

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DENTAL IMPLANTS

Investigation No. 337-TA-934

**NOTICE OF COMMISSION DECISION TO REVIEW IN PART A FINAL INITIAL
DETERMINATION FINDING A VIOLATION OF SECTION 337;
REQUEST FOR WRITTEN SUBMISSIONS**

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 ("final ID") issued on October 27, 2015 finding 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.

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 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 (“IA”) 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).

Having examined the record of this investigation, including the final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part.

Specifically, the Commission has 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 has 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 has 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 has further determined to review the final ID's finding that the 2003 Alpha Bio Tec Catalog anticipates claims 1-5 of the '977 patent.

The Commission has determined not to review the remaining issues decided in the final ID.

The parties are requested to brief their positions on the issues under review with reference to the applicable law and the evidentiary record. In connection with its review, the Commission is particularly interested in responses to the following questions:

1. With respect to the proper construction of the limitation "coronal region having a frustoconical shape" recited in claim 1 of the '977 patent, please address the meaning of the term "frustoconical shape" in the context of claim 1, and, in particular, whether the term is an adjective that merely modifies the claimed "coronal region" or whether the term may refer to an independent structure comprised within the claimed "coronal region." In addition, please address the significance of the clause "wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region" recited in claim 1 to the appropriate construction of the limitation "coronal region having a frustoconical shape." Please discuss all governing precedent with respect to this issue.
2. With respect to whether the 2003 Alpha Bio Tec Catalog is prior art to the '977 patent, please address the significance of the evidence presented in exhibit JX-0278C, and the significance of the inclusion of the catalog in an information disclosure statement to the U.S. Patent and Trademark Office (*see* exhibit CX-0560). In addition, please address any evidence regarding the publication date of the 2003 Alpha Bio Tec

Catalog, as well as any record evidence concerning whether and when the 2003 Alpha Bio Tec Catalog was “publically accessible” prior to the critical date under governing precedent.

3. Please address whether the 2003 Alpha Bio Tec Catalog anticipates the asserted claims of the '977 patent under a construction of the limitation “coronal region having a frustoconical shape” recited in claim 1 that requires the entire coronal region to be frustoconical but does not require any additional functional limitation.
4. With respect to whether the 2003 Alpha Bio Tec Catalog anticipates claim 2 of the '977 patent, please address the significance of the testimony of Nobel’s expert, Mr. Hurson, that one of ordinary skill in the art would understand that any portion of an implant intended to mate with another component, *e.g.* an abutment, would never be acid-etched. In addition, please address whether or not the 2003 Alpha Bio Tec Catalog clearly and convincingly discloses that the bevel of the illustrated 5.0 mm SPI implant is acid etched.
5. Please address whether, under a construction of the limitation “coronal region having a frustoconical shape” recited in claim 1 of the '977 patent that requires the entire coronal region to be frustoconical but does not require any additional functional limitation, the technical prong of the domestic industry requirement is satisfied with respect to claim 1 of the '977 patent.

The parties have been invited to brief only these discrete issues, as enumerated above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties’ existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent(s) being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the

aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 *Fed. Reg.* 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation, including the Office of Unfair Import Investigations, are requested to file written submissions on the issues identified in this notice. Parties to the investigation, including the Office of Unfair Import Investigations, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainant and the Office of Unfair Import Investigations are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is further requested to state the dates that the patents expire, the HTSUS numbers under which the accused products are imported, and any known importers of the accused products. The written submissions and proposed remedial orders must be filed no later than close of business on **January 21, 2016**. Initial submissions are limited to 50 pages, not including any attachments or exhibits related to discussion of the public interest. Reply submissions must be filed no later than the close of business on **January 28, 2016**. Reply submissions are limited to 25 pages, not including any attachments or exhibits related to discussion of the public interest. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-934") in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures*, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

On October 21, 2015, Nobel filed a motion to amend the Administrative Protective Order (“APO”) 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. On November 2, 2015, Respondents and the IA filed oppositions to Nobel’s motion. On November 12, 2015, Nobel filed a motion for leave to file a reply in support of its motion to amend the APO. On November 23, 2015, Respondents filed an opposition to Nobel’s motion for leave to file a reply.

The Commission has determined to deny both Nobel’s motion to amend the APO and motion for leave to file a reply in support of its motion.

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', with a stylized flourish at the end.

Lisa R. Barton
Secretary to the Commission

Issued: January 14, 2016