

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CYTONOME/ST, LLC,	)	CASE NO.: 1:19-cv-00301-RGA
	)	
Plaintiff,	)	
	)	
v.	)	
	)	DEMAND FOR JURY TRIAL
NANOCELLECT BIOMEDICAL, INC.,	)	
	)	
Defendant.	)	
	)	
	)	
	)	
	)	

**DEFENDANT NANOCELLECT BIOMEDICAL, INC.'S
ANSWER AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**

Defendant NanoCollect Biomedical, Inc. ("NanoCollect" or "Defendant") hereby answers and responds to each of the allegations in the Complaint of Plaintiff Cytonome/ST, LLC ("Cytonome" or "Plaintiff") as follows. NanoCollect denies all allegations in Plaintiff's Complaint except those admitted specifically below.

NATURE OF THE ACTION

1. This is a civil action arising under the laws of the United States, 35 U.S.C. § 1, *et seq.*, for patent infringement. Cytonome seeks enhanced damages, prejudgment interest, attorneys' fees, exemplary damages, and any other relief that is available and warranted under applicable laws from NanoCollect. In addition, Cytonome is seeking a permanent injunction against NanoCollect's use of Cytonome's patents.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, NanoCollect admits that Plaintiff purports to bring a civil action for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* NanoCollect denies that it has committed any acts of patent infringement and

denies that Plaintiff is entitled to any relief in this action. NanoCollect denies all remaining allegations contained in paragraph 1 of the Complaint not expressly admitted.

THE PARTIES

2. Cytonome is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 9 Oak Park Drive, Bedford, MA 01730.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, on that basis, denies them.

3. On information and belief, NanoCollect is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6865 Flanders Dr., Suite A, San Diego, CA 92121.

ANSWER: Admit.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction at least under 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect admits that Plaintiff purports to bring an action for alleged patent infringement under the patent laws of the United States, Title 35, United States Code. NanoCollect does not contest that this Court has subject matter jurisdiction over Plaintiff's current claims. NanoCollect denies the remaining allegations contained in paragraph 4 of the Complaint not expressly admitted.

5. On information and belief, NanoCollect has purposefully availed itself of the benefits and protections of the laws of the State of Delaware, and the exercise of jurisdiction by this Court is proper.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect admits that it is a corporation organized and existing under the laws of the State of Delaware. NanoCollect does not contest personal

jurisdiction for the limited purposes of this action only. NanoCollect denies the remaining allegations contained in paragraph 5 of the Complaint not expressly admitted.

6. This Court has personal jurisdiction over NanoCollect because NanoCollect is incorporated under the laws of the State of Delaware.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect admits that it is a corporation organized and existing under the laws of the State of Delaware. NanoCollect does not contest personal jurisdiction for the limited purposes of this action only. NanoCollect denies the remaining allegations contained in paragraph 6 of the Complaint not expressly admitted.

7. This Court also has personal jurisdiction over NanoCollect because NanoCollect has committed acts of patent infringement in this judicial district, has systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district. In particular, on information and belief: (a) NanoCollect owns and/or operates an interactive Internet website, www.nanocollect.com, that is accessible to the residents of Delaware, through which goods, including NanoCollect's "WOLF Cell Sorter" (accused of infringement herein), are advertised and sold; and (b) NanoCollect offers for sale and sells its goods, including its WOLF Cell Sorter, to residents of Delaware through online retailers such as www.biocompare.com.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect denies that it has committed acts of patent infringement. NanoCollect admits that it is a corporation organized and existing under the laws of the State of Delaware. NanoCollect does not contest personal jurisdiction for the limited purposes of this action only. NanoCollect denies the remaining allegations contained in paragraph 7 of the Complaint not expressly admitted.

8. Venue is proper in this federal judicial district pursuant to 28 U.S.C. § 1391(b)(1) and 28 U.S.C. § 1400(b) because NanoCollect is incorporated in the State of Delaware and therefore "resides" in this judicial district.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect admits that Plaintiff purports to base venue on

28 U.S.C. § 1391(b)(1) and 28 U.S.C. § 1400(b). NanoCollect admits that it is a corporation organized and existing under the laws of the State of Delaware. NanoCollect does not dispute that venue is proper in this Court for the limited purposes of this action only. NanoCollect denies the remaining allegations contained in paragraph 8 of the Complaint not expressly admitted.

CYTONOME'S PATENTED TECHNOLOGY

9. A company named "Coventor" was founded in 1996 and originally developed software for designing microelectromechanical systems ("MEMS"). Sometime between 1997 and 1999, Coventor's founder and then-CTO, John Gilbert, built a "microfluidics" group at Coventor that developed software for designing microscale channel systems that handle, process, and analyze particle samples. In 2002, this microfluidics group, including John Gilbert, left Coventor to form "Teragenics," which changed its name to "Cytonome, Inc." within a year. Cytonome, Inc. began developing ultrahigh-throughput microfluidic devices for clinical applications—such as separating desirable cells in a bone marrow sample from undesirable cells and particles in the sample—that could accurately sort particles at a significantly higher rate than conventional machines.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint and, on that basis, denies them.

10. Around 2008, a company known as "STGenetics" ("ST") became aware of Cytonome, Inc.'s technology when looking for ways to improve its own cell sorting technology. One aspect of ST's business is providing semen sorted by sex to "bull studs," who in turn sell the sexed semen to dairy and beef farmers for use in artificial insemination. ST determined that Cytonome, Inc. and its technology could improve ST's existing sorting services. Accordingly, ST joined with Cytonome, Inc. to form Cytonome/ST, LLC ("Cytonome") in 2009.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and, on that basis, denies them.

11. Cytonome has continued to do extensive research, development, testing, and manufacturing of microfluidic devices. Cytonome has created cutting edge microfluidic systems for aligning, analyzing, purifying, and sorting particles using novel, highly-parallelizable "microfluidic chip" designs coupled with advanced optical, electronic, and fluidic control systems. See, e.g., <https://www.cytonome.com/products/gigasort>. Cytonome's efforts have benefited the life sciences, industrial cell processing, cell bioprocessing, and flow cytometry fields by improving the efficiency of processing cells and other particles. See <https://www.cytonome.com/applications/>. Cytonome has recently partnered with leaders in the

biotechnology and pharmaceutical industries, and regularly participates in biotechnology conferences. See <https://www.cytonome.com/news/>.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint and, on that basis, denies them.

12. Cytonome has applied for and obtained dozens of patents to protect its intellectual property in its microfluidic chip and particle-processing technologies.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint and, on that basis, denies them.

CYTONOME’S U.S. PATENT NO. 6,877,528

13. On April 12, 2005, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 6,877,528 (the “’528 Patent”), titled “MICROFLUIDIC SYSTEM INCLUDING A BUBBLE VALVE FOR REGULATING FLUID FLOW THROUGH A MICROCHANNEL.” A true and correct copy of the ’528 Patent is attached to this Complaint as Exhibit 1.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the ’528 Patent to the Complaint as Exhibit 1. NanoCollect further admits that on its face, the ’528 Patent is titled, “Microfluidic System Including a Bubble Valve for Regulating Fluid Flow Through a Microchannel” and indicates that it issued on April 12, 2005. NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 13 of the Complaint, and on that basis, denies them.

14. At all times since the issuance of the ’528 Patent, all rights, title, and interest in and to the ’528 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the ’528 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint, and on that basis, denies them.

15. The '528 Patent relates to a microfluidic device that uses an actuator and buffer to accurately sort particles based on a selected characteristic (e.g., fluorescence). In an exemplary embodiment, the patent discloses a device with microchannels formed in a substrate. These microchannels are capable of flowing a stream of particles, some having the selected characteristic. The device further includes a detector capable of sensing the characteristic and sending a signal to an actuator, informing the actuator that an upcoming particle has the desired characteristic. Based on this signal, the actuator sends a "pressure pulse" into the channel that causes the selected particle to be deflected out of the particle stream and, for example, into a separate subchannel from the non-selected particles. Facilitating this sorting process is a "buffer" positioned on the opposite side of the channel from the actuator. The buffer absorbs the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not reverberate through the channel and impact other particles in the sample. The other particles can therefore be processed and flow into the appropriate subchannel. The disclosed devices can greatly improve sorting efficiency and reduce shear stresses that can damage cells during the sorting process in conventional devices.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '528 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 15 of the Complaint.

16. The claims of the '528 Patent are generally directed to the above-described microfluidic devices and recite, for example, microchannels, actuators, and buffers.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '528 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 16 of the Complaint.

CYTONOME'S U.S. PATENT NO. 8,623,295

17. On January 7, 2014, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,623,295 (the "'295 Patent"), titled "MICROFLUIDIC SYSTEM INCLUDING A BUBBLE VALVE FOR REGULATING FLUID FLOW THROUGH A MICROCHANNEL." A true and correct copy of the '295 Patent is attached to this Complaint as Exhibit 2.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the '295 Patent to the Complaint as Exhibit 2. NanoCollect further admits that on its face, the '295 Patent is titled, "Microfluidic System Including a Bubble Valve for Regulating Fluid Flow Through a Microchannel" and indicates that it issued on January 7, 2014. NanoCollect lacks sufficient

knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 17 of the Complaint, and on that basis, denies them.

18. At all times since the issuance of the '295 Patent, all rights, title, and interest in and to the '295 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the '295 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint, and on that basis, denies them.

19. The '295 Patent relates to a microfluidic system that uses two opposing reservoirs adapted to generate and absorb a pressure pulse that may be used for accurately sorting particles based on a selected characteristic (e.g., fluorescence). In an exemplary embodiment, the patent discloses a system with microchannels formed in a substrate. These microchannels are capable of flowing a stream of particles, some having the selected characteristic. The system further includes a detector capable of sensing the characteristic and sending a signal to an actuator, informing the actuator that an upcoming particle has the desired characteristic. Based on this signal, the actuator sends a "pressure pulse" into the channel that causes the selected particle to be deflected out of the particle stream and, for example, into a separate subchannel from the non-selected particles. Facilitating this sorting process is a "buffer" reservoir positioned on the opposite side of the channel from the actuator connected to another reservoir. Each of these reservoirs are connected to the channel via an aperture. The buffer reservoir absorbs or dampens the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not reverberate through the channel and impact other particles in the sample. The other particles can therefore also be processed to flow into the appropriate subchannel. The disclosed systems can greatly improve sorting efficiency and reduce shear stresses that can damage cells during the sorting process in conventional systems.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '295 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 19 of the Complaint.

20. The claims of the '295 Patent are generally directed to the above-described microfluidic systems and recite, for example, microfluidic flow channels, reservoirs, and apertures for connecting the reservoirs to the flow channels.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '295 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 20 of the Complaint.

CYTONOME'S U.S. PATENT NO. 9,011,797

21. On April 21, 2015, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,011,797 (the “’797 Patent”), titled “MICROFLUIDIC SYSTEM INCLUDING A BUBBLE VALVE FOR REGULATING FLUID FLOW THROUGH A MICROCHANNEL.” A true and correct copy of the ’797 Patent is attached to this Complaint as Exhibit 3.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the ’797 Patent to the Complaint as Exhibit 3. NanoCollect further admits that on its face, the ’797 Patent is titled, “Microfluidic System Including a Bubble Valve for Regulating Fluid Flow Through a Microchannel” and indicates that it issued April 21, 2015. NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 21 of the Complaint, and on that basis, denies them.

22. At all times since the issuance of the ’797 Patent, all rights, title, and interest in and to the ’797 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the ’797 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint, and on that basis, denies them.

23. The ’797 Patent relates to a microfluidic device capable of sorting particles using a pressure pulse and a reservoir that absorbs the pressure pulse. In an exemplary embodiment, the patent discloses a device with microchannels formed in a substrate. These microchannels are capable of flowing a stream of particles, some having a selected characteristic. The device further includes a detector capable of sensing the characteristic and sending a signal to an actuator attached to a sealed reservoir, informing the actuator that an upcoming particle has the desired characteristic. Based on this signal, the actuator sends a “pressure pulse” into the channel that causes the selected particle to be deflected out of the particle stream and, for example, into a separate subchannel from the non-selected particles. Facilitating this sorting process is a second reservoir (e.g., a “buffer” reservoir) positioned on the opposite side of the channel from the actuator. The second reservoir absorbs or dampens the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not reverberate through the channel and impact other particles in the sample. The other particles can therefore also be processed to flow into the appropriate subchannel. The disclosed devices can greatly improve sorting efficiency and reduce shear stresses that can damage cells during the sorting process in conventional devices.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '797 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 23 of the Complaint.

24. The claims of the '797 Patent are generally directed to the above-described microfluidic devices and recite, for example, a reservoir connected to a microfluidic flow channel that absorbs or dampens a pressure pulse propagated across the flow channel.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '797 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 24 of the Complaint.

CYTONOME'S U.S. PATENT NO. 9,339,850

25. On May 17, 2016, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,339,850 (the "'850 Patent"), titled "METHOD AND APPARATUS FOR SORTING PARTICLES." A true and correct copy of the '850 Patent is attached to this Complaint as Exhibit 4.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the '850 Patent to the Complaint as Exhibit 4. NanoCollect further admits that on its face, the '850 Patent is titled, "Method and Apparatus for Sorting Particles" and indicates that it issued May 17, 2016. NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 25 of the Complaint, and on that basis, denies them.

26. At all times since the issuance of the '850 Patent, all rights, title, and interest in and to the '850 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the '850 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint, and on that basis, denies them.

27. The '850 Patent relates to a microfluidic device capable of sorting particles using an actuator for selectively applying a pressure pulse to the particles and a buffer for absorbing or

dampening the pressure pulse. In an exemplary embodiment, the patent discloses a device with microfluidic ducts formed in a substrate. These ducts are capable of flowing a stream of particles, some having a selected characteristic. The device further includes a detector capable of sensing the characteristic and sending a signal to an actuator, informing the actuator that an upcoming particle has the desired characteristic. Based on this signal, the actuator sends a “pressure pulse” into the duct that causes the selected particle to be deflected out of the particle stream and, for example, into a separate subchannel from the non-selected particles. Facilitating this sorting process is a “buffer” reservoir positioned on the opposite side of the channel from the actuator connected to another reservoir. The buffer reservoir absorbs or dampens the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not reverberate through the channel and impact other particles in the sample. The other particles can therefore also be processed to flow into the appropriate subchannel. The disclosed devices can greatly improve sorting efficiency and reduce shear stresses that can damage cells during the sorting process in conventional devices.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the ’850 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 27 of the Complaint.

28. The claims of the ’850 Patent are generally directed to the above-described microfluidic devices and recite, for example, a duct for conveying a stream of particles, an actuator for selectively applying a pressure pulse to the particles, and a buffer configured to fluidically co-operate with the actuator for absorbing or dampening the pressure pulse.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the ’850 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 28 of the Complaint.

CYTONOME’S U.S. PATENT NO. 10,029,263

29. On July 24, 2018, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 10,029,263 (the “’263 Patent”), titled “METHOD AND APPARATUS FOR SORTING PARTICLES.” A true and correct copy of the ’263 Patent is attached to this Complaint as Exhibit 5.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the ’263 Patent to the Complaint as Exhibit 5. NanoCollect further admits that on its face, the ’263 Patent is titled, “Method and Apparatus for Sorting Particles” and indicates that it issued July 24, 2018.

NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the

remaining allegations contained in paragraph 29 of the Complaint, and on that basis, denies them.

30. At all times since the issuance of the '263 Patent, all rights, title, and interest in and to the '263 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the '263 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 30 of the Complaint, and on that basis, denies them.

31. The '263 Patent relates to a microfluidic system that uses a switching device and reservoir to accurately sort particles based on a selected characteristic (e.g., large size). In an exemplary embodiment, the patent discloses a system with microfluidic flow channels formed in a substrate. These channels are capable of flowing a stream of particles, some having the selected characteristic. The system further includes a detector capable of sensing the characteristic and sending a signal to a switching device, informing the switching device that an upcoming particle has the desired characteristic. Based on this signal, the switching device sends a "pressure pulse" into the channel that causes the selected particle to be deflected out of the particle stream and, for example, into a separate subchannel from the non-selected particles. Facilitating this sorting process is a "buffer" reservoir positioned on the opposite side of the channel from the actuator connected to another reservoir. The buffer reservoir absorbs or dampens the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not block or partially block flow of the other particles in the fluidic stream. The other particles can therefore also be processed to flow into the appropriate subchannel. The disclosed systems can greatly improve sorting efficiency and reduce shear stresses that can damage cells during the sorting process in conventional systems.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '263 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 31 of the Complaint.

32. The claims of the '263 Patent are generally directed to the above-described microfluidic systems and recite, for example, a microfluidic flow channel, a detection region, a switching device that delivers a transient pressure pulse to sort particles into at least two separate outlets, and a reservoir adapted for dampening or absorbing the transient pressure pulses.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '263 Patent speaks for itself. On these bases, NanoCollect denies the allegations contained in paragraph 32 of the Complaint.

CYTONOME'S U.S. PATENT NO. 10,029,283

33. On July 24, 2018, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 10,029,283 (the "'283 Patent"), titled "METHOD AND APPARATUS FOR SORTING PARTICLES." A true and correct copy of the '283 Patent is attached to this Complaint as Exhibit 6.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the '283 Patent to the Complaint as Exhibit 6. NanoCollect further admits that on its face, the '283 Patent is titled, "Method and Apparatus for Sorting Particles" and indicates that it issued July 24, 2018.

NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 33 of the Complaint, and on that basis, denies them.

34. At all times since the issuance of the '283 Patent, all rights, title, and interest in and to the '283 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the '283 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 34 of the Complaint, and on that basis, denies them.

35. The '283 Patent relates to a particle sorting chip that uses an actuator provided on a sealed chamber formed in a substrate that is configured to sort particles into outlets based on a selected characteristic (e.g., large size). In an exemplary embodiment, the patent discloses a particle sorting chip with a microfluidic duct formed in a substrate. This duct is capable of flowing a stream of particles, some having the selected characteristic. The chip further includes a detector capable of sensing the characteristic and sending a signal to an actuator, informing the actuator that an upcoming particle has the desired characteristic. Based on this signal, the actuator increases pressure in a chamber below the actuator, which in turn discharges fluid from the chamber into the duct. The discharged fluid causes the selected particle to be deflected out of the particle stream and, for example, into a separate outlet from the non-selected particles. In addition, the chip may include a second chamber positioned on the opposite side of the channel from the actuator. The second chamber can absorb or dampen the pressure pulse, which decreases stress on the selected particles, enables high speed operation, and ensures that the pressure pulse does not block or partially block flow of the other particles in the fluidic stream. The other particles can therefore also be processed to flow into the appropriate outlet. The disclosed chips can greatly improve sorting efficiency and reduce shear stresses that can damage cells during switching operations in conventional particle sorting chips.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '283 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 35 of the Complaint.

36. The claims of the '263 Patent are generally directed to the above-described particle sorting chip and recite, for example, a duct formed in a substrate, a chamber formed in a substrate, and an actuator formed in the substrate configured to increase pressure in the first chamber and to discharge an amount of liquid from the first side opening into the duct during a switching operation.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '263 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 36 of the Complaint.

CYTONOME'S U.S. PATENT NO. 10,065,188

37. On September 4, 2018, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 10,065,188 (the "'188 Patent"), titled "ACTUATION OF PARALLEL MICROFLUIDIC ARRAYS." A true and correct copy of the '188 Patent is attached to this Complaint as Exhibit 7.

ANSWER: NanoCollect admits that Plaintiff purports to attach a copy of the '188 Patent to the Complaint as Exhibit 7. NanoCollect further admits that on its face, the '188 Patent is titled, "Actuation of Parallel Microfluidic Arrays" and indicates that it issued September 4, 2018. NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 37 of the Complaint, and on that basis, denies them.

38. At all times since the issuance of the '188 Patent, all rights, title, and interest in and to the '188 Patent have been assigned to Cytonome, and Cytonome is and has been the sole owner of the '188 Patent.

ANSWER: NanoCollect lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 38 of the Complaint, and on that basis, denies them.

39. The '188 Patent relates to a particle processing assembly for sorting individual particles on a particle-by-particle basis based on a selected characteristic (e.g., large size). In an exemplary embodiment, the patent discloses a particle processing assembly with a microfluidic channel formed in a microfluidic chip. This channel is capable of flowing a stream of particles, some having the selected characteristic. The assembly further includes a detector capable of sensing the characteristic and sending a signal to an actuator, informing the actuator that an upcoming particle has the desired characteristic. Based on the received signal, the actuator directs a pressure pulse into the channel, which causes the selected particle to be deflected out of the particle stream and, for example, into a separate outlet from the non-selected particles. The disclosed particle processing assemblies can greatly improve sorting efficiency and reduce shear stresses that can damage cells during switching operations in conventional assemblies.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '188 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 39 of the Complaint.

40. The claims of the '188 Patent are generally directed to the above-described particle processing assemblies and recite, for example, a microfluidic chip with a switching region interfaced with an actuator external to the chip that directs a pressure pulse for deflecting particles into an appropriate output.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is deemed required, NanoCollect states that the '188 Patent speaks for itself.

On these bases, NanoCollect denies the allegations contained in paragraph 40 of the Complaint.

NANOCOLLECT'S "WOLF CELL SORTER" PRODUCT

41. On information and belief, NanoCollect is in the business of designing, researching, developing, and selling microfluidic devices, systems, and methods used for cell analysis and sorting. On information and belief, NanoCollect announced the launch of its WOLF Cell Sorter product in the United States on June 15, 2016. On information and belief, NanoCollect makes, uses, imports, sells, and/or offers to sell—and continues to make, use, import, sell and/or offer to sell—the WOLF Cell Sorter in the United States. NanoCollect's website, for example, offers to "DEMO OR QUOTE" the WOLF Cell Sorter. <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that it is in the business of designing, researching, developing, and selling microfluidic devices, systems, and methods used for cell analysis and sorting. NanoCollect states that on July 12, 2016 it announced the private launch of the WOLF Cell Sorter at CYTO 2016. NanoCollect further admits that it makes, uses, sells, and/or offers to

sell the WOLF Cell Sorter in the United States. NanoCollect denies the remaining allegations contained in paragraph 41 of the Complaint not expressly admitted.

42. On its website, NanoCollect states that the WOLF Cell Sorter “uses an on-chip piezoacoustic actuator that gently directs cells into collection channels.” *Id.* Moreover, according to the website, the WOLF Cell Sorter “system allows cell analysis and sorting to take place within a disposable chip.” *Id.*

ANSWER: Admit.

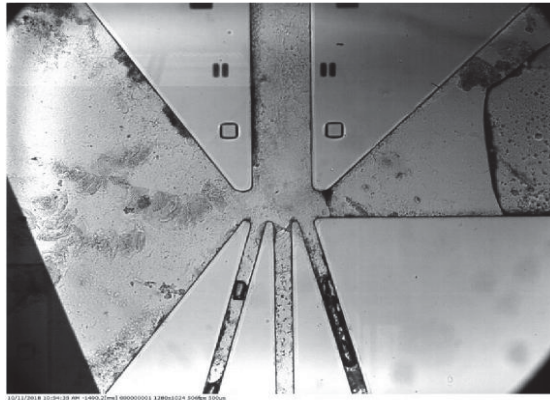
43. NanoCollect’s website also demonstrates the operation of its WOLF Cell Sorter using an animation. *See id.* Screenshots from this animation show that the WOLF Cell Sorter includes microchannels with an actuator and buffer used to sort individual cells based on a predetermined, detectable characteristic:



ANSWER: NanoCollect admits that its website presents a simplified portrayal of its WOLF Cell Sorter using an animation. However, NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and

channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 43 of the Complaint.

44. Inspection of a WOLF Cell Sorter product further shows that the WOLF Cell Sorter includes actuator and “buffer” reservoirs to generate and absorb pressure pulses for sorting particles, as shown in the photograph below. A flexible membrane covers at least a portion of the chip, including above the buffer reservoir. This flexible membrane absorbs the pressure pulse generated by the actuator.



ANSWER: Denied.

45. The screenshot below taken from a video publication for the WOLF Cell Sorter also shows the WOLF microfluidic chip comprising a flexible membrane extending at least over the buffer reservoir. The flexible membrane deforms when the actuator applies a pressure pulse across the channel, which facilitates absorption of the pressure pulse.



See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocollect WOLF Cell Sorter Intro”).

ANSWER: Denied.

46. The cell processing system of the WOLF Cell Sorter, however, was previously invented, patented, and developed by Cytonome.

ANSWER: Denied.

COUNT I — INFRINGEMENT OF THE '528 PATENT

47. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-46.

48. NanoCollect directly infringes, and/or induces the infringement of, at least claim 18 of the '528 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

49. The WOLF Cell Sorter includes every element of at least claim 18 of the '528 Patent, literally or equivalently, which recites:

A microfluidic device, comprising:

a channel for conveying a stream of particles in a carrier fluid;
an actuator for selectively applying a pressure pulse to the stream
to deflect a particle in the stream of particles from the stream of
particles; and
a buffer for absorbing the pressure pulse.

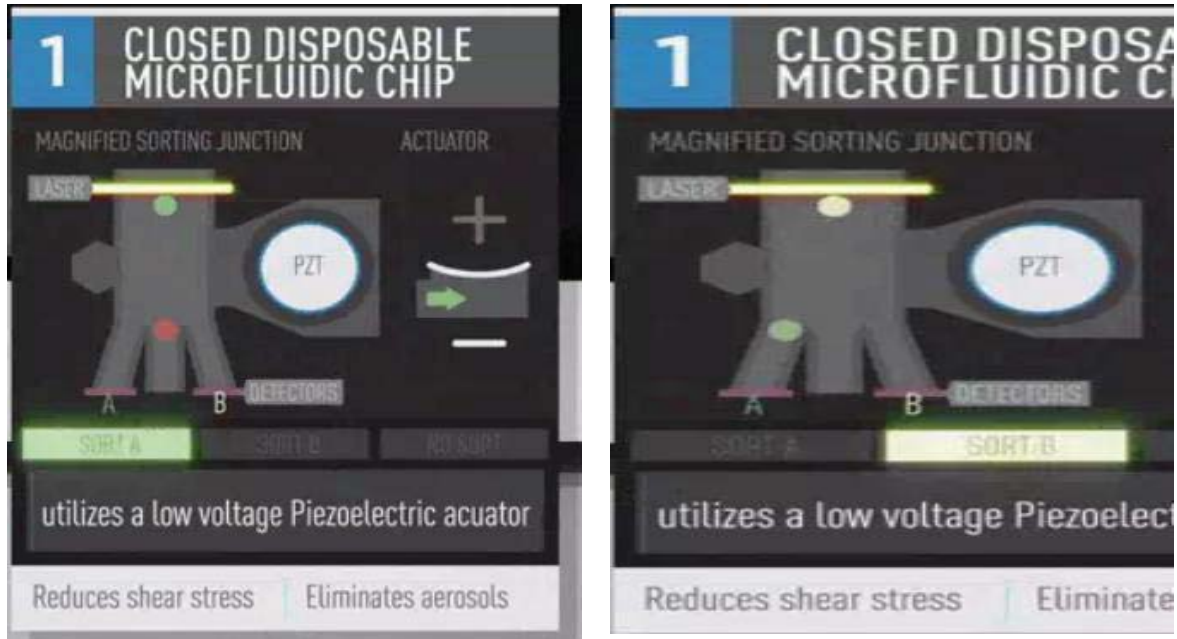
ANSWER: Denied.

50. The WOLF Cell Sorter is a microfluidic device. For instance, the NanoCollect website states that the WOLF Cell Sorter is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 50 of the Complaint not expressly admitted.

51. Furthermore, the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows that particles, such as cells, flow downstream in a channel

through a detector (i.e., a laser). See <https://www.nanocollect.com/wolf-cell-sorter>. NanoCollect's website further explains that the particles are flowed in a "sheath buffer" (i.e., a carrier fluid). <https://www.nanocollect.com/cell-line-development>. Screenshots of the animation are shown below:



ANSWER: NanoCollect admits that the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. NanoCollect further admits that its website explains that the particles are flowed in a "sheath buffer." NanoCollect further admits that the screenshots of the animation contained in paragraph 51 of the Complaint appear to be as provided on its website. However, NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present

on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 51 of the Complaint not expressly admitted.

52. These screenshots further show a Piezoelectric actuator (“PZT”) configured to selectively apply a pressure pulse to a particle to deflect the selected particle from the stream of particles. The above example shows a “green” particle detected (see top of left screenshot above) and then deflected to the left (see bottom of right screenshot above).

ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 52 of the Complaint not expressly admitted.

53. Additionally, the screenshots show a buffer reservoir protruding from the left side of the channel, opposite the actuator. Such a buffer can absorb the pressure pulse applied by the actuator.

ANSWER: Denied.

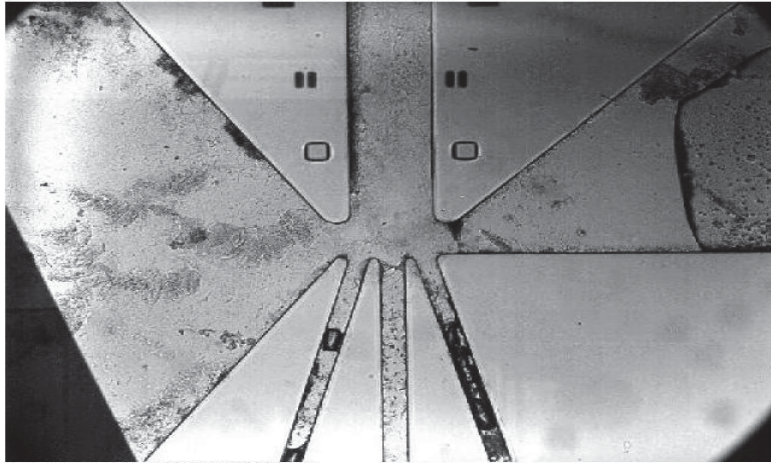
54. As shown in the image below and confirmed by inspection, a flexible membrane is applied at least over the buffer and facilitates the absorption of the pressure pulse:



See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocollect WOLF Cell Sorter Intro”).

ANSWER: Denied.

55. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a microfluidic device with the claimed channel (entering from the top), actuator and buffer:



ANSWER: Denied.

COUNT II — INFRINGEMENT OF THE '295 PATENT

56. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-55.

57. NanoCollect directly infringes, and/or induces the infringement of, at least claim 1 of the '295 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

58. The WOLF Cell Sorter includes every element of at least claim 1 of the '295 Patent, literally or equivalently, which recites:

A microfluidic system comprising:

a microfluidic flow channel formed in a substrate and adapted to facilitate analysis or processing of a sample having one or more particles suspended in a suspension medium flowing through the flow channel;

a first reservoir operatively associated with the flow channel and adapted for dampening or absorbing a pressure pulse propagated across the flow channel; and

a second reservoir operatively associated with the flow channel and adapted for generating the pressure pulse based on a change in volume or pressure in the second reservoir;

wherein the flow channel defines a first aperture for connecting the flow channel relative to the first reservoir and a second aperture for connecting the flow channel relative to the second reservoir, wherein the first aperture is substantially opposite the second aperture.

ANSWER: Denied.

59. The WOLF Cell Sorter is a microfluidic system. For instance, the NanoCollect website states that the WOLF Cell Sorter is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 59 of the Complaint not expressly admitted.

60. Furthermore, the WOLF Cell Sorter includes a microfluidic flow channel formed in a substrate adapted to facilitate analysis or process of a sample having one or more particles suspended in a suspension medium. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows that particles, such as cells, flow downstream in a channel through a detector (i.e., a laser). See <https://www.nanocollect.com/wolf-cell-sorter>. Screenshots of the animation are shown below:



ANSWER: NanoCollect admits that the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. NanoCollect further admits that the screenshots of the animation contained in paragraph 60 of the Complaint appear to be as provided on its website. However, NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 60 of the Complaint not expressly admitted.

61. Furthermore, two articles—titled “Epigenomic Analysis of Sorted Retinal Ganglion Cells using ATAC-seq” and “Gentle Selection of Cells Results in Higher Outgrowth”—available on NanoCollect’s website describes using the WOLF Cell Sorter to analyze and process cells prepared in a “cell suspension.” See <https://www.nanocollect.com/resources>.

ANSWER: Admit.

62. Additionally, the WOLF Cell Sorter has a first reservoir operatively associated with the flow channel and adapted for dampening or absorbing a pressure pulse propagated across the flow channel. As the screenshots above show, there is a reservoir protruding from and connected to the left side of the channel, opposite the Piezoelectric actuator (“PZT”). This reservoir can absorb or dampen the pressure pulse applied by the actuator that was propagated across the flow channel.

ANSWER: Denied.

63. As shown in the image below and confirmed by inspection, a flexible membrane is applied over the first (buffer) reservoir and facilitates the absorption and dampening of the pressure pulse:



See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocollect WOLF Cell Sorter Intro”).

ANSWER: Denied.

64. Furthermore, the WOLF Cell Sorter has a second reservoir operatively associated with the flow channel and adapted for generating the pressure pulse based on a change in volume or pressure in the second reservoir. As shown in the above screenshots, the WOLF Cell sorter has an actuator that compresses downward when appropriately energized. This creates a change in volume and pressure in the reservoir in communication with the actuator. The actuator can also be energized in the opposing direction, which causes the reservoir to deflect upward, also generating a pressure pulse based on a change in volume and pressure:



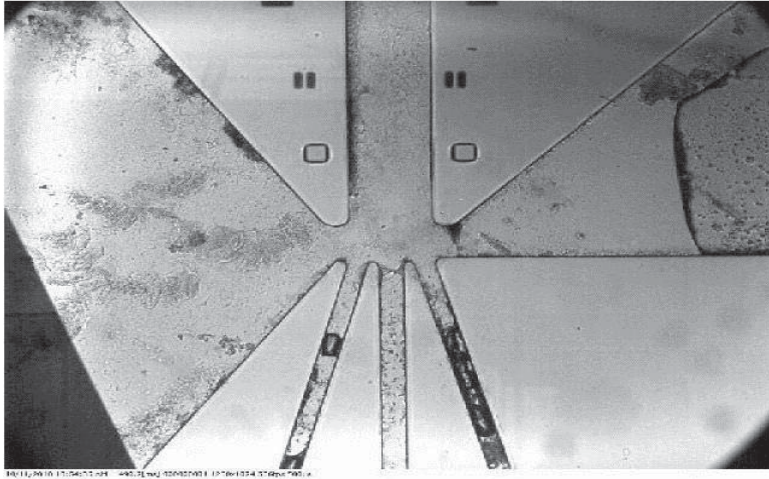
ANSWER: Denied. NanoCollect further states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and

operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

65. The screenshots further show that the flow channel defines a first aperture for connecting the flow channel to the first reservoir and a second aperture for connecting the flow channel to the second reservoir and that the first aperture is substantially opposite the second aperture.

ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 65 of the Complaint not expressly admitted.

66. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a microfluidic system with the claimed microfluidic flow channel (entering from the top), a first reservoir for absorbing a pressure pulse and having an aperture connecting it to the flow channel (right reservoir), and a second reservoir opposite the first reservoir for generating the pressure pulse and having an aperture connecting it to the flow channel (left reservoir):



ANSWER: Denied.

COUNT III — INFRINGEMENT OF THE '797 PATENT

67. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-66.

68. NanoCollect directly infringes, and/or induces the infringement of, at least claim 5 of the '797 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

69. The WOLF Cell Sorter includes every element of at least claim 5 of the '797 Patent, literally or equivalently, which recites:

A microfluidic device adapted to facilitate analysis or processing of a sample, the microfluidic device comprising:

a microfluidic flow channel formed in a substrate, the flow channel having a width and a length that exceeds the width; and

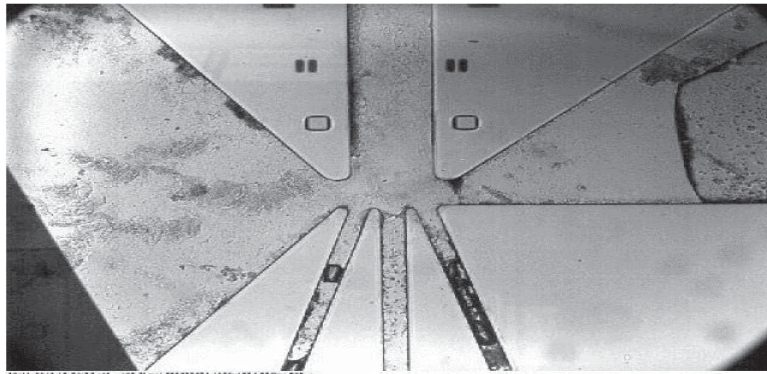
a first reservoir in fluid communication with the flow channel adapted for dampening or absorbing a pressure pulse propagated across the width of the flow channel, wherein the first reservoir is otherwise sealed from an exterior environment.

ANSWER: Denied.

70. The WOLF Cell Sorter is a microfluidic device adapted to facilitate analysis or processing of a sample. The WOLF Cell Sorter analyzes and processes a sample by detecting and sorting the particles in a sample. For instance, the NanoCollect website states that the WOLF Cell Sorter is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 70 of the Complaint not expressly admitted.

71. Furthermore, the WOLF Cell Sorter includes a microfluidic flow channel formed in a substrate that has a length that exceeds the width, as shown in the photograph of a WOLF Cell Sorter microfluidic chip:



ANSWER: Denied.

72. The WOLF Cell Sorter also has a first reservoir in fluid communication with the flow channel adapted for dampening or absorbing a pressure pulse propagated across the width of the flow channel, wherein the first reservoir is otherwise sealed from an exterior environment. This reservoir is shown on the right side of the flow channel in the photograph above and is sealed from the exterior environment.

ANSWER: Denied.

73. As shown in the image below and confirmed by inspection, a flexible membrane is applied over the first (buffer) reservoir and facilitates the absorption and dampening of the pressure pulse:



See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocelllect WOLF Cell Sorter Intro”).

ANSWER: Denied.

74. Additionally, the screenshots below also show that the WOLF Cell Sorter has a reservoir protruding from and connected to the left side of the channel, opposite the Piezoelectric actuator (“PZT”), that is not open to the exterior environment. See <https://www.nanocelllect.com/wolf-cell-sorter>. This reservoir can absorb or dampen the pressure pulse applied by the actuator and propagated across the flow channel:



ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The

illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 74 of the Complaint not expressly admitted.

75. The above example shows a “green” particle detected (see top of left screenshot above) and then deflected to the left (see bottom of right screenshot above) after the actuator propagates a pressure pulse into the flow channel.

ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 75 of the Complaint not expressly admitted.

COUNT IV — INFRINGEMENT OF THE '850 PATENT

76. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-75.

77. NanoCollect directly infringes, and/or induces the infringement of, at least claim 1 of the '850 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

78. The WOLF Cell Sorter includes every element of at least claim 1 of the '850 Patent, literally or equivalently, which recites:

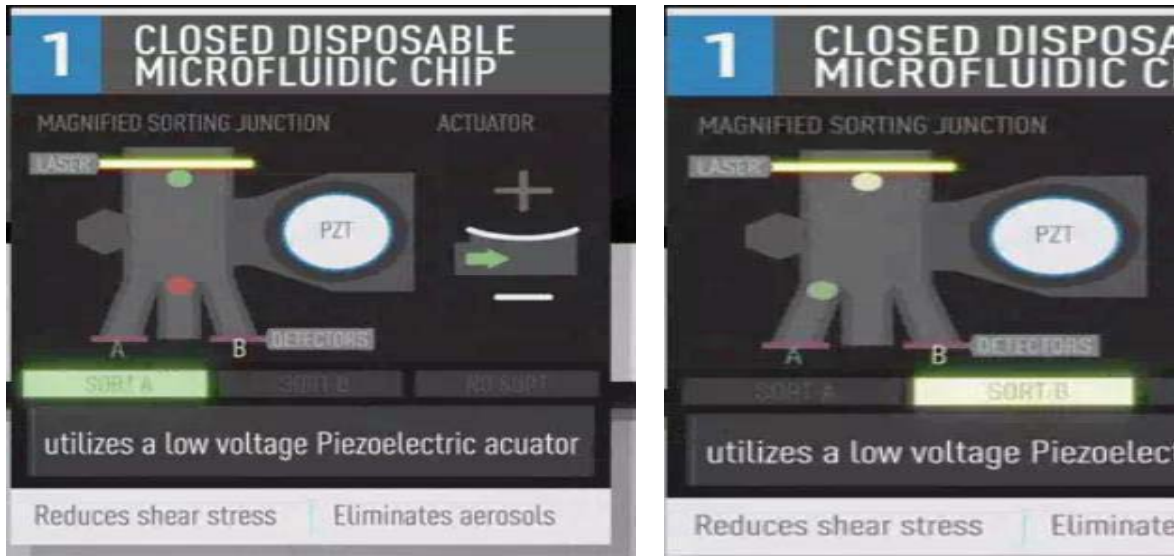
A particle sorting system, comprising:
a duct for conveying a stream of particles, comprising an inlet, and
a plurality of outlets including a first outlet and a second outlet, wherein
the particles normally flow from the inlet into the first outlet;
an actuator for selectively applying a pressure pulse to deflect a selected
particle in the stream of particles into the second outlet when a predetermined
characteristic is detected; and
a buffer configured to fluidically co-operate with the actuator for
absorbing or dampening the pressure pulse to allow other particles in the stream
of particles to normally flow into the first outlet while the deflected particle flows
into the second outlet.

ANSWER: Denied.

79. The WOLF Cell Sorter is a particle sorting system. For instance, the NanoCollect website states that the WOLF Cell Sorter is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 79 of the Complaint not expressly admitted.

80. Furthermore, the WOLF Cell Sorter includes a duct for conveying a stream of particles, comprising an inlet and a plurality of outlets including a first outlet and a second outlet, wherein the particles normally flow from the inlet into the first outlet. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows that particles, such as cells, flow downstream in a duct through a detector (i.e., a laser) and into one of three outlets. See <https://www.nanocollect.com/wolf-cell-sorter>. Screenshots of the animation are shown below:



ANSWER: NanoCollect admits that the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. However, NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 80 of the Complaint not expressly admitted.

81. These screenshots further show a Piezoelectric actuator (“PZT”) actuator for selectively applying a pressure pulse to deflect a selected particle in the stream of particles into the second outlet when a predetermined characteristic is detected. The above example shows a particle having a preselected characteristic detected by a laser (see top of left screenshot above) and then deflected to the left (see bottom of right screenshot) and into a left (i.e., “second”) outlet. The left screenshot also shows a “red” particle demonstrating that particles which are not selected, and thus not deflected, “normally flow into [a] first” outlet.

ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are

not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 81 of the Complaint not expressly admitted.

82. Additionally, the screenshots show a triangular reservoir protruding from the left side of the channel, opposite the actuator. Such a buffer is configured to fluidically cooperate with the actuator for absorbing or dampening the pressure pulse to allow other particles in the stream of particles to normally flow into the first outlet while the deflected particle flows into the second outlet.

ANSWER: Denied.

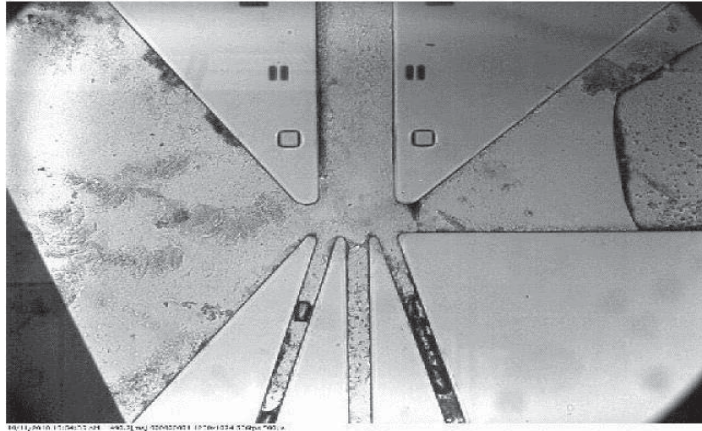
83. As shown in the image below and confirmed by inspection, a flexible membrane is applied over the buffer and facilitates the absorption and dampening of the pressure pulse:



See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocollect WOLF Cell Sorter Intro”).

ANSWER: Denied.

84. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a microfluidic device with the claimed duct (entering from the top), actuator (attached to the left reservoir), and buffer (right reservoir):



ANSWER: Denied.

COUNT V — INFRINGEMENT OF THE '263 PATENT

85. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-84.

86. NanoCollect directly infringes, and/or induces the infringement of, at least claim 1 of the '263 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

87. The WOLF Cell Sorter includes every element of at least claim 1 of the '263 Patent, literally or equivalently, which recites:

A microfluidic system for sorting particles, the microfluidic system comprising:

a first microfluidic flow channel formed in a particle processing component substrate having an upstream inlet configured to introduce a fluidic stream having a plurality of particles into the first microfluidic flow channel and downstream outlets configured to output portions of the fluidic stream of particles;

a detection region located downstream of the inlet, the detection region configured to allow a particle having a predetermined characteristic to be sensed, the sensed particle being one of the plurality of particles in the fluidic stream; and

a switching device located downstream of the detection region, the switching device operatively coupled to the first microfluidic flow channel to deliver a transient pressure pulse in a direction substantially perpendicular to a flow direction of the fluidic stream of particles,

wherein the transient pressure pulse displaces and separates a selected single sensed particle from the fluidic stream of particles,

wherein the selected particle is displaced and separated from the fluidic stream of particles in a switching region,

wherein the fluidic stream of unselected particles flows into a first downstream outlet configured to output a first portion of the fluidic stream of particles,

wherein the selected particle flows into a second downstream outlet configured to output a second portion of the fluidic stream of particles,

wherein the transient pressure pulse is not generated downstream of the switching region,

wherein the switching device, when activated, does not block or partially block flow of the fluidic stream of particles, and

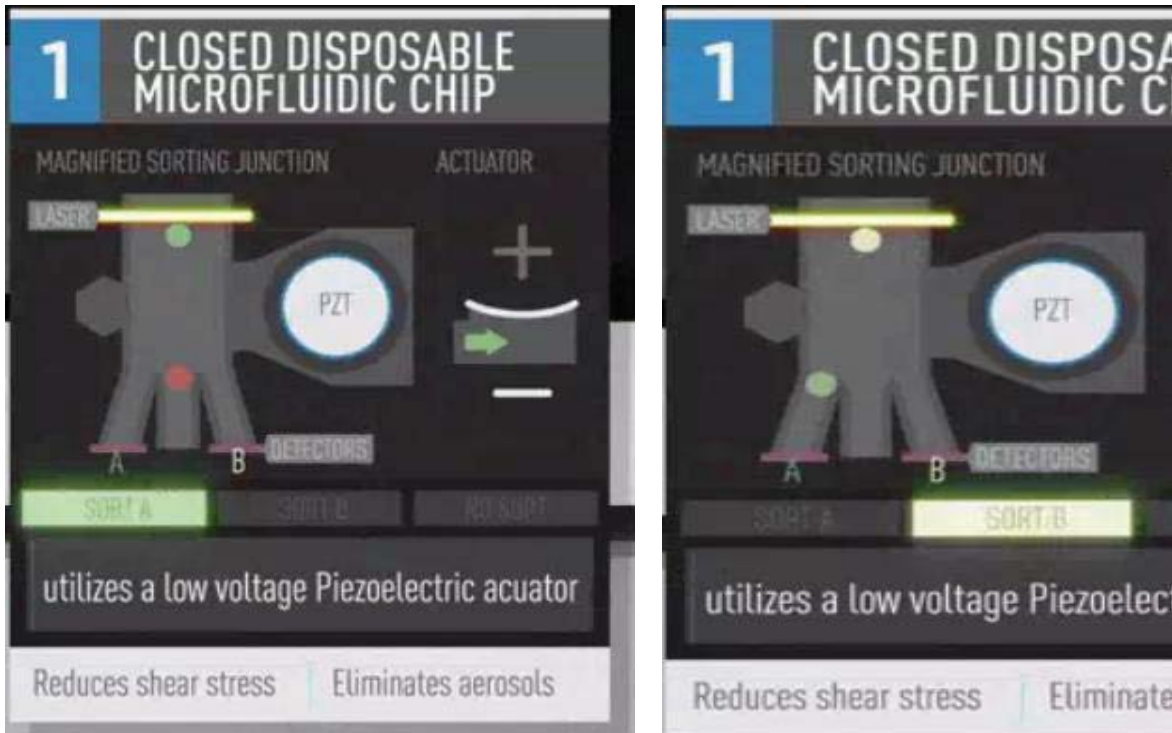
wherein the particle processing component substrate includes a reservoir adapted for dampening or absorbing the transient pressure pulse propagated across the microfluidic channel.

ANSWER: Denied.

88. The WOLF Cell Sorter is a microfluidic system for sorting particles. For instance, the NanoCollect website states that the WOLF Cell Sorter is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 88 of the Complaint not expressly admitted.

89. Furthermore, the WOLF Cell Sorter [sic] a first microfluidic flow channel formed in a substrate with an upstream inlet configured to introduce a fluidic stream having a plurality of particles into the channel. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows a channel with particles, such as cells, flowing downstream through a detector (i.e., a laser). See <https://www.nanocollect.com/wolf-cell-sorter>. Screenshots of the animation are shown below:



ANSWER: NanoCollect admits that the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 89 of the Complaint not expressly admitted.

90. As shown in the screenshots above, the WOLF Cell Sorter has downstream outlets configured to output portions of the fluidic stream of particles. In this example, a portion of the stream consisting of “green” particles is output into the far left channel, while the “red” particles are output into the center channel.

ANSWER: Denied. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

91. The screenshots also show a detection region located downstream of the inlet, indicated by the “laser” that detects the cells. The detection region is configured to sense a particle having a predetermined characteristic, in this case a “green” particle.

ANSWER: Denied. NanoCollect states further that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

92. Furthermore, the screenshots show a switching device located downstream of the detection region. In this WOLF Cell Sorter, the switching device is a Piezoelectric actuator (“PZT”) that is operatively coupled to the first microfluidic flow channel through an opening in the side of the channel, as shown. The PZT delivers a transient pressure pulse in a direction substantially perpendicular to a flow direction of the fluidic stream of particles, which in this example causes the “green” particle to move to the left as shown in the right screenshot above. In other words, the transient pressure pulse displaces and separates a selected single particle from the fluidic stream of particles in the switching region.

ANSWER: Denied.

93. Furthermore, the unselected particles, indicated by the “red” particle in the right screenshot above, flows into a middle (i.e., “first”) downstream outlet configured to output a first

portion of the fluidic stream of particles. Meanwhile, the green (i.e., “selected”) particle flows into a left (i.e., “second”) downstream outlet.

ANSWER: Denied. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

94. Additionally, the WOLF Cell Sorter’s substrate has a reservoir adapted for dampening or absorbing the transient pressure pulse propagated across the microfluidic channel. As shown in the screenshots above, there is a triangular reservoir protruding from and connected to the left side of the channel, opposite the Piezoelectric actuator (“PZT”). This buffer can absorb or dampen the pressure pulse applied by the actuator and propagated across the flow channel.

ANSWER: Denied.

95. As shown in the image below and confirmed by inspection, a flexible membrane is applied over the first (buffer) reservoir and facilitates the absorption and dampening of the pressure pulse:



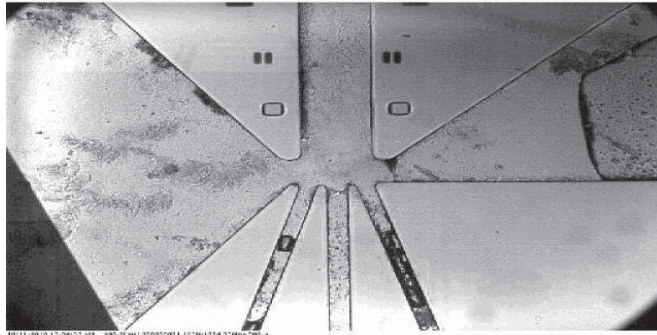
See <https://www.youtube.com/watch?v=e3DMwUz799w> (“Nanocollect WOLF Cell Sorter Intro”).

ANSWER: Denied.

96. Moreover, this transient pressure pulse is not generated downstream of the switching region because of the buffer. Because the pressure pulse is absorbed by the buffer reservoir, the pulse does not propagate downstream. The buffer also prevents the switching device from blocking or partially blocking the flow of the particles by preventing the pressure pulse from propagating upstream.

ANSWER: Denied.

97. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a microfluidic system with the claimed microfluidic flow channel with a detection region (located in the channel entering from the top), a switching device (above the left reservoir) that generates a pressure pulse at a switching region, multiple outlets (bottom three channels), and a reservoir for dampening or absorbing the transient pressure pulse (right reservoir):



ANSWER: Denied.

COUNT VI — INFRINGEMENT OF THE '283 PATENT

98. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-97.

99. NanoCollect directly infringes, and/or induces the infringement of, at least claim 1 of the '283 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

100. The WOLF Cell Sorter includes every element of at least claim 1 of the '283 Patent, literally or equivalently, which recites:

A particle sorting chip comprising:
a duct configured to convey particles in a stream, the duct including an inlet and a plurality of flow-through outlet channels formed in a substrate;
a first chamber formed in the substrate, the first chamber in fluid communication with the duct via a first side opening and otherwise sealed, the first side opening positioned upstream of the plurality of flow-through outlet channels; and
an actuator provided on the substrate and associated with the first chamber, the actuator configured to increase a pressure within the first chamber and to discharge an amount of fluid from the first side opening into the duct during a switching operation.

ANSWER: Denied.

101. The WOLF Cell Sorter is a particle sorting chip. For instance, the NanoCollect website describes the WOLF Cell Sorter as a “chip” and states that it is “based on microfluidic sorting technology.” <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 101 of the Complaint not expressly admitted.

102. Furthermore, the WOLF Cell Sorter includes a duct configured to convey particles in a stream, the duct including an inlet and a plurality of flow-through outlet channels formed in a substrate. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows that a stream of particles, such as cells, flow downstream in a duct through a detector (i.e., a laser) and into one of three outlets. See <https://www.nanocollect.com/wolf-cell-sorter>. Screenshots of the animation are shown below:



ANSWER: NanoCollect admits that the WOLF Cell Sorter includes a channel for conveying a stream of particles in a carrier fluid. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 102 of the Complaint not expressly admitted.

103. These screenshots further show a chamber formed in the substrate on the right side of the duct and in fluid communication with the duct via a side opening. This chamber is sealed to the external environment. The side opening is also positioned upstream of the three flow-through outlet channels shown at the bottom of the screenshot.

ANSWER: Denied. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works

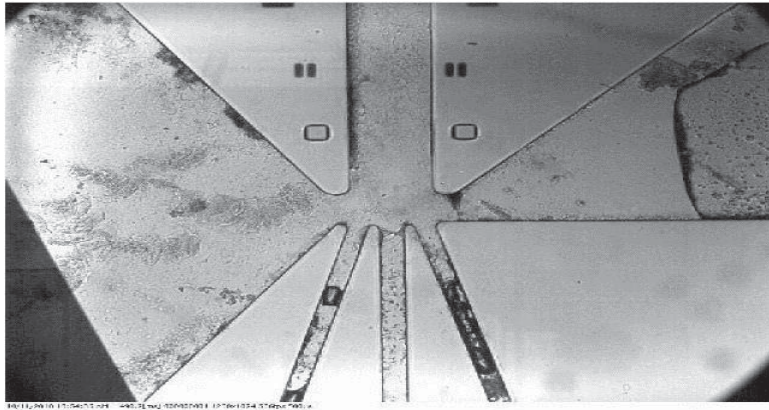
and are not, and do not intend to be, fully representative examples of how the device functions.

The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

104. Connected to the first chamber is a Piezoelectric actuator (“PZT”) actuator provided on the substrate. The actuator configured to increase a pressure within the first chamber and to discharge an amount of fluid from the first side opening into the duct during a switching operation. In doing so, the PZT deflects a selected particle into an outlet. The above example shows a particle having a preselected characteristic (represented by a green color) detected at the top of the left screenshot and then deflected to the left and into a left (i.e., “second”) outlet (see bottom of right screenshot above).

ANSWER: NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation. NanoCollect denies the remaining allegations contained in paragraph 104 of the Complaint not expressly admitted.

105. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a particle sorting chip with the claimed duct (entering from the top), reservoir (left), and actuator (attached to the left reservoir).



ANSWER: Denied.

COUNT VII — INFRINGEMENT OF THE '188 PATENT

106. Cytonome realleges, and incorporates by reference in full herein, each of the preceding paragraphs.

ANSWER: NanoCollect re-asserts and incorporates by reference its responses to paragraphs 1-105.

107. NanoCollect directly infringes, and/or induces the infringement of, at least claim 1 of the '188 Patent, either literally or under the doctrine of equivalents, by making, using, selling, importing, and/or offering to sell within the United States without authority or license, at least the WOLF Cell Sorter microfluidic device. Further discovery may reveal additional infringing products.

ANSWER: Denied.

108. The WOLF Cell Sorter includes every element of at least claim 1 of the '188 Patent, literally or equivalently, which recites:

A particle processing assembly for sorting individual particles on a particle-by-particle basis from a stream of particles, the particle processing assembly comprising:

a microfluidic chip including at least one microsorter having a switching region and a microfluidic channel formed in the microfluidic chip fluidically coupled to a sample input a keep output, a waste output, and the switching region,

wherein the switching region interfaces with at least one actuator external to the microfluidic chip, and

wherein the switching region, when actuated by the actuator upon detection of a predetermined characteristic of a selected particle, directs a pressure

pulse across the microfluidic channel to deflect the selected particle from the stream of particles.

ANSWER: Denied.

109. The WOLF Cell Sorter is a particle processing assembly for sorting individual particles on a particle-by-particle basis from a stream of particles. For instance, the NanoCollect website purports that the WOLF Cell Sorter is “based on microfluidic sorting technology” and that “24 microliters per minute of sample can be processed” with the WOLF Cell Sorter. <https://www.nanocollect.com/wolf-cell-sorter>.

ANSWER: NanoCollect admits that the WOLF Cell Sorter is based on microfluidic sorting technology, as provided on its website. NanoCollect denies the remaining allegations contained in paragraph 109 of the Complaint not expressly admitted.

110. Furthermore, the WOLF Cell Sorter [sic] a microfluidic chip including a microsorter with a switching region. NanoCollect’s animation showing the operation of the WOLF Cell Sorter taken from its website shows that a stream of particles, such as cells, flow downstream in a channel through a detector (i.e., a laser) and into one of three outlets. See <https://www.nanocollect.com/wolf-cell-sorter>. Connected to the first chamber is an external Piezoelectric actuator (“PZT”) actuator provided on the substrate. The screenshots further show a switching region interfaces with the actuator and is configured to provide a pressure pulse to individually selected particles. In this switching region, when a predetermined characteristic of a selected particle is detected, the actuator directs a pressure pulse across the microfluidic channel to deflect the selected particle from the stream of particles. Screenshots of the animation are shown below:



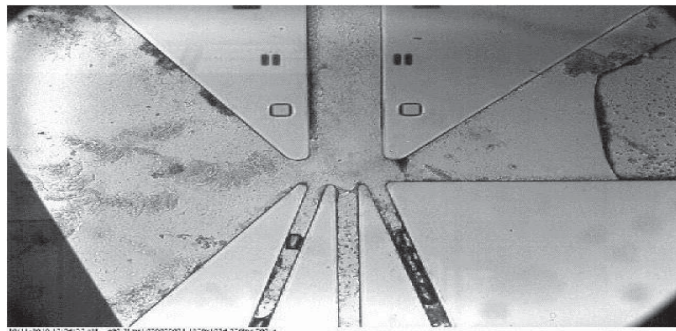
ANSWER: Denied. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions. The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

111. These screenshots further show a microfluidic channel formed in the microfluidic chip that is fluidically coupled to a sample input, a switching region, and multiple outputs. For example, the green particle is selected and deflected in the switching region such that it flows into a “keep output” (the bottom left channel), while the non-selected “red” particle flows into a “waste output” (the bottom middle channel).

ANSWER: Denied. NanoCollect states that the referenced animations and descriptions of the WOLF Cell Sorter on its website are simplified illustrations of how the WOLF Cell Sorter works and are not, and do not intend to be, fully representative examples of how the device functions.

The illustrations provided on its website simplify both the design and operation of the WOLF Cell Sorter. The product is physically different than the depictions in addition to operating differently. For example, the illustrations are missing components and channels that are present on the WOLF Cell Sorter during operation.

112. The photograph below of a microfluidic chip taken from a WOLF Cell Sorter further shows that the Wolf Cell Sorter is a particle processing assembly with the claimed microfluidic channel connected to a switching region that generates a pressure pulse from an actuator for deflecting particles into appropriate outputs:



ANSWER: Denied.

PLAINTIFF'S PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. NanoCollect further denies that Plaintiff is entitled to the relief requested in the Complaint or to any relief whatsoever. Plaintiff's requests should, therefore, be denied in their entirety and with prejudice. Plaintiff should take nothing from NanoCollect, and NanoCollect should be awarded its costs.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, NanoCollect asserts the following affirmative defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff. NanoCollect's investigation of its defenses is

continuing, and NanoCollect reserves all rights to allege additional defenses that may now exist or become known through the course of discovery or further investigation in this case.

FIRST DEFENSE

(Invalidity)

The claims of the '528, '295, '797, '850, '263, '283, and '188 patents are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting.

SECOND DEFENSE

(Noninfringement)

NanoCollect has not directly or indirectly infringed any valid claim of the '528, '295, '797, '850, '263, '283, and '188 patents, literally or under the doctrine of equivalents. The manufacture, use, offer for sale, and/or sale of the WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '528, '295, '797, '850, '263, '283, and '188 patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE

(Limitation on Damages)

Plaintiff's claims for damages, if any, against NanoCollect for alleged infringement is limited in whole or in part by 35 U.S.C. §§ 287, 288.

FOURTH DEFENSE

(No Notice)

To the extent Plaintiff asserts that NanoCollect indirectly infringes, either by contributory infringement or inducement of infringement, NanoCollect cannot be liable to Plaintiff for the acts

alleged to have been performed before NanoCollect had knowledge that its actions would cause the alleged infringement.

FIFTH DEFENSE

(File Wrapper Estoppel and/or Disclaimer)

By reason of proceedings in the United States Patent and Trademark Office, and by reason of amendments, disclaimers, disavowals, admissions, representations, arguments, and/or statements made by the applicants or on their behalf, Plaintiff is estopped from construing the claims of the asserted patents to cover and/or include any acts or products of NanoCollect.

RESERVATION OF DEFENSES

NanoCollect reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case including, without limitation, all defenses governed by Rules 8, 9, and 12 of the Federal Rules of Civil Procedure. Defendants further reserve the right to supplement and/or amend these defenses.

COUNTERCLAIMS

For its counterclaims against Cytonome/ST, LLC (“Cytonome” or “Counterclaim Defendant”), NanoCollect Biomedical, Inc. (“NanoCollect” or “Counterclaim Plaintiff”) states as follows:

PARTIES

1. NanoCollect is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6865 Flanders Dr., Suite A, San Diego, CA 92121.
2. Upon information and belief, Cytonome is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 9 Oak Park Drive, Bedford, MA 01730.

JURISDICTION AND VENUE

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

4. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. The Court has personal jurisdiction over Counterclaim Defendant because Counterclaim Defendant commenced and continues to maintain this action against NanoCollect in this judicial district.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1400(b), and because Counterclaim Defendant has consented to venue in this Court by filing the instant action in this judicial district.

FACTUAL BACKGROUND

7. Cytonome has alleged in the instant action that Cytonome is the owner of all rights, title, and interest in and to U.S. Patent Nos. 6,877,528 (the “’528 Patent”), 8,623,295 (the “’295 Patent”), 9,011,797 (the “’797 Patent”), 9,339,850 (the “’850 Patent”), 10,029,263 (the “’263 Patent”), 10,029,283 (the “’283 Patent”), and 10,065,188 (the “’188 Patent”) (collectively, “the patents-in-suit”).

8. Upon information and belief, Cytonome is the present owner by assignment of the whole right, title, and interest of the patents-in-suit. The patents-in-suit are attached as Exhibits 1-7 to the Complaint.

9. On February 12, 2019 Cytonome filed the instant action against NanoCollect alleging infringement of the patents-in-suit.

COUNT 1: DECLARATORY JUDGMENT OF INVALIDITY OF THE '528 PATENT

10. NanoCollect repeats and realleges the allegations in Paragraphs 1-9 as if fully set forth herein.

11. Cytonome has asserted the '528 Patent against NanoCollect in the instant action.

12. NanoCollect denies infringement of the '528 Patent and alleges that the '528 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

13. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '528 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

14. NanoCollect is entitled to a judicial declaration that the claims of the '528 Patent are invalid.

**COUNT 2: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '528 PATENT**

15. NanoCollect repeats and realleges the allegations in Paragraphs 1-14 as if fully set forth herein.

16. Cytonome has asserted the '528 Patent against NanoCollect in the instant action.

17. NanoCollect denies infringement of the '528 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '528 Patent, either literally or under the doctrine of equivalents.

18. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '528 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

19. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '528 Patent, either literally or under the doctrine of equivalents.

COUNT 3: DECLARATORY JUDGMENT OF INVALIDITY OF THE '295 PATENT

20. NanoCollect repeats and realleges the allegations in Paragraphs 1-19 as if fully set forth herein.

21. Cytonome has asserted the '295 Patent against NanoCollect in the instant action.

22. NanoCollect denies infringement of the '295 Patent and alleges that the '295 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

23. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '295 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

24. NanoCollect is entitled to a judicial declaration that the claims of the '295 Patent are invalid.

**COUNT 4: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '295 PATENT**

25. NanoCollect repeats and realleges the allegations in Paragraphs 1-24 as if fully set forth herein.

26. Cytonome has asserted the '295 Patent against NanoCollect in the instant action.

27. NanoCollect denies infringement of the '295 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '295 Patent, either literally or under the doctrine of equivalents.

28. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '295 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

29. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '295 Patent, either literally or under the doctrine of equivalents.

COUNT 5: DECLARATORY JUDGMENT OF INVALIDITY OF THE '797 PATENT

30. NanoCollect repeats and realleges the allegations in Paragraphs 1-29 as if fully set forth herein.

31. Cytonome has asserted the '797 Patent against NanoCollect in the instant action.

32. NanoCollect denies infringement of the '797 Patent and alleges that the '797 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

33. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '797 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

34. NanoCollect is entitled to a judicial declaration that the claims of the '797 Patent are invalid.

**COUNT 6: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '797 PATENT**

35. NanoCollect repeats and realleges the allegations in Paragraphs 1-34 as if fully set forth herein.

36. Cytonome has asserted the '797 Patent against NanoCollect in the instant action.

37. NanoCollect denies infringement of the '797 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '797 Patent, either literally or under the doctrine of equivalents.

38. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '797 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

39. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '797 Patent, either literally or under the doctrine of equivalents.

COUNT 7: DECLARATORY JUDGMENT OF INVALIDITY OF THE '850 PATENT

40. NanoCollect repeats and realleges the allegations in Paragraphs 1-39 as if fully set forth herein.

41. Cytonome has asserted the '850 Patent against NanoCollect in the instant action.

42. NanoCollect denies infringement of the '850 Patent and alleges that the '850 Patent is invalid for failure to comply with one of more of the requirements for patentability set

forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

43. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '850 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

44. NanoCollect is entitled to a judicial declaration that the claims of the '850 Patent are invalid.

**COUNT 8: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '850 PATENT**

45. NanoCollect repeats and realleges the allegations in Paragraphs 1-44 as if fully set forth herein.

46. Cytonome has asserted the '850 Patent against NanoCollect in the instant action.

47. NanoCollect denies infringement of the '850 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '850 Patent, either literally or under the doctrine of equivalents.

48. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '850 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

49. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '850 Patent, either literally or under the doctrine of equivalents.

COUNT 9: DECLARATORY JUDGMENT OF INVALIDITY OF THE '263 PATENT

50. NanoCollect repeats and realleges the allegations in Paragraphs 1-49 as if fully set forth herein.

51. Cytonome has asserted the '263 Patent against NanoCollect in the instant action.

52. NanoCollect denies infringement of the '263 Patent and alleges that the '263 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

53. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '263 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

54. NanoCollect is entitled to a judicial declaration that the claims of the '263 Patent are invalid.

**COUNT 10: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '263 PATENT**

55. NanoCollect repeats and realleges the allegations in Paragraphs 1-54 as if fully set forth herein.

56. Cytonome has asserted the '263 Patent against NanoCollect in the instant action.

57. NanoCollect denies infringement of the '263 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '263 Patent, either literally or under the doctrine of equivalents.

58. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '263 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.\

59. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '263 Patent, either literally or under the doctrine of equivalents.

COUNT 11: DECLARATORY JUDGMENT OF INVALIDITY OF THE '283 PATENT

60. NanoCollect repeats and realleges the allegations in Paragraphs 1-59 as if fully set forth herein.

61. Cytonome has asserted the '283 Patent against NanoCollect in the instant action.

62. NanoCollect denies infringement of the '283 Patent and alleges that the '283 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

63. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '283 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

64. NanoCollect is entitled to a judicial declaration that the claims of the '283 Patent are invalid.

**COUNT 12: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '283 PATENT**

65. NanoCollect repeats and realleges the allegations in Paragraphs 1-64 as if fully set forth herein.

66. Cytonome has asserted the '283 Patent against NanoCollect in the instant action.

67. NanoCollect denies infringement of the '283 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '283 Patent, either literally or under the doctrine of equivalents.

68. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '283 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

69. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '283 Patent, either literally or under the doctrine of equivalents.

COUNT 13: DECLARATORY JUDGMENT OF INVALIDITY OF THE '188 PATENT

70. NanoCollect repeats and realleges the allegations in Paragraphs 1-69 as if fully set forth herein.

71. Cytonome has asserted the '188 Patent against NanoCollect in the instant action.

72. NanoCollect denies infringement of the '188 Patent and alleges that the '188 Patent is invalid for failure to comply with one of more of the requirements for patentability set forth in Title 35 of the United States Patent Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112 and/or double patenting.

73. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '188 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

74. NanoCollect is entitled to a judicial declaration that the claims of the '188 Patent are invalid.

**COUNT 14: DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '188 PATENT**

75. NanoCollect repeats and realleges the allegations in Paragraphs 1-74 as if fully set forth herein.

76. Cytonome has asserted the '188 Patent against NanoCollect in the instant action.

77. NanoCollect denies infringement of the '188 Patent and alleges that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '188 Patent, either literally or under the doctrine of equivalents.

78. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the infringement of the '188 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

79. NanoCollect is entitled to a judicial declaration that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter does not and will not infringe any valid or enforceable claim of the '188 Patent, either literally or under the doctrine of equivalents.

COUNTERCLAIM PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, NanoCollect respectfully requests entry of judgment in its favor and against Cytonome providing the following relief:

a) Declaring that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter has not infringed, does not infringe and would not infringe any

valid or enforceable claim of the '528, '295, '797, '850, '263, '283, and '188 patents, either literally or under the doctrine of equivalents;

b) Declaring that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter has not, does not, and would not induce the infringement of any valid or enforceable claim of the '528, '295, '797, '850, '263, '283, and '188 patents;

c) Declaring that the manufacture, use, importation, offer for sale, and/or sale of NanoCollect's WOLF Cell Sorter has not, does not, and would not contributorily infringe any valid or enforceable claim of the '528, '295, '797, '850, '263, '283, and '188 patents;

d) Declaring that the claims of the '528, '295, '797, '850, '263, '283, and '188 patents are invalid;

e) Ordering that Cytonome's Complaint be dismissed with prejudice and judgment entered in favor of NanoCollect;

f) Denying the relief sought in Plaintiffs' Complaint in its entirety;

g) Ordering that judgment be entered in favor of NanoCollect on each of its affirmative defenses, and any additional defenses that discovery may reveal;

h) Declaring this case exceptional and awarding NanoCollect its reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

i) Awarding NanoCollect such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, NanoCollect hereby demands a jury trial on any and all issues appropriately triable before a jury.

Dated: April 19, 2019

WILSON SONSINI GOODRICH &
ROSATI, P.C.

/s/ Ian R. Liston

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Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2019, I caused the foregoing Defendant Nanocollect Biomedical, Inc.'s Answer and Counterclaims to Plaintiff's Complaint to be served by CM/ECF upon the following counsel of record:

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