In the Matter of

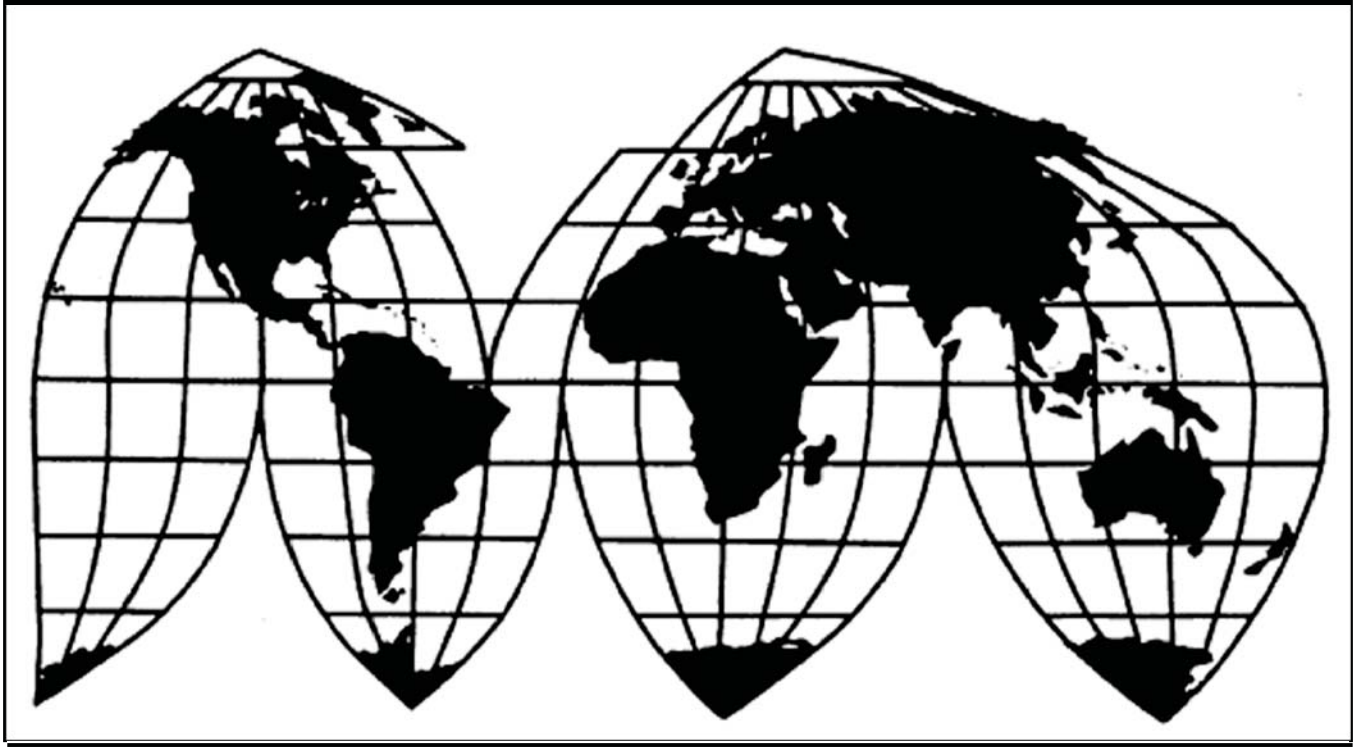
Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof

Investigation No. 337-TA-604

Volume 1 of 2

Publication 4139 **April 2010**

U.S. International Trade Commission



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In the Matter of

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

In the Matter of **CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND RELATED INTERMEDIATE COMPOUNDS THEREOF**	**Investigation No. 337-TA-604**

NOTICE OF COMMISSION DETERMINATION TO REVIEW A FINAL INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination ("ID") of the presiding administrative law judge ("ALJ") in the above-captioned investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"). The ALJ found no violation of section 337 except with respect to certain non-participating and defaulted respondents.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. 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 (*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 May 10, 2007, based upon a complaint filed on behalf of Tate & Lyle Technology Ltd. of London, United Kingdom, and Tate & Lyle Sucralose, Inc. of Decatur, Illinois (collectively, "Tate & Lyle"). The complaint alleged violations of section 337(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of sucralose, sweeteners containing sucralose, and related intermediate compounds thereof by reason of infringement of various claims of United States Patent Nos. 4,980,463 ("the '463 patent"); 5,470,969 ("the '969 patent"); 5,034,551 ("the '551 patent"); 5,498,709; and 7,049,435. The notice of investigation named twenty-five respondents.

On August 15, 2007, the Commission issued notice of its determination not to review an ID allowing JK Sucralose, Inc. to intervene as a respondent to the investigation. On August 30, 2007, the Commission issued notice of its determination not to review an ID terminating the investigation with respect to ProFood International Inc. on the basis of a consent order. On October 3, 2007, the Commission issued notice of its determination not to review an ID adding Heartland Sweeteners, LLC as a respondent to the investigation.

On September 22, 2008, the presiding administrative law judge issued a final initial determination ("final ID") finding no violation of section 337 in the above-identified investigation (with the exception of certain non-participating and defaulted respondents).

On October 6, 2008, Tate & Lyle, four sets of respondents, and the Commission investigative each filed a petition for review. On October 14, 2008, each filed a response.

Having examined the final ID, the petitions for review, the responses thereto, and the relevant portions of the record in this investigation, the Commission has determined to review the final ID in its entirety.

The Commission requests briefing based on the evidentiary record on the issues on review. The Commission is particularly interested in responses to the following questions:

(1) Regarding the issue of whether 19 U.S.C. § 1337(a)(1)(B)(ii) extends to the '551, '969, and '463 patents: Is this issue a matter of jurisdiction or does it go to the merits of whether there is a violation of section 337? Does the exclusion order in the investigation which was the subject of *In re Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934) suggest that § 1337(a)(1)(B)(ii) has the same scope as 35 U.S.C. § 271(g)?

(2) Would a sucralose product containing the tin catalyst that is addressed by the process claimed in the '551 patent be safe for human consumption and otherwise salable as a commercial product? In your response, please include a discussion of the testimony of Dr. Fraser-Reid at page 1874 of the transcript.

(3) Is there infringement of the asserted claims of the '463 patent under the doctrine of equivalents?

(4) Was the presence of 1',6'-dichlorosucrose-6-ester necessary to distinguish the asserted claims of the '463 patent from the prior art? Is it necessary to interpret the phrase "in situ" in the Mufti reference in order to determine the validity of the '463 patent?

(5) What proof would be necessary for Tate & Lyle to show infringement of the asserted claims of the '551 and '969 patents?

(6) Are the asserted claims of the '551 and '969 patents invalid for obviousness in light of the use of organic tin catalysts in the prior art?

In connection with the final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents 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 are likely to do so. For background information, see the Commission Opinion, *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360.

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.

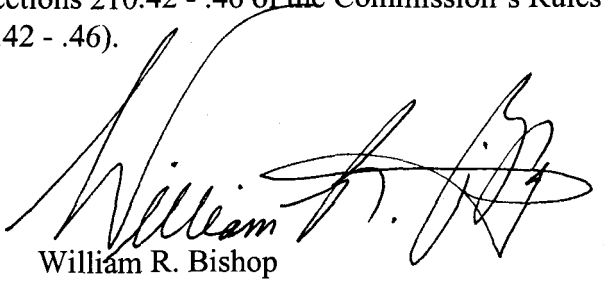
If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount to be determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation, including references to exhibits and testimony. Additionally, the parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the ALJ's recommended determination on remedy and bonding. Complainant and the Commission investigative attorney are also requested to submit proposed remedial orders for the Commission's consideration. Complainant is requested to supply the expiration dates of the patents at issue and the HTSUS numbers under which the accused products are imported. The written submissions and proposed remedial orders must be filed no later than the close of business on December 5, 2008. Reply submissions must be filed no later than the close of business on December 12, 2008. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original and 12 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of 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 is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and under sections 210.42 - .46 of the Commission's Rules of Practice and Procedure (19 C.F.R. §§ 210.42 - .46).

By order of the Commission.



William R. Bishop
Acting Secretary to the Commission

Issued: November 21, 2008

CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND COMPONENTS THEREOF **337-TA-604**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION DETERMINATION TO REVIEW A FINIAL INITIAL DETERMINATION OF THE ADMINISTRATIVE LAW JUDGE** has been served by hand upon the Commission Investigative Attorney, Christopher G. Paulraj, Esq., and the following parties as indicated, on NOV 24 2008.

Marilyn R. Abbott, Secretary
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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND RELATED INTERMEDIATE COMPOUNDS THEREOF**	**Investigation No. 337-TA-604**

COMMISSION OPINION

PUBLIC VERSION

TABLE OF CONTENTS

PUBLIC VERSION

On April 3, 2009, the Commission determined to terminate the above-captioned investigation with a finding that there is no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337") on the merits with respect to any of the asserted patents and that it had determined to issue a limited exclusion order directed to certain products of defaulting and non-participating respondents with respect to U.S. Patent Nos. 5,470,969; 5,498,709; and/or 7,049,435. This opinion sets forth the reasons for the Commission's final determination. The Commission hereby adopts the administrative law judge's conclusions and findings of fact set out in his final initial determination ("final ID") to the extent not inconsistent with this opinion.

I. BACKGROUND

A. Procedural History

This investigation was instituted on May 10, 2007, based upon a complaint filed on behalf of Tate & Lyle Technology Ltd. of London, United Kingdom and Tate & Lyle Sucralose, Inc. of Decatur, Illinois (collectively, "Tate & Lyle") on April 6, 2007, and supplemented on April 13, 18, 23, and 25, 2007. 72 *Fed. Reg.* 26,645 (May 10, 2007). The complaint alleged violations of subsection (a)(1)(B) of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sucralose, sweeteners containing sucralose, and related intermediate compounds thereof by reason of infringement of various claims of United States Patent Nos. 5,470,969 ("the '969 patent"); 5,034,551 ("the '551 patent"); 4,980,463 ("the '463 patent"); 5,498,709 ("the '709 patent"); and 7,049,435 ("the '435 patent"). The notice of investigation named twenty-five firms as respondents. With additions and deletions, there were

twenty-six respondents at the time of the final ID. These respondents are divided into four groups:

A. Participating manufacturing respondents:

Changzhou Niutang Chemical Plant Co. ("Changzhou Niutang Chemical")
Guangdong Food Industry Institute and L&P Food Ingredient Co., Ltd. ("GDFII")
Hebei Sukerui Science and Technology Co., Ltd. ("Hebei Sukerui Science")
JK Sucralose, Inc. ("JK Sucralose") (added by intervention)

B. Participating non-manufacturing respondents:

Beijing Forbest Chemical Co., Ltd. and Beijing Forbest Trade Co., Ltd. ("Forbest Chemical/Forbest Trade")
Forbest International USA, LLC ("Forbest USA")
U.S. Niutang Chemical, Inc. ("U.S. Niutang")
Garuda International, Inc. ("Garuda")
Heartland Packaging Corporation ("Heartland Packaging")
Heartland Sweeteners LLC ("Heartland Sweeteners") (added subsequently)
MTC Industries, Inc. ("MTC")
Nantong Molecular Technology Co., Ltd. ("Nantong MTC")

C. Non-participating respondents (respondents who did not participate in the investigation but for which no default ruling was made) (see ID at 14-15):

AIDP, Inc. ("AIDP")
Fortune Bridge Co., Inc. ("Fortune Bridge")
Nu-Scaan Nutraceuticals ("Nu-Scaan")
CJ America, Inc. ("CJ America")
Vivion, Inc. ("Vivion")
ProFood International, Inc. ("ProFood") (terminated via consent order)

D. Defaulting respondents (Commission Notice Aug. 27, 2007):

Gremount International Co., Ltd. ("Gremount")
Hebei Province Chemical Industry Academe ("Hebei Academe")
Hebei Research Institute of Chemical Industry ("Hebei Research")
Lianyungang Natiprol (Int'l) Co., Ltd. ("Lianyungang Natiprol")
Ruland Chemistry Co., Ltd. ("Ruland")
Shanghai Aurisco International Trading Co., Ltd. ("Shanghai Aurisco")
Zhongjin Pharmaceutical (Hong Kong) Co. ("Zhongjin")

1. Addition of Parties, Termination of Parties, and Narrowing of the Issues

On August 15, 2007, the Commission issued notice of its determination not to review an ID (Order No. 7) allowing JK Sucralose to intervene as a respondent in the investigation. On August 30, 2007, the Commission issued notice of its determination not to review an ID (Order No. 12) terminating the investigation with respect to ProFood on the basis of a consent order. On October 3, 2007, the Commission issued notice of its determination not to review an ID (Order No. 17) adding Heartland Sweeteners, LLC ("Heartland Sweeteners") as a respondent in the investigation.

On January 22, 2008, the Commission issued notice of its determination not to review an ID (Order No. 38) allowing Tate & Lyle to withdraw all asserted claims of the '709 patent with respect to respondents Changzhou Niutang Chemical, GDFII, Hebei Sukerui Science, Heartland Sweeteners, Heartland Packaging, MTC, Nantong Molecular, Garuda, Forbest Trade/Forbest Chemical, and Forbest USA, and to withdraw all asserted claims of the '435 patent with respect to Hebei Sukerui Science, Forbest Chemical/Forbest Trade, Heartland Sweeteners, Heartland Packaging, MTC, and Nantong MTC, and holding that the claims against JK Sucralose for infringement of the '969 and '551 patents are now moot.

2. Pertinent Motions

In its notice of investigation, the Commission stated:

> The Commission notes that some of the patents at issue may cover processes that produce chemical precursors or intermediates of sucralose or that recover certain chemical catalysts from the synthesis. In instituting this investigation, the Commission has not made any determination as to the scope of [19] U.S.C. § 1337(a)(1)(B)(ii) or whether 337(a)(1)(B)(ii) is sufficiently broad as to encompass such processes. Accordingly, the presiding administrative law judge may wish to consider these fundamental issues at an early date. Any such

> decision should be issued in the form of an initial determination (ID) under Rule 210.42(c), 19 C.F.R. § 210.42(c). The ID will become the Commission's final determination 45 days after the date of service of the ID unless the Commission determines to review the ID. Any such review will be conducted in accordance with Commission Rules 210.43, 210.44 and 210.45, 19 C.F.R. §§ 210.43, 210.44, and 210.45.

Id.

On June 12, 2007, certain respondents filed a motion to terminate the investigation with respect to the '463, '969, and '551 patents, arguing that the Commission lacked jurisdiction over the asserted claims, stating that the claims did not fall within the scope of 19 U.S.C. § 1337(a)(1)(B)(ii). On August 8, 2007, the ALJ issued Order No. 11, an ID denying the motion to terminate. On September 24, 2007, the Commission issued notice of its determination to review and vacate the ID and providing questions for the parties to brief and for the ALJ to rule on in his final ID. ID at 5.

On February 4, 2008, the ALJ issued Order No. 48 granting a joint motion filed by certain respondents to preclude Tate & Lyle from relying on certain late-produced materials relating to testing of certain samples from plant inspections, *e.g.*, the Crich Supplemental Report, portions of the Sands Supplemental Report, and certain testing from Bodycote and Ciba, firms engaged by Tate & Lyle. ID at 8. The late-filed materials which Tate & Lyle attempted to rely on related to the '463, '969, and '551 patents. On February 11, 2008, the ALJ denied reconsideration of this order in Order No. 56. ID at 8.

On February 7, 2008, the ALJ issued an order (Order No. 52), denying a motion by Tate & Lyle for a presumption under 35 U.S.C. § 295 that Changzhou Niutang Chemical, U.S. Niutang, and GDFII infringe the '969 and '551 patents. *See* ID at 8.

3. The ALJ's Final ID; Petitions for Review

The ALJ held an evidentiary hearing on February 21-29, 2008. ID at 9. On September 22, 2008, the presiding administrative law judge issued a final initial determination ("final ID") finding no violation of section 337 in the above-identified investigation (with the exception of certain non-participating and defaulted respondents). The ALJ also certified the evidentiary record to the Commission.[1]

As a preliminary matter, the ALJ held that the asserted claims of the '463 and '969 patents covered a process for making the imported product (sucralose) within the contemplation of 19 U.S.C. § 1337(a)(1)(B)(ii), but that the asserted claims of the '551 patent did not, treating this issue as a matter of jurisdiction.

With regard to those respondents who participated in the investigation and did not default, the ALJ found that there was no infringement of the asserted claims of any of the asserted patents. In addressing the question of infringement, the ALJ confirmed his earlier decision to exclude certain late-produced evidence relating to the '463, '969, and '551 patents sought to be admitted by complainants and his earlier decision to deny complainants' motion for a presumption under 35 U.S.C. § 295 to demonstrate infringement of the '969 and '551 patents by four respondents. The ALJ did find that certain defaulting and non-participating respondents had infringed the asserted claims of the '463, '969, '551, '709 and/or '435 patents.

The ALJ held that the asserted claims of the '463 patent were not invalid for anticipation under 35 U.S.C. § 102 and/or obviousness under 35 U.S.C. § 103, and were not invalid for lack

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[1] Tate & Lyle argues on review that some of the exhibits it offered that were not admitted into evidence should have been.

of written description or indefiniteness under 35 U.S.C. § 112. However, the ALJ did find the asserted claims of the '463 patent invalid for lack of enablement under 35 U.S.C. § 112. The ALJ held that the asserted claims of the '969 patent and the '551 patent were not invalid for anticipation under 35 U.S.C. § 102 or obviousness under 35 U.S.C. § 103. None of the respondents argued that the '709 patent or '435 patent was invalid.

The ALJ found that the economic prong of the domestic industry requirement was met for all of the patents. The ALJ found that the technical prong of the domestic industry requirement was met with respect to all patents except for the '463 patent.

In his recommended determination on remedy and bonding, the ALJ stated that a general exclusion order is not warranted. However, the ALJ recommended cease and desist orders against certain respondents with a significant domestic inventory in the event that the Commission found these respondents in violation, and a bond in the amount of 100% of entered value in the event that the Commission issues a remedial order. ID at 226-28.

Six petitions for review and contingent petitions for review were filed by, respectively: (1) Tate & Lyle, (2) Changzhou Niutang Chemical, GDFII, U.S. Niutang, and Garuda (collectively, "Changzhou Niutang"), (3) Hebei Sukerui Science, Beijing Forbest Chemical, Beijing Forbest Trade, and Forbest USA (collectively, "Hebei Sukerui"), (4) Heartland Packaging and Heartland Sweeteners (collectively, "Heartland"), (5) JK Sucralose, and (6) the Commission investigative attorney ("IA").[2]

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[2] The petitions for review filed by respondents substantially overlapped. This was also true of the oppositions to Tate & Lyle's petition for review filed by those respondents. The petition for review and opposition of Changzhou Niutang provided the most detailed arguments of the several respondents and were usually representative of the arguments of the other

The petitions for review variously challenged (a) whether the Commission's authority under section 337(a)(1)(B)(ii) extends to process patents covering steps that do not directly yield the imported product, and in particular, whether the Commission's authority extends to the '463, '969, and '551 patents given that the end product of the asserted claims of these patents is not sucralose, but either an intermediate or a recovered catalyst, (b) the construction of the asserted claims of the '463 patent and whether the asserted claims of the '463 patent are infringed, literally or under the doctrine of equivalents, and whether they are invalid for anticipation, obviousness, failure to satisfy the written description requirement, failure to satisfy the enablement requirement, or indefiniteness, (c) whether a domestic industry exists with respect to the asserted claims of the '463 patent, and (d) whether the asserted claims of the '969 and '551 patents are infringed and whether they are invalid for anticipation or obviousness.

4. The Commission's Notice of Review; Briefing on Review

On November 21, 2008, the Commission issued notice of its determination to review the final ID in its entirety. 73 *Fed. Reg.* 72526 (Nov. 28, 2008). The Commission requested briefing on the issues on review, as well as remedy, the public interest, and bonding, including responses to certain questions. Submissions and reply submissions were filed by, respectively: (1) Tate & Lyle, (2) Changzhou Niutang, (3) Hebei Sukerui, (4) Heartland, (5) JK Sucralose, (6) MTC and Nantong MTC, and (7) the IA.[3] On January 14, 2009, one group of respondents submitted a

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respondents.

[3] As with the petitions for review, the submissions filed by the four sets of respondents substantially overlapped. This was also true of the oppositions to Tate & Lyle's petition for review filed by those respondents. The submissions of Heartland and MTC and Nantong MTC rely on the submissions of the other respondents. The submissions of Changzhou Niutang provided the most detailed arguments of the several respondents and were usually representative

version of complainants' reply submission marked to indicate where complainants allegedly had attempted to rely on materials which had not been admitted into evidence by the ALJ.

B. The Asserted Patents

The imported product is a sweetener which has the generic name sucralose, and which is sold by the complainants under the brand name Splenda®. The asserted patent claims at issue are process claims related to steps for the manufacture of sucralose.[4] Sucralose is made from sucrose (table sugar) by chlorination, *i.e.*, replacing three specific hydroxyl groups of sucrose with chlorine atoms.[5] Four of the patents teach distinct steps of a process for making sucralose, the individual steps consisting of:

> (1) "masking" the most reactive of the eight hydroxyl groups of sucrose with an ester group in the presence of a tin catalyst (esterification) so that this hydroxyl group does not react with chlorine in the next step (the '969 patent);
> (2) Replacing three of the remaining seven hydroxyl groups with chlorine (chlorination) (the '463 patent);
> (3) Removing the ester masking group (de-esterification) to produce a reaction mixture which includes sucralose (the '709 patent); and
> (4) Removing the impurities of the reaction mixture to produce purified sucralose (the '435 patent).

The fifth patent teaches a liquid/liquid extraction to extract the tin compound used in the esterification step from the reaction mixture for eventual reuse (the '551 patent).

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of the arguments of the other respondents.

[4] The product patent on sucralose, also assigned to Tate & Lyle, expired on March 6, 2001. U.S. Patent No. 4,435,440.

[5] Hydroxyl (-OH) groups are also known as alcohol groups when attached to an organic molecule. In sucralose, three of the eight hydroxyl groups of sucrose are replaced with chlorine atoms.

PUBLIC VERSION

II. STANDARD OF REVIEW

Under the Administrative Procedure Act, upon review of the initial determination of the ALJ, "the agency has all of the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule." 5 U.S.C. § 557(b) (*quoted in Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324 (U.S.I.T.C. Aug. 6, 1992)); 19 C.F.R. § 210.45(c). In other words, once the Commission decides to review the decision of the ALJ, the Commission may conduct a review of the findings of fact and conclusions of law presented by the record under a *de novo* standard.

Claim construction is treated as a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372-74, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed.Cir.1998) (*en banc*). Assessment of literal infringement, based upon claim construction, is an issue of fact. *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998). Infringement under the doctrine of equivalents is also an issue of fact. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 38 (1997). Anticipation, based on claim construction, is an issue of fact. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1379 (Fed. Cir. 2005). Obviousness is a matter of law based on underlying factual findings. *DyStar Textilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). Satisfaction of the written description requirement is an issue of fact. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d at 1320, 1323 (Fed. Cir. 2000). Satisfaction of the enablement requirement is a matter of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). Definiteness is a

matter of law. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986).

III. SECTION 337(a)(1)(B)(ii): WHETHER SUCRALOSE IS "MADE...UNDER, OR BY MEANS OF" THE PROCESSES OF THE '463, '969, AND '551 PATENTS

As noted above, all of the asserted patents are process patents. The importation of articles made by a patented process is governed by section 337(a)(1)(B)(ii), which provides:

> (a)(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ...
>
> (B) 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--
>
> ...
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent....

19 U.S.C. § 1337.

Respondents have argued that sucralose, the subject of this investigation, is not "made...under, or by means of" the processes claimed in the '463, '969, or '551 patents. In keeping with the Federal Circuit's guidance in *Amgen, Inc. v. ITC*, we assume jurisdiction and consider this an issue that goes to the merits of whether there is a violation of section 337. 902 F.2d 1532, 1536 (Fed. Cir. 1990) ("where a tribunal's subject matter jurisdiction is based on the same statute which gives rise to the federal right,...the tribunal should assume jurisdiction and treat...the merits of the case.")

A. The ALJ's ID

The '463, '969, and '551 patents cover intermediates of sucralose and the recovery of a catalyst used in making an intermediate. The ALJ stated that the plain language of the statute

does not explicitly speak to the question of whether the Commission's authority under section 337(a)(1)(B)(ii) extends to processes for making intermediates used to make the imported article or to processes for the recovery of catalysts used to make such intermediates. He therefore looked to the legislative history of section 337(a)(1)(B)(ii) and that of its predecessor statute, section 337a (former 19 U.S.C. § 1337a). ID at 42.

Referring first to a statement by Senator Lautenberg, a sponsor of the bill that would amend section 337 to include section 337(a)(1)(B)(ii),[6] the ALJ stated that it was the intent of Congress "to address the unfair acts of foreign companies who 'import products manufactured [abroad] using patented [] engineering technology.'" ID at 42 (quoting 134 Cong. Rec. S10711, S10714). He noted that respondents could not lawfully practice the claimed processes of the '463 and '969 patents in the United States. He concluded that "[t]herefore, if Respondents used Complainants' processes for production of sucralose, intermediate compounds of sucralose or catalysts used in the creation of sucralose, the use of the patented processes and the subsequent importation of products resulting from the use of such patented processes are the unlawful activities that Congress intended to address in enacting Section 337." ID at 43.

He found that his interpretation "is further supported by the legislative history of the predecessor statute of § 337(a)(1)(B)(ii), namely Section 1337a." ID at 43. His analysis included a discussion of the CCPA's decision in *In re Northern Pigment*, 71 F.2d 449 (CCPA 1934),

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[6] In 1988, Congress enacted the Omnibus Trade and Competitiveness Act (OTCA), which, *inter alia*, substantially amended section 337, including repealing section 337a and replacing it with section 337(a)(1)(B)(ii). The Federal Circuit has noted that the legislative history indicates that 19 U.S.C. § 1337(a)(1)(B)(ii) was meant to re-enact former section 337a and thus that section 337(a)(1)(B)(ii) has the same scope as former section 337a. *Amgen, Inc. v. ITC*, 902 F.2d 1532, 1538-1539 (Fed. Cir. 1990).

which formed part of the backdrop to the enactment of the predecessor provision to section 337(a)(1)(B)(ii). He stated that in that case, the CCPA "found that the scope of original Section 337 encompassed products that are other than those that are the direct result of the patented process." He noted that the exclusion order recommended by the Commission in the investigation underlying *Northern Pigment* encompassed not only yellow oxides of iron, but also oxides which had been "calcined or burned or processed in any other manner," specifically red oxides. ID at 43-44.

The ALJ noted that in *Amgen, Inc. v. ITC*, 902 F.2d 1532, 1538-1539 (Fed. Cir. 1990), the Federal Circuit explained that § 1337(a)(1)(B)(ii) re-enacted § 1337a without a change in scope. In particular, he noted that § 1337a was intended to overrule the CCPA's decision in *In re Amtorg,* 75 F.2d 826, 22 CCPA 558 (1935), which in turn had overruled *In re Northern Pigment Co.*, 71 F.2d 447, 449, 22 CCPA 166, 168 (1934), thus reinstating *Northern Pigment*. ID at 43-45. The ALJ stated that "Since *Northern Pigment* involved products that were further processed from those that were the direct result of the process covered by the patent at issue, it is clear that an intermediate product would also be covered if it meets the other requirements of the statute." ID at 45.

The ALJ held that the '463 and '969 patents fell within the scope of section 1337(a)(1)(B)(ii) because the direct products of the processes claimed in those patents "are chemical precursors of sucralose," and thus, according to the ALJ, can be considered "produced...by means of a process covered by the claims." However, he held that the same is not the case for the '551 patent because the '551 patent does not yield a precursor of sucralose, but rather is directed to the recovery and reuse of a tin catalyst. ID at 46-49. He added that the tin

catalyst is not chemically related to sucralose and that the recovery step had not been shown necessary to make sucralose. In arriving at his conclusion, the ALJ rejected the IA's "nexus" test, whereby a "nexus" must exist between the imported article and the alleged unfair act to establish a violation under section 337(a)(1)(B)(ii). ID at 46.[7] He examined the holdings in *Kinik Co. v. ITC,* 362 F.3d 1359 (Fed. Cir. 2004), and *Microsoft Corp. v. AT&T*, 550 U.S. 437, 127 S. Ct. 1746 (2007), and stated that "the 'materially changed' defense of § 271(g) is irrelevant to the scope of relief available to a party under § 1337(a)(1)(B)(ii)" and that "no showing has been made that Section 271(f) would restrict this Commission's jurisdiction under Section 337." ID at 46-47.

B. The Issue on Review

As indicated above, the ALJ found that the Commission's process patent provision extends to the '463 and '969 patents, which relate to processes for intermediates used to produce sucralose, but found that it does not extend to the '551 patent, which relates to recovery of the organotin catalyst used in a process to produce one of those intermediates. Tate & Lyle has argued that the latter finding is erroneous; the respondents have argued that the former is

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[7] The ALJ noted that an argument was raised as to whether trace amounts of the intermediates (the direct products of each of the patented processes which require further processing to become sucralose) contained in the imported sucralose can be a separate basis for jurisdiction. The ALJ held that this matter was more appropriately addressed under the infringement analysis for each patent. *See* ID at 48. However, he did not ultimately address that argument when discussing infringement or elsewhere in the ID. The issue was raised in the IA's post-hearing brief at 22 and 117-19, and in Tate & Lyle's post-hearing brief at 38, but after the ALJ did not adjudicate the issue, Tate & Lyle did not raise the issue in its petition for review. Tate & Lyle has stated in a reply submission that the issue is now not properly before the Commission. Tate & Lyle Reply to Changzhou Niutang Submission at 188. The Commission concurs. *See generally* Commission Rule 210.43(b)(2).

erroneous. The IA agrees with the ALJ's conclusion, but argues that his basis for reaching it was erroneous.

C. Statutory Language

As noted above, the process patent provision of section 337 provides as follows:

> (a)(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ...
>
> (B) 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--
>
> ...
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent....

19 U.S.C. § 1337(a)(1)(B)(ii).

In pertinent part, therefore, the statute makes unlawful the importation of "articles that – are made, produced, processed, or mined under, or by means of, a [patented] process."[8]

We first look to the words of the statute to determine whether a particular patent is within the scope of section 337(a)(1)(B)(ii) with respect to the imported article under investigation.[9] The statute is ambiguous as to whether sucralose is "an article" that is "made. . . under, or by means of" the patented processes at issue. On one hand, respondents argue that sucralose is not the "article" that is made by the patented process; rather, argue respondents, the "article" is an intermediate, or a catalyst. On the other hand, Tate and Lyle argues that the imported sucralose

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[8] We will refer to this phrase as "made. . . under, or by means of."

[9] Commissioner Lane does not join in the remainder of this paragraph because she views the statutory directive as clear but would nevertheless look to the legislative history to give further meaning to the words of the statute.

was "made, produced, [or] processed" according to its patented processes in that the processes were used to make its precursor chemical products or to remove a catalyst from the reaction mixture. We, however, find no clear language in the statute that makes clear whether either of these competing interpretations of section 1337(a)(1)(B)(ii) is correct. In other words, the statute does not provide unambiguous guidance as to which steps are encompassed by the words "made . . . under, or by means of" where an article is made in a sequence of multiple steps. Therefore, we must turn to the legislative history to give further meaning to the words of the statute.

D. The History of the Legislation: Evolution from Predecessor Provisions and Related Judicial and Administrative Decisions

The Federal Circuit in *Amgen* explained that in enacting section 337(a)(1)(B)(ii), Congress intended to re-enact former section 337a. Congress had enacted section 337a to reinstate precedents under section 316 of the Tariff Act of 1922 and under section 337 of the Tariff Act of 1930 that had been overruled by *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935). In this section, we describe the history of the Tariff Act of 1922 and the Tariff Act of 1930 that led to the enactment of former section 337a and ultimately section 337(a)(1)(B)(ii).

1. Section 316 of the Tariff Act of 1922

The Commission's process patent provision has its origin in Commission and judicial precedent under section 316 of the Tariff Act of 1922, the predecessor to section 337. Section 316(a) of the Tariff Act of 1922 provided as follows:

> (a) That unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are hereby declared unlawful, and when found

> by the President to exist shall be dealt with, in addition to any other provisions of law, as hereinafter provided.

42 Stat. 947, Pub. L. 67-318 (Sept. 21, 1922)

. In *Synthetic Phenolic Resin, Form C, and Articles Made Wholly or in Part Thereof* the Commission found unfair methods of competition in the importation of synthetic phenolic resin, Form C,[10] and articles made wholly or in part thereof, such as cigar and cigarette holders and other molded products, made abroad using patented processes.[11] U.S. Tariff Commission, Report No. 3, at 15 (1930). One of the patents (U.S. Patent No. 942,809) covered a method for making synthetic phenolic resin, Form C, by reacting a phenolic body with formaldehyde in the presence of a base. The second (U.S. Patent No. 1,424,738) covered a method of fusing synthetic phenolic resin material, Form C, together with materials of different colors. In each case, the direct result of the patented process was a material which could then be used to make various articles, such as the imported products. The Commission recommended that the President issue an exclusion order, based in part on the recited process claims.[12] The Court of Customs and Patent Appeals subsequently affirmed the Commission. *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930), *cert. denied sub nom. Frischer & Co. v. Tariff Commission & Bakelite Corporation,* 282 U.S. 852 (1930).

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[10] This material was trademarked "Bakelite" and was one of the first "plastics." *Synthetic Phenolic Resin*, Report at 16.

[11] A number of patents are mentioned in the Commission's report, but only two (U.S. Patent Nos. 942,809 and 1,424,738) were the subject of discussion in the Commission's report and the eventual remedial order. The '809 patent expired on December 6, 1926, prior to the Commission's final report, though it had, however, been the subject of a temporary remedial order published April 26, 1926.

[12] The Commission also found unfair methods of competition based on likelihood of confusion in violation of the trademark rights of the Bakelite Corporation, the complainant.

2. Section 337 of the Tariff Act of 1930, As Originally Enacted

Section 316(a) of the Tariff Act of 1922 was reenacted as section 337 of the Tariff Act of 1930. After the original enactment of section 337, the Commission conducted an investigation entitled *Oxides of Iron Suitable for Pigment Purposes*, Inv. No.337-4 (Tariff Commission 1934). Original section 337(a) provided:

> Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are hereby declared unlawful, and when found by the President to exist shall be dealt with, in addition to any other provisions of law, as hereinafter provided.

Pub. L. 71-361, 46 Stat. 703, 741 (1930). In *Iron Oxides*, the Commission found unfair methods of competition in the importation of iron oxide pigment made from iron ore using patented processes (reacting metallic iron with an oxidizing agent in the presence of a ferrous salt and heat and an improvement in which a colloidal ferric hydrate was added to the solution). The Commission recommended issuance of an exclusion order at the conclusion of the investigation covering the subject imports: a yellow pigment directly produced by the patented process and a red pigment which was a dehydrated form of the yellow pigment. The Court of Customs and Patent Appeals subsequently affirmed the Commission in *In re Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

The Commission followed *Iron Oxides* when it decided *Phosphate Rock*, Inv. No. 337-3. In that investigation, the Commission found unfair methods of competition based on the importation of phosphate rock or apatite which had been processed (concentrated) by a froth

flotation method covered by the claims of two patents. Tariff Commission 17th Annual Report at 41 (1933) and 18th Annual Report at 41 (1934). The imported phosphate rock appears to have been the direct product of the patented process. The Court of Customs and Patent Appeals subsequently reversed the Commission's determination in *Phosphate Rock* in *In re Amtorg*, holding that section 337 did not apply to articles made by patented processes. In so doing, the court also overruled *Northern Pigment* and *Frischer*.

3. The Original Process Patent Provision (Section 337a)

Reaction to *Amtorg* was unfavorable and an attempt was soon made to overrule it by legislation. After conducting hearings on the impact of *In re Amtorg* in 1938, Congress passed former section 337a (former 19 U.S.C. § 1337a) which provided as follows:

> The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

54 Stat. 724 (July 2, 1940). The statute was intended to overrule *In re Amtorg*. There is little legislative history on section 337a and much of what exists is specific to imports of the phosphate rock that were the subject of *Amtorg*. "Importation of Goods Covered by United States Patents (Process Patents on Phosphate Rock)," Hearings before the Committee on Patents, Subcommittee on Phosphate Rock Process Patents, H.R. 7851, H. Rep. (May 5, 1938); "Reference to Certain Mining Practices and Defining Unfair Trade Practices in Certain Instances," 76th Cong. 2d Sess., H. Rep. No. 1781 (to accompany H.R. 8285) (March 13, 1940).

4. Current Section 337(a)(1)(B)(ii)

In 1988, Congress enacted the OTCA, which, *inter alia*, substantially amended section 337, including repealing section 337a and replacing it with section 337(a)(1)(B)(ii). The Federal Circuit has noted that the legislative history indicates that 19 U.S.C. § 1337(a)(1)(B)(ii) was meant to re-enact former section 337a and thus that section 337(a)(1)(B)(ii) has the same scope as former section 337a. *Amgen, Inc. v. ITC*, 902 F.2d 1532, 1538-1539 (Fed. Cir. 1990). Current 19 U.S.C. § 1337(a)(1)(B)(ii) provides as follows:

> (a)(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> ...
>
> (B) 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--
>
> ...
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent....

19 U.S.C. § 1337.

Separately, the OTCA added section 271(g) to the patent law, which addressed process patents in the context of Title 35, the Patent Act. It provides as follows:

> (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

> (1) it is materially changed by subsequent processes; or
> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g).

A provision of the OTCA provides that § 271(g) is not intended to alter any remedies under section 337:

> (c) RETENTION OF OTHER REMEDIES.–The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

Pub. L. 100-418 § 9006(c), 102 Stat. 1567 (Aug. 23, 1988), codified at 35 U.S.C. § 271 note.

E. Construction of Section 337(a)(1)(B)(ii)

The ALJ and the parties discussed the legislative history set out above and how, if at all, it provides guidance in interpreting the reach of the process patent provision of section 337(a)(1)(B)(ii). We summarize their analyses before setting forth our own.

1. The ALJ's ID

As noted above, the ALJ construed section 337(a)(1)(B)(ii) to extend to imports of products made by patented processes even if those products are not the direct products of those processes so long as the direct products of those processes were the precursors of the imported products. He then found the '463 and '969 patents came within this definition, but that the '551 patent did not.

2. Changzhou Niutang's Submissions[13]

In arguing that section 337(a)(1)(B)(ii) does not cover the asserted patents, Changzhou Niutang argues that the term "articles" does not include intermediates made by a patented process even if those intermediates are precursors in the manufacture of the articles that are actually imported. Changzhou Niutang Petition at 8. Changzhou Niutang states that the words of a statute are given their ordinary meaning, citing *FDIC v. Meyer*, 510 U.S. 471, 476 (1994), and submits that the statute only prohibits the importation of "articles" made by a patented process. Changzhou Niutang Petition at 7-8. Changzhou Niutang argues that *Northern Pigment* is not relevant because it had nothing to do with intermediate articles. Changzhou Niutang Submission at 11.[14]

3. Tate & Lyle's Submissions

In arguing that section 337(a)(1)(B)(ii) does cover all of the asserted patents, Tate & Lyle states that the statutory language "made, produced, processed, or mined under, or by means of a process covered by the claims of a valid and enforceable United States patent" applies to processes to make or produce intermediates because the ultimate articles are made and produced by means of these processes. Tate & Lyle Response to Changzhou Niutang at 4. Tate & Lyle argues that the plain language of § 1337(a)(1)(B)(ii) is unambiguous. Tate & Lyle Response to Changzhou Niutang at 4. Tate & Lyle believes that the plain language of 19 U.S.C. §

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[13] Much of the discussion in the parties' submission on the reach of section 337(a)(1)(B)(ii) is intermixed with discussion of whether that provision, properly understood, applies to the '463 and '969 patents in the case.

[14] The other three groups of respondents make similar arguments to those of Changzhou Niutang. Hebei Sukerui Petition at 30; JK Sucralose Petition at 37; Heartland Petition at 3.

1337(a)(1)(B)(ii) supports their position that the statute's authority covers articles which are further processed after the patented process, because the articles are still made by a patented process. Tate & Lyle Submission at 19-27.

Tate & Lyle further argues that the legislative history of 19 U.S.C. § 1337(a)(1)(B)(ii) and related precedent encompass intermediate processes used to make an imported product. Tate & Lyle Response to Changzhou Niutang at 5-15. Tate & Lyle also cites as precedent three Commission determinations in which it states the Commission exercised authority under section 337(a)(1)(B)(ii) and, in the latter two cases, found a violation. Tate & Lyle Response to Changzhou Niutang at 15-16 and Tate & Lyle Submission at 40-41 (citing *Certain Anisotropically Etched One Megabit and Greater DRAMs and Products Containing Such DRAMs* ("*DRAMs*"), Inv. No. 337-TA-345; *Certain Methods for Extruding Plastic Tubing* ("*Plastic Tubing*"), *Inv. No. 337-TA-110;* and *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same* ("*Rubber Antidegradants*"), Inv. No. 337-TA-533).[15]

4. *The IA's Submissions*

The IA proposes the use of a "nexus" test in interpreting the scope of section 337(a)(1)(B)(ii). The IA states that although the words of the statute do not contain the word "nexus," the agency may find a nexus requirement based upon the legislative history, and argues there is deference under *Chevron* to an agency's interpretation of an ambiguous statute. IA

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[15] We note that the Commission deemed any issue related to the scope of section 337(a)(1)(B)(ii) to be waived in *Rubber Antidegradants*. The investigation in *DRAMs* was terminated pursuant to a settlement agreement. Notice (March 9, 1994). In *Plastic Tubing*, the question of applicability of section 337(a)(1)(B)(ii) was not discussed in the Commission's opinion.

Petition at 7 (referring to *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)). The IA points to various ALJ opinions and to a plurality opinion by three Commissioners in *Certain Welded Stainless Steel Pipe and Tube* which states that "[i]t therefore becomes crucial to discern some nexus between unfair methods or acts and importation before this Commission has power to act." IA Petition at 11 (quoting *Certain Welded Stainless Steel Pipe and Tube*, Inv. No. 337-TA-29, USITC Pub. No. 863 (1978), Opinion of Commissioners Minchew, Moore, and Alberger at 11-12). The IA's main concern is that if the ALJ's approach to 19 U.S.C. § 1337(a)(1)(B)(ii) were adopted, a violation of section 337 could be found by reason of a process for making a component of an imported article, where the product of the process is far removed from the imported article. *See* IA Petition at 6; IA Reply Submission at 17-18. The IA states that *Northern Pigment* covered "imported articles beyond the immediate product of an asserted patented process." IA Submission at 10. However, the IA states that the Commission and CCPA did not define the metes and bounds of the statute in that case and that the issue was not discussed in terms of "material change," which are the words of 35 U.S.C. § 271(g). IA Submission at 10-11.

5. Discussion

The legislative history of section 337(a)(1)(B)(ii) indicates that it was meant to reenact former section 337a without change. In turn, section 337a was enacted to overturn *In re Amtorg* which had reversed *Phosphate Rock* and overruled *Northern Pigment* and *Frischer*. We therefore understand former section 337a, re-enacted as current section 337(a)(1)(B)(ii), to have reinstated the holdings of *Northern Pigment* and *Frischer,* as well as *Iron Oxides, Phosphate*

Rock, and *Synthetic Phenolic Resin*, which we discussed earlier in section II.D.3. In these cases, the Commission recommended the exclusion of articles made by patented processes, including articles which were further processed. We recognize that apparently no party disputed the Commission's authority to recommend the exclusion of these further processed articles during the proceedings before the agency or on appeal. Nevertheless, because the agency and court opinions indicated that the imported articles underwent further processing prior to importation, it appears that Congress had no objection to the Commission's conduct under the law when it subsequently reinstated these holdings through legislation. That view is consistent with the legislative history of the OTCA, which included amendments intended to strengthen the protection of process patents. *See, e.g.*, S. Rep. 100-83 at 29-31 (1987). We also observe that while these cases indicate that further processing of a certain extent does not remove an article from the scope of section 337(a)(1)(B)(ii), they do not, however, necessarily represent the maximum further processing that may be performed on an article without removing it from the reach of the statute.

F. Other Relevant Case Law

In *Kinik Co. v. ITC*, 362 F.3d 1359 (Fed. Cir. 2004), the Federal Circuit addressed, among other issues, whether defenses provided in 35 U.S.C. § 271(g) were applicable in an action brought under 19 U.S.C. § 1337(a)(1)(B)(ii). These defenses limit infringement of process patents under § 271(g) to situations in which the product of the process has not been materially transformed or which has been made a minor component of a larger article. Because of strong

disagreement among the ALJ and the parties on whether *Kinik* decided the extent of the process patent provision of section 1337(a)(1)(B)(ii), a closer examination of the decision is warranted.[16]

In the agency proceeding from which the *Kinik* litigation arose, the Commission affirmed an order of the ALJ that the defenses to infringement contained in 35 U.S.C. § 271(g), *i.e.*, section 271(g)(1) and (2), were not available in a case based on section 337(a)(1)(B)(ii) and that those defenses had not been timely raised. *Certain Abrasive Products Made Using a Process for Powder Preforms, and Products Containing Same*, Inv. No. 337-TA-449 (Commission Opinion Affirming ALJ Order No. 40). In making its decision, the Commission noted that section 9003 of the Process Patent Amendments Act added section 271(g) to the patent law. The Commission also found that section 9006(c) of the Process Patent Amendments Act made it clear that the defenses of section 271(g)(1) and (2) would not apply to section 337 cases, given that section 9006(c) provides that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available...under section 337 of the Tariff Act of 1930, or under any other provision of law." Additionally, the Commission found that section 271(g) explicitly restricted its application to cases under Title 35 because it expressly stated that the exceptions to

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[16] Citing *Kinik*, The ALJ found that the "materially changed" defense of 35 U.S.C. § 271(g) "is irrelevant to the scope of relief available to a party under § 1337(a)(1)(B)(ii)." ID at 47. Tate & Lyle states that in *Kinik* the Federal Circuit affirmed the "Commission's ruling that the defenses established in § 271(g), covering process patents, are not available in 19 U.S.C. § 1337(a)(1)(B)(ii) actions." Tate & Lyle Response to Changzhou Niutang at 14 (quoting 362 F.3d 1359, 1363 (Fed. Cir. 2004)); Tate & Lyle Submission at 39. Changzhou Niutang states that *Kinik* is not relevant because the defenses of 35 U.S.C. § 271(g) are not at issue and because *Kinik* did not construe 19 U.S.C. § 1337(a)(1)(B)(ii). Changzhou Niutang Submission at 9 n.3. The IA argues that *Kinik* stands for the proposition that 35 U.S.C. § 271(g) and 19 U.S.C. § 1337(a)(1)(B)(ii) are not coextensive. IA Submission at 10-11.

infringement in sections 271(g)(1) and (2) were "for purposes of this title [Title 35]" and thus that those defenses do not apply to cases brought under section 337, which is part of Title 19. On these bases, the Commission concluded that defenses enumerated in 35 U.S.C. § 271(g) were not available to respondents in an action brought under 19 U.S.C. § 1337(a)(1)(B)(ii).

The accused infringer in the *Abrasives* case, Kinik Co., appealed the Commission's final determination to the Federal Circuit, arguing numerous points, including that the Commission erred in holding that Kinik could not rely on the defenses in section 271(g)(1) and (2). On appeal, the Federal Circuit agreed with the Commission's interpretation of the statutory provisions and the legislative history with respect to the inapplicability of the section 271(g) defenses. *Kinik*, 362 F.3d at 1362 ("We affirm the Commission's ruling that the defenses established in § 271(g) are not available in § 1337(a)(1)(B)(ii) actions."). However, the Court reversed the Commission's finding of infringement on an unrelated basis because it disagreed with the Commission's claim construction. *Id.*

Tate & Lyle argues that *Kinik* stands for the proposition that the authority of the Commission under section 337(a)(1)(B)(ii) extends to products made abroad by a process patented in the United States, no matter how much further they are processed. Tate & Lyle Response to Changzhou Niutang at 14 (quoting 362 F.3d 1359, 1363 (Fed. Cir. 2004)); Tate & Lyle Submission at 39. We cannot agree with Tate & Lyle's interpretation of the Court's holding in that case. Based on the holding that § 271(g) defenses are inapplicable in actions under § 1337(a)(1)(B)(ii), Tate & Lyle infers that the court also reached a holding on the extent of the process patent provision of § 337(a)(1)(B)(ii). That leap is unwarranted, however, because the

issue of the reach of the process patent provision at issue here was not addressed by the court in *Kinik*. In other words, there remains the distinct question of the extent to which the statutory language "articles . . . made . . . under, or by means of, a [patented] process" encompasses articles that are further processed prior to importation. We understand the Federal Circuit's statement that § 271(g) defenses do not apply to section 337(a)(1)(B)(ii) to mean that 35 U.S.C. § 271(g) does not inform the analysis of 19 U.S.C. § 1337(a)(1)(B)(ii), and therefore that 19 U.S.C. § 1337(a)(1)(B)(ii) must be analyzed independently.[17] [18]

Respondents argue that *Microsoft Corp. v. AT&T*, 550 U.S. 437, 127 S. Ct. 1746 (2007), is also pertinent to our inquiry. In *Microsoft*, the Supreme Court had before it an AT&T patent on a computer capable of digitally encoding and compressing recorded speech. Microsoft Windows operating system incorporated software code that, when installed in a computer, enabled that computer to process speech in a manner claimed by AT&T's patent. AT&T brought an action for infringement of its patent under 35 U.S.C. § 271(f). The Court held that the export of Microsoft's Windows on a disk which would be duplicated abroad and the copies installed on computers sold abroad did not constitute infringement of AT&T's patent under 35 U.S.C. § 271(f). *Microsoft Corp.*, 127 S. Ct. at 1752.

The Court first found that a copy of Windows, not Windows in the abstract, qualified as a component under § 271(f). Next, the Court found that the absence of anything addressing

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[17] We note that in both *Abrasives* and *Kinik*, the statements that § 271(g) defenses do not apply to section 337(a)(1)(B)(ii) cases were dicta, though for different reasons in the two cases.

[18] We also note that the argument that Kinik would have raised, had the § 271(g) defense applied, was that the additional heating step in its process put it within that defense. Thus it appears that only limited further processing would have been involved. Further, there would have been no issue regarding an intermediate or recovery of a catalyst.

copying in the text weighed against a judicial determination that replication abroad of a master disk dispatched from the United States "supplies" the foreign-made copies from the United States within the intent of § 271.

Microsoft cautions that statutes should be interpreted to limit the extraterritorial application of United States law in the absence of a clear statement by Congress. *Microsoft* derives this canon from notions of national sovereignty and deference to the policy judgments of foreign law. *See Microsoft*, 127 S.Ct. at 1746, 1759 ("As a principle of general application, moreover, we have stated that courts should 'assume that legislators take account of the legitimate sovereign interests of other nations when they write American laws.' Thus, the United States accurately conveyed in this case: 'Foreign conduct is [generally] the domain of foreign law,' and in the area here involved, in particular, foreign law 'may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions.'"). An additional principle was also enunciated in *Microsoft*. Like section 337(a)(1)(B)(ii), § 271(f) was enacted to overrule a specific case. In such a circumstance, *Microsoft* cautions that when Congress addresses a gap in the statute, the court should avoid stretching that statutory language "beyond the text Congress composed" in order to address another arguable gap. *Microsoft*, 127 S. Ct. at 1757, 1759-60. The Supreme Court acknowledged, however, that the text of § 271(f) did, in at least one respect, "reach past the facts" of the case being overruled. 127 S. Ct. at 1760 n.18.

The Federal Circuit used a similar approach in *Amgen*, where it was urged to construe section 337(a)(1)(B)(ii). In that case, Amgen argued that the importation of erythropoietin made

abroad by using host cells alleged to be covered by Amgen's patent constituted importation of a product made by a process covered by the claims of that patent within the meaning of section 337(a)(1)(B)(ii). The Federal Circuit noted that section 337a was specifically enacted to overrule *In re Amtorg* and that nothing in the legislative history supported the appellant's position that the statute was intended, contrary to its plain meaning, to prohibit the importation of goods made by a process which merely used abroad a product, apparatus, or material patented in this country. *Amgen*, 902 F.2d 1532, 1539-40 (Fed. Cir. 1990).

G. Application to the '463, '969, and '551 Patents

Tate & Lyle contends that sucralose is produced "by means of" the '463 and '969 patents, according to the general definition of the word "means" and further argues that the legislative history and precedent support jurisdiction over the '463 and '969 patents. Tate & Lyle Submission at 24-26, 30-41. Changzhou Niutang argues that under the ordinary meaning of the word "article," sucralose is not an article produced by means of the '463 or '969 patents and submits that the legislative history, including *Northern Pigment*, supports its position. Changzhou Niutang Submission at 136-39. The IA argues that the '463 and '969 patents are within the scope of section 337(a)(1)(B)(ii) because there is a nexus between the alleged infringement of the patents and the importation of sucralose. IA Submission at 26. The IA states that the intermediates resulting from the claimed processes are chemically very close to the imported sucralose, that the complete process for the conversion of sucrose to sucralose is not a lengthy process, and that the specifications of the '463 and '969 patents "posit the use of the resultant chemical intermediates in the eventual synthesis of sucralose." IA Submission at 26.

Based on our analysis of the statutory language, the history of the legislation, and other relevant case law, we find no disapproval of agency recommendations that articles made by a patented process be excluded from importation notwithstanding that they underwent at least some further processing prior to importation. While we do not understand the further processing described in past investigations necessarily to represent the maximum permitted under the statute, we also bear in mind the cautionary principles set out in *Microsoft* regarding the interpretation of statutes with extraterritorial effect and those enacted to overturn a specific case. We find these sources of guidance sufficient to allow us to decide the dispute before us. While an articulation of additional considerations relevant to the application of the statute may be required by a future dispute, the pertinent record facts here represent a straightforward case for both the '463 and '969 patents on the one hand, and the '551 patent on the other.

Specifically, as to the '463 and '969 patents, neither process directly results in sucralose, but each produces intermediates in the chain of production for sucralose in close proximity to the final product. The intermediates produced by the processes in the '463 and '969 patents, 1',4,6'-trichlorosucrose-6-ester and sucrose-6-ester, are further processed, but the record does not show uses for these intermediates other than for making sucralose. Indeed, the specifications of the '463 and '969 patents (in the Background of the Invention section) indicate that these intermediates are intermediates for the production of sucralose. '463 patent, col. 1, lines 18-20 ('It is a major synthesis problem to direct the chlorination of sucrose only to the desired 6', 4, and 1' positions to produce sucralose.[19]"); '969 patent, col. 1, lines 29-34 ("A number of different

[19] Sucralose is 1',4,6'-trichlorosucrose.

synthetic routes for the preparation of sucralose have been developed in which the reactive hydroxyl in the 6 position is first blocked, as by an ester group, prior to the chlorination of the hydroxyls in the 4, 1', and 6' positions, followed by hydrolysis to remove the ester substituent to produce sucralose.") Moreover, there is a short chain of steps from these intermediates to sucralose. The Commission finds that, under these facts, the '463 and '969 patents cover processes by means of which sucralose is made within the meaning of section 337(a)(1)(B)(ii).

This finding that importation of sucralose constitutes a violation of section 337(a)(1)(B)(ii) if it was "made, produced, or processed" under or by means of the processes claimed in the '463 and '969 patents is consistent with the two principles set forth in *Microsoft*. Where, as here, a statute presupposes some degree of extraterritorial application of U.S. law, that application must be reasonably limited in scope; the close interdependence between the patented processes and the production of sucralose makes it reasonable for the Commission to find that sucralose was "made, produced, or processed" under or by means of the processes claimed in the '463 and '969 patents. In addition, this finding does not attribute to "made, produced, or processed" an unreasonable scope of application, nor stretch it in an effort to address a problem of which Congress evinced no recognition when it overruled *In re Amtorg* by means of section 337a.

The ALJ held that the asserted claims of the '551 patent (recovery of the tin catalyst) do not fall within the Commission's jurisdiction because the product of the process of the '551 patent is a tin catalyst, and sucralose is not produced by this process. ID at 46. Tate & Lyle, *inter alia*, submits that the '551 patent does teach a process for producing a precursor of

sucralose, *i.e.*, sucrose 6-ester, that the ALJ mistakenly focused on the recovery of the tin catalyst because of the title of the patent[20] and failed to give the claims their proper scope, since the claims, according to Tate & Lyle, provide that the separation of the tin catalyst from the reaction mixture yields sucrose-6-ester. Tate & Lyle Petition at 7-10; Tate & Lyle Submission at 46-47 (citing, *inter alia*, *Certain Recombinant Erythropoietin*, 337-TA-281, Commission Decision, USITC Pub. No. 2186 (Apr. 10, 1989)). Changzhou Niutang contends that the '551 patent is essentially about extraction of a tin compound and not about production of sucralose, arguing that the ALJ's construction of the scope of the asserted claims of the '551 patent was well supported by the patent and the claim language. Changzhou Niutang Response at 94-95. The IA argues that it is inaccurate for complainants to characterize the '551 patent as generating the sucrose-6-ester because a reaction mixture containing the sucrose-6-ester in the '551 patent claims is a starting material for that claimed process and the sucrose-6-ester remains chemically unchanged by the '551 process, even though the tin is being removed. IA Response at 4.

As to the '551 patent, we agree with the ALJ that sucralose is not produced "by means of" this process for recovering tin. In keeping with *Microsoft*, we have applied section 337(a)(1)(B)(ii) according to its terms, but have not extended it to cover the process of the '551 patent. The direct product of the process of the '551 patent is a (recovered) tin catalyst which is not sucralose and cannot be processed to produce sucralose. The tin catalyst is neither a precursor of sucralose nor is it the imported article. As the IA pointed out, sucrose-6-ester, the building block which later becomes sucralose, is unchanged by the process of the '551 patent.

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[20] The title of the patent is "Process for Recovery of Organotin Esters from Reaction Mixtures Containing the Same and Re-Use of the Recovered Organotin Compounds."

The purpose of the patent is to recycle the catalyst. Thus, sucralose is not processed by means of the '551 patent and the asserted claims of the '551 patent are not for processes for making sucralose within the meaning of section 337(a)(1)(B)(ii).

IV. INFRINGEMENT, VALIDITY, AND DOMESTIC INDUSTRY

A. The '463 Patent

As of the date of the final ID, the complainant accused GDFII, Changzhou Niutang Chemical, Hebei Sukerui Science, JK Sucralose, CJ America, AIDP, Hebei Research, Forbest Chemical/Forbest Trade, Forbest USA, Garuda, Heartland Sweeteners, MTC, Nantong MTC, U.S. Niutang, Fortune Bridge, Gremount, Hebei Academe, Lianyungang Natiprol, Nu-Scaan, Ruland, Shanghai Aurisco, Vivion, and Zhongjin of infringing the asserted claims of the '463 patent via their importation and sale of sucralose.

1. Infringement

Determining infringement is a two-step process which consists of determining the scope of the asserted claim (claim construction) and then comparing the accused product or process to the claim as construed. An accused device literally infringes a patent claim if it contains every limitation recited in the claim. *See, e.g., Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998).

Even where an accused process does not literally infringe an asserted patent claim, it may nevertheless infringe under the doctrine of equivalents, if it performs the same function in the same way to produce the same result, or if the differences between the accused process and the patented process are insubstantial, for each limitation of the claim. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326-27 (Fed. Cir. 2008).

The claim construction for the analysis of infringement is the same claim construction used for the analysis of validity and the technical prong of the domestic industry requirement.

a. Claim Construction

Claim terms are interpreted as they would be understood by a person of ordinary skill in the art in the context of the intrinsic evidence, consisting of the claims, the specification, and the prosecution history, if in evidence, and relevant extrinsic evidence. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1316-17 (citations omitted).

The '463 patent teaches a method for replacing certain hydroxyl groups on the sucrose rings with chlorine at the 1',4, and 6' positions. The inventors of the '463 patent aimed to achieve selective chlorination using a Vilsmeier-type reagent[21] in a process that begins the reaction at a lower temperature (below about 85°C) and later proceeds at a higher temperature (at least 100°C). This process first selectively adds one or two chlorines at the lower temperature at the 1', 4, or 6' positions, and then, after the temperature is raised to at least 100°C, adds a third chlorine at the 1', 4, or 6' positions. The goal is to achieve selective chlorination (at the 1',4, and 6' positions) based on the order of reactivity of the unprotected hydroxyls:

(position) 6' > 4 > 1' > 2, 3, 3'

and minimizing chlorination at the 2, 3, and 3' positions, which are not chlorinated in the desired product. Thus, the patentees sought to first form monochloro-sucrose-6-ester, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester at the lower temperature before forming 1',4,6'-trichlorosucrose-6-ester at the higher temperature. The '463 patent also adds all

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[21] A Vilsmeier-type reagent may be formed by the reaction of an acid chloride and a tertiary amide.

of the reagents at the same time, rather than forming the Vilsmeier-type reagent in advance, though the parties dispute whether adding all reagents at the same time is novel.

Independent claim 1, from which the other claims depend, reads as follows:

> 1. A process for the chlorination of sucrose-6-esters to produce 6', 4,1'-trichloro-sucrose-6-esters which comprises the steps of:
>
> > (a) adding at least seven molar equivalents of an acid chloride to a reaction mixture containing a sucrose-6-ester and a tertiary amide to form a chloroformiminium chloride salt in the presence of said sucrose-6-ester, whereby the chloroformiminium salt forms an O-alkylformiminium chloride adduct with the hydroxyl groups of the sucrose-6-ester;
> > (b) subjecting the reaction mixture product of step (a) to an elevated temperature not higher than about 85°C for a period of time sufficient to produce a mixture of chlorinated sucrose-6-ester products consisting essentially of monochlorosucrose-6-ester, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester; and
> > (c) subjecting the reaction mixture product of step (b) to an elevated temperature of at least about 100°C but not higher than about 130°C for a period of time sufficient to produce a chlorinated product comprising predominantly 1',4,6'-trichlorosucrose-6-ester.

The ALJ construed limitations for all three steps, but eventually found noninfringement solely on the basis of the limitations of step (b), not reaching the question of whether the limitations of steps (a) or (c) were met.[22]

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[22] As discussed *infra*, the ALJ also used this approach to find noninfringement of the '969 and '551 patents. Tate & Lyle challenges the ALJ's ID on the ground that, by not making findings on whether the accused processes met each of the claim limitations, the ALJ violated the Administrative Procedure Act (APA) and the Commission's decision in *Certain Stringed Musical Instruments and Components Thereof* ("*Stringed Instruments*"), Inv. No. 337-TA-586, that the Commission expects the ALJ to reach all issues. *See Stringed Instruments* Comm'n Op. at 1 ("The Commission's rules of practice and procedure provide that the initial determination of the ALJ shall include '...conclusions and the reasons or bases therefor necessary for the disposition of all material issues of fact, law, or discretion presented in the record....' 19 C.F.R. § 210.42(d). Thus, although the Commission may elect in a final determination of no violation not to take a position on other issues, *Beloit Corp. v. Valmet Oy*, 742F.2d 1421, 1423 (Fed. Cir.

b. The ALJ's ID

The ALJ construed the disputed claim terms for step (a) as follows:

"adding" as not requiring any particular order of addition

"at least seven molar equivalents" as "seven moles of acid chloride are added for each mole of sucrose-6-ester"

"acid chloride" as "a substance in which one or more hydroxyl (-OH) groups of an acid is replaced by chlorine."

"sucrose-6-ester" as "a mono-ester of the sucrose molecule where the ester group is on the 6 position, which does not include a sucrose-penta-ester."

"tertiary amide" by its ordinary meaning, which includes DMF.[23]

"to form a chloroformiminium chloride salt in the presence of said sucrose-6-ester" to require the acid chloride to react with the tertiary amide in the presence of the sucrose-6-ester to form a chloroformiminium chloride salt

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1984), the Commission generally anticipates that the ALJs will adjudicate all issues presented in the record."). The ALJ explained that it was not necessary to make factual findings on all claim limitations because he found that the accused processes did not meet one of the limitations, which he found to be dispositive. The complainants argue that it was "legally erroneous" for the ALJ to have failed to address the construction of each claim limitation. Tate & Lyle Submission at 170-71 (citing Commission Rule 210.42(d); 5 U.S.C. § 557(c)(3); *Checkosky v. SEC*, 139 F.3d 221, 226 (D.C. Cir. 1998) ("[A]n agency violates the APA when it fails to include in its adjudicatory decision a meaningful statement of findings and conclusions, and the reasons or basis thereof, on all material issues of fact, law, or discretion presented on the record.") The respondents counter that Tate & Lyle has not provided any authority for its argument that the ALJ must rule on every argument when a single argument is dispositive. Changzhou Niutang Reply Submission at 115. Respondents further submit that the ALJ was consistent with the Commission's statement in *Stringed Instruments* because the ALJ has ruled on every "issue" presented in the record, and points out that the Commission did not reverse the ALJ in *Stringed Instruments*. *Id.* The IA also argues that *Stringed Instruments* allows the ALJ to follow the same procedure as the Commission because the Commission did not remand the investigation to the ALJ. IA Reply Submission at 59-60. Since the claim limitations relied on by the ALJ are not met, the issue is moot. Nevertheless, we reiterate our statement in *Stringed Instruments* that we generally expect the ALJ to adjudicate all issues presented by record.

[23] An amide has a nitrogen bound to the "alpha" carbon of an organic acid. A tertiary amide has a total of three non-hydrogen atoms bound to the nitrogen.

"whereby the chloroformiminium salt forms an O-alkylformiminium chloride adduct with the hydroxyl groups of the sucrose-6-ester" as not requiring the formation of O-alkylformiminium chloride adducts on all seven of the available hydroxyl groups of the sucrose-6-ester.

ID at 73-74.

Only some of the ALJ's rulings construing the limitations of step (a) are the subject of Commission review. These are discussed below.

Step (a): "to form a chloroformiminium chloride salt in the presence of said sucrose-6-ester"

As noted above, the ALJ construed this phrase to require the acid chloride to react with the tertiary amide in the presence of sucrose-6-ester to form a chloroformiminium salt. Although the ALJ held that the reagents do not need to be added in any particular order, he held that sucrose-6-ester must be present when the acid chloride is added to the tertiary amide (DMF). Compare ID at 68 with ID at 75-76. This construction was unfavorable to complainants, who argue that it is erroneous.

Tate & Lyle's Submissions

Tate & Lyle contends that sucrose-6-ester need not be present at the time that the acid chloride and tertiary amide are combined in step (a), as called for by the ALJ's construction. Tate & Lyle argues that the ALJ misconstrued "to form a chloroformiminium chloride salt in the presence of said sucrose-6-ester" in step (a) by inappropriately importing limitations from certain examples of the specification into the claims to require that the chloroformiminium chloride salt form from the direct reaction of a tertiary amide and the acid chloride. Tate & Lyle Petition at 30, 32 (discussing the reaction scheme of figure 2 of the '463 patent); Tate & Lyle Submission at 49-54. According to Tate & Lyle, the ALJ construed the limitation to require the direct reaction

of a tertiary amide and the acid chloride. Tate & Lyle Petition at 30. This is significant according to Tate & Lyle because [[

]]. Tate & Lyle Petition at 31. Tate & Lyle submits that nothing in the claim language supports the ALJ's construction, that the ALJ's construction would improperly exclude multiple examples of the invention disclosed in the patent from the scope of the claims, and that neither the specification nor the prosecution history supports the ALJ's construction. Tate & Lyle Petition at 31-33.

The Respondents' Submissions

Changzhou Niutang argues that Tate & Lyle makes a false distinction between a direct and indirect reaction because the ALJ did not require a direct reaction, but merely that an acid chloride react with a tertiary amide in the presence of sucrose-6-ester. Changzhou Niutang Response at 23-24, 26. Changzhou Niutang states that the patentees made clear in the prosecution history that a key feature of the invention was the formation of chloroformiminium chloride salt by the reaction of a tertiary amide and an acid chloride. Changzhou Niutang Submission at 26 (citing JX-6 at 320). Hebei Sukerui points to the plain language of the claim, "adding...an acid chloride to a reaction mixture containing a sucrose-6-ester and a tertiary amide" to reach the same conclusion as Changzhou Niutang. Hebei Sukerui Submission at 12.

The IA's Submissions

The IA points to statements in the specification that it was a major discovery of this invention that an acid chloride will react with a tertiary amide even when sucrose-6-ester is also

in the solution. IA Response to Petitions at 21 (citing the '463 patent, col. 4, lines 40-50); *see also* IA Review Submission at 17.

Discussion

We agree that an important aspect of the invention in the specification and as argued to the PTO is the direct reaction of the acid chloride and the tertiary amide when sucrose-6-ester is also present, which is what the claim language calls for when it states that the chloroformiminium chloride salt is formed (from its acid chloride and tertiary amide precursors) "in the presence of said sucrose-6-ester." We therefore agree with the ALJ's claim construction of this term. *See* '463 patent, col. 4, lines 38-50; JX-6 (Response of July 18, 1989 at 4-5).

Step (a): "whereby the chloroformiminium salt forms an O-alkylformiminium chloride adduct with the hydroxyl groups of the sucrose-6-ester"

As noted above, the ALJ construed this limitation as not requiring the formation of O-alkylformiminium chloride adducts on all seven of the available hydroxyl groups of the sucrose-6-ester. This construction was unfavorable to respondents, who argue that it is erroneous.

The Respondents' Submissions

Respondents argue that this limitation means that there must be an O-alkylformiminium chloride adduct formed with *each* of the seven available hydroxyl groups of the sucrose-6-ester, in contrast to the ALJ's construction. Changzhou Niutang states that neither example 13 nor any of the examples support the ALJ's broad construction because the claim requires "adding at least seven molar equivalents of an acid chloride to a reaction mixture containing a sucrose-6-ester and a tertiary amide to form a chloroformiminium chloride salt in the presence of said sucrose-6-ester." Changzhou Niutang Response at 26-28. Changzhou Niutang argues that the antecedent

basis for "the hydroxyl groups" must be the groups that exist on sucrose-6-ester and states that the word "the" in the phrase "the hydroxyl groups" refers to all seven hydroxyl groups. Changzhou Niutang Submission at 27-33.

Tate & Lyle's Submissions

Tate & Lyle responds that just because seven molar equivalents of acid chloride are added does not mean that the acid chloride necessarily forms adducts with all seven of the available hydroxyls of the sucrose-6-ester. Tate & Lyle Response to Petitions at 1-2. Tate & Lyle states that Example 13 demonstrates this. Tate & Lyle Reply Submission at 37.

The IA's Submissions

The IA agrees with Tate & Lyle that it is not essential to the invention that all seven hydroxyl groups react with the acid chloride to form adducts. IA Response to Petitions at 51-58.

Discussion

Respondents' claim construction would result in preferred embodiments not being covered by the claims. There is a presumption against a claim construction that reads preferred embodiments out of a claim, *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). While this presumption is rebuttable, in our view, respondents have not sufficiently demonstrated that the presumption has been rebutted. We therefore agree with this aspect of the ALJ's claim construction.

Steps (b) and (c)

Steps (b) and (c) are best analyzed together. The ALJ construed the disputed claim terms for steps (b) and (c) as follows:

Step (b)

"subjecting the reaction mixture product of step (a) to an elevated temperature not higher than about 85°C" as not requiring a discrete heating step that is separate and distinct from the heating in step (c).

"a mixture of chlorinated sucrose-6-ester products consisting essentially of monochorosucrose-6-ester, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester" as requiring substantially all of the sucrose-6-ester to be converted into a mixture of monochlorinated sucrose-6-esters, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester, where little or no trichlorination or higher chlorination has occurred.

Step (c)

"subjecting the reaction mixture product of step (b) to an elevated temperature of at least about 100°C but not higher than about 130°C for a period of time sufficient to produce a chlorinated product comprising predominantly 1',4,6'-trichlorosucrose-6-ester" as requiring 1',4,6'-trichlorosucrose-6-ester to be the most predominant chlorinated sucrose-6-ester product at the end of step (c).

Of these disputed limitations, the following are on review:

Step (b): "subjecting the reaction mixture product of step (a) to an elevated temperature not higher than about 85°C."

The first issue is whether the claims cover a heating process which steadily raises the temperature from below 85°C to above 100°C or whether the heating must be conducted stepwise such that the temperature is first held below 85°C and then quickly raised above 100°C where it is held. As noted above, the ALJ held that the reaction does not require a stepwise heating with discrete heating phases. This construction is unfavorable to respondents, who argue that it is erroneous.

Respondents' Submissions

Changzhou Niutang argues that the claim requires a stepped heating process with one heating step below 85°C and a second heating step at 100-130°C, pointing to the prosecution

history in which the patentee distinguished the claimed invention from the prior art by arguing to the PTO that:

> the two cited [prior art] patents do not teach the phased reaction whereby the chlorination reaction mixture is maintained at a temperature below about 85°C for a period of time sufficient to produce [the mixture of mono and dichlorosucrose produced by step (b)], followed by subjecting the reaction mixture product of the previous step to an elevated temperature not higher than about 125°C for a period of time sufficient to produce [the mixture consisting predominantly 1',4,6'-trichlorosucrose-6-ester produced by step (c)]. It is this discre[te] separation of the two steps, the first being carried out below about 85°C and the second below about 125°C, that is important for the success of the subject claimed invention, and it is this separation of the chlorination reaction into two discrete steps that the cited patents fail to teach

Changzhou Niutang Petition for Review at 27 (quoting JX-6 at 321); Changzhou Niutang Submission at 37.

Tate & Lyle's Submissions

Tate & Lyle argues that the specification states that either a steadily increasing or a stepwise heating process may be used, that the steadily increasing method is identified in the specification as a preferred embodiment, and that there is no advantage of one over the other. Tate & Lyle Reply to Changzhou Niutang Petition at 25 (quoting '463 patent, col. 7, lines 9-17) ("Preferably, the temperature gradient is conducted over a 20-30 min. period, which is sufficient to convert all of the sucrose-6-ester to a mixture of mono- and dichlorinated sucrose-6-esters prior to submission to the harsher trichlorination temperature conditions. Alternatively, discrete incremental heating steps may be employed to effect sequential chlorination stages, however no particular advantages are attendant thereto over a steeper temperature gradient.").

The IA's Submissions

The IA submits that the ALJ correctly construed the claims to include a steadily increasing heating process (a "ramped" process) and not just a stepped process. *See* IA Response to Petitions at 58; IA Reply Submission at 48.

Discussion

We agree with Tate & Lyle that the specification indicates that the heating may be either steadily increasing or stepwise/incremental. This is not inconsistent with the explanation in the prosecution history because in either case the reaction is first below 85°C and then is taken above 100°C. It should not matter whether the reaction is 84°C and then quickly heated to 101°C, or whether the reaction is 80°C, then 81, 82, 83, 84, ...100, 101, 102°C. The reaction may be at a variety of temperatures as long as the temperature is below 85°C and then above 100°C. The key to the invention is that the chlorination proceeds below 85°C to achieve mono- and dichlorination before being raised above 100°C to achieve trichlorination. Further, while the prosecution history is an important part of the "intrinsic evidence" for claim construction, and may govern if there is a disclaimer of claim scope in the prosecution history, no disclaimer has been argued in this case. Moreover, the Federal Circuit has stated that the specification is the single best guide to the interpretation of the claims. *Phillips*, 415 F.3d at 1315. We therefore agree with the ALJ's claim construction.

Step (c): "produc[es] a chlorinated product comprising predominantly 1',4,6'-trichlorosucrose-6-ester"

As noted above, the ALJ construed this limitation as requiring 1',4,6'-trichlorosucrose-6-ester to be the predominant[24] chlorinated sucrose-6-ester product at the end of step (c). This construction is unfavorable to respondents, who argue that it is erroneous.

Respondents' Submissions

Changzhou Niutang argues that when step (c) "produce[s] a chlorinated product comprising predominantly 1',4,6'-trichlorosucrose-6-ester," that 1',4,6'-trichlorosucrose-6-ester must be greater than 50% of all chlorinated products. Changzhou Niutang Brief at 29.

Tate & Lyle's Submissions

Tate & Lyle points to expert testimony and dictionary definitions to argue that "predominantly" means more than the other products, *i.e.*, a plurality, but does not have to be more than 50% of the total, *i.e.*, does not have to be a majority. Tate & Lyle Reply to Changzhou Niutang Petition at 32 (citing Hanessian Dep. at Tr. 99; CX-621C R at Q/A 201; CX-77 at 1078). Tate & Lyle also points out that the 1',4,6'-trichlorosucrose-6-ester would be the predominant chlorinated sucrose-6-ester, and that the claim does not require that the desired trichlorinated species predominates over all chlorinated products in the reaction mixture, because the starting point for step (c) is the "reaction mixture product of step (b)." Tate & Lyle Reply to Changzhou Niutang Petition at 31.

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[24] By predominant, the ALJ meant present in a greater quantity than any other single species. *See* ID at 86.

The IA's Submissions

The IA understands "predominantly" to mean present in an amount greater than other products. IA Response to Petitions at 59.

Discussion

The specification does not suggest a definition of "predominantly" in numerical terms. The purpose of the reaction is to favor chlorination at the positions that will be chlorinated in the final product and to disfavor chlorination at other positions which will result in wasted product. We therefore agree with the ALJ's definition of "predominantly" as a plurality rather than a majority because expert testimony explains that relevant examples in the patent have yields of less than 50%. Tr. at 1493. Indeed, the overall yield for the conversion of sucrose to sucralose was 26% in the first generation of technology and is 42% in the second generation. *See* Tr. at 434-435.

b. Literal Infringement

The ALJ's ID

Allegations Against GDFII, Changzhou Niutang Chemical, Hebei Sukerui Science, and JK Sucralose

In the ID at 87-101, the ALJ found that "none of the four manufacturing Respondents infringe step (b) of claim 1 of the '463 patent." ID at 100. He also found that "[a]s each and every limitation of a claim is required in order to prove infringement, the undersigned does not find it necessary to address all of the other parties' arguments as to infringement under claim 1." ID at 100.

The ALJ found that claim 1 was not infringed because claim step (b) requires "subjecting the reaction mixture product of step (a) to an elevated temperature not higher than about 85°C [to produce] a mixture of chlorinated sucrose-6-ester products consisting essentially of monochlorosucrose-6-ester, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester," but that Tate & Lyle had not proven the formation of 1',6'-dichlorosucrose-6-ester in the accused methods below 85°C. ID at 98. There is no dispute that formation of 1',6'-dichlorosucrose-6-ester is a limitation of the claim which must be met for infringement to have occurred. To show formation of 1',6'-dichlorosucrose-6-ester, Tate & Lyle (according to the IA) relied on HPLC tests conducted for Tate & Lyle by Ciba Specialty Chemicals on samples obtained from Changzhou Niutang's and JK Sucralose's chlorination vessels when the reaction temperature was below 85°C. ID at 94-95.

The ALJ rejected Tate & Lyle's HPLC[25] test data, *inter alia*, because the testing entity, Ciba, did not determine whether the specifications it obtained from Tate & Lyle were reasonable and did not use an adequate standard, but rather used a mixed standard. ID at 99. The HPLC data showed one peak for dichlorosucrose-6-ester which Tate & Lyle asserted shows the presence of both 4,6'-dichlorosucrose-6-ester and 1',6'-dichlorosucrose-6-ester. It appears to be undisputed that this peak shows the presence of 4,6'-dichlorosucrose-6-ester, but the respondents disputed that this peak also shows the presence of 1',6'-dichlorosucrose-6-ester. The ALJ agreed with the respondents. ID at 98-99. The ALJ also rejected Tate & Lyle's use of JK Sucralose's samples as evidence relevant to show infringement by the other manufacturing respondents, *i.e.*, Hebei

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[25]High Performance Liquid Chromatography

Sukerui Science, GDFII, and Changzhou Niutang Chemical. ID at 99-100. The ALJ also found that the mass spectroscopy data relied on by Tate & Lyle based on samples from Hebei Sukerui Science's plant did not establish the presence of 1',6'-dichlorosucrose-6-ester. ID at 100. Finally, the ALJ rejected Tate & Lyle's attempted use of chemical kinetic theory to infer that 1',6'-dichlorosucrose-6-ester necessarily forms below 85°C, given that the theory as relied on by Tate & Lyle was not supported by the scientific literature, as no reference discussed chlorination of the 1' position before the 4 position for any sucrose derivative under any reaction condition. ID at 100. As the ALJ's finding of lack of proof of the formation of 1',6'-dichlorosucrose-6-ester was dispositive for a finding of non-infringement, the ALJ did not find it necessary to analyze whether the other claim limitations were met. ID at 100. The finding of non-infringement of independent claim 1 also resulted in a finding of non-infringement of the other asserted claims which depend from claim 1. ID at 101; *see also* ID at 107, 115-16, 124.

Other Respondents

CJ America is a non-participating respondent, but was not found in default. The ALJ noted that Tate & Lyle had asserted that CJ America admitted infringement. He then stated: "As there is no dispute regarding CJ America's infringement, the undersigned finds that CJ America infringes the asserted claims of the '463 patent." ID at 125. As discussed below, this finding conflicts with a subsequent finding by the ALJ that CJ America does not infringe.

AIDP is a non-participating respondent, but was not found in default. As to AIDP, the ALJ found "that the pre-suit testing does not affirmatively show that AIDP meets each and every

limitation of claim 1 for the same reasons infringement was not proven against the four participating manufacturing Respondents." ID at 126.

Hebei Research was found in default. The ALJ stated that "As Hebei Research has already defaulted in this investigation, the undersigned finds that there is no need to address whether Complainants have affirmatively proved that Hebei infringes the '463 patent." ID at 127. He therefore did not adjudicate whether Hebei Research infringes the asserted claims of the '463 patent on the merits. He did state it was his "understanding that Complainants are attempting to affirmatively prove that certain non-participating Respondents are infringing the patents at issue to support their request for a general exclusion order, which the undersigned does not find to be warranted in the circumstances of this case." ID at 127.

As to certain non-manufacturing participating respondents, specifically [[ ]], [[ ]], [[ ]], [[ ]], [[ ]], [[ ]], and [[ ]], who are alleged to obtain their sucralose from [[ ]], the ALJ found them not to infringe because they obtain their sucralose from the four manufacturing respondents whom he found not to infringe. ID at 127. [[

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As to the remaining non-participating and defaulting respondents, specifically, CJ America, Fortune Bridge, Gremount (default), Hebei Academe (default), Lianyungang Natiprol (default), Nu-Scaan, Ruland (default), Shanghai Aurisco (default), Vivion, and Zhongjin

(default), whose sucralose Tate & Lyle states is obtained from Changzhou Niutang, GDFII, Hebei Sukerui, and/or JK Sucralose, the ALJ stated that because he found the four manufacturing respondents not to infringe, the above-named respondents do not infringe either. ID at 128. The ALJ's finding of non-infringement by CJ America conflicts with his earlier finding that CJ America does infringe because it has admitted infringement.

Tate & Lyle's Submissions

Tate & Lyle has a three-fold argument that it has proven that 1',6'-dichlorosucrose-6-ester forms in the respondents' processes: (1) Tate & Lyle argues that if a desired compound forms at a higher temperature, then it must also form at a lower temperature, with the difference that the reaction to form the desired compound would simply proceed more slowly at the lower temperature. Thus, according to Tate & Lyle, since 1',6'-dichlorosucrose-6-ester was shown to form at temperatures above 85°C, it must also form, though more slowly, at temperatures below 85°C.[26] (2) Tate & Lyle argues that respondents have accepted this theory and admitted that 1',6'-dichlorosucrose-6-ester forms based on this theory because respondents and respondents' experts originally stated that 1',6'-dichlorosucrose-6-ester was present in the prior art based on this theory, in support of their argument that the asserted claims of the '463 patent were anticipated or obvious. Tate & Lyle Petition at 46-49; Tate & Lyle Submission at 58-65. (3) Although the HPLC analyses of samples taken from respondents' factories do not show separate peaks for 4,6'-dichlorosucrose-6-ester and 1',6'-dichlorosucrose-6-ester, Tate & Lyle argues that an HPLC analysis of a [[ ]] sample which shows separate peaks for 4,6'-dichlorosucrose and

[26] We will refer to this argument in our discussion as the kinetic theory.

1',6'-dichlorosucrose (not 4,6'-dichlorosucrose-6-ester and 1',6'-dichlorosucrose-6-ester) demonstrates that 1',6'-dichlorosucrose-6-ester formed in all of the samples. Tate & Lyle Petition at 49-52.

The foregoing arguments apply specifically to the four manufacturing respondents. However, Tate & Lyle argues that certain defaulting and non-participating respondents also infringe the asserted patents. For the '463 patent, Tate & Lyle asserts that CJ America has admitted that it infringes the asserted claims, that pre-suit testing of AIDP's sucralose samples indicates infringement, and that Hebei Research infringes and has defaulted. ID at 125-27. Tate & Lyle also asserts that several respondents have admitted that they sell for importation, import, or sell after importation sucralose manufactured by Changzhou Niutang, GDFII, Hebei Sukerui and/or JK Sucralose, and that these respondents are [[

]]. ID at 127-28. Tate & Lyle also asserts that Heartland Packaging has distributed in the United States sucralose manufactured by at least Changzhou Niutang and Hebei Sukerui. ID at 127.

Respondents' Submissions

Changzhou Niutang responds that the scientific theory relied on by Tate & Lyle does not support Tate & Lyle's position because the 4-position in sucrose-6-ester is more reactive than the 1-position, so 4,6'-dichlorosucrose-6-ester would form before 1',6'-dichlorosucrose-6-ester, and there is no evidence that any 1',6'-dichlorosucrose-6-ester would form. Changzhou Niutang

argues that according to the order of reactivity of the hydroxyls, sucrose-6-ester would first be chlorinated to form 6'-monochlorosucrose-6-ester, which would in turn be chlorinated to form 4,6'-dichlorosucrose-6-ester, which would in turn be chlorinated to form 1',4,6'-trichlorosucrose-6-ester. *See* Changzhou Niutang Reply to Tate & Lyle Petition at 43-44. Moreover, Changzhou Niutang also submits that just because a chemical reaction might occur does not mean that it does occur. Changzhou Niutang Reply to Tate & Lyle Petition at 45.

Changzhou Niutang disputes that its experts conceded the presence of 1',6'-dichlorosucrose-6-ester below 85°C. Changzhou Niutang Reply to Tate & Lyle Petition at 47 (citing Hanessian Tr. 1545:15-1546:16 ("my opinion, has been and always is, that there is no factual confirmatory or unambiguous evidence that the 1',6'-dichlorosucrose-ester is formed or is present in these reactions"); Frasier-Reid Tr. 1905:4-11 ("maybe if we go up to 85 – I mean, up to some temperature higher than 85, rather, then it may form, that 1' position is very, very, very obstinate.").

As to the HPLC of the [[ ]] sample, Changzhou Niutang agrees with the ALJ that the [[ ]] sample was not relevant to other respondents such as Changzhou Niutang Chemical and that Tate & Lyle did not demonstrate a reliable methodology, adding that 1',6'-dichlorosucrose is not 1',6'-dichlorosucrose-6-ester, that 1',6'-dichlorosucrose was not present in any quantifiable amount, that it did not appear as a "fully resolved peak," and that Tate & Lyle's chromatogram [[ ]] was not in evidence because it was struck by the ALJ. Changzhou Niutang Reply to Tate & Lyle Petition at 36-42; Changzhou Niutang Submission at 45-52 (stating, *inter alia*, that CDX-1.115 was not moved into

evidence, and Tate & Lyle used a graph which was part of CX-621P which was proferred but not admitted). Changzhou Niutang also points out that Tate & Lyle's alternate mass spectroscopy analytical method could not differentiate between different dichlorosucrose-6-esters because each dichlorosucrose-6-ester has the same mass. Changzhou Niutang Reply to Tate & Lyle Petition at 39.

The IA's Submissions

The IA submits that the ALJ was correct that Tate & Lyle has not met its burden of showing the existence of 1',6'-dichlorosucrose-6-ester by a preponderance of the evidence, and agrees that much of Tate & Lyle's proferred evidence was unreliable and much of the testimony was not credible. IA Response to Petitions at 26-34; IA Submission at 15 (discussing literal infringement and infringement under the doctrine of equivalents).

Discussion

We agree with respondents and the ALJ that Tate & Lyle's reliance on kinetic theory does not overcome its failure to provide direct evidence in this investigation of actual infringement. With regard to 1',6'-dichlorosucrose-6-ester, we have only competing expert testimony as to whether the peak for 4,6'-dichlorosucrose-6-ester also contains 1',6'-dichlorosucrose-6-ester, or whether the 1',6'-dichlorosucrose in the [[ ]] sample comes from 1',6'-dichlorosucrose-6-ester formed below 85°C. To prevail on infringement before the Commission, the complainants must show a preponderance of the evidence, *i.e.*, that it is more likely than not, that 1',6'-dichlorosucrose-6-ester forms below 85°C in the reactions in question. In our view complainants have not met their burden. We therefore agree with the ALJ's finding that Tate & Lyle has not met its burden of proving infringement of the asserted claims of the '463 patent.

Further, read in context of the full trial transcripts, the experts for the various respondents did not admit that 1',6'-dichlorosucrose-6-ester is formed during the chlorination step of the accused processes. *See* Hanessian Tr. 1545:15-1546:16; Frasier-Reid Tr. 1905:4-11.[27] Other than its scientific theory, and respondents' contradictory assertions, the only evidence relied on by Tate & Lyle to show the presence of 1',6'-dichlorosucrose-6-ester below 85°C is the HPLC of a [[ ]] sample showing 1',6'-dichlorosucrose. But 1',6'-dichlorosucrose is not 1',6'-dichlorosucrose-6-ester. Thus, Tate & Lyle has not shown that 1',6'-dichlorosucrose-6-ester forms below 85°C, and therefore has not proven infringement of the asserted claims of the '463 patent. Of course, even if conclusions could be drawn about the [[ ]] sample, those conclusions would not be evidence of what occurs in the processes of other respondents.

We agree with the ALJ that Tate & Lyle has not shown that Hebei Sukerui Science infringes the asserted claims of the '463 patent because it has not shown that the peak for dichlorosucrose-6-esters on mass spectroscopy can be attributed to 1',6'-dichlorosucrose-6-ester, especially given the conflicting views of experts Dr. Crich and Dr. Baker. ID at 113-14. Thus, we determine that Tate & Lyle has not shown that any of the four manufacturing respondents has infringed the asserted claims of the '463 patent.

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[27] Tate & Lyle's petition for review and Tate & Lyle's review submission state that respondent GDFII allegedly admitted that 1',6'-dichlorosucrose-6-ester forms in the chlorination step of its process: GDFII's Supplemental Response to Interrogatory No. 32 (*discussed* in CX-621RC at 264-65). An examination of the interrogatory response shows that GDFII made the statement in arguing for invalidity of the asserted claims of the '463 patent, but Tate & Lyle is using this admission to argue for infringement of these claims. We note that any admission in an interrogatory response by GDFII cannot be used against other parties. Second, a tribunal is not required to treat an admission in an interrogatory response as fact, even against the party making the interrogatory response, in this case GDFII. *Wright & Miller*, FEDERAL PRACTICE AND PROCEDURE § 2180-81.

We also determine that Tate & Lyle has failed to show (on the merits) that certain non-manufacturing respondents infringe the asserted claims of the '463 patent based on the ALJ's finding that the manufacturing respondents who are said to supply the non-manufacturing respondents do not employ the patented process in their manufacture. These include [[

]]. [[

]] *See* ID at 13, 127. We also include CJ America in this group because, in our view, any admission that it infringes is overcome by a finding on the merits that it does not. We further agree with the ALJ's finding that AIDP does not infringe, a finding that appears to be based on his general rejection of Tate & Lyle's reliance on kinetic theory to demonstrate the presence of 1',6'-dichlorosucrose-6-ester. Finally, even though the ALJ did not rule on whether Hebei Research infringes on the merits, we find no infringement on the basis of lack of proof, as it appears that Tate & Lyle is relying on kinetic theory to demonstrate the presence of 1',6'-dichlorosucrose-6-ester, an approach we find to be insufficient, as noted above.

In its petition for review, Tate & Lyle argued that certain defaulting and non-participating respondents should be found to infringe the '463 patent. Tate & Lyle Petition at 12-15 (relying on alleged admissions of infringement (CJ America and Vivion); Commission Rule 210.16

(certain defaulting respondents[28]); and Commission Rule 210.17 and *Certain Electrical Connectors and Products Containing Same*, Inv. No. 337-TA-374, Order No. 24 (AIDP, Fortune Bridge, and Nu-Scaan)). In its submissions on review, Tate & Lyle repeats these arguments. As discussed above, we have found that CJ America has not been shown to infringe the asserted claims. As to Vivion, we note that Tate & Lyle did not argue in its post-hearing brief that Vivion had admitted infringement and thus has waived this issue. As to AIDP, as discussed above, we have found that the ALJ was correct in finding non-infringement. In its post-hearing brief, Tate & Lyle argued: "Further, each of those Non-Participating and Defaulting Respondents has not participated in this Investigation, did not submit a pre-hearing brief, and did not participate in the hearing thereby depriving Tate & Lyle from obtaining discovery into other sources of their sucralose and waiving their right to contest that they infringed the Asserted Claims of the '463 patent." Tate & Lyle Post-Hearing Brief at 88 (as revised per Order No. 59 on August 13, 2008). There was no request for adverse inferences under Commission Rule 210.17. The ALJ therefore did not err in not making such a finding. In any event, such a ruling would not constitute an affirmative finding of infringement, as is also the case for a finding of default under Commission Rule 210.16. Of course, parties who are declared in default under Commission Rule 210.16 may, as a general rule, be subject to a limited exclusion order. *See also* 19 U.S.C. § 1337(g)(1).

c. Infringement under the Doctrine of Equivalents

The ALJ found that the four manufacturing respondents did not infringe the asserted claims under the doctrine of equivalents, relying specifically on step (b) and its requirement of

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[28] Hebei Research, Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Shanghai Aurisco, and Zhongjin.

production of 1',6'-dichlorosucrose-6-ester during the chlorination steps of the respective accused processes, finding that Tate & Lyle had not shown the presence of an equivalent to the presence of a 1',6'-dichlorosucrose-6-ester being formed below 85°C. ID at 102, 108, 117, 125. He did not separately address equivalents with respect to the remaining respondents.

The Federal Circuit has two articulations of the test for determining infringement under the doctrine of equivalents:

> This court applies two articulations of the test for equivalence. *See Warner-Jenkinson*, 520 U.S. at 40, 117 S.Ct. 1040 (explaining that different phrasings of the test for equivalence may be "more suitable to different cases, depending on their particular facts"). Under the insubstantial differences test, "[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial." *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed.Cir.2004). Alternatively, under the function-way-result test, an element in the accused device is equivalent to a claim limitation if it "performs substantially the same function in substantially the same way to obtain substantially the same result." *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1209-10 (Fed.Cir.2001).

Voda v. Cordis Corp., 536 F.3d 1311, 1326-27 (Fed. Cir. 2008). Under either articulation of the test, equivalence must be determined for each limitation. *See id.*

In response to the Commission's request for briefing on the doctrine of equivalents, Tate & Lyle argues that respondents combine the same reagents, just in a different order. *See* Tate & Lyle Submission at 80-83. Changzhou Niutang argues that Tate & Lyle cannot show equivalence because it has not shown the presence of 1',6'-dichlorosucrose-6-ester, and further that Tate & Lyle never submitted evidence on the issue of equivalence and would in any case be barred from arguing for infringement under the doctrine of equivalents under principles of argument-based prosecution history estoppel because the patentee told the PTO that the 1',6'-dichlorosucrose-6-

ester contributed to the novelty of the invention. Changzhou Niutang Submission at 13-15; *see also* Hebei Sukerui Submission at 8-12; JK Sucralose Submission at 7-11. JK Sucralose argues that Tate & Lyle has not identified any equivalent for 1',6'-dichlorosucrose-6-ester. JK Sucralose Submission at 16. As to legal bars to the application of the doctrine of equivalents, respondents assert waiver and prosecution history estoppel. The IA agrees that Tate & Lyle has not shown the existence of 1',6'-dichlorosucrose-6-ester and that assertion of infringement under the doctrine of equivalents is barred under principles of prosecution history estoppel.

As discussed above, infringement under the doctrine of equivalents is assessed on a limitation by limitation basis. We affirm the ALJ's conclusion that Tate & Lyle has not demonstrated the formation of a 1',6'-dichlorosucrose-6-ester in the accused processes. Moreover, we agree with respondent JK Sucralose that Tate & Lyle has not identified anything that would be equivalent to 1',6'-dichlorosucrose-6-ester in the accused processes. Thus, under the all elements rule, there would be no infringement under the doctrine of equivalents, [[ ]]. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1326-27 (Fed. Cir. 2008) (equivalence must be determined on a limitation by limitation basis).

We do not believe the issue of infringement by equivalents has been waived as it was addressed in the ID at 101 and in Tate & Lyle's petition for review at 58. As to respondents' assertion that infringement under the doctrine of equivalents is barred by prosecution history estoppel, the Federal Circuit has explained that "[A]mendment of a claim in light of a prior art reference, however, is not the sine qua non to establish prosecution history estoppel.

Unmistakable assertions made by the applicant to the Patent and Trademark Office (PTO) in support of patentability, whether or not required to secure allowance of the claim, also may operate to preclude the patentee from asserting equivalency between a limitation of the claim and a substituted structure or process step." *Texas Instruments Inc. v. ITC*, 988 F.2d 1158, 1165 (Fed. Cir. 1993). In our view, the patentee's assertion to the PTO that 1',6'-dichlorosucrose-6-ester contributes to the novelty of the invention does give rise to prosecution history estoppel. *See* JX-6 (Response of July 18, 1989 at 5).

Exclusion of Evidence

Tate & Lyle's Submissions

In connection with his analysis of infringement of the '463 patent, the ALJ excluded certain late-produced evidence which Tate & Lyle sought to have admitted to show the presence of dichlorosucrose-6-esters in the process of the manufacturing respondents below 85°C. Tate & Lyle Submission at 156. Specifically, this evidence includes an HPLC of a [[ ]] sample, which shows separate peaks for 1',6'-dichlorosucrose and 4,6'-dichlorosucrose. Tate & Lyle Reply Submission at 59-60. Tate & Lyle argues that this evidence should have been admitted, and that the 1',6'-dichlorosucrose is evidence of the formation of 1',6'-dichlorosucrose-6-ester, and "validates the kinetic model." Tate & Lyle Reply Submission at 60. Tate & Lyle further claims that Dr. Crich's expert report would have included data showing fully resolved peaks for 1',6'-dichlorosucrose-6-ester. Tate & Lyle Submission at 163-64. Tate & Lyle explains, that as with the evidence proferred to show infringement of the '969 and '551 patents, the ALJ's sole reason for excluding the evidence was that it was produced after the date for expert reports in this Investigation. Tate & Lyle Submission at 157. Tate & Lyle asserts that it

was diligent in its efforts to obtain these samples in a timely manner. Tate & Lyle Submission at 160-162. Tate & Lyle argues that the ALJ's refusal to admit the proferred evidence was an abuse of discretion because Tate & Lyle produced the test results to respondents within 24 hours of receiving them, the start of the hearing was still weeks away, Tate & Lyle offered their testifying experts for additional depositions, the individuals who performed the testing were also available for deposition, and the ALJ failed to consider the probative value of the evidence. Tate & Lyle Submission at 167-68. Tate & Lyle further argues that the exclusion of this evidence undermines Commission policy as it will encourage respondents not to cooperate with discovery requests in future investigations. Tate & Lyle Submission at 169-170.

Respondents' Submissions

Respondents reply that the ALJ properly excluded the late-produced evidence because it was submitted less than a month before the hearing was to begin. Changzhou Niutang Reply Submission at 14. Respondents submit that if complainants had been permitted to introduce this evidence, respondents would have needed an opportunity to conduct their own tests, and would have required further expert reports and depositions. *Id.*

The IA's Submissions

The IA argues that the ALJ properly excluded late-produced evidence, IA Reply Submission at 75 n.17, and states that "Complainants blatantly mischaracterize the excluded evidence." IA Reply Submission at 85 n.25. The IA also states that the proferred evidence shows a distinct peak for 1',6'-dichlorosucrose and for 4,6'-dichlorosucrose, but does not show a distinct peak for 1',6'-dichlorosucrose-6-ester.

Discussion

In our view, the ALJ did not abuse his discretion in refusing to accept evidence produced less than a month before trial. We note that, even if the excluded evidence were considered, the result would not change, since none of the excluded samples demonstrated the presence of 1',6'-dichlorosucrose-6-ester or an equivalent.

2. Anticipation/Obviousness

Anticipation occurs if a single prior art reference contains all of the limitations of the asserted claim. *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. [I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Abbott Labs. v. Baxter Pharmaceutical Prods., Inc* . 471 F.3d 1363, 1368 (Fed. Cir. 2006).

As to obviousness,[29] the Supreme Court in *Graham* explained that one ascertains whether an invention would have been obvious to a person of ordinary skill in the art by examining the

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[29] The Patent Statute provides that an invention may be obvious as follows:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art, keeping in mind such secondary considerations as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). A prima facie case of obviousness may be shown where all of the claimed elements occur in the prior art, and there is a showing that it would have been "obvious" to combine them. Prior to *KSR*, the Federal Circuit required a teaching, suggestion, or motivation to combine the elements found in the prior art. Under the Supreme Court's teaching in *KSR*, a teaching, suggestion, or motivation to combine elements need not come from a prior art reference. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727,1741 (2007).

The ALJ considered whether the prior art references of Jenner, Mufti, Rathbone, and Ballard anticipated or rendered obvious the asserted claims of the '463 patent. The Jenner reference, U.S. Patent No. 4,362,869, protects all five hydroxyl groups which are not replaced with chlorine atoms in the final product. The Mufti reference, U.S. Patent No. 4,380,476, protects only the hydroxyl group at the 6 position to form sucrose-6-ester using a Vilsmeier reaction.[30] The Rathbone reference, U.S. Patent No. 4,617,269, used discrete heating steps for chlorination. The Ballard reference, RX-589, also teaches the use of discrete heating steps. ID at 135-37.

Respondents relied on Mufti and Rathbone for anticipation. However, the ALJ found no anticipation because "neither of these references disclose the formation of the

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[30] One issue in this case is whether Mufti combined the acid chloride and tertiary amide in the presence of sucrose-6-ester, as in the '463 patent, or whether Mufti combined the acid chloride and the tertiary amide before adding sucrose-6-ester.

chloroformiminium chloride sale [*sic*, salt] in the presence of the sucrose-6-ester or the formation of a mixture of chlorinated sucrose-6-ester products consisting essentially of monochlorosucrose-6-ester, 4,6'-dichlorosucrose-6-ester, and 1',6'-dichlorosucrose-6-ester below 85°C." ID at 143-44. As to obviousness, the ALJ found that "none of the additional prior art references cure the defect above because the additional prior art references do not disclose the formation of a mixture of chlorinated sucrose-6-ester products consisting essentially of monochlorosucrose-6-ester, 4,6'-dichlorosucrose-6-ester, a 1',6'-dichlorosucrose-6-ester at below 85°C." ID at 144. The ALJ stated that he found it "unnecessary to determine whether there are secondary considerations of non-obviousness as the undersigned did not find that the '463 patent is obvious above." ID at 147.

Changzhou Niutang argues that if Tate & Lyle's arguments on claim construction and infringement are accepted, then the asserted claims of the '463 patent would be invalid for anticipation or obviousness. Specifically, respondents argue that if the Commission finds 1',6'-dichlorosucrose-6-ester in the accused processes then the Commission must also find it present in Mufti which would result in the invalidation of the asserted claims of the '463 patent by reason of anticipation or obviousness. ID at 143-44, 147. Changzhou Niutang notes that prior art previously considered by the PTO can still invalidate and that the alleged secondary considerations of obviousness are irrelevant because there is no nexus between the commercial success of sucralose and the claimed invention.

Tate & Lyle's Submissions

Tate & Lyle submits that Mufti does not anticipate the asserted claims of the '463 patent because it fails to disclose the formation of a chloroformiminium chloride salt in the presence of sucrose-6-ester. Tate & Lyle further argue Jenner would not cure the defect in Mufti and render the '463 patent obvious because Jenner involved a penta-ester, in which all of the hydroxyls not being chlorinated are protected by ester groups. Tate & Lyle states that it is hindsight to say that the acid chloride and the tertiary amide could be directly reacted in the presence of a mono-ester (sucrose-6-ester) rather than a penta-ester (as in Jenner). Tate & Lyle Reply Submission at 122-23.

The IA's Submissions

The IA argues that none of the prior art anticipates or renders obvious the asserted claims of the '463 patent because no one has proven that 1',6'-dichlorosucrose-6-ester forms in the prior art processes, as required by the claims. IA Reply Submission at 70. The IA further states that neither Mufti nor Rathbone teaches the formation of a chloroformiminium salt in the presence of sucrose-6-ester. The IA explains that respondents have not proven that the formation of the Vilsmeier reagent in Mufti "in situ" necessarily means that that the Vilsmeier reagent was formed in the presence of sucrose-6-ester, *i.e.*, respondents have not proven that "in situ" means anything more than that the Vilsmeier reagent is formed in the same reaction vessel before the addition of sucrose-6-ester. IA Reply Submission at 70-71.

Discussion

In our view, respondents have not demonstrated the presence of 1',6'-dichlorosucrose-6-ester, actually or inherently, in the prior art processes for the same reason that Tate & Lyle has

not shown the presence of 1',6'-dichlorosucrose-6-ester in the accused processes. In addition, none of the references show the formation of the chloroformiminium chloride salt in the presence of the sucrose-6-ester. We therefore agree with the ALJ's finding that the asserted claims of the '463 patent are not invalid for anticipation. Since none of the references show the presence of the 1',6'-dichlorosucrose-6-ester, we also agree with the conclusion of the ALJ that the asserted claims of the '463 patent are not invalid for obviousness. This is because even if there were some reason to combine these references, the combination would not result in the claimed invention.

3. Enablement

To satisfy the enablement requirement of 35 U.S.C. § 112, the specification must teach those of ordinary skill in the art how to practice the claimed invention without undue experimentation. *See, e.g., In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). In the words of the statute, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112.

The ALJ held that the asserted claims of the '463 patent were invalid for failure to satisfy the enablement requirement because there is no direct evidence that the inventors ever confirmed that 1',6'-dichlorosucrose-6-ester forms below 85 °C in the claimed process. ID at 150-51. The ALJ noted that the examples of the '463 patent do not mention that 1',6'-dichlorosucrose-6-ester was detected below 85°C, that the only reference to that ester in the specification is in the brief

summary of the invention where the inventors state they "believe" the chlorination step mixture included the ester. He rejected Tate & Lyle's argument that the "literature," theories of "basic chemistry," and "kinetics" demonstrate that 1',6'-dichlorosucrose-6-ester forms below 85°C, and stated that if the matter were truly one of basic chemistry and kinetics, it would have been simple to show the presence of the ester, but no such test was disclosed or shown to be readily available.

Tate & Lyle argues that the ALJ erred in placing the burden on Tate & Lyle to demonstrate the formation of 1',6'-dichlorosucrose-6-ester, rather than on respondents to prove that the patent is invalid. Tate & Lyle Submission at 94; Tate & Lyle Petition at 60. Tate & Lyle argues that it is also unnecessary to show the formation of 1',6'-dichlorosucrose-6-ester because it is sufficient to follow the steps in examples 7 or 13, but argues that 1',6'-dichlorosucrose-6-ester did form, [[

]]. Tate & Lyle Submission at 93-95; Petition at 59-61. Tate & Lyle also argues that a deacylated standard is sufficient. Tate & Lyle Submission at 95-96; Petition at 60. Tate & Lyle further states that peer reviewed literature "supports the presence of the claimed intermediates." Tate & Lyle Petition at 61; see also Tate & Lyle Submission at 96.

Respondents counter that there is no indication that the ALJ shifted the burden, and that the ALJ was merely summarizing the parties' arguments. Changzhou Niutang Reply Submission at 73 . Respondents argue that it is not sufficient to practice an example, if the patentee does not practice the claims. Changzhou Niutang Reply Submission at 73 (citing *Engel Indus., Inc. v.*

Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991); Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1469-70 (Fed. Cir. 1993)). Respondents argue that there was no appropriate standard available at the time of the invention in 1989 which would have allowed the inventors to distinguish 1',6'-dichlorosucrose-6-ester from 4,6'-dichlorosucrose-6-ester on HPLC. Changzhou Niutang Reply Submission at 75. Respondents also argue that the kinetic theory arguments fail for the same reason that they did for infringement, anticipation, and obviousness. Changzhou Niutang Reply Submission at 75.

The IA agreed with the ALJ's finding that the patent was not enabled, pointing, *inter alia*, to the testimony of one of the inventors, [[

]].

In light of these arguments, we agree with the ALJ that the evidence indicates that the ester has not been shown to be formed in the claimed process below 85°C as claimed. Therefore, the patent cannot disclose how a person of ordinary skill in the art could form the ester under these conditions. We therefore uphold the ALJ's finding that the asserted claims are invalid for lack of enablement.

4. Written Description

The written description requirement is satisfied if the disclosure conveys with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed invention. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000).

The ALJ held that the asserted claims of the '463 patent satisfy the written description requirement "because it is clear what 1',6'-dichlorosucrose-6-ester is, whereas, with the enablement requirement, there was no direct evidence that 1',6'-dichlorosucrose-6-ester was formed, or could be detected, below 85°C." ID at 153. In our view, the ALJ's conclusion is correct, but for the reason that the specification refers to the (supposed) formation of 1',6'-dichlorosucrose ester during the chlorination step, as called for by the claims.

5. Indefiniteness

Claims must be sufficiently definite "to permit a potential infringer to determine whether or not he is infringing" and to permit a court to determine whether "novelty and invention are genuine." *Exxon Research and Eng'g. Co. v. United States*, 265 F.3d 1371, 1378 (Fed. Cir. 2001) (citations omitted). Claims are definite if they are capable of construction. *See id.*

The ALJ found that respondents had failed to demonstrate that the claims were invalid for indefiniteness because "the undersigned [the ALJ] was able to construe all of the disputed claim limitations above." We agree with the ALJ. As noted above, we also agree with the ALJ's construction of the disputed limitations.

6. Domestic Industry

Under the definitions of section 337(a), an industry exists if there is "significant investment in plant and equipment," "significant employment of labor or capital," or "substantial investment in [the patent's] exploitation, including engineering, research and development, or licensing." Section 337(a)(3)(A),(B),(C). 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 of labor or capital are actually related to "articles protected by" the intellectual property right which

forms the basis of the complaint. Section 337(a)(3); *see Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, USITC Pub. 3003 (Nov. 1996), Comm'n Op. at 14-17. 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. *Certain Stringed Musical Instruments*, Inv. No. 337-TA-586, Comm'n Op. at 13-14.

The ALJ held that Tate & Lyle did not satisfy the technical prong of the domestic industry requirement with respect to the asserted claims of the '463 patent because Tate & Lyle did not meet its burden of proving that 1',6'-dichlorosucrose-6-ester forms in its process as required by the claims. ID at 133. He found that [[

]]. As discussed above, Tate & Lyle's reliance on kinetic theory is insufficient to show that this limitation is met. We therefore agree with the ALJ's finding that Tate & Lyle did not meet the technical prong of the domestic industry requirement with respect to the asserted claims of the '463 patent.

B. The '969 and '551 patents[31]

As of the date of the final ID, complainants asserted the '969 and '551 patents against Changzhou Niutang Chemical and GDFII, as well as certain non-manufacturing participating respondents, and certain non-participating and defaulted respondents, *i.e.*, CJ America, AIDP,

[31] There is no dispute as to certain issues, such as whether there is a domestic industry that satisfies the asserted '969 and '551 patents.

Garuda, Heartland Sweeteners, [[ ]], [[ ]], U.S. Niutang, Nu-Scaan, Shanghai Aurisco, and Zhongjin. We have found that sucralose is not produced "under, or by means of" the process of the '551 patent. *Supra*, section II.D.6. Nevertheless, we have chosen to examine both the '969 and '551 with respect to the issues of infringement and validity as presented to us by the petitions for review.

1. Infringement of the '969 and '551 patents

The '969 patent is directed to the use or presence of a DSDE catalyst to add an ester group to sucrose to make sucrose-6-ester which is then ready for the steps of the '463 patent, while the '551 patent is directed to a liquid-liquid extraction to recover the DSDE catalyst from a reaction mixture which includes sucrose-6-ester. Independent claim 20 of the '969 patent, from which the other asserted claims of the '969 patent depend, and independent claim 1 of the '551 patent, from which all of the other asserted claims of the '551 patent depend, call for the use or presence of a DSDE catalyst, specifically a 1,3-diacyloxy-1,1,3,3-tetra(hydrocarbyl)distannoxane. Thus all of the asserted claims of the '969 and '551 patents require the use or presence of a DSDE catalyst.

The ALJ's ID

The ALJ construed disputed limitations of the '969 and '551 patents,[32] but found non-infringement solely on the basis that Tate & Lyle failed to prove that the two manufacturing respondents (Changzhou Niutang Chemical and GDFII) use a DSDE (tin diester) catalyst[33] in

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[32] The ALJ's claim construction was not the subject of any petition for review.

[33] distannoxane diester (which is a catalyst with two tin atoms and two ester groups, one off of each tin atom).

their processes. The ALJ found that the evidence showed that manufacturing respondents Changzhou Niutang Chemical and GDFII use [[

]]. ID at 170. He rejected the allegation that the presence of tin in Changzhou Niutang Chemical's and GDFII's bulk sucralose and plant inspection samples indicated that the plant inspection did not accurately reflect the processes used by those two respondents. ID at 171.

The ALJ found that AIDP does not infringe, stating that he "agrees with Respondents that the evidence based on the pre-suit testing does not affirmatively show that AIDP infringes either the '969 or '551 patents for the same reasons infringement was not proven against Changzhou Niutang or GDFII, namely because the presence of organic butyl tin was not confirmed in AIDP's pre-suit sample." ID at 173.

The ALJ found that CJ America infringes because "there is no dispute regarding CJ America's infringement," noting Tate & Lyle's assertion that CJ America has admitted infringement. ID at 173.

[[

]] Since he found that neither Changzhou Niutang Chemical nor GDFII infringed, he also found that these respondents did not infringe. ID at 174.

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[34] [[
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As to non-participating respondent Nu-Scaan and defaulting respondents Shanghai Aurisco and Zhongjin, the ALJ, noting that liability of these respondents was premised on infringement by Changzhou Niutang Chemical and GDFII, also found that these respondents did not infringe. The ALJ's findings related to whether infringement had been shown on the merits. Under section 337(g) and Commission Rule 210.16, defaulting respondents may be the subject of limited exclusion orders even in the absence of an affirmative showing of infringement.

a. Preliminary Issues

Before addressing the ALJ's findings regarding infringement, it is necessary to address two preliminary issues, *i.e.*, whether the ALJ was correct in refusing to accord Tate & Lyle a presumption of infringement under 35 U.S.C. § 295, and whether the ALJ properly excluded certain late-produced evidence sought to be admitted by Tate & Lyle.

Whether the ALJ was Correct that Tate & Lyle is Not Entitled to a Presumption Under 35 U.S.C. § 295 that Respondents Infringed the Asserted Claims of the '969 and '551 Patents

In connection with the issue of infringement of the '969 and '551 patents, the ALJ refused to accord Tate & Lyle a presumption under 35 U.S.C. § 295 that Changzhou Niutang Chemical, U.S. Niutang, and GDFII infringe "since there is no evidence that Respondents failed to participate in discovery or hindered Complainants from being able to make a reasonable effort to determine their manufacturing processes." ID at 172-73.

Tate & Lyle's Submissions

Tate & Lyle first argues that it is entitled to a presumption under 35 U.S.C. § 295[35] that the imported articles were made by an infringing method. Tate & Lyle explains that under the statute, an accused product shall be presumed to be made by the patented process if (1) there is a substantial likelihood that the product was made by the patented process and (2) the plaintiff has made a reasonable effort to determine the process actually used and was unable to so determine. Tate & Lyle Petition at 88 (discussing 35 U.S.C. § 295). Tate & Lyle cites the legislative history and Federal Circuit law which explains that less than a preponderance[36] of evidence is required where the defendant has been non-cooperative. Tate & Lyle Petition at 89 (relying on S. Rep.

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[35] The statute provides:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds--
> (1) that a substantial likelihood exists that the product was made by the patented process, and
> (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

35 U.S.C. § 295.

[36] Although a party must demonstrate facts by a preponderance of the evidence in most civil cases, *i.e.*, that it is more likely than not that a fact is true, the laws of evidence do provide for various kinds of evidentiary presumptions which may be used to satisfy a burden of production, or in this case, a burden of proof, if certain predicate conditions are established for using the presumption. Under 35 U.S.C. § 295, the predicate conditions are establishing a "substantial likelihood" of infringement and inability to determine what process was actually used after making a reasonable effort to do so.

No. 100-83 (1987) at 45 and *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. U.S. International Trade Comm'n*, 224 F.3d 1356, 1359-60 (Fed. Cir. 2000)).

Respondents' Submissions

Changzhou Niutang states that to shift the burden of proof through a presumption under 35 U.S.C. § 295 is a drastic measure tantamount to a sanction and was created for the situation where importers and manufacturers reside outside the reach of United States discovery mechanisms, but that no such sanction would be warranted here because respondents have provided thousands of pages of documents regarding their processes, including batch records, notebooks, operation manuals and other materials, as well as deposition testimony. Changzhou Niutang Response at 80-83. Changzhou Niutang contends that complainants have not shown that they could not determine the processes used by respondents, that they are merely rehashing old discovery disputes, and that they have received all relevant discovery regarding respondents' processes which is sufficient as a matter of law. Changzhou Niutang Response to Petition at 87-94. Moreover, Changzhou Niutang argues that complainants cannot show that there is a substantial likelihood that respondents' sucralose was ever made according to the claims of the '969 or '551 patents. Changzhou Niutang Response to Petition at 83. Changzhou Niutang analogizes the case here to the *Aventis* case in which a court did not find the presence of a chemical compound sufficient grounds for a presumption under 35 U.S.C. § 295 of infringement of a process patent. Changzhou Niutang Petition at 83-87 (discussing *Aventis Pharms., Inc. v. Barr Labs.*, 411 F.Supp.2d 490, 514 (D.N.J. 2006) ("In the absence of evidence about how many

possible fexofenadine production processes exist, Plaintiffs cannot establish a substantial likelihood that the [patented] process was used by showing that one other process was not used").

The IA's Submissions

The IA agrees with the ALJ that Tate & Lyle has not satisfied the two-pronged test for obtaining a presumption of infringement under 35 U.S.C. § 295. The IA explains that Tate & Lyle has not demonstrated a substantial likelihood that the infringing process is used because the presence of dibutyl tin does not necessarily indicate the use of DSDE. IA Reply Submission at 81 (discussing *Aventis*, 411 F.Supp.2d at 510-512). The IA explains that Tate & Lyle has not demonstrated inability to conduct discovery, noting that Tate & Lyle did not make any allegations that respondents' discovery responses were inadequate and that Tate & Lyle did not seek any sanctions pursuant to Commission Rule 210.33. IA Reply Submission at 84.

Discussion

The ALJ properly found that Tate & Lyle did not meet the test for obtaining a presumption of infringement, as it did not show an inability to access the factories nor did it show a substantial likelihood that respondents' sucralose is made using the processes of the '969 or '551 patents since the presence of dibutyl tin does not necessarily indicate the use of DSDE. *See* RX-828C at 41-42; RX-829 at 29-30; RX-832 at 13. We therefore we agree with the conclusion of the ALJ on this point.

Exclusion of Evidence

In connection with his analysis of infringement of the '969 and '551 patents, the ALJ excluded certain late-produced evidence which Tate & Lyle sought to have admitted. Tate & Lyle argues that this evidence should have been admitted.

Tate & Lyle's Submissions

As it did before the ALJ, Tate & Lyle argues that the presence of inorganic tin and dibutyl tin in samples taken from respondents' factories indicates the presence of DSDE. Tate & Lyle Submission at 104-133. Tate & Lyle submits expert testimony that the presence of dibutyl tin could indicate that DSDE was present because dibutyl tin can be a decomposition product of DSDE. Some of the samples showing dibutyl tin and certain expert testimony interpreting these samples that Tate & Lyle seeks to rely on in making this argument were excluded by the ALJ as having been submitted late. Tate & Lyle argues that the ALJ erred in excluding this evidence, blaming the late nature of the reports on respondents' insistence that Tate & Lyle ship the samples themselves.

Respondents' Submissions

Respondents state that Tate & Lyle received adequate discovery and that respondents were not the cause of Tate & Lyle's lateness. Respondents explain that they allowed full access to their facilities, which Tate & Lyle toured, but that they would not ship samples in the first instance because they did not know how to ship internationally samples containing corrosive chemicals. Changzhou Niutang Reply to Tate & Lyle Petition at 3-4; *see also* Changzhou Niutang Reply Submission at 114-115.

The IA's Submissions

The IA states that the ALJ did not abuse his discretion in excluding the late evidence. IA Response to Petitions at 11-17.

Discussion

The issue is reviewed *de novo* by the Commission, 5 U.S.C. § 557(b) (*quoted in Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324 (U.S.I.T.C. Aug. 6, 1992)); Commission Rule 210.45(c). In our view, the ALJ properly precluded this evidence because Tate & Lyle was aware of the deadline for production of evidence and could itself have arranged for transport of the samples rather than relying on respondents to transport the samples. Further, as discussed below, even if the evidence had been admitted, it would not have changed the result.

b. Literal Infringement

Tate & Lyle's Submissions

Tate & Lyle argues that the presence of dibutyl tin in respondents' factories indicates the use of DSDE. Petition for Review at 67-68 (DSDE can degrade into dibutyl tin).

Respondents' Submissions

Respondents state that Tate & Lyle has not provided evidence of the use of DSDE in their process. Changzhou Niutang Reply Submission at 77-86. Respondents argue that the presence of dibutyl tin does not necessarily mean that DSDE was present.

The IA's Submissions

The IA submits that Tate & Lyle has not shown the presence of DSDE, even with the laboratory evidence of other forms of tin. IA Reply Submission at 74-78. The IA agrees with the ALJ that there were also credibility problems with the interpretation of the data, specifically that the experts did not adequately supervise the testing and that the testing was inconsistent. IA Reply Submission at 75-76.

Discussion

As noted above, the ALJ's ruling on infringement with regard to the manufacturing respondents rests on his finding that Tate & Lyle's failed to demonstrate that DSDE was used in the accused processes. We agree with the ALJ that the presence of inorganic or dibutyl tin does not prove that DSDE was used. We therefore agree with the ALJ's finding that the asserted claims of the '969 and '551 patents are not literally infringed by Changzhou Niutang Chemical or GDFII. We note that, even if the excluded evidence were considered, the result would not change, since none of the excluded samples contained DSDE and the presence of dibutyl tin does not prove the use of DSDE. See IA Response Submission at 75 n.17 ("The Bodycote testing...only shows the detection of organic tins, which the ID finds to be plausibly explained by other reasons explained below.")

As to the non-manufacturing respondents, we make the following determinations:

With respect to AIDP, we agree with the ALJ that AIDP does not infringe since the presence of organic butyl tin was not confirmed in the AIDP sample. ID at 173. We note that while AIDP was a so-called non-participating respondent, it was not found in default under Commission Rule 210.16.

As to CJ America, it is a so-called non-participating respondent, but has not been found in default. It has admitted infringement of the '969 and '551 patents.[37] Unlike the situation with regard to the '463 patent, there is no conflicting finding of non-infringement for the '969 patent by CJ America.

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[37] The '551 patent is not within the scope of section 337(a)(1)(B)(ii).

With respect to the non-manufacturing participating respondents, and the non-participating and defaulted respondents, their liability is dependent on that of their suppliers, the manufacturing respondents. Since the latter were found not to infringe, the ALJ correctly found that the former do not infringe either. We note that while Tate & Lyle argued infringement by Heartland Packaging in its post-hearing brief, it did not allege infringement by Heartland Packaging in its complaint.

In its petition for review, Tate & Lyle stated as follows:

> ...Like CJ America, Vivion also filed a response to the Complaint admitting infringement of the '969 and '551 patents. (See Vivion Response to Complaint (Sept. 23, 2008).) For the same reasons as CJ America, Vivion should be found to infringe the '969 and '551 patents based on its admissions of such infringement. But, for the same reasons discussed with respect to the '463 patent, the ID was incorrect when it did not find that defaulting and non-participating Respondents AIDP, Nu-Scaan, Shanghai Aurisco, and Zhongjin infringe the '969 and '551 patents.
>
> In light of Commission Rules 210.16(b)(3) and 210.17, Commission precedent as expressed in *Electrical Connectors*, as well as law of the case set forth in the Commission's Notice Not to Review the Initial Determination Finding Seven Respondents in Default, and in light of the reasoning set forth above, each of AIDP, Nu-Scaan, Shanghai Aurisco, and Zhongjin should be found to infringe the '969 and '551 patents. The ID's failure to do so was an erroneous conclusion of law.

Tate & Lyle Petition at 15.

However, in its submission on review, Tate & Lyle simply stated:

> The ALJ improperly declined to find infringement of certain associated patents by certain defaulting Respondents. Tate & Lyle fully addresses and incorporates the arguments and evidence referenced regarding this issue in Section II(A)(3)(a) of its Brief on Remedy, the Public Interest and Bond. Indeed, the ALJ's failure to properly find infringement by the defaulting and non-participating Respondents was a legal error that detrimentally impedes the Commission decision on the appropriate scope of relief.

Tate & Lyle Submission at 155. The cited portion of Tate & Lyle's remedy brief is identical to the corresponding section of its petition for review. In its post-hearing brief to the ALJ however, Tate & Lyle did not rely on these arguments, but rather on CJ America's admission, AIDP's pre-suit sample, and for the non-manufacturing participating respondents, as well as Nu-Scaan, Shanghai Aurisco, and Zhongjin, the derivative liability from Changzhou Niutang Chemical and/or GDFII. In addition, with regard to Nu-Scaan, Shanghai Aurisco, and Zhongjin, Tate & Lyle stated that these respondents have "not participated in the Investigation, did not submit a pre-hearing brief, and did not participate in the hearing..." Tate & Lyle Post-Hearing Brief at 136.

As to Vivion, notwithstanding any alleged admission, Tate & Lyle did not argue that Vivion infringed the '969 and '551 patents in its post-hearing brief and the ALJ did not address such infringement. As noted above, the liability of non-manufacturing participating respondents and the non-participating and defaulting respondents (except for AIDP and CJ America) is based on the liability of the manufacturing respondents. Since the latter do not infringe, the former do not infringe either. As to Nu-Scaan, it was a non-participating respondent which was not found in default. There was no express request for a finding of adverse inferences under Commission Rule 210.17 against Nu-Scaan. Shanghai Aurisco and Zhongjin were found to be in default under Commission Rule 210.16. A ruling of default under Commission Rule 210.16 does not constitute a finding of infringement on the merits, though it may form the basis of a limited exclusion order under section 337(g).[38]

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[38] Tate & Lyle did not raise the issue of infringement by equivalents in its post-hearing brief, and the ALJ did not address it. Tate & Lyle did not raise the issue of doctrine of

2. Anticipation and Obviousness

a. The '969 Patent: Anticipation and Obviousness

The '969 patent uses DSDE as a catalyst to effect esterification of sucrose. This catalyst may be recovered from the reaction mixture by using the '551 method:

DSDE –> DBBS –> **DSDE** (begin again)

(DSDE is the catalyst and DBBS is the combination of DSDE with sucrose)

The prior art for the '969 patent includes the Navia '746 patent, the Otera reference, the Wagner reference, the David reference, and the '551 patent.[39] According to its abstract, Navia discloses the reaction of sucrose with a 1,3-di(hydrocarbyloxy)-1,1,3,3-tetra(hydrocarbyl)distannoxane to produce a 1,3-di(6-O-sucrose)-1,1,3,3-tetra(hydrocarbyl)distannoxane, which can be acylated to produce a sucrose-6-ester. The Navia '746 patent used a DHTO-type tin catalyst. The Otera reference describes how solvent polarity affects tetrabutyl tin esterification of such substrates as benzyl alcohol and methyl butyrate. The Wagner reference, RX-397, teaches the use of a dibutyl tin catalyst to esterify certain simple sugars. The David reference is a review article which describes the esterification of sugar

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equivalents in its petition for review of the final ID, which had decided infringement adversely to it. Thus, the issue of equivalents of the '969 and '551 patents is waived because it was not before the ALJ and is waived at least under Commission Rule 210.43(b)(2) ("Any issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination (unless the Commission chooses to review the issue on its own initiative under § 210.44)."). *See also Broadcom v. ITC*, 542 F.3d 894, 901 (Fed. Cir. 2008).

[39] The '551 patent is assigned to Tate & Lyle but the invention claimed therein was invented by a different group of inventors (a different so-called "inventive entity"). Thus the '551 patent can serve as a means of invalidating the '969 patent.

derivatives at specific positions using tributyl tin. As noted above, the '551 patent teaches the removal of DSDE from a reaction mixture containing DSDE, a sucrose-6-ester, and a polar aprotic solvent.

The ALJ's ID

Anticipation

The ALJ noted that the respondents did not make a separate argument regarding anticipation in their post-hearing briefs, ID at 182, and therefore limited his analysis to obviousness.

Obviousness

The ALJ held that the asserted claims of the '969 patent are not invalid for obviousness, giving the following as his reasons: "First, Respondents only made general arguments that a certain combination of references render the '969 patent obvious without arguing any specific references in combinations. Second, even taking these references in combination, the references do not disclose the specific process using DSDE for acylation, as required by the '969 patent." ID at 185.

Respondents' Submissions

Changzhou Niutang argues that, contrary to the ALJ, the '969 patent is invalid in light of prior art, specifically that the organic tin catalysts of the '969 patent would have been obvious in light of the Navia '746 patent, which forms DSDE. Changzhou Niutang Petition at 83-84. Changzhou Niutang asserts that the Navia reference can also be combined with other references, including the Vernon reference and various scientific articles which discuss how the organic tin catalysts can form complexes with sucrose derivatives. Changzhou Niutang Petition at 85-90.

Changzhou Niutang argues that the disclosure in the Navia '746 reference would have provided the motivation to use DSDE as a catalyst. Changzhou Niutang Submission at 129.

The other respondents do not address these patents in their petitions for review or submissions.

Tate & Lyle's Submissions

Tate & Lyle argues that the ALJ was correct that the asserted claims of the '969 patent would not have been considered obvious over the asserted prior art. Tate & Lyle Response to Changzhou Niutang's Petition at 82. Tate & Lyle submits, *inter alia*, that the DBTO organic tin in the Navia '746 reference is different than the DSDE organic tin in the '969 patent, and that the DSDE formed in the Navia process is formed as an unwanted byproduct. Tate & Lyle Response to Changzhou Niutang's Petition at 82-89. Tate & Lyle states that the DSDE did not participate in the acetylation process in the prior art. Tate & Lyle Reply Submission at 163.

The IA's Submissions

The IA agrees that the asserted claims of the '969 patent were not obvious, explaining that the organic tin compound used in the Navia '764 reference is very different from the organic tin catalyst used in the process of the '969 patent. IA Response at 68-69.

Discussion

We agree with the ALJ that the '969 patent is not invalid for obviousness. The method of the Navia '746 patent was to use a DHTO tin catalyst which formed DSDE as a byproduct of the reaction. Navia did not use DSDE as a catalyst. The disclosure in the '551 patent, which is argued to show how to modify the Navia '746 patent to recover DSDE, does not render the '969 patent obvious because the '551 patent and Navia do not teach that DSDE may be used as a

catalyst. Thus, even if there was a reason to combine the references, the combination would not result in the claimed invention.

b. The '551 Patent: Anticipation and Obviousness

The prior art for the '551 patent included the Navia '746 patent, which taught a process for making sucrose-6-ester using an organotin catalyst, the Moore reference, which taught an extraction across a liquid-liquid partition (a so-called "liquid-liquid extraction"), and the Wagner reference, which taught the use of a dibutyl tin catalyst to esterify the simple sugars which are part of the building blocks of RNA.

The ALJ's ID

With regard to anticipation, respondents relied only on the Navia '746 patent. The ALJ held that the Navia '746 patent does not anticipate the '551 patent because the Navia '746 patent does not teach the extraction process of the '551 patent. ID at 189.

With regard to obviousness, the respondents relied on the Navia '746 patent in combination with the Moore and/or Wagner references. The ALJ found that respondents had failed to meet their burden to show by clear and convincing evidence that the prior art references rendered the patent obvious because the references do not show a liquid/liquid extraction, or the use of a small amount of water. ID at 191.

Respondents' Submissions

As to anticipation, Changzhou Niutang states that the asserted claims of the '551 patent are anticipated by Navia '746 because that reference teaches the use of "recovery procedures that are known in the art." Changzhou Niutang Petition for Review at 81 (citing RX-168, col. 5, lines 47-49).

As to obviousness, Changzhou Niutang asserts that, contrary to the ALJ, the elements of the asserted claims '551 are disclosed in the prior art: use of a liquid-liquid extraction (Moore), use of water to increase the efficiency of a liquid-liquid extraction (standard laboratory knowledge), use of tin catalysts (Navia), use of an organic solvent that is not soluble in water (Navia), and use of DMF (Navia). Changzhou Niutang Petition at 78-83. Thus, Changzhou Niutang disagrees with the ALJ and asserts that the addition of water to facilitate a liquid-liquid organic extraction is standard laboratory knowledge known in the art.

The other respondents do not address these patents.

Tate & Lyle's Submissions

Tate & Lyle argues that claims 1-4 and 11-22 of the '551 patent are not anticipated by the asserted prior art because Navia does not teach the formation of sucrose-6-ester, only the formation of an intermediate which can be reacted with an acylating agent to form sucrose-6-ester, and because Navia teaches the recovery of sucrose-6-ester using evaporation and filtering techniques, rather than the liquid-liquid extraction of the '551 patent. Tate & Lyle Response to Changzhou Niutang's Petition for Review at 75. As to obviousness, Tate & Lyle argues that claims 1-4 and 11-22 of the '551 patent would not have been considered obvious over the asserted prior art because Navia taught away from dissolving both the sucrose-6-ester and the tin compound, thereby teaching away from the use of a liquid-liquid extraction. Tate & Lyle Response to Changzhou Niutang's Petition at 79. Moreover, Tate & Lyle argues that it would not have been obvious to add a small amount of water to the liquid-liquid extraction, citing the testimony of Dr. Sands that a person of ordinary skill would not have been motivated to add

water because it would have to be removed before the chlorination step. Tate & Lyle Response to Changzhou Niutang's Petition at 79.

The IA's Submissions

The IA agrees with the ALJ that the asserted claims of the '551 patent were not anticipated or obvious, explaining that the organic tin compound used in the Navia '764 reference is very different from the organic tin catalyst used in the process of the '551 patent. IA Response at 68-69.

Discussion

We agree with the ALJ that the asserted claims of the '551 patent are not invalid for anticipation or obviousness. We agree with the ALJ that the Navia '746 patent does not anticipate the '551 patent because it does not teach the use of a liquid-liquid extraction. We also agree with the ALJ that the asserted claims of the '551 patent are not invalid for obviousness, since Moore does not cure the defect in Navia because Moore does not teach the use of a small amount of water to improve the liquid-liquid extraction. The Wagner reference does not teach the use of water with a liquid-liquid extraction. Moreover, we agree with Tate & Lyle that Navia taught away from the use of water because Navia taught away from dissolving the sucrose-6-ester and tin catalyst in water.

C. The '709 and '435 Patents

As of the date of the final ID, complaints asserted the '709 and the '435 patents against certain defaulting and non-participating entities.[40] [41] Specifically, Tate & Lyle asserted the '709

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[40] Independent claim 8 of the '709 patent recites:

patent against AIDP, CJ America, Hebei Research, Fortune Bridge, Nu-Scaan, Vivion, Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Shanghai Aurisco, and Zhongjin. Tate & Lyle asserted the '435 patent against Hebei Research, Fortune Bridge, Vivion, Gremount,

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8. A process for producing sucralose from a feed mixture of (a) 6-O-acyl-4,1',6'-trichloro-4,1',6'-trideoxygalactosucrose, (b) salt including alkali metal or alkaline earth metal chloride, (c) water, and (d) other chlorinated sucrose by-products, in a reaction medium comprising a tertiary amide, wherein said process comprises:
(i) removing said tertiary amide to produce an aqueous solution of (a), (b) and (d) from which a major proportion of the tertiary amide in said feed mixture has been removed;
(ii) deacylating the 6-O-acyl-4,1',6'-trichloro-4,1',6'-trideoxygalactosucrose by raising the pH of the aqueous solution product of step (i) to a pH of at least about 11 (±) at a temperature and for a period of time sufficient to effect said deacylation, to produce an aqueous solution comprising sucralose, salt including alkali metal or alkaline earth metal chloride, and other chlorinated sucrose by-products; and
(iii) recovering sucralose from the product of step (ii).

[41] Claim 1 of the '435 patent recites:

1. A method for removing impurities from a starting composition including sucralose; first and second impurities, each of said first and second impurities comprising one or more related halogenated sucrose derivatives; and a first solvent; the method comprising the steps of: (a) extracting the starting composition with a second solvent at least partially immiscible with the first solvent to transfer the first impurities into said second solvent, thereby converting the starting composition to a partially purified composition comprising the sucralose, the second impurities, and the first solvent; (b) extracting the partially purified composition with a third solvent at least partially immiscible with the first solvent to transfer the sucralose into said third solvent while retaining the second impurities in said first solvent; and (c) recovering said sucralose from the third solvent via crystallizing said sucralose; wherein the first impurities comprise tetrachlorosucrose, and wherein in step (a) at least half of the tetrachlorosucrose is transferred to the second solvent while at least half of the sucralose is retained in the first solvent.

Hebei Academe, Lianyungang Natiprol, and Ruland. None of these are manufacturers. Tate & Lyle had previously alleged infringement of these patents by manufacturing respondents Changzhou Niutang Chemical, GDFII, and Hebei Sukerui Science, but later withdrew those allegations. The ALJ made separate infringement findings for each of the defaulting and non-participating respondents, as discussed below.

The '709 Patent – Infringement

AIDP was a non-participating respondent, but was not found to be in default. Tate & Lyle relied on the testimony of one of its chemists to show infringement by AIDP. The ALJ found that testimony "insufficient to affirmatively prove that AIDP infringes the asserted claims of the '709 patent. Dr. Flora did not perform or oversee any of the tests regarding AIDP. In addition, no one who conducted the tests was called to testify regarding the methodology used or the reliability of the results. Even if the tests were reliable, however, the tests which show the mere presence of detected impurities is not conclusive that AIDP infringes the deacylation process disclosed in the '709 patent." ID at 194.

CJ America was a non-participating respondent, but was not found in default. As to CJ America, the ALJ, noting that Tate & Lyle had asserted that CJ America had admitted infringement, stated: "As there is no dispute regarding CJ America's infringement, the undersigned finds that CJ America infringes the asserted claims of the '709 patent." ID at 194.

Fortune Bridge was a non-participating respondent, but was not found in default. As to Fortune Bridge, the ALJ stated: "As there is no dispute regarding Fortune Bridge's infringement, the undersigned finds that Fortune Bridge infringes the asserted claims of the '709 patent." ID at

195. The ALJ treated non-participating respondents Nu-Scaan and Vivion similarly. The ALJ also treated defaulting respondents Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Shanghai Aurisco, and Zhongjin similarly.

Hebei Research was found in default. As to Hebei Research, the ALJ stated: "As Hebei Research has already defaulted in this investigation, the undersigned finds that there is no need to address whether complainants have affirmatively proved that Hebei Research infringes the '709 patent." By way of explanation, the ALJ stated in a footnote: "It is the undersigned's understanding that Complainants are attempting to affirmatively prove that certain non-participating Respondents are infringing the patents at issue to support their request for a general exclusion order, which the undersigned does not find to be warranted in the circumstances of this case." ID at 197 n.11.

The '435 Patent – Infringement

CJ America was a non-participating respondent, but was not found in default. As to CJ America, the ALJ, noting that Tate & Lyle had asserted that CJ America had admitted infringement, stated: "As there is no dispute regarding CJ America's infringement, the undersigned finds that CJ America infringes the asserted claims of the '435 patent." ID at 204.

Fortune Bridge was a non-participating respondent, but was not found in default. As to Fortune Bridge, the ALJ stated: "As there is no dispute regarding Fortune Bridge's infringement, the undersigned finds that Fortune Bridge infringes the asserted claims of the '435 patent." ID at 195. The ALJ treated non-participating respondent Vivion similarly. The ALJ also treated

defaulting respondents Gremount, Hebei Academe, Liangyungang Natiprol, and Ruland similarly.

Hebei Research was found in default. As to Hebei Research, the ALJ stated: "As Hebei Research has already defaulted in this investigation, the undersigned finds that there is no need to address whether complainants have affirmatively proved that Hebei Research infringes the '435 patent." By way of explanation, the ALJ stated in a footnote: "It is the undersigned's understanding that Complainants are attempting to affirmatively prove that certain non-participating Respondents are infringing the patents at issue to support their request for a general exclusion order, which the undersigned does not find to be warranted in the circumstances of this case." ID at 207 n.11.

Tate & Lyle's Submissions

In its petition for review, Tate & Lyle argued that AIDP should be found to infringe the '709 patent. Specifically, Tate & Lyle argued that in light of Commission Rule 210.17, *Electrical Connectors*, and "in light of the reasoning set forth with respect to the '463 patent, AIDP should be found to infringe the '709 patent." Tate & Lyle Petition at 15. In its submission on the issues on review, Tate & Lyle stated:

> The ALJ improperly declined to find infringement of certain associated patents by certain defaulting Respondents. Tate & Lyle fully addresses and incorporates the arguments and evidence referenced regarding this issue in Section II(A)(3)(a) of its Brief on Remedy, the Public Interest, and Bond. Indeed, the ALJ's failure to properly find infringement by the defaulting and non-participating Respondents was a legal error that detrimentally impedes the Commission decision on the appropriate scope of relief.

Tate & Lyle Submission at 155. Tate & Lyle's submission on remedy on this point is identical to its petition for review. In its post-hearing brief, however, Tate & Lyle relied solely on alleged record evidence of infringement by AIDP. Tate & Lyle Post-Hearing Brief at 146-47.

The Respondents' Submissions

The Respondents do not appear to have petitioned or briefed the issue of infringement of the '709 and '435 patents.

The IA's Submissions

The IA has objected to the ALJ's ultimate finding that respondent CJ America infringed the asserted claims of the '435 patent because Tate & Lyle did not assert the '435 patent against CJ America in its Complaint. IA Response to Petitions at 2.

Discussion

With respect to AIDP, the ALJ's finding of non-infringement of the '709 patent is correct. Tate & Lyle's attempt to rely on Commission Rule 210.17 comes too late, as it is an argument that it could have made but failed to make before the ALJ. While the ALJ found that CJ America infringes the '709 patent, there is no conflicting finding of non-infringement, as with the '463 patent, and thus its admission stands. The ALJ's findings that Fortune Bridge, Gremount, Hebei Academe, Lianyungang Natiprol, Nu-Scaan, Ruland, Shanghai Aurisco, Vivion, and Zhongjin infringed the '709 patent on the merits are inadequate as no reasons are given for the findings. Similarly, the ALJ's findings that Fortune Bridge, Gremount, Hebei Academe, Lianyungang, Natiprol, Ruland, and Vivion infringe the '435 patent on the merits is inadequate as no reasons are given for the findings. As to Hebei Research, the ALJ did not make a ruling on the merits, but Tate & Lyle has not petitioned on this issue. As the IA points out,

Tate & Lyle did not accuse CJ America of infringement of the '435 patent in its complaint. As noted previously, respondents defaulted under Commission Rule 210.16 (Gremount, Hebei Academe, Hebei Research, Lianyungang Natiprol, Ruland, Shanghai Aurisco, and Zhongjin) may still be the subject of a limited exclusion order even if infringement is not found on the merits. *Compare* 19 U.S.C. § 1337(g)(1) (limited exclusion order may be entered against defaulting respondent) *with id.* § 1337(g)(2) (general exclusion order may be entered in case of defaulters only upon showing of substantial, reliable, and probative evidence of violation, and where other criteria for a general exclusion order are met). Nu-Scaan, Vivion, and Fortune Bridge were not found in default, but could be the subject of adverse inferences under Commission Rule 210.17, as requested by Tate & Lyle before the ALJ, which can include a finding of violation.

V. REMEDY, THE PUBLIC INTEREST, AND BONDING

The ALJ's Recommended Determination

The ALJ stated that a general exclusion order is not warranted in this investigation because complainants failed to prove affirmative infringement of the asserted patents by any of the respondents in the investigation, as well as any other non-named respondents. ID at 226.

With regard to cease and desist orders, the ALJ noted that according to the IA, there is unrebutted evidence that [[ ]], Garuda, U.S. Niutang, [[ ]], Forbest USA, and MTC Industries each maintain commercial quantities of sucralose within the United States. ID at 227. He thus found that in the event the Commission finds a violation by any of the "domestic Respondents," complainants have shown that cease and desist orders are warranted against them.

The ALJ recommended a bond in the amount of 100% of the entered value of the infringed imported products to permit importation during the Presidential review period pursuant to section 337(j).

Tate & Lyle's Submissions

Tate & Lyle submits that a general exclusion order is necessary under both 19 U.S.C. § 1337(d)(2)(A) and (B). Tate & Lyle argues that a general exclusion order is necessary under 19 U.S.C. § 1337(d)(2)(A) to prevent circumvention of an exclusion order limited to respondents' products. Tate & Lyle further argues that certain companies doctor documents, altering their certificates of analysis to disguise the source of their sucralose. Tate & Lyle Submission on Remedy at 6-7. Tate & Lyle also argues that certain manufacturers conceal their identities, pointing out that manufacturers rarely, if ever, identify themselves on their product packaging and labeling, making it impossible for Customs to determine the source of their manufacture. Tate & Lyle Submission on Remedy at 7. Tate & Lyle also describes rapidly evolving distribution networks in which subsidiaries are created and renamed, and sucralose changes hands making it difficult to trace and establish the identity of the manufacturer. Tate & Lyle Submission on Remedy at 7-17 (including diagrams of complex relationships among entities).

Tate & Lyle argues that a general exclusion order is necessary under 19 U.S.C. § 1337(d)(2)(B) because there is a widespread pattern of violation of section 337, it is difficult to identify the source of infringing products, and there are significant incentives for foreign competitors to enter the U.S. market. Tate & Lyle argues that it established the sucralose market, its sucralose is profitable, it has established consumer demand and products, there are profitable

retail distribution channels, there are profitable industrial distribution channels, and there are available distributors. Tate & Lyle Submission on Remedy at 18-25. Tate & Lyle submits that "business conditions are such that (a) there is a history of unauthorized use of the accused products, (b) there is established demand for the accused products in the United States, (c) there are economic incentives for foreign manufacturers to target the U.S. market, (d) there are additional foreign manufacturers capable of importing accused products, and (e) there are low barriers to entry into the United States of new foreign manufacturers of accused products." Tate & Lyle Submission on Remedy at 17-18. In addition, Tate & Lyle argues that they meet the *Spray Pumps* factors which they submit support the issuance of a general exclusion order in this case. Tate & Lyle Submission on Remedy at 25 (citing *Certain Airless Paint Spray Pumps and Components Thereof*, Inv. No. 337-TA-90, USITC Pub. No. 1199, Comm'n Op. At 17 (1981)).

Tate & Lyle further submits that the ALJ erred in concluding that the defaulting respondents and non-participating respondents did not justify the issuance of a general exclusion order. Tate & Lyle submits that the ID's conclusion that certain defaulting and non-participating respondents do not infringe the asserted patents depends upon legal error. Tate & Lyle contends that certain defaulting and non-participating respondents should be found to infringe the '463 patent, arguing that AIDP deprived Tate & Lyle of any discovery and any opportunity to obtain the full range of its products for laboratory testing. Tate & Lyle argues that AIDP should similarly be found to infringe the '709 patent. Tate & Lyle Submission on Remedy at 32. Tate & Lyle Submission on Remedy at 28-31. Tate & Lyle also contends that certain defaulting and non-participating respondents should be found to infringe the '969 and '551 patents, noting that

CJ America admitted infringement in its response to the complaint, citing ID at 173, and arguing that Vivion did the same. Tate & Lyle Submission on Remedy at 31. Tate & Lyle argues that Commission precedent justifies issuance of a general exclusion order based on the defaulting and non-participating respondents. Tate & Lyle Submission on Remedy at 31-34.

Tate & Lyle also requests cease and desist orders against respondents JK Sucralose, Garuda, U.S. Niutang, Heartland Sweeteners, Forbest USA, and MTC in the event that the Commission finds a violation of section 337. Tate & Lyle Submission on Remedy at 36. Tate & Lyle contends that these companies possess U.S. inventories.

Tate & Lyle submits that its production capacity is such that U.S. consumers would not be adversely affected by an exclusion of infringing sucralose, and that it is unaware of any other public interest issue that would militate against the entry of the proposed relief. Tate & Lyle Submission on Remedy at 37-38. Tate & Lyle contends that there is a public interest in the protection of its intellectual property rights. Tate & Lyle Submission on Remedy at 38.

As to bonding, Tate & Lyle argues for a bond set at 100 percent of the entered value of infringing imported merchandise because it argues that there is no way to determine a reasonable royalty rate and there is no price differential upon which to base the amount of any bond.

Respondents' Submissions

Changzhou Niutang submits that any remedial orders issued by the Commission should exempt sucralose imported or sold by GDFII and the Niutang Respondents. Changzhou Niutang Reply Submission at 117. Changzhou Niutang submits that its entities do not infringe the asserted patent claims and therefore, any exclusion order, general or limited, that the

Commission might issue should have a provision that: "This Order does not apply to any sucralose, sweeteners containing sucralose, or related intermediate compounds thereof that are manufactured, imported or sold by any of the following entities: Changzhou Niutang Chemical Plant Co., Ltd., U.S. Niutang Chemical, Inc., Guangdong Food Industry Institute, L&P Food Ingredient Co., Ltd. or Garuda International Co., Ltd." Changzhou Niutang Reply Submission at 117. Changzhou Niutang submits that a certification provision is not necessary, and that their products should simply be exempted from any remedial order that might issue. Changzhou Niutang Reply Submission at 118-120. Changzhou Niutang further states that U.S. Niutang and Garuda should not be subject to any cease and desist orders. Changzhou Niutang Reply Submission at 121. JK Sucralose argues that it should not be subject to any cease and desist order because it does not use an infringing process and Tate & Lyle has not demonstrated significant U.S. inventories. JK Sucralose Reply Submission at 20. Respondents do not appear to have briefed the issues of public interest or bonding.

The IA's Submissions

The IA submits that a general exclusion order is not appropriate in this investigation, and argues that a limited exclusion order and cease and desist orders should be directed to respondents found to be in violation and respondents found to be in default. IA Submission at 27-31. The IA contends that Tate & Lyle has not satisfied the *Spray Pumps* factors which require showing "numerous" foreign manufacturers and widespread infringement, stating that Tate & Lyle has not presented any evidence concerning the pendency of foreign infringement suits based upon foreign patents which correspond to the domestic patents at issue, or any other evidence

which demonstrates a history of unauthorized use of the patented invention. IA Submission at 29. The IA states that Tate & Lyle has shown demand in the U.S. market for the product. IA Submission at 29. The IA submits that his recommended remedy of a limited exclusion order is not contrary to the public interest, and does not implicate any particular public interest or health concerns. IA Submission at 32. The IA recommended bonding at 100% of the entered value if a violation is found. IA Submission at 34.

Discussion

As discussed above, the '463 patent was not shown to be infringed on the merits. Further, it is invalid and Tate & Lyle was found to have failed to meet the domestic industry requirement with respect to that patent. Thus, there is no violation of section 337 and no remedy is appropriate even against defaulters. The '551 patent is not for a process for making sucralose within the meaning of section 337(a)(1)(B)(ii) and thus cannot be the basis of a violation in this case. In our view, this situation is similar to that where a patent is found invalid, in which case no relief issues, even against defaulters. Thus, relief in this case can only be issued with respect to the '969, '709, and '435 patents. As to the '969 patent, CJ America has admitted infringement and Shanghai Aurisco and Zhongjin have defaulted. For the '709 and '435 patents, CJ America has admitted infringement of the '709 patent; respondents Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, and Hebei Research have defaulted with respect to both patents; Shanghai Aurisco and Zhongjin have defaulted with respect to the '709 patent; non-participating respondents Vivion and Fortune Bridge are subject to adverse inferences with respect to the '709 and '435 patents under Commission Rule 210.17; and non-participating respondent Nu-Scaan is

subject to adverse inferences with respect to the '709 patent under Commission Rule 210.17. This is essentially a default case with respect to the '969, '709 and '435 patents. A general exclusion order can issue in a default case only if the criteria of section 337(g)(2) are met:

> (2) In addition to the authority of the Commission to issue a general exclusion from entry of articles when a respondent appears to contest an investigation concerning a violation of the provisions of this section, a general exclusion from entry of articles, regardless of the source or importer of the articles, may be issued if--
> (A) no person appears to contest an investigation concerning a violation of the provisions of this section,
> (B) such a violation is established by substantial, reliable, and probative evidence, and
> (C) the requirements of subsection (d)(2) of this section are met.

19 U.S.C. § 1337(g)(2). Thus, a general exclusion order in a default case can issue only if there is substantial, reliable, and probative evidence of infringement and violation. *See, e.g.*, *Certain Sildenafil or any Pharmaceutically Acceptable Salt Thereof, such as Sildenafil Citrate, and Products Containing Same*, Inv. No. 337-TA-489, Comm'n Op. at 5.[42] Establishment of a violation by substantial, reliable, and probative evidence is required in any case in order to obtain a general exclusion order. This criterion is not met here. We therefore determine that the

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[42] In addition, issuance of a general exclusion order under section 337(g) also requires that the criteria for a general exclusion order under section 337(d) are met:

> (d)(2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that--
> (A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or
> (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

19 U.S.C. § 1337(d)(2).

appropriate form of relief in this investigation is a limited exclusion order directed to the respondents listed above, with the caveat that the order not apply to sucralose supplied to these respondents by the manufacturing respondents who were found to either not infringe or against whom infringement allegations were withdrawn as to the asserted patents. A certification provision is appropriate in this case. The respondents against whom a cease and desist order was sought were not found to infringe the '969, '709, and '435 patents and were not found in default.

Before issuing an order, the Commission also considers 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(g)(1). No party argues that the public interest would preclude issuance of a remedy here, and there is no evidence indicating any such public interest concerning the imported product.

As to bonding, during the 60-day period of Presidential review for exclusion orders, respondents are "entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3). In view of the lack of adequate pricing data, we agree with the ALJ that bonding should be in the amount of 100% of entered value, which is the Commission's practice in such circumstances. *See, e.g., Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Commission Op. at 26-27 (July 1997).

PUBLIC VERSION

By order of the Commission.

Marilyn R. Abbott
Secretary to the Commission

Issued: 4/28/09

CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND COMPONENTS THEREOF **337-TA-604**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **COMMISSION OPINION** Investigative Attorney, Christopher G. Paulraj, Esq., and the following parties as indicated, on April 29, 2009.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
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ON BEHALF OF COMPLAINANTS TATE & LYLE TECHNOLOGY LIMITED AND TATE & LYLE SUCRALOSE, INC.:

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ON BEHALF OF RESPONDENTS CHANGZHOU NIUTANG CHEMICAL PLANT CO., LTD., GUANGDONG FOOD INDUSTRY INSTITUTE, GARUDA INTERNATIONAL CO., LTD., L & P FOOD INGREDIENT CO., LTD. AND U.S. NIUTANG CHEMICAL, INC.

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND RELATED INTERMEDIATE COMPOUNDS THEREOF**	**Investigation No. 337-TA-604**

NOTICE OF COMMISSION ISSUANCE OF A LIMITED EXCLUSION ORDER; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued a limited exclusion order against eleven respondents in the above-captioned investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), and has terminated the investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. 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 (*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 May 10, 2007, based upon a complaint filed on behalf of Tate & Lyle Technology Ltd. of London, United Kingdom, and Tate & Lyle Sucralose, Inc. of Decatur, Illinois (collectively, "Tate & Lyle"). The complaint alleged violations of section 337(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of sucralose, sweeteners containing sucralose, and

related intermediate compounds thereof by reason of infringement of various claims of United States Patent Nos. 4,980,463 ("the '463 patent"); 5,470,969 ("the '969 patent"); 5,034,551 ("the '551 patent"); 5,498,709 ("the '709 patent"); and 7,049,435 ("the '435 patent"). The notice of investigation named twenty-five respondents.

On August 15, 2007, the Commission issued notice of its determination not to review an ID allowing JK Sucralose, Inc. ("JK Sucralose") to intervene as a respondent in the investigation. On August 30, 2007, the Commission issued notice of its determination not to review an ID terminating the investigation with respect to ProFood International Inc. on the basis of a consent order. On October 3, 2007, the Commission issued notice of its determination not to review an ID adding Heartland Sweeteners, LLC ("Heartland Sweeteners") as a respondent in the investigation. The respondents who remain parties to the investigation are therefore: Changzhou Niutang Chemical Plant Co. ("Changzhou Niutang Chemical"); Guangdong Food Industry Institute and L&P Food Ingredient Co., Ltd. ("GDFII"); Hebei Sukerui Science and Technology Co., Ltd. ("Hebei Sukerui Science"); JK Sucralose; Beijing Forbest Chemical Co., Ltd.; Beijing Forbest Trade Co., Ltd.; Forbest International USA, LLC; U.S. Niutang Chemical, Inc.; Garuda International, Inc.; Heartland Packaging Corporation; Heartland Sweeteners; MTC Industries, Inc.; Nantong Molecular Technology Co., Ltd.; AIDP, Inc.; Fortune Bridge Co., Inc. ("Fortune Bridge"); Nu-Scaan Nutraceuticals ("Nu-Scaan"); CJ America, Inc. ("CJ America"); Vivion, Inc. ("Vivion"); Gremount International Co., Ltd. ("Gremount"); Hebei Province Chemical Industry Academe ("Hebei Academe"); Hebei Research Institute of Chemical Industry ("Hebei Research"); Lianyungang Natiprol (Int'l) Co., Ltd. ("Lianyungang Natiprol"); Ruland Chemistry Co., Ltd. ("Ruland"); Shanghai Aurisco Trading Co., Ltd. ("Shanghai Aurisco"); and Zhongjin Pharmaceutical (Hong Kong) Co. ("Zhongjin"). Some of these respondents have been found in default.

On September 22, 2008, the presiding administrative law judge issued a final initial determination ("final ID") finding no violation of section 337 (with the exception of certain non-participating and defaulted respondents). On October 6, 2008, Tate & Lyle, four sets of respondents, and the Commission investigative attorney ("IA") each filed petitions for review. On November 21, 2008, the Commission issued notice of its determination to review the final ID in its entirety and requested briefing on the issues on review and on remedy, the public interest, and bonding, including responses to certain questions.

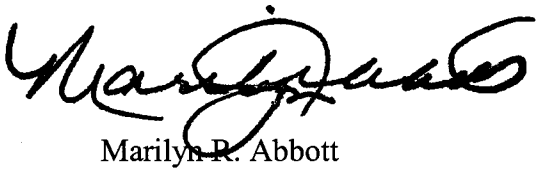
On review, the Commission found no violation on the merits with respect to the '463, '969, and '551 patents, for the reasons set forth in the Commission opinion. As to the '969 patent, respondents Shanghai Aurisco and Zhongjin were previously found to have defaulted. Additionally, the Commission found CJ America, Inc. to have admitted infringement and to have agreed to the entry of an exclusion order as to the '969 patent. As to the '709 and '435 patents, respondents Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, and Hebei Research were previously found to have defaulted with respect to the '709 and '435 patents, and Shanghai Aurisco and Zhongjin were previously found to have defaulted with respect to the '709 patent. Additionally, the Commission found CJ America to have admitted infringement and to have agreed to the entry of a remedial order as to the '709 patent, that non-participating respondents

Vivion and Fortune Bridge were subject to adverse inferences with respect to the '709 and '435 patents under Commission Rule 210.17, and that non-participating respondent Nu-Scaan was subject to adverse inferences with respect to the '709 patent under Commission Rule 210.17.

The Commission has determined that the appropriate form of relief in this investigation is a limited exclusion order prohibiting the unlicensed entry of certain sucralose and sweeteners containing sucralose by reason of infringement of one or more of claims 20, 21-26, 28, and 29 of the '969 patent by Shanghai Aurisco, Zhongjin, and CJ America; of claims 8, 9, and 13 of the '709 patent by Gremount, Hebei Academe, Lianyungang Natiprol, Hebei Research, Ruland, Shanghai Aurisco, Zhongjin, CJ America, Nu-Scaan, Vivion, and Fortune Bridge; and of claim 1 of the '435 patent by Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Hebei Research, Vivion, and Fortune Bridge, with the caveat that the order not apply to sucralose supplied to these respondents by the manufacturing respondents who were found to either not infringe or against whom infringement allegations were withdrawn as to the patents asserted in the investigation. These manufacturing respondents are Changzhou Niutang Chemical, GDFII, Hebei Sukerui Science, and JK Sucralose. The Commission further determined that the public interest factors enumerated in section 337(d)(1),(g)(1), 19 U.S.C. § 1337(d)(1),(g)(1), do not preclude issuance of the limited exclusion order. Finally, the Commission determined that the bond under the limited exclusion order during the Presidential review period shall be in the amount of 100 percent of the entered value of the imported articles. The Commission's orders were delivered to the President and the United States Trade Representative on the day of their issuance.

The Commission has therefore terminated this investigation. 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 sections 210.16(c) and 210.41-.42, 210.50 of the Commission's Rules of Practice and Procedure (19 CFR § 210.16(c) and § 210.41-.42, 210.50).

By order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

Issued: April 6, 2009

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND RELATED INTERMEDIATE COMPOUNDS THEREOF**	**Inv. No. 337-TA-604**

LIMITED EXCLUSION ORDER

Respondents Shanghai Aurisco Trading Co., Ltd. ("Shanghai Aurisco") and Zhongjin Pharmaceutical (Hong Kong) Co. ("Zhongjin") were previously found to have defaulted with respect to U.S. Patent No. 5,470,969 ("the '969 patent"). Additionally, the Commission found CJ America, Inc. ("CJ America") to have admitted infringement and to have agreed to the entry of an exclusion order as to the '969 patent. Respondents Gremount International Co., Ltd. ("Gremount"), Hebei Province Chemical Industry Academe ("Hebei Academe"), Hebei Research Institute of Chemical Industry ("Hebei Research"), Lianyungang Natiprol (Int'l) Co., Ltd. ("Lianyungang Natiprol"), and Ruland Chemistry Co., Ltd. ("Ruland") were previously found to have defaulted with respect to U.S. Patent No. 5,498,709 ("the '709 patent") and U.S. Patent 7,049,435 ("the '435 patent"), and Shanghai Aurisco and Zhongjin were previously found to have defaulted with respect to the '709 patent. Additionally, the Commission found CJ America to have admitted infringement and to have agreed to the entry of an

exclusion order as to the '709 patent, that non-participating respondents Vivion, Inc. ("Vivion") and Fortune Bridge Co., Inc. ("Fortune Bridge") were subject to adverse inferences with respect to the '709 and '435 patents under Commission Rule 210.17, and that non-participating respondent Nu-Scaan Nutraceuticals ("Nu-Scaan") was subject to adverse inferences with respect to the '709 patent under Commission Rule 210.17.

The Commission has determined that the appropriate form of relief in this investigation is a limited exclusion order prohibiting the unlicensed entry of certain sucralose and sweeteners containing sucralose by reason of infringement of one or more of claims 20, 21-26, 28, and 29 of the '969 by Shanghai Aurisco, Zhongjin, and CJ America; of claims 8, 9, and 13 of the '709 patent by Gremount, Hebei Academe, Lianyungang Natiprol, Hebei Research, Ruland, Shanghai Aurisco, Zhongjin, CJ America, Nu-Scaan, Vivion, and Fortune Bridge; and of claim 1 of the '435 patent by Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Hebei Research, Vivion, and Fortune Bridge, with the caveat that the order not apply to sucralose supplied to these respondents by the manufacturing respondents who were found to either not infringe or against whom infringement allegations were withdrawn as to the patents asserted in the investigation. These manufacturing respondents are Changzhou Niutang Chemical Plant Co. ("Changzhou Niutang Chemical"), Guangdong Food Industry Institute and L&P Food Ingredient Co., Ltd. ("GDFII"), Hebei Sukerui Science and Technology Co.,

Ltd. ("Hebei Sukerui Science"), and JK Sucralose, Inc. ("JK Sucralose").

The Commission has further determined that the public interest factors enumerated in 19 U.S.C. § 1337(d)(1),(g)(1) do not preclude issuance of the limited exclusion order, and that the bond during the Presidential review period shall be in the amount of 100% of entered value of the sucralose and sweeteners containing sucralose that are subject to this Order.

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

1. The Commission has determined that sucralose and sweeteners containing sucralose of or obtained from Shanghai Aurisco, Zhongjin, CJ America, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or any of their successors or assigns, that is made by a process covered by one or more of claims 20, 21-26, 28, and 29 of U.S. Patent No. 5,470,969 shall be 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 patent, except under license of the patent owner or as provided by law, with the caveat that this exclusion shall not apply to sucralose supplied to these respondents by Changzhou Niutang Chemical, GDFII, Hebei Sukerui Science, and JK Sucralose.

2. The Commission has determined that sucralose and sweeteners containing sucralose of or obtained from Gremount, Hebei Academe, Lianyungang Natiprol, Hebei Research, Ruland, Shanghai Aurisco, Zhongjin, CJ

America, Nu-Scaan, Vivion, and Fortune Bridge, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or any of their successors or assigns, that is made by a process covered by one or more of claims 8, 9, and 13 of U.S. Patent No. 5,498,709 shall be 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 patent, except under license of the patent owner or as provided by law, with the caveat that this exclusion shall not apply to sucralose supplied to these respondents by Changzhou Niutang Chemical, GDFII, Hebei Sukerui Science, and JK Sucralose.

3. The Commission has determined that sucralose and sweeteners containing sucralose of or obtained from Gremount, Hebei Academe, Lianyungang Natiprol, Ruland, Hebei Research, Vivion, and Fortune Bridge, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or any of their successors or assigns, that is made by a process covered by claim 1 of U.S. Patent 7,049,435 shall be 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 patent, except under license of the patent owner or as provided by law, with the caveat that this exclusion shall not apply to sucralose supplied to these respondents by Changzhou Niutang Chemical, GDFII, Hebei Sukerui Science, and

JK Sucralose.

4. Sucralose and sweeteners containing sucralose that are excluded by paragraphs 1-3 of this Order are entitled to entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of 100% of entered value 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.* 43251), from the day after this Order is received by the United States Trade Representative 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 date of receipt of this action.

5. At the discretion of U.S. Customs and Border Protection ("CBP") and pursuant to procedures it establishes, persons seeking to import sucralose and sweeteners containing sucralose containing same 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 paragraphs 1 through 9 of this Order. At its discretion, Customs may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the

certification.

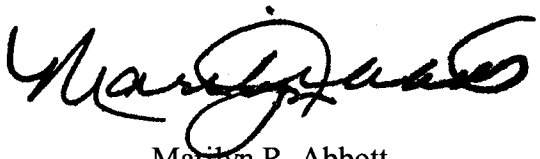
6. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to sucralose and sweeteners containing sucralose that are imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.

7. 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.

8. 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 the U.S. Bureau of Customs and Border Protection.

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

By Order of the Commission.



Marilyn R. Abbott
Secretary

Issued: April 6, 2009

CERTAIN SUCRALOSE, SWEETENERS CONTAINING SUCRALOSE, AND COMPONENTS THEREOF **337-TA-604**

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION ISSUANCE OF A LIMITED EXCLUSION ORDER; TERMINATION OF INVESTIGATION** Investigative Attorney, Christopher G. Paulraj, Esq., and the following parties as indicated, on April 7th 2009.

Marilyn R. Abbott, Secretary
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