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

137. Claim 27 of the '416 Patent depends from claim 17 and recites:

A system according to claim 17, further comprising:

an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.

138. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

139. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

140. The Accused Products have an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device.

141. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.

142. Claim 28 of the ’416 Patent depends from claim 17 and recites:

A system according to claim 17, further comprising:

a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored volume of collected plasma component.

143. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

144. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

145. The Accused Products have a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container.

146. The Accused Products calculate volume of pure plasma collected within the plasma container based, at least in part, on the monitored volume of collected plasma component.

147. Claim 29 of the ’416 Patent depends from claim 17 and recites:

A system according to claim 17, further comprising:

a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored weight of collected plasma component.

148. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

149. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

150. The Accused Products have a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container.

151. The Accused Products calculate the volume of pure plasma collected within the plasma container based, at least in part, on the monitored weight of collected plasma component.

152. Claim 30 of the ’416 Patent depends from claim 17 and recites:

A system according to claim 17, further comprising:

an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device,

the controller configured to determine the donor's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor.

153. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

154. The Accused Products are a system according to claim 17. *See* ¶¶ 113-125, *supra*.

155. The Accused Products have an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device.

156. The Accused Products have a controller configured to determine the donor's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor.

157. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

158. On information and belief, at least as of its receipt of the October 1, 2024 notice letter, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’416 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT’s partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’416 Patent.

159. In particular, on information and belief, Terumo BCT’s actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

160. On information and belief, Terumo BCT is liable for contributory infringement of the ’416 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the ’416 Patent. The Accused Products are a material component for use in practicing the ’416 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the ’416 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are plasma collection systems, containing all the structural elements claimed in the ’416 Patent, specifically designed for plasma collection.

161. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the ’416 Patent. For example, the Accused Products constitute a material part of the invention claimed because they contain each and every element of the claimed system, including a venous-access device, blood component separation device, plasma container, first line, first pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

162. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

163. As a consequence of Terumo BCT’s direct and indirect infringement of the ’416 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be irreparably harmed.

164. On information and belief, Terumo BCT’s infringement of the ’416 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT’s infringing acts are enjoined by this Court.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 10,980,926

165. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

166. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claim 8 of the '926 Patent by making, using, selling, and/or offering for sale the Accused Products.

167. Claim 8 of the '926 Patent covers a novel plasma collection system and recites:

A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device, the controller configured to calculate (1) a volume of anticoagulant to be collected with plasma component in the plasma container, the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma, the system configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

168. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

169. The Accused Products are a system for collecting plasma.

170. The Accused Products have a venous-access device for drawing whole blood from a donor and returning blood components to the donor.

171. The Accused Products have a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component

separation device having an outlet and being configured to send the plasma component to a plasma container.

172. The Accused Products have a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump.

173. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

174. The Accused Products have a controller configured to control the operation of the blood component separation device.

175. The controllers of the Accused Products are configured to calculate a volume of anticoagulant to be collected with plasma component in the plasma container, the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor.

176. The controllers of the Accused Products are also configured to calculate a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor.

177. The controllers of the Accused Products are also configured to calculate a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma.

178. The Accused Products are configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

179. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

180. On information and belief, at least as of its receipt of the October 1, 2024 notice letter, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’926 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT’s partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’926 Patent.

181. In particular, on information and belief, Terumo BCT’s actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

182. On information and belief, Terumo BCT is liable for contributory infringement of the ’926 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the ’926 Patent. The Accused Products are a material component for use in practicing the ’926 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the ’926 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a plasma collection

system, containing all the structural elements claimed in the ’926 Patent, specifically designed for plasma collection.

183. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the ’926 Patent. For example, the Accused Products constitute a material part of the invention claimed because they contain each and every element of the claimed system, including a venous-access device, blood component separation device, plasma container, blood draw line, blood draw pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

184. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

185. As a consequence of Terumo BCT’s direct and indirect infringement of the ’926 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

186. On information and belief, Terumo BCT’s infringement of the ’926 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT’s infringing acts are enjoined by this Court.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 10,980,934

187. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

188. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claim 23 of the '934 Patent by making, using, selling, and/or offering for sale the Accused Products.

189. Claim 23 of the '934 Patent covers a novel plasma collection system and recites:

A system for collecting plasma comprising:

a blood processing device including: a venous-access device for drawing whole blood from a donor and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the first line being controlled by a blood draw pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor, (2) calculate a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) calculate a target collection volume based, at least in part, on the calculated target plasma volume to collect.

190. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

191. The Accused Products are a system for collecting plasma.

192. The Accused Products have a blood processing device including a venous-access device for drawing whole blood from a donor and returning blood components to the donor.

193. The Accused Products have a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component

separation device having an outlet and being configured to send the plasma component to a plasma collection container.

194. The Accused Products have a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the first line being controlled by a blood draw pump.

195. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

196. The Accused Products have a controller.

197. The controllers of the Accused Products are configured to calculate a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor.

198. The controllers of the Accused Products are also configured to calculate a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma.

199. The controllers of the Accused Products are also configured to calculate a target collection volume based, at least in part, on the calculated target plasma volume to collect.

200. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

201. On information and belief, at least as of its receipt of the October 1, 2024 notice letter, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’934 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited

to, Terumo BCT's partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the '934 Patent.

202. In particular, on information and belief, Terumo BCT's actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

203. On information and belief, Terumo BCT is liable for contributory infringement of the '934 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the '934 Patent. The Accused Products are a material component for use in practicing the '934 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the '934 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a plasma collection system, containing all the structural elements claimed in the '934 Patent, specifically designed for plasma collection.

204. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the '934 Patent. For example, the Accused Products constitute a material part of the invention claimed because it contains each and every element of the claimed system, including a venous-access device, blood component separation device, plasma collection container, blood draw line, blood

draw pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

205. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

206. As a consequence of Terumo BCT's direct and indirect infringement of the '934 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

207. On information and belief, Terumo BCT's infringement of the '934 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 11,738,124

208. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

209. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claims 11, 13, 14, 15, 16, 17, and 18 of the '124 Patent by making, using, selling, and/or offering for sale the Accused Products.

210. Claim 11 of the '124 Patent covers a novel plasma collection system and recites:

A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a subject and returning blood components to the subject;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the blood draw pump, the controller configured to calculate (1) a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

211. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

212. The Accused Products are a system for collecting plasma.

213. The Accused Products have a venous-access device for drawing whole blood from a subject and returning blood components to the subject.

214. The Accused Products have a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container.

215. The Accused Products have a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump.

216. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

217. The Accused Products have a controller configured to control the operation of the blood component separation device and the blood draw pump.

218. The controllers of the Accused Products are configured to calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject.

219. The controllers of the Accused Products are also configured to calculate a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component.

220. The controllers of the Accused Products are configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

221. Claim 13 of the '124 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source,

the controller further configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

222. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

223. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

224. The Accused Products have an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source.

225. The Accused Products have a controller configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source.

226. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

227. Claim 14 of the '124 Patent depends from claim 11 and recites:

A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

228. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

229. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

230. The Accused Products have a controller configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood.

231. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

232. Claim 15 of the '124 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device,

the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.

233. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

234. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

235. The Accused Products have an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device.

236. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.

237. Claim 16 of the ’124 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored volume of collected plasma component.

238. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

239. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

240. The Accused Products have a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container.

241. The Accused Products calculate the volume of pure plasma collected within the plasma container based, at least in part, on the monitored volume of collected plasma component.

242. Claim 17 of the ’124 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container,

the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored weight of collected plasma component.

243. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

244. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

245. The Accused Products have a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container.

246. The Accused Products calculate the volume of pure plasma collected within the plasma container based, at least in part, on the monitored weight of collected plasma component.

247. Claim 18 of the '124 Patent depends from claim 11 and recites:

A system according to claim 11, further comprising:

an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device,

the controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject.

248. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

249. The Accused Products are a system according to claim 11. *See* ¶¶ 210-220, *supra*.

250. The Accused Products have an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device.

251. The Accused Products have a controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the subject.

252. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

253. On information and belief, at least as of its receipt of the October 1, 2024 notice letter, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’124 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT’s partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’124 Patent.

254. In particular, on information and belief, Terumo BCT’s actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

255. On information and belief, Terumo BCT is liable for contributory infringement of the ’124 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the ’124 Patent. The Accused Products are a material component for use in practicing the ’124 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the ’124 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are plasma collection systems, containing all the structural elements claimed in the ’124 Patent, specifically designed for plasma collection.

256. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the ’124 Patent. For example, the Accused Products constitute a material part of the invention claimed because they contain each and every element of the claimed system, including a venous-access device, blood component separation device, plasma container, blood draw line, blood draw pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

257. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

258. As a consequence of Terumo BCT’s direct and indirect infringement of the ’124 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

259. On information and belief, Terumo BCT’s infringement of the ’124 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT’s infringing acts are enjoined by this Court.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 12,171,916

260. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

261. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claim 7 of the ’916 Patent by making, using, selling, and/or offering for sale the Accused Products.

262. Claim 7 of the ’916 Patent covers a novel plasma collection system and recites:

A system for collecting plasma, comprising:

a venipuncture needle configured to draw whole blood from a donor;

a blood separator configured to separate the whole blood into a plasma product and a second blood component comprising red blood cells, the blood separator having a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container;

a donor line fluidly coupled to the venipuncture needle configured to introduce the whole blood from the donor to the blood separator, flow through the donor line being controlled by a first pump;

an anticoagulant line coupled to an anticoagulant source, the anticoagulant line configured to combine anticoagulant with the whole blood from the donor, flow through the anticoagulant line being controlled by a second pump;

a touchscreen configured to receive input from an operator; and

a controller programmed to control operation of the system, the controller coupled to the touchscreen and programmed to receive at least a donor’s weight and hematocrit, to determine a target volume for plasma product and/or raw plasma based at least in part on the weight and hematocrit, to control the system to operate draw and return phases to withdraw whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor.

263. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

264. The Accused Products are a system for collecting plasma.

265. The Accused Products have a venipuncture needle configured to draw whole blood from a donor.

266. The Accused Products have a blood separator configured to separate the whole blood into a plasma product and a second blood component, the second blood component including red blood cells and the blood separator having a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container.

267. The Accused Products have a donor line fluidly connected to the venipuncture needle and configured to introduce drawn whole blood to the blood separator, the flow through the first line being controlled by a first pump.

268. The Accused Products have an anticoagulant line coupled to an anticoagulant source, the anticoagulant line configured to combine anticoagulant with the whole blood from the donor, the flow through the anticoagulant line being controlled by a second pump.

269. The Accused Products have a touchscreen configured to receive input from an operator.

270. The Accused Products have a controller programmed to control operation of the system.

271. The controllers of the Accused Products are coupled to the touchscreen and programmed to receive at least a donor's weight and hematocrit.

272. The controllers of the Accused Products are also programmed to determine a target volume for plasma product and/or raw plasma based at least in part on the weight and hematocrit.

273. The controllers of the Accused Products are also programmed to control the system to operate draw and return phases to withdraw whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor.

274. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

275. On information and belief, Terumo BCT has induced and continues to induce others to infringe at least one claim of the '916 Patent under 35 U.S.C. § 271(b) by, among other things,

actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT's partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the '916 Patent.

276. In particular, on information and belief, Terumo BCT's actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

277. On information and belief, Terumo BCT is liable for contributory infringement of the '916 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the '916 Patent. The Accused Products are a material component for use in practicing the '916 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the '916 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a plasma collection system, containing all the structural elements claimed in the '916 Patent, specifically designed for plasma collection.

278. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the '916 Patent. For example, the Accused Products constitute a material part of the invention claimed because it contains each and every element of the claimed system, including a venipuncture needle,

blood separator, plasma product collection container, donor line, first pump, anticoagulant line, anticoagulant source, second pump, touchscreen, and a controller configured to carry out the claimed functionality.

279. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

280. As a consequence of Terumo BCT's direct and indirect infringement of the '916 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

281. On information and belief, Terumo BCT's infringement of the '916 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

COUNT VII – INFRINGEMENT OF U.S. PATENT NO. 12,186,474

282. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

283. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claim 9 of the '474 Patent by making, using, selling, and/or offering for sale the Accused Products.

284. Claim 9 of the '474 Patent covers a novel plasma collection system and recites:

A system for collecting plasma, comprising:

a venipuncture needle configured to draw whole blood from a donor;

a blood separator configured to separate the whole blood into a plasma product and a second blood component comprising red blood cells, the blood separator having a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container;

a donor line fluidly coupled to the venipuncture needle configured to introduce the whole blood from the donor to the blood separator, flow through the donor line being controlled by a first pump;

an anticoagulant line coupled to an anticoagulant source, the anticoagulant line configured to combine anticoagulant with the whole blood from the donor, flow through the anticoagulant line being controlled by a second pump;

a touchscreen configured to receive input from an operator; and

a controller programmed to control operation of the system, the controller coupled to the touchscreen and programmed to receive at least a donor's weight, height and hematocrit and to determine a target volume for plasma product comprising raw plasma and anticoagulant, wherein the target volume for plasma product is determined prior to withdrawing the whole blood from the donor based at least in part on the donor's total blood volume and/or the donor's plasma volume, the controller programmed to then control the system to operate a plurality of draw and return cycles to withdraw whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor.

285. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

286. The Accused Products are a system for collecting plasma.

287. The Accused Products have a venipuncture needle configured to draw whole blood from a donor.

288. The Accused Products have a blood separator configured to separate the whole blood into a plasma product and a second blood component, the second blood component including red blood cells and the blood separator having a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container.

289. The Accused Products have a donor line fluidly connected to the venipuncture needle and configured to introduce drawn whole blood to the blood separator, the flow through the first line being controlled by a first pump.

290. The Accused Products have an anticoagulant line coupled to an anticoagulant source, the anticoagulant line configured to combine anticoagulant with the whole blood from the donor, the flow through the anticoagulant line being controlled by a second pump.

291. The Accused Products have a touchscreen configured to receive input from an operator.

292. The Accused Products have a controller programmed to control operation of the system.

293. The controllers of the Accused Products are coupled to the touchscreen and programmed to receive at least a donor's weight, height, and hematocrit.

294. The controllers of the Accused Products are also programmed to determine a target volume for plasma product including raw plasma and anticoagulant, the target volume for plasma product determined prior to withdrawing the whole blood from the donor based at least in part on the donor's total blood volume and/or the donor's plasma volume.

295. The controllers of the Accused Products are also programmed to control the system to operate draw and return cycles to withdraw whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor.

296. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

297. On information and belief, Terumo BCT has induced and continues to induce others to infringe at least one claim of the '474 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others

including, but not limited to, Terumo BCT's partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the '474 Patent.

298. In particular, on information and belief, Terumo BCT's actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

299. On information and belief, Terumo BCT is liable for contributory infringement of the '474 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the '474 Patent. The Accused Products are a material component for use in practicing the '474 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the '474 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a plasma collection system, containing all the structural elements claimed in the '474 Patent, specifically designed for plasma collection.

300. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the '474 Patent. For example, the Accused Products constitute a material part of the invention claimed because it contains each and every element of the claimed system, including a venipuncture needle, blood separator, plasma product collection container, donor line, first pump, anticoagulant line,

anticoagulant source, second pump, touchscreen, and a controller configured to carry out the claimed functionality.

301. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

302. As a consequence of Terumo BCT's direct and indirect infringement of the '474 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

303. On information and belief, Terumo BCT's infringement of the '474 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

COUNT VIII – INFRINGEMENT OF U.S. PATENT NO. 12,324,873

304. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

305. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claims 13, 17, 18, 19, 20, and 21 of the '873 Patent by making, using, selling, and/or offering for sale the Accused Products.

306. Claim 13 of the '873 Patent covers a novel plasma collection system and recites:

A system for collecting plasma, comprising:

a venous-access device for drawing whole blood from a subject and returning blood components to the subject;

a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container;

a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;

an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood; and

a controller configured to control the operation of the blood component separation device and the blood draw pump, the controller configured to calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject.

307. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

308. The Accused Products are a system for collecting plasma.

309. The Accused Products have a venous-access device for drawing whole blood from a subject and returning blood components to the subject.

310. The Accused Products have a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container.

311. The Accused Products have a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump.

312. The Accused Products have an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood.

313. The Accused Products have a controller configured to control the operation of the blood component separation device and the blood draw pump, the controller configured to calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject.

314. Claim 17 of the '873 Patent depends from claim 13 and recites:

> A system according to claim 13, wherein the controller is further configured to calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, the volume of pure plasma collected within the plasma collection container based, at least in part, upon the volume of anticoagulant in the collected plasma component.

315. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

316. The Accused Products are a system according to claim 13. *See* ¶¶ 306-313, *supra*.

317. The Accused Products have a controller configured to calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, the volume of pure plasma collected within the plasma collection container based, at least in part, upon the volume of anticoagulant in the collected plasma component.

318. Claim 18 of the '873 Patent depends from claim 17 and recites:

> A system according to claim 17, further comprising:
>
> an anticoagulant source weight sensor configured to measure a weight of the anticoagulant source,
>
> the controller further configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source,
>
> the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

319. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

320. The Accused Products are a system according to claim 17. *See* ¶¶ 306-313, *supra*.

321. The Accused Products have an anticoagulant source weight sensor configured to measure a weight of the anticoagulant source.

322. The Accused Products have a controller configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source.

323. The Accused Products calculate the volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

324. Claim 19 of the ’873 Patent depends from claim 13 and recites:

> A system according to claim 13, wherein the controller is configured to monitor the operation of an anticoagulant pump to determine a total volume of anticoagulant introduced into the system.

325. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

326. The Accused Products are a system according to claim 13. *See* ¶¶ 306-313, *supra*.

327. The Accused Products have a controller configured to monitor the operation of an anticoagulant pump to determine a total volume of anticoagulant introduced into the system.

328. Claim 20 of the ’873 Patent depends from claim 13 and recites:

> A system according to claim 13, further comprising:
>
> a plasma collection container weight sensor configured to monitor the volume of plasma component collected within the plasma collection container.

329. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

330. The Accused Products are a system according to claim 13. *See* ¶¶ 306-313, *supra*.

331. The Accused Products have a plasma collection container weight sensor configured to monitor the volume of plasma component collected within the plasma collection container.

332. Claim 21 of the ’873 Patent depends from claim 13 and recites:

> A system according to claim 13, further comprising:

a plasma collection container weight sensor configured to monitor a weight of plasma component collected within the plasma collection container,

the calculated volume of pure plasma collected within the plasma collection container based, at least in part, on the monitored weight of collected plasma component.

333. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

334. The Accused Products are a system according to claim 13. *See* ¶¶ 306-313, *supra*.

335. The Accused Products have a plasma collection container weight sensor configured to monitor a weight of plasma component collected within the plasma collection container.

336. The Accused Products calculate the volume of pure plasma collected within the plasma collection container based, at least in part, on the monitored weight of collected plasma component.

337. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

338. On information and belief, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’873 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others including, but not limited to, Terumo BCT’s partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the ’873 Patent.

339. In particular, on information and belief, Terumo BCT’s actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

340. On information and belief, Terumo BCT is liable for contributory infringement of the ’873 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the ’873 Patent. The Accused Products are a material component for use in practicing the ’873 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the ’873 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a plasma collection system, containing all the structural elements claimed in the ’873 Patent, specifically designed for plasma collection.

341. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the ’873 Patent. For example, the Accused Products constitute a material part of the invention claimed because it contains each and every element of the claimed system, including a venous-access device, blood component separation device, plasma collection container, blood draw line, blood draw pump, anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

342. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring

customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

343. As a consequence of Terumo BCT's direct and indirect infringement of the '873 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

344. On information and belief, Terumo BCT's infringement of the '873 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

COUNT IX – INFRINGEMENT OF U.S. PATENT NO. 12,377,204

345. Haemonetics realleges and incorporates the allegations set forth in the foregoing paragraphs of this Second Amended Complaint as if fully set forth herein.

346. On information and belief, Terumo BCT has infringed and continues to infringe, directly and indirectly, literally and under the doctrine of equivalents, at least claims 23, 29, and 30 of the '204 Patent by making, using, selling, and/or offering for sale the Accused Products.

347. Claim 23 of the '204 Patent covers a novel plasma collection system and recites:

A system for collecting plasma, comprising:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor;

a blood component separation device for separating the drawn whole blood into a plasma component and at least a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to (1) receive individual characteristics of the donor, the individual characteristics including a weight, height, and hematocrit of the donor, and (2) calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor, the donor's total blood volume based, at least in part, on the weight and height of the donor, the target plasma amount to collect being tailored to the individual characteristics of the donor.

348. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

349. The Accused Products are a system for collecting plasma.

350. The Accused Products have a venous-access device for drawing whole blood from a donor and returning blood components to the donor.

351. The Accused Products have a blood component separation device for separating the drawn whole blood into a plasma component and at least a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container.

352. The Accused Products have a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump.

353. The Accused Products have an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood.

354. The Accused Products have a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to (1) receive individual characteristics of the donor, the individual characteristics including a weight, height, and hematocrit of the donor, and (2) calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor, the donor's total blood

volume based, at least in part, on the weight and height of the donor, the target plasma amount to collect being tailored to the individual characteristics of the donor.

355. Claim 29 of the ’204 Patent depends from claim 23 and recites:

> The system according to claim 23, wherein the target plasma amount to collect is an optimized safe amount to be collected from the donor.

356. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

357. The Accused Products are a system according to claim 23. *See* ¶¶ 347-354, *supra*.

358. The target plasma amount to collect by the Accused Products is an optimized safe amount to be collected from the donor.

359. Claim 30 of the ’204 Patent depends from claim 23 and recites:

> The system according to claim 23, further comprising:
>
> a plasma collection container weight sensor configured to monitor a volume or weight of plasma component collected within the plasma collection container.

360. The Accused Products contain each of the above limitations. *See* **Exhibit J**.

361. The Accused Products are a system according to claim 23. *See* ¶¶ 347-354, *supra*.

362. The Accused Products have a plasma collection container weight sensor configured to monitor a volume or weight of plasma component collected within the plasma collection container.

363. On information and belief, Terumo BCT markets and sells the Accused Products in the United States to its partners, clients, customers, and/or end users who use the Accused Products across this country and in this District.

364. On information and belief, Terumo BCT has induced and continues to induce others to infringe at least one claim of the ’204 Patent under 35 U.S.C. § 271(b) by, among other things, actively aiding and abetting others to infringe with specific intent or willful blindness, such others

including, but not limited to, Terumo BCT's partners, clients, customers, and/or end users, whose use of the Accused Products constitutes direct infringement of at least one claim of the '204 Patent.

365. In particular, on information and belief, Terumo BCT's actions that aid and abet others such as its partners, clients, customers, and/or end users to infringe include advertising and distributing the Accused Products and providing instruction materials, training, and services regarding the Accused Products.

366. On information and belief, Terumo BCT is liable for contributory infringement of the '204 Patent under 35 U.S.C. § 271(c) for offering to sell and selling in the United States the Accused Products which are especially made or adapted for use to infringe the '204 Patent. The Accused Products are a material component for use in practicing the '204 Patent, are specifically made for an infringing use, and are not a staple article of commerce suitable for a non-infringing use. For example, the Accused Products and the example functionality described above have no substantial non-infringing uses, but are specifically designed to practice the claims of the '204 Patent. The Accused Products have no substantial non-infringing uses because the accused functionality is an integral part of the Accused Products and must be performed for the Accused Products to perform their intended purpose. Indeed, the Accused Products are a system for collecting plasma, containing all the structural elements claimed in the '204 Patent, specifically designed for plasma collection.

367. In addition, the Accused Products provided by Terumo BCT constitute a material part of the claimed invention, providing all components and features of the claimed system of the '204 Patent. For example, the Accused Products constitute a material part of the invention claimed because it contains each and every element of the claimed system, including a venous-access device, blood component separation device, plasma collection container, first line, first pump,

anticoagulant line, anticoagulant source, and a controller configured to carry out the claimed functionality.

368. On information and belief, the infringing acts of each partner or customer regarding the Accused Products are attributable to Terumo BCT. For example, on information and belief, Terumo BCT directs and controls the activities or actions of its third-party customers in connection with the Accused Products by contractual agreement, or otherwise providing, or requiring customers to provide, information and instructions to end users of the Accused Products which, when followed and used, result in infringement.

369. As a consequence of Terumo BCT's direct and indirect infringement of the '204 Patent, both literally and under the doctrine of equivalents, Haemonetics has been and continues to be harmed.

370. On information and belief, Terumo BCT's infringement of the '204 Patent will continue in the future, and Haemonetics will be irreparably harmed as a consequence unless Terumo BCT's infringing acts are enjoined by this Court.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Haemonetics demands a trial by jury on all triable issues.

PRAYER FOR RELIEF

WHEREFORE, Haemonetics demands judgment for itself and against Terumo BCT as follows:

A. An adjudication that Terumo BCT has infringed the Asserted Patents;

B. An award of a preliminary and permanent injunction enjoining Terumo BCT from continuing to infringe, directly and indirectly, the Asserted Patents;

C. An award of damages to be paid by Terumo BCT adequate to compensate Haemonetics for Terumo BCT's infringement of the Asserted Patents that is no less than a reasonable royalty for the use of the Accused Products or lost profits suffered by Haemonetics;

D. An adjudication that Terumo BCT's infringement has been willful and an award of treble damages;

E. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of Haemonetics' reasonable attorneys' fees; and

F. An award to Haemonetics of such further relief at law or in equity as this Court deems just and proper.

Dated: August 12, 2025

/s/ Carolyn Juarez

Carolyn Juarez
NOD Law PC
726 Front St.
Suite 220
Louisville, CO 80027-1881
Telephone: (720) 536-4904
Email: carolyn@nod-law.com

Erik B. Milch
Elizabeth Shrieves
Proskauer Rose LLP
1001 Pennsylvania Ave., NW
Suite 600 South
Washington, DC 20004-2533
Telephone: (202) 416-6899
Email: emilch@proskauer.com
Email: eshrieves@proskauer.com

Joseph M. Drayton
Connor J. Villar
Proskauer Rose LLP
Eleven Times Square
New York, NY 10036-8299
Telephone: (212) 969-2900
Email: cvillar@proskauer.com
Email: jdrayton@proskauer.com

Alan S. Teran
Proskauer Rose LLP
2255 Glades Road
Suite 421 Atrium
Boca Raton, FL 33431-7360
Telephone: (561) 995-4723
Email: ateran@proskauer.com

Attorneys for Plaintiff Haemonetics Corporation

CERTIFICATE OF SERVICE

I hereby certify that, on August 12, 2025, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Carolyn Juarez
Carolyn Juarez
Counsel for Haemonetics Corp.