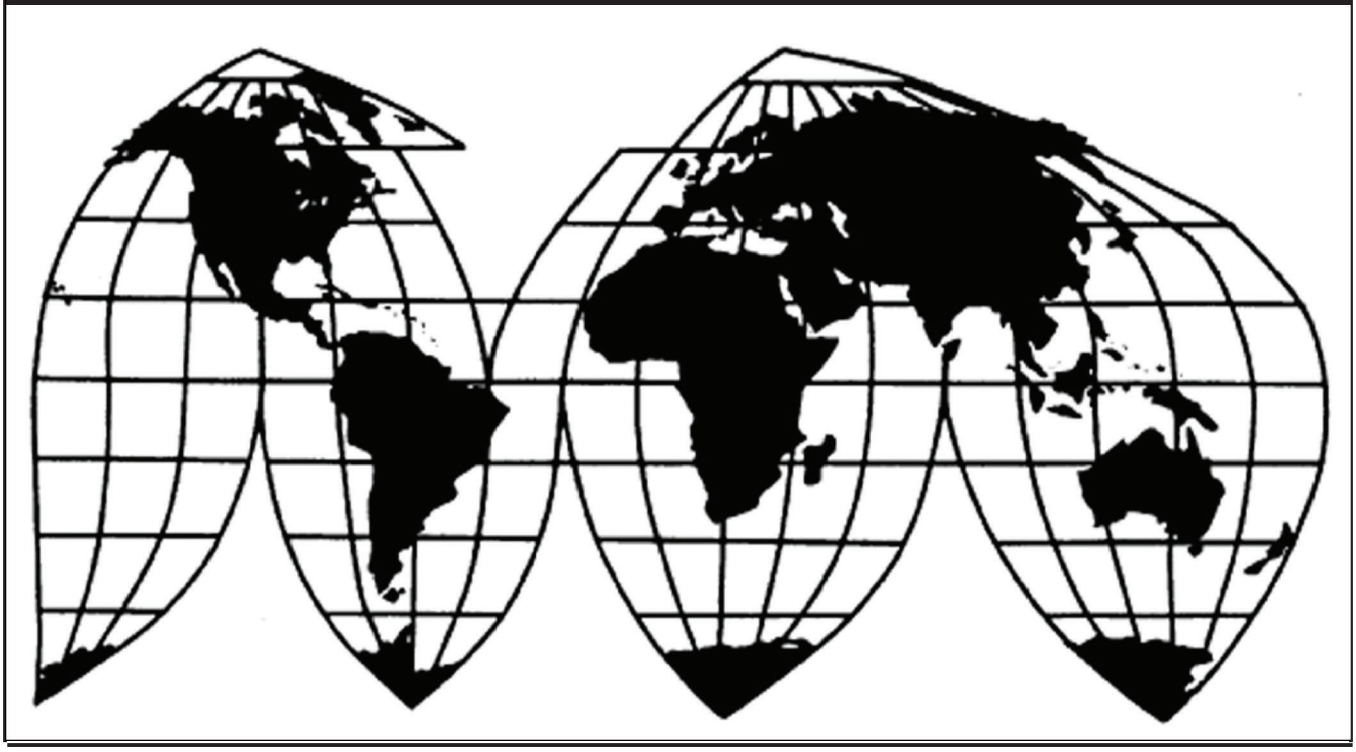
In the Matter of

CERTAIN DENTAL IMPLANTS

337-TA-934

Publication 4905 **June 2019**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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U.S. International Trade Commission

Washington, DC 20436
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In the Matter of

CERTAIN DENTAL IMPLANTS

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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 Instradent 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 submited a post-RD statement on the public interest

pursuant to Commission Rule 210.50(a)(4). On December 14, 2015, Nobel submited 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.

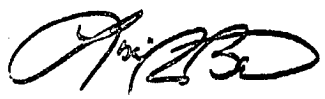
The Commission has further determined that consideration of the public interest factors enumerated in section 337(d) (19 U.S.C. § 1337(d)) does not preclude issuance of the limited exclusion order. The Commission has determined that the bond for temporary importation during the period of Presidential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

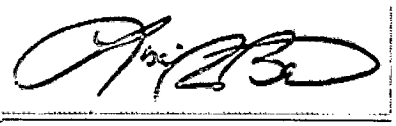


Lisa R. Barton
Secretary to the Commission

Issued: April 26, 2016

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Todd P. Taylor, Esq., and the following parties as indicated, on **April 26, 2016.**



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Nobel Biocare Services AG and Nobel Biocare USA, LLC:

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☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents Instradent USA, Inc. and JJGC Industria e Comercio de Materiais Dentarios S/A:

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Washington, DC 20007-5109

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN DENTAL IMPLANTS	**Inv. No. 337-TA-934**

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (9 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Respondents Instradent USA, Inc. and JJGC Indústria e Comércio de Materiais Dentários S/A (collectively "Respondents") of certain dental implants covered by one or more of claims 1-5 of U.S. Patent No.8,714,977 ("the '977 patent), or claims 15, 18, 19, 30, and 32 of U.S. Patent No. 8,764,443 ("the '443 patent").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting entry of infringing dental implants that are manufactured abroad by or on behalf of, or imported by or on behalf of Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns.

The Commission has further determined that the public interest factors enumerated in 19 § 1337(d) do not preclude issuance of the limited exclusion order, and that the bond during

the period of Presidential review shall be in the amount of $120 per unit of covered products.

Accordingly, the Commission hereby **ORDERS** that:

1. Dental implants that infringe one or more of claims 1-5 of the '977 patent, or claims 15, 18, 19, 30, and 32 of the '443 patent that are manufactured by, or on behalf of, or imported by or on behalf of Instradent USA, Inc. and JJGC Indústria e Comércio de Materiais Dentários S/A or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining term of the patents, except under license of the patents' owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the aforesaid dental implants are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of $120 per unit pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 *Fed. Reg.* 43,251), from the day after this Order is received by the United States Trade Representative, and until such time as the United States Trade Representative notifies the Commission that this action is approved or disapproved but, in any event, not later than 60 days after the issuance of receipt of this Order.

3. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to procedures it establishes, persons seeking to import dental implants that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their

knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

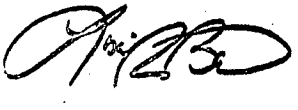
4. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to infringing dental implants that are imported by or for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedures described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

6. The Secretary shall serve copies of this Order upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and CBP.

7. Notice of this Order shall be published in the *Federal Register*.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: April 26, 2016

PUBLIC CERTIFICATE OF SERVICE

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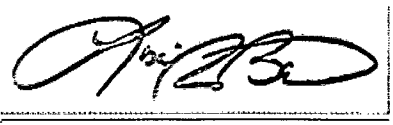

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Nobel Biocare Services AG and Nobel Biocare USA, LLC:

John B. Sganga, Jr., Esq.
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On Behalf of Respondents Instradent USA, Inc. and JJGC Industria e Comercio de Materiais Dentarios S/A:

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☐ Other:_____

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 Instradent 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 submited a post-RD statement on the public interest

pursuant to Commission Rule 210.50(a)(4). On December 14, 2015, Nobel submited 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.

Lisa R. Barton
Secretary to the Commission

Issued: January 14, 2016

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Todd P. Taylor, Esq., and the following parties as indicated, on **January 14, 2016.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Nobel Biocare Services AG and Nobel Biocare USA, LLC:

John B. Sganga, Jr., Esq.
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☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents Instradent USA, Inc. and JJGC Industria e Comercio de Materiais Dentarios S/A:

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN DENTAL IMPLANTS	Investigation No. 337-TA-934

COMMISSION OPINION

I. BACKGROUND

A. Procedural History[1]

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"), 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[2] and JJGC Indústria e Comércio de Materiais Dentários S/A of Curitiba, Brazil ("JJGC") (collectively, "Respondents"). The Office of Unfair Import Investigations was also named as a party to the investigation.

[1] The procedural history of the investigation prior to the issuance of the final initial determination is fully set forth in that document. *See* Final ID at 1-2.

[2] As noted below, the corporate name of Neodent USA, Inc. has been corrected to Instradent USA, Inc. The term "Respondents" used herein shall refer to the named respondents, including Instradent USA, Inc.

On April 7, 2015, Nobel filed a motion to partially terminate the investigation as to claims 16 and 29 of the '443 patent. On April 8, 2015, the ALJ granted the motion. Order No. 22 (Apr. 8, 2015). On April 29, 2015, the Commission determined not to review Order No. 22. Notice (Apr. 29, 2015).

On April 8, 2015, Nobel and Respondents filed a joint motion to amend the Complaint and Notice of Investigation to reflect a corporate name change, effective August 15, 2014, of respondent Neodent USA to Instradent USA, Inc. ("Instradent"). On April 9, 2015, the ALJ granted the joint motion. Order No. 24 (Apr. 9, 2014). On May 6, 2015, the Commission determined not to review Order No. 24. Notice (May 6, 2015).

The ALJ held an evidentiary hearing on July 7-10, 2015. The ALJ thereafter received post-hearing briefing from the parties.

On October 27, 2015, the ALJ issued his final initial determination ("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 finds 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 finds 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 finds 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 ALJ recommended in his RD that the appropriate remedy is a limited exclusion order barring entry of Respondents' infringing dental implants. The ALJ did not recommend issuance of cease and desist orders against any respondent. The ALJ 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.[3] 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 of the '977 patent. Nobel also requested, if the Commission determined not to review the ALJ's finding that the 2003 Alpha Bio Tec Catalog is prior art, that the Commission review the Final ID's construction of the limitation "the coronal region having 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 the asserted claims 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 frustoconical shape," the 2003 Alpha-Bio Tec Catalog does not anticipate the asserted claims of the '977 patent.

On November 17, 2015, Respondents and the Commission investigative attorney ("IA")

[3] Complainants' Petition for Review of Initial Determination (Nov. 9, 2015) ("Pet."). Nobel did not seek review of the Final ID's findings with respect to claim 19 of the '977 patent. *Id.* at 6. The Commission therefore finds that all of the Final ID's findings with respect to claim 19 of the '977 patent are moot has Nobel as effectively withdrawn its allegations as to that claim from the investigation.

each filed responses opposing Nobel's petition for review.[4]

On December 10, 2015, Respondents filed public interest statements pursuant to Commission Rule 210.50(a)(4). On December 14, 2015, Nobel filed public interest statements pursuant to Commission Rule 210.50(a)(4). No comments were received in response to the Commission's request for public interest statements filed in the Federal Register. *See* 80 *Fed. Reg.* 76574-75 (Dec. 9, 2015).

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.[5] On November 2, 2015, Respondents and the IA filed oppositions to Nobel's motion.[6] 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. [7]

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[4] Respondents' Response to Complainants' Petition for Review of the Initial Determination (Nov. 17, 2015) ("Resp. Opp."); Response of the Office of Unfair Import Investigations to Complainants' Petition for Commission Review of the Final Initial Determination (Nov. 17, 2015) ("IA Opp.").

[5] Nobel's Memorandum in Support of its Motion to Amend the Protective Order (Oct. 21, 2015).

[6] Respondents' Memorandum in Opposition to Complainants' Motion to Amend the Protective Order (Nov. 2, 2015); Commission Investigative Staff's Response to Complainants' Motion to Amend the Protective Order (Nov. 2, 2015).

[7] Respondents' Memorandum in Opposition to Complainants' Motion for Leave to File a Reply to Motion to Amend the Protective Order (Nov. 23, 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).[8] 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." *Id.* at 3472. 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. *Id.* 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. *Id.* 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. *Id.* In connection with its review, the Commission posed several questions to the parties. *Id.* at 3472.

The Commission denied Nobel's motion to amend the APO and 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.[9] On January 28, 2016, the parties filed response

[8] No party petitioned for review of the Final ID's findings with respect to the '443 patent, and the Commission determined not to review these findings. *See* 81 *Fed Reg.* at 3742.

[9] Complainants' Initial Written Submission Pursuant to Commission's Notice Dated January 14, 2016 (Jan. 21, 2016) ("Comp. Br."); Respondents' Initial Submission in Response to Notice of Commission Decision to Review in Part a Final Initial Determination Finding a Violation of

submissions.[10]

B. Patent at Issue[11]

The '977 patent is entitled "Condensing Skeletal Implant That Facilitate Insertions" and is directed to bone anchorage implants and more particularly to a screw form dental implant designed to produce bone condensation during insertion.[12] Dental implants are placed in a patient's jawbone to serve as an anchor for a dental prosthesis such as an artificial tooth. The '977 patent has 20 claims, of which claims 1-5 are currently asserted against Respondents.[13]

Claim 1 is directed toward a dental implant comprising a coronal region (the region positioned closest to the crest of the jawbone where the teeth are located) and an apical region (the region positioned below the coronal region and that is inserted deeper into the jawbone). The coronal region has a frustoconical shape, and the diameter of the apical end of the coronal

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Section 337; Request for Written Submissions (Jan. 21, 2016) ("Resp. Br."); Submission of the Office of Unfair Import Investigations in Response to Notice of Commission Decision to Review in Part a Final Initial Determination (Jan. 21, 2016) ("IA Br.").

[10] Complainants' Reply to the Written Submissions of Respondents and the Staff to the Commission (Jan. 28, 2016) ("Comp. Resp."); Respondents' Reply Submission in Response to Notice of Commission Decision to Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions (Jan. 28, 2016) ("Resp. Resp."); Office of Unfair Import Investigations' Reply to Complainants' Response to the Notice of Commission Decision to Review in Part a Final Initial Determination (Jan. 28, 2016) ("IA Resp.").

[11] Because the Commission did not review any aspect of the Final ID with respect to the '443 patent, we discuss only claims 1-5 of the '977 patent.

[12] Bone condensation refers to the ability of a device being placed into bone to compress the bone outwardly (away from the implant) during insertion.

[13] As noted above, the Commission has determined that all findings related to claim 19 in the ID are moot inasmuch as Nobel does not seek review of the Final ID with respect to claim 19 of the '977 patent. Pet. at 6.

region is larger than the diameter of the coronal end of the coronal region. The diameter of the apical region is larger at the coronal end of the apical region of the implant than at the apical end of the apical region of the implant, and the implant is substantially flat at the apical end of the implant. The claimed dental implant further comprises a pair of helical threads extending along at least a portion of the apical region where the blades of the threads are deeper and sharper at the apical end of the implant and become progressively more shallow and blunter toward the coronal end of the apical region. The claimed dental implant also includes a bone tap, which defines the start of the helical threads. The thread step of the helical threads, which is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, is between 1.5-2.5 mm.

Dependent claims 2-5 recite additional limitations for the claimed dental implant, including: the coronal region has a surface configured to be in contact with bone (claim 2); the apical end of the coronal region defines an upper limit of the threads (claim 3), the threads adjacent to the apical end of the dental implant are self-tapping (is capable of being inserted into bone without need for a preparatory hole being drilled) (claim 4); and the apical end of the dental implant includes a spiral tap which extends from one side of the implant to the opposite side and extends along more than a third of the length of the implant (claim 5).

C. Products at Issue

The accused products include certain models of Instradent's Drive CM dental implants. ID at 4; Amended Joint Statement of Accused Products (Mar. 4, 2015). The parties agreed to designate three representative products for purposes of the infringement analysis, including: (1) the 5.0 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.686) as representative

of the accused 5.0 mm Drive CM dental implants; (2) the 4.3 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.628) as representative of the accused 4.3 mm Drive CM dental implants; and (3) the 3.5 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.683) as representative of the accused 3.5 mm Drive CM dental implants. *Id.* Nobel accused the Drive CM 4.3 mm and 5.0 mm of infringing the '977 patent.[14] *Id.* at 5. The following is a complete listing of accused products:

Product Name	**Diameter x Length**	**Product No.**
Drive CM	3.5 mm x 8.0	109.692
Drive CM	3.5 mm x 10.0	109.682
Drive CM	3.5 mm x 11.5	109.693
Drive CM	3.5 mm x 13.0	109.683
Drive CM	3.5 mm x 16.0	109.684
Drive CM	4.3 mm x 8.0	109.689
Drive CM	4.3 mm x 10.0	109.688
Drive CM	4.3 mm x 11.5	109.627
Drive CM	4.3 mm x 13.0	109.628
Drive CM	4.3 mm x 16.0	109.629
Drive CM	5.0 mm x 8.0	109.690
Drive CM	5.0 mm x 10.0	109.685
Drive CM	5.0 mm x 11.5	109.691

[14] Nobel Biocare also accused all three representative models, *i.e.*, the Drive CM 3.5 mm, 4.3 mm, and 5.0 mm of infringing the '443 patent.

Drive CM	5.0 mm x 13.0	109.686
Drive CM	5.0 mm x 16.0	109.687

See Comp. Br. at 35-36

II. STANDARD OF REVIEW

Once the Commission determines to review an initial determination, its review is conducted *de novo*. *Certain Polyethylene Terephthalate Yarn and Prods. Containing Same*, Inv. No. 337-TA-457, Comm'n Op. at 9 (June 18, 2002). Upon review, the "Commission has 'all the powers which it would have in making the initial determination,' except where the issues are limited on notice or by rule." *Certain Flash Memory Circuits and Prods. Containing Same,* Inv. No. 337-TA-382, USITC Pub. 3046, Comm'n Op. at 9-10 (July 1997) (quoting *Certain Acid-Washed Denim Garments and Accessories,* Inv. No. 337-TA-324, Comm'n Op. at 5 (Nov. 1992)). Commission practice in this regard is consistent with the Administrative Procedure Act. *Certain EPROM, EEPROM, Flash Memory, and Flash Microcontroller Semiconductor Devices and Prods. Containing Same,* Inv. No. 337-TA-395, Comm'n Op. at 6 (Dec. 11, 2000) ("*EPROM*"); *see also* 5 U.S.C. § 557(b).

Upon review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge. The Commission may also make any findings or conclusions that in its judgment are proper based on the record in the proceeding." 19 C.F.R. § 210.45. This rule reflects the fact that the Commission is not an appellate court, but is the body responsible for making the final agency decision. On appeal, only the Commission's final decision is at issue. *See Spansion, Inc. v. Int'l*

Trade Comm'n, 629 F.3d 1331, 1349 (Fed. Cir. 2010); *EPROM* at 6 (citing *Fischer & Porter Co. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1574, 1576-77 (Fed. Cir. 1987)).

III. ANALYSIS CONCERNING ISSUES ON REVIEW

A. Claim Construction

Claim construction "begin[s] with and remain[s] centered on the language of the claims themselves." *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 830 (Fed. Cir. 2003); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The language used in a claim bears a "heavy presumption" that it has the ordinary and customary meaning that would be attributed to the words used by persons skilled in the relevant art. *Phillips*, 415 F.3d at 1312-13. To help inform the court of the ordinary meaning of the words, a court may consult the intrinsic evidence, including the claims themselves, the specification, and the prosecution history, as well as extrinsic evidence, such as dictionaries and treatises and inventor and expert testimony. *Id.* at 1314. In particular "the specification 'is always highly relevant to the claims construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1315 (citations omitted).

A court must "take care not to import limitations into the claims from the specification." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009). "When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application 'unless the patentee has demonstrated a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction."'" *Id.* (citations omitted). "By the same token, the claims cannot enlarge what is patented beyond what the inventor has described as the invention. Thus this court may reach a narrower construction,

limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method." *Id.* (citations omitted).

Alternatively, where a patent discloses multiple embodiments, "a claim need not cover all embodiments." *Intamin, Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1337 (Fed. Cir. 2007); *see also Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015); *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008). Rather, "[i]t is often the case that different claims are directed to and cover different disclosed embodiments." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008).

"[T]he distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice . . . [h]owever, the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." *Phillips*, 415 F.3d at 1323 (citations omitted). In attempting to discern whether a "patentee is setting out specific examples of the invention . . . or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive . . . [t]he manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent." *Id.*

Claim 1 of the '977 patent recites the following, with the currently disputed limitation—"the coronal region having a frustoconical shape"— highlighted:

1. A dental implant comprising:

a body;

a coronal region of the body, **the coronal region having a frustoconical shape** wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region;

an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core and the apical end of the core is substantially flat; and a pair of helical threads extending from the body along at least a portion of the apical region, each of the threads comprising an apical side, a coronal side, and a lateral edge connecting the apical side and the coronal side, a base connecting the threads to the core, a thread height defined between the lateral edge and the base, the lateral edge having a variable width that is expanded along a segment in the direction of the coronal end of the apical region, so that a least width of the lateral edge of the threads is adjacent the apical end of the apical region and a greatest width of the lateral edge of the threads is adjacent the coronal end of the apical region, and the threads having a variable height that is expanded substantially along the segment of the implant in the direction of the apical end of the apical region, so that a least height of the threads is adjacent the coronal end of the apical region and a greatest height at apical end of the apical region; and

a bone tap, wherein the helical threads starts at said bone tap and said substantially flat apical end of the core;

wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5-2.5 mm.

'977 patent at 17:51–18:18.

1. Final ID

The parties proposed the following claim constructions:

Claim Term	Nobel	Respondents	Staff
"the coronal region having a frustoconical shape" (claim 1)	"the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion"	"the coronal region has, partly or entirely, a frustoconical shape"	"the coronal region has, partly or entirely, a frustoconical shape"

Id.[15] The Final ID construes the limitation "the coronal region having a frustoconical shape" recited in claim 1 of the '977 patent to mean "the coronal region has, partly or entirely, a frustoconical shape." Final ID at 24.

The ALJ noted a conflict between the parties' proposed claim constructions concerning "whether the interpretation of 'having' is open-ended or closed-ended, thereby determining whether the coronal region could have additional shapes besides a frustoconical shape." *Id.* In other words, one conflict between the competing proposed constructions is whether the phrase "frustoconical shape" modifies the claimed "coronal region" as an adjective, meaning the coronal region as a whole has a frustoconical shape, or whether a "frustoconical shape" is a distinct feature that may comprise a portion or the entire claimed "coronal region."

The ALJ found that the "language of claim 1 itself does not require that the term 'having' be construed as closed-ended" as it "neither requires that the whole coronal region have a frustoconical shape, nor does it exclude the coronal region from having additional shapes besides a frustoconical shape." *Id.* at 25. Nor, the ALJ found, does the claim language "use the term 'having' in a manner indicating an objective intent to require that the entire coronal region have a frustoconical shape." *Id.*

[15] "Frustoconical" refers to the shape defined by the frustrum of a cone: a cone in which the plane cutting off the apex is parallel to the base.

Turning to the specification of the '977 patent, the ALJ found that the disclosure supports construing the term "having" as open-ended. *Id.* The ALJ noted that the "specification generally describes the claimed coronal region as the region of the implant above the threads, *i.e.*, the apical region." *Id.* The ALJ found that "the specification, and in particular illustrations of Figures 5, 8, and 9, makes clear that the claimed coronal region may include other shapes (and angles) besides a frustoconical shape." *Id.* at 25-26. The ALJ also stated that the "adopted construction . . . also [covers] the embodiments shown in Figures 12, 17, and 18, in which the entire coronal region has a frustoconical shape." *Id.* at 26. The ALJ criticized Nobel's proposed construction as "an attempt to read the embodiments disclosed in Figure 12 in claim 1." *Id.* The ALJ also noted that "Nobel's expert testified that Nobel's proposed construction conflicts with the teachings of the '977 specification." *Id.* (citing Hurson, Tr. at 203, 204).[16]

2. Analysis

The full wording of the relevant limitation of claim 1 is: "a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region." '977 patent at 17:53-56. The primary disputes between the parties are: (1) whether the term "having a frustoconical shape" in the limitation "the coronal region having a frustoconical shape" recited in claim 1 of the '977 patent is an adjectival phrase modifying the claimed "coronal region"; and (2) whether the term "having" is open or closed-ended.

[16] The parties also contested whether the construction of the limitation "coronal region having a frustoconical shape" should include a functional limitation proposed by Nobel: "that permits bone to relapse upon implant insertion." *Id.* The Commission finds that the ALJ properly rejected the functional portion of Nobel's construction and affirms the Final ID on that issue.

Starting with the words of the claim, the disclosure of the '977 patent does not use the term "frustoconical shape" except in claim 1 itself. Nor does the disclosure refer to any specific "shape" included in the coronal region, frustoconical or otherwise. The parties, however, generally agree that the "wherein" 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") indicates the required orientation of the "frustoconical shape," regardless of whether it comprises the entirety of the "coronal region" or merely a portion of the "coronal region."[17] *See* Comp. Br. at 9; Resp. Br. at 11; IA Br. at 10.

The IA argues that the language of the wherein clause indicates that the claimed "coronal region" may have more than one coronal or apical end. *See* IA Br. at 10. There is no support for this interpretation in the disclosure of the '977 patent. The disclosure consistently uses the terms coronal end and apical end to identify specific points, such as the coronal end and apical end of the implant, and never suggests there may be multiple such ends for a given region. *See, e.g.*, '977 patent at 4:9-13 (describing a dental implant having a body with an apical end and a coronal end, and also including threads having an apical side and a coronal side), 8:12-13 (describing coronal and apical ends of the implant), 9:17-28 (describing the thread profile as the threads progress between the coronal and apical ends of the implant), 9:44-45 (describing the apical and coronal sides of the thread turns).

Respondents refer to the "coronal end" and "apical end" of the "coronal region" as

[17] A "wherein" clause can be a useful guide to determining the meaning of other terms in a claim limitation. *See Trading Technologies Intern., Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1354 (Fed. Cir. 2010) (finding that the district court properly limited a claim limitation to a particular embodiment where suggested by the "wherein" clause).

specific points, but argue that the "wherein" clause "merely places a relative limitation on the diameters at either end of the coronal region" but does not "expressly . . . require that the diameter at the apical end be the largest diameter of the coronal region, or that the diameter at the coronal end be the smallest diameter . . . ." Resp. Br. at 10, 11. The specification of the '977 patent is silent on this point as it does not provide any information concerning the relative diameters of any portion of the coronal region of the disclosed implant.

We do, however, agree with Respondents that the language of claim 1 is broad enough to cover a coronal region that is not entirely a frustoconical shape. Specifically, Respondents note that, even considering the "wherein" clause, the claim language would still encompass, for example, "a coronal region in which a frustocone sits atop a cylindrical portion in the coronal region – as that too would meet the limitation that a diameter at the apical end of the coronal region is larger than a diameter at the coronal end of the coronal region." Resp. Resp. at 7. For support, Respondents point to an exhibit illustrated in Nobel's initial submission, referencing a 1999 textbook entitled "Implant Dentistry" (RX-0153, Fig. 23-11). *Id.* at 7 n. 3 (citing Comp. Br. at 9). According to Respondents, the textbook "discloses both a frustoconical coronal region as well as a coronal region that comprises a frustoconical portion sitting atop a cylindrical portion of the coronal region (depending on the end point of the coronal region) . . . ." *Id.*

While the analogy is not perfect, since Respondents do not explain whether the textbook identifies which specific portion of the implant may be considered the coronal region, the example does support the broader point. Namely the language of claim 1 would include, for example, an implant in which the coronal region includes both a cylinder shape with a frustoconical shape on top of it, so long as the diameter of the cylinder (which in this example is

at the apical end of the coronal region) is larger than the narrowest portion of the frustocone (which is located at the coronal end of the coronal region).

We acknowledge Nobel's argument that "specifying that a structure has a certain shape, *e.g.*, that it has a round shape, is inconsistent with that structure having a different shape, such as a square shape." Comp. Br. at 5. In asserting that the term "frustoconical shape" should be considered an adjective that modifies "coronal region," Nobel notes that the inventors could have used phrases more indicative of something having an independent structure within it, such as "frustoconical part," "frustoconical section," or "frustoconical portion" instead of using the more ambiguous term "frustoconical shape." *Id.* at 4. For example, claim 1 recites "a pair of helical threads extending from the body along *at least a portion* of the apical region," indicating that the patentees knew how to claim something less than the whole when such was the intent. '977 patent at 17:62-63. Similarly, claim 1 also recites "the apical region having a core with a tapered *region*," suggesting that the entirety of the core need not be tapered. '977 patent at 17:57-58 (emphasis added). In addition, claim 19 of the '977 patent, which depends from claim 9, recites a dental implant "wherein a most coronal aspect of the coronal end is tapered" again indicating clearly that not all of the coronal end need be tapered.

As Respondents and the IA note, however, claim 9 recites the manner in which the variable height of threads of the novel implant are "progressively expanded substantially along the entire threaded region," indicating that the patentees knew how to indicate the whole of a region when so desired, thus, showing the converse is also true. *See* Resp. Br. at 3; IA Br. at 9. An examination of the claims recited in the '977 patent therefore provides no definitive support for interpreting the limitation "coronal region having a frustoconical shape" as limited to the

shape of the coronal region as a whole.

The term "having" is a transitional phrase which may be either open or closed-ended. The Federal Circuit has noted, however, that "the term 'having' does not convey the open-ended meaning as strongly as 'comprising.' 'Having,' for instance, does not create a presumption that the body of the claim is open." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l*, 246 F.3d 1336, 1348 (Fed. Cir. 2001). As such, the Court has explained that "[t]ransitional phrases such as . . . 'having' . . . must be interpreted in light of the specification to determine whether open or closed language is intended." *Lampi Corp. v. American Power Prods, Inc.*, 228 F.3d 1365, 1376 (Fed. Cir. 2000) (citing Manual of Patent Examining Procedure § 2111.03 (7th ed. rev.2000)).[18]

Turning to the disclosures in the specification, Nobel argued in its petition for review that claim 1 does not cover the dental implants disclosed in Figures 5, 8, 9 of the '977 patent, but rather "encompasses at least the dental implants shown in Figures 12, 17A-H and 18." Pet. at 25. In response to the IA's assertion that Nobel fails to "even attempt to identify other claims in the asserted patent or in other related patents that read on these embodiments" (IA Br. at 10), Nobel argues that several other claims, both in the '977 patent and in related patents, cover Figures 5, 8, and 9. Specifically, Nobel notes that claim 19 of the '977 patent recites that the "most coronal

[18] Nobel argues that since the term "having" appears in the body of claim 1 rather than as a transitional phrase in the preamble of the claim, no special rules for transitional signals applies in this case. Comp. Resp. at 2. However, in *Lampi*, the transitional phrase also appeared in the body of the claim. Nobel's argument on this point is therefore unpersuasive. *See Lampi*, 228 F.3d at 1369 (claim 11).

aspect of the coronal end is tapered coronally forming narrower coronal edge."[19] Comp. Resp. 3; '977 patent at 17:21-23. Nobel asserts that "Claim 19 therefore encompasses implants such as those in Figures 5, 8, and 9 whose coronal region includes a taper (*i.e.*, frustoconical shape) at its 'most coronal aspect,' regardless of whether the remainder of the coronal region is also frustoconical." *Id.* Nobel argues that the "language of Claim 19 stands in sharp contrast to the language of Claim 1, which attributes the frustoconical shape to the entire coronal region, not the 'most coronal aspect' of that region." *Id.*[20]

The specification of the '977 patent provides numerous embodiments of the novel dental implant, of which the implants illustrated in Figures 1, 5, 6, and 12 are named as preferred embodiments. '977 patent at 10:9, 12:10. The specification explains that the implants illustrated in Figures 1-7 are "completely sharply tapered" along their entire length (toward the apical end) such that the "most coronal region" of those embodiments are "very broad." *Id.* at 11:24-26. As such, these embodiments would not appear to be covered by claim 1, which arguably requires that at least a portion of the coronal region be an inverse frustocone.

The first mention of a coronal region featuring any sort of inverse tapering is in

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[19] Claim 19 depends from claim 9, which recites a "dental implant comprising . . . a coronal end of the body . . . ." '977 patent at 18:36-38.

[20] Nobel also relies on U.S. Patent No. 7,597,557 ("the '557 patent"), a grandparent of the '977 patent that shares a common specification with the '977 patent. *Id.* (citing JX-0025). Nobel argues that, while claim 1 of the '557 patent covers Figures 5, 8, and 9, it clearly does not cover Figure 2, which shows a conventional core shape. Comp. Resp. at 4. This argument is less persuasive than Nobel's argument regarding claim 19 of the '977 as the patent states that the implant of Figure 2 is prior art and obviously not intended to be covered by the claims. *See* '977 patent at 8: 10-12 ("In order to clarify the novelty of the new implant it will be compared to a regular tapered implant like the implant illustrated in FIG. 2.").

connection with Figure 8.[21] Specifically, the specification discloses the following:

> When an implant is *completely sharply tapered as are the implants described above* its most coronal region becomes very broad. This broad coronal is appropriate for regions with very low density cortical bone since it compress[es] the cortical bone. In cases the cortical bone is not very soft this can interfere with the insertion of the implant. There are also clinical evidences that when the coronal region is broad the blood supply to the bone around the implant is disturbed resulting in higher incidence of bone resorbtion [*sic*] and implant failure. Therefore if the cortical bone is not very soft the coronal region preferably should be less tapered [than] the body of the implant. *The most coronal part of the coronal region is even preferably inverse tapered **48** as illustrated in FIG. 8.*

Id. at 11:24-36 (emphasis added). While this embodiment is clearly covered by claim 19, which recites, a "dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge[,]" the question is whether it is also covered by claim 1.

The language of claim 1, including the wherein clause, requires that the apical end of the claimed coronal region be larger in diameter than the coronal end of the coronal region. The Federal Circuit has cautioned against attempting to imbue patent figures with specific scale or dimensions where the specification is silent as to such details. *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005). As such, it is impossible to discern whether the implant

[21] Claim 1 recites that the core of the apical region tapers toward the apical end of the core. *See* '977 patent at 17:57-61 ("an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core . . . ."). The parties agree that 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" in claim 1 indicates the orientation of the "frustoconical shape" of the "coronal region," namely that the "frustoconical shape" tapers in the opposite direction toward the coronal end of the implant, or is inversely tapered. *See* Comp. Br. at 9; Resp. Br. at 11.

illustrated in Figure 8, or the related embodiment illustrated in Figure 9, satisfies claim 1.

The only disclosed embodiments in which the apical end of the coronal region is clearly larger in diameter than the coronal end is the one illustrated in Figure 12 and its related figures, *e.g.*, Figures 17A-H, 18. *See* '977 patent at 12:10-13, 43-44 ("In another preferred embodiment illustrated in FIG. 12 the coronally tapered region [**90**] is placed inside the bone so the bone can grow above this region. The tapered region **90** is below the bone level **91**. . . . The threads begin[] preferably at the wider area of the coronally tapered region **92** . . . .").[22] The parties do not dispute that claim 1 covers the embodiment disclosed in Figure 12, 17A-H, and 18. However, while claim 1 may cover only certain disclosed embodiments, where the claim language is broad enough to cover more than the disclosed embodiments, it would be inappropriate to limit the claim only to those specific embodiments. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'") (internal citations omitted)).

Based on the preceding discussion, the Commission construes the claim limitation "the coronal region having a frustoconical shape" to mean "the coronal region has partly or entirely, a frustoconical shape."[23]

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[22] There are numerous mistakes in labeling in the specification of the '977 patent. In particular, the disclosure mistakenly refers to "coronally tapered region **85**" instead of "coronally tapered region **90**," the latter of which matches the labeling in Figure 12. In addition, the disclosure refers to element **12** in Figure 12 as "the wider area of the coronally tapered region **92**."

[23] Although the wording of this claim construction mirrors the construction in the Final ID, it is

B. Infringement

Section 337(a)(1)(B) covers all forms of infringement specified in § 271 of the Patent Act. Direct infringement includes the making, using, selling, offering for sale and importing into the United States an infringing product, without authority. 35 U.S.C. § 271(a). *See Suprema, Inc. v Int'l Trade Comm'n*, 796 F.3d 1338 (Fed. Cir. 2015) (affirming the Commission's finding that section 337 covers indirect infringement). A determination of patent infringement encompasses a two-step analysis. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1449 (Fed. Cir. 2001). First, the court determines the scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device. *Id.* "Literal infringement of a claim exists when each of the claim limitations reads on, or in other words is found in, the accused device." *Allen Eng. Corp. v. Bartell Indus.*, 299 F.3d 1449, 1345 (Fed. Cir. 2002). To establish infringement, there must be a preponderance of evidence. *See Kao Corp. v. Unilever United States, Inc.*, 441 F.3d 963 (Fed. Cir. 2006).

The Final ID finds that "the accused 4.3 mm and 5.0 mm Drive CM products meet each limitation of, and thus infringe, claim 1 of the '977 patent. Final ID at 37 (citing JX-0312C (4.3 mm Drawing); JX-0313C (5.0 mm Drawing); CX-1030C Hurson WS) at Q77-88, Q94-95; CPX-0006 (4.3 mm Drive CM , Model No. 109.627)). The Final ID notes that respondent Instradent did not contest infringement under the ALJ's adopted claim constructions. *Id.* (citing Respondents' Post-Hearing Brief at 32-37 (Aug. 3, 2015)). The Final ID also finds that Instradent did not dispute that the accused products satisfy, and thus infringe, the additional limitations recited in asserted dependent claims 2-5. *Id.* at 41-42. The Final ID also finds,

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based on modified reasoning as discussed above.

however, that the evidence does not "support a finding that the accused products infringe claim 1 under the alternate construction of the term 'the coronal region having a frustoconical shape' as proposed by Nobel, *i.e.*, 'the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion,'" because the accused products do not satisfy the functional portion of Nobel's proposed claim construction. *Id.*

The Commission determined to review the Final ID's finding of infringement based on its decision to review the construction of the claim limitation "coronal region having a frustoconical shape" recited in claim 1 of the '97 patent. *See* 81 *Fed. Reg.* at 3472. As the Final ID notes, however, there is no dispute between the parties on the issue of infringement under the ALJ's construction. *See* Final ID at 40; JX-312C and JX-313C (engineering drawings of the accused products showing that the coronal regions are completely frustoconical).

We therefore affirm the Final ID's finding that the accused products infringe claims 1-5 of the '977 patent given that the Commission's construction of the claim limitation "coronal region having a frustoconical shape" mirrors the ALJ's claim construction.

C. Domestic Industry

Section 337 declares unlawful the importation, the sale for importation or the sale in the United States after importation of articles that infringe a valid and enforceable U.S. patent "only if an industry in the United States, relating to articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2); *Certain Ammonium Octamolybdate Isomers*, Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C. Jan. 2004). Under Commission precedent, this "domestic industry requirement" of section 337 consists of an economic prong (*i.e.*, the activities of, or investment in, a domestic industry) and a technical

prong (*i.e.*, whether complainant's articles are protected by the asserted intellectual property rights). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12-14, 2009 WL 5134139 (U.S.I.T.C. Dec. 2009). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011).

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. §1337 (a)(2); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (U.S.I.T.C. Jan. 16, 1996). "In order to satisfy the technical prong of the domestic industry requirement, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers*, Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C., Jan. 2004).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C., May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990); *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. The technical prong of the domestic industry can be satisfied

either literally or under the doctrine of equivalents. *See Certain Refrigerators and Components Thereof*, Inv. No. 337-TA-632, Comm'n Op. on Remand at 66-67 (Mar. 11, 2010) (public ver.) (affirming Final ID's finding that technical prong was satisfied under the doctrine of equivalents).

The Final ID finds that Nobel has satisfied the domestic industry requirement with respect to the '977 patent. Final ID at 45-54 (discussing the technical prong), 126-135 (discussing the economic prong). No party petitioned for review of any aspect of the Final ID's findings concerning the economic prong of the domestic industry requirement. With respect to the technical prong, the ALJ found that, under the claim constructions he adopted, the domestic industry products satisfy all the asserted claims of the '977 patent. *Id.* at 47-51.

Because the Commission construes the claim limitation "coronal region having a frustoconical shape" to mean "the coronal region has, partly or entirely, a frustoconical shape," which mirrors the Final ID's claim construction, the Commission affirms the Final ID's finding that Nobel has satisfied the technical prong of the domestic industry requirement.

D. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). A claimed invention may be anticipated by a variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102. For example, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." A party challenging the validity of a patent based on a printed publication must prove facts showing that the publication qualifies as prior art under § 102 by

clear and convincing evidence. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 936-37 (Fed. Cir. 1990) (affirming a district court's finding that a document did not qualify as a printed publication where defendant failed to prove by clear and convincing evidence that "anyone could have had access to the documents by the exercise of reasonable diligence.").

A determination that a patent is invalid as anticipated under 35 U.S.C. § 102 requires a finding, based upon clear and convincing evidence, that each and every limitation is found either expressly or inherently in a single prior art reference. *See Celeritas Techs. Inc. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). Anticipation is a question of fact, including whether a limitation, or element, is inherent in the prior art. *In re Gleave*, 560 F.3d 1331, 1334-35 (Fed. Cir. 2009). The limitations must be arranged or combined the same way as in the claimed invention, although an identity of terminology is not required. *Id.* at 1334 ("the reference need not satisfy an *ipsissimis verbis* test"); MPEP § 2131.

In addition, the prior art reference's disclosure must enable one of ordinary skill in the art to practice the claimed invention "without undue experimentation." *Gleave*, 560 F.3d at 1334-35. A prior art reference that allegedly anticipates the claims of a patent is presumed enabled; however, a patentee may present evidence of nonenablement to overcome this presumption. *Impax Labs., Inc. v. Aventis Pharmaceuticals Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006). Moreover, "whether a prior art reference is enabling is a question of law based upon underlying factual findings." *Gleave*, 560 F.3d at 1335.

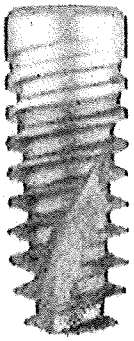
1. Final ID

Respondents asserted that the March 2003 Product Catalog of Alpha Bio Tec, Ltd. ("2003 Alpha Bio Tech Catalog") (RX-0658) anticipates the asserted claims of the '977 patent.

Final ID at 60. In particular, the Final ID finds that the "2003 Alpha Bio Tec Catalog was 'publicly accessible' more than one year before the effective filing date, *i.e.*, May 23, 2004, of the '977 patent." *Id.* at 61 (citing *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) ("A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.")). The Final ID notes that the 2003 Alpha Bio Tec Catalog includes a 2003 copyright designation. *Id.* (citing RX-0658 at 1, 57).

The Final ID finds that the 2003 Alpha Bio Tec Catalog "depicts and describes the SPI Implant as a 'tapered implant with large variable thread design double thread 2x2.1 mm.'" *Id.* (citing RX-0658 at 17). Specifically, the Final ID relies on the 5.0 mm SPI design disclosed in the catalog to find anticipation:

SPI implant 5mmd



Id. (citing RX-0658 at 16); *see also id.* at 63-64.[24] The Final ID finds that in a November 4, 2007, email that attached several publications, including the 2003 Alpha Bio Tec Catalog, one of the named inventors of the '977 patent, Mr. Ben-Zion Karmon, "indicated that the attached publications [ ]" *Id.* at 61-62 (citing JX-0281C (Karmon 2007 e-mail) at 1; *see also* JX-0225C (Karmon 2009 e-mail) at 2-3)). The Final ID also finds that Alpha Bio Tec began selling the SPI Implants in 2003. *Id.* at 62 (CX-1028 (Fromovich WS) at Q5). The Final ID further finds that "[a]s part of its doctor training program, Alpha Bio Tec distributed the catalog to doctors." *Id.* (citing Fromovich, Tr. at 371-372, 409).[25]

The Final ID rejects Nobel's argument that "the record evidence fails to suggest that the catalog was ever 'widely distributed,'" noting that the "case law does not set forth a 'widely distributed' standard for qualifying prior art . . . but rather a 'publicly accessible' standard." *Id.* The Final ID finds that "Alpha Bio Tec gave copies of the sales catalog to interested doctors who attended courses taught by Dr. Fromovich[,]" who is one of the named inventors of the '977 patent. *Id.* at 63 (citing Fromovich, Tr. at 353-54, 371-73, 409). The Final ID also finds no evidence that "the doctors were restricted from copying the catalog or from disseminating the catalogs to others." *Id.*

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[24] The Final ID also illustrates a 3.75mm SPI implant, but since the Final ID does not find the disclosure of that model anticipates the asserted claims of the '977 patent, we do not discuss it further.

[25] The Final ID also mentions an issue of the Israeli Dental Update dated January – February 2003, which advertised the SPI Implants. *Id.* at 62 (citing RX-0088 at 9-10, translations at 23-24). The Final ID does not find that the journal anticipates the asserted claims of the '977 patent.

2. Analysis

Respondents rely on the following evidence to show that the 2003 Alpha Bio Tec Catalog qualifies as prior art to the '977 patent:

> The publication states "March 2003" on its face and includes a 2003 copyright notice; (2) the corresponding SPI implants shown in the Catalog were on sale in late 2002 and early 2003; (3) the Israeli Dental Update Journal, which undisputedly published in January or February 2003, shows and describes the same Alpha Bio Tec SPI implant; (4) Dr. Fromovich had the Catalog at the IDS Conference in Cologne in March 2003; and (5) Dr. Fromovich also used the Catalog as a teaching aid long before the critical date.

Resp. Resp. at 12. Taking the evidence piece by piece, we find that Respondents have failed to show by clear and convincing evidence that the catalog is prior art under § 102(b).

a. Catalog Copyright Date and Printed Date

The Federal Circuit has explained, in considering whether a catalog constituted a printed publication under § 102, that the catalog "must have been disseminated or otherwise made accessible to persons interested and ordinarily skilled in the subject matter to which the advertisement relates *prior to the critical date*." *Orion IP, LLC v. Hyundai Motor America*, 605 F.3d 957, 974 (Fed. Cir. 2010) (emphasis added); *see also Carella v. Straight Archery and Pro Line Co.*, 804 F.2d 135, 139 (Fed. Cir. 1986) (finding that a mailer did not qualify as a statutory bar under § 102 where there was no "evidence presented as to the date of receipt of the mailer by any of the addressees" (citing *Protein Foundation, Inc. v. Brenner*, 260 F. Supp. 519, 520 (D.D.C. 1966) (a magazine is effective as a printed publication under § 102 on the date it reaches the addressee, not on the date of the mailing)).

The fact that the 2003 Alpha Bio Tec Catalog allegedly has a March 2003 publication date and a 2003 copyright designation (RX-0658 at 1, 57) is not dispositive of the reference's

status as prior art under § 102. We agree with Nobel that the mere existence of a printed date is insufficient to establish that the document was publicly accessible as of that date, *i.e.*, that the document was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l*, 511 F.3d at 1194; *see also Open Text S.A. v. Box, Inc.*, No. 13-cv-04910-JD, 2015 WL 4940798, at *6-7 (N.D. Ca. Aug. 19, 2015) ("Copyright and printing dates may indicate when the document was created, but they do not prove the necessary predicate to establishing 'public accessibility' – that the document was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.") (internal quotation marks omitted); ; *Ex Parte Rasmussen*, No. 2011-007741, 2013 Pat. App. LEXIS 5245, at *9 (P.T.A.B. Aug. 2, 2013) (printed dates did not prove a catalog was "actually published and hence publicly accessible as of [that date]"); *CNET Networks, Inc. v. Etilize, Inc.*, 584 F. Supp. 2d 1260, 1273-74 (N.D. Cal. 2008) (a copyright date on a product user guide was insufficient to prove public accessibility); *Hilgraeve, Inc. v. Symantec Corp.*, 271 F.Supp.2d 964, 976 (E.D. Mich. 2003) ("mere citation to the date imprinted on a document, without more, is insufficient to establish that a product was known or used by others on that date"). As the Court has explained, "[i]f anything, the dates imprinted upon these documents establish simply the date of copyright, or the date that the document was created or printed." *Hilgraeve, Inc.*, 271 F.Supp.2d at 976. It takes more for a defendant to satisfy the burden of establishing invalidity by clear and convincing evidence. *Id.*

Moreover, if the mere fact that a reference exists in physical (or appropriate digital) format were sufficient, cases discussing whether or not a reference is actually available and

locatable by relevant persons would not exist. *See, e.g., Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 689 F.3d 1374, 1381 (Fed. Cir. 2012) (finding that an article was publicly available where the website hosting the article was "open to any internet user by the critical date" and where "an interested researcher would have found the [] article using that website's own search functions and applying reasonable diligence."). As the IA correctly notes, the Federal Circuit has explained that "'[a]ccessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to . . . there is no requirement to show that particular members of the public actually received the information.'" IA Opp. at 21 (citing *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988)).

However, there is no evidence that the 2003 Alpha Bio Tec Catalog, which the evidence demonstrates was provided to practitioners only under specific circumstances, *i.e.*, during training courses, could be obtained by a practitioner simply if they wanted it or whether the catalog was available before the critical date. Where there is no evidence that any practitioner had an opportunity to receive the catalog before the critical date, the question remains whether the catalog may be considered "publicly accessible" under § 102. As such, there is little probative value in relying on the date printed on the 2003 Alpha Bio Tec Catalog to establish that the catalog is a printed publication under 35 U.S.C. § 102(b) under governing precedent.

b. Contemporaneous Sales

Respondents also assert that the "early 2003 publication date of the Alpha Bio Tec Catalog is further corroborated by contemporaneous sales of the SPI implants described in the catalog." Resp. Br. at 17 (citing CX-1028 (Fromovich Witness Statement ("WS")) at Q5). Respondents' contention that "the corresponding SPI implants shown in the Catalog were on sale

in early 2003" in Israel is of dubious relevance. *See* Resp. Opp. at 9. Respondents never raised an on-sale bar challenge before the ALJ, nor could they as the pre-AIA version of 35 U.S.C. § 102, which applies to the '997 patent, required a product to be "on sale in this country" in order to qualify as prior art. *See* Pet. at 16. Furthermore, although the ALJ mentioned the fact that "Alpha Bio Tec began selling the SPI Implants in 2003" (Final ID at 62), he did not appear to rely on any commercial version of the SPI implant in finding the asserted claims of the '977 patent anticipated. Furthermore, as Nobel noted, "[n]or would such sales indicate when the Alpha-Bio Tec Catalog – the reference on which the ALJ relied – was used in training courses or otherwise made accessible to the public." Pet. at 16.

Moreover, Dr. Fromovich testified that, subsequent to development of a commercial version of the Alpha-Bio SPI implant, which the company "sold primarily in Israel beginning in 2003 . . . In the 2003-2004 timeframe, Dr. Karmon and I worked with two other colleagues, Professor Nitzan Bichaco and Dr. Yuval Jacoby [all of whom are named inventors on the '977 patent] to make improvements to the design of the dental implant. The four of us filed an international patent application on the improved dental implant in May 2004." CX-1028 at Q5. There is no evidence that the version of the implant Dr. Fromovich sold in early 2003 was the same as the "improved dental implant" for which he and his colleagues filed the patent application leading to the '977 patent.

c. Israeli Dental Update Journal

Respondents also argued that the Israeli Dental Update Journal published in early 2003 discloses the same implant disclosed in the 2003 Alpha Bio Tec Catalog. Resp. Br. at 17-18; Resp. Opp. at 9. The Final ID, however, does not rely on the journal in finding anticipation. *See*

Final ID at 63-64.

Moreover, Nobel disputes whether the journal discloses the 5.0 mm implant the ALJ found anticipates the asserted claims of the '977 patent. Pet. at 16-17. Nobel argues rather that the journal discloses a different implant, in particular "one of the smaller 3.75 mm or 4.2 mm SPI implants." *Id.* While the 2003 Alpha Bio Tec Catalog discloses all three models (*see* RX-0658 at 16), the Final ID relies on only the 5.0 mm implant. Final ID at 63-64. It is not clear from the exhibit of the Israeli journal which model of the SPI implant is pictured, and the reference fails to specifically identify the model. *See* RX-008 at 10, 23-26 (translation).

Given that the standard for finding anticipation is clear and convincing evidence, there is insufficient evidence to find that the Israeli Dental Update Journal discloses the 5.0 mm SPI implant, notably where the ALJ declined to make such a finding. Respondents' reliance upon the journal to support the March 2003 publication date therefore fails. Moreover, as Nobel correctly noted, an advertisement in a separate document does not prove that the 2003 Alpha Bio Tec Catalog "was used in training courses or otherwise made accessible to the public before the critical date." Pet. at 17.

d. March 2003 Trade Show in Cologne, Germany

Although not mentioned in the Final ID, Respondents argued in their post hearing reply brief that Dr. Fromovich "prepared the March 2003 catalog in advance of the March 2003 IDS trade show" in Cologne, Germany, and that "Dr. Fromovich 'normally brought a digital version of a catalog to show to potential distributors' at the IDS trade show." Respondents' Post-Hearing Reply Brief at 28-29 (Aug. 17, 2015). Respondents made the same argument in their response to Nobel's petition for review. *See* Resp. Opp. 10-11 (citing Complainants' Post-

Hearing Brief at 75 (Aug. 3, 2015)). Respondents imply that this information, which was presented in Nobel's post-hearing brief, amounts to an admission by Nobel. *Id.* at 10.

Dr. Fromovich testified with reasonable certainty that he attended the conference. Fromovich, Tr. at 404:4-8, 404:22-405:5; 408:7-409:1. However, Dr. Fromovich testified with notably less certainty regarding whether he took the catalog to the conference. *Id.* at (404:9-15 ("Q. did you bring this catalogue, RX-0658, with you to the conference? A. This is what I told you before, that I not [*sic*] recall, unlikely to be there but I do not recall. Q. So you don't recall whether you brought a catalog with you? A. No, I don't recall if the catalog was there."); *see also* 405:6-8 ("My next question is, you're not sure if you had the printed catalog with you; right? A. Yes, I'm not recall [*sic*] if we print the catalog."). When asked if, lacking print copies, he "would have brought a digital version of the catalog to show people[,]" Dr. Fromovich explained that "if the catalog normally is not ready, sometimes we have a version that we get, even if it's not complete, if you want to show something. This is possible." *Id.* at 405:17-22. However, he testified that he could not recall whether he took a digital version to the 2003 conference. *See id.* at 406:4-7 ("Q. But right now, you're not sure whether you had a digital version with you or not; right? A. I'm not recalling. I cannot recall this. It is a lot of years ago."), 409:4-5 ("Q. So but right now as to whether you had a catalog or a digital version of the catalog, you're not sure? A. I told you, I doubt.").

This testimony demonstrates that at no time did Dr. Fromovich definitively say that he took a print version or even a digital version to the IDS conference in 2003. Moreover, as Nobel notes, Respondents did not argue that "a potential digital presentation to a doctor at the IDS conference sufficed to make RX-0658 a printed publication." Pet. at 15 at n 3 (citing *In re*

Klopfenstein, 380 F.3d 1345, 1349 n.4 (Fed. Cir. 2004) ("a presentation that includes a transient display of slides is likewise not necessarily a 'printed publication.'"). Dr. Fromovich was, however, adamant that, even if he or his colleagues were to take the catalog to the conference, they would not distribute the catalog. *See* Fromovich, Tr. at 403:1-6 ("Q. But you said when you went to Cologne with the catalog, were you free to sell while you were in Cologne? A. No. it's forbidde[n] by the general. Forbidden. Nobody sell in Germany and nobody bring catalog. If I go to Nobel, you will not get the catalog, no way."). The evidence related to a trade show, therefore, fails to establish that the catalog was disseminated or otherwise made accessible to persons interested and ordinarily skilled in the art. *See Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1330 (Fed. Cir. 2004).

e. Training Courses

The Final ID finds that the 2003 Alpha Bio Tec Catalog "was sufficiently accessible to interested doctors and other members of the public before the '977 patent's critical date of May 23, 2003," and, thus, qualifies as prior art under 35 U.S.C. § 102(b) based on the ALJ's finding that "Alpha Bio Tec gave copies of the sales catalog to interested doctors who attended courses taught by Dr. Fromovich." Final ID at 62-63 (citing Fromovich, Tr. at 371-372, 409). Dr. Fromovich, however, never testified concerning when these courses took place and, in particular, whether they took place prior to the critical date of the '977 patent. *See* Fromovich, Tr. at 371:6-372:23, 409:7-14. Nobel argued that "the record contains no evidence that any such training courses occurred before the critical date, or how many copies of the Catalog if any, were allegedly provided to doctors during these courses." Pet. at 10 Specifically, Nobel noted that:

> neither Dr. Fromovich nor any other witness at the hearing testified (1) that Alpha-Bio Tec conducted training courses between the drafting of the catalog in March 2003 and the critical date of May 23, 2003; (2) that the Catalog was printed in time to be used at training courses in that time period, and was actually used in such courses; and (3) how many clinicians attended training courses in that time period. Thus, while the Catalog was certainly used in training courses at some point, the evidence is absolutely silent about ***when*** the Catalog was used in training courses and ***how extensively***.

Id. at 12 (emphasis in original); *see also* Comp. Br. at 20. Nobel points out that Respondents never elicited testimony from Dr. Fromovich concerning "whether Alpha-Bio Tec held any training courses between March and May 2003, whether the new catalog (as opposed to the prior catalog) was used at any such training courses, or how many dentists might have attended." *Id.* at 14; *see also id.* at 13-14 (citing Fromovich, Tr. at 371-72). Respondents do not cite any evidence in the record identifying the dates of any training course during which the catalog was disseminated to doctors that occurred prior to the critical date. Without such evidence showing the dates that the training courses took place, it is impossible to determine whether the fact that practitioners received the catalog qualifies the catalog as a "printed publication" under § 102(b).

f. Emails from Nobel's Patent Counsel and Inventor Dr. Ben-Zion

Respondents contend that "communications between Nobel Biocare and [the law firm of] Knobbe Martens, which prosecuted the '977 Patent, show that the prosecuting attorneys understood by January 2009 that the 2003 Alpha Bio Tec Catalog was [

]" Resp. Opp. at 16 (citing JX-0278C at p. 2); *see also* JX-0277C. Respondents further note that Dr. Fromovich and his patent attorney, Mr. Narula, submitted the cover page of the Alpha Bio Tec Catalog to the Patent Office as part of an information disclosure statement

("IDS") affirmatively representing that it "published before May 21, 2003." Resp. Opp. at 11 (citing CX-0560 at 6-7).

Respondents also relied on an e-mail (JX-0225C) from one of the named inventors, Dr. Karmon, as proof that the 2003 Alpha Bio Tec Catalog was publicly available before the critical date of the '977 patent. Resp. Opp. at 16-17. Respondents argued that Dr. Karmon's email is an admission against interest that shows "the inventors admitted the prior art printed publication status of the 2003 Alpha Bio Tec Catalog, as well as other materials publicly disclosing the features of the SPI Implant as early as December 2002." *Id.* at 16. Respondents contended that, in the April 2009 e-mail, "Dr. Karmon Ben-Zion stated unequivocally that [

]" *Id.* (citing JX-0225C at p. 3).

Exhibit JX-0277C documents a series of emails in January 2008 between Linus Bystrom, Nobel's in-house counsel, and Knobbe Martin attorneys Nathan Smith and Rabi Narula. *See* JX-0277C at 1-4. On January 11, 2008, Mr. Bystrom sent Mr. Smith and Mr. Narula the cover sheet of the 2003 Alpha Bio Tec Catalog, as well as the Israeli journal article, along with a translation, stating [ ]. *Id.* at 3-7. This statement by Mr. Bystrom does not establish whether the catalog was "disseminated or otherwise made available" as of the publication date. Mr. Smith reaches a similar conclusion in his responsive email on January 12, 2008. Specifically, Mr. Smith explained that [

] *Id.* at 1-2 (emphasis in original). Nothing in Mr. Smith's statement would indicate that he placed any weight on Mr. Bystrom's use of the word [ ] Rather, Mr. Smith concluded that [

] *Id.* at 2. He then indicated that [

] *Id.* at 3.

On January 6, 2009, Mr. Narula contacted Nobel to discuss submitting the 2003 Alpha Bio Tec Catalog in an IDS in conjunction with another patent application in the '977 patent family.[26] In his email, Mr. Narula states that [

]. . . ." JX-0278C at 2. The record, however, is apparently silent concerning what this [ ] consists of, or whether there was, in fact, any additional analysis following Mr. Smith's January 2008 communication.

While Nobel's assumption may be unwarranted that Mr. Narula was still "operating under Mr. Smith's assumptions" from January 2008 (Comp. Br. at 15), there is nothing in the record to indicate whether or not this was the case. If Nobel is correct, then Mr. Narula was merely operating out of an abundance of caution, and we should afford little weight to his statement that the catalog [ ] *See id.* If Mr. Narula did perform some unknown further analysis during the intervening year, without

[26] Nobel indicates this was the '260 application. Comp. Br. at 15.

knowing what that analysis was, we cannot know what evidence he relied on in concluding that the catalog was publicly accessible as of a certain date. Nor can we know what date he determined to be the publication date within the meaning of § 102(b). We must also consider that Mr. Narula did not definitively conclude that the catalog was prior art and, instead, merely determined it was in the best interests of his client to submit the catalog in an IDS, again out of an abundance of caution. Either way, Mr. Narula's statement without further context does not rise to the level of clear and convincing evidence.

As for the statement of Dr. Karmon in his April 2009 email that the catalog and journal were [ ] and that [ ] (JX-0225C at 3), Respondents and the IA again place too much weight to Dr. Karmon's use of the word [ ] Whether the catalog existed in physical form by March 2003 is not dispositive of whether the catalog should be considered a "printed publication" under § 102(b). Dr. Karmon makes no mention of when, whether, or how the catalog was made "sufficiently publicly accessible that a member of the interested public can locate it" as of March 2003. *See SRI Int'l, Inc.*, 511 F.3d at 1194.

Respondents insist that Nobel's in-house patent counsel, Mr. Bystrom, "would have appreciated the meaning of 'publication' within the context of patent law" and tellingly never corrected or admonished Dr. Karmon for his "supposed improper use of the term 'publication' or reject[ed] his conclusion that the Alpha Bio Tec Catalog and Israel Dental Update Journal are prior art." Resp. Resp. at 8. It is not clear that anything can be read into the fact that Mr. Bystrom did not comment on Dr. Karmon's use of the word [ ] Mr. Bystrom merely

thanked Dr. Karmon for his input and corrected a mistake made by Nobel's previous patent counsel. JX-0225C at 2 [

] We are not aware of any case law, and Respondents and the IA do not provide any, that stands for the proposition that a negative inference should be drawn against Mr. Bystrom's decision not to quibble with Dr. Karmon's choice of layman's terminology. Certainly Mr. Bystrom's non-statement does not rise to the level of clear and convincing evidence. The Commission therefore declines to find that the statements made by either Mr. Narula or Dr. Karmon constitute admissions that the 2003 Alpha Bio Tec catalog was a "printed publication" as of the critical date.

g. IDS Disclosure

With respect to the disclosure of the 2003 Alpha Bio Tec catalog in the IDS reflected in exhibit (CX-0560), Nobel argues that the significance of the inclusion of the 2003 Alpha Bio Tec Catalog is twofold. First, Nobel asserts, "the listing of the catalog shows that Mr. Narula . . . was acting based on assumptions he and Mr. Smith had made in order to fully evaluate and disclose the most complete record of potential art to the examiner" thus forestalling "any question of inequitable conduct." Comp. Br. at 16.[27] Second, Nobel contends, "the fact [that] the patent examiner received and considered the catalog, and still allowed the '977 patent claims, demonstrates the validity of those claims even in view of the Alpha Bio Tec Catalog." *Id.* at 17.

Nobel also notes that "federal regulations dictate that '[t]he filing of an information disclosure statement ***shall not be construed to be an admission*** that the information cited in the

[27] Nobel notes that the ALJ rejected Respondents' inequitable conduct arguments, finding that Respondents failed to prove Mr. Narula withheld or misrepresented any known material prior art with the specific intent to deceive the Patent Office. *Id.* at 16 n. 4 (citing Final ID at 71).

statement is, or is considered to be, material to patentability as defined in § 1.56(b).'" *Id.* (emphasis in original) (citing 37 C.F.R. § 1.97(h); MPEP Section 609). Nobel asserts that "the Federal Circuit has repeatedly confirmed that a patentee's inclusion of a reference in an information disclosure statement does not constitute an admission that the reference is prior art." *Id.* (citing, *e.g.*, *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 866 (Fed. Cir. 2010); *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003) ("Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be material to prosecution of the pending claims. 37 C.F.R. § 1.56(a) (2000); *see A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392 (Fed.Cir.1986).").

Respondents argue that 37 C.F.R. § 197(h) actually "relates specifically to admissions concerning materiality of information, not the date of publication of a reference." Resp. Resp. at 10. Respondents contend that this "is not the typical case, addressed in Complainants' case citations, where a patentee submitted a reference in an Information Disclosure Statement without commenting whether the reference constituted 'prior art.'" *Id.* (citing Comp. Br. at 17).

In *ResQNet.com, Inc.*, the defendant argued that the patentee's inclusion of certain disputed prior art references in an IDS submitted to the Patent Office during a reexamination proceeding for a different patent was tantamount to an admission by the patentee that the manuals were printed publications. 594 F.3d at 866. The Federal Circuit held that the patentee "did not convert these manuals into printed publication prior art by including them with the IDS submitted to the PTO. No other evidence of publication of public availability was provided." *Id.* In *Abbott Laboratories*, the Court explained that

> According to Patent Office rules, "[t]he filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to the patentability defined in § 1.56(b)." 37 C.F.R. § 1.97(h) (2000). While valid prior art may be created by the admissions of a party, these admissions are generally characterized by statements made during prosecution describing certain work as "prior art." *See In re Nomiya,* 509 F.2d 566, 571 n. 5 (CCPA 1975); *In re Fout,* 675 F.2d 297, 300–01 (CCPA 1982). Under certain circumstances, even an express representation that a reference cited in an IDS is prior art to pending claims is not sufficient to create prior art by admission. *Riverwood Int'l Corp. v. R.A. Jones & Co.,* 324 F.3d 1346 (Fed.Cir.2003). Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be material to prosecution of the pending claims. 37 C.F.R. § 1.56(a) (2000); *see A.B. Dick Co. v. Burroughs Corp.,* 798 F.2d 1392 (Fed.Cir.1986).

334 F.3d at 1279.

The Court's statement in *Abbott* is very clear that the mere inclusion of a reference in an IDS is not sufficient to conclusively determine that the reference is in fact prior art. Rather, the only inference which may properly be drawn is that the patent applicant believed the reference may be material. This consideration is not limited to the content of a reference but also equally applies to whether a reference may be considered prior art with respect to its publication date. Neither Respondents nor the IA assert that the patentees characterized the 2003 Alpha Bio Tec Catalog as prior art during prosecution of the '977 patent, *e.g.* by specifically identifying the catalog as prior art in the application or in response to an examiner's rejection. As such, the Commission declines to find that the inclusion of the 2003 Alpha Bio Tec Catalog in the IDS reflected in exhibit CX-0560 (at 6-7) is an admission that the catalog was a "printed publication" as of the critical date.

Based on the preceding discussion, the Commission finds that Respondents have failed to

show by clear and convincing evidence that the 2003 Alpha Bio Tec Catalog qualifies as a "printed publication" prior art reference under 35 U.S.C. § 102(b).

In summary, the Commission finds a violation of section 337 with respect to claims 1-5 of the '977 patent. As noted previously, the Final ID findings concerning claim 19 of the '977 patent are moot as Nobel has essentially withdrawn its contentions as to that claim. The Final ID also found a violation with respect to asserted claims 15, 18, 19, 30, and 32 of the '443 patent.[28] *Id.* at 136. No party petitioned for review of the Final ID's findings with respect to the '443 patent, and the Commission determined not to review the Final ID with respect to the '443 patent. *See* 81 *Fed. Reg.* at 3472.

E. Public Interest, Remedy, and Bonding

1. Limited Exclusion Order

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). A limited exclusion order directed to a respondent's infringing products is among the remedies that the Commission may impose. *See* 19 U.S.C. § 1337(d).

a. RD

Before the ALJ, Nobel argued that it is entitled to a limited exclusion order ("LEO") should the Commission find a violation of section 337. RD at 3. Respondents argued that an LEO is not necessary because respondent Instradent stopped importing the accused Drive CM 2 Dental Implants into the United States as of February 2015. *Id.* (citing Resp. Post-Hearing Br. at 23, 238; RX-0005C (Speck Direct WS ("DWS")) at Q13; RX-0001C (Benjaminsen DWS) at

[28] The Final ID did not find a violation with respect to claim 17 of the '443 patent. *Id.*

Q32-37)). The IA argued that an LEO is appropriate.

The ALJ recommended that the Commission should issue an LEO should it find a violation of section 337. *Id.* at 4-5. Specifically, the ALJ credited Nobel's argument that, although Instradent may no longer import the accused products, "Respondents have not agreed to a consent order with regard to any future importation or sale of the accused Drive CM implants" but rather "admitted at the hearing that they are currently selling the accused Drive CM in the United States." *Id.* at 3-4 (citing Comp. Post-Hearing Br. at 238; Tr. at 987:14-17). Nobel contended that without a binding commitment from Respondents to cease further activity, Respondents are not barred from importing the accused Drive CM implants at any time in the future, and therefore "an exclusion order is necessary to prevent such activities from occurring." *Id.* at 4.

The ALJ also noted the IA's argument that "Respondents have apparently redesigned their Drive CM product line . . . and are currently importing this new design under the same part numbers as the Accused Drive CM implants (RX-0002C (Golin WS) at Q/A 57)." *Id.* The IA noted that "[t]his new design was presented to Complainants during fact discovery and they specifically decided not to accuse the redesigned products." *Id.* The IA asserted, however, that any LEO the Commission issues should include a certification provision. *Id.* The ALJ agreed that "the exclusion order should include a provision that allows Instradent to certify, pursuant to procedures to be specified by U.S. Customs and Border Protection ["CBP"], that it is familiar with the terms of the order, that it has made appropriate inquiry, and that, to the best of its knowledge and belief, the products being imported are not excluded from entry under the order." *Id.* at 5. The ALJ stated that a certification provision would account for the fact that

"Instradent's redesigned Drive CM product line is shipped using the same part numbers as products currently accused in this investigation, and it may be difficult to determine upon visual inspection whether or not certain products are subject to exclusion." *Id.*

b. Analysis

Nobel asserts that the ALJ's recommendation of an LEO should apply equally to any violation found with respect to the asserted claims of the '443 and '977 patents. Comp. Br. at 35-36. Regarding the recommended certification provision, Nobel argues it would be difficult for CBP to monitor Respondents' compliance with the provision because of Respondents' use of the same part numbers for both the accused and redesigned Drive CM implants. *Id.* at 37. Nobel also argues that "dental implants are shipped in packaging that makes their external features difficult to discern upon visual inspection." *Id.* Accordingly, Nobel contends, "it would be difficult, if not impossible, for U.S. Customs to determine whether an import with the part numbers identified above is an infringing implant, or whether it is a new design, based on the part number alone." *Id.* In lieu of a certification provision, Nobel requests that the LEO "apply to every implant that has the [same] product numbers as the infringing implants, and that Respondents more clearly identify any Drive CM implants that are not subject to the exclusion order in this investigation." *Id.* at 38. Nobel further requests that Respondents be required "to provide U.S. Customs with the dates of manufacture and lot numbers for all infringing Drive CM implants" so that CBP "can then compare these dates of manufacture and lot numbers to any future shipments of Drive CM implants that are brought into the United States, in order to determine whether any such shipments should be excluded." *Id.*

Respondents again argue that an LEO "would serve no purpose, because the accused

implants are not being imported into the United States." Resp. Br. at 27. Rather, Respondents assert, "[a]s of early 2015, Respondents no longer imported the accused Drive CM 2 implant and, instead, only imported their new design, the Drive CM 4 implant." *Id.* (RX-0001C (Benjaminsen DWS) at Q32-37; RX-0005C (Speck DWS) at Q11-17)). Respondents request, however, that if the Commission determines to issue an LEO, it adopt the LEO proposed by the IA "with one minor modification to simplify identification of Respondents' implants not accused of infringement and not in suit . . . ." Resp. Resp. at 22. Specifically, Respondents note that "the packaging for Respondents' implants not accused in this Investigation includes a white dot approximately 5 mm in diameter or silver dot approximately 10 mm in diameter on the upper-right portion of the back of the packaging, whereas the packaging on Respondents' allegedly infringing implants does not include a white or silver dot." *Id.* Respondents therefore request that the Commission add the following sentence to the end of the first number paragraph of the IA's proposed LEO: "Non-infringing dental implants not subject to this Limited Exclusion Order may be identified by the presence of a white dot approximately 5 mm in diameter, or silver dot approximately 10 mm in diameter, located on the upper-right portion of the back of the packaging of the dental implant." *Id.* at 23.

The IA argues that an LEO is an appropriate remedy. IA Br. at 20. The IA also recommends that the LEO include a certification provision, arguing that the provision "would be especially helpful here where the Complainants have already examined Respondents' redesigned products and declined to accuse them." *Id.*

Other than their assertion that they no longer import the accused products, Respondents do not provide any reason the Commission should decline to issue an LEO as recommended by

the ALJ. Respondents do not provide citation to any Commission precedent where the Commission has considered a party's assertion concerning its business practices as a reason against issuing an exclusion order where otherwise appropriate. Respondents do not argue that they no longer import dental implants of any kind, although such an assertion would not be dispositive of the issue. Rather, Respondents contend they no longer import the implants specifically accused in this investigation. However, Commission exclusion orders are not typically limited to the articles specifically adjudicated during an investigation. *See Certain Hardware Logic Emulation Systems and Components Thereof*, 337-TA-383, Comm'n Op. at 23 (Mar. 1, 1998) ("[T]he Commission's long-standing practice is to direct its remedial orders to all products covered by the patent claims as to which a violation has been found, rather than limiting its orders to only those specific models selected for the infringement analysis."). As such, the question of whether any future imports are subject to the exclusion order is to be determined by CBP consistent with the guidance provided by the Commission or in an advisory or modification proceeding before the Commission. Accordingly, the Commission has determined to issue an LEO covering imported dental implants than infringe claims 1-5 of the '977 patent and claims 15, 18, 19, 30, and 32 of the '443 patent.

With regard to respondents' redesigned products, the Commission notes that Nobel was informed of these products during fact discovery in the proceedings before the ALJ. *See* Joint Statement of Accused Products at 1 n. 1 (Feb. 1, 2015); Amended Joint Statement of Accused Products at 1 n. 1 (March 4, 2015). Despite such notice, Nobel represented in its remedy briefing that the redesigned products are outside the scope of the limited exclusion order. Moreover, the remedy briefing submitted by the respondents and the IA indicates all parties'

concurrence with the RD that the redesigned products should be outside the scope of any remedial order issued by the Commission.

Nobel has raised concerns regarding whether the inclusion of a certification provision in the LEO may be adequate to enable CBP to police the respondents' imports to ensure that only redesigned implants are permitted entry into the United States. The Commission has commonly included certification provisions in LEOs where respondents import both infringing and non-infringing products. *See, e.g., Certain Minoxidil Powders, Salts, and Compositions for Use in Hair Treatment*, Inv. No. 337-TA-267 (1988); *Certain Curable Fluoroelastomer Compositions and Precursors Thereof*, Inv. No. 337-TA-364, USITC Pub. 2890 (May 8, 1995). Moreover, certification provisions are generally included where CBP may be unable to easily determine by inspection whether an imported product violates a particular exclusion order. *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 72 (June 3, 2009) (public version).

The facts Nobel has noted indicate that a certification provision is specifically appropriate in this case. Moreover, certification provisions were designed to allow CBP significant flexibility in determining whether to exclude goods alleged to not to be covered by an exclusion order. CBP can therefore make the determination regarding what information it requires Respondents to provide in order to invoke the certification provision. We note that inclusion of a certification provision does not deprive Nobel of the right to bring an enforcement action should it believe Respondents are abusing the certification provision. With respect to Nobel's proposed alternative to including a certification provision concerning distinct product packaging or marking, CBP has discretion to make a determination regarding whether each of Respondents'

entries are subject to the LEO based on information and supporting documentation required to be provided to CBP by Respondents.

Regarding Respondents' proposed addition to the IA's draft LEO to include a notation for specific packaging identifiers in the order, we again note that Commission exclusion orders do not typically identify specific model numbers for exclusion. Respondents' suggestion does not indicate that it would be appropriate or necessary to depart from the Commission's practice. Rather, CBP has the discretion to consider Respondents' alleged marking, and any required supporting documentation and information, in connection with administering the certification provision of the LEO.

Based on the preceding discussion, the Commission has determined to issue an LEO covering imported dental implants that infringe claims 1-5 of the '977 patent and claims 15, 18, 19, 30, and 32 of the '443 patent and include a certification provision allowing Respondents to certify that any dental implants it imports during pendency of the LEO does not fall under the order. However, we note that, because Nobel has not accused Respondents' redesigned dental implants, those products are not part of the investigation and have, therefore, not been adjudicated.

2. **Cease and Desist Order**

The Commission is not issuing a cease and desist order in this investigation because the Commissioners are divided 3-3 on whether a cease and desist order is appropriate.[29, 30, 31, 32, 33]

[29] *See* Additional Views of Chairman Broadbent, Vice Chairman Pinkert and Commissioners Williamson and Johanson.

[30] Vice Chairman Pinkert and Commissioners Williamson and Johanson find that a cease and

desist order against respondent Instradent is not appropriate. The record does not contain information beyond [ ] concerning the amount of Drive CM 2 implants in inventory. However, there is no dispute that imports of these implants ceased in early February 2015. Between [ ], when there were [ ] units in inventory, and [ ], when there were [ ] units in inventory, the average depletion rate was about [ ] units per month. Between [ ] and [ ], when there were only [ ] units in inventory, the average depletion rate was over [ ] units per month. Given these unrefuted data, we find that the ALJ reasonably concluded that, in the [ ] between the most recent inventory numbers (from [ ]) and the target date (February 29, 2016), "domestic inventories of the accused products will have dropped below a commercially significant amount by the time the target date of the investigation is reached." RD at 9. We note that an average depletion rate of only a little over [ ] units per month would be necessary to eliminate all or substantially all of the inventory on hand in [ ].

Nobel merely speculates that the significant reduction in inventory from [ ] through [ ] would somehow not have continued through to the present, and that a commercially significant inventory would remain. However, based on the facts discussed above, we find that Nobel has failed to meet its burden of proof, and therefore would not have determined to issue a cease and desist order to respondent Instradent.

[31] Chairman Broadbent, Commissioner Schmidtlein, and Commissioner Kieff find that a cease and desist order against respondent Instradent is appropriate. The Commission usually issues cease and desist orders when the respondents have commercially significant domestic operations or inventory of infringing products that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, and Components Thereof*, Inv. No. 337-TA-486, Comm'n Op. at 17 (July14, 2003). But commercially significant domestic operations or inventories are not a statutory requirement. *See* 19 U.S.C. § 1337(f)(1). The record here shows that [ ] infringing Drive CM implants of various diameters and lengths existed in U.S. inventory at the time of the evidentiary hearing in July 2015, valued at [ ]. RX-0672C; Tr. at 947:3-6, 949:6-12; 981:6-13; *see also* Comp. Br. at 39. Respondents' remedy briefing rests upon these July 2015 inventory levels. Resp. Br. at 28-29; Resp. Resp. at 23-24. Chairman Broadbent, Commissioner Schmidtlein and Commissioner Kieff find these inventories to be commercially significant. Before the ALJ, Respondents projected that their inventories would [ ] by the target date of this investigation (Resp. Post-Hr'g Br. at 239), but their estimate was unsupported and unreliable. *See, e.g.*, Tr. at 972-985; *see also* Comp. Br. at 39-40. Respondents' remedy briefing before the Commission provides no indication that these proven inventories have fallen below commercially significant levels.

[32] Commissioner Schmidtlein further observes that the statutory language of section 337(f)(1) leaves it to the discretion of the Commission and does not establish any particular test or standard for issuing a cease and desist order aside from consideration of the public interest

The following is provided for the purposes of background.

a. RD

Nobel argued before the ALJ that because respondent Instradent maintains a "significant U.S. inventory of infringing, imported accused Drive CM in the United States, which sells at a price of $160 per implant and could be sold as to undercut the remedy provided by an exclusion order, a cease-and-desist order should appropriately be directed to Instradent." RD at 6 (citing Comp. Post-Hearing Br. at 244-45; Tr. at 947:3-6, 946:6-7). Nobel also noted that "Instradent sells surgical tools, such as drills, as well as laboratory and prosthetic components for use with the accused Drive CM implant that would generate additional revenue beyond [] just the sales of

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factors. *See Gamut Trading Co. v. U.S. Int'l Trade Comm'n*, 200 F.3d 775, 784 (Fed. Cir. 1999) (explaining that the Commission has broad discretion in selecting a remedy). The Commission is therefore not obligated to confirm the existence of commercially significant domestic inventories or operations prior to issuing a cease and desist order.

From a practical standpoint, and after further reflection, Commissioner Schmidtlein fails to see the value gained by requiring parties and the Commission to expend time and resources addressing the extent of domestic inventory levels or operations as a predicate to issuing cease and desist orders. In her view, there is little harm if an order issues even though respondent does not maintain a commercially significant domestic inventory. On the other hand, the requirement carries risk of harm for the complainant since the Commission may, for whatever reason, decide not to issue a cease and desist order even though a commercially significant inventory actually exists at the time of the Commission's determination. As an example, inventory levels may only become commercially significant after the record is developed in the investigation. In such a circumstance, the complainant will not be afforded complete relief for the section 337 violation.

Commissioner Schmidtlein therefore supports issuance of a cease and desist order in this investigation even if Nobel failed to establish the presence of a commercially significant domestic inventory of accused product. Nobel requested the remedy against domestic respondent Instradent, which the undisputed record shows maintained some inventory of accused product during the investigation. In her view, while there may be other bases, this is a sufficient basis to issue a cease and desist order against Instradent.

[33] *See* Additional Views Of Commissioner Kieff.

the accused Drive CM implant if no cease-and-desist order were to issue." *Id.* (citing Tr. 948:11-14, 20-22; JX-0247C at 1-3). Nobel further noted that William Benjaminsen, Instradent's current General Manager, "testified that he had 'no idea' how long [] it would take for clinicians to restore all those sold accused Drive CM implants, Tr. at 988:4-12, and that it could 'potentially' be [ ] . . ., Tr. at 988:13-14." *Id.* at 6-7.[34] Nobel also argued that because "Respondents have not agreed to cease further activity in the U.S. with regard to the accused Drive CM implants . . . Nobel has no assurances that the existing inventory will be completely depleted by the estimated time frame provided by Respondents, particularly if Respondents are now focusing their efforts on selling and supporting a design that is different from the accused Drive CM implants." *Id.* at 7. Specifically, Nobel argued that

> It may be that Respondents' redesigned product is not experiencing the same level of acceptance as the accused Drive CM product with Respondents' customers, which include users of the NobelActive® implant, and thus Respondents are unwilling to withdraw the accused product from the U.S. market. Respondents should not be permitted to continue sales of accused Drive CM as a hedge against uncertainty surrounding their redesign, and a cease-and-desist order for the existing inventory is proper. Indeed, even "a single item of inventory could constitute a commercially significant inventory." *See Certain Agricultural Vehicles and Components Thereof*, Inv. No. 337-TA-487, Comm'n Action Notice, 2004 ITC LEXIS 964, at *210 (Dec. 2004) (citing *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383 (Temporary Relief), USITC Pub. 2991 (September 1996), Comm'n. Opn. 6.).

Id.

Respondents argued before the ALJ that issuance of a cease and desist order is not

[34] According to the hearing transcript, clinicians practice both placing and restoring implants. *See, e.g.*, Tr. at 950, 954.

appropriate because "Instradent no longer imports the Drive CM 2 Dental Implants into the U.S. and what little stock remains in the U.S. will likely be exhausted by the time the Commission will consider remedies." *Id.* at 7 (citing Resp. Post-Hearing Br. at 239). Respondents further argued that "[a[lternatively, to the extent any inventory remains at the time the Commission will consider remedies, such amount will certainly not be 'commercially significant' given that the imports would have ceased one year prior." *Id.* Respondents asserted that "[a]s of [ ], Instradent stopped importing into the U.S. the Drive CM 2 Dental Implants and began importing (and indeed will only import) the new design Drive CM 4 implant" which Nobel has not accused of infringement. *Id.* at 7-8. Respondents noted that as of April 20, 2015, [o]nly [ ] units of the Drive CM 2 Dental Implants remained in Instradent USA's inventory" which is "expected to be exhausted on average within approximately [ ] (RX-0001C (Benjaminsen DWS) at Q38-Q42)." *Id.* at 8. Respondents noted that, as of July 6, 2015, "only approximately [ ] units of the Drive CM 2 Dental Implants remained in Instradent's inventory . . . ." *Id.* (citing RX-0672C (Printout of Inventory Data); Benjaminsen, Tr. at 990:2-23).

The IA argued that "a cease and desist order would not be appropriate because the evidence shows that as of the Target Date of February 29, 2016, the Respondents are unlikely to have any commercially significant inventory in the United States." *Id.* (citing IA Post-Hearing Br. at 74). Specifically the IA asserted that

> the evidence shows that Respondent JJGC has ceased manufacturing the Accused Drive CM products (RX-0005C (Figueredo WS) at Q/A 16, 17); JJGC has stopped selling and shipping the Accused Drive CM products for ultimate importation or delivery to Neodent [now Instradent] in the United States (RX-

> 0005C (Figueredo WS) at Q/A 15); JJGC ceased shipping the Accused Drive CM products as of early February 2015 (RX-0005C (Figueredo WS) at Q/A 13; JX-0150C (Neodent Responses to ROGs) at No. 38); as of February 9, 2015, the U.S. inventory of Accused Drive CM products was expected to total [ ] JX-0150C (Neodent Responses to ROGs) at No. 38); and, as of March 17, 2015 (at the present usage rate), Respondents expected its U.S. inventory to be depleted within [ ]. *Id.*

Id.

The ALJ recommended, based on the parties' arguments, that the Commission should not issue a cease and desist order to Instradent. *Id.* at 9. Specifically, the ALJ found that "importation of the accused products into the United States was stopped as of [ ], and that domestic inventories of the accused products will have dropped below a commercially significant amount by the time the target date of this investigation is reached." *Id.*

b. Parties Arguments Before the Commission

Nobel asserts that "[d]uring pendency of this investigation, Respondents' inventory of Drive CM [ ]." Comp. Br. at 39 (citing CX-0427C (Respondent Neodent's Fourth Supp'l Objections and Responses to Nobel's Interrogatory No. 25) at 94)); JX-0204C (McPike Designated Dep.) at 233:9-12; RX-0672C, Tr. at 981:6-9). Nobel argues that evidence concerning the rate of sales of the accused products that occurred before introduction of the redesigned implants is unreliable since "[n]ow that Respondents are selling a redesigned Drive CM implant, there is no assurance that the sell-off of inventory of infringing implants will occur at the same rate as historical sales, and thus commercially significant inventory could remain in the U.S. at the time of the Final

Determination." *Id.* 39-40.

Nobel argues that although "Respondents rely upon historical documents to estimate that their U.S. inventory will be depleted well before the Final Determination, the evidentiary record on these estimates suggests that inventory may still exist in the U.S." Comp. Resp. at 24. Specifically, Nobel notes that, Respondents estimated that their April 29, 2015 inventory of [ ] units, valued at [ ], would likely be depleted in [ ]. *Id.* at 24 (citing Resp. Br. at 29). Nobel further notes that the IA relied on estimates that Respondents' U.S. inventory as of February 2015 of [ ] implants, valued at [ ], would be depleted in [ ]. *Id.* (citing IA Br. at 22). Nobel argues, however, that "at the July 2015 evidentiary hearing, one month before the inventory was estimated to have been completely exhausted, Respondents still had over [ ] implants, valued at [ ], in U.S. inventory." *Id.* at 24-25 (citing RX-0672C; Tr. at 981:6-17). Nobel argues that, had Respondents actually depleted their inventory in [ ], "one would have expected Respondents to announce that fact in any of the numerous post-hearing filings they have made to the Commission since that time, including their most recent submission in January 2016." *Id.* at 25.

Respondents argue that Nobel incorrectly focuses on "a single model of the Drive CM 2 implant (the 3.5 x 16 mm model)," which Respondents contend "[ ]." Resp. Resp. at 23-24. Respondents note that "Complainants offer no discussion of the 14 other models of accused products[,]" the inventory of which Respondents assert "[ ]." *Id.* at 24. Respondents rely on exhibit RX-0672C (Updated July 6, 2015

Inventory Data), which shows that [

] still in inventory as of that time. *Id.*

3. **Bonding**

Pursuant to section 337(j)(3), the administrative law judge and the Commission must determine the amount of bond to be required of a respondent during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(h), 210.50(a)(3). The complainant bears the burden of establishing its request for an appropriate bond amount to be imposed on respondents' continued activities during the Presidential review period based on the record. *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. 337-TA-533, Comm'n Op. at 39-40 (July 21, 2004) ("In our view, the complainant has the burden of supporting any proposition it advances, including the amount of the bond.").

When reliable price information is available, the Commission has often set bond by eliminating the differential in sales prices between the domestic product and the imported, infringing product. *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes,* Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus,* Inv. No. 337-TA-337, USITC Pub. No. 2670, Comm'n Op. at 41-43 (1995).

A 100 percent bond has been required when no effective alternative existed. *Certain Flash Memory Circuits and Products Containing Same,* Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

a. RD

Nobel argued before the ALJ that the bond amount "should be determined by multiplying the number of units of infringing imported product by the average sales price of the NobelActive® implant. RD at 10 (citing Comp. Post-Hearing Br. at 246-47). Specifically, Nobel asserted that exhibit "CX-272C lists total revenue [ ] and total units [ ] of NobelActive® implants sold in the U.S., and dividing those numbers yields an average selling price of [ ]." *Id.* As an alternative to the lost-revenue approach, Nobel requested that "the bond be set at the entered value of the accused product, which is $160/unit, or as the price differential between the two products, which is approximately [ ]/unit, (the difference between Nobel's average selling price of [ ] from CX-272C and the entered value of the accused products of $160), multiplied by the number of units of infringing product imported by Respondents during the presidential review period." *Id.*

Respondents argued that, because they ceased importing the accused Drive CM 2 implants as of February 2015 and have no intention to resume selling or importing the Drive CM 2 implants, "there can be no competitive injury arising out of infringement during the Presidential review period and thus a bond is not warranted." *Id.* at 11 (citing Resp. Post-Hearing Br. at 244-45). Respondents asserted that Nobel "failed to present any accepted theory

upon which they are entitled to receive a bond . . . [f]or example, Complainants have not alleged or demonstrated any price differential between the Drive CM 2 Dental Implants and the NobelActive implants. Nor have Complainants alleged or shown that there is an established royalty for the asserted patents upon which the bond can be determined." Respondents requested that, should the Commission, however, determine a bond is necessary, the bond should be set at zero. *Id.* Respondents argued that "Complainants' [lost revenues] theory should be rejected because Complainants cite no legal authority to demonstrate that lost revenues or lost profits are an accepted method for determining bond." *Id.* at 12

The IA asserted that "the evidence supports a bond based on [

] *Id.* (citing IA Post-Hearing Br. at 79; Comp. Post-Hearing Br. at 158).

The ALJ recommended that, should the Commission determine that a violation of section 337 has occurred, that "the bond for any importations of infringing products during the Presidential review period should be set at $120 per unit, [

] *Id.*

b. Analysis

Nobel states that it agrees with the ALJ's recommended bond of $120/implant based on [

] Comp. Br. at 41 (citing Tr. 947:3-6, 949:6-12 ($160 per Drive CM is the list price)). The IA notes that it supports the recommended bond of "$120 per unit, [

] IA Br. at 23 (citing RD at 12).

Respondents state that, since they are no longer importing the accused Drive CM 2 implants, they do not dispute the ALJ's proposed bond amount. Resp. Resp. at 24.

Based on the preceding discussion, the Commission sets the bond at $120 per unit of covered products imported during the period of Presidential review.

4. **Public Interest**

Sections 337(d) and (f) of the Tariff Act of 1930, as amended, direct the Commission to consider certain public interest factors before issuing a remedy. These public interest factors include the effect of any remedial order on the "public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. §§ 1337(d), (f).

The Commission did not instruct the ALJ to issue a recommended determination concerning the public interest in this investigation. *See* 19 C.F.R. § 210.50(b)(1).

Nobel notes that the "parties agree that public interest issues are not impacted by the limited exclusion order set forth in the Recommended Determination on Remedy and Bonding." Comp. Br. at 42. Nobel explains that an LEO "would further the public interest of barring importation of products that infringe U.S. patents" and asserts that Nobel "can satisfy any demand for the excluded products." *Id.* (citing Doc. No. 570723; CX-1034 (Nye St.) at Q52-53 (explaining Nobel's manufacturing capacity to produce additional NobelActive® implants); CX-0741 at 40 (setting forth Nobel's production volumes in 2014); Tr. 972:24-973:4; Tr. 974:3-5 (testimony estimating the historical turnover of the infringing Drive CM implants at [

]). Nobel asserts that "a remedy that would require Respondents to more clearly distinguish between the excluded implants and the redesigned implants, as explained in the

Certification section above, would also further the public interest, as it would reduce the burden of U.S. Customs in monitoring the exclusion order." *Id.* at 42-43. Nobel further asserts that its requested remedy "would also provide more certainty to clinicians and customers as to which design of the Drive CM implant is being used in a given surgical procedure." *Id.* at 43.

The IA notes that "all parties agree" that the public interest factors enumerated in 19 U.S.C. §§ 1337(d) and (f) "do not argue against the issuance of a remedy." IA Br. at 22.

Respondents do not present any discussion of the public interest in their initial submission. *See* Resp. Br. In their response submission, Respondents argue that "neither Complainants' proposed limited exclusion order nor a cease-and-desist order would be in the public interest." Resp. Resp. at 25. Specifically, Respondents assert that "Complainants offer no reason why creating a needlessly complicated procedure for Respondents to import non-infringing implants would be in the public interest, especially when there is nothing to suggest that Respondents would ever circumvent an exclusion order." *Id.* Respondents argue that "Complainants' proposed exclusion order would harm the public interest, because it would create additional costs for Respondents' Drive CM 4 implants, which compete with Complainants' NobelActive implants." *Id.* Respondents also contend that "with respect to the cease-and-desist order," there is no basis for Nobel's unwarranted assumption that "Respondents' customers [would] have reason to doubt Respondents as to which version of the Drive CM implant that they have been sold." *Id.*

As discussed above, the Commission rejects Nobel's request that the LEO require Respondents to alter their business practices concerning how they mark their products. The record demonstrates that Nobel has the manufacturing capacity to supply the U.S. market.

Further, the record contains no evidence to indicate that the issuance of remedial order[s] would have any effect on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or on United States consumers. None of the parties or the members of public have expressed any public interest concerns with respect to the issuance of an LEO. Accordingly, the Commission finds that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not weigh against issuance of a remedy in this investigation.

IV. CONCLUSION

For the reasons discussed above, the Commission finds a violation of section 337 with respect to claims 1-5 of the '977 patent and claims 15, 18, 19, 30, and 32 of the '443 patent. The Commission has determined to issue an LEO barring importation of dental implants that infringe those claims. The Commission has found that the public interest factors set forth in 19 U.S.C. § 1337(d)(1) do not weigh against the issuance of the LEO in this investigation. The Commission has further determined to set the bond at $120 per unit of covered products imported during the period of Presidential review.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: May 11, 2016

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DENTAL IMPLANTS**	**Investigation No. 337-TA-934**

ADDITIONAL VIEWS OF CHAIRMAN BROADBENT, VICE CHAIRMAN PINKERT AND COMMISSIONERS WILLIAMSON AND JOHANSON

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for a violation of Section 337. 19 U.S.C. § 1337(f)(1). Cease and desist orders are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order. *See, e.g., Certain Protective Cases and Components Thereof,* Inv. No. 337-TA-780, Comm'n Op. at 28 (Nov. 19, 2012) (quoting *Certain Laser Bar Code Scanners and Scan Engines, Components Thereof, and Products Containing Same,* Inv. No. 337-TA-551, Comm'n Op. (Pub. Version) at 22 (June 14, 2007)); *Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, And Components Thereof,* Inv. No. 337-TA-486, Comm'n Op. at 17 (July 14, 2003).

The law makes a distinction between violation and remedy and each must be supported separately. The Commission makes its determination as to whether a cease and desist order is necessary in a particular investigation based on the evidence in the record.[35] A complainant

[35] Section 337(d)(1) states that if a violation is found the Commission "shall" issue a limited exclusion order unless there are overriding public interest considerations. 19 U.S.C. § 1337(d)(1). In contrast, the statute gives the Commission discretion to make a determination

seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation. [36] *Certain Integrated Repeaters, Switches, Transceivers, and Products Containing Same,* Inv. No. 337-TA-435, Comm'n Op. at 27 (Aug. 16, 2002) ("...[C]omplainants bear the burden of proving that respondent has such an inventory. Because complainants failed to sustain their burden, we have determined not to issue a cease and desist order."). If a complainant fails to adequately support its requested cease and desist order, this relief is not granted. S*ee, e.g., Id.; Certain Crawler Cranes and Components Thereof,* Inv. 337-TA-887, Comm'n Op. at 73-74 (May 6, 2015) (Commission determined not to issue a cease and desist order as to a certain crane model based on lack of commercially significant inventory).

Here, as it does in every investigation, the Commission sought briefing (in its notice of review of the remand ID in this investigation) on the issues of the appropriate remedy, bonding, and the public interest in the event of a violation. 81 Fed. Reg. 8096, 8097 (February 17, 2016). In response to the notice, the parties provided briefing directed to these issues; none disputed the

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regarding the necessity of a cease and desist order (absent public interest concerns). 19 U.S.C. § 1337(f)(1). *See also* H.R. Rep. No. 100-40, at 160 (1987) ("When the Commission determines that both remedies [*i.e.*, an exclusion order and cease and desist order] are necessary, it should be without legal question that the Commission has authority to order such relief."). Thus, a finding of a violation does not result in an automatic grant of a cease and desist order.

[36] Similar to requests for a cease and desist order, the complainant bears the burden of establishing its request for an appropriate bond amount to be imposed on respondents' continued activities during the Presidential review period based on the record. *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. 337-TA-533, Comm'n Op. at 39-40 (July 21, 2004) ("In our view, the complainant has the burden of supporting any proposition it advances, including the amount of the bond."); *see also Certain Marine Sonar Imaging Systems, Products Containing the Same, and Components Thereof*, Inv. 337-TA-926, Comm'n Op. at 59 (Dec. 17, 2015).

Commission's longstanding precedent regarding cease and desist orders. We also note that where particular concerns or issues arise relating to the appropriate remedy or the public interest, the Commission can, and does, request briefing on such specific issues at the appropriate procedural juncture, in its notice regarding review of the underlying ID, which contains the Commission's request for briefing on remedy, the public interest, and bonding. *See, e.g., Certain Stainless Steel Products, Certain Processes for Manufacturing or Relating to Same, and Certain Products Containing Same,* Inv. No. 337-TA-933, 81 Fed. Reg. 7584 (Feb. 12, 2016) (requesting briefing, in the notice of review, regarding two remedial issues: the Commission's authority to order disgorgement of trade secrets in respondents' possession; and whether the circumstances in the investigation warrant the issuance of immediate relief).

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN DENTAL IMPLANTS**	**Investigation No. 337-TA-934**

ADDITIONAL VIEWS OF COMMISSIONER KIEFF

I. PROCESS: PRACTICE AND PRESUMPTION

I write separately to make clear that I would benefit from additional input, perhaps from the parties or the public, to improve my understanding of the following two aspects of our legal framework, including what significance they may have, if any, in the decision-making the Commission should conduct in cases such as this one: (1) whether we have a practice of not issuing Cease and Desist Orders (CDOs) in the absence of commercially significant inventory in the United States; and (2) perhaps because of this potential practice, whether the law provides a presumption against a CDO unless the patentee proves the existence of such inventory. [37] I think

[37] For example, the Commission opinion in *Certain Integrated Repeaters, Switches, Transceivers, and Products Containing Same*, addresses the topic by stating as follows:

> The Commission issues cease and desist orders where "commercially significant" inventories of infringing products are present in the United State[s], and complainants bear the burden of proving that respondent has such an inventory. Because complainants failed to sustain their burden, we have determined not to issue a cease and desist order.

Inv. No. 337-TA-435, Comm'n Op. at 27 (Public Ver.) (Aug. 16, 2002) (citing Final Initial Determination at 207 (July 19, 2001)). Yet, the Commission has issued CDOs to enforce patent claims where, at least with respect to some of the infringed patent claims, a commercially significant domestic inventory was not established, in part because the proven presence of commercially significant domestic inventories is not a statutory requirement. *See* 19 U.S.C. § 1337(f)(1). *See, e.g., Certain Sleep-Disordered Breathing Treatment Systems and Components*

the Commission is at its best when we are as deliberate and informed as reasonably practicable when indicating that something may amount to an established practice or create a presumption. I also recognize that such interest in receiving additional briefing is to some extent in conflict with our existing norms of using our best efforts in individual cases to avoid adding either delay or costs to the parties of preparing legal briefs. Nevertheless, practice and presumptions often arise through a process of accretion by individual cases, meaning the work must be done at some point in one such case. In addition, such practice and presumptions can be especially relevant if the Commission is not of one mind. For both of these reasons, I think that our collective interests in the deliberative process combined with the parties' due process interests in knowing how close the scales may be balanced on these particular issues in their particular case, militate in favor of the Commission taking the opportunity to seek additional briefing and to engage in more

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Thereof, Inv. No. 337-TA-890, Comm'n Op. at 49 (Public Ver.) (January 16, 2015) ("The Commission declines to restrict issuance of cease and desist orders to only the patent claims for which it was established that commercially significant inventory of infringing products exists in the United States.") (dissenting footnote by Commissioner Johanson omitted); and *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making the Same*, Inv. No. 337-TA-833, Comm'n Op. at 147 (Public Ver.) (April 9, 2014) ("Although Respondents dispute whether these digital data sets may constitute inventory, the Commission nonetheless has authority to issue a cease and desist order for any violation found because the presence of a U.S. inventory is not a statutory requirement.") (Commission opinion, from which Commissioner Johanson dissented) (reversed on other ground: the question of whether the statute reaches certain infringing electronic data sets). Furthermore, the legislative history for our statute at least suggests that the Commission's authority to issue CDOs should be interpreted broadly, and a commercially significant inventory is but an example of when such a remedy may be appropriate. *See* H.R. Rep. No. 100-40, at 159-60 (1987) ("For example, a cease and desist order prohibiting a domestic respondent from selling the imported infringing product in the United States may be appropriate when the product has been stockpiled during the pendency of an investigation and an exclusion order may be appropriate to prevent future shipments of the infringing product. When the Commission determines that both remedies are necessary, it should be without legal question that the Commission has authority to order such relief.").

deliberation. For example, in this case we could have asked the parties and the public to provide, perhaps within no more than 10 pages and within no more than two weeks, briefing on something like the following three questions, and we could have committed ourselves to then reaching decisions on these questions within an additional two weeks, thereby only adding a net of one month to the timing of this case:

(1) Does the Commission have an established practice of issuing CDOs only when a respondent maintains a commercially significant inventory of infringing products in the United States?

(2) Is there a presumption against the issuance of a CDO unless the patentee proves the existence of such inventory?

(3) What legal authority governs the question of whether the Commission should issue a CDO, what burdens and presumptions (if any) apply to this question, and what should the Commission decide when applying that legal authority to a case in which there is a good faith dispute about the levels of infringing inventory in the United States?

II. CDOs APPROPRIATELY ALLOCATE RISK OF EXISTING INFRINGING INVENTORY TO THE AJUDICATED INFRINGER

By the time we come to the question of whether to issue a CDO, we know as well as we can that we have an adjudicated infringer of a valid patent. At that point, I do not understand how much value to our decision-making process can be achieved by asking the parties to offer extensive evidence and argument, including rebuttal and cross-examination, and the like, about the true and correct volume of infringing inventory that actually exists within the United States.

An adjudicative-search for highly accurate decision-making about such inventory levels is expensive for all involved: the Commission and all parties.[38] Yet the true state of such inventory is that it is either relatively high, or relatively low. If it is low, a CDO will have little impact; and so there is no harm to issuing one. If it is high, then a CDO will have big impact that seems to be at least appropriate (if not required) to protect a legal right we have just adjudicated to have been infringed; while at the same time being merely *in personam* over only the individual party who has been adjudicated to be infringing. Put differently, a decision about whether to grant a CDO inevitably allocates the risk of getting wrong the exact amount of inventory. Given our statutory obligation to protect those rights that have been adjudicated to be violated (including our adjudication that there has been importation of infringing product), I would need to learn more before concluding that it makes sense to allocate this risk to the party we just adjudicated had its rights violated instead of to the party we just adjudicated was the one who did the violating. The goal is not to be punitive; but to avoid the high costs of striving for perfection at this phase of a process that costs all parties a great deal of expense, delay, and uncertainty. Where there is credible evidence in the record supporting good faith dispute about the levels of infringing inventory in the United States, the award of a CDO against the party who's particular actions have been adjudicated to be infringing, would provide helpful certainly to all involved about the legal significance of those actions and the underlying adjudicated rights, which are widely recognized virtues of a well-functioning legal system.

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[38] Unlike where no importation of <u>any</u> infringing inventory has taken place. *See, e.g., Certain Crawler Cranes and Components Thereof*, Inv. 337-TA-887, Comm'n Op. at 73 (Public Ver.) (May 6, 2015) (". . . [Respondent] has imported one crane into the United States; it has never imported the original UltraLift package which is a required component of the infringing article with respect to claims 23-26 of the '928 patent.").

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISION OPINION** has been served by hand upon the Commission Investigative Attorney, Todd P. Taylor, Esq., and the following parties as indicated, on **May 11, 2016.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Nobel Biocare Services AG and Nobel Biocare USA, LLC:

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On Behalf of Respondents Instradent USA, Inc. and JJGC Industria e Comercio de Materiais Dentarios S/A:

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436

In the Matter of **CERTAIN DENTAL IMPLANTS**	**Investigation No. 337-TA-934**

INITIAL DETERMINATION

Administrative Law Judge David P. Shaw

Pursuant to the notice of investigation, 79 Fed. Reg. 63940 (Oct. 27, 2014), this is the final initial determination in *Certain Dental Implants*, U.S. International Trade Commission Investigation No. 337-TA-934.

It is held that a violation of section 337 of the Tariff Act, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain dental implants with respect to asserted claims 15, 18, 19, 30, and 32 of U.S. Patent No. 8,764,443. A violation of section 337 has not been found with respect to asserted claims 1-5 or 19 of U.S. Patent No. 8,714,977 or asserted claim 17 of U.S. Patent No. 8,764,443.

PUBLIC VERSION

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The following abbreviations may be used in this initial determination:

ALJ	Administrative Law Judge
CDX	Complainants' Demonstrative Exhibit
CPX	Complainants' Physical Exhibit
CX	Complainants' Exhibit
Dep.	Deposition
EDIS	Electronic Document Imaging System
JDX	Joint Demonstrative Exhibit
JPX	Joint Physical Exhibit
JX	Joint Exhibit
MPEP	Manual of Patent Examining Procedure
PTAB	Patent Trial and Appeal Board
PTO	U.S. Patent and Trademark Office
RDX	Respondents' Demonstrative Exhibit
RPX	Respondents' Physical Exhibit
RWS	Rebuttal Witness Statement
RX	Respondents' Exhibit
SDX	Staff's Demonstrative Exhibit
SPX	Staff's Physical Exhibit
SX	Staff's Exhibit
Tr.	Transcript
WS	Witness Statement

I. Background

A. Institution of the Investigation

By publication of a notice in the *Federal Register* on October 27, 2014, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(B) 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 dental implants by reason of infringement of one or more of claims 1-5 and 19 of the '977 patent [U.S. Patent No. 8,714,977] and claims 15-19, 29, 30, and 32 of the '443 patent [U.S. Patent No. 8,764,443], and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

79 Fed. Reg. 63940 (Oct. 27, 2014).

The Commission named as complainants Nobel Biocare Services AG of Kloten, Switzerland and Nobel Biocare USA, LLC of Yorba Linda, California (collectively, "Nobel").

The Commission named as respondents Neodent USA, Inc. ("Neodent USA" or "Instradent USA") of Andover, Massachusetts and JJGC Indústria e Comércio de Materiais Dentários S/A ("JJGC") of Paraná, Brazil (collectively, "Neodent," "Instradent," or "Respondents").

The Office of Unfair Import Investigations ("Staff" or "OUII") was also named as a party to the investigation. *Id.*

B. Procedural History

The target date for completion of this investigation was set at 16 months, *i.e.*, February 29, 2016.[1] Order No. 5 (Dec. 9, 2014).

Nobel filed an unopposed motion to terminate the investigation in part based on the withdrawal of asserted claims 16 and 29 of U.S. Patent No. 8,764,443. The administrative law judge granted the motion in an initial determination. Order No. 22 (Apr. 8, 2015), *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Granting Complainants' Unopposed Motion to Partially Terminate the Investigation As to Certain Claims of U.S. Patent No. 8,764,443 (Apr. 29, 2015).

The private parties filed a joint, unopposed motion seeking to amend the complaint and notice of investigation to reflect the fact that respondent Neodent USA, Inc. changed its name to Instradent USA, Inc. effective August 15, 2014. The administrative law judge granted the motion in an initial determination. Order No. 24 (Apr. 9, 2015), *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Granting a Joint Motion to Amend the Complaint and Notice of Investigation (May 6, 2015); 80 Fed. Reg. 27188 (May 12, 2015).

Order No. 20 issued on April 2, 2015, and denied Respondents' motion for leave to file an amended identification of expert witnesses. The procedural schedule required all parties to identify expert witnesses by February 11, 2015. Respondents did not seek leave to amend their identification of expert witnesses until nineteen days after the deadline. Order No. 20 at 4. Order No. 30 issued on July 2, 2015, and granted Nobel's

[1] February 27, 2016 falls on a Saturday. *See* 19 C.F.R. § 201.14(a).

motion to strike certain expert reports, and denied Respondents' motion for reconsideration of Order No. 20. Respondents failed again to explain their delay in seeking leave to make a late witness identification when they knew they would not make the deadline for identification, and when the administrative law judge had made other accommodations in the procedural schedule. Order No. 30 at 2 & n.2. Expert witness statements submitted for individuals not properly identified were stricken inasmuch as their expert reports should not have been filed, and their witness statements were submitted in violation of the procedural schedule, Order Nos. 20 and 30, and the Ground Rules (Order No. 2).

A prehearing conference was held on July 7, 2015, with the evidentiary hearing in this investigation starting immediately thereafter. The hearing ended on July 10, 2015. *See* Order No. 6 (Dec. 9, 2014); Prehearing Tr. 1-43 (July 7, 2015); Hearing Tr. 1-1047. The administrative law judge requested that the parties file post-hearing briefs of no longer than 250 pages, with reply briefs not to exceed 100 pages. Prehearing Tr. 9-10 (July 7, 2015).

Nobel subsequently filed two unopposed motions to reopen the record. The administrative law judge granted the motions. *See* Order No. 34 (July 20, 2015); Order No. 35 (Aug. 20, 2015).

C. The Private Parties

Nobel Biocare Services AG is a Swiss company with a place of business in Kloten, Switzerland. *See* Compl. ¶ 7. Nobel Biocare USA, LLC is a Delaware limited liability company with its principal place of business in Yorba Linda, California. *See id.*

Nobel Biocare Services AG and Nobel Biocare USA, LLC are related subsidiaries of Nobel Biocare Holding AG, a Swiss company. *See id.*

Instradent USA, Inc., formerly known as Neodent USA, Inc., is a Delaware corporation having a place of business in Andover, Massachusetts. Instradent Resp. to Am. Compl. ¶ 16. JJGC Indústria e Comércio de Materiais Dentários S/A is a Brazilian company with headquarters in Paraná, Brazil. *Id.* ¶ 17.

D. The Accused Products

Nobel accuses Instradent's Drive CM dental implants of infringing certain claims of the asserted '977 and '443 patents. The specific model numbers of the accused Drive CM implants are set forth in the Amended Joint Statement of Accused Products (EDIS Doc. No. 552535) filed by the parties on March 4, 2015. The parties have agreed to designate three representative products for purposes of the infringement analysis. *See* Joint Stipulation Regarding Representative Accused Products (EDIS Doc. No. 552534) (Mar. 4, 2015). Specifically, the parties identify (1) the 5.0 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.686) as representative of the accused 5.0 mm Drive CM dental implants, (2) the 4.3 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.628) as representative of the accused 4.3 mm Drive CM dental implants, and (3) the 3.5 mm x 13 mm Neodent Drive CM dental implant (Prod. No. 109.683) as representative of the accused 3.5 mm Drive CM dental implants. *See id.* at 1.

With respect to the technical prong of the domestic industry requirement, Nobel contends that its NobelActive® NP and RP implants practice the '977 and '443 patents.

The following table summarizes Nobel's contentions with respect to the accused products and domestic industry products at issue in this investigation:

Implant	'977 Patent Claims	'443 Patent Claims
NobelActive® 3.5 mm		15, 17-19, 30, 32
NobelActive® 4.3 mm	1-5, 19	15, 17-19, 30, 32
NobelActive® 5.0 mm	1-5, 19	15, 18-19, 30
Drive CM 3.5 mm		15, 17-19, 30, 32
Drive CM 4.3 mm	1-5, 19	15, 17-19, 30, 32
Drive CM 5.0 mm	1-5, 19	15, 17-19, 30, 32

Compls. Br. at 1.

II. Jurisdiction

No party has contested the Commission's personal jurisdiction over it. *See, e.g.*, Resps. Br at 13-14; Staff Br. at 15. Indeed, all parties appeared at the evidentiary hearing and presented evidence. It is found that the Commission has personal jurisdiction over all parties.

No party has contested the Commission's *in rem* jurisdiction over the accused products. *See, e.g.*, Compl. Br. at 9-13; Resps. Br at 13-14; Staff Br. at 14-15. Nobel has based its importation arguments on completed acts of importation. Indeed, Instradent concedes that it has imported the accused Drive CM 2 Dental Implants into the United States. Resps. Br. at 14. Even though Instradent argues that it has not imported any infringing article in violation of section 337 with respect to the '977 patent, *see* Resps. Br. at 14, it is nevertheless found that the Commission has *in rem* jurisdiction over all products accused under the asserted patents.

No party has contested the Commission's jurisdiction over the subject matter of this investigation. *See, e.g.*, Compl. Br. at 9-13; Resps. Br at 13-14; Staff Br. at 14-15. Indeed, as indicated in the Commission's notice of investigation, discussed above, this investigation involves the alleged importation of products that infringe United States patents in a manner that violates section 337 of the Tariff Act, as amended. Accordingly, it is found that the Commission has subject matter jurisdiction over this investigation.

III. Ownership and Standing

A. General Principles of Law

Commission Rule 210.12 requires that intellectual property-based complaints filed by a private complainant "include a showing that at least one complainant is the owner or exclusive licensee of the subject intellectual property." 19 C.F.R. § 210.12(a)(7). In determining whether this requirement is met, the Commission has applied the standing requirement established by the U.S. district courts in patent infringement cases. *See Certain Catalyst Components and Catalysts for the Polymerization of Olefins*, Inv. No. 337-TA-307, Comm'n Op., 1990 ITC LEXIS 224, at *50 (June 18, 1990) ("[W]e see little basis for inferring a different standing requirement under section 337 than the courts have established in patent infringement cases.").

In U.S. district courts and before the Commission, "[t]he question of standing to assert a patent claim is jurisdictional." *SiRF Tech. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1325 (Fed. Cir. 2010). A complainant bears the burden to prove it has standing. *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Initial Determination at 14, (Dec. 1, 2008) (citing *Ortho Pharm.*

Corp. v. Genetics Institute, Inc., 52 F.3d 1026, 1033 (Fed. Cir. 1995)), *rev'd on other grounds*, Comm'n Op., 2009 WL 1520119 (May 20, 2009).

The Commission may exercise jurisdiction only if a complainant has standing to sue on the date it files the operative complaint. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 570 n.5 (1992) ("[S]tanding is to be determined as of the commencement of suit."); *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1364 (Fed. Cir. 2010); *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003).

A plaintiff in a patent infringement case has standing to sue in its own name alone where it is the patentee or assignee of all legal rights to the asserted patent; a plaintiff may also have standing alone when it has received "all substantial rights" to the patent, which "amounts to an assignment or a transfer of title." *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339-40 (Fed. Cir. 2007). Patentees can transfer away rights in their patents and, "[w]hen a plaintiff lacking a sufficiently large portion of rights brings suit, that plaintiff does not have standing to sue on his own, and the suit must be dismissed, or additional holders of rights under the patent must be joined as parties to the suit." *Alfred E. Mann Found. for Scientific Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010). Although holders of patents can be characterized as patentees, assignees, exclusive licensees, or non-exclusive licensees, the Federal Circuit has emphasized "the substance of the rights conferred . . . , not[] the characterization of those rights as exclusive licenses or otherwise." *Morrow*, 499 F.3d at 1340 n.7.

To determine whether a plaintiff holds "all substantial rights" in a patent, the Federal Circuit has considered a non-exhaustive list of factors (some of which apply in

the context of an exclusive license only): (1) the nature and scope of the right to bring suit; (2) the exclusive right to make, use, and sell products or services under the patent; (3) the scope of the licensee's right to sublicense; (4) the reversionary rights to the licensor following termination or expiration of the license; (5) the right of the licensor to receive a portion of the proceeds from litigating or licensing the patent; (6) the duration of the license rights; (7) the ability of the licensor to supervise and control the licensee's activities; (8) the obligation of the licensor to continue paying maintenance fees; and (9) any limits on the licensee's right to assign its interests in the patent. *Azure Networks v. CSR PLC*, 771 F.3d 1336, 1343 (Fed. Cir. 2014) (citing *Mann*, 604 F.3d at 1360-61), *cert. granted and judgment vacated on other grounds*, *CSR PLC v. Azure Networks*, 135 S. Ct. 1846 (Apr. 20, 2015).

B. The '977 Patent

Instradent alleges that Nobel lacks standing to assert the '977 patent in this investigation inasmuch as Nobel does not possess all substantial rights to the patent.[2] Resps. Br. at 14-23. Nevertheless, the record evidence demonstrates that Nobel Biocare AG holds "a sufficiently large portion of [the] bundle of rights" to be considered the patent owner. *See Azure Networks*, 771 F.3d at 1343.

1. Factual Background

The '977 patent application was filed on November 26, 2012 as a continuation application and issued on May 6, 2014, listing four named inventors. JX-0001 ('977

[2] Instradent previously moved for summary determination on the issue of whether or not Nobel has standing to assert the '977 patent in this investigation. Instradent's motion was denied. Order No. 32 (July 2, 2015).

patent). On its face, the '977 patent claims priority through a chain of continuation applications to U.S. Patent Application No. 10/558,260 ("the '260 application"),[3] which is the national stage application of PCT application No. PCT/IL/2004000438 ("the '438 PCT application") filed on May 23, 2004. *Id.*

In June 2005, the four named inventors of the '977 patent and Alpha-Bio Tech Ltd. (collectively, "the Seller") entered into a Patent Transfer and Consultancy Agreement ("Transfer Agreement") with complainant Nobel Biocare AG concerning a dental implant platform (defined as the "Invention") that is the subject matter of the '438 PCT application (defined, in part, as the "Patent Application"). JX-0478C (Patent Transfer and Consultancy Agreement); CX-1025C (Collins WS) Q33-37. Under the agreement, the "[

]." JX-0478C (Patent Transfer and Consultancy Agreement) § 3.1. Further, the Seller agreed to "[

]." *Id.* § 3.5.

On October 31, 2006, the four named inventors of the '977 patent executed an Assignment to "sell, assign and transfer to" complainant Nobel Biocare AG their "entire right, title, and interest in and to the invention entitled: 'Condensing Skeletal Implant that Facilitates Insertion,'" described in U.S. Patent Application No. 10/558,260. JX-0475

[3] The '260 application matured into U.S. Patent No. 7,597,557.

('977 assignment) at 3. The 2006 assignment was recorded with the PTO on November 20, 2006. *Id.* at 1. No other documents were recorded for U.S. Patent Application No. 10/558,260 (now U.S. Patent No. 7,597,557) or the '977 patent.

In 2008, Nobel Biocare Holding acquired Alpha-Bio Tech Ltd. and its intellectual property rights. *See* Compl. ¶ 23; JX-0301C (2008 Share Purchase Agreement); CX-1025C (Collins WS) Q68-69.

2. Analysis

The record evidence shows that the named inventors of the '977 patent, as well as Alpha-Bio Tech Ltd., assigned their "entire right, title, and interest in and to" the '260 application, which is the parent U.S. application to the '977 patent, to complainant Nobel Biocare AG. JX-0475 ('977 assignment). This assignment was recorded with the PTO and attached to the complaint in this investigation. *See* Compl. Ex. 3. In a separate agreement, however, Nobel Biocare AG licensed certain rights in the '977 patent back to the named inventors and Alpha-Bio Tech Ltd. JX-0478C (Patent Transfer and Consultancy Agreement). As set forth in more detail below, the evidence shows that Nobel Biocare AG nevertheless holds a sufficiently large portion of the bundle of rights to be considered the owner of the '977 patent. Accordingly, Nobel has standing to assert the '977 patent in this investigation pursuant to section 337.

a. Assignment of the '977 Patent to Nobel

The Transfer Agreement provides for the assignment of the '438 PCT application and continuations thereof from the inventors to Nobel Biocare AG. JX-0478C (Patent Transfer and Consultancy Agreement) § 3.1. Specifically, Section 3.1 states:

[

]

Id. (emphasis added.)

Proprietary Rights is defined in Section 3.4 to "[

]." JX-0478C (Patent Transfer and Consultancy Agreement) § 3.4. Indeed, Dr. Ophir Fromovich, the then-CEO of Alpha-Bio Tech Ltd. and one of the named inventors of the '977 patent, testified:

[

]

CX-1028C (Fromovich WS) Q11; *see also* CX-1028C (Fromovich WS) at Q10-13; Fromovich Tr. 363-364 ("[

].").

The Sellers also agreed to "[

]." JX-0478C (Patent Transfer and Consultancy Agreement) § 3.5. After the '260 application, which is the national stage application of the '438 PCT application, was filed at the PTO, the named inventors executed the '977 patent assignment and recorded it with the PTO. JX-0475 ('977 assignment).

Relevant case law instructs: "An official assignment document or recording of an assignment creates a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment." *Certain Optical Disc Drives*, Inv. No. 337-TA-897, Comm'n Op. Remanding the Investigation at 8 (Jan. 7, 2015) (citing *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010)). Yet, "[p]ossession of a recorded assignment is only the beginning of the analysis. 'To determine whether an agreement to transfer rights to a patent at issue amounts to an assignment or a license, we must ascertain the intention of the parties and examine the substance of what was granted.'" *See Certain Electronic Devices with Communication Capabilities, Components Thereof, and Related Software*, Inv. No. 337-TA-808, Order No. 15: Initial Determination at 8 (June 29, 2012) (*citing Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1340 (Fed. Cir. 2006)).

The language of the '977 patent assignment is clear and unambiguous. The named inventors agreed to "sell, assign and transfer to" Nobel Biocare AG their "entire right, title, and interest in and to" the invention entitled "Condensing Skeletal Implant that Facilitates Insertion" as described in '260 application. JX-0475 ('977 assignment) at 3. The '977 patent assignment does not indicate that the assigned rights were subject to any agreement (including the Transfer Agreement), license, restriction, or encumbrance of any kind. *Id.*

Nevertheless, under the Transfer Agreement, the named inventors held [

]. Section 3.9 of the Transfer Agreement, dated June 2005, states in part:

[

]

JX-0478C (Patent Transfer and Consultancy Agreement) § 3.9.

The evidence shows, however, that [

]. CX-1025C (Collins WS) Q39-40; Collins Tr. 53-55, 65-66.

Instradent also alleges that, under the Termination Provision of the Transfer Agreement, [ ]. Resps. Br. at 22-23. The record evidence shows otherwise. Section 9.2 does provide a mechanism for either party [

]." JX-0478C (Patent Transfer and Consultancy Agreement) §§ 9.2, § 9.4. Therefore, the express language of the Transfer Agreement demonstrates that the assignment of the '977 patent to Nobel would survive termination of the Transfer Agreement and remain in effect.

b. Grant-Back Provisions

As discussed above, as evidenced by the '977 patent assignment, the named inventors assigned their "entire right, title, and interest in and to" the '260 application to Nobel Biocare AG. Nevertheless, the Transfer Agreement contains provisions showing that [ ]. JX-0478C (Patent Transfer and Consultancy Agreement). The evidence shows, however, that the [ ] do not deprive Nobel of standing to assert the '977 patent in this investigation.

For example, the Transfer Agreement provides that "[

]." JX-0478C (Patent Transfer and Consultancy Agreement) § 3.3. Despite this [

]. *See id.*

Moreover, Nobel Biocare AG [

]

JX-0478C (Patent Transfer and Consultancy Agreement) § 9.2.

Other factors considered in determining whether a party holds "a sufficiently large portion of [the] bundle of rights" to be considered the patent owner weigh in favor of a determination that the balance of rights to the '977 patent has remained with Nobel Biocare AG. *See Azure Networks*, 771 F.3d at 1343. Even though the Transfer Agreement contains provisions showing that Nobel Biocare AG contractually agreed [

], the evidence shows that Nobel Biocare AG nevertheless holds a sufficiently large portion of rights in the '977 patent for purposes of standing.

Accordingly, it is determined that both complainants have standing to assert the '977 patent in this investigation.

C. The '443 Patent

Jan Hall, the named inventor of the '443 patent, executed an assignment of the patent to Nobel Biocare Services AG on July 1, 2005. JX-0002 ('443 patent) at 2; JX-0476 at 3 (certified assignment from Jan Hall to Nobel Biocare Services AG). This assignment was recorded with the U.S. Patent and Trademark Office on January 31, 2011. JX-0476 at 1 ("THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON JANUARY 31, 2011"). Further, Nobel Biocare Services AG has granted Nobel Biocare USA, LLC an exclusive license to practice the '443 patent in the United States. CX-0373C (intercompany license agreement); CX-1025C (Collins WS) at Q20-26.

Accordingly, it is determined that both complainants have standing to assert the '443 patent in this investigation.

IV. Importation

A. General Principles of Law

This investigation was instituted to determine whether a violation of section 337 has occurred in "the importation into the United States, the sale for importation, or the sale within the United States after importation" of certain products. *See* 78 Fed. Reg. 36573 (June 18, 2013); 19 U.S.C. § 1337(a)(1)(B) (making unlawful, in certain circumstances, the "importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that . . . infringe a valid and enforceable United States patent . . . ."). It has long been recognized that an importation of even one accused product can satisfy the importation requirement of section 337. *See Certain Trolley Wheel Assemblies*, Inv. No. 337-TA-161, Comm'n Op. at 7-8, USITC Pub. No. 1605 (Nov. 1984) (deeming the importation requirement satisfied by the importation of a single product of no commercial value).

B. Importation of the Accused Products

It is undisputed that JJGC has sold the accused Drive CM implants for importation into the United States, and that Instradent has sold the same accused products in the United States after importation. In particular, Instradent concedes that JJGC manufactures the accused products in Brazil. *See, e.g.*, Instradent Resp. to Am. Compl. ¶ 18 ("Instradent admits that JJGC manufactures and packages the Accused Products

outside the United States."); JJGC Resp. to Am. Compl. ¶ 18; CX-0433C (JJGC Resp. to Interrog. No. 3) at 14; CX-0436 (Resps. Resp. to RFA No. 40) at 26-27; JX-0149C (Instradent Resp. to Interrog. No. 3) at 14.

Instradent also concedes that Instradent USA imports the accused products into the United States and sells the accused products in the United States after importation. *See, e.g.*, Instradent Resp. to Am. Compl. ¶ 18 ("Instradent admits that Instradent imports and sells the Accused Products in the Unites States after importation."); CX-0433C (JJGC Resp. to Interrog. No. 3) at 14; CX-0436 (Resps. Resp. to RFA Nos. 41, 42) at 27-28; JX-0149C (Instradent Resp. to Interrog. No. 3) at 14.

Accordingly, the record evidence establishes that the accused products have been imported in to the United States, thereby satisfying the importation requirement of section 337.

V. The '977 Patent

A. Asserted Claims

Asserted U.S. Patent No. 8,714,977 ("the '977 patent") is titled, "Condensing Skeletal Implant That Facilitate Insertions." JX-0001 ('977 patent). The '977 patent issued on May 6, 2014, and the named inventors are Ophir Fromovich, Yurval Jacoby, Nitzan Bichacho, and Ben-Zion Karmon. *Id.*

Nobel asserts independent claim 1 and dependent claims 2, 3, 4, 5, and 19.[4] The relevant claims read as follows:

[4] Claim 19 depends from independent claim 9, which is not asserted in this investigation.

1. A dental implant comprising:

a body;

a coronal region of the body, the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region;

an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core and the apical end of the core is substantially flat; and

a pair of helical threads extending from the body along at least a portion of the apical region, each of the threads comprising an apical side, a coronal side, and a lateral edge connecting the apical side and the coronal side, a base connecting the threads to the core, a thread height defined between the lateral edge and the base, the lateral edge having a variable width that is expanded along a segment in the direction of the coronal end of the apical region, so that a least width of the lateral edge of the threads is adjacent the apical end of the apical region and a greatest width of the lateral edge of the threads is adjacent the coronal end of the apical region, and the threads having a variable height that is expanded substantially along the segment of the implant in the direction of the apical end of the apical region, so that a least height of the threads is adjacent the coronal end of the apical region and a greatest height at apical end of the apical region; and

a bone tap, wherein the helical threads starts at said bone tap and said substantially flat apical end of the core;

wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5-2.5 mm.

2. The implant of claim 1, wherein the coronal region has a surface configured to be in contact with bone.

3. The implant of claim 1, wherein the apical end of the coronal region defines an upper limit of the threads.

4. The implant of claim 1, wherein the threads adjacent the apical end of the body are self-tapping.

5. The implant of claim 1, wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant.

9. A dental implant comprising:

a body;

a coronal end of the body;

and an apical end of the body;

the apical end having a tapered core, the apical end includes at least one region having two tapered variable profile helical threads extending along the core, each thread having an apical side, a coronal side, a lateral edge connecting the apical side and the coronal side, a base touching the core, a height defined between the lateral edge and the base, a variable length of the lateral edge being progressively expanded substantially along the region of the apical end in the direction of the coronal end, so that a least length of the lateral edge of the thread is adjacent the apical end and a greatest length of the lateral edge of the thread is adjacent the coronal end, and a variable height being progressively expanded substantially along the entire threaded region of the implant in the direction of the apical end, so that a least height of the thread is adjacent the coronal end and a greatest width of the thread is adjacent the apical end,

wherein the core is more tapered than the threads and wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5-2.5 mm.

19. A dental implant according to claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge.

B. Claim Construction

1. General Principles of Law[5]

Claim construction begins with the plain language of the claim.[6] Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent.[7] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006).

In some instances, claim terms do not have particular meaning in a field of art, and claim construction involves little more than the application of the widely accepted meaning of commonly understood words. *Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.*

In many cases, claim terms have a specialized meaning, and it is necessary to determine what a person of skill in the art would have understood the disputed claim language to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use

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[5] The legal principles set forth in this section apply equally to the claim construction of the '443 patent.

[6] Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

[7] Factors that may be considered when determining the level of ordinary skill in the art include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). The public sources identified in *Phillips* include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.*

In cases in which the meaning of a claim term is uncertain, the specification usually is the best guide to the meaning of the term. *Id.* at 1315. As a general rule, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). The specification is, however, always highly relevant to the claim construction analysis, and is usually dispositive. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316.

Claims are not necessarily, and are not usually, limited in scope to the preferred embodiment. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003); *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1314 (Fed. Cir. 2008) ("[The] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the

claims."). Nevertheless, claim constructions that exclude the preferred embodiment are "rarely, if ever, correct and require highly persuasive evidentiary support." *Vitronics*, 90 F.3d at 1583. Such a conclusion can be mandated in rare instances by clear intrinsic evidence, such as unambiguous claim language or a clear disclaimer by the patentees during patent prosecution. *Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000); *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence consists of all evidence external to the patent and the prosecution history, and includes inventor testimony, expert testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. Inventor testimony can be useful to shed light on the relevant art. In evaluating expert testimony, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. *Id.* at 1318. Extrinsic evidence may be considered if a court deems it helpful in determining the true meaning of language used in the patent claims. *Id.*

2. Level of Ordinary Skill

Nobel proposes that a person of ordinary skill in art with respect to the '977 patent should be defined as "either a mechanical engineer with at least two years of experience in the design, development, research or testing of dental implants, or a clinician experienced in the implantation of dental implants." *See* Compls. Br. at 13. Instradent proposes that a person of ordinary skill in the art be defined as "a person

having at least a bachelor-level degree in mechanical or bio-medical engineering and a few years of experience in the design and development of dental implants, or a dental provider trained in the practice of implanting dental implants." *See* Resps. Br. at 62. The Staff generally supports the definition proposed by Nobel. *See* Staff Br. at 20.

As proposed by Nobel and the Staff, a person of ordinary skill in the art with respect to the '977 patent is defined as either a mechanical engineer with at least two years of experience in the design, development, research or testing of dental implants, or a clinician experienced in the implantation of dental implants. This definition is consistent with the disclosure of the '977 patent and cited prior art, whereas Instradent's proposed definition excludes academics who research and test dental implants, and publish the results of their research in scholarly journals. *See* Compls. Br. at 14; Staff. Br. at 20.

3. Disputed Claim Terms

a. "the coronal region having a frustoconical shape" (claim 1)

Below is a chart setting forth the parties' proposed constructions.[8]

[8] This initial determination addresses the disputed claim terms identified by the parties as needing construction. *See* Joint Outline of Issues to Be Decided (EDIS Doc. No. 562314) ("Joint Outline of Issues"). The parties identified the claim terms for construction in a joint filing required by Ground Rule 11, which provides: "On the same day the initial posthearing briefs are due, the parties shall file a comprehensive joint outline of the issues to be decided in the final Initial Determination. The outline shall refer to specific sections and pages of the posthearing briefs. Moreover, the claim terms briefed by the parties must be identical. For example, if the construction of the claim term 'wireless device' is disputed, the parties must brief that exact claim term. If a party briefs only a portion of the claim term such as 'wireless' or 'device,' that section of the brief will be

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"the coronal region having a frustoconical shape"	"the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion"	"the coronal region has, partly or entirely, a frustoconical shape"	"the coronal region has, partly or entirely, a frustoconical shape"

The claim term "the coronal region having a frustoconical shape" appears in claim 1 of the '977 patent. As proposed by Instradent and the Staff, the term "the coronal region having a frustoconical shape" is construed to mean "the coronal region has, partly or entirely, a frustoconical shape," a construction that comports with the understanding of a person having ordinary skill in the art.

The first conflict between the two constructions proposed by the parties concerns whether the interpretation of "having" is open-ended or closed-ended, thereby determining whether the coronal region could have additional shapes besides a frustoconical shape. The intrinsic evidence, *i.e.*, the figures and descriptions set forth in the specification of the '977 patent, demonstrates that "having" should be construed as open-ended. Such an open-ended construction allows some portion of the coronal region to have other shapes in addition to a frustoconical shape. *See, e.g.*, *Lampi Corp. v.*

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stricken." Ground Rule 11 (emphasis original) (attached to Order No. 3 (Amended Ground Rules) (Nov. 21, 2014)).

Pursuant to the procedural schedule set forth in Order No. 6 (Dec. 9, 2014), the parties submitted Joint Claim Construction Charts setting forth proposed constructions for claim terms requiring construction. The Attachment to this filing (EDIS Doc. No. 552295) shall hereinafter be referred to as "Joint Claim Construction Chart."

American Power Products Inc., 228 F.3d 1365, 1376 (Fed. Cir. 2000) (construing the term "having" as open-ended, allowing the inclusion of other components in addition to those cited). By contrast, Nobel's proposed construction construes "having" as closed-ended, requiring that the coronal region as a whole have a frustoconical shape and precluding the possibility that the coronal region could have any additional shapes. The intrinsic evidence does not support such a construction.

The language of claim 1 itself does not require that the term "having" be construed as closed-ended. In particular, it neither requires that the whole coronal region have a frustoconical shape, nor does it exclude the coronal region from having additional shapes besides a frustoconical shape. Moreover, the claim language does not use the term "having" in a manner indicating an objective intent to require that the entire coronal region have a frustoconical shape. *Innova*, 381 F.3d at 1116 ("The inquiry into the meaning that claim terms would have to a person of skill in the art at the time of the invention is an objective one.").

The specification of the '977 patent also demonstrates that the term "having" should be construed as open-ended. The specification generally describes the claimed coronal region as the region of the implant above the threads, *i.e.*, the apical region.[9] The specification, and in particular the illustrations of Figures 5, 8, and 9, makes clear that the claimed coronal region may include other shapes (and angles) besides a frustoconical

[9] As discussed in a separate section below, the parties have agreed that the claim term "coronal region" should be construed to mean "a region of the implant body closer to the crest of the jawbone when the implant is fully implanted."

shape. JX-0001 ('977 patent) at Figs. 5, 8, 9. The adopted construction covers these embodiments and also the embodiments shown in Figures 12, 17, and 18, in which the entire coronal region has a frustoconical shape. *Id.* at Figs. 12, 17, 18. Therefore, in the context of the '977 patent, one of ordinary skill in the art would construe the claim term "the coronal region having a frustoconical shape" to mean "the coronal region has, partly or entirely, a frustoconical shape."

By contrast, Nobel's proposed construction is an attempt to read the embodiment disclosed in Figure 12 into claim 1. Indeed, during the evidentiary hearing, Nobel's expert testified that Nobel's proposed construction conflicts with the teachings of the '977 specification. *See* Hurson Tr. 203, 204.

The second conflict between the two constructions proposed by the parties concerns whether or not the functional claim limitation "that permits bone to relapse upon implant insertion" should be read into the claim language. Nobel's expert, Mr. Hurson, testified regarding Nobel's proposed claim construction:

> [A] person of ordinary skill who has read the '977 patent would understand that the patent is not about manufacturing techniques, but about how the functional features of the implant's exterior interact with the bone to provide high stability in soft bone and to preserve hard and soft tissue. The coronal taper discussed in the '977 patent is one such feature . . . .

CX-1030C (Hurson WS) at Q31.

Nobel argues that "[the coronal taper must] must be large enough to allow the compressed bone to relapse around the coronal region." Hurson Tr. 208-209, 300-301; CX-1036C (Sullivan WS) at Q54, Q58. In particular, it is argued that one of ordinary

skill in the art would understand that the frustoconical coronal region is not any minuscule edge break or bevel, and that the claim term "should be construed to require a coronal taper that is large enough to allow the bone to relapse over the implant." *See* Compls. Br. at 16, 30. The record evidence, however, does not support Nobel's proposed construction.

As an initial matter, the claim term is clear and unambiguous, and any reference to the size of the frustoconical region or to any potential bone relapse should not be read into the claim from the specification. *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1371 (Fed. Cir. 2001) ("[L]imitations from elsewhere in the specification will not be read in where, as here, the claim terms are clear."). In addition, inasmuch as the claim term "the coronal region having a frustoconical shape" is written in structural terms, it is improper to construe it as having a functional limitation. *See Schwing GMBH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002) ("Where a claim uses clear structural language, it is generally improper to interpret it as having functional requirements."). Moreover, injecting a functional limitation into claim 1 would only confuse, and not clarify, the meaning of the term. In particular, the specification states:

> The coronal region of the implant is preferably converging coronally. This region is to be placed below the bone level and the bone is covering this region because *the implant is designed to allow insertion with a small diameter drill and to allow elastic expansion of the cortical bone.*

JX-0001 ('977 patent) at col. 2, lns. 62-66 (emphasis added).

The specification therefore teaches that the ability of the bone to relapse is correlated with the size of the drill used to prepare the osteotomy, and not with the size of the frustoconical region of the dental implant. Indeed, Nobel's expert, Dr. Richard Sullivan, testified that the coronal region of the dental implant would not permit the bone to relapse if a large-diameter drill is used to create an over-sized osteotomy. Sullivan Tr. 125. Therefore, infringement under Nobel's proposed construction would depend in part upon the ability of the bone to relapse, which in turn would depend upon the size of the osteotomy. *See* Hurson Tr. 300-301.

Relevant case law instructs that "it is usually improper to construe non-functional claim terms in system claims in a way that makes infringement or validity turn on their function." *Superior Indus., Inc. v. Masaba, Inc.*, No. 2013-1302, 2014 WL 163046, at *5 (Fed. Cir. Jan. 16, 2014) (unpublished). "Construing a non-functional term in an apparatus claim in a way that makes direct infringement turn on the use to which an accused apparatus is later put confuses rather than clarifies, frustrates the ability of both the patentee and potential infringers to ascertain the propriety of particular activities, and is inconsistent with the notice function central to the patent system." *Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1090 (Fed. Cir. 2009) (noting that the problem with injecting a use limitation into a claim written in structural terms is that "the same apparatus might infringe when used in one activity, but not infringe when used in another").

In sum, the record evidence demonstrates that one of ordinary skill in the art at the time of the '977 invention would interpret the claim term "the coronal region having a

frustoconical shape" to mean "the coronal region has, partly or entirely, a frustoconical shape."

b. "a greatest width of the thread" (claim 9)

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"a greatest width of the thread"	"a greatest height of the thread"	Indefinite[10]	"a greatest height of the thread

The claim term "a greatest width of the thread" appears in claim 9 of the '977 patent. As proposed by Nobel and the Staff, the term "a greatest width of the thread" is construed to mean "a greatest height of the thread." This construction comports with the understanding of a person of ordinary skill in the art when viewing the term in the context of the claim language and specification of the '977 patent. In particular, the record evidence shows that a person of ordinary skill would interpret the term "width" appearing in the phrase "a greatest width of the thread" to mean "height." CX-1030 (Hurson WS) at Q32 (discussing how one of ordinary skill in the art would understand the term "width" in the context of the claim language).

By contrast, the record evidence does not support Instradent's contention that this claim term is indefinite. A claim is indefinite only if, in light of the specification and prosecution history, it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct.

[10] The general legal principles underlying Instradent's claim of indefiniteness are set forth below in the section relating to invalidity of the '977 patent.

2120, 2124 (2014). The evidence adduced during the hearing demonstrates that a person of ordinary skill in the art would have a reasonable certainty as to the scope of claim 9. *See, e.g.*, JX-0001 ('977 patent) at col. 2, lns. 46-48, col. 5, lns. 27-29, col. 18, lns. 9-12; CX-1030C (Hurson WS) at Q32.

c. "a most coronal aspect" / "a most coronal aspect of the coronal end is tapered coronally" (claim 19)

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"a most coronal aspect" / "a most coronal aspect of the coronal end is tapered coronally"	"the most coronal end tapers in the coronal direction and permits bone to relapse upon implant insertion"	"a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant"	"a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant"

The claim terms "a most coronal aspect" and "a most coronal aspect of the coronal end is tapered coronally" appear in claim 19 of the '977 patent. As proposed by Instradent and the Staff, these terms are construed to mean "a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant."

As with the construction of the claim 1 term "the coronal region having a frustoconical shape," the dispute with respect to the claim terms here is whether or not the functional limitation "permits bone to relapse upon implant insertion" should be read into claim 19. *See* Compls. Br. at 41; Resps. Br. at 28-32. For the reasons set forth

above in connection with the claim 1 term "the coronal region having a frustoconical shape," the record evidence demonstrates that this structural claim term should be construed to mean "a furthermost portion of the coronal end (from the apical end) has a width that is reduced in the direction of the coronal end of the implant."

4. Undisputed Claim Terms[11]

a. "a coronal region" / "a coronal region of the body"

The parties agree that the claim terms "a coronal region" and "a coronal region of the body," which appear in claim 1 of the '977 patent, should be construed to mean "a region of the implant body closer to the crest of the jawbone when the implant is fully implanted." *See* Joint Claim Construction Chart at 2.

b. "substantially flat" (claim 1)

The parties agree that the claim term "substantially flat," which appears in claim 1 of the '977 patent, should be construed to mean "mainly flat." *See* Joint Claim Construction Chart at 2.

c. "along a segment" / "along the segment" (claim 1)

The parties agree that the claim terms "along a segment" and "along the segment," which appear in claim 1 of the '977 patent, should be construed to mean "along a section of 'a portion of the apical region.'" *See* Joint Claim Construction Chart at 2.

[11] Although this initial determination need only construe the disputed claim terms set forth in the Joint Outline of Issues, the parties' proposed constructions of undisputed claim terms identified as needing construction are included here for completeness.

d. "surface configured to be in contact with bone" (claim 2)

The parties agree that the claim term "surface configured to be in contact with bone," which appears in claim 2 of the '977 patent, should be construed to mean "designed or constructed to enhance osseointegration." *See* Joint Claim Construction Chart at 2.

e. "defines an upper limit" (claim 3)

The parties agree that the claim term "defines an upper limit," which appears in claim 3 of the '977 patent, should be construed to mean "sets a boundary beyond which the threads do not extend." *See* Joint Claim Construction Chart at 2.

f. "region" (claim 9)

The parties agree that the claim term "region," which appears in claim 9 of the '977 patent, should be construed to mean "area or section." *See* Resps. Br. at 25.

g. "wherein the core is more tapered than the threads" (claim 9)

The parties agree that the claim term "wherein the core is more tapered than the threads," which appears in claim 9 of the '977 patent, should be construed to mean "the angle of a line (which is a continuation of the border of a core segment between two adjacent helical threads) relative to the longitudinal axis of the implant is greater than the angle of a line (which connects the tips of the helical threads) relative to the longitudinal axis of the implant." *See* Joint Claim Construction Chart at 2.

h. "a coronal end" / "a coronal end of the body" (claim 9)

The parties agree that the claim terms "a coronal end" and "a coronal end of the body," which appear in claim 9 of the '977 patent, should be construed to mean "the end of the implant body closest to the crest of the jawbone when the implant is fully implanted." *See* Joint Claim Construction Chart at 2.

i. "apical end" (claim 9)

The parties agree that the claim term "apical end," which appears in claim 9 of the '977 patent, should be construed to mean "the end of the implant body farthest from the crest of the jawbone when the implant is fully implanted." *See* Joint Claim Construction Chart at 2.

C. Infringement

1. General Principles of Law[12]

a. Direct Infringement[13]

Under 35 U.S.C. §271(a), direct infringement consists of making, using, offering to sell, or selling a patented invention without consent of the patent owner. The complainant in a section 337 investigation bears the burden of proving infringement of the asserted patent claims by a "preponderance of the evidence." *Certain Flooring Products*, Inv. No. 337-TA-443, Comm'n Notice of Final Determination of No Violation

[12] The legal principles set forth in this section apply equally to the infringement analysis of the '443 patent.

[13] Nobel alleges only that the accused products directly infringe the asserted patents; there are no allegations of indirect infringement. *See* Compls. Br. at 41-66, 155-65.

of Section 337, 2002 WL 448690, at *59, (Mar. 22, 2002); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376 (Fed. Cir. 1998).

Literal infringement of a claim occurs when every limitation recited in the claim appears in the accused device, *i.e.*, when the properly construed claim reads on the accused device exactly.[14] *Amhil Enters., Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996); *Southwall Tech. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed Cir. 1995).

If the accused product does not literally infringe the patent claim, infringement might be found under the doctrine of equivalents. "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)). "The determination of equivalence should be applied as an objective inquiry on an element-by-element basis."[15] *Id.* at 40.

"An element in the accused product is equivalent to a claim limitation if the differences between the two are insubstantial. The analysis focuses on whether the

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[14] Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). If an accused device lacks a limitation of an independent claim, the device cannot infringe a dependent claim. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

[15] "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1130 (Fed. Cir. 2011).

element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *AquaTex Indus. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (quoting *Graver Tank*, 339 U.S. at 608); *accord Absolute Software*, 659 F.3d at 1139-40.[16]

Prosecution history estoppel can prevent a patentee from relying on the doctrine of equivalents when the patentee relinquished subject matter during the prosecution of the patent, either by amendment or argument. *AquaTex*, 419 F.3d at 1382. In particular, "[t]he doctrine of prosecution history estoppel limits the doctrine of equivalents when an applicant makes a narrowing amendment for purposes of patentability, or clearly and unmistakably surrenders subject matter by arguments made to an examiner." *Id.* (quoting *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1344 (Fed. Cir. 2005)).

b. Induced Infringement

With respect to induced infringement, section 271(b) of the Patent Act provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "To prevail on a claim of induced infringement, in addition to inducement by the defendant, the patentee must also show that the asserted patent was directly infringed." *Epcon Gas Sys. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002). Further, "[s]ection 271(b) covers active inducement of infringement,

[16] "The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by *Graver Tank* as bearing upon whether the accused device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge." *Warner-Jenkinson*, 520 U.S. at 36.

which typically includes acts that intentionally cause, urge, encourage, or aid another to directly infringe a patent." *Arris Group v. British Telecomms. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011). The Supreme Court recently held that "induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, -- U.S. --, 131 S. Ct. 2060, 2068 (2011). The Court further held: "[g]iven the long history of willful blindness[ ] and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b)." 131 S. Ct. at 2060 (footnote omitted).

c. Contributory Infringement

As for contributory infringement, section 271(c) of the Patent Act provides: "Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c).

Section 271(c) "covers both contributory infringement of system claims and method claims." *Arris*, 639 F.3d at 1376 (footnotes omitted). To hold a component supplier liable for contributory infringement, a patent holder must show, *inter alia*, that (a) the supplier's product was used to commit acts of direct infringement; (b) the

product's use constituted a material part of the invention; (c) the supplier knew its product was especially made or especially adapted for use in an infringement" of the patent; and (d) the product is not a staple article or commodity of commerce suitable for substantial noninfringing use. *Id.*

2. Claim 1

Under the claim constructions adopted above, the record evidence demonstrates that the accused 4.3 mm and 5.0 mm Drive CM products meet each limitation of, and thus infringe, claim 1 of the '977 patent. JX-0312C (4.3 mm Drawing); JX-0313C (5.0 mm Drawing); CX-1030C (Hurson WS) at Q77-88, Q94-95; CPX-0006 (4.3 mm Drive CM, Model No. 109.627). In particular, Nobel's expert testified that the accused 4.3 mm and 5.0 mm Drive CM products satisfy all of the limitations of claim 1 (including the disputed limitation "the coronal region having a frustoconical shape") under the adopted constructions. CX-1030C (Hurson WS) at Q94-95. Moreover, Instradent does not contest that the accused products satisfy all limitations of claim 1 under the adopted claim constructions. *See* Resps. Br. at 32-57. Indeed, Instradent conceded that certain limitations of claim 1 are present in the accused 4.3 mm and 5.0 mm Drive CM products, and its expert testified that the accused 4.3 mm and 5.0 mm Drive CM products have a coronal taper. CX-0436C (Neodent Responses to RFAs) at Nos. 2-20; RX-0003C (Bernardes WS) at Q19-35.

Accordingly, it is determined that the accused products infringe claim 1 of the '997 patent under the adopted claim constructions.

a. Alternate Analysis Under Nobel's Proposed Claim Construction[17]

As set forth above, the unrebutted record evidence demonstrates that the accused products infringe claim 1 of the '977 patent under the adopted claim constructions. The evidence does not, however, support a finding that the accused products infringe claim 1 under the alternate construction of the term "the coronal region having a frustoconical shape" as proposed by Nobel, *i.e.*, "the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion."

As an initial matter, Nobel offers the following chart summarizing unrebutted evidence showing that the accused products satisfy certain limitations of claim 1 under its proposed construction of "the coronal region having a frustoconical shape":

Claim	Limitation	Evidence
Claim 1	A dental implant comprising:	JX-0551C (catalog) at 10 ("implant with a conical central core").
	a body; a coronal region of the body,	CX-0436 at RFA Nos. 2–3
	the coronal region having a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region;	No admission of infringement under Nobel's proposed construction.
	an apical region of the body, the apical region having a core with a tapered region wherein a diameter of an apical end of the core is smaller than a diameter of a coronal end of the core and the apical end of the core is substantially flat; and	CX-0436 at RFA Nos. 5-8

[17] This section summarizes the infringement analysis under Nobel's proposed construction for the sake of completeness.

Claim	Limitation	Evidence
	a pair of helical threads extending from the body along at least a portion of the apical region,	CX-0436 at RFA No. 9
	each of the threads comprising an apical side, a coronal side, and a lateral edge connecting the apical side and the coronal side, a base connecting the threads to the core, a thread height defined between the lateral edge and the base	CX-0436 at RFA Nos. 10–14
	the lateral edge having a variable width that is expanded along a segment in the direction of the coronal end of the apical region, so that a least width of the lateral edge of the threads is adjacent the apical end of the apical region and a greatest width of the lateral edge of the threads is adjacent the coronal end of the apical region	CX-0436 at RFA No. 15
	and the threads having a variable height that is expanded substantially along the segment of the implant in the direction of the apical end of the apical region, so that a least height of the threads is adjacent the coronal end of the apical region and a greatest height at apical end of the apical region	CX-0436 at RFA No. 16
	a bone tap, wherein the helical threads starts at said bone tap and said substantially flat apical end of the core	CX-0436 at RFA Nos. 17–19
	wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is between 1.5 – 2.5 mm	CX-0436 at RFA No. 20

See Compls. Br. at 42-43.

As shown by the chart, the primary dispute between the parties with respect to infringement is whether or not the accused products satisfy the claim limitation "the coronal region having a frustoconical shape" under Nobel's proposed construction. *See* Compls. Br. at 46-65; Resps. Br. at 32-57; Staff Br. at 42-43.

In support of its infringement argument, Nobel presented testimony from its expert, Dr. Sullivan, who testified that he personally observed bone relapse over the coronal regions of various 5.0 mm Drive CM implants during five implant surgeries performed on March 6, 2015. CX-1036C (Sullivan WS) at Q43-45, Q70-123. Nobel also offered the testimony of Mr. Hurson, who testified that he was "confident that the coronal taper on the Drive CM permits compressed bone to relapse" given the "size and location of the Drive CM's coronal taper, which is similar to and appears based on the coronal taper on the NobelActive implant." CX-1030C (Hurson WS) at Q88. Mr. Hurson, who also relied on Dr. Sullivan's opinions and data, concluded that "bone relapsed around the coronal taper of the 5.0 mm Drive CM implants that were inserted into soft bone, i.e., Type III or Type IV bone" during the surgeries that Dr. Sullivan observed. CX-1030C (Hurson WS) at Q52-53, Q89-93; Hurson Tr. 171-173.

Nevertheless, the record evidence shows that Mr. Hurson did not perform any testing for purposes of this investigation, has never measured bone relapse, and does not know if anybody has ever measured bone relapse. Hurson Tr. 175, 303. Instradent's expert, Dr. Sergio Bernardes, testified that he reviewed the materials provided by Dr. Sullivan and found them inconclusive as to whether or not bone relapse occurred as required by Nobel's proposed construction of claim 1. RX-0013C (Bernardes RWS) at

Q79. He also testified that Nobel did not demonstrate through published literature that its claims regarding "bone relapse" and "coronal tapers" were substantiated. RX-0013C (Bernardes RWS) at Q83.

Therefore, under Nobel's proposed construction of "the coronal region having a frustoconical shape," *i.e.*, "the coronal region as a whole has a frustoconical shape that permits bone to relapse upon implant insertion", the evidence does not support a finding that the accused 4.3 mm and 5.0 mm Drive CM products satisfy the "coronal region having a frustoconical shape" limitation of claim 1.

3. Claim 2

Claim 2 depends from claim 1 and adds the additional claim limitation "wherein the coronal region has a surface configured to be in contact with the bone." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* JX-0551 (catalog) at 4 ("the uniform roughness results in a surface topography optimized for osseointegration"), 10. Instradent does not dispute that this claim limitation is satisfied. *See* Resps. Br. at 32-57.

Accordingly, it is determined that the accused products infringe claim 2 of the '977 patent.

4. Claim 3

Claim 3 depends from claim 1 and adds the additional limitation "wherein the apical end of the coronal region defines an upper limit of the threads." The record evidence demonstrates that the accused products satisfy this additional claim limitation.

See CX-0436 (Instradent Resp. to RFAs) at RFA No. 21. Instradent does not dispute that this claim limitation is satisfied. *See* Resps. Br. at 32-57.

Accordingly, it is determined that the accused products infringe claim 3 of the '977 patent.

5. Claim 4

Claim 4 depends from claim 1 and adds the additional limitation "wherein the threads adjacent the apical end of the body are self-tapering." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* CX-0436 (Instradent Resp. to RFAs) at RFA No. 22. Instradent does not dispute that this claim limitation is satisfied. *See* Resps. Br. at 32-57.

Accordingly, it is determined that the accused products infringe claim 4 of the '977 patent.

6. Claim 5

Claim 5 depends from claim 1 and adds the additional limitation "wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* CX-0436 (Instradent Resp. to RFAs) at RFA Nos. 23-24. Instradent does not dispute that this claim limitation is satisfied. *See* Resps. Br. at 32-57.

Accordingly, it is determined that the accused products infringe claim 5 of the '977 patent.

7. Claim 9[18]

The record evidence demonstrates that the accused products satisfy all limitations of claim 9 under the claim constructions adopted above. For example, Nobel offers the following chart summarizing the relevant evidence with respect to claim 9:

Claim	Limitation	Evidence
Claim 9	a body; a coronal end of the body; and an apical end of the body;	CX-0436 at RFA Nos. 2–3, 25-26
	the apical end having a tapered core,	CX-0436 at RFA No. 27
	the apical end includes at least one region having two tapered variable profile helical threads extending along the core,	CX-0436 at RFA No. 28
	each thread having an apical side, a coronal side, a lateral edge connecting the apical side and the coronal side, a base touching the core, a height defined between the lateral edge and the base,	CX-0436 at RFA Nos. 29–31, 33
	a variable length of the lateral edge being progressively expanded substantially along the region of the apical end in the direction of the coronal end, so that a least length of the lateral edge of the thread is adjacent the apical end and a greatest length of the lateral edge of the thread is adjacent the coronal end,	CX-0436 at RFA No. 34
	and a variable height being progressively expanded substantially along the entire threaded region of the implant in the direction of the apical end, so that a least height of the thread is adjacent the coronal end and a greatest width of the thread is adjacent the apical end	CX-0436 at RFA No. 35
	wherein the core is more tapered than the threads and	CX-0436 at RFA No. 36

[18] Although independent claim 9 is not asserted in this investigation, asserted dependent claim 19 depends from claim 9.

Claim	Limitation	Evidence
	wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5–2.5 mm.	CX-0436 at RFA No. 20

See Compls. Br. at 43-44.

Instradent does not dispute that the accused products satisfy these limitations under the adopted claim constructions. *See* Resps. Br. at 32-57.

Accordingly, it is determined that the accused products satisfy all limitations of claim 9 of the '977 patent.

8. Claim 19

Claim 19 depends from claim 9 and adds the additional limitation "wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge." The record evidence demonstrates that the accused products satisfy this additional claim limitation under the claim constructions adopted above. JX-0312C (4.3 mm Drawing); JX-0313C (5.0 mm Drawing); CX-1030C (Hurson WS) at Q77-88, Q94-95; CPX-0006 (4.3 mm Drive CM, Model No. 109.627).

Specifically, Nobel's expert testified that the accused 4.3 mm and 5.0 mm Drive CM products satisfy all of the limitations of claim 19 under the adopted construction of "tapered coronally." CX-1030C (Hurson WS) at Q94-95. Moreover, Instradent conceded that certain limitations of claim 19 are satisfied by the accused 4.3 mm and 5.0 mm Drive CM products. CX-0436C (Instradent Resp. to RFAs) at Nos. 2, 3, 20, 25-31,

33-36. In addition, Instradent's expert testified that the accused 4.3 mm and 5.0 mm Drive CM products have a coronal taper. RX-0003C (Bernardes WS) at Q19-35.

Accordingly, it is determined that the accused products infringe claim 19 of the '977 patent under the adopted claim constructions.[19]

D. Technical Prong of the Domestic Industry Requirement

1. General Principles of Law[20]

A violation of section 337(a)(1)(B), (C), (D), or (E) can be found "only if an industry in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Section 337(a) further provides:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

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[19] For the reasons set forth above with respect to claim 1, the record evidence does not support a finding that the accused products infringe claim 19 under Nobel's proposed construction of the term "a most coronal aspect of the coronal end is tapered coronally," *i.e.*, "the most coronal end tapers in the coronal direction and permits bone to relapse upon implant insertion."

[20] The legal principles set forth in this section apply equally to the analysis of the '443 patent.

These statutory requirements consist of an economic prong (which requires certain activities)[21] and a technical prong (which requires that these activities relate to the intellectual property being protected). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 13 (May 16, 2008) ("*Stringed Musical Instruments*"). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011) ("*Navigation Devices*").

"With respect to section 337(a)(3)(A) and (B), the technical prong is the requirement that the investments in plant or equipment and employment in labor or capital are actually related to 'articles protected by' the intellectual property right which forms the basis of the complaint." *Stringed Musical Instruments* at 13-14. "The test for satisfying the 'technical prong' of the industry requirement is essentially same as that for

[21] The Commission practice is usually to assess the facts relating to the economic prong at the time that the complaint was filed. *See Certain Coaxial Cable Connectors and Components Thereof and Products Containing Same*, Inv. No. 337-TA-560, Comm'n Op. at 39 n.17 (Apr. 14, 2010) ("We note that only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3).") (citing *Bally/Midway Mfg. Co. v. U.S. Int'l Trade Comm'n*, 714 F.2d 1117, 1121 (Fed. Cir. 1983)). In some cases, however, the Commission will consider later developments in the alleged industry, such as "when a significant and unusual development occurred after the complaint has been filed." *See Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., at 5-6 (Jan. 20, 2012) ("[I]n appropriate situations based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the complaint.").

infringement, i.e., a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). "With respect to section 337(a)(3)(C), the technical prong is the requirement that the activities of engineering, research and development, and licensing are actually related to the asserted intellectual property right." *Stringed Musical Instruments* at 13.

2. Claim 1

The record evidence demonstrates that the domestic industry products satisfy the limitations of claim 1 of the asserted '977 patent under the claim constructions adopted above.

Inasmuch as the NobelActive® implants are dental implants, they practice the preamble of claim 1. The '977 patent domestic industry products also have a body and a coronal region of the body. CX-1030C (Hurson WS) at Q44, Q45-51 (discussing claim charts marked as CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C showing "the location of the '977 asserted patent claim features on the [NobelActive]"). Engineering drawings of the '977 patent domestic industry products and a physical sample of the NobelActive® 4.3 mm implant further show that the dental implants have a body and a coronal region of the body. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive); CPX-0003 (oversized model).

Nobel also presented evidence showing that the coronal region of the '977 patent domestic industry products have a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region. Nobel's expert Mr. Hurson testified that, based on Nobel's construction, the '977 patent

domestic industry products have a frustoconical shape wherein a diameter of an apical end of the coronal region is larger than a diameter of a coronal end of the coronal region. CX-1030C (Hurson WS) at Q44 ("all the limitations of the asserted claims of the '977 patent are embodied in the 4.3 mm and 5.0 mm NobelActive implants"), Q45-51 (discussing claim charts, marked as CDX-0504C through CDX-0525C and CDX-0526C though CDX-0547C showing "the location of the '977 asserted patent claim features on the ['977 patent domestic industry products]").

As discussed above, the claim term "the coronal region having a frustoconical shape" is construed to mean "the coronal region has, partly or entirely, a frustoconical shape." Nobel's expert Mr. Hurson testified that the '977 patent domestic industry products meet this limitation under this construction. CX-1030C at Q57-58 ("even under Neodent's proposed claim constructions . . . , my opinion is still that the limitations of the asserted claims of the '977 patent are embodied in the 4.3 mm and 5.0 mm NobelActive implants").

Nobel also presented evidence showing that the '977 patent domestic industry products practice the remaining elements of claim 1. Specifically, Mr. Hurson testified that these limitations are literally present in the '977 patent domestic industry products. CX-1030C at Q44, Q45-51 (discussing claim charts CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C). Engineering drawings of the '977 patent domestic industry products and a physical sample of the 4.3 mm NobelActive® dental implant also show that these limitations are literally present. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive®); CPX-0003 (oversized model).

Accordingly, it is determined that the domestic industry products practice claim 1 of the '977 patent under the claim constructions adopted above.

3. Claim 2

Claim 2 depends from claim 1 and adds the additional claim limitation "wherein the coronal region has a surface configured to be in contact with the bone." The record evidence demonstrates that the domestic industry products practice this additional claim limitation.

Specifically, Nobel's witness Mr. Hurson testified that this limitation is literally present in the '977 patent domestic industry products. CX-1030C (Hurson WS) at Q44, Q45-51 (discussing claim charts CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C). Engineering drawings of the '977 patent domestic industry products and a physical sample of the 4.3 mm NobelActive® dental implant also show that this limitation is literally present. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive®); CPX-0003 (model).

Instradent does not dispute that the domestic industry products practice this additional limitation. *See* Resps. Br. at 58-60.

Accordingly, it is determined that the domestic industry products practice claim 2 of the '977 patent.

4. Claim 3

Claim 3 depends from claim 1 and adds the additional limitation "wherein the apical end of the coronal region defines an upper limit of the threads." The record

evidence demonstrates that the domestic industry products satisfy this additional claim limitation.

Nobel offered the testimony of its expert Mr. Hurson to show that this limitation is literally present in the '977 patent domestic industry products. CX-1030C (Hurson WS) at Q44, Q45-51 (discussing claim charts CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C). Engineering drawings of the '977 patent domestic industry products and a physical sample of the 4.3 mm NobelActive® dental implant also show that this limitation is literally present in the domestic industry products. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive®); CPX-0003 (model).

Instradent does not dispute that the domestic industry products practice this additional limitation. *See* Resps. Br. at 58-60.

Accordingly, it is determined that the domestic industry products practice claim 3 of the '977 patent under the claim constructions adopted above.

5. Claim 4

Claim 4 depends from claim 1 and adds the additional limitation "wherein the threads adjacent the apical end of the body are self-tapering." The record evidence demonstrates that the domestic industry products satisfy this additional claim limitation.

Nobel's expert Mr. Hurson testified that this limitation is literally present in the '977 patent domestic industry products. CX-1030C (Hurson WS) at Q44, Q45-51 (discussing claim charts CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C). Engineering drawings of the '977 patent domestic industry products and a physical sample of the 4.3 mm NobelActive® dental implant also show that this

limitation is literally present. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive®); CPX-0003 (model).

Instradent does not dispute that the domestic industry products practice this additional limitation. *See* Resps. Br. at 58-60.

Accordingly, it is determined that the domestic industry products practice claim 4 of the '977 patent under the claim constructions adopted above.

6. Claim 5

Claim 5 depends from claim 1 and adds the additional limitation "wherein the apical end includes a spiral tap, the spiral tap extends from one side of the implant to the opposite side along more than a third of the length of the implant." The record evidence demonstrates that the domestic industry products satisfy this additional claim limitation.

Nobel offered the testimony of its expert Mr. Hurson to show that this limitation is literally present in the '977 patent domestic industry products. CX-1030C (Hurson WS) at Q44, Q45-51 (discussing claim charts CDX-0504C through CDX-0525C and CDX-0526C through CDX-0547C). Engineering drawings of the '977 patent domestic industry products and a physical sample of the 4.3 mm NobelActive® dental implant also show that this limitation is literally present. CX-0569C at 2, 3; CPX-0005 (4.3 mm NobelActive®); CPX-0003 (oversized model).

Instradent does not dispute that the domestic industry products practice this additional limitation. *See* Resps. Br. at 58-60.

Accordingly, it is determined that the domestic industry products practice claim 5 of the '977 patent under the claim constructions adopted above.

7. Claim 9

The unrebutted record evidence demonstrates that the domestic industry products practice all limitations of claim 9 of the '977 patent under the claim constructions adopted above. For example, Nobel provides the following chart that summarizes the relevant evidence with respect to claim 9:

Claim	Limitation	Supporting Evidence
Claim 9	a body; a coronal end of the body; and an apical end of the body;	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0517C; CDX-0539C
	the apical end having a tapered core,	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0518C;CDX-0540C
	the apical end includes at least one region having two tapered variable profile helical threads extending along the core,	JX-0339 at 4 (limitation is present under any proposed construction); CX-0569C at 2, 3; CX-1030C at Q44–51, 57 (limitation is present under either proposed construction); CPX-0003; CPX-0005; CDX-0519C; CDX-0541C
	each thread having an apical side, a coronal side, a lateral edge connecting the apical side and the coronal side, a base touching the core, a height defined between the lateral edge and the base,	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0520C;CDX-0542C
	a variable length of the lateral edge being progressively expanded substantially along the region of the apical end in the direction of the coronal end, so that a least length of the lateral edge of the thread is adjacent the apical end and a greatest length of the lateral edge of the thread is adjacent the coronal end,	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0521C;CDX-0543C

Claim	Limitation	Supporting Evidence
	and a variable height being progressively expanded substantially along the entire threaded region of the implant in the direction of the apical end, so that a least height of the thread is adjacent the coronal end and a greatest width of the thread is adjacent the apical end	JX-0339 at 4 (Respondents contend that the term "greatest width of the thread" is indefinite, but have not alleged that this limitation is missing from the '977 patent domestic industry products); CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0522C; CDX-0544C
	wherein the core is more tapered than the threads and	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0523C;CDX-0545C
	wherein each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by a complete rotation of the dental implant, the thread step is 1.5–2.5 mm.	CX-0569C at 2, 3; CX-1030C at Q44–51; CPX-0003; CPX-0005; CDX-0524C;CDX-0546C

See Compls. Br. at 71-72.

Instradent does not dispute that the domestic industry products practice claim 9 under the adopted claim constructions. *See* Resps. Br. at 58-60.

Accordingly, it is determined that the domestic industry products practice claim 9 of the '977 patent under the claim constructions adopted above.

8. Claim 19

Claim 19 depends from claim 9 and adds the additional limitation "wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge." The record evidence shows that the domestic industry products satisfy the limitations of claim 19 under the claim constructions adopted above.

For example, Nobel provides the following chart summarizing the evidence with respect to claim 19:

Claim	Limitation	Supporting Evidence
Claim 19	A dental implant according to Claim 9, wherein a most coronal aspect of the coronal end is tapered coronally forming narrower coronal edge.	JX-0339 at 4 (limitation is present under any proposed construction); CX-0569C at 2, 3; CX-0660 at Figure 3; CX-1030C at Q44–57 (limitation is present under either proposed construction); CX-1036C at Q63; CPX-0003; CPX-0005; CDX-0525C; CDX-0547C

See Compls. Br. at 73.

Accordingly, it is determined that the domestic industry products practice claim 19 of the '977 patent under the claim constructions adopted above.

E. Validity

1. General Principles of Law[22]

One cannot be held liable for practicing an invalid patent claim. *See Pandrol USA, LP v. AirBoss Railway Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003). Nevertheless, each claim of a patent is presumed to be valid, even if it depends from a claim found to be invalid. 35 U.S.C. § 282; *DMI Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986).

A respondent that has raised patent invalidity as an affirmative defense must overcome the presumption of patent validity by "clear and convincing" evidence of

[22] The legal principles set forth in this section apply equally to the validity analysis of the '443 patent.

invalidity. *Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

a. Anticipation

Anticipation under 35 U.S.C. § 102 is a question of fact. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1347 (Fed. Cir. 2007). Section 102 provides that, depending on the circumstances, a claimed invention may be anticipated by variety of prior art, including publications, earlier-sold products, and patents. *See* 35 U.S.C. § 102 (*e.g.*, section 102(b) provides that one is not entitled to a patent if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States").

The general law of anticipation may be summarized, as follows:

> A reference is anticipatory under § 102(b) when it satisfies particular requirements. First, the reference must disclose each and every element of the claimed invention, whether it does so explicitly or inherently. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed.Cir.2006). While those elements must be "arranged or combined in the same way as in the claim," *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed.Cir.2008), the reference need not satisfy an *ipsissimis verbis* test, *In re Bond*, 910 F.2d 831, 832-33 (Fed.Cir.1990). Second, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir.2008); *see In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940-44 (1962). As long as the reference discloses all of the claim limitations and enables the "subject matter that falls within the scope of the claims at issue," the reference anticipates -- no "actual creation or reduction to practice" is required. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380-81 (Fed.Cir.2003); *see In re Donohue*, 766 F.2d 531, 533 (Fed.Cir.1985). This is so despite the

> fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed.Cir.1991) (discussing the "distinction between a written description adequate to support a claim under § 112 and a written description sufficient to anticipate its subject matter under § 102(b)").

In re Gleave, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

b. Obviousness

Under section 103 of the Patent Act, a patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[23] 35 U.S.C. § 103. While the ultimate determination of whether an invention would have been obvious is a legal conclusion, it is based on "underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010).

The objective evidence, also known as "secondary considerations," includes commercial success, long felt need, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 13-17 (1966); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). "[E]vidence arising out of the so-called 'secondary

[23] The standard for determining whether a patent or publication is prior art under section 103 is the same as under 35 U.S.C. § 102, which is a legal question. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Secondary considerations, such as commercial success, will not always dislodge a determination of obviousness based on analysis of the prior art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (commercial success did not alter conclusion of obviousness).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.*

Specific teachings, suggestions, or motivations to combine prior art may provide helpful insights into the state of the art at the time of the alleged invention. *Id.* at 420. Nevertheless, "an obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way." *Id.* "Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* A "person of ordinary skill is also a person of ordinary creativity." *Id.* at 421.

Nevertheless, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *see KSR*, 550 U.S. at 416 (a combination of elements must do more than yield a predictable result; combining elements that work together in an unexpected and fruitful manner would not have been obvious).[24]

c. Indefiniteness

The definiteness requirement of 35 U.S.C. § 112 ensures that the patent claims particularly point out and distinctly claim the subject matter that the patentee regards to be the invention. *See* 35 U.S.C. § 112, ¶ 2; *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004). If a claim's legal scope is not clear enough so that a person of ordinary skill in the art could determine whether or not a particular product infringes, the claim is indefinite, and is, therefore, invalid. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003).[25]

Thus, it has been found that:

> When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances

[24] Further, "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

[25] Indefiniteness is a question of law. *IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109 (Fed. Cir. 2011).

> in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite.

Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

The Supreme Court recently addressed the issue of indefiniteness, and stated that a finding of indefiniteness should not be found if the claims, "viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus*, 134 S. Ct. at 2129.

d. Lack of a Written Description

The issue of whether a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1188 (Fed. Cir. 2012). A patent's written description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. The test for sufficiency of a written description is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*)).

e. Lack of Enablement

A patent's specification must "enable a person of ordinary skill in the art to make and use the invention." 35 U.S.C. § 112 ¶ 1 (2006). This requirement is met when, at the time of filing the application, one skilled in the art, having read the specification, could

practice the invention without "undue experimentation." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Enablement is a question of law. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984); *Streck, Inc. v. Research & Diagnostic Sys.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012).

When determining whether or not the amount of experimentation required to make and use the claimed invention is undue, courts consider the *Wands* factors: the quantity of experimentation necessary, the amount of direction or guidance presented in the specification, the presence of working samples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).

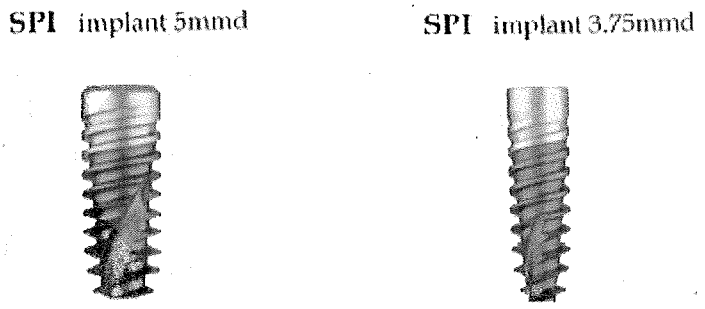
2. Anticipation

Instradent argues that all asserted claims of the '977 patent are invalid as anticipated by the March 2003 Product Catalog of Alpha Bio Tec, Ltd. ("2003 Alpha Bio Tec Catalog") (RX-0658). *See* Resps. Br. at 76-93. The record evidence shows, clearly and convincingly, that the catalog discloses to one of ordinary skill in the art all of the limitations of asserted claims 1-5 and 19 of the '977 patent. Therefore, the 2003 Alpha Bio Tec Catalog renders these claims invalid under Section 102.

a. The 2003 Alpha Bio Tec Catalog Is Prior Art Under 35 U.S.C. § 102

As an initial matter, the evidence shows that the catalog qualifies as prior art under Section 102. The 2003 Alpha Bio Tec Catalog was "publicly accessible" more than one year before the effective filing date, *i.e.*, May 23, 2004, of the '977 patent. *SRI Int'l, Inc.*, 511 F.3d at 1194 ("A given reference is 'publicly accessible' upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it."). The 2003 Alpha Bio Tec Catalog, entitled "Product Catalog March 2003," includes a 2003 copyright designation. RX-0658 (2003 Alpha Bio Tec Catalog) at 1, 57.

The catalog depicts and describes the SPI Implant as a "tapered implant with large variable thread design double thread 2x2.1 mm." *Id.* at 17 (INSTRA0001656). The 5.0 mm and 3.75 mm versions are reproduced below.



Id. at 16 (INSTRA0001655).

In an e-mail dated November 4, 2007 that attached three publications, including the 2003 Alpha Bio Tec Catalog, Mr. Ben-Zion Karmon indicated that the attached

publications "[ ]."

JX-0281C (Karmon 2007 e-mail) at 1; *see also* JX-0225C (Karmon 2009 e-mail) at 2-3.

Moreover, in Issue 63 of the Israeli Dental Update dated January – February 2003, the SPI Implant was advertised:

RX-0088 (Melcer Letter) at 9-10 (NBNEO0148997–98), translations at 23-24.

A copy of the advertisement is also stamped (as translated) "Received 6 03 2003," *i.e.*, March 6, 2003. *Id.* at 12 (NBNEO0149000), translation at 26.

The record evidence also shows that Alpha Bio Tec began selling the SPI Implants in 2003. CX-1028C (Fromovich WS) at Q5 ("Alpha-Bio developed a commercial version of the implant – the Alpha-Bio SPI dental implant – that we sold primarily in Israel beginning in 2003."). As part of its doctor training program, Alpha Bio Tec distributed the catalog to doctors. Fromovich Tr. 371-372 ("[ ]"), 409.

Nevertheless, Nobel argues that the record evidence fails to suggest that the catalog was ever "widely distributed," and that the catalog is therefore not prior art to the '977 patent. *See* Compls. Br. at 74-81. The case law does not set forth a "widely distributed" standard for qualifying prior art, however, but rather a "publicly accessible" standard. "A given reference is 'publicly accessible' upon a satisfactory showing that

such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *SRI Int'l*, 511 F.3d at 1194. Moreover, "there are many ways in which a reference may be disseminated to the interested public . . . ." *Id.* The evidence adduced during the hearing demonstrates that Alpha Bio Tec gave copies of the sales catalog to interested doctors who attended courses taught by Dr. Fromovich. Fromovich Tr. at 353-354, 371-372, 372-373, 409. Further, the record evidence does not suggest that the doctors were restricted from copying the catalog or from disseminating the catalogs to others.

Accordingly, in view of this evidence, it is determined that the 2003 Alpha Bio Tec Catalog was sufficiently accessible to interested doctors and other members of the public before the '977 patent's critical date of May 23, 2003, and therefore qualifies as prior art under Section 102.

b. Anticipation of the Asserted Claims

Under the claim constructions adopted above, it is determined that the SPI implant depicted and described in the 2003 Alpha Bio Tec Catalog discloses to one of ordinary skill in the art all limitations of asserted claims 1-5 and 19 of the '977 patent.

Nobel's expert Mr. Hurson testified that the SPI Implant in the 2003 Alpha Bio Tec Catalog discloses all the limitations of non-asserted claim 9, which is similar to claim 1 but does not include the frustoconical coronal region limitation. Hurson Tr. 180-181. Mr. Hurson also testified that the "bevel" at the coronal end of the 5.0 mm SPI implant has a frustoconical shape. Hurson Tr. 291. Therefore, the record evidence demonstrates

that the 5.0 mmm SPI Implant shown in the 2003 Alpha Bio Tec Catalog anticipates claim 1 and claim 19 of the '977 patent.

As for claim 2, the parties agreed that the claim term "surface configured to be in contact with bone" should be construed to mean that the surface is "designed or constructed to enhance osseointegration." The 2003 Alpha Bio Tec Catalog discloses that the SPI Implant's surface is designed to enhance bone healing: "Implant surface: 'Hybrid' design 2/3 apically S.L.A (macro) 20-40μ + (micro) 2μ, 1/3 coronary Acid Etched 5-10μ. Increases clot retention and is conducive to bone healing." RX-0658 (2003 Alpha Bio Tec Catalog) at 16 (INSTRA0001655). The evidence also shows that such frustoconical regions as are disclosed on the 5.00 mm SPI Implant were designed not only to contact abutments, but to also contact bone. RX-0658 (2003 Alpha Bio Tec Catalog) at 31 (INSTRA0001669); Hurson Tr. 211-216. Therefore, the record evidence demonstrates that the 5.0 mmm SPI Implant shown in the 2003 Alpha Bio Tec Catalog anticipates claim 2 of the '977 patent.

As for claim 3, the 5.0 mm SPI Implant includes a coronal region (as defined in the '977 patent specification) having an apical end that defines the upper limit of the threads. RX-0658 (2003 Alpha Bio Tec Catalog) at 16 (INSTRA0001655). Therefore, the record evidence demonstrates that the 5.0 mmm SPI Implant shown in the 2003 Alpha Bio Tec Catalog anticipates claim 3 of the '977 patent.

As for claims 4 and 5, the 5.00 mm SPI Implant includes a spiral tap that is self-tapping and "extends from one side of the implant to the opposite side along more than a third of the length of the implant." RX-0658 (2003 Alpha Bio Tec Catalog) at 16

(INSTRA0001655); *id.* at 17 (INSTRA0001656) ("super self tapping features" and "Spiral tap condense bone for improved stabilization"). Therefore, the record evidence demonstrates that the 5.0 mmm SPI Implant shown in the 2003 Alpha Bio Tec Catalog anticipates claims 4 and 5 of the '977 patent.

Given Mr. Hurson's testimony and the relevant documentary evidence, the 5.0 mm SPI Implant depicted and described in the 2003 Alpha Bio Tec Catalog discloses to one of ordinary skill in the art every limitation of claims 1-5 and 19 of the '977 patent. "Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference." *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002). Nevertheless, the features of the claimed invention disclosed in the 2003 Alpha Bio Tec Catalog are easily understandable. *See Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1374 (Fed. Cir. 2012) ("It is well-established, moreover, that, where the technology involved is easily understandable, expert testimony is not required."); *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369 (Fed. Cir. 2004) (citation omitted) ("In many patent cases expert testimony will not be necessary because the technology will be 'easily understandable without the need for expert explanatory testimony.'").

Therefore, it is determined that Instradent has shown, by clear and convincing evidence, that the asserted claims of the '977 patent are invalid as anticipated under 35 U.S.C. § 102.

3. Obviousness

Instradent argues that all asserted claims of the '977 patent are invalid as obvious over certain combinations of prior art references. *See* Resps. Br. at 93-96. Specifically, Instradent alleges that the asserted claims are obvious in view of U.S. Patent No. 5,810,589 ("Michnick")[26] (JX-0015), the Straumann Schraubenimplantat or Ledermann Implant[27] (RX-0598 and RX-0294), U.S. Patent No. 4,738,623 ("Driskell")[28] (JX-0009), and the 5 mm Octagon Implant shown in the 2002 Anthogyr Catalog[29] (RX-0144). *Id.*

Instradent argues that Michnick teaches "an implant having a frustoconical shaped coronal region," as illustrated in Figure 1 reproduced below:

[26] Michnick issued on September 22, 1998, and therefore qualifies as prior art to the '977 patent. *See* JX-0015 (Michnick).

[27] Instradent has not explained how the Ledermann Implant qualifies as prior art to the '977 patent. *See* Resps. Br. at 93-96; Resps. Reply Br. at 34-36.

[28] Driskell issued on April 19, 1988, and therefore qualifies as prior art to the '977 patent. *See* JX-0009 (Driskell).

[29] The Anthogyr Catalog was published by Anthogyr SAS in 2002 and qualifies as prior art to the '977 patent. *See* RX-0144 (Anthogyr Catalog).

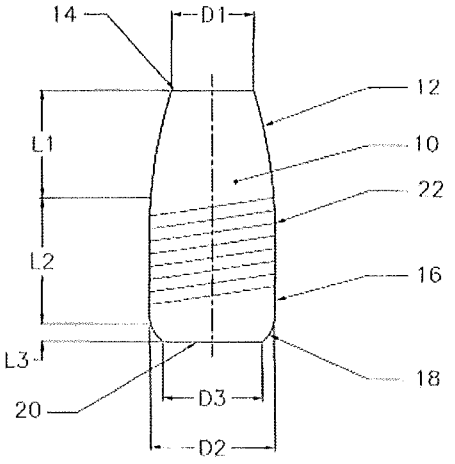
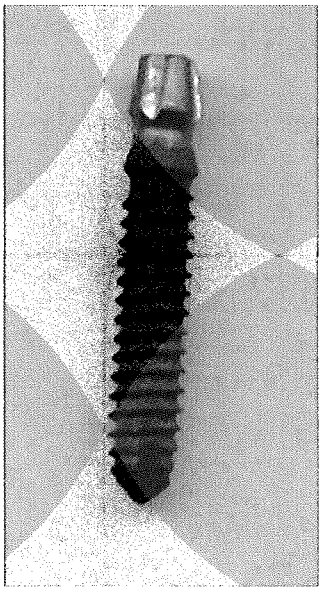


FIGURE 1

See Resps. Br. at 93-94; JX-0015 (Michnick) at Fig. 1.

Instradent offers the Ledermann Implant as "[a]nother example of an implant having a frustoconical shaped coronal region." According to an article cited by Instradent, the Ledermann Implant "is inserted into the jawbone such that the frustoconical shape coronal region is 'countersunk 2 mm below the outer level of bone.'" *See* Resps. Br. at 94-95 (citing RX-0294 (Ledermann article) at Fig. 15). A photo of the Ledermann Implant is reproduced below:



RX-0598 (Ledermann photo).

Instradent further argues:

> Other prior art implants having frustoconical shaped coronal regions include: U.S. Patent No. 4,738,623 ("Driskell") (JX-0009), at Fig. 1, reference numeral 26; and the 5 mm Octagon Implant shown in the 2002 Anthogyr Catalog (RX-0144), at p. 16 (INSTRA0001609). The 2002 Anthogyr Catalog, published by Anthogyr SAS, discloses a number of dental implants, including a 5 mm implant shown at page 16. RX-0144 at p. 16. That 5 mm implant includes a spiral thread, a flat apical end, and axially extending flutes that form a bone tap. *Id.* The 5 mm implant also includes a frustoconical coronal region having an inverse taper, such that a coronal end of the coronal region has a narrower diameter than an apical end of the coronal region. *Id.*

Resps. Br. at 95.

Nevertheless, the record evidence fails to show, clearly and convincingly, that the asserted claims of the '997 patent are invalid under 35 U.S.C. § 103. In particular, Instradent failed to adduce evidence showing why one of ordinary skill in the art would have been motivated to combine the prior art references to achieve the claimed invention.

Specifically, Instradent presented no expert testimony to show that a specific combination of prior art references would have embodied all the limitations of the asserted claims and would have been obvious to one of ordinary skill in the art. *See, e.g.*, *Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1348 (Fed. Cir. 2013) (finding claims not invalid because "[e]xpert testimony was required not only to explain what the prior-art references disclosed, but also to show that a person skilled in the art would have been motivated to combine them in order to achieve the claimed invention," and defendant provided no such expert testimony).

The record evidence instead shows that one of ordinary skill in the art designing an implant would not have been motivated to experiment with frustoconical coronal regions to arrive at the invention claimed in the '977 patents, and that it would not have been obvious to try. In particular, Nobel's expert Mr. Hurson testified regarding a chapter from a book by Dr. Carl Misch, an authority in the field of implant dentistry. *See* Hurson Tr. 266-269; RX-0153 (Misch treatise). Referring to a graphic (reproduced below) showing three implants, one with a cylindrical coronal region, one with an outwardly tapering coronal region, and one with a inwardly tapering coronal region, Mr. Hurson testified that Dr. Misch taught that the coronal region of an implant should be outwardly tapered, which is the opposite of what the '977 patent teaches. *See* Hurson Tr. 266-269.

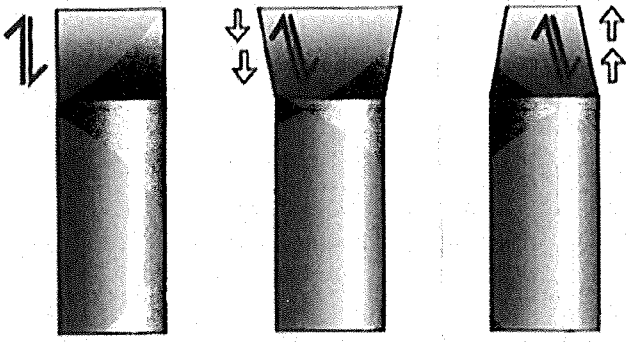


Fig. 23-11 Crest module design affords an opportunity to impose compression on crestal bone.

RX-0153 (Misch treatise) at 340.

Moreover, Nobel introduced compelling evidence of copying as it relates to secondary considerations of non-obviousness. CX-1037C (Hurson RWS) at Q51, Q61. In particular, the evidence supports a finding that JJGC copied the NobelActive® implant or a clone of the implant. [

]. RX-0002C (Golin WS) at Q15-16; Golin Tr. 690-692. [ ]. Golin Tr. 693, 701.

[

]. Golin Tr. 699-700, 701.

For these reasons, the evidence does not support a determination that asserted claims 1-5 and 19 of the '977 patent are obvious under Section 103 in view of the prior art of record.

4. Lack of a Written Description

Instradent argues that the asserted claims of the '977 patent invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 under Nobel's proposed constructions of the claim terms "the coronal region having a frustoconical shape" and "a most coronal aspect of the coronal end is tapered coronally." *See* Resps. Br. at 65-72.

Inasmuch as Nobel's proposed constructions have not been adopted in this initial determination, Instradent's written description arguments will not be addressed here.

5. Lack of Enablement

Instradent argues that the asserted claims of the '977 patent invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1 under Nobel's proposed constructions of the claim terms "the coronal region having a frustoconical shape" and "a most coronal aspect of the coronal end is tapered coronally." *See* Resps. Br. at 72-76.

Inasmuch as Nobel's proposed constructions have not been adopted in this initial determination, Instradent's enablement arguments will not be addressed here.

F. Inequitable Conduct

Instradent argues that Nobel's patent prosecution counsel, Mr. Rabi Narula, committed inequitable conduct during the prosecution of the '977 patent by withholding or misrepresenting known material prior art with the specific intent to deceive the Patent Office. *See* Resps. Br. at 107-30. As discussed below, Instradent has failed to adduce evidence to show, clearly and convincingly, that the actions of Mr. Narula constitute inequitable conduct.

1. General Principles of Law[30]

Every individual associated with the filing and prosecution of a patent application before the PTO has a duty to disclose to the patent examiner all information known to be material to patentability. 37 C.F.R. § 1.56(a). "If inequitable conduct occur[s] with respect to one or more claims of an application, the entire patent is unenforceable." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006).

A patent is unenforceable on the grounds of inequitable conduct if an applicant provides materially false information or withholds material information from the PTO with an intent to mislead or deceive. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (*en banc*) ("*Therasense*"). The Federal Circuit has emphasized that "materiality and intent are separate requirements, and intent to deceive cannot be found based on materiality alone." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 733 (Fed. Cir. 2010). Both materiality and intent to deceive must be proven by clear and convincing evidence. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

There is a lower threshold for establishing materiality than for proving that a patent is invalid. A reference may be material even if it does not render a patent invalid: "Information concealed from the PTO may be material even though it would not invalidate the patent." *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Products Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009) (quoting *Li Second Family Ltd. v. Toshiba Corp.*,

[30] The legal principles set forth in this section apply equally to the analysis of the '443 patent.

231 F.3d 1373, 1380 (Fed. Cir. 2000)); *see Therasense*, 649 F.3d at 1292. Materiality exists if the PTO "would not have allowed a claim had it been aware of the undisclosed prior art." *Therasense*, 649 F.3d at 1291. Information is material when it is not cumulative to information already on record and (1) establishes a prima facie case of unpatentability, alone or in combination with other information; or (2) is contrary to a position taken by applicant in (i) opposing an argument of unpatentability by the USPTO, or (ii) asserting an argument of patentability. 37 C.F.R. § 1.56(b).

To establish an intent to deceive, an accused infringer must show that the patentee acted with the specific intent to deceive the PTO:

> [N]egligence under a "should have known" standard does not satisfy this intent requirement. . . . "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference." . . . In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.

Therasense, 649 F.3d at 1290 (citations omitted).

"[T]he specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Id.* (citations omitted). The evidence "must be sufficient to require a finding of deceitful intent in the light of all the circumstances." *Id.* "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290-91.

2. Factual Background

The asserted '977 patent claims priority to U.S. Patent No. 7,597,557 ("the '557 patent"), which was filed as Application No. 10/558,260 ("the '260 application") on May 23, 2004. *See* JX-0001 ('977 patent). The '557 patent is the national phase application for PCT Application No. IL2004/000438. That PCT application in turn claims its origin from Israeli patent application number 156033. *See* JX-0001 at 2. During prosecution of the Israeli application, a non-party named AB Dental Devices Ltd. submitted a letter to the Israeli Patent Office challenging the patentability of Dr. Fromovich's invention in Israel. *See* JX-0007 at 529-38 (English translation). In the letter, AB Dental alleged that "the implant forming the subject matter of the application" had been depicted in the Israel Dental Update Journal in January 2003, and in the 2003 Alpha-Bio Tec catalog. *Id.* at 531-32. The letter attached four appendices: an Alpha-Bio Implant flyer featuring the SPI implant, the brochure that allegedly appeared in the Journal, an implant pricing flyer, and a single page referred to as the Alpha-Bio catalog, respectively. *Id.* at 539, 541.

On September 4, 2008, the applicant appointed Mr. Narula and the law firm of Knobbe Martens as its attorneys or agents to prosecute the pending U.S. application by filing a revocation and power of attorney with the Patent Office. *See* JX-0007 at 219. Previously, the '260 application was prosecuted by attorney Mark Friedman. *See id.* at 99. At the time the case was transferred to Mr. Narula, Mr. Friedman had not submitted the AB Dental letter or its attachments to the Patent Office. In January 2008, before the application was transferred to Mr. Narula, Nobel [

]. *See* JX-0277C (email correspondence between Linus Bystrom, in-house counsel for Nobel, and attorney Nathan Smith of Knobbe Martens) at 1. Nathan Smith was Mr. Narula's associate who, after conferring with Mr. Narula, advised that the "[

]" inasmuch as the filing date of the Israeli application does not affect the one year grace period under the statute. *Id.* at 2. Mr. Smith also advised that "[

]." *Id.* He noted that

[

]." *Id.* at 3.

Before the '260 application was transferred to Mr. Narula for continued prosecution, all of the independent claims required the condensing core feature of the implant and did not claim a coronal region having a frustoconical shape. *See* JX-0007 at 239-46 (listing amended, withdrawn, and new claims). Further, the Patent Office had issued an Office Action in July 2008 rejecting some of the pending claims. *See id.* at 197. Mr. Narula filed a response to the Office Action on December 30, 2008. *See id.* at 220. That response included new independent claims and claim amendments, none of which related to a coronal region having a frustoconical shape. *See id.* at 239-46.

Soon after, on January 6, 2009, Mr. Narula told Nobel's in-house counsel, Linus Bystrom, [

]. *See* JX-0278C at 2 ("[

]"). Mr. Narula, however, recommended [

]." *Id.*

[ ], Mr. Narula submitted an IDS to the PTO on January 12, 2009, listing fifty-four references. JX-0007 at 410-12. A Notice of Allowance was issued on March 30, 2009 for the '260 application. *See id.* at 419. That same day, Mr. Narula recommended [

]. *See* JX-0278C at 1 ("[

]."). Mr. Narula filed an RCE along with an IDS on June 29, 2009. *See* JX-0007 at 439-41. The IDS included thirteen references. *Id.* at 445. Of those references, the ones at issue in this investigation are: (1) Cite No. 11, which was the translation of the AB Dental letter, translation of all the attachments, and the original Hebrew attachments; (2) Cite No. 12, the engineering drawing of the SPI implant shown in the catalog and brochure; and (3) Cite No. 13, an executed Statement of Relevance from Dr. Fromovich. *Id.* at 529-44. In the Statement of Relevance, inventor Ophir Fromovich identified the AB Dental letter and its attachments, and explained that the implant depicted and described in those documents "is not the dental implant of the present application" because it "does not include a gradually condensing core." *Id.* at 543 (emphasis original).

A second Notice of Allowance was issued on August 3, 2009 for the '260 application. JX-0007 at 588. With that notice, the examiner also provided a signed copy of the IDS form (PTO/SB/08) that Mr. Narula filed on June 29 with the annotation "ALL

REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH." *Id.* at 594. None of the citations discussed above was lined through. *Id.* The examiner indicated that all the listed references were considered on July 21, 2009 (*id.*), and the '260 application was issued on October 6, 2009 as U.S. Patent No. 7,597,557. *See id.*; JX-0025 ('557 patent) at 1. The relevant portions of the annotated IDS form are reproduced below:

Receipt date: 06/29/2009 10558260 - GAU: 3732

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	10/558,260
	Filing Date	December 21, 2006
	First Named Inventor	Ophir Fromovich
	Art Unit	3732
(Multiple sheets used when necessary)	Examiner	Mai, Hao D.
SHEET 1 OF 1	Attorney Docket No.	NOBELB.328NP

	10	3.8D series Threaded Implant, dental implant sold before September 27, 1999, Nobel Biocare.	
	11	Observation by AB Dental Devices Ltd. of Israeli Patent Application No. 156033 (PCT/IL2004/000438), a foreign counter-part of the present application, dated September 7, 2005, including Appendix A, Appendix B and Appendix D.	
	12	Engineering Drawing of SPI 3.75/13 Implant, by Alpha Bio System.	
	13	Statement of Relevance by Ophir Fromovich	

Examiner Signature /Hao D. Mai/		Date Considered 07/21/2009	

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] - Place a check mark in this area when an English language Translation is attached. ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /HDM/

JX-0007 at 594 (highlighting added).

To pursue claims on implant features other than the condensing core, the application that issued as the '977 patent was filed on November 26, 2012 as Application No. 13/685,388 ("the '388 application"). *See* JX-0001 at 2. On December 20, 2012, Mr. Narula filed a first IDS for the '388 application. *See* JX-0567 at 59-63. The IDS

included 113 references. *Id.* at 63. Many of those references were previously submitted by the applicants during prosecution of parent applications. Additionally, Mr. Narula listed the appendices to the AB Dental letter as separate entries on the IDS form. Specifically, Cite No. 106 was "Alpha-Bio Brochure A," Cite No. 107 was "Alpha-Bio Brochure B," Cite No. 108 was "Alpha-Bio Product catalogue,"[31] and Cite No. 112 was the English translation of the AB Dental letter and translation of the appendices. *See id.* at 63. Furthermore, for each of Cites No. 106, 107, and 108, Mr. Narula asked the PTO to treat the documents as though they had been published before the critical date of May 21, 2003. *Id.* ("for purposes of examination, consider published before May 21, 2003").

	106	Alpha-Bio Brochure A, for purposes of examination, consider published before May 21, 2003.		
	107	Alpha-Bio Brochure B for purposes of examination, consider published before May 21, 2003. see footnote below		
	108	Alpha-Bio Product catalogue for purposes of examination, consider published before May 21, 2003.		
	109	Engineering Drawing of SPI 3.75/13 Implant, by Alpha Bio System		
	110	Fernandes, Americo, DMD, "Combining the Single Implant With a CAD/CAM restoration", Dentistry Today, Volume 20 No. 12, dated December 2001. (Note Figure 9)		
	111	Niznick, Gerald A. DMD, MSD. "NobelActive Internal Hex Implant with Long Lead-in Bevel Nobel Marketing Claims this is the "Implant of the Future" Implant Direct, October 16, 2007.		
	112	Observation by AB Dental Devices Ltd. of Israeli Patent Application No. 156033 (PCT/IL2004/000438), a foreign counter-part of the present application, dated September 7, 2005, including Appendix A, Appendix B and Appendix D.		
	113	Statement of Relevance by Ophir Fromovich.		

Id. (highlighting added).

[31] Despite referring to this document as a "catalog," the record does not contain any evidence showing that the original AB Dental letter ever included more than the cover page. Correspondence between the inventors and their patent counsel includes attachments indicating that only the cover page was included. *See, e.g.*, JX-0281C (email correspondence between inventors and patent counsel attaching "catalog March 2003.jpg").

The examiner provided a signed copy of this IDS form (PTO/SB/08) with the annotation "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH." JX-0567 at 100. None of the citations discussed above was lined through. *Id.* The examiner indicated that all the listed references were considered on February 15, 2013, and the '388 application was issued on May 6, 2014 as the '977 patent. *See id.*; JX-0001 at 2. During prosecution of this patent family, from the '260 application to the '977 patent, the applicant filed three RCEs and four continuation applications. During prosecution of these patents, the examiner did not rely on the AB Dental letter or any of its attachments to reject any claims.

3. Summary of the Argument

During prosecution of the '977 patent application, application claims 1-8 (issued claims 1-8) were rejected as obvious. RX-0111 (6/20/13 Final Action) at 3-5. In response, the applicant filed a Request for Continuing Examination ("RCE") amending application claim 1 (issued claim 1) and adding new application claim 10 (issued claim 9) to include the limitation "wherein the thread step is between 1.5 and 2.5 mm." RX-0112 (10/21/13 Amendment) at 2-3, 7. In a subsequent Amendment the applicant amended application claims 1 and 10 (issued claims 1 and 9) to clarify the meaning of thread step: "each of the helical threads have a thread step that is defined as a distance along a longitudinal axis of the dental implant covered by complete rotation of the dental implant." RX-0114 (12/13/13 Amendment) at 2-4. The Examiner then allowed, among others, application claims 1 and 10 (issued claims 1 and 9).

The 2003 Alpha-Bio Tec Catalog discloses a 3.75 mm SPI Implant "with large variable thread design double thread 2x2.1 mm," that is, two threads with a 2.1 mm thread step. RX-0658 (2003 Alpha Bio Tec Catalog) at 16-17 (INSTRA0001655–56). The 2.1 mm thread step therefore falls within the claimed thread step range of "between 1.5 and 2.5 mm."

The 3.75 mm SPI Implant disclosed in the prior-art 2003 Alpha-Bio Tec Catalog and Figure 7B of the '977 patent appear similar:

Id. at 16 (INSTRA0001655); JX-0001 ('977 patent) at Fig. 7B.

Indeed, Nobel Biocare's expert Mr. Hurson testified that they were the same. Hurson Tr. 180-181.

Instead of submitting the entire 2003 Alpha-Bio Tec Catalog (which discloses the 3.75 mm SPI implant having a "2.1 mm" thread step) to the PTO, Messrs. Fromovich, a named inventor of the '977 patent, and Narula (his prosecution attorney) submitted only the cover page of the catalog. CX-1037C (Hurson RWS) at Q24; Hurson Tr. 246. The cover page of the catalog does depict a smaller-diameter SPI Implant, but it does not disclose the thread step of "2.1 mm." RX-0658 (2003 Alpha Bio Tec Catalog) at 1.

Messrs. Fromovich and Narula also submitted to the PTO an engineering drawing of an Alpha Bio Tec SPI 3.75 mm implant. RX-0601 (12/20/12 IDS) at 7; CX-1037C (Hurson RWS) at Q24. In the submitted engineering drawing, the dimensions of the implant (including the thread step) were redacted. JX-0342 (Melcer Letter) at 13; CX-1037C (Hurson RWS) at Q24.

Further, Messrs. Fromovich and Narula also submitted to the PTO an Alpha Bio Tec brochure in Hebrew disclosing an SPI Implant. RX-0088 (Melcer Letter) at 10 (NBNEO0148998). The English translation submitted with the brochure stated that the SPI implant had a thread step of "1.2 mm," *i.e.*, a thread step outside of the claimed range of 1.5 to 2.5 mm. JX-0342 (Melcer Letter) at 8 (INSTRO001761). The correct translation of the Hebrew brochure reveals that the disclosed SPI Implant has, in fact, a thread step of "2.1 mm." RX-0088 (Melcer Letter) at 24.

Based on the above disclosures by the applicant and his attorney to the PTO, Instradent and the Staff argue that there is sufficient evidence to find that Messrs. Fromovich and Narula committed inequitable conduct by concealing from the PTO the fact that the thread step limitation added to issued claims 1 and 9 to secure allowance of the '977 patent was disclosed in 2003 Alpha-Bio Tec Catalog and Hebrew brochure. Specifically, it is argued that the evidence shows that Instradent has satisfied its burden of proving materiality, *i.e.*, that at least claim 9 would not have issued but for the alleged misconduct. *See* Staff Br. at 52-55.

As discussed further in the sections below, it is determined that the record evidence does not show, clearly and convincingly, that (1) the allegedly withheld

information was material to the prosecution of the '977 patent and that (2) Messrs. Fromovich and Narula acted with an intent to deceive the PTO.

4. Materiality

Instradent and the Staff argue that Messrs. Narula and Fromovich deliberately withheld or misrepresented references which they knew to be material during the prosecution of the '977 patent. Those references are: (1) certain pages from the Alpha-Bio Tec 2003 catalog showing the larger-diameter SPI implant, (2) a brochure allegedly published in the Israel Dental Update Journal showing the smaller-diameter SPI implant, (3) an English translation of the brochure, and (4) a redacted engineering drawing of the smaller-diameter SPI implant. Resps. Br. at 107-08; Staff Br. at 53-55.

The record evidence shows, however, that the applicants did in fact submit additional materials to the PTO that disclosed the information Instradent and the Staff argue was intentionally concealed, and that therefore the allegedly withheld information was cumulative and not material to the prosecution of the '977 patent. For example, it is argued that the "product depicted in the Alpha Bio Tec 2003 Catalog satisfied all of the limitations of claim 9 of the '977 patent." Resps. Br. at 107. The product at issue in the Alpha Bio Tec 2003 Catalog was the smaller-diameter SPI implant, which was also shown on the cover page of the catalog and the Israel Dental Update Journal, both of which were disclosed to the Patent Office:

DISCLOSED	DISCLOSED	Allegedly Withheld

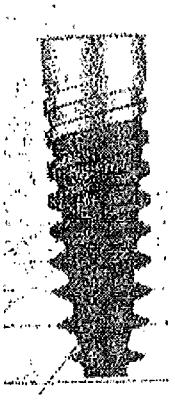
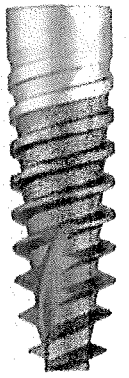

		

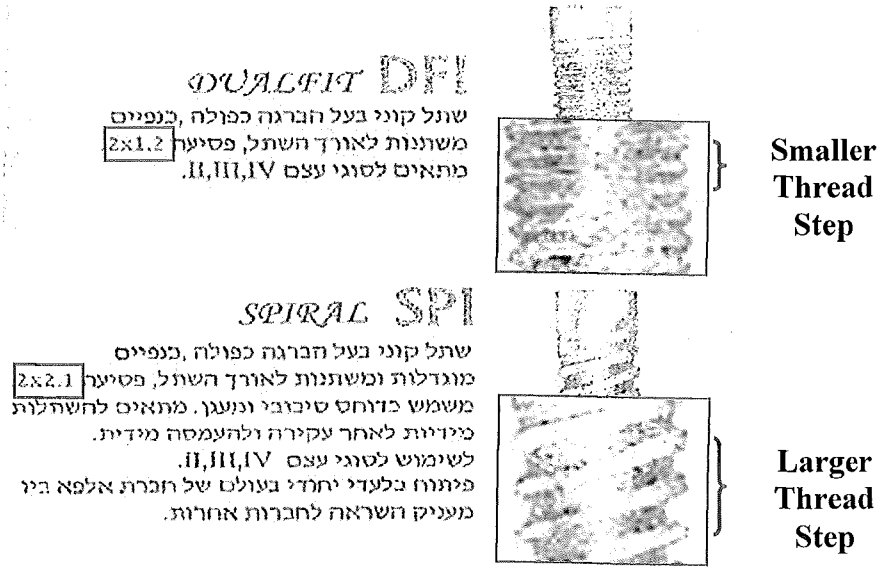
Image from cover of catalog submitted to PTO (JX-0007 at 539)	**Image from the Israel Dental Update Journal submitted to PTO (JX-0007 at 541)**	**Image from other pages of the catalog (RX-0658 at 16)**

a. The Correct Thread Step Measurement Was Disclosed in Multiple Documents Submitted to the Patent Office

It is argued that the disclosures provided by the patentee to the PTO during prosecution of the '977 patent do not show the thread step of the SPI implant, whereas the undisclosed pages of the Alpha Bio Tec 2003 Catalog do. *See* Resps. Br. at 107-08; Staff Br. at 53-54. The record evidence shows otherwise. The disclosed Israel Dental Update Journal brochure specifies the thread step in Arabic numerals as "2x2.1." JX-0007 at 541. Additionally, the English translation of the AB Dental letter also describes the "thread height" as being 2 x 2.1 mm. JX-0007 at 531. The allegedly withheld catalog adds nothing more:

DISCLOSED	**DISCLOSED**	**Allegedly Withheld**
Conical implant with dual thread, Thread height 2 x 2.1.	.2x2.1 השתל, פסיעה *	double thread 2x2.1mm.
Text from the English translation of AB Dental letter submitted to PTO (JX-0007 at 531)	**Text from the Hebrew brochure submitted to PTO (JX-0007 at 541)**	**Text from other pages of the catalog (RX-0658 at 17)**

Moreover, the examiner indicated that the original Hebrew brochure was considered, as shown by his notation on the IDS form. *See* JX-0567 at 100. The Hebrew brochure was listed separately from the translation. JX-0567 at 100. Upon reviewing the original Hebrew brochure, the examiner would have seen from the images that the thread step of the SPI implant is much larger than that of the DFI implant, shown directly above the SPI image. Consistently, the Arabic numerals alongside each image reveal that the thread step is 2.1 mm for the SPI (smaller thread step, above), and only 1.2 mm for the DFI (larger thread step, below):



See JX-0007 at 541 (color annotations added).

Thus, the other pages of the Alpha Bio Tec 2003 Catalog do not add anything to the information that was disclosed and considered by the examiner, and would have been cumulative of that information, even with respect to claim 9. The examiner had multiple documents showing the correct 2.1 mm thread step, and no reason to believe that the one source with a typographical error transposing those numbers would supersede the others. Therefore, inasmuch as the examiner had references showing the correct thread step and never relied on this information to reject the claims, it is determined that the thread step measurement is not "but for" material to the prosecution of the '977 patent.

b. The Frustoconical Shape of the SPI Implant Was Disclosed in Multiple Submitted Documents

The evidence demonstrates that the other pages of the Alpha Bio Tec 2003 Catalog would also have been cumulative of other materials submitted to the PTO or otherwise non-material to the prosecution of the '977 patent for other reasons.

In particular, under the construction of "the coronal region having a frustoconical shape" adopted above, such a feature is disclosed in the engineering drawing that Mr. Narula submitted to the Patent Office. *See* CX-1037C (Hurson WS) at Q24. This feature is also shown in the Israel Dental Update Journal advertisement that was disclosed to the Patent Office, which includes images of both the large and small diameter SPI implants. *See* Compls. Br. at 137. Therefore, the information Mr. Narula submitted to the Patent Office included a "coronal region having a frustoconical shape" under the adopted construction of the term. The disclosure of another image showing the larger-diameter SPI implant would have added nothing new to the materials before the examiner and would have been cumulative.

5. Intent

It has not been shown that the single most reasonable inference to be drawn from the record evidence is an intent to deceive the PTO. Other reasonable inferences, which are discussed further below, include: (1) that Mr. Narula never had the entire 2003 Alpha-Bio Tec catalog in his possession, (2) that he genuinely believed its contents were cumulative of already submitted references, (3) that Mr. Narula and the applicants concluded that the SPI Implant did not include the features claimed in the '260

application (the "condensing cone" feature) or in the '388 application (the tapered coronal region), (4) that Mr. Narula and the applicants were not aware of the transposed digits in the translation of the brochure attached to the AB Dental letter, and (5) the applicants redacted the engineering drawing because of the proprietary nature of the measurements that were irrelevant to the claims at issue and not because of an intent to deceive.

An intent to deceive the PTO on the part of Messrs. Fromovich and Narula is not the single most reasonable inference that can be drawn from the record evidence. A more reasonable inference is that Mr. Narula never had the entire Alpha-Bio Tec catalog. In particular, nothing in the record evidence suggests that Mr. Narula was ever in possession of the entire catalog, and nothing in the record evidence suggests that any attorney involved in the prosecution of the '260 application or any of its continuation applications had any more pages of the catalog than the pages submitted to the PTO. Furthermore, as explained above, Mr. Narula and the applicants had no reason to believe that the catalog contained any information over and above the information contained in the AB Dental letter and appendices, which included images of the SPI implant. Thus, even had Mr. Narula been in possession of the full catalog, a more reasonable inference is that he genuinely believed its contents were cumulative of already submitted references. *See* CX-1038 at (Kunin RWS) at Q108 ("if [an] individual had a good faith belief that the undisclosed information was cumulative information, then the duty of disclosure is not violated"); *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359 (Fed. Cir. 2010) ("[T]he failure to disclose what was believed to be cumulative information [may

be] a mistake or exercise of poor judgment that does not support an inference of intent to deceive.").

Another more reasonable inference that could be drawn from the record evidence is that Mr. Narula and the applicants concluded that the SPI Implant did not include the "condensing cone" feature claimed in the '260 application or the tapered coronal region claimed in the '388 application. The evidence shows that the inventors did in fact reach those conclusions when [

]. *See* JX-0262C at 2 ([

]), 1 ([

]); JX-0007 at 542-43 (Statement of Relevance). The evidence shows that the applicants were not concerned about the disclosure of the SPI implant because it was different from the claimed invention, a fact corroborated by Dr. Fromovich's testimony that the claimed invention was "[

]." Fromovich Tr. 398. Another named inventor, Dr. Karmon, also testified that one of the main differences between the SPI implant and the claimed invention (as it was embodied in the SFB implant) is the "[ ]." *See* RX-0028C at Q122-123 ("[

].”). Therefore, an intent to deceive the PTO is not the single most reasonable inference that can be drawn from the record evidence.

Instradent and the Staff argue that, inasmuch as the thread step measurement of the SPI implant was transposed in the English translation of the Hebrew Alpha Bio Tec brochure that the applicants submitted to the Patent Office, Dr. Fromovich and Mr. Narula must have intentionally provided this incorrect translation in order to deceive the Patent Office. *See* Resps. Br. at 121-25; Staff Br. at 54-55. The evidence shows, however, that this error was made by an independent translator retained by a previous attorney prosecuting the ’260 application, Mark Friedman. *See* RX-0028C at Q199-200 (“Q. . . . So were you involved in any way with the translation of the AB Dental submission that’s on pages 1 through 10? A. The translation, no. Our lawyer sent it to a translation company.”). Further, the evidence suggests that the translation was provided to Mr. Narula during prosecution of the ’260 application, well before the thread step was claimed for the first time in the ’388 application. *See* JX-0567 at 203-11 (adding limitation “wherein the thread step is between 1.5 – 2.5 mm” for the first time in October 21, 2013 Response to Office Action). At that time, a key feature of the claims was the condensing implant core, a feature lacking in the SPI implant. Moreover, there is no evidence suggesting that anyone involved in the prosecution of the ’977 patent was aware of the error in the English translation when it was first submitted to the PTO in June 2009. Therefore, an intent to deceive the PTO is not the single most reasonable inference that can be drawn from the record evidence.

It is also argued that Mr. Narula submitted a redacted copy of an engineering drawing of the SPI implant in order to prevent the PTO from discovering that the SPI implant had a 2x2.1 mm thread step. *See* Resps. Br. at 125-26; Staff Br. at 54-55. Testimony adduced at the hearing, however, suggests that it is common to redact the dimensions from engineering drawings of commercial products for competitive reasons. Fromovich Tr. at 391-392 ("[ ]."). Moreover, the exact dimensions of the implant were unnecessary to show the features relevant to the pending claims in 2009 when the drawing was first submitted, namely, the shape of the implant's core. Further, even if the thread step on the engineering drawing had been relevant to the claims pending at the time, the dimensions from the engineering drawing would have been cumulative with the disclosure in the AB Dental letter accurately translating the thread step as 2x2.1 mm. *See* JX-0007 at 531, 541.

Therefore, based on the record evidence, it is determined that the single most reasonable inference to be drawn is not an intent to deceive the PTO on the part of the applicants or their prosecution counsel. Accordingly, the '977 patent is not unenforceable for inequitable conduct.

VI. The '443 Patent

A. Asserted Claims

Asserted U.S. Patent No. 8,764,443 ("the '443 patent") is titled, "Method for Producing a Surface Structure on an Implant, and Such an Implant." JX-0002 ('443 patent). The '443 patent issued on July 1, 2014, and the named inventor is Jan Hall. *Id.*

Nobel asserts independent claim 15 and dependent claims 17-19, 30, and 32. The relevant claims read as follows:

> 15. A dental implant comprising:
>
> an implant body defining a longitudinal axis and an exterior surface; and
>
> a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface, wherein when seen in side view, the outer surface of the thread comprises a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread, the wave pattern having a respective trough depth in the range of between approximately 25 to 200 μm.
>
> 17. The implant as in claim 15, wherein the troughs of the wave pattern follow the spiral trajectory of the thread along a crest of the thread.
>
> 18. The implant as in claim 15, wherein the wave pattern varies along the implant.
>
> 19. The implant as in claim 15, wherein the trough varies along the spiral trajectory.
>
> 30. The implant as in claim 15, wherein the trough has a depth of between approximately 50 to 150 μm.
>
> 32. The implant as in claim 15, wherein the at least one trough of the wave pattern extends along an apex of the thread.

B. Claim Construction

1. Level of Ordinary Skill

Nobel proposes that a person of ordinary skill in the art with respect to the '443 patent be defined as "either a mechanical engineer with at least two years of experience in the design, development, research or testing of dental implants, or a clinician

experienced in the implantation of dental implants." *See* Compls. Br. at 153. Respondents propose that a person of ordinary skill in the art be defined as "a person having at least a bachelor-level degree in mechanical or bio-medical engineering and three years of experience in the design and development of dental implants, or a dental provider trained in the practice of implanting dental implants." *See* Resps. Br. at 137. The Staff supports Nobel's proposed definition. *See* Staff Br. 57.

As in the case of the '977 patent, a person having ordinary skill in the art with respect to the '443 patent is defined as "either a mechanical engineer with at least two years of experience in the design, development, research or testing of dental implants, or a clinician experienced in the implantation of dental implants." This definition is consistent with the disclosure of the '443 patent and cited prior art, whereas Instradent's proposed definition excludes academics who research and test dental implants, and publish the results of their research in scholarly journals. *See* Compls. Br. at 14, 153; Staff. Br. at 20, 57.

2. Disputed Claim Terms

a. "trough" (claim 15)

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"trough"	"long, narrow depression, as between waves or ridges"	"long depression between peaks and ridges"	"long, narrow depression, as between waves or ridges"

The claim term "trough" appears in claim 15 of the '443 patent. As proposed by Nobel and the Staff, the term "trough" is construed to mean "long, narrow depression, as between waves or ridges." This construction is consistent with the intrinsic evidence, in particular the prosecution history of the '443 patent.

The named inventors of the '443 patent explicitly defined the term "trough" during prosecution as a "long, narrow depression, as between waves or ridges" in accordance with the definition set forth in *The American Heritage Dictionary of the English Language* (4th ed. 2007). *See, e.g.*, JX-0004 ('443 patent file history) at 96, 404.

For example, in a reply brief before Patent Trial and Appeal Board, the patentee defined "trough" and argued that the asserted prior art did not teach such a feature:

> A "trough" is defined as "a long, narrow depression, as between waves or ridges." "Trough," The American Heritage Dictionary of the English Language, 4th ed., Houghton Mifflin Company, 2007. Contrary to the Answer's assertions, Klardie does not teach a long, narrow depression between waves or ridges "on the thread and the entire roughened surface."

Id. at 96. In view of this explicit definition in the file history, the record evidence shows that one of ordinary skill in the art would understand the claim term "trough" to mean a "long, narrow depression, as between waves or ridges."[32]

[32] Instradent argues that the adopted construction of the claim term "trough" "meets neither the written description nor enablement requirements of 35 U.S.C. § 112, first paragraph," and that the "definition of 'trough' in the asserted claims is indefinite and therefore invalid, because the public cannot ascertain the boundaries of the claim." *See* Resps. Br. at 133. Nevertheless, as discussed above, a person having ordinary skill in the art would be able to understand the boundaries of the patent claim when read in light of the patent's disclosure.

b. "wherein the troughs of the wave pattern" (claim 17)

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"wherein the troughs of the wave pattern"	This requires no construction. Alternatively, "wherein all the troughs in the wave pattern on the outer surface of the thread"	"wherein the troughs of the wave pattern (having at least two troughs)"	"wherein the troughs of the wave pattern (having at least two troughs)"

The claim term "wherein the troughs of the wave pattern" appears in claim 17 of the '443 patent. As proposed by Instradent and the Staff, the term "wherein the troughs of the wave pattern" is construed to mean "wherein the troughs of the wave pattern (having at least two troughs)." This definition is consistent with the usage of the term in independent claim 15, from which claim 17 depends, and in which the term first appears.

Specifically, claim 15 recites a wave pattern "with at least one trough." JX-0002 ('443 patent) at col. 7, ln. 39. Claim 17, which depends directly from claim 15, refers to "troughs" in the plural. *Id.* at col. 8, lns. 1-3 ("The implant as in claim 15, wherein the *troughs* of the wave pattern follow the spiral trajectory of the thread along a crest of the thread.") (emphasis added). Therefore, the "wave pattern" recited in claim 17 must have at least two troughs.

This definition is also supported by the '443 patent specification, which discloses wave patterns having multiple troughs. *See, e.g.*, JX-0002 ('443 patent) at col. 3, lns. 2-5 ("In one embodiment, two or more troughs between the peaks can extend substantially

parallel along the spiral trajectory."), col. 5, lns. 29-31 ("Said front parts 21a and 21a" produce two parallel troughs . . . .).

The record evidence therefore demonstrates that a person having ordinary skill in the art would understand the claim term "wherein the troughs of the wave pattern" to mean "wherein the troughs of the wave pattern (having at least two troughs)."

c. "apex" / "apex of the thread" (claim 32)

Claim Term/Phrase	Complainants' Proposed Construction	Respondents' Proposed Construction	Staff's Proposed Construction
"apex" / "apex of the thread"	"outermost point on the thread"	Indefinite	"outermost point on the thread"

The claim terms "apex" and "apex of the thread" appear in claim 32 of the '443 patent. As proposed by Nobel and the Staff, the terms "apex" and "apex of the thread" are construed to mean "outermost point on the thread." This construction comports with the commonly understood meaning of "apex" as the highest point. Inasmuch as dental implants are placed at various angles in a patient's upper and lower jaw, a person having ordinary skill in the art would understand that the "apex of the thread" refers to the outermost point on the thread farthest from the core or body of the implant. *See* CX-1033C (Müftü WS) at Q46.

By contrast, Instradent's contention that the terms "apex" and "apex of the thread" are indefinite is not supported by the record evidence. A claim is indefinite only if, in light of the specification and prosecution history, it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*,

134 S. Ct. at 2124. The evidence adduced during the hearing demonstrates that a person of ordinary skill in the art would have a reasonable certainty as to the scope of claim 32. *See, e.g.*, CX-1033C (Müftü WS) at Q46; JX-0002 ('443 patent) at col. 2, lns. 48-49, Figs. 1, 10.

3. Undisputed Claim Terms

a. "the outer surface of the thread comprises a wave pattern" (claim 15)

The parties agree that the claim term "the outer surface of the thread comprises a wave pattern," which appears in claim 15 of the '443 patent, should be construed to mean "an arrangement of two or more peaks, or one or more troughs, or both on top of the thread that is distinct and separate from the underlying thread pattern." *See* Joint Claim Construction Chart at 4.

b. "crest" / "crest of the thread" (claim 17)

The parties agree that the claim terms "crest" and "crest of the thread," which appear in claim 17 of the '443 patent, should be construed to mean "the outer-most lateral face of the thread." *See* Joint Claim Construction Chart at 4.

c. "wave pattern varies" (claim 18)

The parties agree that the claim term "wave pattern varies," which appears in claim 18 of the '443 patent, should be construed to mean "the wave pattern changes along the axial length of the implant, when seen in side view." *See* Joint Claim Construction Chart at 4.

C. Infringement

1. Claim 15

The record evidence demonstrates that the accused Drive CM implants literally infringe claim 15 of the '443 patent under the claim constructions adopted above.

As an initial matter, the parties do not dispute that the accused devices are dental implants. Therefore, the accused devices practice the claim element recited the preamble.

The record evidence also shows that each of the remaining elements of claim 15 is literally present in each of the accused devices. In particular, Instradent conceded that the 3.5 mm, 4.3 mm, and 5.0 mm Drive CM implants each comprise "an implant body defining a longitudinal axis and an exterior surface; and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface." CX-0436 at (Instradent Resps. to RFA Nos. 37-39) at 25-26. In addition, Nobel's expert Dr. Müftü testified:

> I found that the 3.5 mm, 4.3 mm, and 5.0 mm Drive CM implants comprise "an implant body defining a longitudinal axis and an exterior surface; and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface," as Claim 15 requires.

CX-1033C (Müftü WS) at Q68.

Engineering drawings of the accused implants also show that the claim limitation "an implant body defining a longitudinal axis and an exterior surface; and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface" is literally present. JX-0312C (Drive CM 4.3 mm engineering drawing);

JX-0313C (Drive CM 5.0 mm engineering drawing); JX-0314C (Drive CM 3.5 mm engineering drawing).

The evidence also establishes that the outer surface of the thread on the accused Drive CM implants comprises a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread. For example, Dr. Müftü testified:

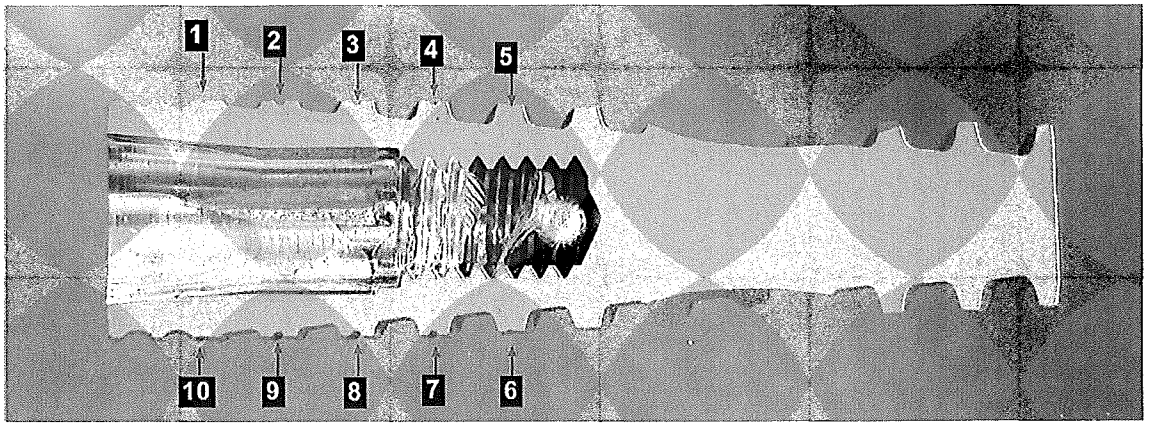
> [W]hen seen from the side view, the outer surface of the thread on these Drive CM implants "comprises a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread."

CX-1033C (Müftü WS) at Q68.

Engineering drawings of the accused implants as well as microscopic photographs of the accused implants show that this wave pattern is literally present on the surface of the threads. JX-0312C (Drive CM 4.3 mm engineering drawing); JX-0313C (Drive CM 5.0 mm engineering drawing); JX-0314C (Drive CM 3.5 mm engineering drawing); CX-0580 (Drive CM 3.5 mm measurements); CX-0581 (Drive CM 4.3 mm measurements); CX-0582 (Drive CM 5.0 mm measurements).

The record evidence also establishes that the depth of the trough on each of the accused Drive CM implants is in the approximate range of 25 to 200 microns. CX-1033C (Müftü WS) at Q68 ("The Drive CM implants that I analyzed each have a trough depth falling within that range."). Dr. Müftü also testified regarding measurements he commissioned of Drive CM implant samples, explaining that he

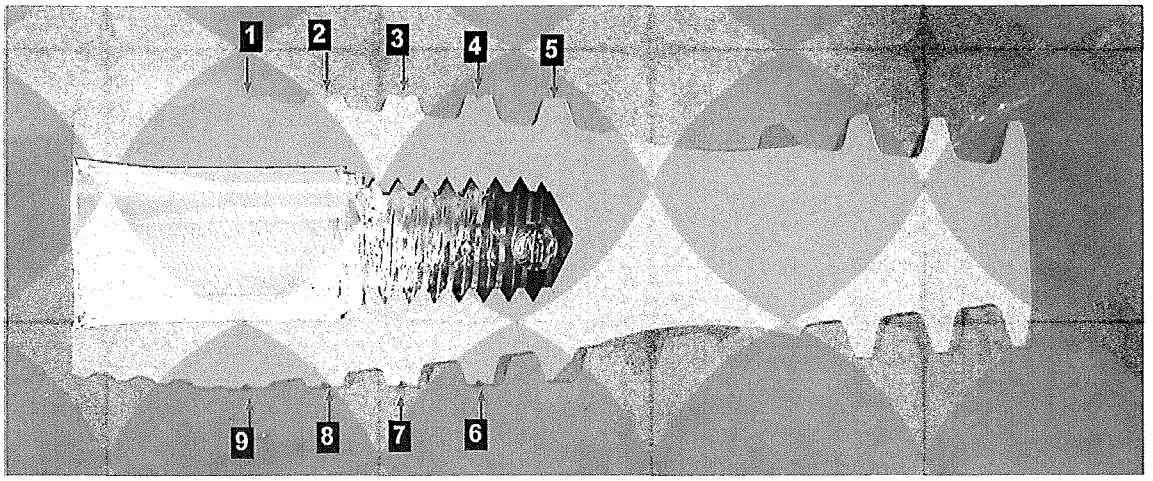
"arranged for Drive CM implant samples to be sectioned and measured in multiple locations using optical microscopy." *Id.* at Q75. The trough depth on the threads of a Drive CM 3.5 mm implant was measured at ten different locations along the thread. CX-0580 at 1 (excerpt shown below); *see also* CX-1033C (Müftü WS) at Q77 (confirming that CX-0580 "contains images of the Drive CM 3.5 mm implant that I had arranged to be sectioned and measured"). All but four of the depth measurements ranged between 57.3 and 73.3 microns. *See* CX-0580 at 2-11 (indicating trough depth measurements of 29.4 microns, 68.7 microns, 71.3 microns, 57.3 microns, 20.3 microns, 19.1 microns, 60.9 microns, 69.6 microns, 73.3 microns, and 15.2 microns). The remaining four depth measurements were at locations near the beginning or the end of the trough. *See id.*



CX-0580 (annotations added).

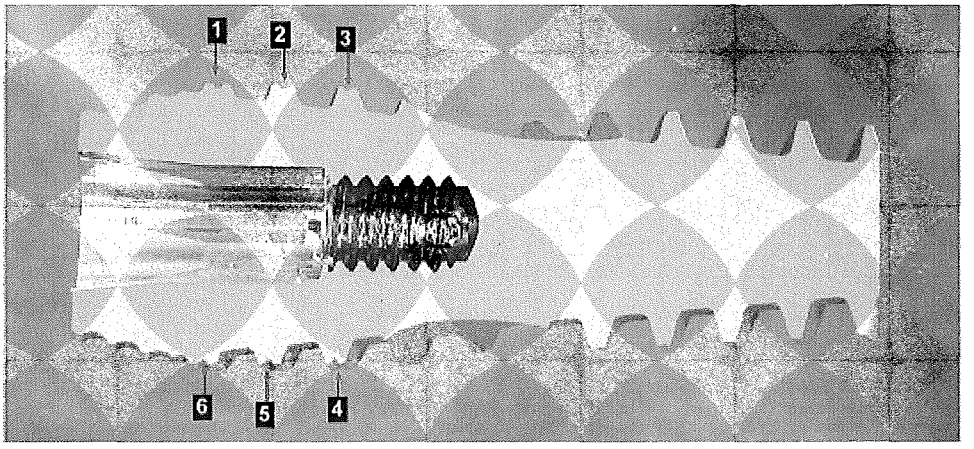
The trough depth on the threads of a Drive CM 4.3 mm implant was measured at nine different locations along the thread. CX-0581 at 1 (excerpt shown below); *see also* CX-1033C (Müftü WS) at Q79 (confirming that CX-0581 "contains images of the Drive CM 4.3 mm implant that I had arranged to be sectioned and measured"). All but one of

the depth measurements ranged between 55.7 and 62.8 microns. *See* CX-0581 at 2-10 (indicating trough depth measurements of 60.5 microns, 62.8 microns, 60.2 microns, 62.3 microns, 13.6 microns, 55.7 microns, 60.5 microns, 60.0 microns, and 59.1 microns). The remaining measurement was at a location near the end of the trough. *See id.*



CX-0581 (annotations added).

The trough depth on the threads of a Drive CM 5.0 mm implant was measured at six different locations along the thread. CX-0582 at 1 (excerpt shown below); *see also* CX-1033C (Müftü WS) at Q81 (confirming that CX-0582 "contains images of the Drive CM 5.0 mm implant that I had arranged to be sectioned and measured"). The depth measurements ranged between 51.1 and 82.1 microns. *See* CX-0582 at 2-7 (indicating trough depth measurements of 81.6 microns, 82.1 microns, 51.1 microns, 53.2 microns, 75.2 microns, and 76.9 microns).



CX-0582 (annotations added).

Dr. Müftü also provided testimony regarding "charts that [he] prepared mapping each element of claims 15, 17-19, 30 and 32 to the structure of Respondents' Drive CM 3.5 mm[, 4.3mm, and 5.0 mm] implant[s]." CX-1033C (Müftü WS) at Q69-74.

Accordingly, it is determined that the accused products infringe claim 15 of the '443 patent.

2. Claim 17

Claim 17 depends from claim 15 and adds the additional limitation "wherein the troughs of the wave pattern follow the spiral trajectory of the thread along a crest of the thread." As discussed above, the claim term "wherein the troughs of the wave pattern" is construed to mean "wherein the troughs of the wave pattern (having at least two troughs)."

Nobel has not offered any evidence to show that the accused products satisfy the additional limitation recited in claim 17 under the adopted claim construction. *See* Compls. Br. at 161.

Accordingly, it is determined that the accused products do not infringe claim 17 of the '443 patent.

3. Claim 18

Claim 18 depends from claim 15 and adds the additional limitation "wherein the wave pattern varies along the implant." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* CX-1033 (Müftü WS) at Q69-74 (confirming that infringement claim charts, including CDX-0616C, CDX-0624C, and CDX-0632C, map the limitation of claim 18 "to the structure of Respondents' Drive CM" implants); JX-0312C (Drive CM 4.3 mm engineering drawing); JX-0313C (Drive CM 5.0 mm engineering drawing); JX-0314C (Drive CM 3.5 mm engineering drawing). As discussed above, the parties have agreed that the claim term "wave pattern varies" should be construed to mean "the wave pattern changes along the axial length of the implant, when seen in side view." Demonstrative slide CDX-0139 illustrates that, when seen in side view, the wave pattern changes inasmuch as the dimensions of the peaks surrounding the troughs change in each thread rotation. Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 134-35.

Accordingly, it is determined that the accused products infringe claim 18 of the '443 patent.

4. Claim 19

Claim 19 depends from claim 15 and adds the additional limitation "wherein the trough varies along the spiral trajectory." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* CX-1033C (Müftü WS) at

Q69-74 (confirming that infringement claim charts, including CDX-0617C, CDX-0625C, and CDX-0633C, map the limitation of claim 19 "to the structure of Respondents' Drive CM" implants); JX-0312C (Drive CM 4.3 mm engineering drawing); JX-0313C (Drive CM 5.0 mm engineering drawing); JX-0314C (Drive CM 3.5 mm engineering drawing). In particular, the evidence shows that the trough on the Drive CM implants varies along the spiral trajectory with respect to the depth of the trough, as demonstrated by the measurements taken at various locations along the spiral trajectory of the trough. *See* CX-0580 (Drive CM 3.5 x 13mm measurements) at 2-11 (indicating trough depth measurements on the Drive CM 3.5 mm implant of 29.4 microns, 68.7 microns, 71.3 microns, 57.3 microns, 20.3 microns, 19.1 microns, 60.9 microns, 69.6 microns, 73.3 microns, and 15.2 microns); CX-0581 (Drive CM 4.3 x 13mm measurements) at 2-10 (indicating trough depth measurements on the Drive CM 4.3 mm implant of 60.5 microns, 62.8 microns, 60.2 microns, 62.3 microns, 13.6 microns, 55.7 microns, 60.5 microns, 60.0 microns, and 59.1 microns); CX-0582 (Drive CM 5.0 x 13mm measurements) at 2-7 (indicating trough depth measurements on the Drive CM 5.0 mm implant of 81.6 microns, 82.1 microns, 51.1 microns, 53.2 microns, 75.2 microns, and 76.9 microns). Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 134-35.

Accordingly, it is determined that the accused products infringe claim 19 of the '443 patent.

5. Claim 30

Claim 30 depends from claim 15 and adds the additional limitation "wherein the trough has a depth of between approximately 50 to 150 μm." The record evidence demonstrates that the accused products satisfy this additional claim limitation. In particular, Dr. Müftü testified that "[t]he measurements of the groove itself confirmed that the 3.5 mm, 4.3 mm, and 5.0 mm Drive CM implants have a groove that is approximately 50-150 microns, and thus satisfy the trough depth requirements of . . . Claim 30." CX-1033C (Müftü WS) at Q75. Nobel also presented evidence showing that measurements of the trough depth at various locations along the threads were approximately between 57.3 and 73.3 microns for the Drive CM 3.5 mm implant (*see* CX-0580 at 2-11), approximately between 55.7 and 62.8 microns for the Drive CM 4.3 mm implant (*see* CX-0581 at 2-10), and approximately between 51.1 and 82.1 microns for the Drive CM 5.0 mm implant (*see* CX-0582 at 2-7). Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 134-35.

Accordingly, it is determined that the accused products infringe claim 30 of the '443 patent.

6. Claim 32

Claim 32 depends from claim 15 and adds the additional limitation "wherein the at least one trough of the wave pattern extends along an apex of the thread." The record evidence demonstrates that the accused products satisfy this additional claim limitation. *See* CX-1033C (Müftü WS) at Q69-74 (confirming that infringement claim charts, including CDX-0619C, CDX-0627C, and CDX-0635C, map the limitation of claim 32

"to the structure of Respondents' Drive CM" implants); JX-0312C (Drive CM 4.3 mm engineering drawing); JX-0313C (Drive CM 5.0 mm engineering drawing); JX-0314C (Drive CM 3.5 mm engineering drawing). As discussed above, the claim term "apex of the thread" is construed to mean "outermost point on the thread." The evidence shows that the troughs on the accused devices extend along the outermost point on the thread, as illustrated in demonstrative slides CDX-0139 and CDX-0627C. Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 134-35.

Accordingly, it is determined that the accused products infringe claim 32 of the '443 patent.

D. Technical Prong of the Domestic Industry Requirement

1. Claim 15

The record evidence demonstrates that the 3.5 mm, 4.3 mm, and 5.0 mm NobelActive® implants practice claim 15 of the '443 patent under the claim constructions adopted above.

As an initial matter, the parties do not dispute that the domestic industry products are dental implants. Therefore, they practice the claim element recited the preamble.

The evidence also shows that each of the remaining elements of claim 15 is literally present in each of the NobelActive® implants. For example, Dr. Müftü testified that he "found that the 3.5 mm, 4.3 mm, and 5.0 mm NobelActive implants comprise 'an implant body defining a longitudinal axis and an exterior surface; and a thread extending about the implant body in a spiral trajectory, the thread defining an outer surface.'" CX-1033C at Q48. Engineering drawings of each size of the NobelActive® implants and

a physical sample of the 4.3 mm NobelActive® implant also show that this feature is literally present. CX-0569C (NobelActive® 3.5 mm, 4.3 mm, and 5.0 mm engineering drawings); CPX-0003; CPX-0005.

Moreover, Dr. Müftü testified:

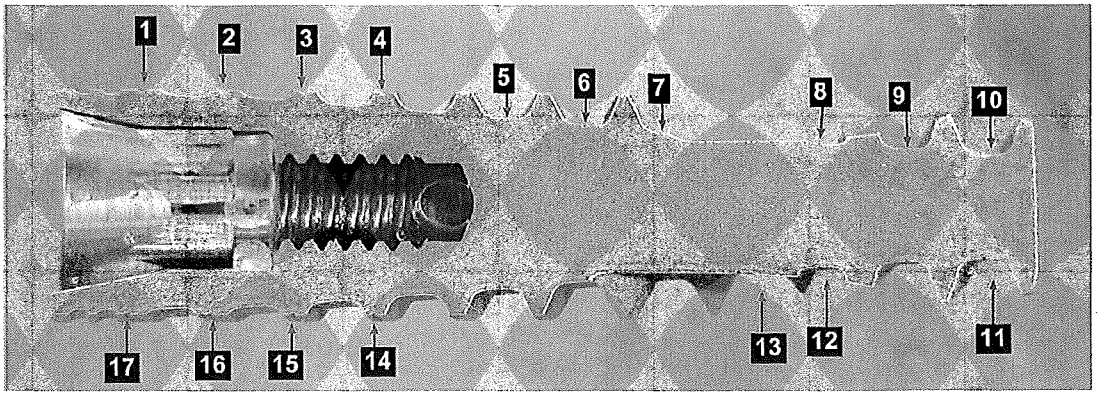
> [W]hen seen from the side view, the outer surface of the thread on these NobelActive implants "comprises a wave pattern with at least one trough, the wave pattern extending generally in the direction of the longitudinal axis of the implant body, the trough extending in a course that substantially follows the spiral trajectory of the thread."

CX-1033C (Müftü WS) at Q48; CX-0569C.

Engineering drawings of the NobelActive® implants, microscopic photographs of the implants, and a physical sample of the 4.3 mm NobelActive® implant also show that the wave pattern on the outer surface of the threads is literally present in the NobelActive® implants. CX-0569C; CX-0577 (NobelActive® 3.5 mm measurements); CX-0578 (NobelActive® 4.3 mm measurements); CX-0579 (NobelActive® 5.0 mm measurements); CPX-0003; CPX-0005. Indeed, the NobelActive® implants include this limitation under any party's proposed construction of "trough" because the proposed constructions vary only in that one construction requires that the depression be narrow, and the other does not.

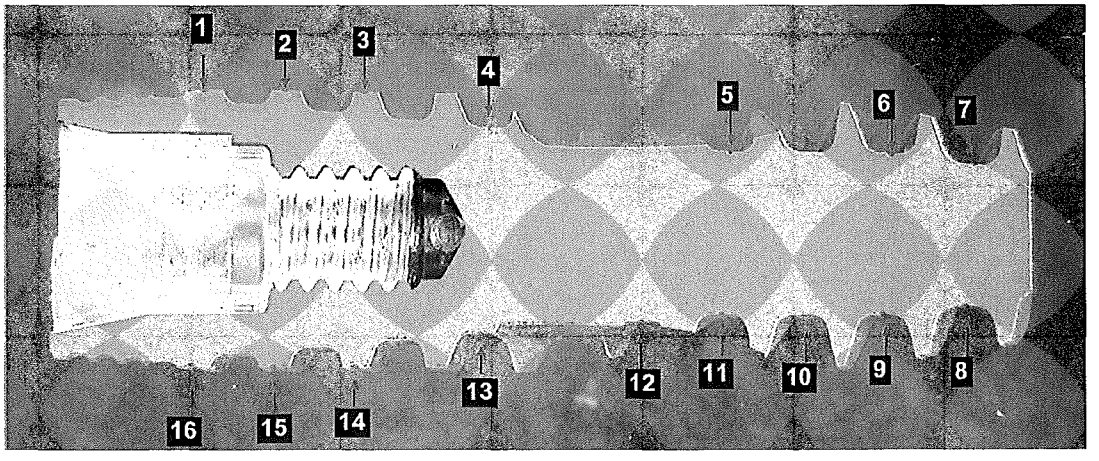
The record evidence also shows that the depth of the trough on each of the NobelActive® implants is between approximately 25 to 200 microns, as required by claim 15. CX-1033C (Müftü WS) at Q48 (testifying that "[t]he NobelActive implants that I analyzed each have a trough depth falling within that range"). In particular,

Dr. Müftü testified that "[t]he measurements of the groove itself confirmed that the 3.5 mm, 4.3 mm, and 5.0 mm [NobelActive® implants] have a groove that is approximately 25-200 microns, as Claim 15 requires." *Id.* at Q55. Dr. Müftü also testified regarding measurements he commissioned of NobelActive® implant samples, explaining that he "arranged for a sample of each of the NobelActive 3.5 mm, 4.3 mm, and 5.0 mm implants to be sections and measured in multiple locations using optical microscopy." *Id.* The trough depth on the threads of NobelActive® 3.5 mm implant was measured at seventeen different locations along the thread. CX-0577 at 1 (excerpt shown below); *see also* CX-1033C at Q57 (confirming that CX-0577 "contains images of the NobelActive 3.5 mm implant that I had arranged to be sectioned and measured"). All but one of the depth measurements ranged between 20.4 and 42.5 microns. *See* CX-0577 at 2-18 (indicating trough depth measurements of 42.5 microns, 40.6 microns, 38.6 microns, 38.0 microns, 20.4 microns, 27.6 microns, 16.1 microns, 30.9 microns, 23.6 microns, 34.1 microns, 40.5 microns, 21.3 microns, 30.1 microns, 30.0 microns, 28.1 microns, 27.9 microns, and 26.6 microns). The remaining measurement was at a location near the flute cutting through the threads of the implant. *See id.*



CX-0577 (annotations added).

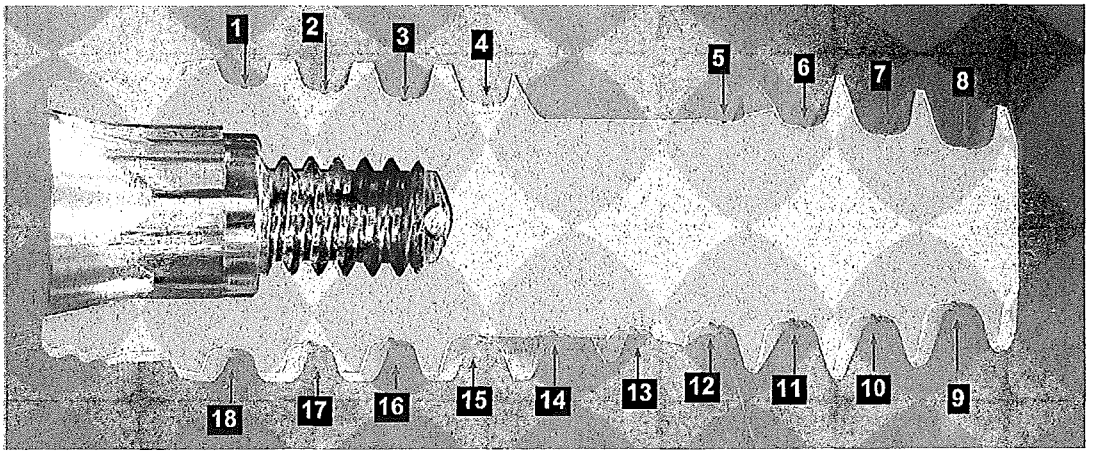
The trough depth on the threads of NobelActive® 4.3 mm implant was measured at sixteen different locations along the thread. CX-0578 at 1 (excerpt shown below); *see also* CX-1033C (Müftü WS) at Q59 (confirming that CX-0578 "contains images of the NobelActive 4.3 mm implant that I had arranged to be sectioned and measured"). All but one of the depth measurements ranged between 29.0 and 63 microns. *See* CX-0578 at 2-17 (indicating trough depth measurements of 45.4 microns, 29.4 microns, 38.9 microns, 29.0 microns, 48.1 microns, 63.0 microns, 34.5 microns, 49.5 microns, 57.0 microns, 18.7 microns, 45.5 microns, 40.6 microns, 41.6 microns, 53.1 microns, 53.1 microns, and 50.4 microns). The remaining measurement was at a location near the beginning or end of the trough. *See id.*



CX-0578 (annotations added).

The trough depth on the threads of NobelActive® 5.0 mm implant was measured at eighteen different locations along the thread. CX-0579 at 1 (excerpt shown below); *see also* CX-1033C (Müftü WS) at Q61 (confirming that CX-0579 "contains images of

the NobelActive 5.0 mm implant that I had arranged to be sectioned and measured"). The depth measurements ranged between 35 and 61 microns. *See* CX-0579 at 2-19 (indicating trough depth measurements of 49.7 microns, 52.6 microns, 59.8 microns, 48.0 microns, 43.5 microns, 39.4 microns, 35.4 microns, 35.3 microns, 35.0 microns, 36.3 microns, 49.2 microns, 53.6 microns, 53.1 microns, 53.6 microns, 40.7 microns, 59.0 microns, 61.0 microns, and 53.9 microns).



CX-0579 (annotations added).

Dr. Müftü also testified regarding "charts that [he] prepared mapping each element of claims 15, 17-19 and 32 to the structure of the NobelActive [implants]." CX-1033C (Müftü WS) at Q49-54.

Accordingly, it is determined that the domestic industry products practice claim 15 of the '443 patent.

2. Claim 17

Claim 17 depends from claim 15 and adds the additional limitation "wherein the troughs of the wave pattern follow the spiral trajectory of the thread along a crest of the

thread." As discussed above, the claim term "wherein the troughs of the wave pattern" is construed to mean "wherein the troughs of the wave pattern (having at least two troughs)."

The record evidence does not show that the accused products satisfy the additional limitation recited in claim 17 under the adopted claim construction. *See* JX-0002 ('443 patent); CX-1033 (Müftü WS) at Q47-65; CX-0579; CX-0569C (Nobel Engineering Drawing).

Accordingly, it is determined that Nobel's domestic industry products do not practice claim 17 of the '443 patent.

3. Claim 18

Claim 18 depends from claim 15 and adds the additional limitation "wherein the wave pattern varies along the implant." The record evidence demonstrates that that each of the 3.5 mm, 4.3 mm, and 5.0 mm NobelActive® implants satisfy this additional claim limitation. *See* CX-1033 (Müftü WS) at Q49-54 (confirming that claim charts, including CDX-0596C, CDX-0603C, and CDX-0609C, map the limitation of claim 18 "to the structure of the NobelActive" implants); CX-0569C (NobelActive® 3.5 mm, 4.3 mm, and 5.0 mm engineering drawings); CPX-0003; CPX-0005. As discussed above, the parties have agreed that the claim term "wave pattern varies" should be construed to mean "the wave pattern changes along the axial length of the implant, when seen in side view." Demonstrative slide CDX-0140 illustrates that, when seen in side view, the wave pattern on the NobelActive® implant changes inasmuch as the dimensions of the peaks surrounding the troughs change in each thread rotation. Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 135-36.

Accordingly, it is determined that Nobel's domestic industry products practice claim 18 of the '443 patent.

4. Claim 19

Claim 19 depends from claim 15 and adds the additional limitation "wherein the trough varies along the spiral trajectory." The record evidence demonstrates that each of the 3.5 mm, 4.3 mm, and 5.0 mm NobelActive® implants satisfies this additional claim limitation. *See* CX-1033C (Müftü WS) at Q49-54 (confirming that claim charts, including CDX-0597C, CDX-0604C, and CDX-0610C, map the limitation of claim 19 "to the structure of the NobelActive" implants); CX-0569C (NobelActive® 3.5 mm, 4.3 mm, and 5.0 mm engineering drawings); CPX-0003; CPX-0005. In particular, the evidence shows that the trough on the NobelActive® implants varies along the spiral trajectory with respect to the depth of the trough, as demonstrated by the measurements taken at various locations along the spiral trajectory of the trough. *See* CX-0577 (NobelActive 3.5 x 15mm measurements) at 2-18 (indicating trough depth measurements of 42.5 microns, 40.6 microns, 38.6 microns, 38.0 microns, 20.4 microns, 27.6 microns, 16.1 microns, 30.9 microns, 23.6 microns, 34.1 microns, 40.5 microns, 21.3 microns, 30.1 microns, 30.0 microns, 28.1 microns, 27.9 microns, and 26.6 microns); CX-0578 (NobelActive 4.3 x 15mm measurements) at 2-17 (indicating trough depth measurements of 45.4 microns, 29.4 microns, 38.9 microns, 29.0 microns, 48.1 microns, 63.0 microns, 34.5 microns, 49.5 microns, 57.0 microns, 18.7 microns, 45.5 microns, 40.6 microns, 41.6 microns, 53.1 microns, 53.1 microns, and 50.4 microns); CX-0579 (NobelActive 5 x 15mm measurements) at 2-19 (indicating trough depth measurements of 49.7 microns,

52.6 microns, 59.8 microns, 48.0 microns, 43.5 microns, 39.4 microns, 35.4 microns, 35.3 microns, 35.0 microns, 36.3 microns, 49.2 microns, 53.6 microns, 53.1 microns, 53.6 microns, 40.7 microns, 59.0 microns, 61.0 microns, and 53.9 microns). Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 135-36.

Accordingly, it is determined that Nobel's domestic industry products practice claim 19 of the '443 patent.

5. Claim 30

Claim 30 depends from claim 15 and adds the additional limitation "wherein the trough has a depth of between approximately 50 to 150 μm." The record evidence demonstrates that each of the 3.5 mm, 4.3 mm, and 5.0 mm NobelActive® implants satisfies this additional claim limitation. In particular, Dr. Müftü testified regarding measurements he commissioned of the NobelActive® implants: "These grooves are also approximately 50-150 microns deep as required by Claim 30." CX-1033C (Müftü WS) at Q48. Nobel also presented evidence showing that measurements of the trough depth at various locations along the threads were approximately between 20.4 and 42.5 microns for the NobelActive® 3.5 mm implant (*see* CX-0577 at 2-18), approximately between 29.0 and 63 microns for the NobelActive® 4.3 mm implant (*see* CX-0578 at 2-17), and approximately between 35 and 61 microns for the NobelActive® 5.0 mm implant (*see* CX-0579 at 2-19). Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 135-36.

Accordingly, it is determined that Nobel's domestic industry products practice claim 30 of the '443 patent.

6. Claim 32

Claim 32 depends from claim 15 and adds the additional limitation "wherein the at least one trough of the wave pattern extends along an apex of the thread." The record evidence demonstrates that the 3.5 mm and 4.3 mm NobelActive® implants satisfy this additional claim limitation. *See* CX-1033C (Müftü WS) at Q49-54 (confirming that claim charts, including CDX-0598C and CDX-0605C map the limitation of claim 32 "to the structure of the NobelActive" 3.5 mm and 4.3 mm implants); CX-0569C (NobelActive® 3.5 mm and 4.3 mm engineering drawings) at 1, 2; CPX-0003; CPX-0005. As discussed above, the claim term "apex of the thread" is construed to mean "outermost point on the thread." The evidence shows that the troughs on the 3.5 mm and 4.3 mm NobelActive® implants extend along the outermost point on the thread, as illustrated in demonstrative slide CDX-0605C. Instradent does not dispute that this limitation is satisfied. *See* Resps. Br. at 135-36.

Accordingly, it is determined that Nobel's domestic industry products practice claim 32 of the '443 patent.

E. Validity

1. Anticipation

Instradent argues that asserted claims 15, 17-19, 30, and 32 of the '443 patent are invalid for anticipation under 35 U.S.C. § 102 because all claim limitations are present in

the endodontic stabilizer disclosed in U.S. Patent No. 4,103,422 ("Weiss").[33] Resps. Br. at 141-53.

Weiss, which was cited by the Examiner during prosecution of the '443 patent, discloses a threaded self-tapping endodontic stabilizer for insertion in the jawbone of the patient's mouth through an aperture in a loose tooth to stabilize the tooth. JX-0020 (Weiss patent) at Abstract. Instradent also contends that the same Weiss endodontic stabilizer is depicted in a book entitled Principles and Practice of Implant Dentistry, by Charles M. Weiss, D.D.S. and Adam Weiss, (1st ed. 2001). *See* Resps. Br. at 142; RX-0147 (Implant Dentistry Book). To show that these prior-art references disclose the claim limitation of a "trough depth in the range of between approximately 25 to 200 μm" as required by independent claim 15, Instradent relies on measurements of Figure 1 of the Weiss patent and of a picture of the stabilizer in the *Implant Dentistry* book, both of which are reproduced below. *See* Resps. Br. at 143-46.

[33] Weiss was issued on August 1, 1978, and therefore qualifies as prior art to the '443 patent, which was filed on December 18, 2002.

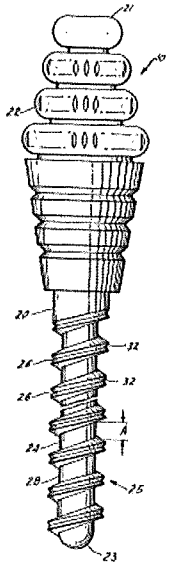


FIG. 1

JX-0120 (Weiss) at Fig. 1.

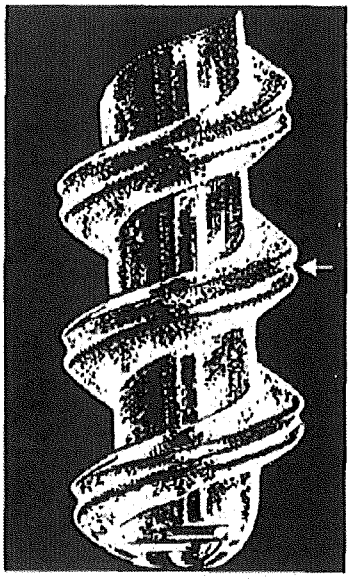


FIG. 19-10 ■ Stabilizer threads with sluiceway indicated by arrow.

JX-0165 (*Implant Dentistry*) at 5.

The evidence does not support a finding, however, that these prior art references disclose every claim limitation of asserted claims 15, 17-19, 30, and 32 of the '443 patent. In particular, Instradent has not shown that either the Weiss patent or *Implant Dentistry* book disclose to one of ordinary skill in the art the claimed trough depth of 25 to 200 μm. Indeed, Nobel's expert Dr. Müftü testified that neither the Weiss patent nor the Weiss book chapter adequately discloses the depth of the grooves at issue. *See* CX-1039 (Müftü WS) at Q63 ("Weiss does not disclose each element of the asserted claims by clear and convincing evidence because it does not adequately disclose the depth of the grooves."). Instradent contends that the grooves on the threading of the endodontic stabilizers shown in the Weiss prior art can be calculated by making measurements on the images and using other dimensions stated in those references, but the Weiss patent's drawings are presumptively not to scale. *See* Resps. Br. 144-46; *see also Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("Under our precedent . . . it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."); *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1268 (Fed. Cir. 2012) ("This court has repeatedly cautioned against overreliance on drawings that are neither expressly to scale nor linked to quantitative values in the specification.").

Dr. Kenneth Judy, a named inventor on the Weiss patent, testified to that end:

> Q. And you don't know if Figure 1 is drawn to scale; is that correct?

A. I do not.

JX-0198 (Judy Dep.) at 126.

Nobel's expert Dr. Müftü also testified: "As an engineer, I see nothing indicating that the patent drawings in the Weiss patent are intended to be precisely to scale to enable dimensions in the micron range to be accurately determined." CX-1039 (Müftü WS) at Q63.

Inasmuch as Instradent did not present any expert testimony regarding the alleged anticipation of the '443 patent by the Weiss endodontic stabilizer, it has not adduced evidence showing that Dr. Müftü's analysis of the depth of the grooves on the Weiss device is not correct. Accordingly, it has not been shown that the Weiss endodontic stabilizer, as described and depicted in the Weiss patent and other publications, discloses clearly and convincingly the 25-200 micron trough depth required by all of the asserted '443 patent claims.

Therefore, Instradent has not met its burden to prove by clear and convincing evidence that the asserted claims of the '443 patent are anticipated pursuant to 35 U.S.C. § 102.

2. Obviousness

Instradent argues that all asserted claims of the '443 patent are invalid as obvious over certain combinations of prior art references. *See* Resps. Br. at 154-58. Specifically, Instradent alleges that the asserted claims are obvious in view of the Weiss endodontic

stabilizer discussed above, U.S. Patent No. 6,129,730 ("Bono")[34] (JX-0017), and U.S. Patent No. 6,364,663 ("Dinkelacker")[35] (JX-0018). *Id.*

Bono discloses a bone screw that has a desirable pullout value for coupling a medical device to a bone. *See* JX-0017 (Bono) at col. 1, lns. 5-8. Bono discloses that the outer surface of the implanted bone screw has a wave pattern with at least one trough, shown in Figure 4 reproduced below. *Id.* at col. 3, lns. 5-9; Fig. 4. Bono discloses that the implanted bone screw has troughs, such as 37, along a crest 35 of the thread. *Id.* at Figs. 3-4.

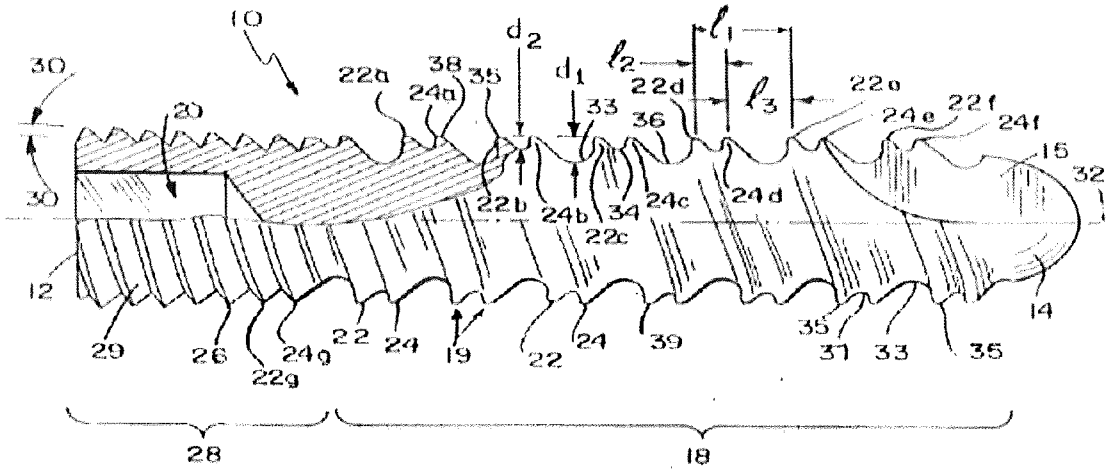


FIG. 4

JX-0017 (Bono) at Fig. 4.

The bone screw disclosed by Bono includes a pair of spiral threads having a spiral groove, with the shallower trough having depth d_2 that extends along the thread.

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[34] Bono was issued on October 10, 2000, and therefore qualifies as prior art to the '443 patent. *See* JX-0017 (Bono).

[35] Dinkelacker was issued on April 2, 2002, and therefore qualifies as prior art to the '443 patent. *See* JX-0018 (Dinkelacker).

Instradent argues that the '443 patent claim limitation "wave patterns hav[ing] a trough with a depth that extends in a spiral course" are shown in Figures 3 and 4 of Bono. *See* Resps. Br. at 155. It is also argued that Bono expressly discloses "a wave pattern with at least one trough disposed on the outer surface of the thread, the trough extending in a course that substantially follows a spiral trajectory of the thread." *Id.*

As for the Dinkelacker reference, it discloses an implant having grooves with a depth in the range of 25-200 microns on the body of the implant. JX-0018 (Dinkelacker) at col. 3, lns. 28-45. These grooves are illustrated in Figure 1 of the Dinkelacker reference, with a close-up of the grooves shown in Figure 4. Both figures are reproduced below:

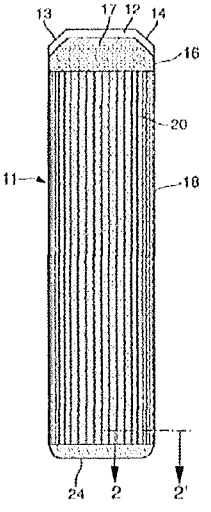

Fig. 1

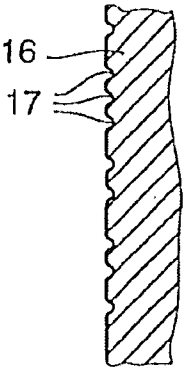

Fig. 4

JX-0018 (Dinkelacker) at Figs. 1, 4.

Based on these disclosures, Instradent argues that Dinkelacker teaches "a dental implant having grooves formed in the outer surface of the implant, tangential to the

longitudinal axis of the implant, tangentially, having a depth of 50-100 microns, which improve osseointegration." *See* Resps. Br. at 156.

Taking these references into account, Instradent argues: "One of ordinary skill would have looked to the disclosure of the above-cited prior art references when improving upon a dental implant to add known features such as a groove having a depth of 25-200 microns to the thread." Resps. Br. at 158. It is further argued:

> [I]n improving upon any of the threaded dental implants cited herein, one of ordinary skill would have looked to the teachings of at least Dinkelacker, in combinations with threaded implants such as Weiss, to add a groove to the outer edge of the thread, with the thread being in the range of 25-200 microns, in order to further promote osseointegration of the implant with the surrounding bone.

Id.

Nevertheless, the record evidence fails to show, clearly and convincingly, that the asserted claims of the '443 patent are invalid under 35 U.S.C. § 103. In particular, Instradent failed to adduce evidence showing why one of ordinary skill in the art would have been motivated to combine the prior art references to achieve the claimed invention. Specifically, Instradent presented no expert testimony to show that a specific combination of prior art references would have embodied all the limitations of the asserted claims and would have been obvious to one of ordinary skill in the art. *See, e.g.*, *Alexsam*, 715 F.3d at 1348 (finding claims not invalid because "[e]xpert testimony was required not only to explain what the prior-art references disclosed, but also to show that a person skilled in the art would have been motivated to combine them in order to achieve the claimed invention," and defendant provided no such expert testimony).

Moreover, as with the '977 patent, Moreover, Nobel introduced compelling evidence of copying as it relates to secondary considerations of non-obviousness. CX-1037C (Hurson RWS) at Q51, Q61. In particular, the evidence supports a finding that JJGC copied the NobelActive® implant or a clone of the implant. [

]. RX-0002C (Golin WS) at Q15-16; Golin Tr. 690-692. [

]. Golin Tr. 693, 701. [

]. Golin Tr. 699-700, 701.

Accordingly, Instradent has not met its burden to prove by clear and convincing evidence that the asserted claims of the '443 patent are obvious pursuant to 35 U.S.C. § 103.

3. Lack of a Written Description

Instradent argues that the asserted claims of the '443 patent are invalid for failure to satisfy the written description and/or utility requirements of 35 U.S.C. § 112. *See* Resps. Br. at 138-40. The record evidence, however, does not support Instradent's argument. In particular, Instradent failed to present expert testimony regarding the understanding of a person having ordinary skill in the art with respect to the '443 patent. In addition, Nobel presented the unrebutted testimony of Dr. Müftü confirming that the asserted claims satisfy the written description requirement. CX-1039C (Müftü WS) at

Q108 ("the asserted claims of the '443 patent are adequately described in the patent specification to satisfy the written description requirement").

4. Lack of Enablement

Instradent argues that the asserted claims of the '443 patent are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112. *See* Resps. Br. at 140-41. Instradent's argument is not supported by the record evidence. In particular, Instradent did not present any expert testimony regarding the understanding of a person having ordinary skill in the art with respect to the '443 patent and whether or not a skilled artisan would have been unable to make the claimed invention without undue experimentation. By contrast, the unrebutted testimony of Nobel's expert Dr. Müftü confirms that the asserted claims of the '443 patent satisfy the enablement requirement. CX-1039C (Müftü WS) at Q112.

F. Inequitable Conduct

Instradent argues that Mr. Narula, prosecution counsel for the '443 patent, committed inequitable conduct during by delaying disclosure of material prior art to the PTO until after he prevailed on appeal to the PTAB tribunal. *See* Resps. Br. at 165-79. The record evidence, fails to support Instradent's position.

Mr. Narula and the applicant submitted U.S. Patent No. 4,103,422 to Weiss et al. ("the '422 patent" or "Weiss"), U.S. Patent No. 6,129,730 to Bono ("the '730 patent" or "Bono"), and U.S. Patent No. 6,364,663 to Dinkelacker ("the '663 patent" or "Dinkelacker") to the Patent Office during prosecution of the '443 patent, and each of those references was considered by the examiner. JX-0004 at 1023-27, 2212-13. Two of

these references were submitted years before the PTAB appeal and years before the '443 patent issued. Specifically, Mr. Narula submitted the Bono reference to the Patent Office in an Information Disclosure Statement ("IDS") on March 12, 2010. JX-0004 at 1023-27. The Weiss patent was cited by the examiner in an office action dated April 30, 2007, years before Mr. Narula submitted the reference again in the February 3, 2014 IDS. JX-0004 at 202-11. Accordingly, Instradent's theory of "delayed disclosure" cannot prevail with respect to the Weiss and Bono references, inasmuch as they were disclosed years before the '443 patent issued.

Instradent's allegations of inequitable conduct based upon a "failure to timely disclose the '663 [Dinkelacker] patent," also cannot prevail. *See* Resps.Br. at 178. The record evidence shows that Mr. Narula submitted this art to the examiner for consideration while prosecution of the '443 patent on the merits was still open. Mr. Narula not only disclosed Dinkelacker to the examiner, but he also ensured that the examiner had time to consider the reference by filing a request for continued examination ("RCE") shortly after an initial notice of allowance. *See* JX-0004 at 1842-43 (RCE form), 2212-13 (IDS form). The evidence does not suggest that "but for" the timing of the disclosure of Dinkelacker, the examiner would have rejected the pending claims of the '443 patent.

Instradent also argues that Messrs. Narula and Hall (the named inventor of the '443 patent) knew that the Weiss and Dinkelacker references "contradicted their arguments on appeal" and delayed disclosure of these references until after prevailing on appeal. Resps. Br. at 172. This argument fails with respect to the Weiss reference for at

least two reasons. First, as discussed above, Weiss was cited in an early office action during prosecution, so there was no delay in disclosure. Second, the applicant's arguments on appeal did not contradict the disclosure in Weiss because Weiss does not disclose the claimed trough depth. *See* CX-1039 (Müftü WS) at Q63. In particular, Mr. Hall submitted a declaration during the prosecution of another application, the '263 application, stating that "Weiss also fails to teach an intermediate wave pattern having a depth in the range of 25 to 200 μm," and the examiner in that case found that Weiss did not teach "the depth of 10 to 75 micrometers." JX-0005 at 233 (emphasis in original), 202.

Instradent's arguments regarding the Dinkelacker reference also cannot prevail. It is argued that, during the appeal of the unrelated '817 application, Mr. Narula distinguished the Dinkelacker patent because it did not teach that grooves on an implant's coronal portion would have an osseointegrating capability. Resps. Br. at 170-71. This was not, however, the argument that Mr. Narula presented to the PTO. JX-0006 at 527 (arguing that a skilled artisan would not be motivated to "take the teachings of Dinkelacker which discloses a groove pattern *for the lower anchoring portions* of the implant . . . and then apply same groove pattern *to the collar portion* of the implant of Ricci") (emphasis added); JX-0006 at 5.

It is further argued that Mr. Narula "had an affirmative obligation to cite the Decision on Appeal in the '817 application to the Board considering the appeal in the '443 prosecution, and to Examiner Eide, but failed to do so," and that Mr. Narula did not "correct the record and inform the panel that there was another pending appeal in a

related application." Resps. Br. at 174. Instradent fails to show, however, that Mr. Narula had a duty of disclosure under the circumstances. Here, Dinkelacker itself expressly contains the disclosure that the Board discussed, and Mr. Narula notified the examiner of the pending '817 application. *See* JX-0018 at col. 6, lns. 23-27. The Board decision from the '817 application, which only summarized the Dinkelacker teachings, is cumulative of the Dinkelacker reference itself, which Mr. Narula did disclose during the pendency of the application for the '443 patent. *See* Compls. Br. at 206.

In addition, Mr. Narula could not have cited "the Decision on Appeal in the '817 application to the Board considering the appeal in the '443 prosecution" because the decision in the '817 application had not issued by the time the '430 application was on appeal. The appeal brief for the '430 application was filed on February 1, 2011 and the reply brief on June 8, 2011 (JX-0004 at 1525, 1602), oral argument was held on June 18, 2013 (*id.* at 1799), and the Board issued its decision on October 17, 2013 (*id.* at 1802). Meanwhile, the decision in the '817 application, which discussed Dinkelacker, did not issue until November 15, 2013. JX-0006 at 630.

Instradent also argues that Messrs. Narula and Hall committed inequitable conduct by delaying disclosure of more than 160 prior art references to the PTO until the very end of the patent prosecution process. *See* Resps. Br. at 177. It is suggested that Messrs. Narula and Hall attempted to hide the most relevant references by concealing them in a much larger submission. *See id.* Nevertheless, courts addressing similar situations have generally rejected such "burial" theories of inequitable conduct. *See Radiancy, Inc. v. Viatek Consumer Prods. Grp.*, No. 13-cv-3767, 2014 U.S. Dist. LEXIS

46024, at *19 (S.D.N.Y. Apr. 1, 2014). Instradent also argues that Messrs. Narula and Hall's timing was designed to lull the examiner into allowing the claims after being "directed by the Board" to allow them. *See* Resps. Br. at 177. The evidence suggests otherwise. Indeed, Mr. Narula's filing of an RCE gave the examiner additional time to consider the additional submitted art following the Board's determination.

Therefore, for the reasons set forth above, it is determined that the '443 patent is not unenforceable for inequitable conduct.

VII. Domestic Industry – Economic Prong

A. General Principles of Law

A violation of section 337(a)(1)(B), (C), (D), or (E) can be found "only if an industry in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). Section 337(a) further provides:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

These statutory requirements consist of an economic prong (which requires certain activities)[36] and a technical prong (which requires that these activities relate to the intellectual property being protected). *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 13 (May 16, 2008) ("*Stringed Musical Instruments*"). The burden is on the complainant to show by a preponderance of the evidence that the domestic industry requirement is satisfied. *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-694, Comm'n Op. at 5 (July 22, 2011) ("*Navigation Devices*").

With respect to the economic prong, and whether or not section 337(a)(3)(A) or (B) is satisfied, the Commission has held that "whether a complainant has established that its investment and/or employment activities are significant with respect to the articles protected by the intellectual property right concerned is not evaluated according to any rigid mathematical formula." *Certain Printing and Imaging Devices and Components*

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[36] The Commission practice is usually to assess the facts relating to the economic prong at the time that the complaint was filed. *See Certain Coaxial Cable Connectors and Components Thereof and Products Containing Same*, Inv. No. 337-TA-560, Comm'n Op. at 39 n.17 (Apr. 14, 2010) ("We note that only activities that occurred before the filing of a complaint with the Commission are relevant to whether a domestic industry exists or is in the process of being established under sections 337(a)(2)-(3).") (citing *Bally/Midway Mfg. Co. v. U.S. Int'l Trade Comm'n*, 714 F.2d 1117, 1121 (Fed. Cir. 1983)). In some cases, however, the Commission will consider later developments in the alleged industry, such as "when a significant and unusual development occurred after the complaint has been filed." *See Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., at 5-6 (Jan. 20, 2012) ("[I]n appropriate situations based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the complaint.").

Thereof, Inv. No. 337-TA-690, Comm'n Op. at 27 (Feb. 17, 2011) ("*Printing and Imaging Devices*") (citing *Certain Male Prophylactic Devices*, Inv. No. 337 TA-546, Comm'n Op. at 39 (Aug. 1, 2007)). Rather, the Commission examines "the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* "The determination takes into account the nature of the investment and/or employment activities, 'the industry in question, and the complainant's relative size.'" *Id.* (citing *Stringed Musical Instruments* at 26).

With respect to section 337(a)(3)(C), whether an investment in domestic industry is "substantial" is a fact-dependent inquiry for which the complainant bears the burden of proof. *Stringed Musical Instruments* at 14. There is no minimum monetary expenditure that a complainant must demonstrate to qualify as a domestic industry under the "substantial investment" requirement of this section. *Id.* at 25. There is no need to define or quantify an industry in absolute mathematical terms. *Id.* at 26. Rather, "the requirement for showing the existence of a domestic industry will depend on the industry in question, and the complainant's relative size." *Id.* at 25-26.

B. The Domestic Industry Articles

A domestic industry is considered to exist with respect to "articles" protected by the patent. 19 U.S.C. § 1337(a)(3). This express articles requirement applies to subparagraphs (A), (B), and (C). *Certain Computers & Computer Peripheral Devices, and Components Thereof and Products Containing Same*, Inv. No. 337-TA-841, Comm'n Op. at 32 (Jan. 9, 2014). To determine what "article" is protected by the patent, the Commission has looked to the "realities of the marketplace." *Certain Integrated Circuit*

Chips and Products Containing the Same, Inv. No. 337-TA-859, Comm'n Op. at 36 (Aug. 22, 2014).

In this investigation, the evidence shows that the domestic industry products NobelActive® NP and RP dental implants are commercialized and used in an environment that includes complementary tools and components, *e.g.*, surgical tools used to insert the implants and prosthetic components to restore the patients' teeth. *See* CX-1032C (McGavock WS) at Q67, Q79, Q85; JX-0305 (2013 iData Report); JX-0560C (2015 iData Report); Mulhern Tr. 880, 881-882, 884; CX-0763 (Am. Identification of Domestic Industry Products). Nobel adduced evidence showing that dental implants cannot be used in isolation, but are normally supplied as part of a complete implant system by the manufacturers. *See* CX-1036C (Sullivan WS) at Q32; Bernardes Tr. 778; Sullivan Tr. 73-74:1; *see also* Mulhern Tr. 895-896. Moreover, Instradent's expert Dr. Bernardes testified that for clinical success, it is best to get the implant and components all from the same company. Bernardes Tr. 778.

The marketplace for dental implants also involves educating dentists how to insert the implants based on the circumstances of the implant site, providing the necessary surgical tools,[37] including drills, for placing the implant, and providing various compatible restorative components. JX-0305 (2013 iData Report); JX-0560C (2015

[37] "[T]here is no requirement that the components must be developed or produced specifically for the domestic industry products." *Certain Kinesiotherapy Devices and Components Thereof*, Inv. No. 337-TA- 823, Comm'n Op. at 27 (July 12, 2013).

iData Report); CX-1036C (Sullivan WS) at Q26-36; CX-1032C (McGavock WS) at Q49-67, Q88, Q161; Mulhern Tr. 878.

Instradent argues that products other than the NobelActive® implant should not be considered as part of the economic prong analysis because they are non-patented components that do not practice either of the asserted patents. *See* Resps. Br. at 182-85. The domestic industry analysis is fact-specific, however, and dependent upon the realities of the marketplace at issue. In previous investigations, the Commission has evaluated whether or not non-patented components are central to allowing the complainant to exploit the patented technology. *See Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, Inv. No. 337-TA-890, Initial Determination at 148-50 (Aug. 21, 2014) (noting that a patented humidifier "cannot be used alone" without the unpatented flow generator). Here, Nobel presented evidence showing that the NobelActive® implants are not used in isolation and require other surgical and prosthetic tools and components to restore a patient's tooth.

C. Analysis

For the reasons set forth below, the evidence supports a finding that the economic prong of the domestic industry requirement has been met for both the asserted patents. The record evidence show that Nobel invests over [ ] in the United States, on an annual basis, for labor costs, operating costs, and capital expenditures related to the NobelActive® NP and RP products. *See* CX-1031C (Jereb WS); CX-1032C (McGavock WS).

Like many complainants appearing before the Commission, Nobel does not normally track expenses and capital expenditures by any particular product. CX-1032C (McGavock WS) at Q82; CX-1031C (Jereb WS) at Q33-34. For the purpose of demonstrating the existence of a domestic industry, therefore, Nobel estimated the percentage of its investments that could be attributed to the NobelActive® NP and RP systems using a relative revenue approach and relative unit volume approach. CX-1032C (McGavock WS) at Q84-97. Such an allocation method is sufficient to demonstrate the investments cited in support of Nobel's domestic industry claims. *See Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, USITC Pub. No. 4120, Comm'n Op. at 25-26 (Dec. 2009) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.").

1. Plant and Equipment

Nobel relies on two domestic sites to establish that it has made a "significant investment in plant and equipment" in the United States. One such site is in Yorba Linda, California, and the second site is in Mahwah, New Jersey. CX-1032C (McGavock WS) at Q103.

The Yorba Linda site includes two buildings, one for manufacturing and the other for commercial activities. CX-1032C (McGavock WS) at Q103. The manufacturing building comprises approximately [ ] and contains [ ] pieces of equipment used to manufacture implant systems, including [ ] pieces of equipment that are directly used to manufacture or package NobelActive® components. *Id.* at Q104. The second building comprises approximately [ ] and houses, for

example, distribution, receiving, customer support, technical support, and training and educational facilities. The latter includes the Nobel Biocare Training Institute. *Id.* at Q103. The equipment present in both buildings at the Yorba Linda site is valued at [ ]. *Id.* at Q108. The evidence shows that investments in plant and equipment in 2014 attributable to the NobelActive® NP and RP systems at this site was at least [ ]. *Id.* at Q111-127. Nobel spent approximately [ ] in 2014 on rent at its Yorba Linda site. *Id.* at Q108. Approximately [ ] of the rent for 2014 is attributable to the NobelActive® NP and RP systems. *Id.* at Q126.

The Mahwah site manufactures simple copings, crowns, bridges, abutments, full-arch bridges, implant overdenture bars, and surgical templates used in conjunction with the patented implant devices. CX-1032C (McGavock WS) at Q128. The building at the Mahwah site comprises approximately [ ] of space, of which approximately [ ] is dedicated to manufacturing. *Id.* at Q129. The equipment at this location is valued at [ ]. *Id.* at Q132. Investments in plant and equipment in 2014 attributable to NobelActive® NP and RP systems at this site was at least [ ]. *Id.* at Q142-143. The record evidence demonstrates that Nobel spent approximately [ ] in 2014 on rent at its Mahwah facility. *Id.* at Q132. Approximately [ ] of this rent expense is attributable to NobelActive® NP and RP systems. *Id.* at Q139.

2. Labor and Capital

Nobel argues that it has engaged in "significant employment of labor or capital" in the United States. *See* CX-1032C (McGavock WS) at Q148-177, Q182. As of 2014,

Nobel had approximately [ ] employees in the United States. *Id.* Excluding sales, marketing, and general administration, approximately [ ] employees are attributable to the NobelActive® NP and RP systems. This amounts to a 2014 labor cost of approximately [ ]. *See id.*

3. Exploitation of the Asserted Patents

"'Exploitation' is a generally broad term that encompasses activities such as efforts to improve, develop, or otherwise take advantage of the asserted patent." *Certain Integrated Circuit Chips and Products Containing the Same*, Inv. No. 337-TA-859, Comm'n Op. at 39 (Aug. 22, 2014). As noted in *Integrated Circuit Chips*, "the more closely related the domestic activities are to the patented technology, the greater may be the weight of the activities in determining whether they constitute a domestic industry." *Id.* at 40.

Nobel argues that it has made a "substantial investment in its exploitation" of the asserted patents, in the form of training and education allocable to the NobelActive® implant. *See* CX-1032C (McGavock WS) at Q185-194. Nobel's investment in training and education relating to NobelActive® began in 2008 when the system was first launched. *Id.* at Q191. Cumulative training and education investments attributable to NobelActive® NP and RP amount to approximately [ ]. *Id.* at Q194-195.

4. Summary

In view of the foregoing evidence, it is determined that Nobel's annual investments of over [ ] in the United States, in the context of the U.S. marketplace for dental implants, are "significant" and "substantial." This includes an

investment of [ ] in 2014 in plant and equipment out of a total investment of [ ].

In a recent panel decision, the Federal Circuit held that qualitative factors alone are insufficient to satisfy the "significant investment" and "significant employment" requirements of section 337. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 885 (Fed. Cir. 2015). Specifically:

> The plain text of § 337 requires a quantitative analysis in determining whether a petitioner has demonstrated a "significant investment in plant and equipment" or "significant employment of labor or capital." [T]he terms 'significant' and 'substantial' refer to an increase in quantity, or to a benchmark in numbers. The plain meaning of an "investment" is "an expenditure of money for income or profit or to purchase something of intrinsic value." Webster's Third New International Dictionary 1190 (1986). An "investment in plant and equipment" therefore is characterized quantitatively, *i.e.*, by the amount of money invested in the plant and equipment. Similarly, "capital" is "a stock of accumulated goods" and "labor" is "human activity that produces goods or provides the services in demand in an economy." *Id.* at 332, 1259. All of the foregoing requires a quantitative analysis in order to determine whether there is a "significant" increase or attribution by virtue of the claimant's asserted commercial activity in the United States.

Id. at 883.

Here, as discussed above, the record evidence shows that Nobel spent approximately [ ] on rent in 2014 at its Yorba Linda and Mahwah facilities, of which approximately [ ] is attributable to the NobelActive® NP and RP systems. The evidence also shows that 2014 investments in plant and equipment at these two sites attributable to the NobelActive® NP and RP systems total at least [ ]. Quantitatively, domestic expenditures of [ ] in rent and [ ] in plant and

equipment for the year 2014 rise to the level of "significant investment" as set forth in section 337(a)(3)(A). It is therefore determined that Nobel has satisfied the economic prong of the domestic industry requirement set forth in 19 U.S.C. § 1337(a)(3)(A).

Moreover, as discussed above, the record evidence shows that Nobel spent approximately [ ] in domestic labor costs attributable to the NobelActive® NP and RP systems in 2014. Quantitatively, this level of domestic expenditure rises to the level of "significant employment of labor and capital" as set forth in section 337(a)(3)(B). It is therefore determined that Nobel has satisfied the economic prong of the domestic industry requirement set forth in 19 U.S.C. § 1337(a)(3)(B).

Further, the cumulative training and education investments attributable to the NobelActive® NP and RP systems, which were discussed above and total approximately [ ], quantitatively satisfies the requirement of "substantial investment" in the exploitation of the asserted patents set forth in section (a)(3)(C). It is therefore determined that Nobel has satisfied the economic prong of the domestic industry requirement set forth in 19 U.S.C. § 1337(a)(3)(C).

VIII. Conclusions of Law

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this investigation.

2. The accused products have been imported into the United States.

3. The accused products infringe asserted claims 1-5 and 19 of U.S. Patent No. 8,714,977 and asserted claims 15, 18, 19, 30, and 32 of U.S. Patent No. 8,764,443.

4. The accused products do not infringe asserted claim 17 of the '443 patent.

5. The domestic industry requirement has been satisfied with respect to the '977 and '443 patents.

6. It has been shown by clear and convincing evidence that asserted claims 1-5 and 19 of the '977 patent are invalid under 35 U.S.C. § 102.

7. It has not been shown by clear and convincing evidence that the asserted claims of the '443 patent are invalid.

8. It has not been shown that the asserted claims of the '977 and '443 patents are unenforceable due to inequitable conduct.

IX. Initial Determination on Violation

Accordingly, it is the initial determination of the undersigned that a violation of section 337 (19 U.S.C. § 1337) has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain dental implants with respect to asserted claims 15, 18, 19, 30, and 32 of U.S. Patent No. 8,764,443.

Further, this initial determination, together with the record of the hearing in this investigation consisting of (1) the transcript of the hearing, with appropriate corrections as may hereafter be ordered, and (2) the exhibits received into evidence in this investigation, is hereby certified to the Commission.

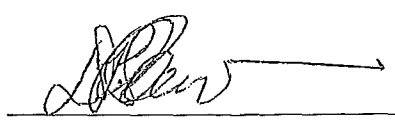
In accordance with 19 C.F.R. § 210.93(c), all material found to be confidential by the undersigned under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this initial determination upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order, as amended, issued in this investigation.

Pursuant to 19 C.F.R. § 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review pursuant to § 210.43(a) or the Commission, pursuant to § 210.44, orders on its own motion a review of the initial determination or certain issues herein.

X. Order

To expedite service of the public version, each party is hereby ordered to file with the Commission Secretary no later than November 9, 2015, a copy of this initial determination with brackets to show any portion considered by the party (or its suppliers of information) to be confidential, accompanied by a list indicating each page on which such a bracket is to be found. At least one copy of such a filing shall be served upon the office of the undersigned, and the brackets shall be marked in red. If a party (and its suppliers of information) considers nothing in the initial determination to be confidential, and thus makes no request that any portion be redacted from the public version, then a statement to that effect shall be filed.



David P. Shaw
Administrative Law Judge

Issued: October 27, 2015

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION – PUBLIC VERSION** has been served by hand upon the Commission Investigative Attorney, **Todd Taylor, Esq.**, and the following parties as indicated, on

NOV 24 2015

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street SW, Room 112A
Washington, DC 20436

FOR COMPLAINANTS NOBEL BIOCARE SERVICES AG AND NOBEL BIOCARE USA, LLC:	
John B. Sganga, Jr., Esq. **KNOBBE, MARTENS, OLSON & BEAR, LLP** 2040 Main Street, 14th Floor Irvine, CA 92614	( ) Via Hand Delivery (X) Express Delivery ( ) Via First Class Mail ( ) Other: _____
FOR RESPONDENTS INSTRADENT USA, INC. AND JJGC INDÚSTRIA E COMÉRCIO DE MATERIAIS DENTÁRIOS S/A:	
Liane M. Peterson, Esq. **FOLEY & LARDNER LLP** Washington Harbour 3000 K Street NW, Suite 600 Washington, DC 20007-5109	( ) Via Hand Delivery (X) Express Delivery ( ) Via First Class Mail ( ) Other: _____