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July 9, 2021

VIA EDIS

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, D.C. 20436

Re: Certain Flocked Swabs, Products Containing Flocked Swabs, And Methods of Using Same, Inv. No. 337-TA-____

Dear Secretary Barton:

In accordance with the Commission's Temporary Change to Filing Procedures dated March 16, 2020, Complainants Copan Italia S.p.A. and Copan Industries, Inc. (together, "Copan" or "Complainants") submit the following documents in support of their request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain flocked swabs, products containing flocked swabs, and methods of using same:

1. One (1) electronic copy of Complainants' verified Complaint, pursuant to Commission Rule 210.8(a)(1)(i) and 210.12(a).

2. One (1) electronic copy of the public exhibits to the Complaint, pursuant to Commission Rules 210.8(a)(1)(i) and 201.12(a)(9)[1], including:

   a. One (1) electronic copy of the certified versions of United States Patent Nos. 9,011,358 ("the '358 Patent"), 9,173,779 ("the '779 Patent"), 10,327,741 ("the '741 Patent") (collectively, the "Asserted Patents"), listed as Exhibits 1, 2 and 3 to the Complaint, pursuant to Commission Rule 210.12(a)(9)(i), and

   b. One (1) electronic copy of certified assignment records for the Asserted Patents, listed as Exhibits 58, 59, 60, 61, 62 and 63 to the Complaint, pursuant to Commission Rule 210.12(a)(9)(ii).

3. One (1) electronic copy of confidential Exhibits 55C, 56C, 57C, 85C, 88C, and 89C to the Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii).

4. One (1) electronic copy of the certified prosecution histories for each of the Asserted Patents, included as Appendices A, C, and E to the Complaint, pursuant to Commission Rule 210.12(c)(1).

[1] Due to the Commission's restrictions on in-person filings in response to COVID-19, Complainants' counsel has retained and will make available upon request samples of the covered products.

5. One (1) electronic copy of each of the patents and applicable pages of each technical reference identified in the prosecution histories of the Asserted Patents as Appendices B, D, and F to the Complaint, pursuant to Commission Rule 210.12(c)(2).

6. A letter and certification requesting confidential treatment for the information contained in confidential Exhibits 55C, 56C, 57C, 85C, 88C, and 89C to the Complaint, pursuant to Commission Rules 201.6 and 210.5.

7. A Statement on the Public Interest regarding the remedial orders sought by the Complainants in the Complaint, pursuant to Commission Rule 210.8(b).

Please contact me with any questions regarding this submission. Thank you for your attention to this matter.

Very truly yours,

/s/ James M. Wodarski

James M. Wodarski
Member

Enclosures

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Washington, D.C. 20436

Re: Certain Flocked Swabs, Products Containing Flocked Swabs, And Methods of Using Same, Inv. No. 337-TA-____

Dear Secretary Barton:

Pursuant to Commission Rules 201.6 and 210.5, Complainants Copan Italia S.p.A. and Copan Industries, Inc. (together, "Copan" or "Complainants") respectfully request confidential treatment of certain confidential business information contained in Confidential Exhibits 55C, 56C, 57C, 85C, 88C, and 89C of the Complaint filed contemporaneously with this letter.

The information contained in the Confidential Exhibits contain confidential data regarding (a) Copan's financial investments and expenditures, (b) Copan's business operations including confidential license information, and (c) technical details regarding the processes for manufacturing and testing the covered products. The information in the Confidential Exhibits qualifies as confidential information pursuant to 19 C.F.R. § 201.6 because:

1. it is not available to the public;

2. the unauthorized disclosure of such information could cause substantial harm to Copan's competitive position; and

3. its disclosure could impair the Commission's ability to obtain information necessary to perform its statutory function.

Non-confidential versions of these exhibits with the confidential information redacted are being filed concurrently.

Please contact me with any questions regarding this submission. Thank you for your attention to this matter.

Very truly yours,

/s/ James M. Wodarski

James M. Wodarski
Member

Enclosures

U.S. INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of **CERTAIN FLOCKED SWABS, PRODUCTS CONTAINING FLOCKED SWABS, AND METHODS OF USING SAME**	**Investigation No. 337-TA-**

COMPLAINANTS' PUBLIC INTEREST STATEMENT

Complainants Copan Italia S.p.A. and Copan Industries, Inc. (together, "Copan" or "Complainants") submit this public-interest statement, as required by 19 C.F.R. § 210.8(b). As discussed below, issuing the requested general exclusion for flocked swabs and products containing flocked swabs will not have an adverse effect on public health or welfare, competitive conditions in the domestic economy, production of like or directly competitive articles within the United States, or American consumers. The requested remedies in this Investigation are limited to infringing flocked swabs that are used for collecting and transporting biological samples for analysis, and kits containing flocked swabs. Because Copan and its licensees and other domestic third parties are able to satisfy market demand for flocked swabs, and other products exist in the market, a general exclusion order protecting Copan's intellectual property rights is in the public interest.

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Over the last year, the COVID-19 pandemic has exponentially increased the demand for certain medical and diagnostic testing products. One such product, the nasopharyngeal flocked swab invented, manufactured, and patented by Copan, played and continues to play a critical role in testing for COVID-19. Accurate testing for COVID-19 is necessary to facilitate the identification of community spread, contact tracing, and other critical analyses to combat the

pandemic. Until the COVID-19 pandemic began, other than *de minimis* production in China, only two producers of flocked swabs existed worldwide: Copan, and Puritan Medical Products ("Puritan"), located in Maine, USA. *See* Ex. 90 (Puritan Diagnostics-Specimen Collection).

When the COVID-19 pandemic first started there were significant shortages of flocked swabs, because demand swelled to a degree that was unanticipated even in the face of an emerging public health crisis. To address these shortages and ensure sufficient supply of these critical swabs, Copan quickly created new manufacturing lines, operated existing manufacturing lines 24/7, and engaged with partners in the medical field to enhance the output of flocked swabs. Copan was not alone in these efforts, as world governments invested in flocked swab infrastructure, and new manufacturers of flocked swabs (such as the named Respondents) entered the international flocked swab market. *See* Ex. 91 (*White House set to use Defense Production Act to ramp up testing swab manufacturing*, CNN, Apr. 20, 2020). Copan has engaged several new entrants to the flocked swab market, entering into various licensing agreements and sharing know-how to ensure a quick deployment of additional flocked swab resources.

With the proliferation of effective vaccines that prevent transmission of COVID-19, as evidenced by Copan's current levels of production of flocked swabs, the demand for flocked swabs has already plateaued at sustainable levels. These vaccines have proven to be remarkably effective at preventing the transmission of COVID-19. *See, e.g.*, Ex. 93 (*Comparing the COVID-19 Vaccines- How Are They Different*, Yale Medicine, June 2, 2021). Importantly, the vaccines have drastically reduced hospitalizations and deaths from COVID-19, thereby reducing and, perhaps eventually, eliminating the pandemic. *See* Ex. 37 (*Real-world studies find COVID vaccines cut infection, hospitalization*, CIDRAP, Apr. 26, 2021). As a result, as vaccinations

continue apace, the urgent need for flocked swabs and associated testing kits to conduct rapid testing, contact tracing, and other information gathering metrics can be managed by the existing domestic manufacturing capacity. Put another way, to the extent there existed a shortage of flocked swabs at the beginning of the pandemic, that shortage is over, and the current chain of authorized manufacturing and distribution capacity can easily handle any future swell in demand. Accordingly, a general exclusion order, and cease and desist orders against the named Respondents, would not disserve the public.

I. How the Articles Subject to the Proposed Remedial Orders are Used in the United States

The accused products are flocked swabs and kits containing flocked swabs. The named Respondents sell these products under various trade names and through various distributors.[1] Flocked swabs are inserted into human orifices to collect biological samples for testing for infectious disease such as influenza and SARS-CoV-2 (the coronavirus that causes COVID-19). These flocked swabs include nasopharyngeal, vaginal, urethra, and other swabs. Flocked swabs are sold in kits that contain a vial filled with transport media, and sometimes another flocked swab or in combination with rapid antigen tests. Flocked swabs are also sold as standalone flocked swabs for other companies to incorporate into kits. Numerous configurations of swab tip sizes, rod lengths, location of breakpoints, and contents of kits are available on the market.

II. There are No Public Health, Safety, or Welfare Concerns Related to the Requested Remedial Orders

Issuance of the requested relief will not have a meaningful adverse effect on the public health, safety or welfare in the United States for at least three reasons. First, there are alternative products on the market, such as foam and cotton swabs, that are approved for use as infectious

[1] As detailed in the complaint, identifying the supply chain of these unauthorized flocked swabs is difficult and unreliable.

disease testing swabs. Such foam and cotton swabs are not accused of infringement of Copan's patents. These products are available from countless suppliers, and have been in common use for years, even after Copan invented flocked swabs.

Second, there is at least one domestic manufacturer of flocked swabs, Puritan, that would not be subject to the exclusion order and cease and desist orders in this Investigation. Puritan is located in Maine, and manufactures its competing flocked swab products in Maine. In addition to its own resources, Puritan has been directly funded by the Federal government's invocation of the Defensive Production Act to address any increases in demand. *See* Ex. 91 (*White House set to use Defense Production Act to ramp up testing swab manufacturing*, CNN, Apr. 20, 2020).

Third, issuance of the requested remedial orders will increase public health, safety and welfare. Many of the infringing flocked swabs violate FDA regulations on labeling by providing incomplete or inappropriate information, for instance, using the FDA logo on the packaging. The FDA bars its logo for commercial use in order to prevent confusion regarding endorsement by the FDA. Additionally, many of the proposed Respondents only recently began manufacturing flocked swabs and it is unknown whether the infringing flocked swabs are manufactured in compliance with the applicable U.S. and international quality and regulatory standards. It is also unclear whether the infringing flocked swabs have been manufactured in appropriate environmental conditions or have been sterilized.

Finally, Copan has licensed its flocked swab patents to several manufacturers and distributors that are also currently supplying the market with flocked swabs. As a result, there are already licensed avenues for the accused and other third party manufacturers to import and sell for importation their infringing flocked swab products, should they choose to do so, rather than selling these swabs for use in the U.S. market after refusing to take a license from Copan.

III. Articles Which Could Replace the Subject Articles If They are Excluded from the United States

As mentioned above, numerous substitute products already exist on the market, such as Copan's flocked swabs, flocked swabs provided by Copan's authorized licensees, and cotton and foam swabs.

IV. Copan, Its Licensees, and Third Party Suppliers Have the Capacity to Immediately Satisfy Market Demand

Copan, its licensees, and third party suppliers will meet any demand created by the exclusion of the named Respondents. This is true even if the relevant market is limited to only flocked swabs, and excludes cotton and foam swabs. This is the case for at least two reasons. First, Copan, its licensees, and other third party suppliers have the manufacturing capacity to replace the infringing flocked swab products provided by the named Respondents that would be excluded at the conclusion of this Investigation, should one institute. Second, the flocked swab market is largely elastic, in that flocked swab products that are excluded from the United States market will be sold elsewhere, creating a market surplus in other jurisdictions thereby causing other, authorized suppliers to redirect their supply to the United States even if a void of flocked swabs is created from the remedial orders.

V. The Requested Remedial Orders Will Have No Effect on Consumers

The requested remedial orders will have no effect on consumers, for the reasons discussed above. In addition, end consumers are largely unaware of the supplier of the flocked swab that is used to test a patient for disease. In other words, patients do not check the source of a flocked swab prior to receiving a test for infectious disease.

For the foregoing reasons, no public-interest concerns preclude the issuance of the proposed general exclusion order and remedies against the named Respondents in this Investigation.

Dated: July 9, 2021

Respectfully submitted,

/s/ James M. Wodarski
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