IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LONZA WALKERSVILLE, INC., 8830 Biggs Ford Road Walkersville, Maryland, 21793 Frederick County and **OCTANE BIOTECH INC.,** 369 Dalton Avenue Kingston, Ontario K7K 6Z1 Canada Plaintiffs, v. **MILTENYI BIOTEC NORTH AMERICA, INC.,** 1201 Clopper Road Gaithersburg, Maryland 20878 Montgomery County Defendant.	Case No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Lonza Walkersville, Inc. ("Lonza") and Octane Biotech Inc. ("Octane") (collectively "Plaintiffs"), by and through their undersigned counsel, file this Complaint against Miltenyi Biotec North America, Inc. ("Miltenyi" or "Defendant"), and allege as follows:

NATURE OF THE CASE

1. This is an action for patent infringement under federal law.

2. Plaintiffs seek injunctive relief and damages under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, arising from Defendant's willful infringement of one or more claims of U.S. Patent Nos. 9,701,932 (the "'932 Patent"); 9,534,195 (the "'195 Patent"); 10,723,986 (the "'986 Patent"); and 10,844,338 (the "'338 Patent") (hereinafter referred to collectively as the

"Asserted Patents"). The Asserted Patents are directed to automated cell therapy manufacturing systems.

3. Defendant has infringed these patents through the manufacture, use, sale, offer for sale, and/or importation into the United States of its line of automated cell therapy manufacturing systems marketed under the name "CliniMACS Prodigy® System," including, among other things, the "CliniMACS® Prodigy Instrument ("the Instrument"), the related "CliniMACS Prodigy® Tubing Sets ("Tubing Sets"), and the CliniMACS® Electroporator ("Electroporator") (hereinafter referred to collectively as the "Accused Products"). Defendant has done this and continues to do this in violation of at least 35 U.S.C. §§ 271(a), (b), (c), and (f).

4. Specifically, in violation of 35 U.S.C. § 271(a), Defendant has offered the Accused Products for sale in the United States through various sales channels, including through its website and its substantial U.S. sales force. For example, Defendant offers the CliniMACS Prodigy® System for sale at https://www.miltenyibiotec.com/US-en/products/cell-manufacturing-platform/clinimacs-prodigy-platform.html. Ex. 5, at 10-15.

5. Further, in violation of 35 U.S.C. § 271(b), Defendant has encouraged others to use the Accused Products in ways that infringe the Asserted Patents. For example, a Miltenyi brochure shows a complete CliniMACS Prodigy® System utilizing the CliniMACS Prodigy® Instrument and CliniMACS Prodigy® Tubing Set 520 in a setup configured for hematopoietic stem cell manufacturing. The features of the Accused Products shown in the Miltenyi brochure infringe the Asserted Patents.

6. Also in violation of 35 U.S.C. §271(b), Defendant has detailed the use of the CliniMACS Prodigy System® in numerous venues, including in videos placed on YouTube.com. The features of the Accused Products described in these videos infringe the Asserted Patents.

7. Defendant continues to encourage and direct consumers to purchase and use the Accused Products through its online and in-person promotion and marketing activities directed to consumers in the United States, despite receiving actual notice that the Accused Products infringe the Asserted Patents.

PARTIES

8. Plaintiff Octane is a Canadian company located at 369 Dalton Avenue in Kingston, Ontario. Octane is the owner of all right, title, and interest in and to the Asserted Patents. Octane partners with therapeutics companies and clinical centers to develop and manufacture potentially life-saving solutions to terminally-ill cancer patients in need.

9. Plaintiff Lonza is a corporation organized and existing under the laws of Delaware, with its principal place of business at 8830 Biggs Ford Road in Walkersville, Maryland 21793. Lonza is the exclusive licensee in this field of all of the Asserted Patents. Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotechnology, and cell therapy markets.

10. Upon information and belief, Defendant Miltenyi is a private company located at 1201 Clopper Road, Gaithersburg, Maryland 20878.

JURISDICTION AND VENUE

11. This Court has original and subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. On information and belief, Miltenyi's principal place of business and headquarters are located in Gaithersburg, Maryland. This Court therefore has personal jurisdiction over Miltenyi.

13. On information and belief, Miltenyi resides in, has committed acts of infringement in, and has a regular and established place of business at its headquarters in Gaithersburg, Maryland. Venue is therefore proper in this District under 28 U.S.C. §§ 1400(b) and 1391(c)(2).

ALLEGATIONS OF FACT

I. Plaintiffs' Technology

A. Octane Researches and Patents Automated Cell Therapy Platforms

14. Octane is a medical technology company with several decades of experience in developing innovative technology extending across many areas of biology, engineering, and software. Octane offers advanced bioreactors, manufacturing equipment and components, as well as bioprocess development for the world's most advanced therapeutic solutions, including cell therapies. Octane partners with therapeutic companies and clinical centers across the globe to further pioneer life-saving innovations, earning Octane a reputation for its high-quality services throughout the industry.

15. Because of this expertise, Octane began researching and developing technology surrounding automated cell therapy manufacturing systems, which led Octane to the Asserted Patents and the development of the Cocoon® Platform. The Cocoon® Platform provides end-to-end manufacturing of cell therapies in a fully enclosed manufacturing system with minimal human intervention. It does this by using custom cassettes and custom programming to ensure maximum flexibility, so that the cell therapy can be custom tailored to the clinical needs of the patient. It also uses digital monitoring and control of temperature, gases, pH, and dissolved oxygen ("DO"). Essentially, it is an "all-in-one" manufacturing system that greatly facilitates the use of cell therapy at the point-of-care.

B. Octane Worked with Lonza to Commercialize the Cocoon® Platform

16. Octane sought a collaborator to help commercialize the Cocoon® Platform. Lonza was the logical choice for an automated cell therapy manufacturing collaborator because of Lonza's long history of cell manufacturing. Lonza, along with its affiliates, has devoted decades and countless resources towards researching, developing, and marketing itself as a leading service provider and manufacturer in cell and gene therapies.

17. Beginning in July 2014, Lonza and Octane began collaborative discussions regarding the development and commercialization of the Cocoon® Platform. On August 30, 2016, Lonza and Octane entered into a Collaboration and Commercialization agreement, which granted Lonza an exclusive license to rights in the Asserted Patents in the field of cell therapy (except for osteopathic applications).

18. After working collaboratively for approximately four years, on October 30, 2018, Lonza, through its affiliates, acquired a controlling stake in Octane, "allow[ing] Lonza to further develop the technology to support the growing need for scalable autologous[1] manufacturing," and sending "a clear message to the market that [Lonza is] committed to making commercially viable and scalable personalized therapies a reality." Ex. 6.

19. Together, Lonza and Octane advanced the development of the Cocoon® Platform. Their objective is to help critically ill patients receive cutting edge cell therapies, derived from the patient's own cells, that could save the patients' lives and treat terminal diseases. Most cell therapy patients, such as cancer patients, who receive treatment with a cell therapy, are terminally ill. Therefore, the time it takes to manufacture the cell therapy is often a matter of life and death. Prior to the origination of the Cocoon® Platform, the manufacture of cell therapies typically required

[1] "Autologous" cell therapies are ones that are made from the patient's own cells.

sending a patient's cells long distances after extraction to centralized manufacturing facilities, and being returned weeks later to be administered to the patient. With the Cocoon® Platform, the manufacturing can take place at the point of care in a hospital or other clinical site, thereby significantly reducing the time between extracting cells from the patient and administering potentially lifesaving treatment. As a result of these efforts between Octane and Lonza, including significant work performed within Lonza's facilities in Maryland, the first human patient was treated with a cell therapy made in the Cocoon® Platform. Ex. 7.

C. The Asserted Patents

20. As a result of some of this work and collaboration, Octane has a series of patents and pending patent applications on this automated bioreactor technology. The Asserted Patents in this case are four of the patents on this technology. The Asserted Patents cover a range of automated systems and modules that can be used for the production of cell-based or cell-derived therapies.

21. The '932 Patent, entitled "Automated Tissue Engineering System," was duly issued by the United States Patent and Trademark Office ("USPTO") on July 11, 2017, and remains unexpired. The '932 Patent is a Division of U.S. Application No. 10/510,777, filed September 29, 2005 (issued as U.S. Patent No. 8,492,140), which is a National Stage entry of PCT/CA03/00519, filed April 8, 2003, and which claims priority to U.S. Provisional Application No. 60/370,209, filed April 8, 2002. A true and correct copy of the '932 Patent is attached to this Complaint as **Exhibit 1**.

22. The '932 Patent includes claim 1, which covers:

> 1. A portable tissue and/or cell culture engineering module, the module comprising;
>
> at least one bioreactor, said bioreactor facilitating cell culture and/or tissue engineering functions;

a fluid containment system in fluid communication with said at least one bioreactor;

a heating and/or mixing chamber to heat and/or mix fluids flowing to said at least one bioreactor; and

one or more sensors configured to actively detect environmental conditions and cell metabolic turnover as a function of time with respect to the progression of the cell culture and/or tissue growth in said at least one bioreactor, said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust the changing environmental conditions responsive to requirements of different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth.

23. The '195 Patent, entitled "Automated Tissue Engineering System," was duly issued by the USPTO on January 3, 2017, and remains unexpired. The '195 Patent is a Division of U.S. Application No. 10/510,777, filed September 29, 2005 (issued as U.S. Patent No. 8,492,140), which is a National Stage entry of PCT/CA03/00519, filed April 8, 2003, and which claims priority to U.S. Provisional Application No. 60/370,209, filed April 8, 2002. A true and correct copy of the '195 Patent is attached to this Complaint as **Exhibit 2**.

24. The '195 Patent includes claim 1, which covers:

1. A bioreactor for facilitating and supporting cellular functions and/or the generation of tissue constructs, said bioreactor comprising;

a bioreactor housing;

one or more ports for media flow;

at least one chamber defined within said bioreactor housing for facilitating and supporting cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources; and

one or more sensors for monitoring and automatically adjusting parameters related to said cellular functions and/or generation of tissue constructs within said at least one chamber, the parameter selected from the group consisting of temperature, pH, dissolved gases selected from oxygen and carbon dioxide, metabolic turnover inclusive of lactic acid and glucose consumption, optical density, light scattering, and images of cell/tissue proliferation, wherein:

the bioreactor is adapted to automatically monitor parameters relayed by the one or more sensors such that optimal conditions are maintained in the bioreactor and to automatically re-adjust the parameters in the bioreactor responsive to the status of cell proliferation and/or tissue formation to generate a desired cell population and/or tissue construct in the bioreactor.

25. The ’986 Patent, entitled “Automated Tissue Engineering System,” was duly issued by the USPTO on July 28, 2020, and remains unexpired. The ’986 Patent is a Division of U.S. Application No. 13/906,719, filed May 31, 2013 (issued as U.S. Patent No. 9,534,195), which is a Division of U.S. Application No. 10/510,777, filed September 29, 2005 (issued as U.S. Patent No. 8,492,140), which is a National Stage entry of PCT/CA03/00519, filed April 8, 2003, and which claims priority to U.S. Provisional Application No. 60/370,209, filed April 8, 2002. A true and correct copy of the ’986 Patent is attached to this Complaint as **Exhibit 3**.

26. The ’986 Patent includes claim 1, which covers:

> 1. An automated method for cell culture and/or tissue engineering, including primary or precursor cells, the method comprising:
>
> a. loading primary or precursor cells within a bioreactor in fluid communication with a media reservoir and flow system, said bioreactor having one or more sensors to detect physiological conditions and parameters of the cell culture and/or tissue engineering process within said bioreactor for active monitoring and active adjustment during the cell culture and/or tissue engineering process by a microprocessor;
>
> b. seeding the cells onto a proliferation substrate or scaffold supported within the bioreactor;
>
> c. proliferating and/or differentiating the cells within the bioreactor; and,
>
> d. actively monitoring and automatically adjusting during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue.

27. The ’338 Patent, entitled “Automated Tissue Engineering System,” was duly issued by the USPTO on November 24, 2020, and remains unexpired. The ’338 Patent is a Division of U.S. Application No. 15/395,371, filed December 30, 2016 (issued as U.S. Patent No. 10,723,986), which is a Division of U.S. Application No. 13/906,719, filed May 31, 2013 (issued as U.S. Patent No. 9,534,195), which is a Division of U.S. Application No. 10/510,777, filed September 29, 2005 (issued as U.S. Patent No. 8,492,140), which is a National Stage Entry of PCT/CA03/00519, filed April 8, 2003, and which claims priority to U.S. Provisional Application No. 60/370,209, filed

April 8, 2002. A true and correct copy of the '338 Patent is attached to this Supplemental Complaint as **Exhibit 4**.

28. The '338 Patent includes claim 1, which covers:

> 1. A cell culture engineering module, the module comprising;
> at least one bioreactor;
> a fluid containment system in fluid communication with the at least one bioreactor; and
> one or more sensors configured to detect changing environmental conditions as a function of time with respect to the progression of a cell culture in the at least one bioreactor, the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter the changing environmental conditions responsive to requirements of different stages of the cell culture until completion of the cell culture.

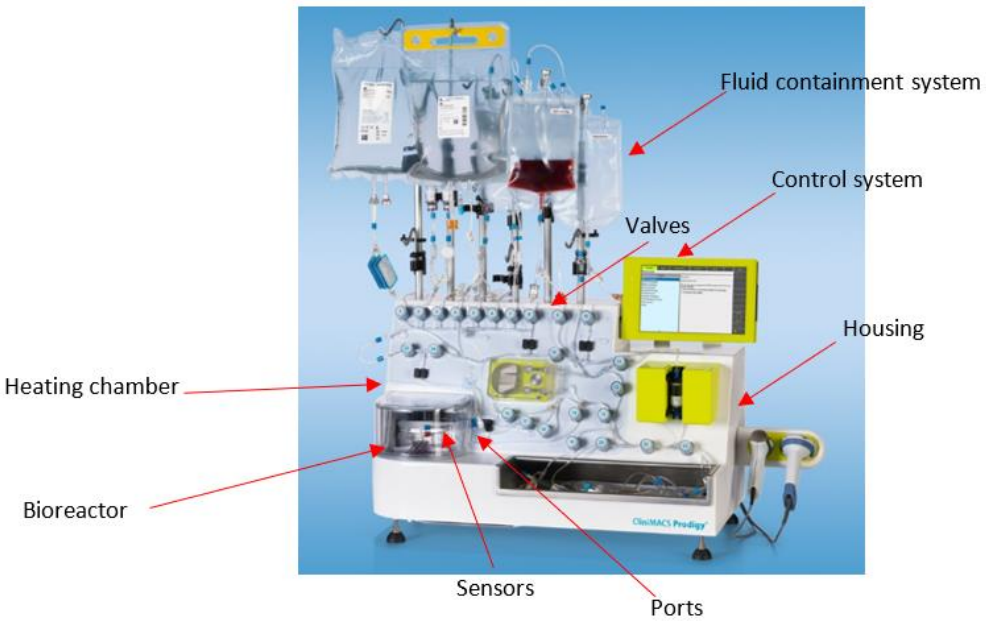
II. Miltenyi's Infringement

29. Defendant and Plaintiffs are direct competitors in the field of automated cell therapy devices and related technologies and services. The Asserted Patents cover a range of automated systems and modules that can be used for the production of cell based or cell-derived therapies. As explained more fully below, the Accused Products meet every limitation of the asserted claims either literally or under the doctrine of equivalents.

A. Miltenyi's Infringing Instrument

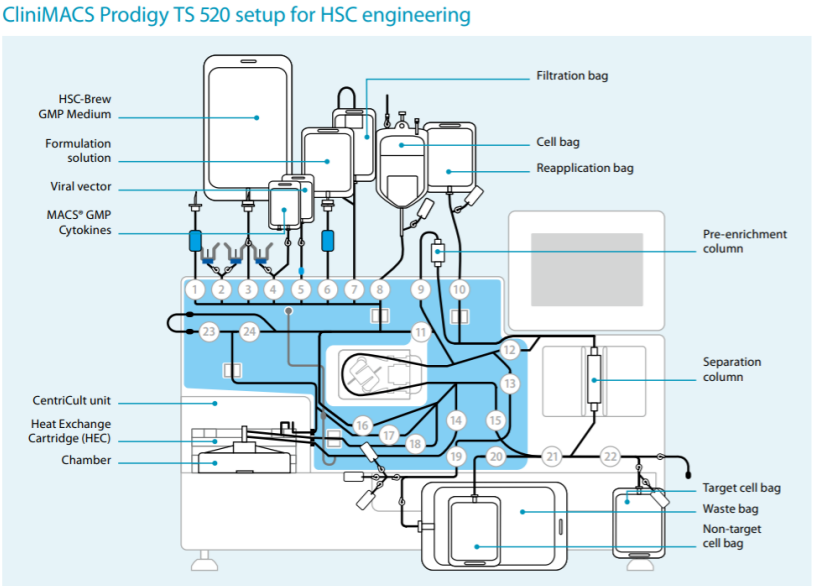
30. Miltenyi's Instrument is a module for cell engineering. As stated on Miltenyi's website: "[t]he CliniMACS Prodigy® is an automated cell processing platform that enables scalable GMP-compliant manufacturing of cell therapy products, on a single device and within a single process setup." Ex. 5, at 2.

31. As shown in the annotated image below, to perform this function, the Instrument has the following features: (a) a bioreactor; (b) a fluid containment system; (c) a heating chamber; and (d) one or more sensors that detect changing environmental conditions as a function of time.



32. As described by Miltenyi in marketing material, the Instrument is designed for "[f]ully-automated, sensor-controlled processes," provides a "high level of automation," and is a "[c]losed system for product and operator safety." Ex. 8, at 7-8. The Instrument uses its sensors to maintain optimal conditions using "sensor-controlled, cell processing capabilities." *Id.* at 6.

33. A schematic showing the Instrument's infringing features is available on Miltenyi's website:



Ex. 9, at 3.

34. The Instrument meets each and every limitation of claims 1-3, 10-11, and 13-22 of the ’932 patent.

35. The Instrument meets each and every limitation of claims 1-2, 7, 9, 13, 18-19, 21, 26, and 28 of the of the ’195 Patent.

36. The Instrument meets each and every limitation of claims 1-5 of the ’986 Patent.

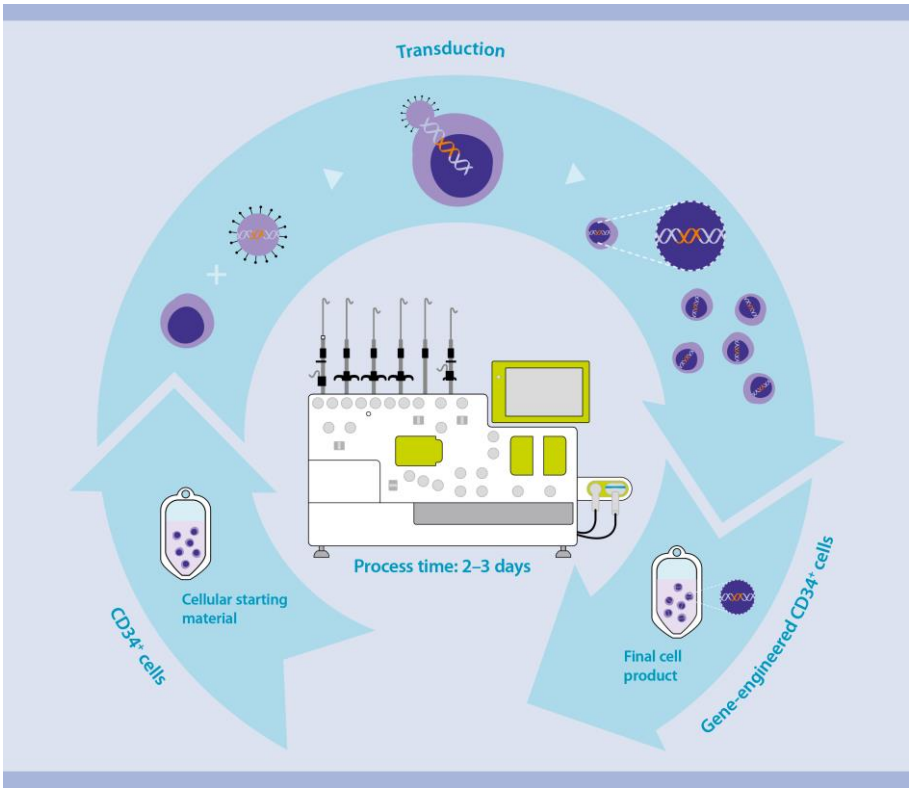
37. The Instrument meets each and every limitation of claims 1-8 and 10-11 of the ’338 Patent.

B. Miltenyi’s Inducement of Infringement

38. Miltenyi has also actively induced its customers to infringe Lonza’s ’986 Patent. As discussed above, this patent is directed to a method for cell culture. Miltenyi publishes numerous brochures detailing how to use its CliniMACS Prodigy® System, including a brochure entitled “Manufacturing of gene-engineered hematopoietic stem cells.” Ex. 10.

39. This brochure, like many other brochures, flyers, trainings, videos, and posters that Miltenyi publishes, describes how to use the Prodigy® System.

40. In the example below, the primary cells are loaded into the bioreactor:

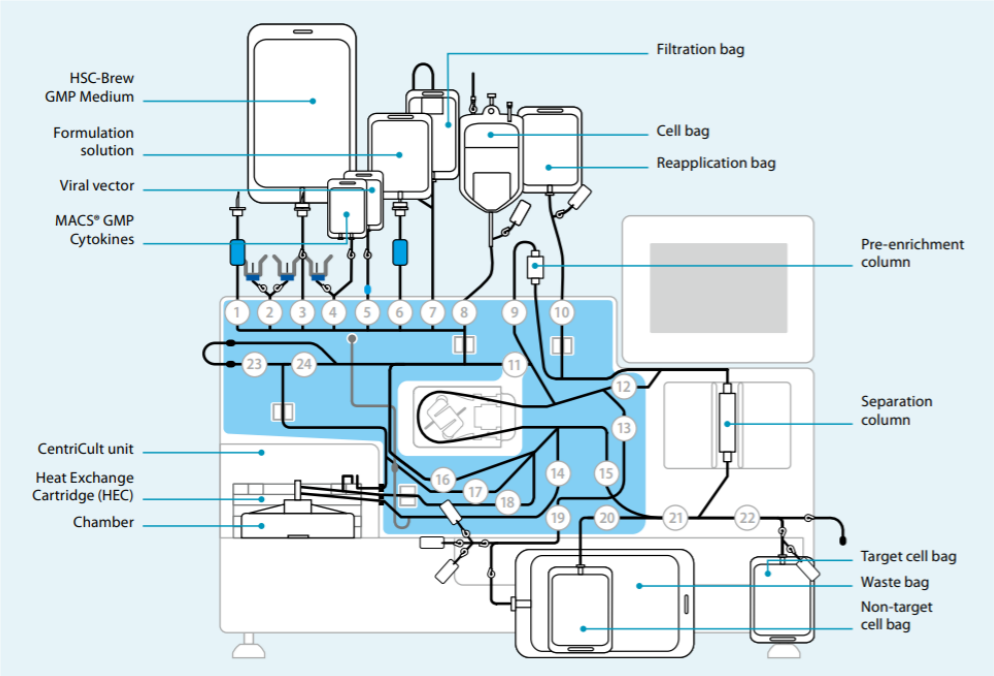


Ex. 10, at 2.

41. This protocol, as well as many others published by Miltenyi, induces customers to infringe claims 1-5 of the ’986 Patent.

42. In another example, a brochure on Miltenyi’s website entitled “Generation of gene-engineered hematopoietic stem cells,” shows a complete CliniMACS Prodigy® System utilizing the CliniMACS Prodigy® Instrument and CliniMACS Prodigy® Tubing Set 520 in a setup configured for hematopoietic stem cell manufacturing, which infringes the Asserted Patents.

CliniMACS Prodigy TS 520 setup for HSC engineering



Ex. 9, at 3.

43. In use, this configuration implements one or more sensors configured to actively detect environmental conditions and cell metabolic turnover as a function of time with respect to the progression of the cell culture and/or tissue growth.

44. This brochure details to customers how to infringe claims 1-5 of the ’986 Patent.

C. Miltenyi’s Infringing Convoyed Products Are Designed Only for Infringing Uses

45. As part of the CliniMACS Prodigy® System, several components are designed for use specifically with the CliniMACS Prodigy® Instrument. These convoyed products are tethered inextricably to the patent infringement activities in which Miltenyi is currently engaged.

46. For example, the Instrument features a housing configured to receive disposable tubing sets, “sterile connections,” a fluid control system that includes a peristaltic pump and controllable valves, and a sensor-based control system that has a “flexible programming suite” to control the instrument and processes. Ex. 8, at 7, 9, 10.

47. The Tubing Sets are specifically designed to work only with the CliniMACS Prodigy® Instrument and are not suitable for any other use. At least seven tubing sets and additional variants thereof are designed, advertised, and sold for use exclusively with the Instrument. Ex. 11, at 1-7. These Tubing Sets and accessories are made, used, sold, and imported by Defendant, including but not limited to the CliniMACS Prodigy® Tubing Sets identified as TS 100, TS 310, TS 500, TS 520, TS 710, TS 720, and TS 730. Sales of these Tubing Sets are exclusively based on the sale and use of the infringing product.

48. Miltenyi also offers "Tube Extensions," which it states are "for the connection of additional containers to a CliniMACS Prodigy® Tubing Set." Ex. 11, at 8.

49. Miltenyi also offers the CliniMACS® Electroporator, which it describes as a "module of the CliniMACS Prodigy® Instrument." *See, e.g.*, Ex. 11, at 11.

50. Miltenyi also offers its "CliniMACS Prodigy® EP-2," which it describes as a "single-use . . . set" that "consists of a sealed pre-assembled tubing pack for cell processing and electroporation." Ex. 11, at 25. Miltenyi states that the CliniMACS Prodigy® EP-2 "has to be used in combination with a CliniMACS Prodigy Tubing Set." *Id.*

51. Miltenyi also offers its "CliniMACS Prodigy® EP-4," which it states consists of a "sealed pre-assembled tubing pack for cell processing and electroporation." Ex. 11, at 27. Miltenyi states that the CliniMACS Prodigy® EP-4 "has to be used in combination with a CliniMACS Prodigy Tubing Set." *Id.*

52. Miltenyi also offers its "CliniMACS® Formulation Set," which it states "consist[s] of [a] sealed pre-assembled tubing pack for cell processing and formulation." Ex. 11, at 29. Miltenyi states that the CliniMACS® Formulation Set "has to be used in combination with a CliniMACS Prodigy Tubing Set." *Id.*

53. Miltenyi also offers its "portfolio of CliniMACS® Reagents" for "clinical-scale cell separation," which Miltenyi markets for use with the CliniMACS Prodigy® Instrument. Ex. 11, at 32. For example, Miltenyi describes its "MACS® GMP T Cell Transact™" reagent as "directly applicable for the use in automated culture systems, such as the CliniMACS Prodigy." *Id.* at 44. Miltenyi further offers "Reagent Bags," which it states are "intended to connect low volume fluids . . . to a CliniMACS Prodigy® Tubing Set." *Id.* at 52.

54. Miltenyi also offers its "CliniMACS® Buffers and Solutions." Miltenyi states that these products are "optimized for use with our automated platforms and care for your cells during every step of cell manufacturing." Ex. 11, at 55. For example, Miltenyi describes its "CliniMACS PBS/EDTA Buffer" as "developed for cell preparation and separation of magnetically labeled cells with the CliniMACS Prodigy Platform and the CliniMACS System." *Id.* In addition, Miltenyi describes its "CliniMACS Electroporation Buffer" as "optimized for the transfection of cells with the CliniMACS Electroporator," which, as stated above, is a module of the CliniMACS Prodigy® Instrument. *Id.*

55. Miltenyi also offers adapters specifically for use with CliniMACS Prodigy® Tubing Sets. For example, Miltenyi offers "Vial Adapters" for "attaching . . . reagent vials to a CliniMACS Prodigy® Tubing Set." Ex. 11, at 57, 60. Miltenyi also offers "Sampling Adapters" for "attachment to a CliniMACS Prodigy® Tubing Set." *Id.* at 63, 66. Further, Miltenyi offers "Sterile Filter Adapters" for "sterile connection of spikeable containers to a CliniMACS Prodigy® Tubing Set." *Id.* at 69. Miltenyi also offers "MPC male Adapters," for "connection of CliniMACS Prodigy® Tubing Set[s] to an external culture vessel." *Id.* at 72.

56. Miltenyi also offers its bags intended for use with the CliniMACS Prodigy® System. For example, Miltenyi offers "Filtration Bags," which it states are "intended to remove

particles and cell aggregates from cell suspensions before being processed within the CliniMACS Prodigy System." Ex. 11, at 75. Miltenyi also offers "Collection Bags," for "collect[ing] fluid and waste during cell processing within the CliniMACS Prodigy System." *Id.* at 77. Miltenyi further offers "CliniMACS Prodigy Supplementary Bags," which it states are "intended to help reduc[e] the user[']s contact to accidentally emitted potentially infectious sample material out of the CliniMACS Prodigy Tubing Set." *Id.* at 79.

57. These convoyed products—including without limitation the Tubing Sets, tube extensions, CliniMACS® Electroporator, CliniMACS Prodigy® EP-2, CliniMACS Prodigy® EP-4, CliniMACS® Formulation Set, CliniMACS® Reagents, CliniMACS® Buffers and Solutions, adapters, and bags—are specifically designed to be used with the infringing CliniMACS Prodigy® System. They are thus inextricably tethered to Miltenyi's ongoing patent infringement activities.

B. Miltenyi's Willfully Infringing Activities

58. The Accused Products meet each and every limitation of the asserted claims of the Asserted Patents either directly or under the doctrine of equivalents.

59. Lonza sent Defendant a letter on May 12, 2021, informing Defendant that the Accused Products were infringing all of the Asserted Patents and several international patents. A true and correct copy of the May 12, 2021 letter is attached to this Complaint as **Exhibit 12**.

60. Despite the fact that Lonza provided actual notice of Defendant's patent infringement, Defendant continues to promote, market, and offer for sale the Accused Products, including by participating in various "conferences and events around the world." Ex. 13, at 1.

61. Defendant has infringed, is infringing, and will continue to infringe (literally and/or under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries, one or more claims of the Asserted Patents through, among other activities, the manufacture, use,

sale, offer for sale, and import in the United States of one or more of the Accused Products, as well as by inducing others to use the Accused Products and perform method claims of the Asserted Patents, in violation of at least 35 U.S.C. §§ 271 (a), (b), (c), and (f).

62. Through sales and marketing activities, including advertising and product labeling, Defendant has and/or will solicit, instruct, encourage, and aid and abet its customers to purchase, use, offer for sale, sell, and import the Accused Products.

63. Defendant has engaged in this conduct willfully, warranting increased damages under 35 U.S.C. § 284. Defendant possessed actual knowledge of all of the Asserted Patents since the dates of their issuance, but in no case later than May 12, 2021. Defendant's conduct is and continues to be willful.

64. Defendant's customers (including distributors and retailers) have infringed, are infringing, and/or will infringe (literally and/or under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries, one or more claims of the Asserted Patents through, among other activities, the use, sale, offer for sale, and/or import in the United States of one or more of the Accused Products.

65. Lonza and Defendant are direct competitors in the market in which the Accused Products are marketed and sold.

66. Defendant's infringement has caused, is causing, and/or will continue to cause Plaintiffs to suffer irreparable injury for which Plaintiffs have no adequate remedy at law, including market price erosion, loss of market share, lost sales, and irreparable harm to their reputation, relationships, and goodwill with their customers, vendors, distributors, industry professionals, and others.

67. Plaintiffs have been and will be damaged by Defendant's infringement, at least in the form of lost customers, reputational damages, and lost profits.

COUNT I
PATENT INFRINGEMENT
('932 Patent)

68. Plaintiffs incorporate by reference the foregoing allegations as if stated fully herein.

69. Defendant has directly infringed, and continues to directly infringe, at least claims 1-3, 10-11, and 13-22 of the '932 Patent by making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

70. The Accused Products meet all limitations of the asserted claims of the '932 Patent.

71. Defendant has also indirectly infringed, and continues to indirectly infringe, one or more claims of the '932 Patent, by contributing to the infringement of others through the making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

72. Defendant has no right or license to sell any product that infringes the '932 Patent, and Plaintiffs have not consented to Defendant's manufacture, use, offer to sell, sale, or import of the Accused Products.

73. Lonza and Defendant are direct competitors in the marketplace.

74. Defendant received actual notice of the '932 Patent prior to the initiation of the present lawsuit and no later than May 12, 2021, but nevertheless willfully continues to make, use, offer to sell, sell, and import in the United States the Accused Products.

75. Plaintiffs are and have been irreparably damaged by Defendant's infringement, and unless Defendant's infringing activities are enjoined by this Court, Plaintiffs will continue to suffer monetary damage, market price erosion, loss of market share, lost sales, and irreparable harm to

their reputation, relationships, and goodwill with their customers, vendors, distributors, industry professionals, and others.

COUNT II
PATENT INFRINGEMENT
(’195 Patent)

76. Plaintiffs incorporate by reference the foregoing allegations as if stated fully herein.

77. Defendant has directly infringed, and continues to directly infringe, at least claims 1-2, 7, 9, 13, 18-19, 21, 26, and 28 of the ’195 Patent by making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

78. The Accused Products meet all limitations of the asserted claims of the ’195 Patent.

79. Defendant has also indirectly infringed, and continues to indirectly infringe, one or more claims of the ’195 Patent, by contributing to the infringement of others through the making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

80. Defendant has no right or license to sell any product that infringes the ’195 Patent, and Plaintiffs have not consented to Defendant’s manufacture, use, offer to sell, sale, or import of the Accused Products.

81. Lonza and Defendant are direct competitors in the marketplace.

82. Defendant received actual notice of the ’195 Patent prior to the initiation of the present lawsuit and no later than May 12, 2021, but nevertheless willfully continues to make, use, offer to sell, sell, and import in the United States the Accused Products.

83. Plaintiffs are and have been irreparably damaged by Defendant’s infringement, and unless Defendant’s infringing activities are enjoined by this Court, Plaintiffs will continue to suffer monetary damage, market price erosion, loss of market share, lost sales, and irreparable harm to

their reputation, relationships, and goodwill with their customers, vendors, distributors, industry professionals, and others.

COUNT III
PATENT INFRINGEMENT
(’986 Patent)

84. Plaintiffs incorporate by reference the foregoing allegations as if stated fully herein.

85. Defendant has directly infringed, and continues to directly infringe, at least claims 1-5 of the ’986 Patent by making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

86. The Accused Products meet all limitations of the asserted claims of the ’986 Patent.

87. Defendant has also indirectly infringed, and continues to indirectly infringe, one or more claims of the ’986 Patent, by contributing to the infringement of others through the making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products, and by inducing end users of the Accused Products to practice infringing methods.

88. Defendant has no right or license to sell any product that infringes the ’986 Patent or practice any method that infringes the ’986 Patent, and Plaintiffs have not consented to Defendant’s manufacture, use, offer to sell, or sale of the Accused Products.

89. Lonza and Defendant are direct competitors in the marketplace.

90. Defendant received actual notice of the ’986 Patent prior to the initiation of the present lawsuit and no later than May 12, 2021, but nevertheless willfully continues to make, use, offer to sell, sell, and import in the United States the Accused Products.

91. Plaintiffs are and have been irreparably damaged by Defendant’s infringement, and unless Defendant’s infringing activities are enjoined by this Court, Plaintiffs will continue to suffer

monetary damage, market price erosion, loss of market share, lost sales, and irreparable harm to their reputation, relationships, and goodwill with their customers, vendors, distributors, industry professionals, and others.

COUNT IV
PATENT INFRINGEMENT
(’338 Patent)

92. Plaintiffs incorporate by reference the foregoing allegations as if stated fully herein.

93. Defendant has directly infringed, and continues to directly infringe, at least claims 1-8 and 10-11 of the ’338 Patent by making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

94. The Accused Products meet all limitations of the asserted claims of the ’338 Patent.

95. Defendant has also indirectly infringed, and continues to indirectly infringe, one or more claims of the ’338 Patent, by contributing to the infringement of others through the making, using, selling, and/or offering to sell within the United States, and/or importing into the United States, the Accused Products.

96. Defendant has no right or license to sell any product that infringes the ’338 Patent, and Plaintiffs have not consented to Defendant’s manufacture, use, offer to sell, sale, or import of the Accused Products.

97. Lonza and Defendant are direct competitors in the marketplace.

98. Defendant received actual notice of the ’338 Patent prior to the initiation of the present lawsuit and no later than May 12, 2021, but nevertheless willfully continues to make, use, offer to sell, sell, and import in the United States the Accused Products.

99. Plaintiffs are and have been irreparably damaged by Defendant’s infringement, and unless Defendant’s infringing activities are enjoined by this Court, Plaintiffs will continue to suffer

monetary damage, market price erosion, loss of market share, lost sales, and irreparable harm to their reputation, relationships, and goodwill with their customers, vendors, distributors, industry professionals, and others.

WHEREFORE, Plaintiffs respectfully seek judgment in their favor on all counts of this Complaint and the following relief:

A. A judgment that Defendant has directly and indirectly infringed one or more claims of each of the Asserted Patents;

B. A judgment that Defendant's infringement has been willful;

C. A judgment permanently enjoining Defendant, its officers, directors, agents, servants, and employees, affiliates, subsidiaries, or others controlled by Defendant, and all persons in active concert or participation with Defendant, from infringing the Asserted Patents—including direct infringement or indirect infringement by inducement and/or contributory infringement of the Asserted Patents—except in connection with any contracts and services in force at the time of this injunction;

D. An award of damages adequate to compensate Plaintiffs for the infringement that has occurred, together with prejudgment interest from the date the infringement began, but in no event less than a reasonable royalty as permitted by 35 U.S.C. § 284;

E. An award of increased damages under 35 U.S.C. § 284 of up to three times the amount of damages assessed;

F. A finding in favor of Plaintiffs that this is an exceptional case under 35 U.S.C. § 285, and an award to Plaintiffs of their costs, including their reasonable attorneys' fees and other expenses incurred in connection with this action; and

G. Any and all such other and further relief as this Court may deem appropriate.

DEMAND FOR JURY TRIAL

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

Dated: January 28, 2022

By: /s/ Shannon Lentz
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