

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DENTAL IMPLANTS

Investigation No. 337-TA-934

**NOTICE OF COMMISSION FINAL DETERMINATION OF VIOLATION
OF SECTION 337; TERMINATION OF INVESTIGATION;
ISSUANCE OF LIMITED EXCLUSION ORDER**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”) in the above-captioned investigation. The Commission has determined to issue a limited exclusion order. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.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: The Commission instituted this investigation on October 27, 2014, based on a Complaint filed by Nobel Biocare Services AG of Kloten, Switzerland and Nobel Biocare USA, LLC of Yorba Linda, California (collectively, “Nobel”), as supplemented. *79 Fed. Reg.* 63940-41 (Oct. 27, 2014). The Complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”), in the sale for importation, importation, and sale within the United States after importation of certain dental implants by reason of infringement of certain claims of U.S. Patent Nos. 8,714,977 (“the ’977 patent”) and 8,764,443 (“the ’443 patent”). The Complaint further alleges the existence of a domestic industry. The Commission’s Notice of Investigation named as respondents Neodent USA, Inc., of Andover, Massachusetts and JJGC Indústria e Comércio de Materiais Dentários S/A of Curitiba, Brazil (collectively, “Respondents”). The Commission previously terminated

the investigation in part as to certain claims of the '443 patent. Notice (Apr. 29, 2015); Order No. 22 (Apr. 8, 2015). The Commission also amended the Notice of Investigation to reflect the corporate name change of Neodent USA, Inc. to Intradent USA, Inc. Notice (May 6, 2015); Order No. 24 (Apr. 9, 2015). The use of the term "Respondents" herein refers to the current named respondents.

On October 27, 2015, the ALJ issued his final ID, finding a violation of section 337 with respect to asserted claims 15, 18, 19, 30, and 32 of the '443 patent, and finding no violation with respect to asserted claim 17 of the '443 patent and all of the asserted claims of the '977 patent. In particular, the final ID finds that the accused products infringe claims 1-5 and 19 of the '977 patent and claims 15, 18, 19, 30, and 32 of the '443 patent, but do not infringe claim 17 of the '443 patent. The final ID also found that Respondents have shown that the asserted claims of the '977 patent are invalid for anticipation under 35 U.S.C. § 102, but have not shown that the asserted claims of the '443 are invalid. In addition, the final ID found that Respondents failed to show that the asserted claims of the '977 and '443 patents are unenforceable due to inequitable conduct. The final ID further found that Nobel has satisfied the domestic industry requirement with respect to both the '977 and '443 patents.

On November 10, 2015, the ALJ issued his recommended determination ("RD") on remedy and bonding. The RD recommended that the appropriate remedy is a limited exclusion order barring entry of Respondents' infringing dental implants. The RD did not recommend issuance of a cease and desist order against any respondent. The RD recommended the imposition of a bond of \$120 per imported unit during the period of Presidential review.

On November 9, 2015, Nobel filed a petition for review of the final ID's finding of no violation with respect to claims 1-5 of the '977 patent. In particular, Nobel requested review of the final ID's finding that the March 2003 Product Catalog of Alpha Bio Tec, Ltd. ("the 2003 Alpha Bio Tec Catalog") constitutes prior art under 35 U.S.C. 102(b), arguing that the catalog was not sufficiently publicly accessible prior to the critical date. Nobel also requested, if the Commission determines not to review the ID's prior art finding, that the Commission review the final ID's construction of the limitation "the coronal region having a frustoconical shape" recited in claim 1 of the '977 patent and, accordingly, review the final ID's finding that the accused products do not infringe claims 1-5 of the '977 patent under Nobel's proposed construction of that limitation. Nobel further argued that, should the Commission agree partially with Nobel concerning the proper construction of the limitation "the coronal region having a frustoconical shape," the 2003 Alpha-Bio Tec Catalog does not anticipate the asserted claims of the '977 patent.

No party petitioned for review of the final ID's finding that there is a violation of section 337 with respect to the '443 patent.

On November 17, 2015, Respondents and the Commission investigative attorney each filed responses opposing Nobel's petition for review.

On December 10, 2015, Respondents submitted a post-RD statement on the public interest

pursuant to Commission Rule 210.50(a)(4). On December 14, 2015, Nobel submitted a post-RD statement on the public interest pursuant to Commission Rule 210.50(a)(4). No responses were filed by the public in response to the post-RD Commission Notice issued on November 12, 2015. *See* Notice of Request for Statements on the Public Interest, 80 *Fed. Reg.* 76574-75 (Dec. 9, 2015), *see also* Correction of Notice, 80 *Fed. Reg.* 77376-77 (Dec. 14, 2015).

On January 14, 2016, the Commission determined to review the Final ID in part with respect to the '977 patent. 81 *Fed. Reg.* 3471-3473 (Jan. 21, 2016). Specifically, the Commission determined to review the final ID's construction of the limitation "coronal region having a frustoconical shape" recited in claim 1 of the '977 patent with regard to whether or not the term "frustoconical shape" is an adjective that modifies the claimed "coronal region" or whether the term is an independent structure that may comprise only a portion of the claimed "coronal region." In accordance with its claim construction review, the Commission further determined to review the final ID's infringement findings with respect to claims 1-5 of the '977 patent, as well as the final ID's finding that the technical prong of the domestic industry requirement is satisfied with respect to claims 1-5 of the '977 patent. The Commission also determined to review the final ID's finding that the 2003 Alpha Bio Tec Catalog is a printed publication under 35 U.S.C. § 102. The Commission further determined to review the final ID's finding that the 2003 Alpha Bio Tec Catalog anticipates claims 1-5 of the '977 patent. In connection with its review, the Commission requested briefing on several questions. *Id.* at 3472.

The Commission determined not to review the remaining issues decided in the final ID, including any of the Final ID's findings with respect to the '443 patent. The Commission also denied a motion filed by Nobel to amend the Administrative Protective Order issued in this investigation to add specific provisions permitting the use of discovery from this investigation in two co-pending proceedings in the U.S. Patent and Trademark Office captioned as *Instradent USA, Inc. v. Nobel Biocare Services AG*, IPR2015-01784, and *Instradent USA, Inc. v. Nobel Biocare Services AG*, IPR2015-01786, as well as Nobel's motion for leave to file a reply in support of its motion. *Id.* at 3473.

On January 21, 2016, the parties filed initial submissions in response to the Commission's request for written submissions. On January 28, 2016, the parties filed response submissions.

Having examined the record of this investigation, including the final ID, the petitions for review, and the responses thereto, and the parties' submissions on review, the Commission has determined to find that a violation of section 337 has occurred. The Commission has determined that the appropriate form of relief is a limited exclusion order under 19 U.S.C. § 1337(d)(1), prohibiting the unlicensed entry of dental implants that infringe any of claims 1-5 of the '977 patent and claims 15, 18, 19, 30, and 32 of the '443 patent.

The Commission has further determined that consideration of the public interest factors enumerated in section 337(d) (19 U.S.C. § 1337(d)) does not preclude issuance of the limited exclusion order. The Commission has determined that the bond for temporary importation during the period of Presidential review (19 U.S.C. § 1337(j)) shall be in the amount of \$120 per

unit of articles subject to the exclusion order. The Commission's order was delivered to the President and the United States Trade Representative on the day of its issuance.

The investigation is terminated.

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 C.F.R. Part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton". The signature is fluid and cursive, with the first name "Lisa" being the most prominent part.

Lisa R. Barton
Secretary to the Commission

Issued: April 26, 2016