

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

DNA GENOTEK INC.,)	
)	
Plaintiff,)	REDACTED - PUBLIC VERSION
)	
v.)	C.A. No. 15-661-SLR
)	
SPECTRUM DNA; SPECTRUM SOLUTIONS)	JURY TRIAL DEMANDED
L.L.C.; and SPECTRUM PACKAGING L.L.C.,)	
)	
Defendants.)	
)	

FIRST AMENDED COMPLAINT

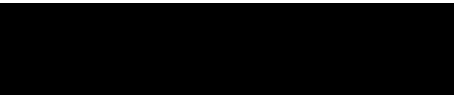
OF COUNSEL:
David C. Doyle
Brian M. Kramer
John R. Lanham
Dean S. Atyia
MORRISON FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, CA 92130
(858) 314-5415

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
300 Delaware Avenue, Suite 1120
SHAW KELLER LLP
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
Attorneys for Plaintiff

Dated: January 22, 2016

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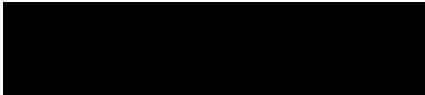
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FIRST AMENDED COMPLAINT

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

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 8,221,381 B2 (“the ’381 patent”) (attached as Exhibit A hereto), false designation of origin, and false advertising.

PARTIES

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

3. Upon information and belief, Defendants Spectrum DNA, Spectrum Solutions L.L.C., and Spectrum Packaging, L.L.C. (collectively “Spectrum”) are Utah limited liability companies with their principal place of business in Draper, Utah.

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over Spectrum because it has purposefully availed itself of the privileges and benefits of the laws of the State of Delaware. Upon information and belief, Spectrum, its agents, subsidiaries, employees, and/or affiliates sell products in Delaware and ship products to Delaware that infringe the '381 Patent. Spectrum maintains at least two websites. It registered the domain name, www.spectrum-dna.com, on July 28, 2015. Spectrum also hired a marketing company that launched an additional website, through which Spectrum markets its DNA collection devices throughout the United States, including Delaware. On information and belief, before July 28, 2015, Spectrum concealed its making, using, selling, and offering for sale of the Spectrum product from DNA Genotek and much of the public. Spectrum, its agents, subsidiaries, employees, and/or affiliates target customers with ties to Delaware through at least one of their websites, which describes Spectrum as a company responding to a need "in the DNA space calling for an innovative saliva DNA collection device" and offering "an innovative device that is user friendly and produces excellent clinical results."

6. Upon information and belief, Defendant Spectrum Solutions L.L.C. manufactures a least one DNA saliva collection device that infringes the '381 Patent. Infringing products include Spectrum Model No. SS-SAL-1. Upon information and belief, Defendant Spectrum DNA sells and offers to sell DNA saliva collection devices that infringe the '381 Patent. Upon information and belief, Defendant Spectrum Packaging L.L.C. assembles and sells DNA saliva

collection devices that are shipped in interstate commerce, including to Delaware, and that infringe the '381 Patent.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

FACTUAL BACKGROUND

8. DNA Genotek is a leading provider of products for biological sample collection, including oral fluid sample collection and stabilization solutions for molecular applications. DNA Genotek has revolutionized the nucleic acid (DNA and RNA) collection market with products that provide substantial advantages over traditional methods of biological sample collection. DNA Genotek's products incorporate proprietary technology that is protected by a robust patent estate.

9. DNA Genotek developed and patented its proprietary saliva DNA collection kits ("DNA Genotek Saliva Collection Products"). DNA Genotek sells the DNA Genotek Saliva Collection Products to customers and distributors worldwide.

10. DNA Genotek is the owner by assignment of all right, title, and interest in and to United States Patent No. 8,221,381 B2 ("the '381 Patent"), entitled "Container System for Releasably Storing a Substance," which duly and legally issued to DNA Genotek, as assignee of Rod Muir, Derek Kirkland, Ian Curry, Roy Sunstrum, Paul Lem, and H. Chaim Birnboim, on July 17, 2012.

11. DNA Genotek filed suit against Ancestry.com DNA, LLC ("Ancestry") in this District, alleging patent infringement, among other claims, because Ancestry offers for sale, sells, markets, and distributes a saliva collection device (the "Ancestry Product") that infringes the '381 Patent. Ancestry is a Delaware corporation that offers DNA testing services to customers researching their ethnic and family histories. Ancestry customers receive in the mail a DNA saliva collection kit and a return envelope to send the collection kit to a lab for DNA

testing. After the testing, Ancestry sends the customer information about the customer's ethnicity and relatives.

12. DNA Genotek has learned that the Ancestry Product is also made, used, offered for sale, marketed, distributed, and/or imported by Spectrum. Upon information and belief, Spectrum also makes, uses, offers for sale, markets, distributes, and/or imports products other than the Ancestry Product that infringe the '381 Patent, including the Spectrum Saliva Collection Kit (the "Spectrum Product").

13. Spectrum has been and is now infringing on one or more claims of the '381 Patent.

14. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product and/or the Spectrum Product.

15. Spectrum is infringing the '381 Patent, either literally or by the doctrine of equivalents.

16. Spectrum was aware of the '381 Patent when engaging in these knowing and purposeful activities and was aware that the making, using, selling, or offering for sale of the Ancestry Product or services incorporating the Ancestry Product constituted an act of infringement of the '381 Patent.

17. Spectrum was aware of the '381 Patent when engaging in these knowing and purposeful activities and was aware that the making, using, selling, or offering for sale of the Spectrum Product or services incorporating the Spectrum Product constituted an act of infringement of the '381 Patent.

18. Spectrum has been aware of the '381 Patent and the applications leading to the publication of the '381 Patent since at least November 14, 2014. The Spectrum Product is an embodiment of a DNA saliva collection device depicted in PCT Patent Application No. WO 2015/017710 A1 (the "'701 Application"), entitled "Sample Collection Device," which was filed on July 31, 2014. On November 14, 2014, the patent office reviewing the '701 Application indicated that the device claimed in the '701 Application would be "easily conceived from the disclosure" two prior art references, including U.S. Patent Application Publication No. 20090216213 (the "'213 Application"). The '213 Application ultimately issued as the '381 Patent.

19. Ancestry is the owner by assignment of the '701 Application. The '701 Application lists Federico Gaeta as an inventor. Federico Gaeta has been employed, at least as a consultant, by both Ancestry, a Delaware corporation, and Spectrum.

20. Federico Gaeta is listed on the Spectrum website in conjunction with the development and production of the infringing Ancestry Product and/or the Spectrum Product.

21. Upon information and belief, Spectrum decided to make the infringing Ancestry Product and/or the infringing Spectrum Product after partnering with Ancestry, Spectrum's largest genotyping customer.

22. The Spectrum website indicates that the Ancestry Product and/or the Spectrum Product are labelled as "Patent Pending." The pending application that encompasses the embodiments of the Ancestry Product and/or the Spectrum Product is the '701 Application.

23. The Spectrum website includes a customer testimonial from an Ancestry employee and inventor listed on the '701 Application praising the company for its assistance in

making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product, which is offered for sale and sold in Delaware.

24. On its website, Spectrum claims to have “[c]omplete fulfillment capabilities,” including “[d]irect shipping” to customers. Examples of products shipped to the District of Delaware described on Spectrum’s website include this device:



This is another example of the Spectrum Product described on Spectrum’s website:



25. Spectrum's website identifies the Ancestry Product as one such product that it manufactures, sells, and ships. Upon information and belief, Spectrum offers for sale and/or ships the Ancestry Product and/or the Spectrum Product to customers throughout the country, including those located in or residing in Delaware.

26. Upon information and belief, apart from its sales of the Ancestry Product and/or the Spectrum Product to individuals throughout the country, including Delaware, Spectrum has offered for sale the Ancestry Product and/or the Spectrum Product to a least one other Delaware Corporation besides Ancestry, namely Complete Genomics Incorporated.

27. The Spectrum Product comprises a cap, funnel, and collection tube. It is packaged in a plastic tray and covered by a label. Each component of the Spectrum Product is [REDACTED], not the United States of America.

28. Spectrum DNA's website includes, among other advertising, a marketing sheet. The marketing sheet depicts the Spectrum Product's components parts, including the cap, funnel, and collection tube. The marketing sheet says "Manufactured by Spectrum Solutions 801-569-0465. This kit is designed for the collection of human saliva samples. Made in USA. Patent Pending."



Manufactured by Spectrum Solutions 801-569-0465. This kit is designed for the collection of human saliva samples. Made in USA, Patent Pending.

www.Spectrum-DNA.com

29. The package label of the Spectrum Product appears throughout the website. The label states that the product is “Made in USA.” Additionally, throughout Spectrum’s website, it states that the product is “Made in USA.” Nowhere does it correct or clarify that the product is actually [REDACTED]. Spectrum’s use of the phrase “Made in USA” throughout its website constitutes commercial speech that, on information and belief, is intended to positively influence public perception of the Spectrum Product.



30. Spectrum reviewed and approved the content of its product label, including the use of the words “Made in USA.” Spectrum’s use of the phrase “Made in USA” on its product label constitutes commercial speech that, on information and belief, is intended to positively influence public perception of the Spectrum Product.

31. In addition to being literally false, Spectrum’s claim that the Spectrum Product is “Made in USA” is misleading and, upon information and belief, has either deceived or has the capacity to deceive a substantial segment of potential customers. Upon information and belief, individuals are more likely to purchase Spectrum’s Products after seeing Spectrum’s false designation of origin and false advertising instead of competing products that do not advertise as “Made in USA.”

32. Upon information and belief, Spectrum also provides potential bulk customers with product samples that include the false claim “Made in USA.”

33. DNA Genotek’s competing DNA Genotek Saliva Collection Products are manufactured in Canada. DNA Genotek does not advertise its products as “Made in USA.” Spectrum’s false and misleading statements have caused and threaten to cause DNA Genotek competitive or commercial injury, including but not limited to DNA Genotek’s ability to compete with Spectrum and to the overall opinion of the DNA Genotek products held by customers and potential customers.

COUNT I – INFRINGEMENT OF THE ’381 PATENT

34. DNA Genotek restates and incorporates by reference paragraphs 1-33, as if fully set forth herein.

35. Spectrum has been and is now infringing one or more claims of the ’381 patent, either literally or by the doctrine of equivalents.

36. Spectrum's infringing activities include making, using, offering for sale, selling, marketing, distributing, and/or importing products that infringe one or more claims of the '381 Patent.

37. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Ancestry Product or services incorporating the Ancestry Product.

38. Spectrum infringes the '381 Patent at least by making, using, offering for sale, selling, marketing, distributing, and/or importing the Spectrum Product or services incorporating the Spectrum Product.

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

40. As a result of Spectrum's infringement of the '381 Patent, DNA Genotek has been and will be damaged, and DNA Genotek is entitled to be compensated for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial, but in no event less than a reasonable royalty.

41. Upon information and belief, Spectrum's infringement of the '381 Patent has been and continues to be willful and deliberate.

42. DNA Genotek has complied with any statutory requirement for placing a notice of its patents on its products, including but not limited to its Oragene•DNA®, Oragene•DISCOVER®, and Oragene•Dx® branded saliva collection kits.

43. Upon information and belief, Spectrum's infringement of the '381 Patent will continue unless enjoined by this Court. As a result of Spectrum's infringement, DNA Genotek has suffered and will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, DNA Genotek is entitled to injunctive relief against such infringement.

44. As a result of Spectrum's infringement, DNA Genotek has suffered and will continue to suffer significant damages.

COUNT II – FALSE DESIGNATION OF ORIGIN

(Lanham Act, 15 U.S.C. § 1125, et. seq.)

45. DNA Genotek restates and incorporates by reference paragraphs 1-44, as if fully set forth herein.

46. The Spectrum Product is sold nationwide in interstate commerce.

47. Spectrum also offers the Spectrum Product for sale from the United States to customers outside the United States.

48. Spectrum designates the geographic origin of the Spectrum Product as the United States by claiming that the Spectrum Product is "Made in USA." Spectrum's designation of the Spectrum Product as "Made in USA" was knowing and willful.

49. Spectrum's designation of the United States as the geographic origin of the Spectrum Product is literally false because the Spectrum Product is actually [REDACTED]

[REDACTED].

50. Spectrum's false designation of origin is likely to confuse and deceive consumers as to the actual origin of the Spectrum Product.

51. Spectrum's false designation is material because it concerns aspects of the Spectrum Product that are essential to customers' purchasing decisions.

52. As a result of Spectrum's false designation, DNA Genotek has been harmed and believes it is likely to be harmed further. The harm caused to DNA Genotek by Spectrum's false designation of origin cannot be compensated by money damages alone.

53. Spectrum's false designation of origin entitles DNA Genotek to treble damages, disgorgement of Spectrum's profits, injunctive relief, marketplace damages, and attorneys' fees.

COUNT III – FALSE ADVERTISING

(Lanham Act, 15 U.S.C. § 1125, et. seq.)

54. DNA Genotek restates and incorporates by reference paragraphs 1-53, as if fully set forth herein.

55. The Spectrum Product is sold nationwide in interstate commerce.

56. Spectrum also offers the Spectrum Product for sale from the United States to customers outside the United States.

57. Spectrum advertises, promotes, and labels the Spectrum Product as “Made in USA.” Spectrum labeling of the Spectrum Product as “Made in USA” was knowing and willful. Spectrum’s knowingly and willfully advertises the Spectrum Product as “Made in USA” on its website.

58. Spectrum’s claim that the Spectrum Product is “Made in USA” is literally false because the Spectrum Product is actually [REDACTED].

59. Spectrum’s claim that the Spectrum Product is “Made in USA” is also misleading and, upon information and belief, has either deceived or has the capacity to deceive a substantial segment of potential customers.

60. As a result of Spectrum’s false advertising, DNA Genotek has been harmed and believes it is likely to be harmed further.

61. The harm caused to DNA Genotek by Spectrum’s false advertising cannot be compensated by money damages alone.

62. Spectrum’s marketing materials designating the Spectrum Product as made in the U.S.A. constitute advertising and promotion. Spectrum’s labelling of the Spectrum Product as made in the U.S.A. constitutes advertising and promotion.

63. Spectrum's false advertising entitles DNA Genotek to treble damages, disgorgement of Spectrum's profits, injunctive relief, marketplace damages, and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, DNA Genotek respectfully requests the following relief:

- (a) Entry of judgment that Spectrum has infringed the '381 patent;
- (b) Preliminary and permanent injunctive relief enjoining Spectrum, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with them, from directly or indirectly infringing the '381 patent;
- (c) An award of damages adequate to compensate DNA Genotek for Spectrum's infringement of the '381 patent;
- (d) An award of increased damages, under 35 U.S.C. § 284, in an amount three times the actual damages awarded to DNA Genotek, by reason of Spectrum's willful infringement of the '381 patent;
- (e) A declaration that this case is exceptional under 35 U.S.C. § 285, 15 U.S.C. § 1117, and/or other applicable authority;
- (f) An award of DNA Genotek's costs and attorneys' fees incurred in connection with this action, under 35 U.S.C. § 285, 15 U.S.C. § 1117, and other applicable authority;
- (g) Preliminary and permanent injunctive relief enjoining Spectrum, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with them, from falsely labeling and advertising products as made in the United States, or otherwise designating the origin of the Spectrum Product as the United States;
- (h) An award of damages adequate to compensate DNA Genotek for Spectrum's Lanham Act violations;
- (i) An award of Spectrum's profits;

- (j) A trebling of damages pursuant to 15 U.S.C. § 1117(a);
- (k) An award of pre-judgment interest; and
- (l) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

DNA Genotek hereby demands trial by jury on all issues so triable.

OF COUNSEL:
David C. Doyle
Brian M. Kramer
MORRISON FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, CA 92130
(858) 314-5415

/s/ Karen E. Keller

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
300 Delaware Avenue, Suite 1120
SHAW KELLER LLP
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com

Attorneys for Plaintiff

Dated: January 22, 2016

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on January 22, 2016, this document was served on the persons listed below in the manner indicated:

BY E-MAIL

David E. Moore
Stephanie E. O'Byrne
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000
dmoore@potteranderson.com
sobyrne@potteranderson.com

Michael J. Sacksteder
FENWICK & WEST LLP
555 California Street
San Francisco, CA 94104
(415) 875-2300
msacksteder@fenwick.com

Melanie L. Mayer
FENWICK & WEST LLP
1191 Second Avenue
Seattle, WA 98101
(206) 389-4510
mmayer@fenwick.com

/s/ Karen E. Keller

Karen E. Keller (No. 4489)
300 Delaware Avenue, Suite 1120
SHAW KELLER LLP
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
Attorneys for Plaintiff