INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1279]

Certain Flocked Swabs, Products Containing Flocked Swabs, and Methods of Using Same; Notice of a Commission Determination to Review in Part a Final Initial Determination; and, on Review, to Find No Violation of Section 337; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the presiding administrative law judge's ("ALJ") final initial determination ("ID") issued on October 28, 2022, finding no violation of section 337, in the above-referenced investigation. On review, the Commission has determined to find no violation of section 337. The investigation is terminated in its entirety.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On September 2, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on a complaint filed by Copan Italia S.p.A. and Copan Industries, Inc. ("Copan," or "Complainants"). 86 FR 49343-44 (Sept. 2, 2021). The complaint alleged a violation of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain flocked swabs, products containing flocked swabs,

and methods of using same by reason of infringement of claims 1, 6-9, 11-14, 16-19, and 21-22 of U.S. Patent No. 9,011,358 ("the '358 patent"); claims 1, 4-6, 8, 9, 11-13, 16-20, and 22-24 of U.S. Patent No. 9,173,779 ("the '779 patent"); and claims 1, 3, 5, 7-10, 18, and 20 of U.S. Patent No. 10,327,741 ("the '741 patent"). The complaint also alleged the existence of a domestic industry.

The notice of investigation named numerous respondents, including Han Chang Medic of Chungnam, Republic of Korea ("HCM"); Wuxi NEST Biotechnology Co., Ltd. of Wuxi, Jiangsu, China; NEST Scientific Inc. and NEST Scientific USA, both of Rahway, New Jersey (collectively, "NEST"); Miraclean Technology Co., Ltd. of Shenzhen, Guangdong, China ("Miraclean"); Vectornate Korea Ltd. of Jangseong, Republic of Korea and Vectornate USA, Inc. of Mahwah, New Jersey (collectively, "Vectornate"); Innovative Product Brands, Inc. of Highland, California ("Innovative"); Thomas Scientific, Inc. of Swedesboro, New Jersey ("TSI"); Thomas Scientific, LLC ("TSL") and Stellar Scientific, LLC ("Stellar"), both of Owings Mills, Maryland; Cardinal Health, Inc. of Dublin, Ohio ("Cardinal"); KSL Biomedical, Inc. and KSL Diagnostics, Inc., both of Williamsville, New York (collectively, "KSL"); Jiangsu Changfeng Medical Industry Co., Ltd. of Yangzhou, Jiangsu, China ("JCM"); No Borders Dental Resources, Inc., dba MediDent Supplies of Queen Creek, Arizona ("MediDent"); BioTeke Corporation (Wuxi) Co., Ltd. of Wuxi, Jiangsu, China ("BioTeke"); Fosun Pharma USA Inc. of Princeton, New Jersey ("Fosun"); Hunan Runmei Gene Technology Co., Ltd. of Changsha, Hunan, China ("HRGT"); VWR International, LLC of Radnor, Pennsylvania ("VWR"); and Slmp, LLC dba StatLab Medical Products of McKinney, Texas ("StatLab"). *Id*. at 49343-44. The Commission's Office of Unfair Import Investigations ("OUII") was also named as a party in this investigation. *Id*. at 49344. After institution, Huachenyang (Shenzhen) Technology Co., Ltd. ("HCY") and HCY USA, LLC ("HCY USA") were allowed to intervene as respondents in this investigation. Order No. 30 (Dec. 7, 2021), *unreviewed by* Notice (Jan. 6, 2021).

On June 15, 2022, a Claim Construction Order (Order No. 51) issued construing claim

terms from the asserted patents. Pursuant to the parties' request, that Order was amended with respect to the definition of level of a person of ordinary skill in the art in Order No. 66 (July 1, 2022). An evidentiary hearing was held on June 27-July 1, 2022.

During the course of the investigation, a number of respondents were terminated from the investigation or were found in default. *See* ID at 7 n.5 (noting termination of the investigation as to KSL, VWR, Cardinal, Innovative, Vectornate, TSL, TSI, Stellar, HCY USA, StatLab, and Fosun); ID at 7 n.6 (citing Order No. 27 (Nov. 15, 2021), *unreviewed*, Comm'n Notice (Dec. 6, 2021) (finding HRGT in default); Order No. 31 (Dec. 15, 2021), *unreviewed*, Comm'n Notice (Jan. 10, 2022) (finding HCM and MediDent in default)). The following respondents remain in the investigation: NEST, JCM, BioTeke, Miraclean, and HCY (collectively, "Respondents").

Also, during the course of the investigation, Complainants withdrew their allegations with respect to claims 7-9, 11-14, 16-19, 21, and 22 of the '358 patent, claims 4-6, 8, 11-13, 16-20, and 22-24 of the '779 patent, and claims 5, 7-9, and 20 of the '741 patent, and the investigation was terminated as to these claims. Thus, claims 1 and 6 of the '358 patent, claims 1 and 9 of the '779 patent, and claims 1, 3, 10, and 18 of the '741 patent remain in the investigation.

On October 28, 2022, the ALJ issued a final ID, finding no violation of section 337 in this investigation. Specifically, the final ID terminated claim 18 of the '741 patent after Complainants did not proceed with this claim at the hearing. With respect to the remaining asserted claims of the '358, '779, and '741 patents, the final ID found no violation based on Complainants' failure of proof with respect to infringement and the technical prong of the domestic industry requirement. The final ID also determined that the asserted patent claims have not been shown to be invalid. The final ID further found that if the asserted domestic industry products satisfy the technical prong of the domestic industry requirement, Complainants have shown that the economic prong of the domestic industry requirement is satisfied with respect to all the asserted patents under section 337(a)(3)(A). On November 14, 2022, the ALJ

issued a recommended determination on remedy, the public interest, and bonding.

Also on November 14, 2022, Complainants, Respondents, and OUII filed separate petitions for review of the final ID. On November 22, 2022, they filed separate replies to the petitions for review.

No submissions were received in response to the Commission's notice soliciting submissions from the public on the public interest issues raised by the recommended determination. 87 FR 70863 (Nov. 21, 2022).

Having reviewed the record of the investigation, including the final ID, the Claim Construction Order, and the parties' submissions, the Commission has determined to review in part the final ID and, on review, affirm the final ID's finding of no violation of section 337 with the supplemental reasoning discussed below. In particular, the Commission has determined to review and adopt the ALJ's claim constructions, including the term "perpendicularly" in the '358 and '779 patent claims and the term "oriented manner" in the '741 patent claims, based on the reasoning provided in the Claim Construction Order and the final ID. The Commission supplements the ID's construction of the term "perpendicularly" with the inventor's statements during prosecution at RX-0309.0270-0271, which further supports the ID's finding at page 50 that the fibers of prior art Griffiths were not flocked in an ordered arrangement normal to the surface although Griffiths employs electrostatic flocking. Copan does not challenge the final ID's findings that Respondents' accused products do not infringe and that the domestic industry products do not practice these limitations under the ALJ's claim constructions. Having failed to show that its alleged domestic industry products practice any of the asserted patents, Copan has necessarily failed to show the existence of a domestic industry under section 337(a)(3) for the asserted patents. Accordingly, the Commission has determined to review and take no position on the economic prong of the domestic industry requirement.

The Commission has also determined to review and adopt the final ID's findings that the JCM accused products do not infringe and that Copan's domestic industry products do not

practice the absorption "by capillarity" limitations of the '358 and '779 patents based on the reasoning provided in the final ID. The Commission supplements the ID's reasoning with the inventor's statements made during prosecution of the '779 patent. In particular, in an August 11, 2014 reply to an office action from June 11, 2014, the inventor argued that a "brush" disclosed in the prior art, Hedberg (U.S. Patent No. 5,623,941) (RX-0141), "does not provide an appreciable capillary action of the fiber layer, since the quantity of liquid collected by dipping the brush in a liquid (please note that a collection of liquid by dipping a device into the liquid does not require a capillary action, since also a spoon can collect liquid when dipped into a liquid container, despite the fact that a spoon evidently has no capillary action) was easily lost by the swab, thus showing the absence of a capillary effect . . . ." JX-0005.1555 (emphasis in original). The Commission finds the inventor's statements during prosecution further support the ID's finding that Dr. Michielsen's testing, which included collecting liquid after dipping an accused swab into beet juice, did not reliably show liquid absorbed solely by capillarity. *See, e.g.*, ID at 103. Thus, the Commission finds the record evidence supports the ID's finding that Dr. Michielsen's testing does not show, by a preponderance of the evidence, that the absorption "by capillarity" limitation is met by the JCM accused products and Copan's domestic industry products. *See* ID at 103-106, 111, 128-29, 131.

Among other findings, the Commission has determined not to review the final ID's findings that BioTeke's redesigned products should be adjudicated and are not infringing and that the asserted claims have not been shown to be invalid.

In addition, the Commission corrects a typographical error on page 151 of the ID. The sentence should read as follows: "the evidence does *not* show, clearly and convincingly, obviousness of any asserted claim . . . ."

Accordingly, the Commission has determined to affirm the ID's finding of no violation of section 337 with the supplemental reasoning discussed above. The investigation is terminated in its entirety.

The Commission vote for this determination took place on March 17, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: March 17, 2023.

Lisa Barton,

Secretary to the Commission.

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