

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

COPAN ITALIA S.P.A., and
COPAN DIAGNOSTICS, INC.,

Plaintiffs,

V.

PURITAN MEDICAL PRODUCTS
COMPANY LLC and
PURITAN DIAGNOSTICS LLC,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

**COPAN ITALIA S.P.A. AND COPAN DIAGNOSTICS, INC.'S
COMPLAINT FOR UNFAIR COMPETITION AND PATENT INFRINGEMENT**

Plaintiffs Copan Italia S.p.A. and Copan Diagnostics, Inc. (together, “Copan”), by and through the undersigned counsel, bring this action for unfair competition against Defendants Puritan Medical Products Company LLC and Puritan Diagnostics LLC (together, “Puritan” or “Defendant Puritan”). In addition, Plaintiff Copan Italia S.p.A., by and through the undersigned counsel, brings this action for patent infringement against Defendants Puritan Medical Products Company LLC and Puritan Diagnostics LLC (together, “Puritan” or “Defendant Puritan”).

Copan alleges as follows:

THE PARTIES

1. Plaintiff Copan Italia S.p.A. is a public company organized under the laws of Italy, having an address of Via F. Perotti 10, 25125, Brescia, Italy.
2. Plaintiff Copan Diagnostics, Inc., a New York corporation, is headquartered at 26055 Jefferson Avenue, Murrieta, California 92562.

3. Copan concentrates its business on making swabs for collecting and transporting biological samples for analysis.

4. Copan Italia S.p.A is the owner of U.S. Patent No. 8,114,027 (“the ’027 Patent”) (attached as Ex. 1), U.S. Patent No. 8,317,728 (“the ’728 Patent”) (attached as Ex. 2), U.S. Patent No. 8,979,784 (“the ’784 Patent”) (attached as Ex. 3), U.S. Patent No. 9,011,358 (“the ’358 Patent”) (attached as Ex. 4), and U.S. Patent No. 9,173,779 (“the ’779 Patent”) (attached as Ex. 5) (collectively the “Asserted Patents”).

5. Defendant Puritan Medical Products Company LLC is a Maine limited liability company having corporate, sales, and administrative offices at 30 Danforth Street, Portland, Maine 04101, and a principal place of business at 31 School Street, Guilford, Maine 04443.

6. Defendant Puritan Diagnostics LLC is a Maine limited liability company, and is an affiliate of Puritan Medical Products Company LLC, with offices in Guilford, Maine.

JURISDICTION AND VENUE

7. This is an action for unfair competition arising under the Lanham Act, 15 U.S.C. § 1125(a), the Maine Uniform Deceptive Trade Practices Act, 10 M.R.S.A. §§ 1211 et seq., and patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271 et seq.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1367(a).

9. This Court has personal jurisdiction over Puritan because Puritan is incorporated in the State of Maine, and Puritan conducts business within the State of Maine, and has committed acts of unfair competition (including deceptive trade practices), and patent infringement, within the State of Maine.

10. Venue is proper in the District of Maine under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), as Puritan maintains a regular and established place of business in this District and is

subject to this Court's personal jurisdiction, and a substantial part of the events giving rise to Copan's unfair competition (including deceptive trade practices) and patent infringement claims occur and have occurred in this District.

11. Puritan, directly and/or through distributors or resellers, makes, sells, and offers for sale its infringing flocked swab products, and uses its flocked swab products in an infringing manner in this District, and has made, sold, and offered to sell its infringing flocked swab products, and has used its flocked swab products in an infringing manner in this District.

12. Puritan purposefully directs the use of the claimed methods of the Asserted Patents in this District, and purposefully directs sales and offers for sale of its infringing flocked swab products toward this District, and/or purposefully directs the manufacture of its infringing flocked swab products in this District.

GENERAL ALLEGATIONS

Background on Copan and Its Invention of Flocked Swabs

13. Copan—named for “Collection and Preservation for ANalysis”—was founded in 1979 by the late Giorgio Triva, in Mantua, Italy. Beginning as a distribution company for laboratory products, Copan shortly thereafter became a manufacturer of its own lab products, such as plastic pipets.

14. In 1982, Giorgio Triva's son, Daniele Triva, a chemical engineer specializing in biotechnology processing, became a General Manager at Copan. Daniele Triva worked closely with his father to redefine Copan's operational structure, and to move Copan towards new technological innovations in preanalytics.

15. Copan continues to be owned and managed by the Triva Family, under the leadership of Stefania Triva.

16. In the late 1990s, microbiology saw a resurgence of interest in preanalytic specimen collection and transport devices, particularly in swabs for collecting biological samples.

17. Despite the similarity in appearance in swabs and swab transport systems, their performance can vary drastically.

18. Throughout the 1990s, Copan worked with the microbiology community to advocate for new protocols for testing, measuring, and comparing swab transport systems' performances.

19. In 2003, Copan and microbiology leaders developed international published standards for transport swabs. These new standards—the Clinical and Laboratory Standards Institute's M40-A standards—created new performance benchmarks for swab collection and transport systems manufacturers.

20. In the early 2000s, Copan's Daniele Triva had a breakthrough idea for a type of swab that would outperform state-of the-art fiber swabs available at the time. Daniele Triva invented flocked swabs for use in collecting and transporting biological specimens. In the context of preanalytic specimen collection and transport devices, "flocking" is the process in which short fibers or fiber particles are deposited onto the tip of a swab's rod to create a flocked layer around the tip of the swab.

21. In 2003, through its extensive research and development efforts, Copan invented the industry's first-ever "flocked" swabs for collection and transport of biological specimens, and Defendant Puritan agrees. According to Puritan "[f]locked swabs first hit the market when Copan released FLOQSwabsTM (made with nylon fibers) in 2003." Puritan Blog Post,

“HydraFlock: The Superior Flocked Swab” at 1 (Mar. 27, 2017) (“March 27th Blog Post”), available at <https://blog.puritanmedproducts.com/why-hydaflock-is-superior-flocked-swab>.

22. Flocked swabs were revolutionary in the industry for collecting and transporting biological specimens, and Defendant Puritan agrees. According to Puritan, “[t]here’s no question that flocked swabs have revolutionized specimen collection.” March 27th Blog Post.

23. Before Daniele Triva invented flocked swabs for collecting biological specimens, fiber swabs consisted of a rod with fibers wrapped around the tip, such as on a Q-tip®.

24. Copan’s flocked swabs are different. Copan’s patented flocked swabs are made by electrostatically depositing and adhering many small fiber particles onto the tip of a swab.

25. The image below from a 2007 Copan brochure provides a visual comparison of a traditional fiber swab (on the left) and a flocked swab (on the right):



26. Traditional fiber swabs absorb biological samples inside a wad of fiber, where the sample stays entrapped.

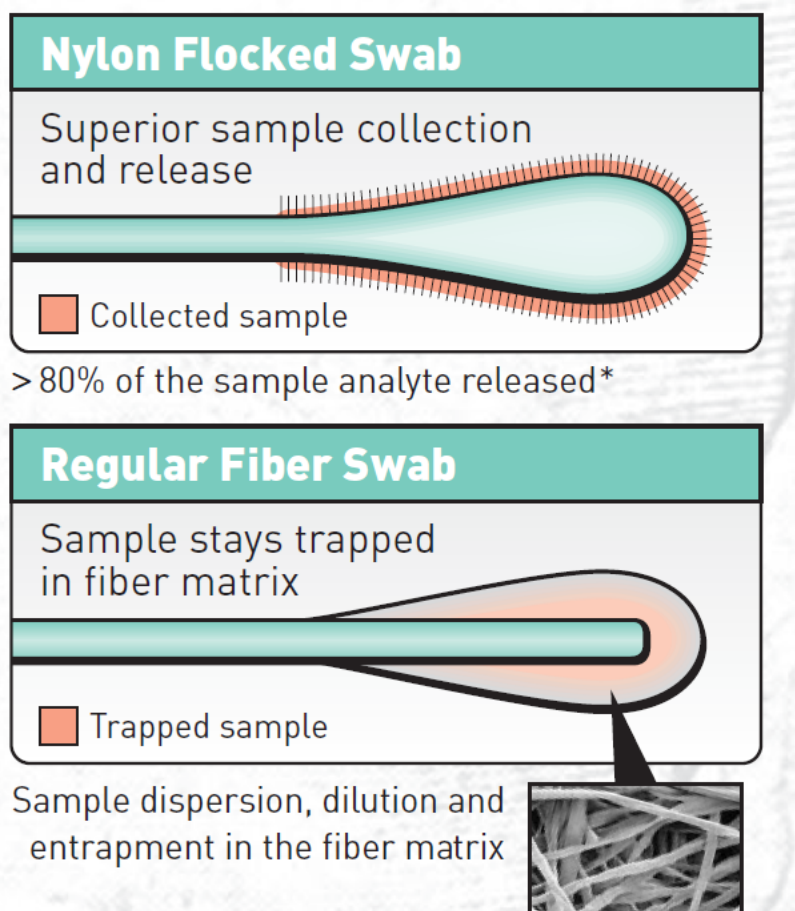
27. Flocked swabs use fibers that are electrostatically deposited onto a shaped tip of the rod, and the biological sample can be quickly collected (absorbed) between the fibers, and then released (eluted). The flocked swab's arrangement of fibers creates capillary action between the fibers to facilitate hydraulic uptake of the liquid biological sample.

28. Copan's flocked swab innovation significantly improved performance in the release step, and in transport.

29. Releasing samples from traditional swabs required the rod and tip to be used like a pen, pressing onto a surface for release of the sample. The "closed" structure of traditional swabs created by the wrapped fiber did not allow for an easy and full release of the sample. The release step of traditional swabs sometimes involved lab technicians "shaving" the fibers off the traditional swabs to release more specimen for the test.

30. In flocked swabs, the sample stays close to the surface of the fibers during transport, and the flocked fibers allow for rapid and almost complete elution of the biological sample for analysis.

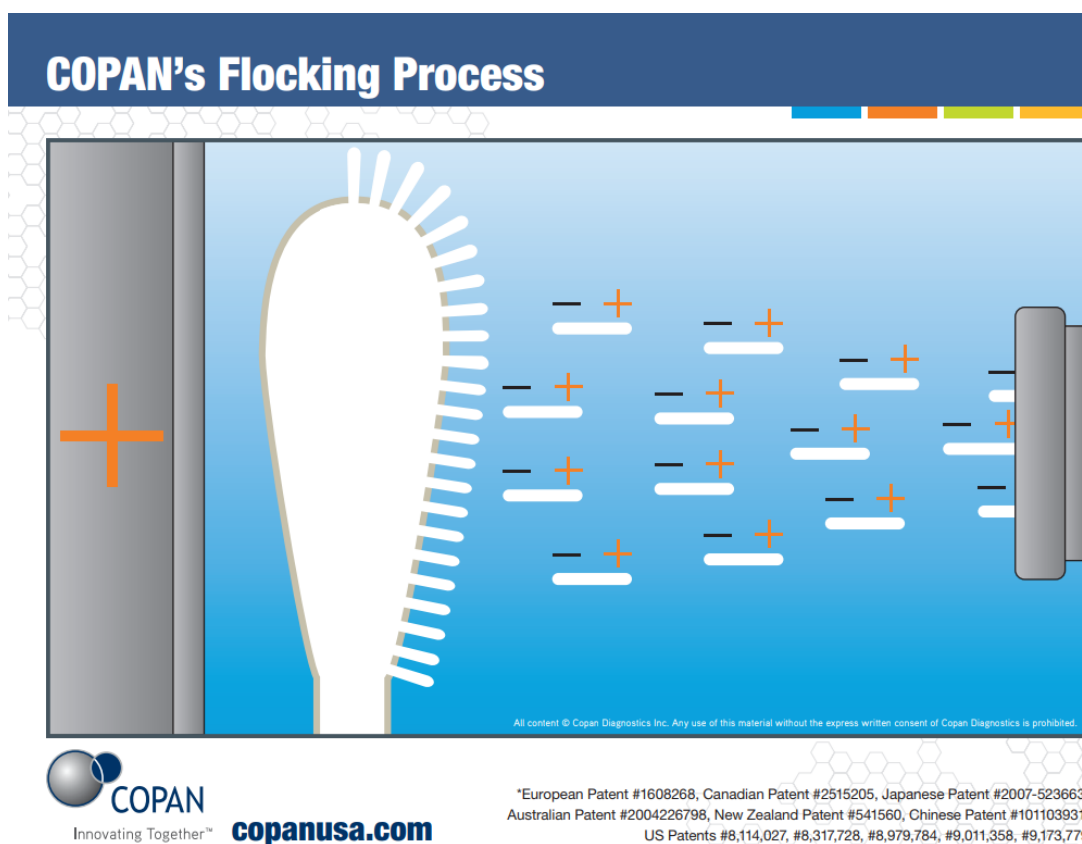
31. The image below from a Copan brochure provides another visual comparison of a traditional fiber swab (on the bottom) and a flocked swab (on the top):



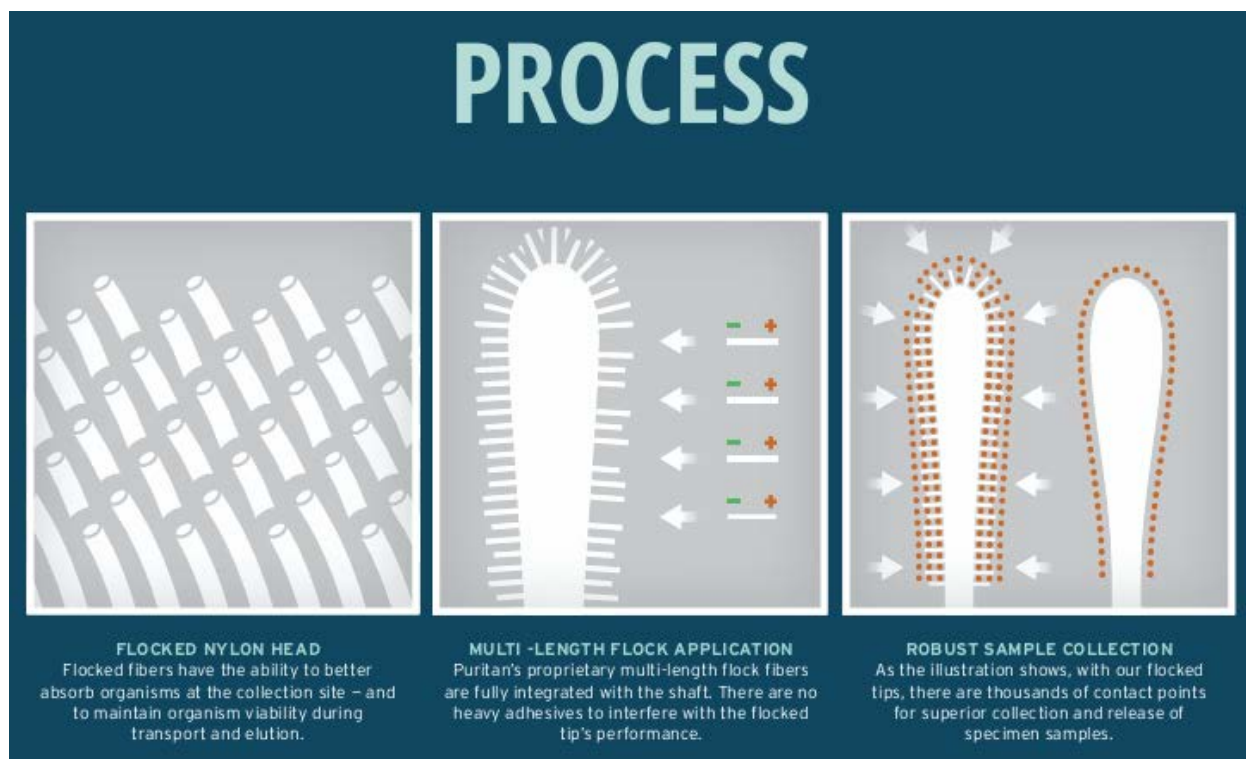
32. Copan’s patented flocked swabs, FLOQSwabs®, comprise of a rod with a tip that can vary in size and shape for different applications and uses, such as nasal or oral swabs for use in virology, or swabs for use in crime scene forensics.

33. Flocking is achieved through an electrostatic flocking process, in which the short fibers are electrically charged and oriented, and propelled by an electrostatic field onto the tip of the swab, so that the fibers are attached to the tip of the rod, and create a flocked layer. *See, e.g., “Copan’s Flocking Process,” available at http://cdn2.copanusa.com/files/9914/4986/2620/Copan_Flocking_Process.pdf.*

34. In the electrostatic flocking process, the swab with adhesive on its tip is inserted in the electrostatic field. A schematic visualization of this process is depicted below:



35. Puritan acknowledges that it employs the same electrostatic flocking process, as depicted in one of Puritan's brochures (which is presently available for download from Puritan's website, entitled "Access Our Flocked Swabs Portal" at <https://info.puritanmedproducts.com/get-all-the-info-you-need-about-puritan-flocked-swabs-0-0?hsCtaTracking=d852c48e-99cf-41e9-a855-d4b0c7d7995c%7Cde70dac2-a821-4dc9-8f71-f9dcda192180>):



Puritan Infographic, “Why Flock?” (2013).

36. Since Copan invented flocked swabs for collecting biological samples, medical professionals and laboratories around the world have switched to flocked swabs because of their benefits, and numerous scientists, organizations, and scientific publications have recognized the superiority of Copan’s flocked swabs. This has occurred despite the higher cost of flocked swabs compared to traditional swabs. *See, e.g.,* Detailed Description of National Institutes of Health’s United States National Library of Medicine (NLM) Clinical Study, “A Comparison of Cotton and Flocked Swabs for Vaginal Self Collection,” posted May 27, 2016, *available at* <https://clinicaltrials.gov/ct2/show/study/NCT02785289> (“While the recent cheap cotton swabs have traditionally been used for deoxyribonucleic acid (DNA) detection, recent studies have questioned their efficacy by reporting the superiority of the more expensive flocked swabs.”).

37. In an article authored in 2005 for the Journal of Clinical Microbiology, the authors concluded that “[t]he use of new flocked swabs, compared to kit swabs, enhanced the

ability of three commercial nucleic acid amplification tests to detect low levels of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* nucleic acids[.]” Chernesky et al., “Use of Flocked Swabs and a Universal Transport Medium To Enhance Molecular Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*,” J. Clin. Microbiol., Vol. 44, No. 3, 1084-86 at 1084 (Mar. 2006).

38. In 2006, scientists for Applied Biosystems conducted a study “designed to evaluate the performance of Copan Forensic Flocked Swab, cotton swab and a swab from other manufacturers for efficiency of collection and recovery of DNA” and concluded that “[f]locked swabs (Copan) exhibited, in general, best performance in terms of collection of sample and recovery of DNA from the swab.” Brevnov, M., “Benchmarking of Applicators,” Applied Biosystems, at 2, 11 (Dec. 13, 2006).

39. In 2008, scientists for the PDA Journal of Pharmaceutical Science and Technology published an article concluding that “[r]ecovery of microorganisms obtained from flocked swabs was on average approximately 60%. . . , while recovery from rayon swabs was approximately 20%[.]” Dalmaso, et al., “Qualification of High-Recovery, Flocked Swabs as Compared to Traditional Rayon Swabs for Microbiological Environmental Monitoring of Surfaces,” PDA J. Pharm. Sci. and Tech., Vol. 62 at 191-99 (2008). Two of the authors for this article were Copan scientists. This article received the 2008 Frederick D. Simon Award for Best Paper Published in the PDA Journal of Pharmaceutical Science and Technology.

40. In 2009, scientists for the Forensic Science International journal published a vaginal sampling study comparing traditional cotton swabs with Copan’s nylon flocked swabs. The study concluded that “[t]he cell elutions from the nylon flocked swabs contained a higher number and more intact cells, which facilitates microscopic examination and made [laser

microdissection] LMD more successful” and that “flocked swabs were found to improve vaginal sampling and hold promise to advance DNA typing in sexual assault cases.” C.C.G. Benschop, et al., “Post-coital vaginal sampling with nylon flocked swabs improves DNA typing,” *Forensic Sci. Int. Genet.* (2009).

41. In 2009, during the H1N1 influenza virus (swine flu) pandemic, the American Society for Microbiology presented a poster on testing patients for the H1N1 virus. “ASM’s Interim Algorithm for Guidance in Testing of Patients with Respiratory Illness for Influenza A (including Novel H1N1),” American Society for Microbiology (Sept. 2009) *available at* https://www.asm.org/division/c/documents/FLU_ASM_Algorithm_10-05-09.pdf. The authors noted that “NP flocked swabs collect better samples than routine np swabs.”

42. The United States Department of Health and Human Services’ Centers for Disease Control and Prevention (CDC) has also recommended flocked swabs, as opposed to traditional cotton swabs. For example, with respect to oral or buccal swab samples in testing for mumps, the CDC states that “[f]locked synthetic swabs appear to be more absorbent and elute samples more efficiently.” CDC website, “Laboratory Testing for Mumps Infection, Specimen Collection, Storage, and Shipment,” *available at* <https://www.cdc.gov/mumps/lab/specimen-collect.html> (last accessed May 30, 2018).

43. Copan’s invention of flocked swabs has also opened the door for Copan’s ESwab®, Liquid Based Microbiology, an innovation in automation used in bacteriology culture diagnostic techniques.

44. In 2007, as part of a collaborative automation project, the Copan team bolted two robots onto a microbiology lab bench, and invited feedback and suggestions from microbiologists and bench technologists. Less than one year later, taking advantage of and

building upon its flocked swabs, Copan launched WASP®—“Walk-Away Specimen Processor”—the first automated specimen processor in its class, allowing for automated specimen processing and multiple tests from the same specimen.

45. In 2011, Copan launched full lab automation for the microbiology laboratory with WASPLab®.

46. Copan actively manufactures, markets and sells its flocked swabs to this day, selling to a customer base Copan has built in the thirteen years since introducing flocked swabs to the market.

47. In this specialized field created by Copan’s innovation of flocked swabs, Copan is a leading developer and producer, producing up to 720,000 flocked swabs a day, with a production capacity of over 100 million flocked swabs annually.

48. Since 2003, Copan has made a substantial investment in its flocked swab technology, including dedicating significant resources to the research, development and manufacturing of flocked swabs, and maintaining facilities around the world, including in Italy and in the United States.

49. Copan Italia S.p.A has received patents in the United States protecting its innovation in flocked swabs. *See, e.g.*, Exs. 1 through 5.

Background on Puritan and Its Entry into the Flocked Swabs Market

50. Puritan is a direct competitor of Copan in the field of preanalytical swabs and transport medium.

51. Puritan began as a manufacturer of toothpicks and wooden tongue depressors, eventually making cotton tipped swabs.

52. Whereas Copan first developed its flocked swab technology in 2003, Puritan began manufacturing and selling flocked swabs around 2010-2011.

53. Medical Wire & Equipment Co, Ltd. (“MWE”) is a distributor for Puritan in the European market.

54. In 2008, before Puritan entered the flocked swabs market, Puritan’s distributor MWE criticized flocked swabs, indicating that, while they may be shown to give excellent release for colored dyes, there has not been a showing that flocked swabs give excellent release for biological samples. Moreover, MWE suggested that flocked swabs may even cause lung disease:

There has recently been interest in ‘flocked swabs’ where the bud is formed by small nylon fibres glued to a shaped plastic stick. These have the advantage of providing a large surface area for bacterial attachment, and can be shown to give excellent release of coloured dyes taken on to the bud in demonstrations. But bacteria are not coloured dyes! Unfortunately some are rather more sticky and actual release can be less than predicted. There have also been reports of lung disease attributed to flock fibres.

MWE website, “A swab is a swab?” (Feb. 2008), *available at*

http://www.mwe.co.uk/modules/downloadable_files/assets/a-swab-is-a-swab.pdf.

55. Before the 2009 swine flu pandemic, Puritan tried to promote the idea that Puritan’s foam swabs were equal to, or better than, flocked swabs. Puritan Press Release, “Study Shows Puritan’s Foam Swabs Provide Superior Influenza Detection,” *available at* <https://www.puritanmedproducts.com/news-and-events/news/post/study-shows-puritans-foam-swabs-provide-superior-influenza-detection> (“A recent study conducted by Nationwide Children’s Hospital in Columbus, Ohio has concluded that Puritan’s foam swabs outperform flocked swabs for detecting influenza.”) (citing Mack, K. et al., “Clinical Performance of Foam vs. Flocked Swabs Collected from the Anterior Nares in a Rapid Antigen Test for Influenza A &

B,” Nationwide Children’s Hospital Poster, *available at* https://www.puritanmedproducts.com/pub/media/alliance/news/files/1948_LAB_Foam_vs_Flocked_poster-2.pdf).

56. Despite Puritan’s initial skepticism, and as shown on the timeline of its history on its website, in 2011, “Puritan’s patented line of high-performance flocked swabs debut[ed] on the market.” Puritan website, *available at* <https://www.puritanmedproducts.com/timeline>.

57. Puritan manufactures its flocked swabs in Guilford, Maine. Puritan sells its flocked swabs, such as Puritan’s HydraFlock® swab and PurFlock Ultra® swab, directly and through distributors in the United States and several European countries.

58. Puritan’s flocked swabs also feature rod tips covered in many small adhered fiber particles that have been deposited using electrostatic flocking (*see also* diagram at ¶ 35, above). Puritan advertises in publicly available documents that its swabs’ flocked features result in superior collection and release for analysis of biological samples compared to traditional spun fiber swabs.

59. Puritan directs users of its products to use its flocked swabs to collect biological specimens, for example, by instructing its end users to “[r]emove swab and collect specimen. Ensure the applicator tip only touches the suspected infectious area to minimize potential contamination.” Puritan Blog Post, “How to Use Flocked Swabs: HydraFlock® & PurFlock Ultra®,” *available at* <https://blog.puritanmedproducts.com/how-to-use-flocked-swabs-hydraflock-purflock-ultra>. In addition, Puritan describes in its product manuals for kits containing HydraFlock, such as for “Puritan® Fecal Opti-Swab® Collection and Transport System,” that the product “is intended for use in the collection and transport of clinical fecal and

rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.”

60. Puritan entered the flocked swab market fully aware of Copan’s patent portfolio on flocked swabs.

61. For example, on April 22, 2011, Copan’s counsel Romano Appoloni stated the following in a letter to Puritan Medical Products, Co. LLC:

Gentlemen,

Our firm represents the companies Copan Italia and Copan Innovation Ltd (IE), owner of the International Patent Application WO2004/086979 covering the pioneering technology for a flocked swab for collecting biological specimens.

A number of patents have been granted therefrom to Copan Innovation Ltd., including Canadian Patent No. CA2515205 granting exclusive patent rights to Copan in Canada on their pioneering flocked swab for collecting biological specimens.

Our clients are aware that your Company, Puritan Medical Products, is currently promoting and marketing in the Canadian market flocked swabs for collecting biological specimens under the marks *HydraFlock™*, *PurFlock™*, *UltraFlock™* swabs (hereinafter, Puritan swabs).

These Puritan Swabs appear to be the subject matter of patent applications in the name of Puritan, such as for instance EP 2263548 A2.

However, it is plain to see that, even if your patent application claims so called ‘*split sea-island bicomponent fibers*’, the Puritan swabs substantially amount to a flocked swab as claimed in CA2515205 by taking advantage of the same basic pioneering inventive concept of a flocked layer of fibers for a high absorption-release effect. . . .

62. On December 22, 2011, the day after Copan published a press release regarding the United States Patent and Trademark Office’s allowance of certain claims of one of Copan’s

U.S. patent applications (which later issued as U.S. Patent No. 8,114,027, one of the asserted patents in this action), Puritan published a responsive press release acknowledging the same:

[Copan's] press release is no doubt referring to U.S. patent application 10/543,873. On December 20, the patent examiner allowed certain claims in the application.

Puritan Press Release dated December 22, 2011, *available at*

<https://www.puritanmedproducts.com/assets/uploads/press-releases/PMP%20response%20to%20Copan%20flock%20patent%20rev-c.pdf>.

63. On December 23, 2011, Puritan, through its outside counsel, wrote a letter to Copan's Daniele Triva stating that "[w]e have reviewed all pending published patent applications assigned to Copan Italia S.P.A and Copan Innovation Limited." In the same letter, Puritan's counsel specifically identifies Copan's U.S. Patent Application No. 10/543,873.

64. In at least one instance, in or around January 2013, a Puritan customer service representative informed a potential customer located in Italy in an email that "[d]ue to Copan's patent on flock swabs, we cannot sell our products into Italy."

65. On March 8, 2016, after all patents asserted in this action had been issued, Puritan, through its counsel, sent a letter to David Skaug-Ellis, the Managing Director of Puritan's distributor, MWE, in connection with the litigation in Germany between Copan and Puritan. Puritan's counsel's letter acknowledges that Copan has "patents in the area of flocked swabs" and that "Copan also has several U.S. Patents[.]"

66. Copan has met with Puritan representatives in the past to try to resolve the patent issues between the parties, but has been unsuccessful.

Puritan's False and Misleading Statements Regarding German Proceedings between Copan and Puritan

67. In 2012, Copan initiated infringement proceedings against Puritan in the Düsseldorf district court, and asserted three German Utility Models (Nos. 20 2004 021 787.2 (“DE ’787”); 20 2004 021 930.1 (“DE ’930”); 20 2004 021 932.8 (“DE ’932”)). Each of the German Utility Models was branched off from Copan’s European patent, EP 1 608 268 B1.

68. At the same time, Copan also initiated inspection proceedings against Puritan concerning the DE ’787. The Düsseldorf district court granted Copan’s request to obtain samples of Puritan’s HydraFlock and PurFlock swabs. The obtained swabs were provided to a court-appointed expert, Dr. Manfred Pinnow, for analysis.

69. Puritan filed an objection to the court’s inspection order.

70. A trial date in the German district court proceedings was set for June 24, 2014. At the hearing, the district court was to address both infringement of the three German Utility Models, and Puritan’s outstanding objection to the inspection order.

71. On June 24, 2014, the Düsseldorf district court first addressed the infringement of the three asserted German Utility Models. Then, with respect to the outstanding objection to the inspection order, the presiding judge observed that the swabs had already been seized and analyzed by Dr. Pinnow, so there was no longer a need for the inspection proceedings. For that reason, the presiding judge asked if Copan would terminate the inspection proceedings, which would resolve the outstanding objection issue. Copan agreed to terminate the inspection proceedings.

72. Concerning the separate issue of the infringement proceedings, the Düsseldorf district court issued its rulings several weeks later. The district court determined that one Copan utility model (DE ’930) was not infringed, and dismissed that proceeding. That determination is

presently on appeal. The district court confirmed that Puritan products infringe DE '932. That ruling is also subject to a pending appeal.

73. As to DE '787, the Düsseldorf district court suspended the infringement proceedings without ruling on, or adjudicating, whether Puritan's flocked swabs infringed the utility model.

74. The Düsseldorf district court suspended the DE '787 proceedings based on a pending cancellation proceeding in the German Patent Office that challenged the validity of the utility model claims.

75. The DE '787 infringement proceedings remain stayed pending the outcome of appellate proceedings as to the validity of the DE '930 before the German Supreme Court.

76. To date, no German court or tribunal has issued an infringement ruling as to DE '787, nor has any court or tribunal otherwise adjudicated Copan's claim that Puritan's flocked swabs infringe Copan's patents.

77. Through the German proceedings, Copan received additional information about the makeup of Puritan's flocked swabs when two experts, Dr. Manfred Pinnow (a court-appointed expert) and Dr. Francesco Gatti (an expert hired by Copan), submitted reports detailing the composition of the swabs at a microscopic level. *E.g.*, Expert Report of Dr. Manfred Pinnow (Jan. 15, 2013) (certified English translation) ("Pinnow Report"); First Affidavit of Expert Dr. Francesco Gatti (June 17, 2015) ("Gatti June 2015 Aff."), Second Affidavit of Expert Dr. Francesco Gatti (Nov. 23, 2015) ("Gatti Nov. 2015 Aff."); Third Affidavit of Expert Dr. Francesco Gatti (Mar. 18, 2016) ("Gatti Mar. 2016 Aff.").

78. Dr. Gatti's findings confirmed Copan's belief that Puritan's flocked swabs feature fibers that have been deposited in an ordered manner by electrostatic flocking, as described in

some Copan patent claims, and that Puritan's fiber arrangement falls within the claimed scope of protection afforded by some of Copan's patents.

79. Dr. Pinnow was never deposed or cross-examined with regard to any of the disclosures or conclusions stated in his report.

80. Puritan, however, repeatedly misstated publicly that the District Court of Düsseldorf had ruled that Puritan's HydraFlock and PurFlock swabs did not infringe DE '787 and established that Puritan's product do not violate Copan's European patent. Such statements, as Puritan must know, are demonstrably false and misleading.

81. On July 8, 2014, Puritan issued false and misleading commercial press releases in connection with the German litigation against Copan.

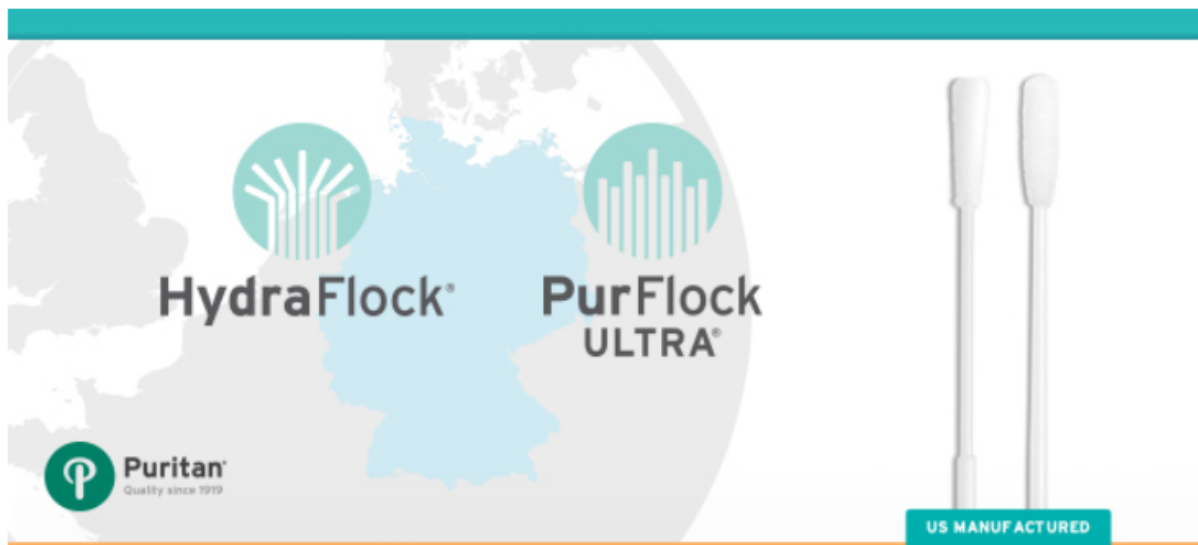
82. On July 8, 2014, Puritan issued a press release, entitled "Puritan Flocked Swabs Not in Violation of Copan European Patent," which contains several demonstrably false and misleading statements. Puritan still actively posts the press release at <https://blog.puritanmedproducts.com/puritan-flocked-swabs-not-in-violation-of-copan-european-patent> ("Puritan Flocked Swabs Not in Violation").

Puritan Blog

Jul 8, 2014

 Print this page

Puritan Flocked Swabs Not in Violation of Copan European Patent



Great news for Puritan customers and distributors! Germany's Düsseldorf Court has ruled that **Puritan's flocked swab products** (the HydraFlock® and PurFlock Ultra® flocked swabs) are flocked differently from Copan's and **do not violate Copan's European patents**.

This ruling ensures unprejudiced freedom for Puritan distributors and customers to sell Puritan's HydraFlock® and PurFlock Ultra® flocked swabs in Europe free from any patent infringement concerns.

83. The title of the press release falsely states that the Düsseldorf Court ruled that Puritan's flocked swabs did not violate Copan's European patent. The European patent was not at issue in the German proceedings. More importantly, the court did not make any infringement judgments with regard to DE '787, nor any Copan patent. Thus, Puritan's statement that the court found that Puritan's flocked swabs did not violate Copan's European patent is demonstrably false, and misleading.

84. The "Puritan Flocked Swabs Not in Violation" press release also includes the false and misleading claim that "[t]his ruling ensures unprejudiced freedom for Puritan

distributors and customers to sell Puritan's HydraFlock® and PurFlock Ultra® flocked swabs in Europe free from any patent infringement concerns."

85. Although Puritan knew, and continues to know, that this press release contained false and misleading claims, it maintains this advertising on its website to this day.

86. A subsequent press release, which Puritan issued on July 8, 2014, entitled "Freedom to Operate for Puritan: Irrevocable Withdrawal of Inspection Proceedings by Copan," contained further demonstrably false and misleading statements. The July 8th press release is *available at* <https://www.puritanmedproducts.com/news-and-events/news/post/freedom-to-operate-for-puritan-irrevocable-withdrawal-of-inspection-proceed> ("Freedom to Operate").



Copan's attack was blown away by the District Court Düsseldorf. At an oral hearing on June 24, 2014 (case no. 4b 176/12), the Court made clear that Puritan's HydraFlock® and PurFlock Ultra® flocked swab products are flocked differently and do not have Copan's claimed fiber arrangement.

In addition, the Düsseldorf Court, often considered the most important European court for enforcement of patent rights, ordered Copan to reimburse Puritan for all attorney fees incurred under applicable German law with respect to the inspection proceedings Copan brought against Puritan.

87. The "Freedom to Operate" press release falsely states that "Copan's attack was blown away by the District Court Düsseldorf." Puritan knew this statement was false, because Copan voluntarily withdrew its evidence seizure and inspection request as to the expired utility

models, only because it had already achieved its goals of seizure and inspection of Puritan's flocked swabs. Moreover, Copan's infringement claims in Germany were subsequently suspended, without ruling, in light of unrelated invalidity litigation on the same utility model, DE '787, while other infringement proceedings proceeded. The infringement proceedings are still suspended.

88. Puritan's second press release also misled the public as to the disposition and findings of the Düsseldorf district court in its statements with regard to the design and structure of Puritan's flocked swabs. The press release states that:

The Court's findings are particularly relevant since the asserted '787 utility model is a branch-off from Copan's European patent EP 1 608 268 B1 relating to the same invention which also requires fibers deposited by flocking in an ordered arrangement of the fibers normal to the surface of the swab. Thus, it can be concluded from the Court's clear position regarding the '787 that **Puritan's HydraFlock® and PurFlock Ultra® flocked swabs are also outside the scope of Copan's European patent.**

(emphasis in original).

89. As Puritan must know, the Düsseldorf district court took no position on the infringement of DE '787, let alone a "clear position" as to infringement of DE '787, or Copan's European patent. Far from stating a clear position on infringement, as Puritan has repeatedly and consistently proclaimed publicly, the proper inference is the opposite. The Düsseldorf district court likely believed that Puritan's infringement of DE '787 was confirmed, but the judges wanted to delay a ruling until the proceedings addressing the validity of the DE '787 claims had been completed. If the Court had come to a "clear position" that Puritan did not infringe DE '787 it would have dismissed, rather than suspended, the proceedings.

90. The press release then concludes with the false statement that Puritan and Puritan's customers have unprejudiced freedom to sell Puritan's flocked swabs:

In light of the clear position expressed by the Court, Copan irrevocably withdrew the inspection proceedings against Puritan. . . . Therefore, **Puritan and Puritan's customers have unprejudiced freedom to sell Puritan's HydraFlock® and PurFlock Ultra® flocked swabs in Europe without concern for Copan's European patent or expired utility models.**

(emphasis in original). Again, Puritan knew that the Düsseldorf district court had not made any judgments with regard to infringement of DE '787, nor any Copan patent.

91. Puritan also sent emails to its customers and distributors that made similar false and misleading statements.

92. In an email on or around July 9, 2014 to a potential customer, Puritan's Executive Vice President of Global Sales, Timothy L. Templet, falsely advertised that "[a] Düsseldorf District Court recently ruled that Puritan's HydraFlock® and PurFlock Ultra® flocked swabs are flocked differently than Copan's and **do not violate Copan's European patents.** That means Puritan customers and distributors can sell our flocked swab products in Europe without fear of patent infringement." (emphasis in original).

93. Puritan's statements were intended to, and did, deceive customers purchasing flocked swabs, and/or influence their product choice in the flocked swab market. For example, Puritan's distributor MWE was deceived by Puritan's misleading commercial press releases on the German litigation. In a MWE press release, MWE stated that:

MWE recently announced a Düsseldorf Court ruling regarding Puritan Medical Products flocked swab...The Düsseldorf Court made clear at the hearing that Puritan's HydraFlock® and PurFlock Ultra® flocked swabs are flocked differently and do not have fibres in an ordered arrangement normal to the surface of the swab as claimed in claim 1 of the '787. The Court's findings are particularly relevant since the asserted '787 utility model is a branch-off from Copan's European patent EP 1 608 268 B1 relating to the same invention which also requires fibres deposited by flocking in an ordered arrangement of the fibres normal to the

surface of the swab. Thus, it can be concluded from the Court's clear position regarding the '787 that **Puritan's HydraFlock® and PurFlock Ultra® flocked swabs are also outside the scope of Copan's European patent.**

MWE press release, entitled "MWE updates customers with more details about the irrevocable withdrawal of the inspection proceedings," (Sept. 2014), *available at* <http://www.mwe.co.uk/events-amp-press/press/mwe-to-push-ahead-with-distribution-of-flocked-swabs/> (emphasis in original).

94. On March 8, 2016, Puritan, through its counsel, sent a letter to David Skaug-Ellis, the Managing Director of Puritan's distributor, MWE, in connection with the litigation in Germany between Copan and Puritan, which also contained misleading and false assertions.

95. In the March 8th letter, Puritan's counsel falsely stated that "Copan also has several U.S. Patents but the claims of the relevant patents related to [Copan's German Utility Models] all contain the 'uniform thickness,' 'ordered arrangement,' and 'normal to the surface' limitations found in Copan's [European patent EP 1 608 268 B1] and which did not apply to Puritan's flocked swab products." This statement, with respect to the claim limitations in all of Copan's U.S. issued patents, is objectively false.

96. Puritan's counsel's letter also falsely and misleadingly insinuates that a non-infringement decision in connection with Copan's German Utility Models and/or its European patent would compel the conclusion of non-infringement with regard to Copan's U.S. patents. Puritan was, and is, well aware that there was no finding of non-infringement with regard to Copan's Utility Model DE '787, that Copan's European patent claims were not adjudicated in the German litigation, and that no court in the United States has construed any of Copan's U.S. patent claims, or made any determinations on infringement of Copan's U.S.-issued patents.

Puritan's False and Misleading Advertising Regarding Flocked Swabs

97. In addition to Puritan's false and misleading public relations campaign in connection with the German litigation, Puritan has also been engaging in an advertising campaign that makes false and misleading claims regarding the design of its HydraFlock® flocked swabs, the appearance, purity, and performance of Copan's flocked swabs, the performance of Puritan's HydraFlock® and PurFlock Ultra® as compared to Copan's flocked swabs, and the "independent" studies Puritan used to support its claims of superior performance.

98. These false and misleading statements appear in numerous Puritan advertisements and blog posts.

99. In Puritan's "Patents. Patents. Patents." advertisement, Puritan makes several false and misleading claims regarding the performance and purity of its HydraFlock® flocked swabs, as compared to its competitor's—Copan's—nylon flocked swabs.

100. First, the "Patents. Patents. Patents." advertisement states that Puritan's HydraFlock® flocked swabs have the "[h]ighest performing collection and elution[.]" but fails to cite a scientific basis for this assertion. Puritan Advertisement, "Patents. Patents. Patents."



PATENTS. PATENTS. PATENTS.

Let's set the record straight. Because the difference is very real.

Now with 14 international patents awarded, it's no wonder Puritan's flocked swabs provide the most efficient **absorption and elution** on the market.



Puritan®
DIAGNOSTICS



207-B76-3311 • puritanmedproducts.com
sales@puritanmedproducts.com

	HydraFlock®	PurFlock Ultra®
PATENTED		
United States	8,274,747	8,400,385 8,274,629
Canada	2,744,262	2,744,618
Europe	226,3549	226,3549
Australia	200341402	200341401
Japan	200262288	200262287
China	ZL 20080049992.1	ZL 20080049999.2
PATENT PENDING		
HongKong	106,293.6	106,294.7

101. The advertisement states, with regard to its competitor's nylon flocked swabs, that "[i]nferior absorption means less release," again, without any citation to a scientific basis for this statement.

102. The advertisement also states that Puritan's HydraFlock® swabs contain "NO fiber treatment – pure specimen collection," and states that the competitor's nylon flocked swabs have "[y]ellow coloring: treated-coated," inferring that the color of the swabs or coating or treatment somehow contaminates the specimen collection, again, without any scientific basis for these assertions.

103. The advertisement ends the comparison noting that Puritan's HydraFlock® swabs are "[c]lean, white & made in the USA!" which falsely and misleadingly infers, again, that Copan's non-white swabs are unclean or less clean than Puritan's. These statements are likely to mislead customers purchasing flocked swabs and/or influence their product choice in the flocked swab market. For example, Hardy Diagnostics, in its TransPRO CVM™ Transport System product guide (*available at* https://catalog.hardydiagnostics.com/cp_prod/Content/pdf/TransPRO_Flier_CVM_web.pdf), has repeated Puritan's misleading language:



104. Finally, the advertisement again insinuates that Copan's flocked swabs are not patent-protected, stating: "Now with 14 international patents awarded, it's no wonder Puritan's flocked swabs provide the most efficient absorption and elution on the market." Yet again, the

advertisement fails to include the factual basis for its assertion that Puritan's flocked swabs provide the most efficient absorption and elution on the market.

105. In Puritan's March 27th Blog Post, Puritan makes further false and misleading statements.

106. In the March 27th Blog Post, Puritan notes, without a factual basis, that Puritan's HydraFlock® swabs "feature significant improvements in both materials and construction."

107. The March 27th Blog Post further asserts, without scientific support, that "HydraFlock swabs are composed of a 'fiber-within-fiber' design, with pores that facilitate greater sample absorption, retention, and faster release. Our unique flocking process results in split ends that provide even greater surface area for sample retention and friction for faster sample disruption and collection." This statement is false.

108. Finally, Puritan falsely asserts in its March 27th Blog Post that independent studies corroborate its claims: "Looking for an unbiased opinion? Independent studies have confirmed the superiority of HydraFlock's collection and release properties to FLOQ[S]wabs."

109. However, Puritan failed to mention in its blog post that the "independent" studies it referenced were actually *paid for by Puritan*.

110. For example, on December 13, 2013, Puritan posted a press release stating that "[o]ur unique flocking process for the HydraFlock® swabs results in split ends that provide even greater surface area for sample retention and friction for faster sample disruption and collection," and that "[w]hen we say our products exhibit vastly superior performance and utility, we don't want you to have to take our word for it. We want the raw data to speak for itself." Puritan Press Release, "Independent Study Confirms Superior Performance of HydraFlock® Swabs,"

available at <https://blog.puritanmedproducts.com/bid/358540/independent-study-confirms-superior-performance-of-hydraflock-swabs>.

Puritan Blog

Dec 17, 2013

 Print this page

Independent Study Confirms Superior Performance of HydraFlock® Swabs



African Journal of Microbiology Research
Vol. 7(31), pp. 4039-4048, 2 August, 2013
[Read the Study](#)

111. The study referenced in this press release is a study from the African Journal of Microbiology Research. Harry, Kathryn, et al., “Comparison of physical characteristics and collection and elution performance of clinical swabs,” African Journal of Microbiology Research, Vol. 7, No. 31, pp. 4039-4048 (Aug. 2, 2013), available at https://www.puritanmedproducts.com/pub/media/studies/Comparison_of_physical_characteristics_and_collection_and_elution_performance_of_clinical_swabs.pdf. In this study, on the acknowledgements page, the authors state that “[t]he work was conducted at CET LLC,

Winston-Salem, NC facility and *was funded by Puritan Medical Products Co., LLC, Guilford, ME, USA.*” (emphasis added).

ACKNOWLEDGEMENTS

The work was conducted at CET LLC, Winston-Salem, NC facility and was funded by Puritan Medical Products Co., LLC, Guilford, ME, USA.

Thus, Puritan’s statement that the study was “independent” is false.

112. On November 30, 2015, Puritan posted a blog entitled “How to Choose a Flocked Swab for Flu Testing,” on its website, which contained further false and misleading statements. Puritan Blog Post, “How to Choose a Flocked Swab for Flu Testing,” (“November 30th Blog Post”) *available at* <https://blog.puritanmedproducts.com/how-to-choose-a-flocked-swab-for-flu-testing>. The blog is presently available on the Puritan website in its blog archive.

113. The November 30th Blog Post appeared to compare Puritan’s flocked swabs with “standard” nylon flocked swabs, which are those made by Copan.

114. Puritan’s November 30th Blog Post falsely stated that:

Nylon swabs use surface tension between the fibers to trap biological material for sampling, which is great for collecting specimen, but not so great for eluting the specimen for testing. It’s estimated that as little as 15 percent of the organisms collected by traditional nylon flocked swabs are released for testing.

The post continues by stating, without factual basis, that “Puritan’s HydraFlock® and PurFlock Ultra® swabs are made with a bicomponent filament material that allow for not only superior collection but more complete elution, steps vital to obtaining accurate results.”

115. Puritan also advanced in the November 30th Blog Post its own unproven theory that the splayed end design of the HydraFlock swabs improves performance. For example, Puritan’s blog post misleadingly states that:

While standard flocked swabs do have a design superior to traditional spun fiber swabs, only Puritan has a proprietary manufacturing process that offers swabs with multi-length flock fibers providing you with the most efficient collection and elution on the market. Each fiber of Puritan's HydraFlock® swabs is split into multiple tips, allowing for greater collection surface area and easier release of specimen particles.

116. Dr. Gatti, Copan's textile expert in the German Utility Model proceedings, empirically refuted Puritan's claim of improved performance from splaying the ends of its HydraFlock swabs. To the contrary, Dr. Gatti demonstrated that Puritan's HydraFlock splayed ends "do not increase the quantity of liquid absorbed in an appreciable way." Gatti June Aff. at 19. Dr. Gatti noted that HydraFlock's splayed ends make up less than 5% of the length of the fiber bundles in Puritan's HydraFlock swabs. Dr. Gatti also noted that when HydraFlock swabs are observed under a microscope, the surface of the liquid collected remains substantially below the level of the splayed ends of HydraFlock's fibers, just as is the case for the liquid collected between the fibers in Copan's swabs.

117. Puritan's statements on the supposed benefits of its misleading splayed end design theory were intended to, and did, deceive customers purchasing flocked swabs, and/or influence their product choice in the flocked swab market. For example, Puritan's distributor MWE was deceived by Puritan's misleading splayed end design theory. In a brochure, MWE stated that:

[W]ith HydraFlock® the effect is enhanced because the individual fibres are splayed at the outer end to create a vast microstructure, so that absorption and elution are rapid and very effective.

MWE brochure, entitled "PurFlock® & HydraFlock®," *available at*

http://www.mwe.co.uk/modules/downloadable_files/assets/purflock--hydraflock.pdf

118. Puritan's November 30th Blog Post also misleadingly suggests that Puritan's swabs are superior, because its swabs are not treated or coated, unlike Copan's swabs, citing to yet another study paid for by Puritan:

Our multi-length flock fibers are adhered to the shaft by a proprietary process that eliminates the need for excessive adhesive or fiber treatments that can interfere with collection, ensuring flawless specimen purity...The Competition offers flocked swabs that have been coated with biopolymers to 'improve the recovery and survival of organisms.' However, [a] study published in the Indian Journal of Medical Microbiology concluded that coating flocked swab tips does 'not uniformly demonstrate higher recovery compared with their uncoated counterparts.'

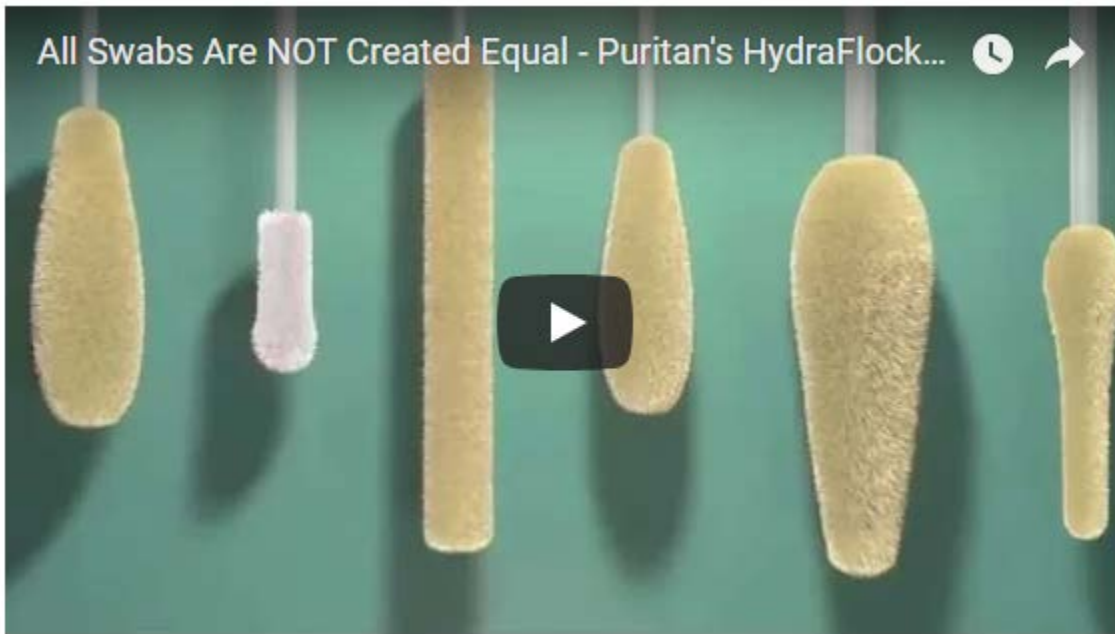
see Harry, KH et al., "Effect of protein coating of flocked swabs on the collection and release of clinically important bacteria," Indian Journal of Medical Microbiology, Vol. 32, No. 3 at 301-03 (2014) ("The work was conducted at CET LLC, Winston-Salem, NC, USA facility. The work was funded by Puritan Medical Products Co. LLC." (emphasis added)).

119. Here, Puritan in its November 30th Blog Post fails to mention that the study it cites in support of these assertions was *not* in fact independent, but rather, a Puritan paid-for study. Puritan continues to direct and fund studies by scientists and lab technicians on its flocked swabs. See, e.g., Puritan Blog Post, "Puritan's Fecal Opti-Swab® Collection & Transport System Delivers," (May 17, 2018), available at <https://blog.puritanmedproducts.com/puritan-fecal-opti-swab-eccmid-2018> (citing recent study).

120. Finally, the November 30th Blog Post falsely suggests that Copan may not be able to meet market needs in an emergency, due to the fact that Copan manufactures its flocked swabs abroad, and imports them into the United States: "One final thing to consider when choosing a flocked swab, particularly during the flu season, is that some companies may not be able to deliver the necessary inventory quickly and reliably as you need. Puritan does all of our

manufacturing right here in the U.S.A., and because of that we can respond to market needs with the highest quality products delivered on time.”

121. The November 30th Blog Post also included an embedded video, entitled “All Swabs are NOT Created Equal – HydraFlock flocked swabs,” which repeated many of the false and misleading claims included in the blog post.



122. The video is currently available on Puritan’s website at <https://blog.puritanmedproducts.com/how-to-choose-a-flocked-swab-for-flu-testing>.

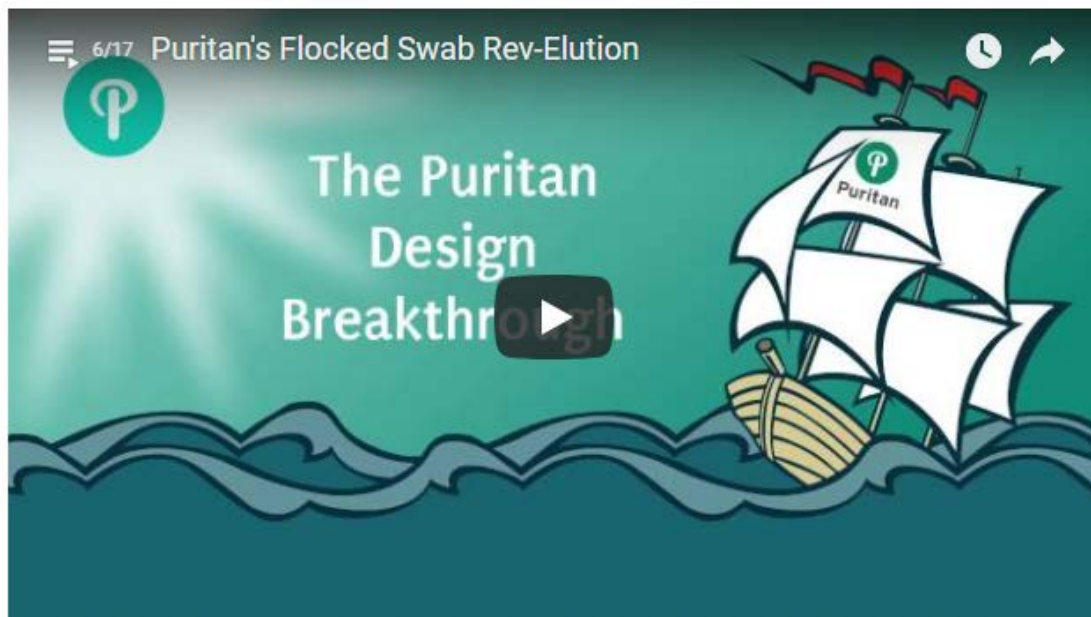
123. Puritan’s video attempts to compare Copan flocked swabs and HydraFlock, using data from Puritan’s paid-for study that was published in the Indian Journal of Medical Microbiology. The video misleadingly states that:

Original flocked swabs for sample collection are comprised of nylon mono-filament fibers that use surface tension to capture biological materials between the fibers themselves. This is great for collecting, but when it comes time to elute the sample for study, the filaments also serve to trap their contents, releasing as little as 15 percent of the collected materials. In the case of weak signal study targets, this low resolution can render the samples

unusable for analysis. Puritan's HydraFlock technology breaks this pattern, by transforming the chemical surface properties of the fibers and using a bi-component filament material and a proprietary construction process that splits the end of each fiber into multiple ultra-fine heads. During sample collection, this dramatically increased surface area results in significantly greater uptake. But the real difference is that captured samples are far more readily released at the time of elution, allowing higher resolution analysis with less sample material.

Nov. 30th video at 0:19 – 1:23.

124. Puritan continues its attack on Copan's flocked swabs in its next video advertisement, "Puritan's Flocked Swab Rev-Elution," which contains several false and misleading statements about the efficacy of Copan's products and the "superior" performance of HydraFlock swabs based on their design. The video was embedded in a blog post dated May 27, 2014, and is still available on Puritan's website at <https://blog.puritanmedproducts.com/bid/386969/join-puritan-s-flocked-swab-rev-elution>.



125. The May 27th video makes several unsupported and misleading statements, which incorrectly suggest that Copan's flocked swabs have inferior performance, purity, and

availability. First the video states that “[s]tandard design means less collection and less elution of sample specimen.” May 27th Video at 0:59.



126. Next, the video falsely states that “[y]ellow coloring can mean impurities.” May 27th Video at 1:04.



127. Next, the video states that “Foreign manufacturing means less reliable availability.” May 27th Video at 1:07.



128. The video also makes false and misleading statements regarding the design and performance of HydraFlock swabs. “Puritan’s flocked specimen collection devices have a patented, Rev-Elutionary design that features intricate fiber technology, with multi-length, split-end fibers. This results in a versatile brush-like swab with increased surface area and tension.” May 27th Video at 2:09-2:26. The video continued stating, without factual basis, “Because there is more surface area and no inner fabric to reabsorb specimens, our flocked specimen collection devices provide the most efficient collection and elution on the market. This means you get maximum specimen preservation through rapid collection and elution and . . . better results.”

FALSE ADVERTISING

COUNT I

**Violation of Section 43(a)(1)(B) of the Lanham Act – False Advertising
(*Copan Italia S.p.A. and Copan Diagnostics, Inc. v.
Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

129. Plaintiffs restate and incorporate by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

130. In connection with its advertising and press releases, as set forth above, Defendant Puritan has made false and misleading representations of fact, and false and misleading descriptions of fact about the nature, characteristics, and qualities of its own flocked swab products, as well as Copan's flocked swab products.

131. Defendant Puritan's false and misleading advertising misrepresents the nature, characteristics, and qualities of both its own flocked swabs and Copan's flocked swab products, including the efficacy and purported superior performance of its HydraFlock® design, and the efficacy, purity, and performance of Copan's flocked swab products.

132. Defendant Puritan's false and misleading advertising misrepresents the infringing nature of its flocked swab products, the nature of the results of German litigation between Copan and Puritan, and Puritan and its customers' liability with regard to infringement of Copan's United States and European patents in connection with Copan's flocked swab technology.

133. Defendant Puritan's misrepresentations materially influenced, and are likely to influence, consumer purchasing decisions.

134. Defendant Puritan's false and misleading advertising has deceived and continue to deceive consumers as to Puritan's assertions of Copan's inferior quality, purity, performance, and availability in times of crisis, HydraFlock® swabs' superior performance as compared to Copan flocked swabs, the infringing nature of its flocked swab products, the nature of the results

of German litigation between Copan and Puritan, and Puritan and its customers' liability with regard to infringement of Copan's United States and European patents in connection with Copan's flocked swab technology.

135. Defendant Puritan has placed its false and misleading advertising in interstate commerce.

136. Puritan's false and misleading advertising has resulted, and is likely to result, in lost sales for Copan's flocked swab products, and damage to its business reputation, through Puritan's assertions of Copan's inferior quality, purity, performance, and availability in times of crisis, and false and misleading claims of HydraFlock[®] swabs' superior performance as compared to Copan flocked swabs, among other false claims.

COUNT II
Violation of the Maine Uniform Deceptive Trade Practices Act
10 M.R.S.A. §§ 1211 et seq.
(Copan Italia S.p.A. and Copan Diagnostics, Inc. v.
Puritan Medical Products Company LLC and Puritan Diagnostics LLC)

137. Plaintiffs restate and incorporate by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

138. The Maine Uniform Deceptive Trade Practices Act, 10 M.R.S.A. §§ 1211 et seq. (the "MUDTPA") prohibits unfair, deceptive, or misleading trade practices in the course of business.

139. In connection with its advertising and press releases, as set forth above, Defendant Puritan has made false and misleading representations of fact that (i) cause a likelihood of misunderstanding as to a certification by another, (ii) represent that Puritan's flocked swab products have approval or characteristics that they do not have, (iii) represent that Puritan's flocked swab products are of a particular standard when they are another, and (iv) disparage

Copan and Copan's flocked swab products, in violation of at least Sections 1212(1)(C), (E), (G), and (H) of the MUDTPA.

140. Defendant Puritan's false and misleading advertising misrepresents the nature, characteristics, and qualities of Puritan's flocked swabs, as well as Copan's flocked swab products, including the infringing nature of its flocked swab products, the nature of the results of German litigation between Copan and Puritan, and Puritan and its customers' liability with regard to infringement of Copan's United States and European patents in connection with Copan's flocked swab technology.

141. Puritan's false, misleading, and disparaging advertising influenced, and is likely to influence, consumer purchasing decisions.

142. Defendant Puritan's false and misleading advertising has resulted, and is likely to result, in a loss of sales for Copan's flocked swab products and damage to its business reputation through Puritan's assertions of Copan's inferior quality, purity, performance, and availability in times of crisis, and false and misleading claims of HydraFlock[®] swabs' superior performance as compared to Copan flocked swabs, among other false claims.

143. Unless enjoined, Puritan's false and misleading advertising will continue, causing continued damage to Copan's business reputation and continued lost sales.

144. Copan requests an injunction enjoining Puritan from its false and misleading advertising campaigns, which disparage Copan's flocked swab products, in addition to attorneys' fees and costs under Section 1213 of the MUDTPA.

PATENT INFRINGEMENT

145. Plaintiff Copan Italia S.p.A brings this action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

COUNT III
Direct Infringement of U.S. Patent No. 8,114,027
(*Copan Italia S.p.A. v.*
***Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

146. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

147. Copan Italia S.p.A is the owner, by assignment, of U.S. Patent No. 8,114,027 (“the ’027 Patent”). A true copy of U.S. Patent No. 8,114,027 granted by the U.S. Patent & Trademark Office is attached as Exhibit 1.

148. Defendant Puritan has directly infringed, and is continuing to directly infringe, literally or under the doctrine of equivalents, at least independent claim 1 of Copan’s ’027 Patent by making, using, selling, and/or offering for sale its flocked swabs in the United States, in violation of 35 U.S.C. § 271(a).

149. Defendant Puritan has knowledge of the ’027 Patent.

150. Defendant Puritan’s acts of direct infringement of the ’027 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

151. A patent infringement claim chart comparing the claim elements of independent method claim 1 of the ’027 Patent to Puritan’s flocked swabs made and sold for use of the claimed method by Puritan is attached to this Complaint as Exhibit 6.

COUNT IV
Indirect Infringement of U.S. Patent No. 8,114,027
(Copan Italia S.p.A. v.
***Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

152. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

153. Defendant Puritan has indirectly infringed, and is continuing to indirectly infringe, literally or under the doctrine of equivalents, at least independent claim 1 of Copan's '027 Patent, in violation of 35 U.S.C. §§ 271(b), (c).

154. Defendant Puritan's flocked swabs are apparatuses especially made or adapted for infringing use, and Defendant Puritan sells and has sold its flocked swabs for use in practicing the methods claimed in the '027 Patent.

155. Puritan's flocked swabs constitute a material part of the patented method claimed by Copan's '027 Patent, and are not staple articles or commodities of commerce suitable for a substantial noninfringing use.

156. Defendant Puritan, with specific intent, actively induces third-party direct infringers—such as Puritan's customers, and end users of its flocked swabs, including scientists, medical professionals, and lab technicians—to practice the invention claimed by Copan's '027 Patent, and Puritan has knowledge that the induced acts constitute patent infringement.

157. Defendant Puritan's acts of indirect infringement of the '027 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

158. A patent infringement claim chart comparing the claim elements of independent method claim 1 of the '027 Patent to Puritan's flocked swabs made and sold for use of the

claimed method by Puritan's customers and end users of its flocked swabs is attached to this Complaint as Exhibit 6.

COUNT V
Direct Infringement of U.S. Patent No. 8,317,728
(Copan Italia S.p.A. v.
***Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

159. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

160. Copan Italia S.p.A is the owner of U.S. Patent No. 8,317,728 ("the '728 Patent"). A true copy of U.S. Patent No. 8,317,728 granted by the U.S. Patent & Trademark Office is attached as Exhibit 2.

161. Defendant Puritan has directly infringed, and is continuing to directly infringe, literally or under the doctrine of equivalents, at least independent claim 1 of Copan's '728 Patent by making, using, selling, and/or offering for sale its flocked swabs in the United States, in violation of 35 U.S.C. § 271(a).

162. Defendant Puritan has knowledge of the '728 Patent.

163. Defendant Puritan's acts of direct infringement of the '728 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

164. A patent infringement claim chart comparing the claim elements of independent method claim 1 of the '728 Patent to Puritan's flocked swabs made and sold for use of the claimed method by Puritan is attached to this Complaint as Exhibit 7.

COUNT VI
Indirect Infringement of U.S. Patent No. 8,317,728
(Copan Italia S.p.A. v.
***Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

165. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

166. Defendant Puritan has indirectly infringed, and is continuing to indirectly infringe, literally or under the doctrine of equivalents, at least independent claim 1 of Copan's '728 Patent, in violation of 35 U.S.C. §§ 271(b), (c).

167. Defendant Puritan's flocked swabs are apparatuses especially made or adapted for infringing use, and Defendant Puritan sells and has sold its flocked swabs for use in practicing the methods claimed in the '728 Patent.

168. Puritan's flocked swabs constitute a material part of the patented method claimed by Copan's '728 Patent, and are not staple articles or commodities of commerce suitable for a substantial noninfringing use.

169. Defendant Puritan, with specific intent, actively induces third-party direct infringers—such as Puritan's customers, and end users of its flocked swabs, including scientists, medical professionals, and lab technicians—to practice the invention claimed by Copan's '728 Patent, and Puritan has knowledge that the induced acts constitute patent infringement.

170. Defendant Puritan's acts of indirect infringement of the '728 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

171. A patent infringement claim chart comparing the claim elements of independent method claim 1 of the '728 Patent to Puritan's flocked swabs made and sold for use of the

claimed method by Puritan's customers and end users of its flocked swabs is attached to this Complaint as Exhibit 7.

COUNT VII
Direct Infringement of U.S. Patent No. 8,979,784
(Copan Italia S.p.A. v.
***Puritan Medical Products Company LLC and Puritan Diagnostics LLC*)**

172. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

173. Copan Italia S.p.A is the owner of U.S. Patent No. 8,979,784 ("the '784 Patent"). A true copy of U.S. Patent No. 8,979,784 granted by the U.S. Patent & Trademark Office is attached as Exhibit 3.

174. Defendant Puritan has directly infringed, and is continuing to directly infringe, literally or under the doctrine of equivalents, at least independent claim 1 of Copan's '784 Patent by making, using, selling, and/or offering for sale its flocked swabs in the United States, in violation of 35 U.S.C. § 271(a).

175. Defendant Puritan has knowledge of the '784 Patent.

176. Defendant Puritan's acts of direct infringement of the '784 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

177. A patent infringement claim chart comparing the claim elements of independent claim 1 of the '784 Patent to Puritan's flocked swabs is attached to this Complaint as Exhibit. 8.

COUNT VIII

**Direct Infringement of U.S. Patent No. 9,011,358
(Copan Italia S.p.A. v. Puritan Medical Products Company LLC and Puritan Diagnostics LLC)**

178. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

179. Copan Italia S.p.A is the owner of U.S. Patent No. 9,011,358 (“the ’358 Patent”). A true copy of U.S. Patent No. 9,011,358 granted by the U.S. Patent & Trademark Office is attached as Exhibit 4.

180. Defendant Puritan has directly infringed, and is continuing to directly infringe, literally or under the doctrine of equivalents, at least independent claims 1, 14, 23, and 24 of Copan’s ’358 Patent by making, using, selling, and/or offering for sale its flocked swabs in the United States, in violation of 35 U.S.C. § 271(a).

181. Defendant Puritan has knowledge of the ’358 Patent.

182. Defendant Puritan’s acts of direct infringement of the ’358 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

183. A patent infringement claim chart comparing the claim elements of independent claim 24 of the ’358 Patent to Puritan’s flocked swabs is attached to this Complaint as Exhibit 9.

COUNT IX

**Indirect Infringement of U.S. Patent No. 9,011,358
(Copan Italia S.p.A. v. Puritan Medical Products Company LLC and Puritan Diagnostics LLC)**

184. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

185. Defendant Puritan has indirectly infringed, and is continuing to indirectly infringe, literally or under the doctrine of equivalents, at least independent claims 1, 14, 23, and 24 of Copan's '358 Patent, in violation of 35 U.S.C. §§ 271(b), (c).

186. Defendant Puritan's flocked swabs are apparatuses especially made or adapted for infringing use, and Defendant Puritan sells and has sold its flocked swabs for use in practicing the methods claimed in the '358 Patent.

187. Puritan's flocked swabs constitute a material part of the patented method claimed by Copan's '358 Patent, and are not staple articles or commodities of commerce suitable for a substantial noninfringing use.

188. Defendant Puritan, with specific intent, actively induces third-party direct infringers—such as Puritan's customers, and end users of its flocked swabs, including scientists, medical professionals, and lab technicians—to practice the invention claimed by Copan's '358 Patent, and Puritan has knowledge that the induced acts constitute patent infringement.

189. Defendant Puritan's acts of indirect infringement of the '358 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

190. A patent infringement claim chart comparing the claim elements of independent claim 24 of the '358 Patent to Puritan's flocked swabs is attached to this Complaint as Exhibit 9.

COUNT X
Direct Infringement of U.S. Patent No. 9,173,779
(Copan Italia S.p.A. v. Puritan Medical Products Company LLC and Puritan Diagnostics LLC)

191. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

192. Copan Italia S.p.A is the owner of U.S. Patent No. 9,173,779 (“the ’779 Patent”). A true copy of U.S. Patent No. 9,173,779 granted by the U.S. Patent & Trademark Office is attached as Exhibit 5.

193. Defendant Puritan has directly infringed, and is continuing to directly infringe, literally or under the doctrine of equivalents, at least independent claims 1 and 13 of Copan’s ’779 Patent by making, using, selling, and/or offering for sale its flocked swabs in the United States, in violation of 35 U.S.C. § 271(a).

194. Defendant Puritan has knowledge of the ’779 Patent.

195. Defendant Puritan’s acts of direct infringement of the ’779 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

196. A patent infringement claim chart comparing the claim elements of independent claim 1 of the ’779 Patent to Puritan’s flocked swabs is attached to this Complaint as Exhibit 10.

COUNT XI
Indirect Infringement of U.S. Patent No. 9,173,779
(Copan Italia S.p.A. v. Puritan Medical Products Company LLC and Puritan Diagnostics LLC)

197. Plaintiff Copan Italia S.p.A restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

198. Defendant Puritan has indirectly infringed, and is continuing to indirectly infringe, literally or under the doctrine of equivalents, at least independent claims 1 and 13 of Copan’s ’779 Patent, in violation of 35 U.S.C. §§ 271(b), (c).

199. Defendant Puritan’s flocked swabs are apparatuses especially made or adapted for infringing use, and Defendant Puritan sells and has sold its flocked swabs for use in practicing the methods claimed in the ’779 Patent.

200. Puritan's flocked swabs constitute a material part of the patented method claimed by Copan's '779 Patent, and are not staple articles or commodities of commerce suitable for a substantial noninfringing use.

201. Defendant Puritan, with specific intent, actively induces third-party direct infringers—such as Puritan's customers, and end users of its flocked swabs, including scientists, medical professionals, and lab technicians—to practice the invention claimed by Copan's '779 Patent, and Puritan has knowledge that the induced acts constitute patent infringement.

202. Defendant Puritan's acts of indirect infringement of the '779 Patent are willful, and have caused and will continue to cause substantial damage and irreparable harm to Copan, and Copan has no adequate remedy at law.

203. A patent infringement claim chart comparing the claim elements of independent claim 1 of the '779 Patent to Puritan's flocked swabs is attached to this Complaint as Exhibit 10.

PRAYER FOR RELIEF

WHEREFORE, Copan requests the Court grant the relief set forth below:

A. Enter judgment that Defendant Puritan has engaged in false advertising and unfair competition in violation of Section 43(a)(1)(B) of the Lanham Act and deceptive trade practices in violation of Sections 1211 et seq. of the Maine Uniform Deceptive Trade Practices Act;

B. Grant injunctive relief enjoining Puritan and its officers, agents, employees, and all persons or entities in active concert or participation with them, from further false advertising, unfair competition, and deceptive trade practices;

C. Award Copan damages adequate to compensate Copan for Puritan's acts of false advertising and unfair competition (including deceptive trade practices), together with pre-judgment and post-judgment interest thereon;

D. Enter judgment that Puritan has directly and indirectly infringed, and continues to directly and indirectly infringe, one or more claims of the Asserted Patents;

E. Enter judgment that Puritan's acts of patent infringement are willful;

F. Temporarily, preliminarily, or permanently enjoin Puritan, its parents, subsidiaries, affiliates, divisions, officers, agents, servants, employees, directors, partners, representatives, all individuals and entities in active concert and/or participation with it, and all individuals and/or entities within its control from engaging in the aforesaid unlawful acts of patent infringement;

G. Order Puritan to account for and pay damages caused to Plaintiff by Defendant's unlawful acts of patent infringement;

H. Award Copan increased damages and attorney fees pursuant to 35 U.S.C. §§ 284 and 285;

I. Award Copan the interest and costs incurred in this action; and

J. Grant Copan such other and further relief, including equitable relief, as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all issues deemed to be triable by a jury.

Dated: June 1, 2018

Respectfully submitted,

/s/ Rebecca Gray Klotzle

Rebecca Gray Klotzle, Esq., Maine Bar No. 4927

Curtis Thaxter LLC

One Canal Plaza, Suite 1000

Portland, ME 04101

(207) 774-9000, ext. 209

rklotzle@curtisthaxter.com

Pro Hac Vice To Be Filed:

James M. Wodarski

Michael C. Newman

Matthew A. Karambelas

Courtney Herndon

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

One Financial Center

Boston, MA 02111

Telephone: (617) 542-6000

Counsel for Plaintiffs

Copan Italia S.p.A. and Copan Diagnostics, Inc.