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7 Attorneys for Plaintiff
 DNA GENOTEK INC.

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 10 **UNITED STATES DISTRICT COURT**
 11 **SOUTHERN DISTRICT OF CALIFORNIA**

12
 13 DNA GENOTEK INC., a Canadian
 Corporation,

14 Plaintiff,

15 v.

16 SPECTRUM SOLUTIONS L.L.C.,
 17 a Utah Limited Liability Company,

18 Defendant.

Case No. 21-cv-0516-DMS-LL

**SECOND AMENDED COMPLAINT
 FOR PATENT INFRINGEMENT**

JURY TRIAL DEMANDED

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1 Plaintiff DNA Genotek Inc. (“DNA Genotek”), by its attorneys, for its
2 Second Amended Complaint, alleges as follows:

3 1. This is an action for patent infringement arising under the patent laws
4 of the United States, Title 35, United States Code, involving United States Patent
5 No. 10,619,187 (“the ’187 patent”) (attached hereto as Exhibit A) and United States
6 Patent No. 11,002,646 (“the ’646 patent”) (attached hereto as Exhibit B).

7 **PARTIES**

8 2. Plaintiff DNA Genotek is a Canadian corporation with its principal
9 place of business in Kanata, Ontario. DNA Genotek is a wholly-owned subsidiary
10 of OraSure Technologies, Inc., a Delaware corporation with its principal place of
11 business in Bethlehem, Pennsylvania.

12 3. Upon information and belief, Spectrum Solutions L.L.C. is a Utah
13 limited liability company with its principal place of business in Draper, Utah.
14 Upon information and belief, Spectrum DNA is a division of Spectrum Solutions
15 L.L.C. (collectively “Spectrum”). Spectrum Solutions L.L.C. was formerly known
16 as Spectrum Packaging, L.L.C. Spectrum sells saliva DNA collection devices.

17 **JURISDICTION AND VENUE**

18 4. This is an action for patent infringement arising under the patent laws
19 of the United States, Title 35, Section 1, et seq. of the United States Code. This
20 Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

21 5. This Court has personal jurisdiction over Spectrum because it has
22 purposefully availed itself of the privileges and benefits of the laws of the State of
23 California. For example, infringing Spectrum products are being used by local
24 hospitals in this District as part of their COVID-19 testing procedures. Upon
25 information and belief, Spectrum, its agents, subsidiaries, employees, market
26 products in California and ship products to California that infringe the ’187 patent
27 and the ’646 patent. In addition, Spectrum has proposed staffing and leasing
28 facilities in San Diego, CA, for the processing of DNA saliva samples.

1 biological sample collection, including oral fluid sample collection and stabilization
2 solutions like the ones at issue in this case. DNA Genotek has revolutionized the
3 nucleic acid (DNA and RNA) collection market with products that provide
4 substantial advantages over traditional methods of biological sample collection.
5 DNA Genotek's products incorporate proprietary technology that is protected by a
6 robust patent estate.

7 11. Among its many inventions, DNA Genotek developed and patented its
8 proprietary saliva DNA collection kits ("DNA Genotek Saliva Collection
9 Products"). DNA Genotek sells the DNA Genotek Saliva Collection Products to
10 customers and distributors worldwide, including in this District. Throughout the
11 COVID-19 pandemic, DNA Genotek has been a leader in providing reliable saliva
12 collection devices for COVID-19 testing. For example, *Time* declared DNA
13 Genotek's OMNIgene Oral saliva collection kit for COVID-19 samples to be
14 among *Time*'s Best Inventions of 2020. See [https://time.com/collection/best-](https://time.com/collection/best-inventions-2020/5911390/orasure-omnigene-oral/)
15 [inventions-2020/5911390/orasure-omnigene-oral/](https://time.com/collection/best-inventions-2020/5911390/orasure-omnigene-oral/) (last visited Jan. 26, 2021).

16 12. On March 3, 2020, DNA Genotek entered into an IP Purchase and
17 Assignment Agreement with AboGen, Inc. to purchase AboGen, Inc.'s entire
18 portfolio of patents and patent applications. As a result of this transaction, the '646
19 patent was duly and legally issued to DNA Genotek, as assignee of Youssef
20 Biadillah and Stephen D. Andrews.

21 13. Spectrum has a history of infringing patents that protect DNA Genotek
22 Saliva Collection Products. DNA Genotek sued Spectrum for patent infringement
23 of U.S. Patent No. 8,221,381 B2 in the District of Delaware, *DNA Genotek Inc. v.*
24 *Spectrum Solutions L.L.C. et al*, Case. No. 15-cv-00661-SLR (D. Del. filed July 30,
25 2015). Later, DNA Genotek sued Spectrum for patent infringement of U.S. Patent
26 No. 9,207,164 B2 in this District, *DNA Genotek Inc. v. Spectrum Solutions L.L.C.*,
27 Case No. 16-cv-1544-JLS-NLS (S.D. Cal. filed June 20, 2016). DNA Genotek and
28 Spectrum entered into the February 6, 2017 Settlement Agreement to resolve DNA

1 Genotek’s outstanding claims against Spectrum arising out of Spectrum’s
2 marketing, manufacture, use, sale, and distribution of products that infringe DNA
3 Genotek’s patents.

4 14. Several months after signing the Settlement Agreement, DNA Genotek
5 sued Spectrum in this District for breach of contract for Spectrum’s breach of the
6 Settlement Agreement, *DNA Genotek Inc. v. Spectrum Solutions L.L.C.*, Case No.
7 17-cv-1650-L-RBB. The Settlement Agreement included licensing provisions that
8 required Spectrum to cease all sales of infringing Spectrum devices, except that for
9 a limited period, Spectrum was allowed to wrap up business with five specific
10 customers. Spectrum breached the Settlement Agreement by offering infringing
11 devices for sale to customers other than the five permitted customers. The parties
12 settled the lawsuit when Spectrum provided an accounting of its unauthorized offers
13 for sale. DNA Genotek filed a motion to dismiss the lawsuit on April 25, 2018.
14 The Court granted the motion to dismiss the following day.

15 15. DNA Genotek is the owner by assignment of all right, title, and
16 interest in and to the ’187 patent, which duly and legally issued to DNA Genotek,
17 as assignee of H. Chaim Birnboim, on April 14, 2020.

18 16. DNA Genotek is the owner by assignment of all right, title, and
19 interest in and to the ’646 patent, which was assigned to DNA Genotek by Youssef
20 Biadillah and Stephen D. Andrews on March 3, 2020, as a result of DNA Genotek’s
21 IP Purchase and Assignment Agreement with AboGen, Inc.

22 17. Spectrum has been and is now infringing one or more claims of the
23 ’187 patent and the ’646 patent.

24 18. Spectrum infringes the ’187 patent and the ’646 patent, either literally
25 or under the doctrine of equivalents, by making, using, offering for sale, selling
26 and/or importing the Spectrum Product.

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1 19. On information and belief, Spectrum has been aware of the '187 patent
2 at least as early as April 14, 2020. Spectrum has been aware of the patent
3 application leading to the '187 patent at least as early as April 8, 2020.

4 20. Spectrum was aware of the '646 patent before the filing of this Second
5 Amended Complaint.

6 21. Spectrum was aware of the '187 patent and the '646 patent when
7 engaging in these knowing and purposeful activities and was aware that the making,
8 using, selling, or offering for sale of the Spectrum Product or services incorporating
9 the Spectrum Product constituted an act of infringement of the '187 patent and the
10 '646 patent.

11 22. On its website, Spectrum claims to be the “manufacturer and supplier”
12 of the SDNA-1000 and SDNA-2000. Examples of products shipped to the
13 Southern District of California described on Spectrum’s website include this
14 device:



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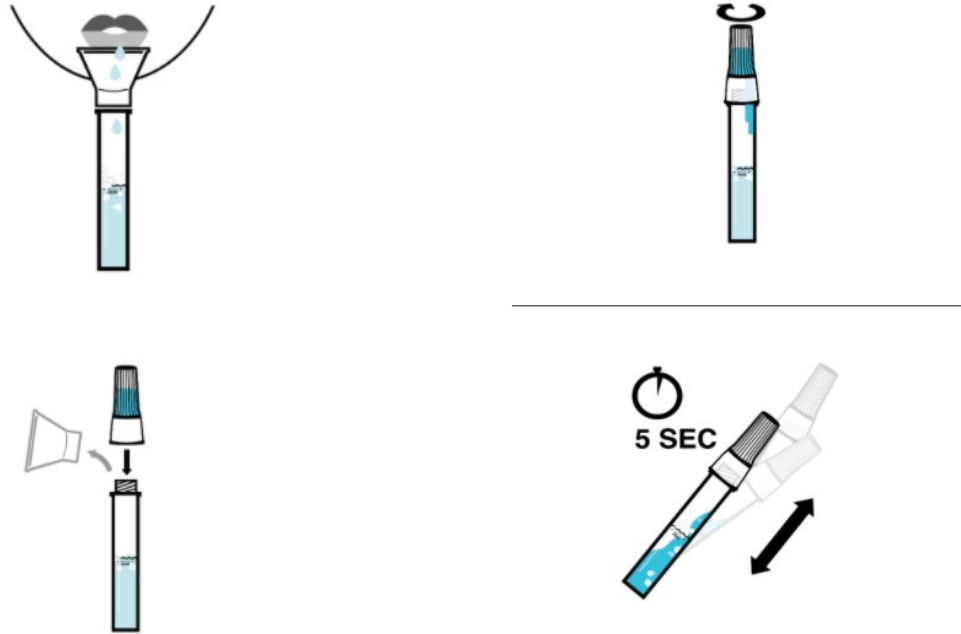
1 23. Spectrum includes nearly identical photographs of its device on its
2 website:



18 24. Upon information and belief, apart from its sale of the Spectrum
19 Product to individuals throughout the country, including in California, Spectrum
20 has shipped and offered for sale the Spectrum Product to persons and/or entities
21 who maintain business operations and headquarters in the Southern District of
22 California.

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1 25. Spectrum includes a step-by-step graphic on its website for how its
2 infringing device functions:



15 26. Spectrum's Product is configured such that when sealably closed, the
16 opening in the sealed cap causes the barrier to mechanically disestablish to release
17 the DNA stabilizing reagent from the cap of the kit into the saliva sample inside the
18 tube. A photograph of the sealing cap with the barrier dissembled is shown below:



25 27. Spectrum's Product includes a vial, or sample collection vessel, with a
26 reservoir and connection member; a cap with a reagent chamber and a
27 complementary connection member; and a movable annular valve with inner and
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1 outer cylinders. Inner cylinders are sometimes referred to as “posts” and outer
2 cylinders are sometimes referred to as “rings.” The cap depicted above on the left
3 holds a reagent (not depicted) for preserving a collected DNA sample. The inner
4 cylinder of the Spectrum Product (right end of the above picture) includes a fluid
5 vent in a side wall. The outer cylinder (middle piece) includes an aperture that
6 accommodates at least part of the inner cylinder. Together, the inner and outer
7 cylinders create an annular valve as claimed in the ’646 patent.

8 **COUNT I – INFRINGEMENT OF THE ’187 PATENT**

9 28. DNA Genotek restates and incorporates by reference paragraphs 1-27,
10 as if fully set forth herein.

11 29. Spectrum has been and is now infringing one or more claims of the
12 ’187 patent, either literally or by the doctrine of equivalents.

13 30. The claims of the ’187 patent cover an invention related to the
14 preservation and extraction of nucleic acids from saliva. For example, claim 1
15 covers:

16 “A device for receiving and preserving nucleic acid in a biological sample,
17 said device comprising:

- 18 (a) one or more walls defining a containment vessel having a top
19 having an opening, and a closed bottom having a sample receiving
20 area for holding said biological sample, said opening for receiving a
21 liquid sample and for sealably receiving a sealing cap, said top having
22 an opening for receiving a biological sample from the mouth of a user
23 and further comprising at least one marking on said one or more walls
24 which corresponds to a fluid volume in the sample receiving area;
25 (b) a reagent compartment having a barrier, said barrier sealing and
26 containing reagents in said reagent compartment and capable of
27 disestablishment to release said reagents into the sample receiving
28 area;

1 (c) reagents in the reagent compartment for preserving nucleic acids
2 potentially present in the sample wherein said reagents comprise a
3 denaturing agent, a chelator and a buffer agent; and,
4 (d) the sealing cap, whereby the device is configured such that, when
5 sealably closing said opening with said sealing cap, the barrier
6 mechanically disestablishes to release said reagents to form a mixture
7 of reagents and said biological sample wherein said buffering agent
8 maintains a pH of said mixture equal to or above 5.0 to preserve
9 nucleic acids potentially present in the sample.” (Ex. A at 19:34-59.)

10 31. The preamble of claim 1 of the ’187 patent recites a device for
11 receiving and preserving nucleic acid in a biological sample.

12 32. The Spectrum Product is a device that receives a biological sample
13 containing nucleic acid and preserves the nucleic acid therein.

14 33. To the extent the preamble to claim 1 is a claim limitation, the
15 Spectrum Product meets the preamble of claim 1 of the ’187 patent.

16 34. Limitation (a) of claim 1 of the ’187 patent recites one or more walls
17 defining a containment vessel having a top having an opening, and a closed bottom
18 having a sample receiving area for holding said biological sample, said opening for
19 receiving a liquid sample and for sealably receiving a sealing cap, said top having
20 an opening for receiving a biological sample from the mouth of a user and further
21 comprising at least one marking on said one or more walls which corresponds to a
22 fluid volume in the sample receiving area.

23 35. As depicted above and as described in Spectrum’s user instructions
24 and marketing materials, the Spectrum Product includes a tube with one continuous
25 wall, which is a containment vessel for collecting a saliva sample. The containment
26 vessel has a top with an opening for receiving a liquid sample and a closed “V”-
27 shaped bottom that holds the liquid sample. Spectrum instructs the user to deposit
28 saliva from his or her mouth into the collection tube through the opening on the top.

1 There is a black wavy line on the wall of the containment vessel, which depicts the
2 fill line for a user's saliva in the sample receiving area. The opening sealably
3 receives a sealing cap when the cap is threaded closed onto the tube.

4 36. The Spectrum Product meets limitation (a) of claim 1 of the '187
5 patent.

6 37. Limitation (b) of claim 1 of the '187 patent recites a reagent
7 compartment having a barrier, said barrier sealing and containing reagents in said
8 reagent compartment and capable of disestablishment to release said reagents into
9 the sample receiving area.

10 38. The cap of the Spectrum Product includes a reagent compartment,
11 which holds a stabilizing fluid reagent. This reagent compartment has a sleeve
12 valve comprising a moveable (relative to the reagent compartment) inner post and
13 fixed (relative to the reagent compartment) outer ring. When the outer ring is
14 positioned at the top of the inner post, it occludes reagent sample, thereby providing
15 a barrier between the reagent and sample receiving area. The components of the
16 sleeve valve on the Spectrum Product seal and contain the stabilizing fluid reagent
17 in the cap compartment. This barrier is capable of disestablishment when the
18 sleeve valve's inner post slides relative to the outer ring to reveal vents on the inner
19 post. This disestablishment releases the reagent from the cap, allowing the reagent
20 to empty into the sample receiving area of the collection tube.

21 39. The Spectrum Product meets limitation (b) of claim 1 of the '187
22 patent.

23 40. Limitation (c) of claim 1 of the '187 patent recites reagents in the
24 reagent compartment for preserving nucleic acids potentially present in the sample
25 wherein said reagents comprise a denaturing agent, a chelator and a buffer agent.

26 41. The Spectrum Product has reagents in the reagent compartment, shown
27 by the stabilization fluid in the cap compartment. The reagent in the cap
28 compartment of the Spectrum Product is a DNA stabilizing solution to stabilize

1 DNA in the collected saliva sample. The reagent in the Spectrum Product includes
2 a denaturing agent, a chelator, and a buffer agent.

3 42. The Spectrum Product meets limitation (c) of claim 1 of the '187
4 patent.

5 43. Limitation (d) of claim 1 of the '187 patent recites the sealing cap,
6 whereby the device is configured such that, when sealably closing said opening
7 with said sealing cap, the barrier mechanically disestablishes to release said
8 reagents to form a mixture of reagents and said biological sample wherein said
9 buffering agent maintains a pH of said mixture equal to or above 5.0 to preserve
10 nucleic acids potentially present in the sample.

11 44. The cap compartment of the Spectrum Product contains the reagent
12 and is threaded closed onto the collection tube. When the sealing cap is threaded
13 closed onto the tube, the tube mechanically disestablishes the sleeve valve's barrier
14 to release the DNA stabilizing reagent from the cap into the tube, thereby mixing
15 the reagent with the biological sample. The buffering agent in the Spectrum
16 Product maintains a pH of the mixture above 5.0 to preserve nucleic acids
17 potentially present in the sample.

18 45. The Spectrum Product meets limitation (d) of claim 1 of the '187
19 patent.

20 46. Spectrum's infringing activities include making, using, offering for
21 sale, selling, and/or importing into the United States products that infringe one or
22 more claims of the '187 patent.

23 47. Spectrum's infringing activities violate 35 U.S.C. § 271.

24 48. As a result of Spectrum's infringement of the '187 patent, DNA
25 Genotek has been and will be damaged, and DNA Genotek is entitled to be
26 compensated for such damages pursuant to 35 U.S.C. § 284 in an amount to be
27 determined at trial, but in no event less than a reasonable royalty.
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1 49. Upon information and belief, Spectrum’s infringement of the ’187
2 patent will continue unless enjoined by this Court. As a result of Spectrum’s
3 infringement, DNA Genotek has suffered and will continue to suffer irreparable
4 harm for which there is no adequate remedy at law. Accordingly, DNA Genotek is
5 entitled to injunctive relief against such infringement.

6 50. As a result of Spectrum’s infringement, DNA Genotek has suffered
7 and will continue to suffer significant damages.

8 **COUNT 2 – INFRINGEMENT OF THE ’646 PATENT**

9 51. DNA Genotek restates and incorporates by reference paragraphs 1-50,
10 as if fully set forth herein.

11 52. Spectrum has been and is now infringing one or more claims of the
12 ’646 patent, either literally or by the doctrine of equivalents.

13 53. The claims of the ’646 patent cover an invention related to a kit for
14 collecting and preserving a biological sample. For example, claim 1 covers:

15 “A kit for collecting and preserving a biological sample, the kit comprising:

16 [(i)] a sample collection vessel, the sample collection vessel
17 comprising:

18 [(i.a)] a sample collection reservoir having an opening
19 configured to receive the biological sample from a user into the
20 sample collection reservoir;

21 [(i.b)] a connection member disposed on an exterior portion of
22 the sample collection vessel and adjacent to the opening;

23 [(ii)] a cap, the cap comprising:

24 [(ii.a)] a reagent chamber configured to store a reagent; and

25 [(ii.b)] a complementary connection member configured to
26 engage the connection member of the sample collection vessel;
27 and
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1 [(iii)] a movable annular valve configured to associate with the cap
2 and with the opening of the sample collection reservoir, the movable
3 annular valve comprising:

4 [(iii.a)] an inner cylinder in fluid-tight association with the cap
5 and comprising a sidewall, the sidewall comprising a fluid vent;
6 and

7 [(iii.b)] an outer cylinder in fluid-tight association with the
8 inner cylinder and associated with the opening of the sample
9 collection reservoir, the outer cylinder comprising an aperture
10 defined by an interior sidewall of the outer cylinder,

11 [(iii.c)] wherein the aperture accommodates at least a portion of
12 the inner cylinder,

13 [(iii.d)] wherein the interior sidewall obstructs the fluid vent
14 when the movable annular valve is closed, and

15 [(iii.e)] wherein the interior sidewall does not obstruct the fluid
16 vent when the movable annular valve is open.” (Ex. B 22:16-
17 47.)

18 54. The preamble of claim 1 of the '646 patent recites a kit for collecting
19 and preserving a biological sample.

20 55. The Spectrum Product is a kit that collects and preserves a biological
21 sample.

22 56. To the extent the preamble to claim 1 is a claim limitation, the
23 Spectrum Product meets the preamble to claim 1 of the '646 patent.

24 57. Limitations (i)-(i.b) of claim 1 of the '646 patent recite a sample
25 collection vessel, the sample collection vessel comprising: a sample collection
26 reservoir having an opening configured to receive the biological sample from a user
27 into the sample collection reservoir; a connection member disposed on an exterior
28 portion of the sample collection vessel and adjacent to the opening.

1 58. The Spectrum Product contains a vial that is used to collect biological
2 samples, as evidenced by the “spit to here” indicator on the vial. Spectrum’s vial
3 has a threaded end with threads on the exterior wall of the vial, meeting the claimed
4 “a connection member disposed on an exterior portion of the sample collection
5 vessel and adjacent to the opening.”

6 59. The Spectrum Product meets limitations (i)-(i.b) of claim 1 of the ’646
7 patent.

8 60. Limitations (ii)-(ii.b) of claim 1 of the ’646 patent recite a cap, the cap
9 comprising: a reagent chamber configured to store a reagent; and a complementary
10 connection member configured to engage the connection member of the sample
11 collection vessel.

12 61. The Spectrum Product includes a cap for storing reagent, which
13 engages with the vial via complimentary threads.

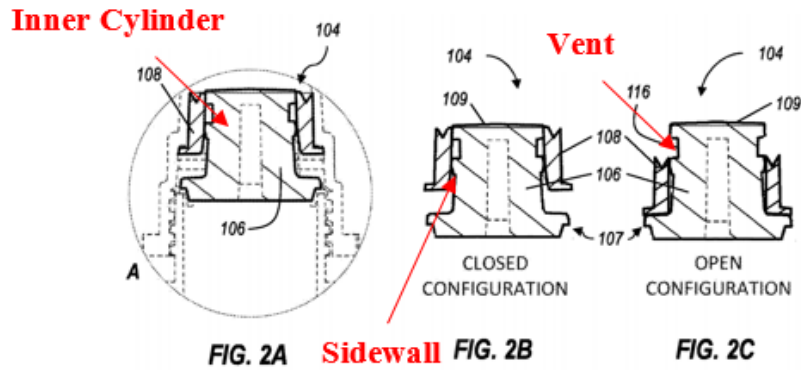
14 62. The Spectrum Product meets limitations (ii)-(ii.b) of claim 1 of the
15 ’646 patent.

16 63. Limitations (iii)-(iii.e) of claim 1 of the ’646 patent recite a movable
17 annular valve configured to associate with the cap and with the opening of the
18 sample collection reservoir, the movable annular valve comprising: an inner
19 cylinder in fluid-tight association with the cap and comprising a sidewall, the
20 sidewall comprising a fluid vent; and an outer cylinder in fluid-tight association
21 with the inner cylinder and associated with the opening of the sample collection
22 reservoir, the outer cylinder comprising an aperture defined by an interior sidewall
23 of the outer cylinder, wherein the aperture accommodates at least a portion of the
24 inner cylinder, wherein the interior sidewall obstructs the fluid vent when the
25 movable annular valve is closed, and wherein the interior sidewall does not obstruct
26 the fluid vent when the movable annular valve is open.

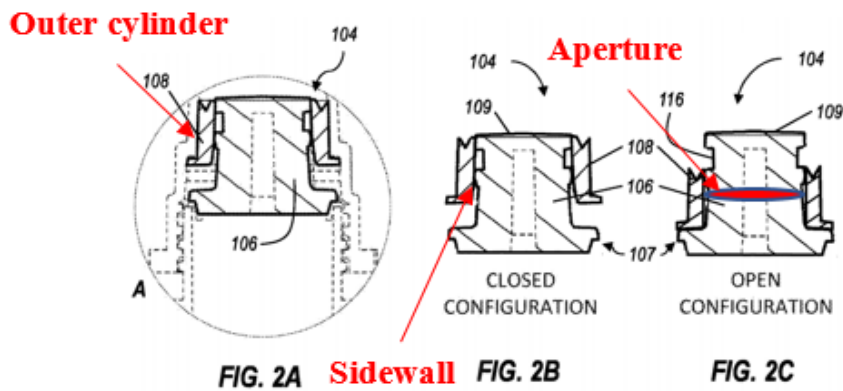
27 64. The Spectrum Product includes a moveable annular valve. The
28 packaging for the SDNA-1000 product includes the words “patent pending.”

1 Figures 1-5 below are engineering drawings from U.S. Patent Publication No.
 2 2020/0397418A1, which appears to correspond to the Spectrum SDNA-1000 and
 3 SDNA-2000 products. Figures 1-5 further illustrate how the elements in the
 4 Spectrum Product correspond to claim limitations (iii.a)-(iii.e):

5
 6 **Figure 1:**



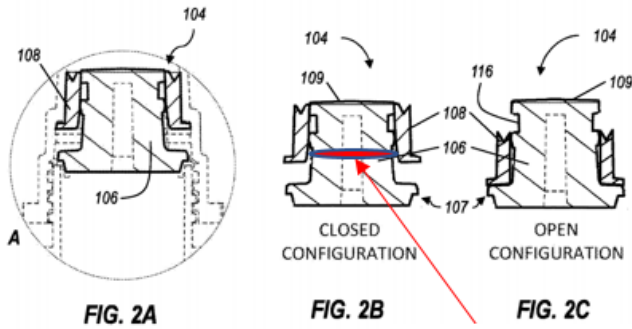
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 15 **Figure 2:**



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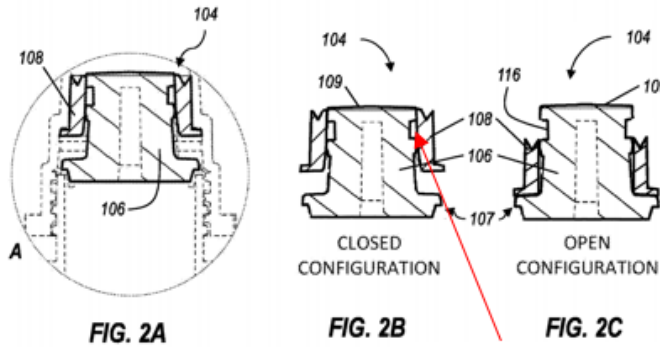
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Figure 3:



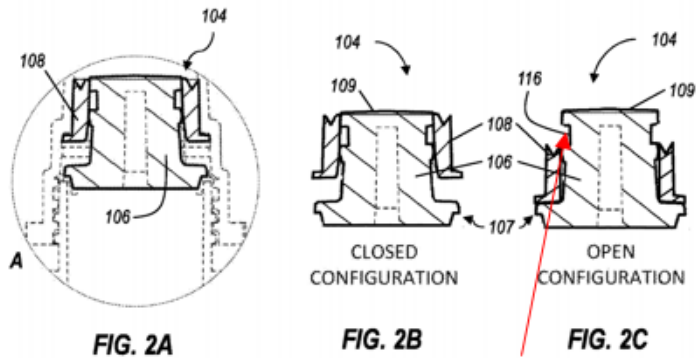
**Aperture
accommodates
inner cylinder**

Figure 4:



**Interior sidewall
obstructs vents**

Figure 5:



**Interior sidewall
does not obstruct
vent**

1 (d) A declaration that this case is exceptional under 35 U.S.C. § 285,
2 and/or other applicable authority;

3 (e) An award of DNA Genotek’s costs and attorneys’ fees incurred in
4 connection with this action, under 35 U.S.C. § 285, and other applicable authority;

5 (f) An award of pre-judgment interest; and

6 (g) Such other and further relief as this Court deems just and proper.

7 **DEMAND FOR JURY TRIAL**

8 DNA Genotek hereby demands trial by jury on all issues so triable.
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12 Dated: August 4, 2021

MORRISON & FOERSTER LLP

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15 By: /s/ Brian M. Kramer
16 Brian M. Kramer
BMKramer@mofo.com

17 Attorney for Plaintiff
18 DNA GENOTEK INC.
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CERTIFICATE OF SERVICE

I hereby certify that on August 4, 2021, a copy of the foregoing document was filed electronically with the Clerk of the Court using the Court’s CM/ECF electronic filing system, which will send an electronic copy of this filing to all counsel of record.

/s/ Brian M. Kramer
Brian M. Kramer