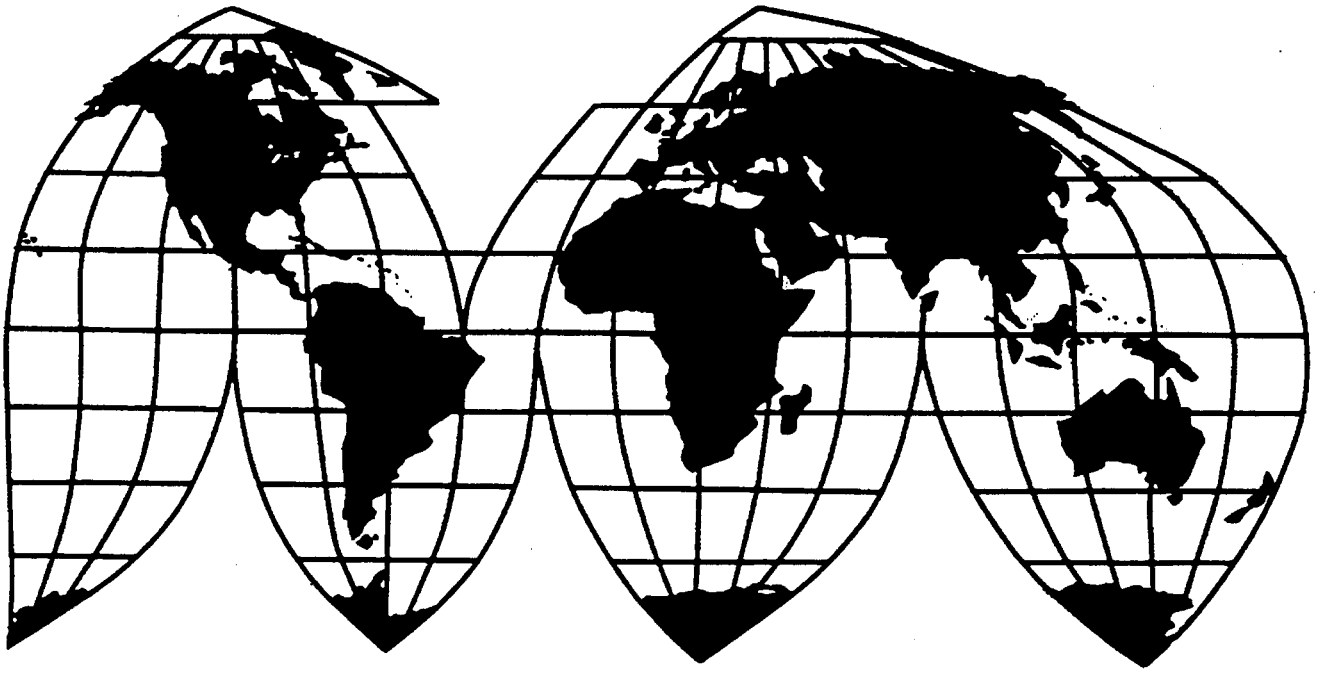
In the Matter of

Certain Acesulfame Potassium and Blends and Products Containing Same

Investigation No. 337-TA-403

Publication 3164 **March 1999**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

Lynn M. Bragg, Chairman
Marcia E. Miller, Vice Chairman
Carol T. Crawford
Jennifer A. Hillman
Stephen Koplan
Thelma J. Askey

Address all communications to
Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

U.S. International Trade Commission

Washington, DC 20436

In the Matter of

Certain Acesulfame Potassium and Blends and Products Containing Same

Publication 3164

March 1999

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

DOCKET

In the Matter of

CERTAIN ACESULFAME POTASSIUM AND BLENDS AND PRODUCTS CONTAINING SAME

Inv. No. 337-TA-403

NOTICE OF COMMISSION DETERMINATIONS NOT TO REVIEW AN INITIAL DETERMINATION FINDING NO VIOLATION OF SECTION 337 OF THE TARIFF ACT OF 1930 AND NOT TO REVIEW AN ORDER DENYING A MOTION FOR SANCTIONS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has made a final determination of no violation of section 337 of the Tariff Act of 1930, as amended, in the above-captioned investigation. The Commission determined not to review an initial determination (ID) of the presiding administrative law judge (ALJ) finding no violation of section 337 and not to review ALJ Order No. 23 which denied a motion for sanctions.

FOR FURTHER INFORMATION CONTACT: Cynthia P. Johnson, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3098. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*).

SUPPLEMENTARY INFORMATION:

The Commission instituted this investigation on November 14, 1997, based on a complaint filed by Nutrinova Nutrition Specialties and Food Ingredients GmbH of Frankfurt am Main, Federal Republic of Germany, and Nutrinova Inc., of Somerset, New Jersey (collectively referred to as "complainants"). 62 *Fed. Reg.* 62070 (1997). The complaint named four respondents -- Hangzhou Sanhe Food Company Ltd., of Zheijiang, People's Republic of China; JRS International, Inc., of Garfield, New Jersey; Dingsheng, Inc., of Temple City, California; and WYZ Tech., of Chino, California. Hangzhou Sanhe Food Additives Factory, of Hangzhou, Zheijiang, Peoples Republic of China was subsequently added as a respondent.

Complainants alleged that respondents had violated section 337 by importing into the United States, selling for importation, and/or selling within the United States after importation certain acesulfame potassium or blends or products containing same by reason of infringement of claims 1, 2, 3, 4 or 5 of U.S. Letters Patent 4,695,629 ("the '629 patent") or claims 1 or 2 of U.S. Letters Patent 4,158,068 ("the '068 patent"). Acesulfame potassium is an artificial sweetener.

The ALJ held a tutorial on the technology of artificial sweeteners and the processes for their manufacture on June 5, 1998. The evidentiary hearing was held from June 29, 1998, to July 10, 1998.

On May 12, 1998, complainants filed a motion seeking the imposition of monetary and non-monetary sanctions against respondents for respondents' failure to provide timely discovery. The motion was supported in part and opposed in part by the Commission investigative attorney (IA) and opposed by respondents. On August 14, 1998, the ALJ issued Order No. 23, denying complainants' motion for sanctions, but offering complainants an opportunity to seek reopening of the record for the purpose of presenting additional facts and arguments relevant to respondents' belatedly -produced discovery. Complainants declined to seek reopening of the record.

On November 20, 1998, the ALJ issued his final ID, in which he concluded that there was no violation of section 337, based on the following findings: (a) claims 1-5 of the '629 patent are not infringed by respondents' accused process; (b) claims 1-2 of the '068 patent are invalid as obvious over the prior art; (c) claims 1-2 of the '068 patent are not infringed by respondents accused product.

On December 3, 1998, complainants filed a petition for review of the ID and Order No. 23, arguing that the ALJ erred in all of his adverse findings relating to failure to impose sanctions and in his infringement analysis of the '629 patent. Complainants did not petition for review of the findings in the ID with respect to the '068 patent. The IA also petitioned for review of the ID and Order No. 23 on policy grounds. On December 10, 1998, respondents filed a response to the petitions for review. The IA also filed a response to complainants' petition for review.

The authority for the Commission's determinations is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.42). Copies of the ALJ's ID and all other nonconfidential 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.

By order of the Commission.

Donna R. Koehnke

Donna R. Koehnke
Secretary

Issued: January 15, 1999

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	)	
	)	
CERTAIN ACESULFAME POTASSIUM AND BLENDS AND PRODUCTS CONTAINING SAME	)	Investigation No. 337-TA-403
	)	
	)	
	)	

99 FEB -9 P2:07

INITIAL DETERMINATION
Administrative Law Judge Sidney Harris

Pursuant to the Notice of Investigation, 62 Fed. Reg. 62070 (1997), this is the administrative law judge's Initial Determination in the Matter of Certain Acesulfame Potassium Blends and Products Containing Same, United States International Trade Commission Investigation No. 337-TA-403. 19 C.F.R. § 210.42(a).

The administrative law judge hereby determines that no violation of section 337 of the Tariff Act of 1930, as amended, has been found in the importation into the United States, sale for importation, or the sale within the United States after importation of certain acesulfame potassium blends and products containing same by reason of infringement of claims 1, 2, 3, 4 or 5 of United States Letters Patent 4,695,629, or claims 1 or 2 of United States Letters Patent 4,158,068.

TABLE OF CONTENTS

I. BACKGROUND

A. Procedural History

By publication in the Federal Register on November 20, 1997, this investigation was instituted pursuant to an Order of the United States International Trade Commission which issued on November 14, 1997, after consideration of a complaint filed on October 16, 1997, and supplemented on October 30 and November 10, 1997, on behalf of Nutrinova Nutrition Specialties and Food Ingredients GmbH, D - 65 926, Frankfurt am Main, Federal Republic of Germany, and Nutrinova Inc., 25 Worlds Fair Drive, Somerset, New Jersey 08873. *See* 62 Fed. Reg. 62070 (1997); 19 C.F.R. § 210.10(b).

The Commission's Order required that pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of 19 U.S.C. § 1337(a)(1)(B) in the importation into the United States, the sale for importation, or sale within the United States after importation of certain acesulfame potassium or blends or products containing same by reason of infringement of claims 1, 2, 3, 4 or 5 of U.S. Letters Patent 4,695,629 or claims 1 or 2 of U.S. Letters Patent 4,158,068, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337. 62 Fed. Reg. 62071 (1997).

The Commission named Nutrinova Nutrition Specialties and Food Ingredients GmbH, and Nutrinova Inc. as the complainants,[1] and the

---

[1] During the course of this investigation, and in the Initial

(continued...)

following companies as respondents:

> Hangzhou Sanhe Food Company Ltd., 258 Qiutao Road, Hangzhou, Zheijiang, People's Republic of China;
>
> JRS International, Inc., 141 Lanza Avenue, Bldg. 12, Garfield, New Jersey 07026;
>
> Dingsheng, Inc., 5323 Tyler Avenue, Temple City, California 91780;
>
> WYZ Tech, Inc., 4570 Eucalyptus Ave. #B, Chino, California 91710.

62 Fed. Reg. 62071 (1997).

Juan Cockburn, Esq. of the Office of Unfair Import Investigations ("OUII") was designated as the Commission Investigative Attorney. *Id.*

On February 7, 1998, complainants filed a motion to amend the complaint and for an initial determination adding an additional respondent. The Commission determined not to review the initial determination of the administrative law judge (Order No. 7), adding the following company as a respondent in this investigation:

> Hangzhou Sanhe Food Additives Factory, 258 Qiutao Road, Hangzhou, Zheijiang, People's Republic of China.

---

[1](...continued)
Determination, complainants are sometimes referred to singly or collectively as "Nutrinova."

Nutrinova is a subsidiary that is completely owned by Hoechst AG ("Hoechst"). Lipinski Tr. 5; Klug Tr. 383. Nutrinova was created relatively recently, on September 1, 1997. Lipinski Tr. 5. Thus, Hoechst is sometimes referred to in the hearing testimony and this Initial Determination in connection with complainants' past experimentation with, and production of, acesulfame potassium, and with respect to Nutrinova personnel who are former Hoechst employees.

See 63 Fed. Reg. 26208 (1998).[2]

On June 5, 1998, a tutorial was held, during which all parties were represented. The parties were given the opportunity to provide technological background information, which although relevant to the patents-in-suit and the prior art, is of a general background nature and is not in controversy. A public transcript was made of the tutorial session, and is referred to in portions of this Initial Determination. *See* Order No. 16 (concerning the tutorial session).

On June 29, 1998, a pre-hearing conference was held at which complainants, respondents and OUII were represented.[3]

The hearing in this investigation commenced on June 29, 1998, and concluded on July 10, 1998. All parties were represented at the hearing. Post-hearing briefs, proposed findings of fact and conclusions of law, as well as replies thereto, were subsequently filed by all parties.

Shortly after the hearing, on July 24, 1998, respondents and complainants filed a stipulation agreeing that the following exhibits should be admitted into evidence: CPX-2, RX-107C and RX-139C. The

---

[2] In accordance with the practice of the parties during the pre-hearing, hearing and post-hearing phases of this investigation, respondents Hangzhou Sanhe Food Company Ltd. and Hangzhou Sanhe Food Additives Factory may be referred to as "Sanhe" or "the Sanhe respondents."

[3] No jurisdictional challenge was made in this investigation. The administrative law judge finds that the Commission has personal jurisdiction over the parties and subject matter jurisdiction over this investigation. *See* FF II 1-16.

Commission Investigative Staff has no objection to the stipulation. The stipulation is APPROVED, and the above exhibits are admitted into the evidentiary record.

Certain issues were raised before and during the hearing with respect to certain forms of compelled discovery that were belatedly provided by respondents. The compelled discovery at issue consisted of voluminous documents falling into four categories: (1) Workshop Processing Records; (2) Batch Reports; (3) Construction and Equipment Installation Plans, Drawings and Invoices; and (4) Invoices for the Processing of . In particular, on May 12, 1998, complainants filed their "Motion of Complainants for Sanctions Against Respondents for Failure to Comply with Discovery Orders." Numerous pleadings were filed in consequence of complainants' motion for sanctions, including post-hearing memoranda which were received until July 29, 1998.

In their motion for sanctions, complainants sought the imposition of monetary and non-monetary sanctions, including a default judgment to the effect that respondents infringe the '629 patent-in-suit, or in the alternative, that numerous adverse inferences be drawn against respondents, and that respondents be precluded from introducing into evidence any documents which were subject to an earlier discovery order (Order No. 4) and which were produced in a tardy fashion. The Commission Investigative Staff supported in part and opposed in part complainants' motion for sanctions.

In Order No. 23, the administrative law judge denied complainants' motion for sanctions for the reasons detailed therein. In summary, the administrative law judge found that although all of the compelled discovery was eventually produced, some of the critical documents were not produced until quite late in the investigation. However, it was also found that the delays in production were not caused by bad faith on respondents' part, a plan to deceive either complainants or the Commission, a flagrant disregard of discovery order, or other egregious conduct. Rather, the delays were caused by numerous problems associated with transnational discovery such as language barriers, restrictions on the flow on information during discovery imposed by Chinese law, and the severe lack of staff in China capable of assisting with discovery. In view of the reasons for the delays and the fact that it was not in the public interest to disregard a large amount of seemingly probative, reliable evidence which was used at the hearing by respondents and to a certain extent by complainants, the administrative law judge denied complainants' motion for sanctions and also determined not to strike or reject several of respondents' exhibits that consisted of the evidence in question.

Nevertheless, the administrative law judge determined that in order to cure prejudice caused by the late production of the discovery, complainants must be offered the opportunity to reopen the record and, if necessary, to present additional facts and arguments

relevant to respondents' belatedly produced documents. The administrative law judge in Order No. 23 further held that he would consider proposals to cure or ameliorate the prejudice caused to complainants by late production of discovery, including proposals for respondents to bear the costs incurred by complainants in reopening the record. Order No. 23 at 13.

On August 26, 1998, complainants filed a response to Order No. 23 in which they stated that they would not seek to have the record reopened. Complainants took the position that reopening the record could not alleviate the prejudice caused by respondents, and that reopening the record would create additional prejudice by depriving complainants of the prompt resolution of this investigation. For this reason, the record was not reopened with respect to the late discovery produced from respondents.

Additional issues were raised after the close of the hearing.

On August 18, 1998, respondents filed their "Motion of Respondents to Admit RX-255C into the Record." Respondents' motion was granted by Order No. 25. RX-255C contains summaries of tests conducted on behalf of complainants of acesulfame potassium manufactured by companies other than Sanhe. In response to Order No. 25, the parties made additional filings, including a Motion of the Commission Investigative Staff to Admit Proposed Exhibit RX-105C into Evidence as Exhibit SX-5C (Motion Docket No. 403-49); respondents' Motion to Admit Additional Exhibits Pursuant to Order No. 25 (Motion

Docket No. 403-50); Memorandum of Complainants Regarding Exhibit RX-255C and Motion to Admit Exhibits CX-191C to CX-201C into the Record (Motion Docket No. 403-52); Motion of Complainants for Leave to File Reply ... to Admit Exhibit CX-202C, and Submission of Better Copy of Exhibit CX-194C (Motion Docket No. 403-53); and Motion of Complainants for Leave to File Reply Memorandum in Support of Motion to Admit Exhibit CX-202C and Submission of Complete Test Results (Exhibit CX-194C) (Motion Docket No. 403-54).[4] Motion Nos. 403-49, 50, 52, 53 and 54 are GRANTED.

On September 11, 1998, respondents filed a motion for leave to file a supplemental post-hearing reply memorandum, arguing that new arguments were raised in the reply memoranda of complainants and the Commission Investigative Staff (Motion Docket No. 403-48). On September 23, 1998, respondents filed a motion for leave to reply to the opposition of complainants to their motion to file a supplemental post-hearing reply (Motion Docket No. 403-51). Exhibit 1 to Motion No. 403-51 is proposed Exhibit RX-258C, excerpts from the deposition of Mr. Qiu Xue Yang. Respondents' Motion No. 403-48 for leave to file

---

[4] On October 1, 1998, respondents filed a memorandum in opposition to complainants' motion to admit CX-191C to CX-201C, or in the alternative, motion for leave to submit comments concerning complainants' new exhibits and to admit RX-258C and RX-259C. On October 2, 1998, respondents filed a response to the Commission Investigative Staff's motion to admit RX-105C into evidence and conditional request to admit RX-104C into evidence. As seen above, the administrative law judge has determined to admit the exhibits proposed by complainants and the Commission Investigative Staff. Both of respondents' conditional requests are also granted.

a supplemental reply is GRANTED. Respondents' Motion No. 403-51 is granted and RX-258C is received into evidence for the limited purpose of demonstrating the deposition testimony contained therein and not for the truth of the matters asserted.

Furthermore, respondents and complainants have filed motions for sanctions pursuant to 19 C.F.R. § 210.4. Those motions are ruled upon under separate cover.

Any additional motions not previously ruled upon are denied.

The following abbreviations may be used in this Initial Determination:

ALJ - Administrative Law Judge

CX - Complainants' Exhibit

CPX - Complainants' Physical Exhibit

RX - Respondents' Exhibit

RPX - Respondents' Physical Exhibit

SX - Commission Investigative Staff ("OUII") Exhibit

FF - Finding of Fact

PFF - Proposed FF

PRFF - Proposed Reply FF

PCL - Proposed Conclusion of Law

Dep. - Deposition

Tr. - Transcript.

B. Technological Background

This investigation concerns an artificial sweetener called acesulfame potassium, which is sometimes referred to as acesulfame-K or ASK. ALJ Ex. 1, Tutorial Tr. 7, 10-14.

Some of the issues raised in this investigation, particularly with respect to the '068 patent, pertain to the taste characteristics of acesulfame potassium when it is used in combination with other sweeteners. Other issues, particularly with respect to the '629 patent, pertain to the chemical processes by which acesulfame potassium may be obtained from other chemical starting materials. Consequently, the parties provided background information relevant to the nature and study of sweetness as a taste, as well as information relevant to the general chemistry used to make chemicals such as acesulfame potassium.

General Characteristics of Sweeteners and Sweetener Mixtures

Experts who study taste recognize four basic types of taste. Those four basic tastes are: sweet, salty, sour, and bitter. *See* ALJ Ex. 1, Tutorial Tr. 11. Sugar (i.e., sucrose or saccharose) is the standard by which to judge the taste of any other sweetener. ALJ Ex. 1, Tutorial Tr. 11, 14, 21.

In the study of taste, the term "taste intensity" refers to the strength of taste perception. "Taste quality" refers to the aspects contributing to the overall perception of taste. "Taste liking" refers to the acceptance of a certain taste profile by people,

including the preference for one taste over another. ALJ Ex. 1, Tutorial Tr. 14.

Sweeteners can be divided into three categories: sugar, bulk sweeteners, and intense sweeteners. ALJ Ex. 1, Tutorial Tr. 12. Sugars are metabolized in the human body and provide energy. ALJ Ex. 1, Tutorial Tr. 12. Bulk sweeteners are metabolized into the body, but do not normally provide the same amount of energy as sugars. The sweetness level of bulk sweeteners is lower than sugars. ALJ Ex. 1, Tutorial Tr. 12. Intense sweeteners are much stronger in sweetness than the other two categories. Furthermore, they are either not converted into energy in the human body at all, or if they are, their energy contribution is insignificant. ALJ Ex. 1, Tutorial Tr. 12-13.

All non-sugar sweeteners have other tastes in addition to sweetness, and thus, they fall short of exactly matching the taste of sucrose. ALJ Ex. 1, Tutorial Tr. 21. However, intense sweeteners deliver a sweet taste at a much lower concentration than sucrose. ALJ Ex. 1, Tutorial Tr. 14.

Mixing or blending sweeteners sometimes yields varying results. For example, the term "additivity" when applied to mixtures of sweeteners means that when mixing two or more components together, the mixture would be as strong as the sum of the taste intensities of the components. ALJ Ex. 1, Tutorial Tr. 15. However, "synergism" occurs when one mixes two or more components and the mixture is sweeter than

one would expect on the basis of the sum of the taste intensities of the components. ALJ Ex. 1, Tutorial Tr. 15. This phenomenon involves sweetness enhancement, and is sometimes referred to as "quantitative synergism." ALJ Ex. 1, Tutorial Tr. 21.

Whether a sweetener mixture is additive or "hyperadditive" (i.e., synergistic) depends upon the specific mixture. Currently, it is not always possible to predict with certainty whether the effect of mixing sweeteners will be additive or synergistic, or -- in rare cases -- antagonistic such that there is taste suppression. *See* ALJ Ex. 1, Tutorial Tr. 15, 109-110.

There are several reasons to blend sweeteners, including cost savings. If synergy is the result of a blend, then one can use less sweetener and thereby reduce the costs to make the food product. Also, if one blends sweeteners together, it may be possible to get an improvement in taste quality. In that case, there is "qualitative synergism." ALJ Ex. 1, Tutorial Tr. 21.

Taste testing is used extensively to evaluate sweeteners and the effects of sweetener blends.

One common way to measure sweetness is with "equal-sweetness matches." This involves a taste test in which there are beverages whose concentration of sweetness is not known to a group of panelists.[5]

---

[5] To measure the potency of a group of sweeteners, the sweeteners must be tested under equal conditions. ALJ Ex. 1, Tutorial Tr. 15.

In fact, there may be sugar solutions that start as low as one percent (which is hardly sweet). They proceed through 10 percent (which is the sweetness of many sugar-sweetened beverages), and range as high as 15 percent. The panelists are asked to taste each solution, and to select which tastes as sweet as a test product. By averaging this data, one can determine which sweetness reference (i.e., which concentration of sugar in solution) corresponds to the sweetness of the test product. ALJ Ex. 1, Tutorial Tr. 22-23, 105.

Taste panels may also be used to understand the many sensations of sweetness experienced by individuals. A taste panel consists of a group of people trained to recognize the different sensory characteristics. The panelists taste the products and discuss among themselves the characteristics that they perceive to obtain agreement from the group as a whole. ALJ Ex. 1, Tutorial Tr. 24-25. To create a report card for sweeteners, panelists will rate the sweetener on each set of characteristics, typically on a scale of 1 to 9, or 1 to 100. After the taste tests are completed, a "spider plot" (showing each attribute as a spoke) is created, showing a profile of attributes the panelists have sensed. ALJ Ex. 1, Tutorial Tr. 25-27. For example, the attributes which are plotted might include characteristics of "off-flavor," mouth drying, bitter aftertaste, pure sweetness, etc. ALJ Ex. 1, Tutorial Tr. 25.

"Spider plots" are an easy way to understand the quality profile of different products. To the degree that the profiles look alike,

the products have similar quality of taste. To the degree that the spider plots look different from each other samples will exhibit different taste qualities. ALJ Ex. 1, Tutorial Tr. 27.

Taste quality includes the aspect of time because this quality of taste is influenced by how fast the taste rises when the substance is in contact with the tongue and how fast the taste perception declines when the product is in the mouth. Sucrose has a very specific time-intensity profile, with a fairly fast onset of sweetness yet is not too lingering. ALJ Ex. 1, Tutorial Tr. 29.

By blending sweeteners, one may sometimes achieve a better temporal profile for the sweetener blend than for each individual sweetener. ALJ Ex. 1, Tutorial Tr. 110-111. Time intensity has an important role. It is a significant factor for sweetener blends, especially for acesulfame and aspartame. ALJ Ex. 1, Tutorial Tr. 30.

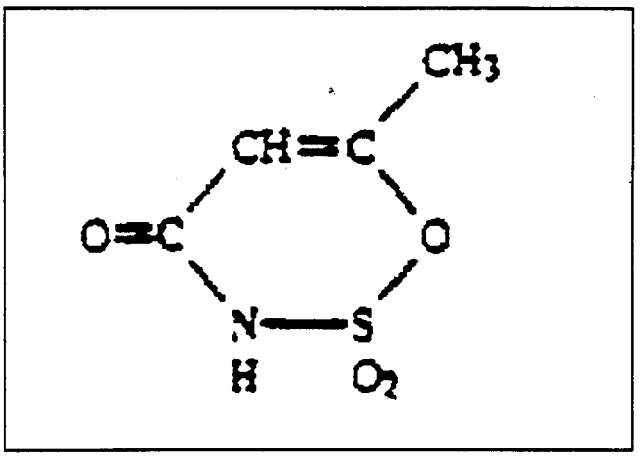
"Taste liking" can also be measured. For example, in a head-to-head preference test, people are offered two products and asked which is the sample they personally prefer. Subjects may also be asked to rate a product on a scale ranging, for example, from a score indicating dislike to a score indicating a product that is liked extremely. ALJ Ex. 1, Tutorial Ex. at 30-31.

Chemical Background of Acesulfame Potassium

Acesulfame potassium, the sweetener at issue in this investigation is made of organic molecules. ALJ Ex. 1, Tutorial

Tr. 35. Organic chemistry is defined as the chemistry of carbon-containing compounds. Common elements present in these compounds include hydrogen, nitrogen, oxygen and sulfur. ALJ Ex. 1, Tutorial Tr. 35.

Acesulfame potassium is the potassium salt of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide, a molecule of which is represented in the '629 patent, as follows:



CX 5 ('629 Patent) at col. 1, lines 11 through 19.

In synthetic organic chemistry, one looks for different ways to make particular molecules, such as the acesulfame potassium molecule. ALJ Ex. 1, Tutorial Tr. 56, 96. The '629 patent at issue in this investigation claims a process for synthesizing acesulfame, including the potassium salt thereof. *See* CX 5 ('629 Patent).

Acesulfame is one of over 11 million organic compounds. One way in which organic compounds are categorized is by generalities called "functional groups." Functional groups are based upon the way in

which a series of molecules may react, and also the sites on the molecules at which chemical reactions are expected to occur. ALJ Ex. 1, Tutorial Tr. 35, 43. Of the 11 million organic compounds known, there are only about 15 or 16 functional groups. ALJ Ex. 1, Tutorial Tr. 37.

A second way of classifying molecules relates to the molecule's structural representation. For example, some molecules are cyclic (i.e., they form rings), while others are acyclic or noncyclic. ALJ Ex. 1, Tutorial Tr. 36-37, 41.

A third form of molecule classification involves nomenclature that indicates which elements are present. For example, "hydrocarbons," contain only the elements hydrogen and carbon. ALJ Ex. 1, Tutorial Tr. 36, 46.

Focusing on functional groups (i.e., the site or sites on a molecule at which a chemical reaction is likely to occur) is particularly useful when working with large molecules that may have only one functional group. ALJ Ex. 1, Tutorial Tr. 44. However, there may be more than one functional group present in the same molecule. ALJ Ex. 1, Tutorial Tr. 53. Functional groups are particularly important in synthetic organic chemistry in which a reaction or series of reactions is used to obtain a desired chemical product from starting materials.

"Reagents" or "reactants" are other names for the starting materials in a process. ALJ Ex. 1, Tutorial Tr. 99. The result of a

first reaction is referred to as an "intermediate," which serves as the reagent or starting material for the second reaction, and so forth until the desired product is obtained in the final step of the synthesizing process. ALJ Ex. 1, Tutorial Tr. 99.

A "solvent" is a liquid used to dissolve things and make it easy for a reaction to take place. Solvents may also assist in controlling temperature, as in the case of liquids that help to disperse heat, i.e., speed-up cooling. ALJ Ex. 1, Tutorial Tr. 100.

"By-products" are products formed during a reaction that are not the desired product of the reaction. Also, "impurities" may appear in a reaction although one does not want them to be present. ALJ Ex. 1, Tutorial Tr. 99. For example, if an intermediate does not react completely, or if side reactions occur, there are impurities. ALJ Ex. 1, Tutorial Tr. 99-100.

After a desired reaction is completed and a final product is obtained, by-products and impurities must be removed. Several methods are commonly used to separate the desired product from the by-products and impurities. ALJ Ex. 1, Tutorial Tr. 101.

For example, if the by-products are solid and the desired product is dissolved in a liquid, filtration might be used to isolate the desired product. Liquids can often be separated based upon differences in boiling point, and thus a distillation process might also be an option. Extraction is another method, and it is based upon differences in solubility and the formation of layers, as, for

example, in the case of oil and water. ALJ Ex. 1, Tutorial Tr. 101-102.

Finally another method, which was referred to extensively in this case, is the separation of materials based on differential solubility in a one-solvent system through crystallization and recrystallization. For example, if one has collected a solid reaction product that contains an impurity, one might dissolve all the solid material in a solvent, typically often with the application of heat. As the solution is cooled, material that is less soluble will tend to crystallize, while material that is more soluble will tend to stay dissolved. Crystallization can be repeated, although it is rare to get everything to crystallize completely. ALJ Ex. 1, Tutorial Tr. 102-103.

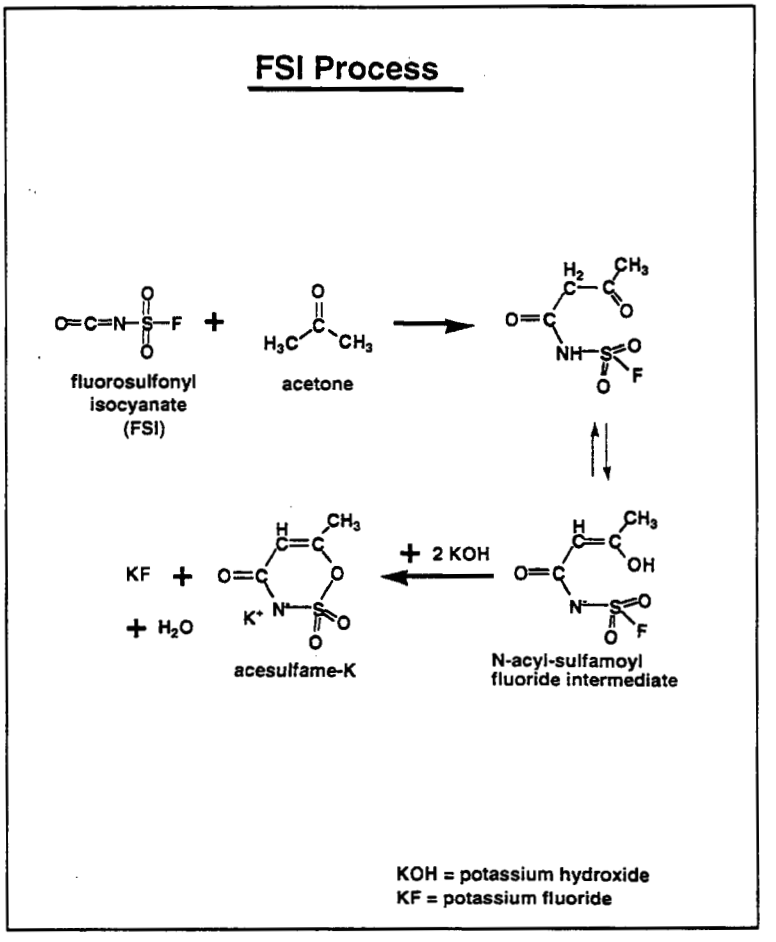
During the tutorial session and later during the hearing, three processes were discussed for the production of acesulfame potassium. One is the "FSI process," which has as one of its starting materials fluorosulfonyl isocyanate (FSI). Another is the "ASF process," which has as one of its starting materials aminosulfonyl fluoride (ASF). The third is the process of the '629 patent, which uses sulfamic acid and diketene as starting materials. *See* ALJ Ex. 1, Tutorial Tr. 64, 98.

There was no material disagreement among the parties, either during the tutorial session or during the hearing, as to the basic chemistry involved in the FSI, ASF and '629 processes. Rather, the

dispute among the parties relating to the '629 patent was centered more around the question of which process or processes the Sanhe respondents have used, or currently use, to make their acesulfame potassium product.

In order to make this judgment it is important to understand a few common and distinguishing characteristics of each of the three processes, particularly the starting materials or reagents used and some of the by-products or impurities that often result in using these processes.

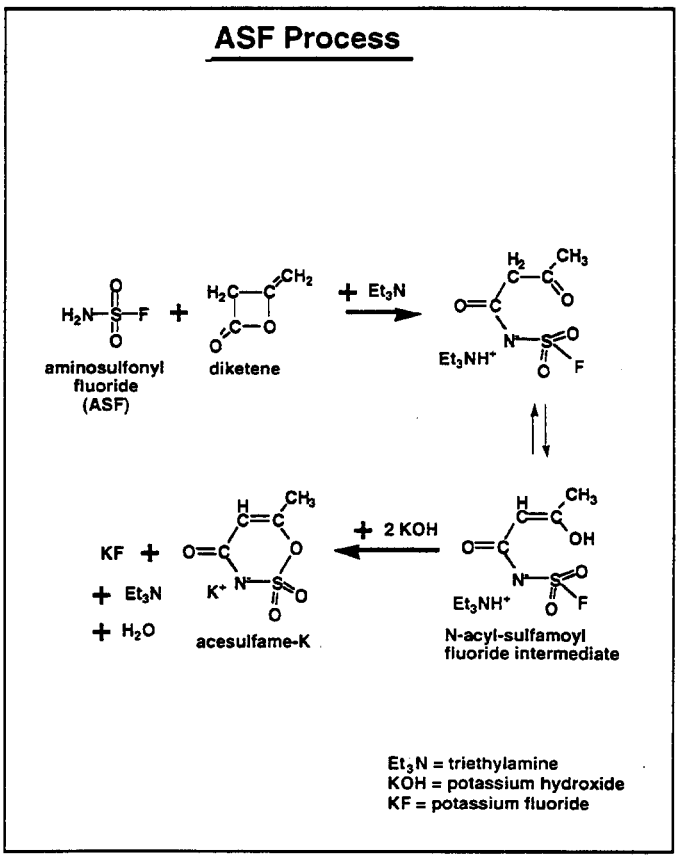
The FSI process may be represented as follows:



RX-124 at 2.

The first step of the FSI process is to react FSI with a reagent such as acetone. The intermediate formed is acyl-sulfamoyl fluoride. Two forms of the intermediate exist at the same time in a sort of equilibrium in which a very rapid interchange occurs in the solution. As seen in the diagram, although many elements of the acesulfame molecule are present in the intermediate, the final ring structure has not yet been achieved. However, ring closure can be achieved with a cyclization reaction involving the use of potassium hydroxide. As seen in the diagram above, the result is acesulfame potassium, along with the by-products of potassium fluoride (KF) and water (H_2O). ALJ Ex. 1, Tutorial Tr. 96-97.

The ASF process may be represented as follows:

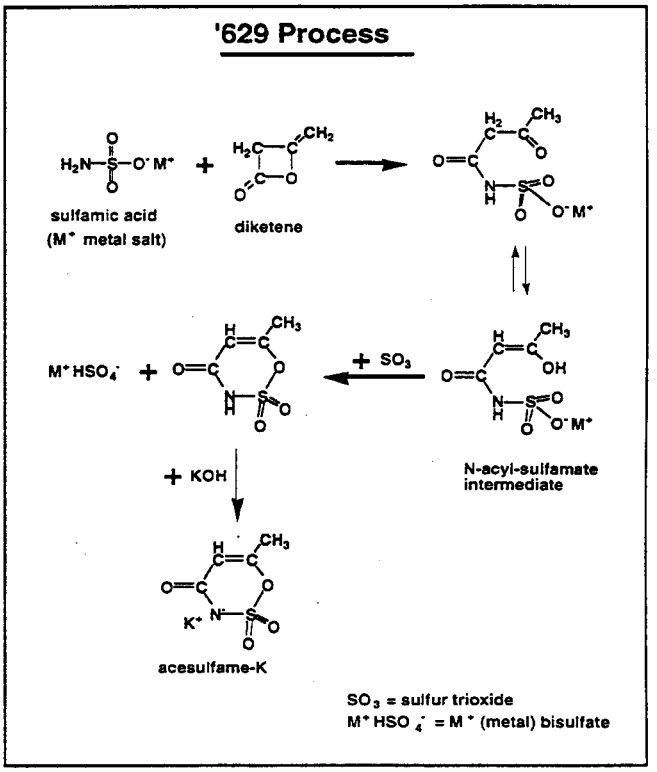


RX-124 at 3.

In this process, aminosulfonyl fluoride (ASF) is reacted with diketene. Triethylamine is also used in the reaction to make it faster. As seen in the diagram, the resulting intermediate is N-acyl-sulfamoyl fluoride, similar to that obtained in the FSI reaction. The intermediate is cyclized using potassium hydroxide in order to obtain acesulfame potassium. A comparison of the intermediate molecule and the acesulfame potassium molecule shows that fluoride is eliminated, and thus constitutes the "leaving group" in the reaction. In the ASF

process, as in the FSI process, there are components in the final mixture aside from acesulfame potassium. Those components include triethylamine and water. ALJ Ex. 1, Tutorial Tr. 65, 97-98.

The process of the '629 patent may be represented as follows:



RX-124 at 4.

As seen in the above diagram, the '629 process starts with sulfamic acid and diketene. As in the other processes, an intermediate is obtained in an equilibrium mixture. However, in the '629 process, the intermediate lacks a fluoride (F), and instead has another oxygen (O). ALJ Ex. 1, Tutorial Tr. 97-98.

In order to perform the ring closure in the '629 process, one must use a reagent that is considered more powerful than the potassium

hydroxide used in the FSI and ASF processes. In the '629 process, sulfur trioxide (SO_3), a dehydrating agent, is used. The reaction with sulfur trioxide produces a bisulfate ion, and cyclic sulfamic acid which is converted into acesulfame potassium through the use of potassium hydroxide. ALJ Ex. 1, Tutorial Tr. 98.

Each of the three processes discussed in this investigation for the production of acesulfame potassium has advantages and disadvantages from a manufacturing perspective. For example, the '629 process uses sulfamic acid, which is much more readily available than ASF. However, in the case of the '629 process, a stronger cyclization reaction is needed, and sulfur trioxide (SO_3) is used rather than potassium hydroxide to effect the ring closure. ALJ Ex. 1, Tutorial Tr. 98-99.

II. IMPORTATION AND SALE

The statutory requirement of importation and/or sale has not been raised as an issue in contention in this investigation. Respondents have stipulated that they have imported accused product into the United States. *See* FF II 1-16.

III. VALIDITY

No party challenges the validity of the '629 patent. However, respondents argue that the '068 patent is invalid for obviousness under 35 U.S.C. § 103, and for failure to comply with the requirements of 35 U.S.C. § 112.

The claims of the '068 patent are as follows:

1. A sweetener mixture having an improved saccharose-like taste and consisting of

(a) the potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide and

(b) a further sweetener selected from the group consisting of

(i) aspartyl phenyl-alanine methyl ester,

(ii) the sodium salt of cyclohexyl sulfamic acid,

(iii) the sodium salt of saccharin, and

(iv) neohesperidin-dihydrochalcone,

wherein the ratio by weight of (a) to (b) in such a mixture is from 1:10 to 10:1 for sweetener (b)(i), 3:1 to 1.12 for sweetener (b)(ii), 1:2 to 10:1 for sweetener (b)(iii), and 5:1 to 20:1 for sweetener (b)(iv).

2. A sweetener mixture as in claim 1 wherein said further sweetener is (b)(i) and wherein the ratio by weight of (a) to (b)(i) in such a mixture is from 2:5 to 5:2.

3. A sweetener mixture as in claim 1 wherein said further sweetener is (b)(ii) and wherein the ratio by weight of (a) to (b)(ii) in such a mixture is from 1:2 to 1:12.

4. A sweetener mixture as in claim 1 wherein said further sweetener is (b)(iii) and wherein the ratio by weight of (a) to (b)(iii) in such a mixture is from 1:1 to 8:1.

5. A sweetener mixture as in claim 1 wherein said further sweetener is (b)(iv) and wherein the ratio

by weight of (a) to (b)(iv) in such a mixture is from 8:1 to 15:1.

CX-1 ('068 Patent) at col. 4, lines 29-39.

A. *Obviousness*

A patent is presumed to be valid. 35 U.S.C. § 282. The presumption of validity attaches to each claim independently of all other claims. *See Jones v. Hardy*, 727 F.2d 1524, 1528 (Fed. Cir. 1984). A party seeking to invalidate a patent must prove facts establishing invalidity by clear and convincing evidence, and the ultimate burden of persuasion never shifts from the patent challenger. *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986).

In order to prove invalidity under section 103 of the Patent Act, it must be demonstrated by clear and convincing evidence that the claimed invention would have been obvious in light of the combined teachings of items of prior art relied upon by respondents. *See Graham v. John Deere Co.*, 383 U.S. 1, 37 (1966); *Jones v. Hardy*, 727 F.2d at 1530-32.

An analysis for obviousness under section 103 requires a determination of the scope and content of the prior art, a determination of the differences between the prior art references and the claimed invention, and consideration of the secondary indicia of nonobviousness. *Litton Sys. v. Honeywell*, 87 F.3d 1559, 1566 (Fed. Cir. 1996); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods.*, 21 F.3d

1068, 1071 (Fed. Cir. 1994) (citing *Graham*, 383 U.S. at 17). In addition, it must be shown that one of ordinary skill would have known to combine the prior art references. *See Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988); *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992)("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.").

Respondents argue that the '068 patent is invalid in view of the level of ordinary skill in the relevant art and several prior art references that were not before the patent examiner during the prosecution of the '068 patent.[6] Respondents' Post-Hr'g Br. at 44-49; Respondents' Reply Br. at 21-24. Their arguments are opposed by complainants and the Commission Investigative Staff. *See* Complainants' Post-Hr'g Br. at 24-25, 28-36; Complainants' Reply Br. at 13-15; OUII Post-Hr'g Br. at 37-39; OUII Reply Br. at 12-13.

---

[6] Respondents point out that the references at issue were before the appeal board in the Netherlands where the counterpart to the '068 patent was challenged and found to be invalid. *See* Respondents' Post-Hr'g Br. at 49; RX-155. However, the administrative law judge has not taken those foreign proceedings into consideration in making a determination as to patent validity in this investigation. Among the problems posed by reliance upon the proceedings in the Netherlands is the fact that it has not been shown that the legal standards used in the Netherlands for making a validity determination are the same or similar to those used in the United States.

The terms of the '068 patent claims have well-recognized meanings.[1] No disputes have arisen with respect to the construction of the '068 patent claims that are pertinent to the validity issues in this investigation. *See* Complainants' Post-Hr'g Br. at 25. Nevertheless, it is important to establish the nature of the claimed invention so that in reviewing the prior art, one can gauge whether or not it rendered the claims of the of the '068 patent obvious.

The specification of the '068 patent describes the task facing the inventors and the resolution of that task, as follows:

> A known advantageous sweetener is acetosulfame, (generic name: acetosulfame-potassium salt), which is the potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide. Its sweetness is about 80 to 250 times that of saccharose (cane or beet sugar) [cf. table 1, page 143 of the journal "Chemie in unserer Zeit," No. 5 (1975)]. The sweetness of this sweetening agent is evolved very rapidly and fades only very slowly. The after taste is insignificant and can be noticed only in rather high concentrations. Thus acetosulfame could be suitably used alone for the sweetening of food, pharmaceuticals, cosmetics and animal feed. Nevertheless, it was desirable to improve especially its saccharose-like taste; acetosulfame is very sweet, like all the other synthetic sweeteners, but its quality of sweet taste differs from that of saccharose. The sweet taste of saccharose, however, sets the standard for the evaluation of all sweeteners, as has been mentioned above.
>
> The task of the present invention was, consequently, to improve the saccharose-like taste of acetosulfame.
>
> This task could be solved according to the

---

[1] The Background section of this Initial Determination contains definitions of terms and concepts relevant to the claims of the '068 patent.

> invention by mixing acetosulfame with further known artificial sweeteners. The present invention, consequently, relates to a sweetener mixture having an improved saccharose-like taste and consisting of
>
> (a) acetosulfame and
>
> (b) at least a further artificial sweetener, selected especially from the class of the aspartyl peptide esters, the sulfamate sweeteners, the sulfimide sweeteners and the dihydrochalcone sweeteners.

CX-1 ('068 Patent) at col. 1, lines 38-68.

Thus, the claimed invention was the improvement of the saccharose-like taste (i.e., or the sucrose-like taste[8]) of acesulfame potassium through the mixture of acesulfame potassium with certain other sweeteners.[9] Indeed, as seen for the claim language quoted above, the claims are drawn to "[a] sweetener mixture having an improved saccharose-like taste." Another effect of mixing high-potency sweeteners may be a synergistic effect (i.e., the disproportionate intensity of sweetness that is discussed in the Background section above). However, synergy is not part of the claimed invention.

The '068 patent issued in 1979, based upon an application filed in the United States in 1977, with a foreign application priority date of 1976 (Germany). CX-1. A person of ordinary skill working in the relevant art in the mid-1970s would have been someone working for a university or a food company, or possibly in the government, with a

---

[8] Saccharose is sucrose. *See* Walters Tr. 1133.

[9] Witnesses for both complainants and respondents testified that the sweeteners recited in the '068 patent claims are high-potency sweeteners. Complainants' Post-Hr'g Br. at 25.

Bachelor's degree, typically in food science or food chemistry, and possibility a Master's degree or Ph.D. This individual would typically have had five to ten years of experience. Walters Tr. 1129-1130. By the mid-1970s, a number of high-potency sweeteners had been already used or sold. Saccharin had been in use for a long time, and dulcin had been in use for a period of time until it fell out of use in the 1960s. Cyclamate was discovered in 1937 and used until the 1960s. Acesulfame had been discovered in 1965 and was being intensely studied by the mid-1970s. Walters Tr. 1130.

For the purposes of an analysis of patent validity or invalidity, "[t]he person of ordinary skill is a hypothetical person who is presumed to be aware of all pertinent prior art." *Custom Accessories v. Jeffrey-Allan Indus.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

The specific prior art references relied upon by respondents in this investigation are described below.

The Paul Article

RX-11 contains a German article, "Der Süßungsgrad von Dulcin und Saccharin," by Dr. Theodor Paul, from the journal *Chemiker Zeitung*, which was published in 1921. The exhibit also contains an abstract of the article in English, which was published in *Chemical Abstracts* in 1921, and which summarizes the key points of the article.

The Paul article describes the blending of dulcin and saccharin, the two high-potency sweeteners that were known at that time. Although

dulcin was no longer in use by the mid-1970s, the information contained in the Paul article would have been known to one of ordinary skill. Furthermore, one of ordinary skill would have been interested in its structure and taste. Walters Tr. 1130-1131.

As stated in the abstract, the Paul article indicates that the taste of the mixed solution is "more pleasant" than that of saccharin alone.[:9] Respondents' expert, Dr. Walters,[:10] explained what that

---

[:9] The Paul article also shows that when one blends saccharin and dulcin, there is synergy, i.e., an increase in the level of sweetness beyond what you would expect based on the individual concentrations alone. RX-11; Walters Tr. 1130-1131.

[:10] Dr. Walters earned a Bachelor of Science degree in Pharmacy from the University of Wisconsin in 1974, and a Ph.D. in Medicinal Chemistry from the University of Kansas in 1978. After receiving his Ph.D., Dr. Walters did post-doctoral work for a year and a half at Indiana University. In 1979, he began work in the basic flavor chemistry department of Kraft Foods, where he studied taste components. In 1982, Dr. Walters went to work for the G.D. Searle Company, and in late 1982, he became involved in a plan for research on a new sweetener at Searle, later known as NutraSweet. In the mid-1980s, Monsanto bought the Searle company and shortly after that made the NutraSweet business into a separate business unit. At NutraSweet, Dr. Walters was involved in the discovery of new high-potency sweeteners. While at NutraSweet, Dr. Walters was promoted to the position of group leader, where he directed the research of a group of synthetic chemists who were making high-potency sweeteners, and was involved in taste panel studies. He also had experience with a pilot plant facility which chemists in his group used from time to time to make chemicals. Dr. Walters is listed as a co-inventor on two patents for a series of high-potency sweeteners developed during his work at Searle and NutraSweet. In 1991, Dr. Walters left NutraSweet to join the biochemistry department at the Finch University of Health Sciences at the Chicago Medical School, where he has been teaching biochemistry to medical students. He has continued to do research in sweeteners, including the mechanisms of sweet and bitter taste and how they interact. Walters Tr. 1122-1128; RX-46(A).

(continued...)

terminology would have meant to one of skill in the art, as follows:

> Q And what would one of ordinary skill have understood to be meant by the phrase "more pleasant"?
>
> A More pleasant than the taste of saccharin alone would mean that it tastes better, and the standard for a sweet taste is sucrose.
>
> Q Why was sucrose the standard for sweet taste?
>
> A Sucrose is the sweetener we're most accustomed to, that's table sugar, so that's what we're accustomed to. If we have a sweetener that tastes different from that, we consider it not as good.

Walters Tr. 1131.

The Vincent et al. Article

RX-23 is a paper published in 1955 in the *Journal of the American Pharmaceutical Association* by Vincent and a group of co-workers from Abbott Laboratories, including Fred Helgren. The article deals with the combination of cyclamate plus saccharin. RX-23; Walters Tr. 1132. A number of tests were conducted with ratios ranging from 1:10 to 10:1. "[I]t was concluded that the 10:1 ratio of cyclamate to saccharin is most satisfactory from the standpoints of minimizing off taste and of emphasizing desirable qualities of sweetness." CX-23 at 443.

This article would have taught one of ordinary skill in the art in

---

[11](...continued)
At the hearing, Dr. Walters was accepted as an expert in sweeteners and high-potency sweeteners, including the chemistry and biology of sweeteners. Walters Tr. 1128-1129.

the mid-1970s that blending saccharin and cyclamate would create synergy. Moreover, a higher level of sweetness was observed. Furthermore, the article notes that a majority of the tasters commented on the "clean, sweet taste" of the combination. The phrase "clean, sweet taste" means less of the "off" tastes of saccharin and cyclamate, and therefore a taste which is more like sucrose than either sweetener alone. RX-23; Walters Tr. 1133.

In addition, the Vincent article states with respect to the tasters reporting a "clean" and sweet taste that "a surprising number volunteered that 'Those are the sucrose solutions in this series,' when it was the combination they had tasted." This means that many of the panelists thought that the combination tasted like sucrose, that is, had a more saccharose-like taste. RX-23 at 445; Walters Tr. 1133. Although the precise number of panelists volunteering this comment is not known, it was significant to the authors of this article that comparisons were made to sucrose, and these comments would be of interest to one of skill in the art.

The Ueno Article

RX-25 is an article entitled "A Novel Method for the Utilization of Artificial Sweeteners," from a Japanese food science journal, published in 1964 by workers at Ueno Pharmaceutical Company. In this article, the authors discussed combinations of saccharin and dulcin. RX-25; Walters Tr. 1134.

This article discusses various binary blends of high-potency sweeteners: dulcin, saccharin and cyclamate. In RX-25, the authors state that:

> It has been said that when a number of seasoning agents are blended together, mutual defects are eliminated the greater the number blended, and a particular flavour emerges. The same is true for artificial sweeteners. It is well known that when two or more types of sweeteners are mixed, there is not a mere summation of the respective sweetness. The sweetness contained will be greater than this, and furthermore, a delicious sweetness is produced.

RX-25 at 12-13.

Complainants argue that "delicious sweetness" is not defined from a scientific perspective. *See* Complainants' Post-Hr'g Br. at 31. However, one of ordinary skill would interpret the phrase "delicious sweetness" to mean that the taste is more like sucrose, since sucrose was the standard those of ordinary skill in the art were trying to achieve in blending sweeteners. RX-25; Walters Tr. 1134-1135.

Complainants argue that the published studies of their expert, Dr. Moskowitz,[11] showed that the conclusions of the Ueno article were wrong.

---

[11] Dr. Harold Moskowitz received a B.A. in 1965 in psychology and mathematics from Queens College. In 1969, he received a Ph.D. from Harvard University in experimental psychology with a specialty in psychophysics, which is the study of the relation of physical stimuli to sensory responses. His specific subspecialty in psychophysics was the study of the sense of taste. Dr. Moskowitz began work as a government research scientist at the U.S. Army Natick laboratories in Massachusetts in 1969, doing research on sweetness and other areas of sensory perception until 1975. In 1975, Dr. Moskowitz founded a market research company called MPI Sensory Testing, to take these methods of sensory measurement of foods and consumer products into the

(continued...)

Complainants refer to CX-39B, "The Tastes of Artificial Sweeteners and Their Mixtures," by Moskowitz and Klarman. Indeed, Dr. Moskowitz testified that his study showed that a combination of sweeteners often was worse than either component. Moskowitz Tr. 248; *see* Complainants' PFF 1255-1256.

Respondents argue in response that "to the extent certain combinations could be worse than others, the optimal combination could be obtained through routine experimentation using taste tests that were well-known to those of skill in the art by the 1970s." *See* Respondents' Reply to the Proposed Findings of Fact and Conclusions of Law of Complainants at 95.

One of ordinary skill in the art would be presumed to have had knowledge of both the Ueno article and published work of Dr. Moskowitz, and to therefore have understood that not all combinations of high-potency sweeteners, in any ratios whatsoever, will yield improved taste. However, the skilled person would also have known of the positive Ueno teaching, and furthermore would have taken note of the positive results discussed in the Ueno article involving the combination of the high-

---

[12](...continued)
commercial realm. In 1978, Dr. Moskowitz left MPI Sensory Testing, and founded Developmetrics, a company devoted to the same area. In 1981, with a partner, he formed Moskowitz Jacobs, and is currently the CEO of Moskowitz Jacobs Inc. Moskowitz Jacobs is a marketing research company, specializing in the sensory evaluation of consumer products in concepts and in package design. Dr. Moskowitz was accepted as an expert in the sensory perception of sweeteners. Moskowitz Tr. 205-214.

potency sweeteners. *See* CX-25 at 13-14.

The Yamane Article

RX-17 is a Japanese article on sweeteners that was edited by Takeo Yamane, and published in 1966.

At the top of page 216, the article states as follows:

> It has long been recognized from experience that when sweeteners are used together, the level of sweetness is increased synergistically, and in the case of synthetic sweeteners, too, when these are used with each other or when they are used along with sugar or some other such sweetener, the level of sweetness is considerably raised in comparison to the sum of the levels of sweetness when used individually.

RX-17; Walters Tr. 1135.

The article further notes that "in particular, by the combined use of synthetic sweeteners, *it is clear there is a reduction in the bitterness or unpleasant taste which is their particular disadvantage.*" By "synthetic sweeteners," the authors are referring to high-potency sweeteners. RX-17 at 216-17 (emphasis added); Walters Tr. 1136-1137.

As in the case of the Ueno article, the Yamane article would have taught someone of ordinary skill in the art that by blending sweeteners, one can reduce the amount of bitter or unpleasant or off tastes and create a taste that is better, and therefore more like sucrose. *See* Walters Tr. 1137.

The Yamaguchi et al. Patent

RX-20 is a Japanese patent to Yamaguchi and others, which was published in 1972. According to the patent, "[t]he present invention relates to a method of enhancing the potency and improving the taste quality of artificial sweeteners." Specifically, the patent deals with blends of aspartame with other high-potency sweeteners, including saccharin and cyclamate. RX-20; Walters Tr. 1137. According to RX-20, as a result of investigations into the taste characteristics of aspartame, "the present inventors have discovered that if APM [aspartame] is mixed with saccharin or cyclamic acid (cyclamate), sweetness is markedly enhanced by synergistic action between the inherent sweetness of the two components, and at the same time, the unpleasant taste which is a characteristic of artificial sweeteners is eliminated by this mixing, and the quality of the taste is dramatically improved." RX-20.

Complainants argue that this reference pertains only to the specific sweeteners covered by the patent, and would not teach that other mixtures of high-intensity sweeteners would have similar results. Complainants' Post-Hr'g Br. at 32. RX-20 would have taught one of ordinary skill in the art in the mid-1970s working in the sweetener area that by blending aspartame with other high-potency sweeteners, one can improve the taste quality. RX-20; Walters Tr. 1138. The patent provides yet another example of benefits resulting from the mixture of high-potency sweeteners, including blends with aspartame.

The Prior Art in Combination

None of the prior art discussed above (RX-11, RX-17, RX-20, RX-23 and RX-25) was before the Patent Office during the prosecution of the '068 patent. *See* CX-1; Walters Tr. 1138. Moreover, the prior art cited by respondents and relied upon by Dr. Walters in his expert testimony at the hearing is more relevant than the prior art that was before the Patent Office because the prior art discussed at the hearing deals specifically with blends of high-potency sweeteners.[13] Walters Tr. 1138-1139.

In the prior art relied upon in this investigation, there were explicit suggestions to blend high-potency sweeteners to improve taste, as in the case of the Ueno and Yamane articles. Furthermore, there were implicit suggestions to blend based upon the fact that so many combinations of high-potency sweeteners had improved taste.

Indeed, collectively, the prior art would have taught one of ordinary skill in the mid-1970s that there were four high-potency sweeteners that had been studied up to that point (i.e., saccharin, aspartame, cyclamate and dulcin), and six possible pairs of sweeteners that could be considered. Out of those six possible pairs of sweeteners, five had been evaluated and all five showed not only

---

[13] For example, a patent concerning a blend of aspartame and saccharin was before the PTO, RX-6 (U.S. Patent No. 3,780,189). However, that patent disclosed "enhanced sweetening potency" or synergy, and not improved taste quality. *See* RX-6; Walters Tr. 1138-1139.

synergy, but more importantly, improved taste, i.e., made the taste more sucrose-, or "saccharose-" like. *See* Walters Tr. 1139.

In addition to the fact that favorable results were obtained by blending other high-potency sweeteners, one faced with the task of improving the taste of acesulfame potassium would have observed that the acesulfame potassium molecule is structurally very similar to the saccharin molecule, which was used extensively in the prior art.[14]

Based on what was known about structure-activity relationships, if saccharin showed synergy and improved taste, then it was very likely that acesulfame potassium would also show synergy and improved taste when blended with other high-potency sweeteners. Walters Tr. 1140. This expectation would have been based on the fact that one of ordinary skill in the art in the mid-1970s would have expected similar structures to behave similarly.[15] Walters Tr. 1140.

---

[14] At the hearing, Dr. Walters provided a visual illustration of the structural similarity between saccharin and acesulfame potassium. RPX-38; Walters Tr. 1143-1144.

[15] Dr. Walters explained part of the theoretical basis for this expectation which was prevalent, at least in the 1970s, as follows:

> Q Is there something called a lock and key analogy in the area?
>
> A Yes, the lock and key analogy applies to structure activity relationships in general, was proposed, I believe, in the 1890s by Ehrlich in Germany.
>
> Q Can you explain what that is? Maybe you can use the flip chart.

(continued...)

Indeed, RX-176 ("Structure-Taste Relationships of Some Dipeptides"), RX-183 ("Aspects of Functional Groups and Flavor"), RX-184 ("Dependence of Relative Sweetness on Hydrophobic Binding") and RX-192 ("Relationship Between Taste and Structure in Some Derivatives of Meta-Nitaniline") are typical structure-activity studies showing the relationship between taste and chemical structures. None of these studies concerns acesulfame potassium. However, these studies show that one of ordinary skill in the art in the mid-1970s would have been familiar with these types of studies, and would have considered the structure of acesulfame potassium (and the similarity to saccharin) when

---

[15](...continued)

> A I think I can explain the lock and key analogy fairly easily. The idea is that whatever the receptor is which detects a molecule, whether it's a sweetener or a drug or whatever, the receptor molecule is a lot like a lock and the molecule that fits into it and triggers the response is like a key. So if you have a particular receptor, in this case a sweet receptor, and one key fits into it and then you come along with a second molecule that's a lot like the first one, a very similar key, essentially, and it also triggers sweetness, then there's a very high probability that both of those keys are fitting into the same lock.
>
> Whereas if you have a very different structure and it tastes sweet, that's good evidence there may be a second kind of receptor that's responsible for the response. In the case of sweeteners, if you have two very different kinds of receptors, that might account for synergy.

Walters Tr. 1140. *See also* Walters Tr. 1120-1121 (The lock and key model is useful, even taking into account the fact that small changes in a certain portion of a molecule may have large effects on taste).

considering its taste and the effect that it may have in a blend. Walters Tr. 1141-1143.

For example, in a 1973 paper by Clauss and Jensen of Hoechst describing acesulfame, they noticed the similarity in structure between saccharin and acesulfame, and made an analog of their acesulfame structure which was as close in structure as possible to saccharin.[16] RX-29; RPX-38; Walters Tr. 1145. According to the Clauss and Jensen article, saccharin, acesulfame, and the acesulfame analog all tasted sweet and had some bitter taste as well. Walters Tr. 1147; RX-29.

It would have been obvious to one of ordinary skill in the art in the mid-1970s that if saccharin has the effect of producing synergy with other sweeteners, and has the effect of producing better taste qualities when blended with other sweeteners, then it was highly likely that acesulfame potassium would produce similar results when blended with other sweeteners. Walters Tr. 1146. By the mid-1970s, saccharin had been shown to have both synergy and improved taste qualities when blended with other sweeteners. Walters Tr. 1146-1147.

Based upon the information available to one of ordinary skill in the art in the mid-1970s, it is clear that while one would not have been

---

[16] An "analog" refers to a small change in chemical structure, such as changing only a few atoms in a complex molecule, so that one can still recognize the similarity between the two compounds. Walters Tr. 1147. It was recognized in the 1970s that in complex structures sometimes even a small change will result in a loss of sweet taste, yet a small change in another portion on the same molecule will not have a large effect on taste. Walters Tr. 1147-1148, 1207-1209; CX-40; CX-185.

completely certain that a blend of acesulfame potassium with another high-potency sweetener such as aspartame would result in a more saccharose-like taste, one would have had a high expectation that such a favorable result would be obtained. One's expectation of a favorable result would have been well-grounded in the teachings of the prior art.

Obviousness does not require absolute predictability. A claimed invention is not patentable where "the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art." *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). *See Gillette Co. v. S.C. Johnson & Son*, 919 F.2d 720, 725 (Fed. Cir. 1990); *In re Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

Based on the prior art in the mid-1970s, one of ordinary skill would have had a very good expectation (more than a reasonable likelihood of success) that in blending high-potency sweeteners, including acesulfame potassium, there would be both synergy and more importantly, improved taste. *See* Walters Tr. 1139.

Two articles by complainants' expert, Dr. Moskowitz, which were cited in the '068 patent, would not have taught one of ordinary skill in the art in the mid-1970s anything relating to taste quality. The first article deals with taste intensities to the exclusion of taste, while the second article deals with taste hedonics (whether panelists liked the sample) rather than on taste quality. Something may, for example, be very sweet, yet so strong as to be displeasing. CX-39(a), CX-39(b);

Walters Tr. 1152-1154. Thus, the art submitted and considered in this investigation is not cumulative of the art considered by the Patent Office.

The secondary considerations relied upon by complainants do not counter the strong evidence of invalidity presented by the prior art. Complainants argue that Dr. Lipinski testified that after trying without success to use masking agents to improve the taste of acesulfame potassium, he was surprised at the results he achieved when acesulfame potassium was blended with other high-potency sweeteners because the effect exceeded his expectations. Dr. Lipinski testified that he was surprised at the results of blending acesulfame potassium with other sweeteners. However, it is difficult to attribute meaning to his present recollection of surprise because the record is not clear as to key facts relating to Dr. Lipinski and his work at the time of the claimed '068 invention. He could not remember when he began working on the claimed invention, which sweeteners he first tried to blend with acesulfame potassium, or what contributions listed co-inventor Erich

---

"Objective evidence" of nonobviousness, or "secondary considerations," may include copying, long felt but unsolved need, failure of others, *see Graham v. John Deere Co.*, 383 U.S. at 17-18, commercial success, *see In re Huang*, 100 F.3d at 139-40, unexpected results created by the claimed invention, unexpected properties of the claimed invention, *see In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997), licenses showing industry respect for the invention, *see Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed.Cir.1997), and skepticism of skilled artisans before the invention, *see In re Dow Chem. Co.*, 837 F.2d at 473. *See, generally, In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998).

Lück made to the claimed invention. Furthermore, his laboratory notebooks have been lost or destroyed. *See* RPX-19C (Lipinski Dep. Designations) Tr. 48, 55-61, 69-70; Lipinski Tr. 120. Consequently, little weight is given by the administrative law judge to Dr. Lipinski's expression of "surprise" at the results of blending in view of the prior work of Hoechst, and other prior art, and the lack of any objective evidence supporting this conclusion.

Complainants argue that the unexpected sucrose-like taste is further shown by a study commissioned by Hoechst in the 1980s that found that despite the fact that customers in the United States were used to the taste of aspartame, they strongly preferred the taste of acesulfame potassium and aspartame. *See* Complainants' Post-Hr'g Br. at 34. However, the relevancy of such a study to the question of obviousness is unclear. It has not been argued that the taste of aspartame is better than a mixture of aspartame and acesulfame potassium. On the other hand, given the prior art discussed above, it is not surprising that the blending of high-potency sweeteners would improve taste.

Complainants argue that the addition of acesulfame potassium to aspartame improved taste quality, thus resolving a long felt but unresolved need. *See* Complainants' Post-Hr'g Br. at 35. However, as pointed out by respondents it is difficult to equate that fact with nonobviousness, inasmuch as Hoechst held a patent on acesulfame potassium until recently, and therefore other companies could not attempt to blend ASK with other sweeteners. *See* Respondents' Reply Br.

at 24.

Finally, no party has contested the assertion that a mixture of acesulfame potassium with another high-potency sweetener has enjoyed commercial success. However, that fact does not override the clear evidence presented by the prior art as to the obviousness of the claimed invention of the '068 patent.[18]

With respect to the fact that the claims require specific ratios of sweeteners, respondents argue that once it was known to combine sweeteners, determining the ratios that would achieve the optimum taste characteristics would be a matter of routine experimentation. Respondents' Post-Hr'g Br. at 48 (citing Walters Tr. 1151-1152); Moskowitz Tr. 306-307. Dr. Lipinski admitted that at the time the application for the '068 patent was filed, there had been no experiments to determine which ratios of sweeteners would produce the best results, and in fact, the applicants did not know which ratios would produce the best taste when blending sweeteners. Lipinski Tr. 116-120; RPX-19C

---

[18] In many cases, secondary consideration may be highly probative in making a determination of whether a claimed invention is "obvious." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) ("[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record."). However, "the weight to be accorded evidence of secondary considerations is to be carefully apprised in relation to the facts of the actual case in which it is offered." *Cable Elec. Prods. v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985). Indeed, "the weight of secondary considerations may be of insufficient weight to override a determination of obviousness based on primary considerations ...." *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997)(rehearing denied)(suggestion for rehearing in *banc* declined)(citing *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

(Lipinski Dep. Designations) Tr. 72-73, 79-80.

Patents have been found to be invalid when only some degree of experimentation was required to arrive at optimal ranges, ratios, or dosages. *See, e.g., Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 809 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989)("The evidence at trial showed that, though requiring time and care, the experimentation needed to arrive at the claimed dosages was nothing more than routine.").

There is no evidence that the ratios recited in the claims of the '068 were arrived through anything other than customary methods, or that the results of mixing sweeteners in the recited ratios were in any way unexpected. *See In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996)("[O]ne of ordinary skill would have experimented with various thicknesses to obtain an optimum range. Because Huang does not contend that he has achieved unexpected results by increasing the thickness of the polyurethane layer, the Board properly concluded that the prior art grips in combination with Lau created a prima facie case of obviousness.")

Once one of ordinary skill in the art in the 1970s had decided that there would be a high likelihood of success in blending ASK and other high-potency sweeteners, one could have determined the best ratios for blending the sweeteners through a very straightforward set of experiments that could be done with a taste panel, having them taste different ratios of the sweeteners. Walters Tr. 1151; Moskowitz Tr. 306-307. One of ordinary skill in the art would have known how to do

this type of taste test. Most of the larger food companies already had facilities to do this sort of testing, with trained panels already in place. This type of taste test is very straightforward and would take perhaps one or two weeks. Walters Tr. 1152.

In summary, there is clear and convincing evidence that the '068 patent claims would have been obvious to someone skilled in the art in the mid-1970s because there was a substantial body of art showing that when one blends high-potency sweeteners in easily defined ratios, one is highly likely to get improved taste. To one of ordinary skill in the art, improved taste meant more like sucrose because sucrose is the gold standard for sweeteners. *See* Walters Tr. 1155.

B. 35 U.S.C. § 112, ¶ 1.

Respondents argue that the '068 patent is invalid for failure to meet the requirements of 35 U.S.C. § 112, paragraph 1. They argue that the inventor admitted that he had no basis for any ratios when the application for the '068 patent was filed, and therefore the patent failed to satisfy the enablement requirement of section 112. *See*, Respondents' Post-Hr'g Br. at 49-50; Respondents' Reply at 24 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1556 (Fed. Cir. 1991) and *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir.), *cert. denied*, 112 S.Ct. 169 (1991)).

Complainants and the Commission Investigative Staff oppose respondents' arguments concerning section 112. Complainants argue that

respondents have never questioned whether the claimed blends provide a more sucrose-like taste, and further that the evidence shows Dr. Lipinski disclosed in his application precisely the same ranges found in the '068 patent claims. Complainants' Reply Br. at 15-16.

In *Fiers*, the Federal Circuit affirmed a PTO rejection of a patent application for lack of enablement, stating that "one cannot describe what one has not conceived." In *Fiers*, there was a serious question as to whether the portion of the patent application relating to a particular DNA necessary to the claimed invention was merely a "wish" or a "conjecture." 984 F.2d at 1171. However, the facts in *Fiers* differ from those in this case.

In this case, Dr. Lipinski had difficulty explaining why he selected the ratios recited in the claims of the '068 patent, and in recalling all the experiments that he may have performed prior to filing his patent application in the United States. Nevertheless, it appears that he based his patent experiments and his patent claims on preconceived expectations that he and others had at Hoechst concerning the total contribution that one sweetener would have to the total taste. The ratios found in the specification and the claims appear to be based on experiments that he ran at Hoechst, especially since the ratios are found in the Examples disclosed in the patent application. *See* CX-2; CX-1. Furthermore, no party has alleged that the '068 patent fails to

enable one of ordinary skill to practice the claims of the '068 patent.[19]

Therefore, there is a lack of clear and convincing evidence that the '068 patent is invalid for failure to comply with 35 U.S.C. § 112, ¶ 1.

IV. INFRINGEMENT

Complainants assert that respondents have infringed all claims of United States Patent No. 4,695,629, and claims 1 and 2 of United States Letters Patent 4,158,068. Complainants' theories of infringement differ for each patent. For example, with respect to the '629 patent, complainant relies on a presumption of infringement under 35 U.S.C. § 295; and with respect to the '068 patent, complainants charge that respondents have induced infringement thereof. A discussion of the particular law required for an infringement analysis under each patent is contained below in the section dedicated to each patent. However, a more general discussion of the law of patent infringement follows immediately, and it applies to the issues raised under both patents.

---

[19] The Federal Circuit distinguished its holding in *Fiers* in the case of *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1228 (Fed. Cir.), *reh'g denied* (1994). In *Burroughs*, the Federal Circuit held that "an inventor need not know that his invention will work for conception to be complete . . . . He need only show that he had the idea; the discovery that an invention actually works is part of reduction to practice." With respect to *Fiers*, the Federal Circuit stated, "[h]ere, though, Burroughs Wellcome's inventions use a compound of known structure; the method of making the compound is also well known." *Id.* at 1229.

A. General Law of Claim Construction and Infringement

Claim Construction

In order to perform a patent infringement analysis, any claim must first be construed to determine its proper scope and meaning.[22] *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974 (Fed. Cir. 1985); *Lemelson v. General Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 1053, 113 S.Ct. 976 (1993).

The construction of patent claims is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)(*en banc*), *aff'd*, 116 S.Ct. 1384 (1996); *Tandon Corp. v. Int'l Trade Comm'n*, 831 F.2d 1017, 1021 (Fed. Cir. 1987).

"Claims must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979 (quoting *Autogiro Co. v. United States*, 384 F.2d 391, 197 (Ct. Cl. 1967)). However, in considering the claims in view of the specification, it must be remembered that "[t]he written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of the claims." *Markman*, 52 F.3d at 980.

To construe claim language, one "should also consider the patent's prosecution history, if it is in evidence." *Id.* Indeed, the

---

[22] With respect to the '629 patent, no substantial disputes exist among the parties concerning claim construction. *See* OUII Post-Hr'g Br. at 8 n.9. Consequently, the meaning of the claims of the '629 is not discussed in a separate section, although the claims are described as part of the infringement analysis contained herein.

prosecution history (or "file wrapper") "is of primary importance in understanding the claims." *Id.*

Extrinsic evidence may also be used to construe patent claims. Such evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Extrinsic evidence may, for example, help to explain scientific principles, technical terms, or the state of the art at the time of the invention. *Id.* Furthermore, "[e]xpert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used." *Markman*, 52 F.2d at 979 (quoting *Fonar Corp. v. Johnson & Johnson*, 821 F.2d 627, 631 (Fed. Cir. 1987). *See also SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988)("Moreover, claims should be construed as one of ordinary skill in the art would construe them.").

A "court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent." *Markman*, 52 F.3d at 979 (quoting *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 546 (1871)). A trial judge has sole discretion to decide whether or not he needs, or desires, an expert's assistance to understand a patent. *Markman*, 52 F.3d at 981 (quoting *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984)).

Infringement

To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly. *Southwall Technologies*, 54 F.3d at 1575. *Accord Graver Tank & Mfg. Co. v. Linde Co.*, 339 U.S. 605, 607 (1950)(Literal infringement of the asserted claim occurs "[i]f accused matter falls clearly within the asserted claim ....").

Limiting patent enforcement exclusively to literal infringement "would place the inventor at the mercy of verbalism and would be subordinating substance to form." *Graver Tank*, 339 F.2d at 607. Thus, if the accused product or process does not literally infringe the patent at issue, it may infringe under the doctrine of equivalents. *See In re Certain Doxorubicin and Preparations Containing Same*, 20 U.S.P.Q.2d 1602, 1608 (United States Int'l Trade Comm'n 1991).

Infringement may be found under the doctrine of equivalents if an accused product that does not literally infringe the patent claim performs substantially the same function in substantially the same way to obtain substantially the same result.[21] *Graver Tank*, 339 U.S. 605, 608 (1950); *Valmont Indus. v. Reinke Mfg.*, 983 F.2d 1039, 1043 (Fed.

---

[21] In *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S.Ct. 1040, 1054 (1997); the Supreme Court held that "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element."

Cir. 1993); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir.)(*en banc*), *cert. denied*, 485 U.S. 961, 1009 (1987). Equivalency must be proven on a limitation-by-limitation basis. *Warner-Jenkinson*, 117 S.Ct. at 1049; *Pennwalt*, 833 F.2d at 935.

The doctrine of equivalents is limited in that it will not extend (1) to cover an accused device in the prior art, or (2) to allow the patentee to recover through equivalents coverage given up through prosecution. *Pennwalt*, 833 F.2d at 934 n.1. In *Warner-Jenkinson*, the Supreme Court held that prosecution history estoppel can serve as a limitation on the doctrine of equivalents. Specifically, the Court noted that amendments made expressly to avoid the prior art or adopted as a substitute for a broader one previously used could result in prosecution history estoppel. *Warner-Jenkinson*, 117 S.Ct. at 1049-50.

The Federal Circuit has explained that "the essence of prosecution history estoppel is that a patentee should not be able to obtain, through the doctrine of equivalents, coverage of subject matter that was relinquished during prosecution to procure issuance of the patent." *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951-52 (Fed. Cir. 1994).

A party alleging infringement has the burden of proving infringement by a preponderance of the evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984); *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983). The question of infringement of properly interpreted claims is one of fact. *Mannesman Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282 (Fed.

Cir. 1986).

B. The '629 Patent

Each claim of the '629 patent is asserted by complainants in this investigation. The claims of the '629 patent are as follows:

> 1. A process for the preparation of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide and its non-toxic salts by ring closure of an acetoacetamide derivative, which comprises using as the acetoacetamide derivative acetoacetamide-N-sulfonic acid or its salts, and carrying out the ring closure by the action of at least the approximately equimolar amount of SO_3, where appropriate in an inert inorganic or organic solvent, and then, where appropriate, also neutralizing with a base the 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide which is produced in the form of the acid in this reaction.
>
> 2. The process as claimed in claim 1, wherein the SO_3 is used in a molar excess of up to about 20-fold, preferably about 3- to 10-fold, in particular about 4-to 7-fold, relative to the acetoacetamide-N-sulfonic acid (salts).
>
> 3. The process as claimed in claim 1, wherein the inert inorganic solvent used is liquid SO_2, and the inert organic solvent used is at least one solvent from the following group:
>
> > halogenated aliphatic hydrocarbons, preferably having up to 4 carbon atoms,
> >
> > esters of lower alochols [sic] and carbonic acid, preferably methyl and ethyl carbonate,
> >
> > lower nitroalkanes, preferably having up to 4 carbon atoms, collidine and sulfolane.

> 4. The process as claimed in claim 1, wherein the ring closure reaction is carried out at temperatures between about -70° and +175°C., preferably between about -40° and +10° C.
>
> 5. The process claimed in claim 1, wherein the 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide, which is produced in the form of the acid, is extracted from the sulfuric acid reaction medium using a halogenated solvent or an ester of carbonic acid or of an organic carboxylic acid, and, where appropriate, neutralizing with a base the sulfuric acid which has been carried over.

CX 5 ('629 Patent) at col. 18, line 45 through col. 20, line 7.

Section 295

It is evident from the claims of the '629 patent, and it is undisputed in this investigation, that the claims are process patent claims. With respect to the '629 patent, complainants, supported by the Commission Investigative Staff, rely on a presumption of infringement and burden-shifting as provided for under 35 U.S.C. § 295.

Section 295 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 so to 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.A. § 295 (1998 Supp.).

Section 295 was added to the patent law by the Process Patents Amendments Act of 1988. The leading case to date that interprets and applies section 295 is *Pfizer Inc. v. F & S Alloys and Minerals Corp.*, 856 F. Supp. 808 (S.D.N.Y. 1994),[22] which has been relied on by all parties in this investigation.

In applying section 295, the court in *Pfizer* held that if it is established by a preponderance of the evidence that there is a substantial likelihood that the defendant uses the patented process to manufacture the products at issue and that the plaintiff has made a reasonable effort to determine the actual process used but was unable to do so, then the accused process is assumed to infringe the patent and the burden shifts to the defendant to establish that the accused process does not infringe. 856 F.2d at 810.

In their post-hearing brief, complainants argue that unlike the court in *Pfizer*, which applied the "preponderance of the evidence standard" to establish the first prong of section 295, the legislative history of section 295 shows that "less than a preponderance of the evidence is required to establish 'substantial likelihood.'"

---

[22] For a discussion of section 295 which emphasizes the *Pfizer* case, *see* Donald S. Chisum, *Chisum on Patents*, § 16.02[6][d][vi] (1998)(hereinafter "Chisum").

Complainants' Post-Hr'g Br. at 4-5 (quoting Senate Report, S. Rep. No. 100-83, 100th Cong., 1st Sess. at 57 (1987)(emphasis in original)).

In this investigation it will not be necessary to determine whether complainants are correct in their argument that they need not show by a preponderance of the evidence a substantial likelihood that respondents used the patented process. The administrative law judge has determined that complainants have failed to establish the second prong of section 295 because the evidence of record demonstrates the process used by the Sanhe respondents to manufacture the accused acesulfame potassium. *See Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1368 n.6 (Fed. Cir. 1996)("Section 295 is inapplicable in the present case, *inter alia*, because [the patentee] was able to determine the process [the accused infringer] used to manufacture [the imported product].")[23]

Complainants encountered numerous problems when they conducted

---

[23] There was also an investigation at the Commission, which pre-dates the *Novo Nordisk* case before the Federal Circuit, in which it was stated that section 295 could not apply because there was a failure to meet the requirements of the second prong, which has to do with discovery of the actual accused process. In *Certain Pressure Transmitters*, the administrative law judge held, in an unreviewed portion of the Initial Determination, that "[the complainant] did not invoke a presumption of infringement under the Process Patent Act, 35 U.S.C. § 295, and could not have done so because respondents allowed reasonable discovery of the processes by which their imported products were made." *Certain Pressure Transmitters*, Inv. No. 337-TA-304, Initial Determination at 36 (July 2, 1990), 55 Fed. Reg. 34627 (1990)(determining not to review the portion of the initial determination pertaining to section 295). It is noteworthy that in *Pressure Transmitters* respondents would have escaped the application of section 295 because they had provided "reasonable discovery."

discovery of Sanhe in China, and a substantial portion of important discovery was not provided until quite late in the investigation. However, complainants refused a suggestion to cure prejudice or damage caused by late-produced discovery by reopening the record at respondents' expense to ameliorate or cure any prejudice.

The legislative history of section 295 contemplates discovery of foreign manufacturers such as the Sanhe respondents, and the steps that might be taken in a reasonable attempt to ascertain the details of the accused process. The antecedent Senate Report states that:

> The reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction .... [T]he Committee expects protective orders to be used in encouraging foreign manufacturers to supply information pertinent to a process patent infringement suit revolving around goods made by such manufacturers. If information is obtained under a protective order that definitively determines the process used to make the goods in question, the presumption would not be applicable.

S. Rep. No. 100-83 at 58.

In this case, the implementation and modification of a protective order, as well as special efforts by respondents, complainants and the administrative law judge were required in order to obtain adequate discovery from the Sanhe respondents, an organization that works under the supervision of the Chinese government. Ultimately, respondents provided laboratory notebooks, raw material receipts, equipment sales contracts, copies of appraisal reports provided to the Chinese

government, and a variety of additional documents and other discovery, including a factory inspection. It is the judgment of the administrative law judge that the discovery has yielded an adequate record from which the details of the accused process can be determined.

Complainants argue that respondents' process has changed over time, and that the process shown to complainants during the plant inspection in China is not the process used previously in the recent past to produce acesulfame potassium. It is also argued the discovery provided by respondents, including even the late-produced documentary evidence, fails to demonstrate how the Sanhe respondents manufacture acesulfame potassium.

However, complainants' arguments, which are in large part supported by the Commission Investigative Staff, rely on a close technical review of the record from the perspective of an infringement analysis. The fact that the evidence must be closely analyzed to determine the process does not mean that respondents failed to provide adequate discovery, such that one must invoke section 295 in lieu of the normal methods of proof. Consequently, the evidence related to the question of whether respondents infringe the '629 patent is discussed below in terms of the usual and normal infringement analysis rather than with reference to section 295.

Complainants and respondents addressed the evidence relating to alleged infringement of the '629 patent in five categories. The administrative law judge has similarly determined to address the

evidence in these five categories.

Tests of Respondents' Products

Dr. Udo Dettmeier, one of complainants' expert witnesses, testified that it may be possible to identify the production process used to make acesulfame potassium by analyzing the by-products found in a sample of the product. *See* Dettmeier Tr. 605. Relying upon that premise, complainants argue that by analyzing the amounts of sulfate and fluoride found in respondents' final acesulfame potassium products, they can determine whether the Sanhe respondents used the process of the '629 patent, or whether they used the FSI process or the ASF process.[24] Complainants' Post-Hr'g Br. at 6-7.

Prior to the filing of their complaint, complainants obtained samples from respondents JRS International, Inc. ("JRS"), and WYZ Tech, Inc. of imported acesulfame potassium manufactured by the Sanhe respondents. When the samples were received by complainants, they were assigned the internal designations Fremd No. 127 (JRS) and Fremd No. 128 (WYZ).[25] Fremd No. 127 and Fremd No. 128, as well as other samples were

---

[24] An overview of the FSI, ASF and '629 processes is contained, *supra*, in the Background section of this Initial Determination.

[25] Samples Fremd No. 127 and No. 128 were each divided into two parts. One part was kept in Nutrinova's laboratory, and the other was sent for testing. Klug Tr. 399-400.

The testing was performed for Nutrinova by Institut Fresenius in Germany, a well-regarded laboratory that, among other things, performs (continued...)

tested on two occasions, i.e., September 1997 and October 1997. Complainants' Post-Hr'g Br. at 6-7.

Complainants state that the September 1997 tests of Fremd No. 127 "showed a huge amount of sulfate (14,600 milligrams per kilogram of acesulfame potassium)." They also state that no fluoride was detected in the September test of Fremd No. 127. Complainants state that the September 1997 test for sulfate of Fremd 128 also showed "a large amount of sulfate (410 milligrams per kilogram of acesulfame potassium)," and that no fluoride was detected. Complainants' Post-Hr'g Br. at 6-7.

Complainants state that in order to confirm the September 1997 results, a second set of sulfate and fluoride tests of Fremd No. 127 and No. 128 were performed in October 1997 using more sensitive testing methods. According to complainants, the October tests of Fremd No. 127 "once again showed a huge amount of sulfate (14,600 milligrams per kilogram and 12,900 milligrams per kilogram)," and an amount of fluoride right at the level of detection. They state that the October tests of Fremd No. 128 "once again showed a large amount of sulfate (410 milligrams per kilogram and 360 milligrams per kilogram)," and fluoride

---

[28](...continued)
independent chemical analyses. Klug Tr. 400. Dr. Klug, Nutrinova's Director of Quality and Integrated Management Systems, visited Institut Fresenius, discussed the standards and analyses to be applied to the testing, and supplied the samples to the Institut for testing. Klug Tr. 383-402.

The samples were labeled "Fremd" because "Fremd" is German for "foreign," which in this case means that the sample did not originate from Hoechst production. Klug Tr. 398.

right at the level of detection. Complainants argue that fluoride right at the level of detection "means that there could be no fluoride in the sample or, if any was present, it was only in the smallest traces." Complainants' Post-Hearing Br. at 7.

Complainants argue that based upon the test results showing "a very high level of sulfate and no, or virtually no fluoride, Dr. Dettmeier concluded that samples Fremd Nos. 127 and 128 could only have been manufactured by the '629 process." Complainants reason that the only other two known processes, the FSI process and the ASF process, would not produce the sulfate levels found in these samples and would as well show clearly detectable levels of fluoride. Complainants' Post-Hr'g Br. at 7.

Complainants argument also relies upon a comparison of respondents' products manufactured before the complaint was filed in this investigation and samples taken in discovery during the Sanhe plant inspection.[26] Complainants argue that their test results conclusively show that respondents changed their process.[27] *See* Complainants' Post-Hr'g Br. at 8-10; Complainants' Reply at 2.

According to complainants, the sulfate test results on the plant

---

[26] The tests performed on the samples taken for complainants during the plant inspection were performed by Sani-Pure Laboratories of Saddle River, New Jersey. *See* Stalick Tr. 758.

[27] Complainants admit that the process demonstrated during the plant inspection in China does not infringe any claim of the '629 patent. RX-152 (Response of Complainants to Respondents' First Request for Admission).

inspection samples showed that sample #7 (taken after the first crystallization in the Sanhe process) showed milligrams of sulfate per kilogram of acesulfame potassium and milligrams of fluoride per kilogram of acesulfame potassium. Sample #8 (taken from a production run carried out at some time before the inspection) is alleged by complainants to show amounts of sulfate and milligrams of fluoride per kilogram of acesulfame potassium. Sample R000966 (which complainants say was "purportedly from the production run during the plant inspection") shows ppm (parts per million) sulfate and ppm fluoride. Thus, it is argued, the test results on the plant inspection samples show precisely the opposite of the pre-complaint samples, i.e., sulfate and amounts of fluoride. Complainants' Post-Hr'g Br. at 8.

The Commission Investigative Staff supports complainants' arguments concerning the sulfate and fluoride levels in respondents' products. The Commission Investigative Staff notes that Hoechst samples produced using the '629 process had undetectable concentrations of both sulfate and fluoride, whereas the Hoechst samples that were produced using the FSI process (a process in which fluoride is a starting material), showed fluoride levels above the quantification levels in the September and October analyses, and minimal if any concentrations of sulfate. OUII Post-Hr'g Br. at 20-21. The Commission Investigative Staff also notes a change in the samples of respondents' products over time, with the more recently obtained samples, including samples taken

during the April 20-21, 1998 plant inspection in China, showing fluoride and sulfate levels. Thus, it is argued that the recently obtained samples were made using the process that respondents claim to use, and the earlier samples were produced using the '629 process. OUII Post-Hr'g Br. at 21-25.

In opposition to the arguments of complainants and the Commission Investigative Staff, respondents, relying on the testimony of their expert, Dr. Walters, argue that while it is undisputed that the presence of fluoride indicates use of a non-infringing process in the production of acesulfame potassium, if fluoride is absent, it is impossible to tell whether it is because of the process used to make ASK or because the material was purified to the point that fluoride is no longer present or detectable. Furthermore, it is argued that the presence or absence of sulfate is even less useful in making a determination as to the manufacturing process used because sulfate can result from the FSI process, the ASF process or the '629 process. Respondents argue that

and therefore were likely made by a method other than the '629 process. Respondents' Reply at 2.

Respondents argue that there is no inconsistency between complainants' alleged test results and the process used by Sanhe because as shown by the evidence presented at the hearing, including the testimony of complainants' experts, the amounts of fluoride and sulfate

in the final product depend on a number of different factors, including the method of purification, the type of extraction solvent used, the amount of the extraction solvent, and the number of cyrstallizations following extraction. Respondents' Post-Hearing Br. at 22. Indeed, respondents argue that sulfate was detected in some samples of Sanhe's acesulfame potassium because Sanhe has at times used

during its purification process, and it is undisputed that such a practice would result in the presence of sulfate in the finished product. It is further argued that the level of fluoride in Sanhe products would be low since the product

. Respondents' Post-Hr'g Br. at 22-23.

Before determining the significance, if any, that may be attributed to the presence or absence of sulfate and fluoride in respondents' products, it is necessary to evaluate the expert testimony concerning detection of those chemicals in finished acesulfame potassium.[26]

As stated above, complainants' expert testified that testing for levels of sulfate and fluoride in acesulfame potassium can reveal the manufacturing process used. Dr. Dettmeier advanced such a theory throughout this investigation, and complainants place particular emphasis on the portion of his hearing testimony in which he described how he arrived at his view concerning the analysis of by-products or

---

[26] The significance of in finished acesulfame potassium products is discussed separately, *infra*.

impurities such as sulfate and fluoride in acesulfame potassium. *See* Complainants' Post-Hr'g Br. at 6 (citing CPFF 199-202).

In testimony, Dr. Dettmeier stated that Nutrinova asked him his opinion of whether one can identify processes by analyzing by-products. He answered Nutrinova that based on his experience at Hoechst, in general it was possible to do so. Nutrinova also asked whether he could identify processes for making acesulfame potassium by analyzing by-products. Dr. Dettmeier reviewed his own knowledge concerning acesulfame potassium processes, including the FSI process (which was developed by Hoechst) and the '629 process, and also conducted a literature search of all known processes described in patents. He also considered the availability of raw materials, the handling of intermediates, and other variables. Dettmeier Tr. 604.

---

[29] Dr. Dettmeier retired from Clariant on July 30, 1998. Hoechst owns a 45% interest and has 10% of the voting rights in Clariant, a Swiss company. Hoechst sold one of its chemical divisions to Clariant in 1997. Dettmeier Tr. 589, 593-594.

Dr. Dettmeier studied organic chemistry at the University of Cologne, and completed his studies in 1968 with a doctorate degree. After completing his education, Dr. Dettmeier started to work as a chemist in a company owned by Hoechst AG. His job at that time was to develop processes and products in the field of organic chemistry. Dettmeier Tr. 590. He then accepted a position as an assistant to a member of the board of Hoechst AG who was responsible for research and development. Following that assignment, Dr. Dettmeier went back to the Division of Organic Chemicals. He stayed there as a leader of the laboratory for a year. At the end of 1974, Dr. Dettmeier was named a group leader. One year later, Dr. Dettmeier was given responsibility for the whole department that worked with organic chemicals. The department included about a 100 chemists, engineers, and a small group responsible for analytical chemistry. A pilot plant and laboratories were part of the department. Dettmeier Tr. 590-594.

Dr. Dettmeier testified that having finished his research into the question posed by Nutrinova, he was able to conclude that there are two categories of production processes: "one was processes which start with fluoride containing intermediates for starting materials, and the other group of processes were processes which use SO_3 as a cyclization agent." Dettmeier Tr. 604-605. Thus, Dr. Dettmeier responded to Nutrinova's question of whether one can identify the process used to make acesulfame potassium by analyzing the by-products in the finished product. Dr. Dettmeier stated that "[i]f one has the chance to identify processes by analyzing the by-products, then the best chance one would have [is] to look at the traces of fluoride and sulfates." Dettmeier Tr. 605.

The testimony of respondents' expert, Dr. Walters, did not appear to take issue with that of Dr. Dettmeier concerning the basic science supporting Dr. Dettmeier's method of analysis. However, it did underscore the practical problems that arise when attempting to rely on an analysis of by-products to determine the process by which acesulfame potassium was made.

Dr. Walters on direct testified as follows:

> Q Now, Dr. Walters, do you have an opinion about whether Complainants' test results of Sanhe samples are evidence that Sanhe has used a different process in the past?
>
> A Yes, I do.
>
> Q What is your opinion?
>
> A My opinion is that based on simply on fluoride and sulfate levels, you really can't say anything at

all about the process that was used.

Q What does the level of fluoride tell you?

A Well, the fluoride level tells you if there is fluoride present, it tells you that there's a good probability that the ASK was made with a fluorene containing reagent, something like ASF or FSI, but if the fluoride is absent, you don't know whether it's because the '629 process was used or whether it's absent because the material was simply purified to the point that fluoride is not there anymore.

Q What about sulfate, what does the presence of sulfate tell you?

A I think sulfate is even less useful in this respect, because we've seen samples from the FSI process that contain sulfate, we've seen that in the process that Sanhe uses, sulfate is there because they have used , so it has nothing to do with the '629 process. And in fact, the '629 samples that Hoechst analyzed had the lowest level of sulfate of any.

Q Where have we seen evidence of sulfate in the FSI samples?

A One of the old Hoechst samples that was analyzed contained sulfate.

Q And what would the lack of sulfate tell you?

A Again, lack of sulfate doesn't tell you much, because you don't know the reason that it's absent, you don't know if it was absent because of the process not involving sulfate, you don't know whether it's absent because it was simply purified to the point that the sulfate is not detectable anymore.

Q Now, Dr. Walters, it's been suggested that the older Sanhe samples had higher sulfate and lower fluoride and the more recent samples have , and that that's evidence that Sanhe used a different process in the past. Do you agree with that?

A No.

Q Why not?

That's --

MR. SCHILL [for Complainants]: Objection, your Honor; there's lack of foundation for this. It's not lower -- it's not lower fluoride. There's no fluoride.

JUDGE HARRIS: Or un --

MR. HNATH [for Respondents]: Low or no fluoride.

JUDGE HARRIS: Undetectable.

MR. HNATH: Undetectable, yes.

JUDGE HARRIS: So the question is modified. Do you want to restate it?

BY MR. HNATH:
Q Yes. It's been suggested that older Sanhe samples have higher sulfate and fluoride below the detection limit, and that more recent samples have

. In your opinion, does that show that Sanhe used an infringing process in the past?

A No, it shows really nothing about the process for synthesizing the ASK. It goes much more to the way that the ASK was purified. It shows that very different methods were used to purify those two samples.

Walters Tr. 1175-1177.

There is evidence in this investigation of changing sulfate and/or fluoride levels in the products of both complainants and respondents. As the expert testimony at the hearing showed, different processes may leave behind different by-products in a manufacturer's finished acesulfame potassium. However, there are many reasons why sulfate or

fluoride may be present or absent from finished products, which are not necessarily connected to the starting materials used in the basic ASK production process. Consequently, chemical analysis alone, particularly of sulfate and fluoride in a finished ASK product, cannot definitively demonstrate which production process was used. In some cases, the presence or absence of sulfate and/or fluoride found in an ASK product may not be dispositive or even probative of the manufacturing process. At best, the presence or absence of these substances is a departure point for further inquiry.

With respect to complainants' ASK products (made by Hoechst), complainants provided examples in which they used the '629 process to manufacture acesulfame potassium. Certain samples of Hoechst '629 acesulfame potassium had undetectable concentrations of both sulfate and fluoride. Complainants also had tests run on samples of acesulfame potassium that was made with Hoechst's former manufacturing process, which was an FSI process. Fluoride was detectable in each of the Hoechst FSI samples. Sulfate, if it was present at all, was undetectable in one of the Hoechst FSI samples, but sulfate was detected in two of the Hoechst FSI samples. In the September test, a value of 30 ppm for sulfate was reported. In October, the values of 10, and less than 10 were reported. These values are relatively small in that they were at or near the level of detection for the tests that were performed in September and October on complainants' behalf, and they were smaller than those reported for respondents' products which, according to Dr.

Dettmeier, were roughly about 300 ppm. Klug Tr. 427-432; Dettmeier Tr. 641-644; CX-48C; CX-49C. Nevertheless, some explanation must be made for the sulfate found in Hoechst FSI samples.

Dr. Dettmeier used the following diagram to testify concerning the Hoechst FSI process to make "Sunett," an acesulfame potassium product:

See CX-78C.

Dr. Dettmeier's testimony centered around an early step in the Hoechst FSI process that starts with the reaction product

Thus, according to Dr. Dettmeier, the used to make FSI "could be the

source for the sulfate." Distillation is used in Hoechst's FSI process as a means of purification. Although FSI can be distilled, sulfate cannot. Therefore, Dr. Dettmeier expected that "traces" or "minor amounts" of sulfate would be found in the distillate. Dettmeier Tr. 641-644; CX-78C.

Although it appeared that Dr. Dettmeier could not say with complete certainty that the use of was the reason that various amounts of sulfate were detected in Hoechst's acesulfame potassium, his explanation appears plausible.

Therefore, it is not clear at what amount the presence of sulfate should be considered indicative of the '629 process. Is the threshold 300 ppm, 30 ppm, 10 ppm or some other level? Certainly, the significance of sulfate in a sample of acesulfame potassium cannot be determined by an arbitrary criterion such as the sensitivity of the test employed, and whether the minimum level of detection happens to be 10 or 30 or a higher level.[30] The testimony of complainants' witnesses underscores the point that one cannot simply look at the presence of sulfate in an acesulfame potassium product -- at any level --and conclude that the '629 process was used. There must be room to consider the reason the sulfate is present. Similar considerations must also be given to the presence or absence of fluoride in a sample of acesulfame

---

[30] *Cf.* OUII Post-Hr'g Br. at 21 (The Commission Investigative Staff argues that "[s]ince the levels 'detected' were exactly at the limits of detection rather than greatly in excess thereof, they are immaterial for purposes of indicating practice of the '629 process.").

potassium.

According to complainants, the reason samples of Hoechst acesulfame potassium made with a former FSI process had 10 to 30 ppm of sulfate in them is due to the process for making the FSI starting material. It had nothing to do with practice of the '629 patent. *See* Complainants' Reply Br. at 8; Complainants' PFF 599, 600. The question is then presented as to whether there are facts of record to explain the roughly 300 ppm of sulfate in respondents' earlier products, and also to explain changes in the amount of fluoride found in respondents' products.

In fact, the record contains persuasive evidence why some of respondents' acesulfame potassium products have contained sulfate, and also why the levels of fluoride appear to have changed over time. Extensive testimony from Mr. Qiu (the individual who is responsible for the development of Sanhe's process, and who plays a key role in Sanhe's day-to-day manufacturing operations), supported by documentary evidence, provides a valuable insight into the Sanhe process for making acesulfame potassium.

Mr. Qiu received a degree in 1985 from Zhejiang Industrial University, where his courses included chemistry, organic chemistry, chemical engineering, mathematics, high polymer materials, metallic and non-metallic materials, and corrosion theory. Qiu Tr. 837-838. As an honors graduate he was able to obtain employment at Zhejiang Chemical Industrial Institute, which is one of the largest institutes of its kind

in China with over 1,000 researchers and 7 separate departments. Qiu Tr. 838-839.

While at the Institute, Mr. Qiu began work in relating to food additives, including acesulfame potassium. Qiu Tr. 840, 874. He conducted literature searches and experimentation concerning acesulfame potassium, including work in Sanhe's laboratory before he was a Sanhe employee. Mr. Qiu considered a number of different ways of making acesulfame potassium. He decided against using method because he considered the materials used to make too dangerous. He knew that the use of SO_3 for ring closure was patented in China and elsewhere. He concluded that for him the key to making acesulfame potassium would be process. Qiu Tr. 875-884. In , and throughout much of , Mr. Qiu conducted extensive research and experimentation into the production of , which would be needed in the type of process he had decided to use. Qiu Tr. 878-891.

At the close of his experimentation, Mr. Qiu became an employee of Hangzhou Sanhe Food Additives Factory in , at which time he and Sanhe's Director, Mr. Zong, began their concerted efforts to take Sanhe's production of ASK from the laboratory stage to the pilot plant stage. Qiu Tr. 884, 892; Zong Tr. 1063-1064.[31]

Construction of the pilot plant began some time in

---

[31] For information relating to governmental approval, the acquisition of land and equipment, and other aspects of the commencement of pilot plant operations *see, e.g.*, Qiu Tr. 892-897, 947-958; CX-97C; RX-196C; RX-202C.

and was completed about . Acesulfame potassium was first made at the pilot facility some time in . Qiu Tr. 896-897.[32]

In the first few months of the pilot experiment, the acesulfame potassium manufactured by Sanhe , which is undesirable in acesulfame potassium. Qiu Tr. 898

One possible cause of

. Qiu Tr. 897.

In addition,

. He thought that this would

. Therefore, in the early stages of the pilot experiment,

. It was only later that he realized

. Qiu Tr. 897-898.

In order to

. He testified that he also considered .

---

[32] Although Sanhe has produced a substantial amount of acesulfame potassium since it initiated production,

. Qiu Tr. 922-925; RX-201C.

However,

Qiu Tr. 898-899.

Mr. Qiu searched the literature and found that

. Therefore, he tried

Qiu Tr. 899-900.

During the hearing, Mr. Qiu illustrated the above method in which he

. *See* Qiu Tr. 901-902; RPX-29C; RPX-30C. He described the process in which

. Qiu Tr. 901-902.

---

[33] The term "ASH" has been used in this investigation to refer to the sweetener acid itself, without the potassium. ASH may be neutralized, for example with potassium hydroxide, and turned into acesulfame potassium. In certain processes, ASH and ASK may be converted back and forth. *See, e.g.*, Reuschling Tr. 331-332, 352.

Mr. Qiu testified that at the time he used this method

. He testified that

. Although Mr. Qiu

. Qiu Tr. 902; *see* Walters Tr. 1178-1179.

During the pilot experiment phase, approximately of acesulfame potassium was processed

. Qiu Tr. 900.

Mr. Qiu's testimony concerning

is further confirmed by records kept at the time that procedure was being used. *See* RX-205C.

In the initial stages of the pilot experiment, the workers had to be trained, and were acting directly under Mr. Qiu's instructions. In

, as the workers began to have more familiarity with the process, the factory formally set up the acesulfame potassium workshop, and the workers were required to keep workshop records.[34] Qiu Tr. 903-04.

The workshop process records refer to the purification method which Mr. Qiu described in his testimony,

. *See* RX-205(A)C at R001405-412

Qiu Tr. 905-906.

In , Mr. Qiu started using

. The product made using

. Therefore, there was no need to continue to use

. Qiu Tr. 906-907.

With respect to fluoride content, Mr. Qiu testified that

. Thus, the fluoride content in early samples of Sanhe's product would be expected to be very low, since the product

. Qiu Tr. 908-910, 1029; RPX-31C and RPX-32C.

Mr. Qiu testified that initially,

---

[34] At certain points in the manufacturing process, raw materials at the Sanhe plant are kept in barrels with numerical codes written on them. Workers in the Sanhe plant use those numerical codes in the workshop records to refer to the materials. Mr. Qiu pointed out barrels with numerical codes during the plant inspection. He subsequently answered question from respondents' counsel concerning the codes, and offered to do so for all parties. Qiu Tr. 1002-1003, 1048; Walters Tr. 1191.

Qiu

Tr. 910-911.

According to Mr. Qiu,

Therefore, using this process, it would be expected that the amount of fluoride would be very small or not detectable. Qiu Tr. 910-911; RPX-31C, RPX-32C, and RPX-33C.

Complainants do not accept Mr. Qiu's explanation as to why the acesulfame potassium made early in Sanhe's production contained relatively high amounts of sulfate and little or no fluoride. Their criticisms of the process described above fall into several categories, viz.: (1) respondents admit they cannot match samples Fremd Nos. 127 and 128 to of acesulfame potassium .

(2) the certificate of analysis sent with sample Fremd No. 127 clearly indicates that the sample was manufactured on , and, thus

(3) Mr Qiu testified that

, but if this explanation is applied to sample Fremd No. 127 it would mean that

. Mr. Qiu admitted that

; (4) Mr. Qiu had no information concerning the actual level of sulfate in any of the acesulfame potassium produced

; and (5) although respondents claim that

, the record shows that

.[35] *See* Complainants' Reply at 7.

No party has attempted to establish a chain of custody of any of the ASK samples relied upon by complainants that conclusively demonstrates when the ASK was manufactured. Furthermore, the certificate that has a and which was provided with the ASK that was put into sample Fremd No. 127, does not, however, disprove respondents' arguments, and in fact is consistent with their argument that it was from an early production that was subject to the .

---

[35] The Commission Investigative Staff also relies upon a comparison of certain samples given to Sani-Pure for testing, i.e., a comparison of Sample 6 with Samples 7 and 8. *See* OUII Br. at 24. However, Sample 6 was provided in liquid form, while Samples 7 and 8 are powders. One cannot make such a comparison of fluoride contents between liquid and powder samples. *See* Dettmeier Tr. 661-662. Furthermore, Sample 8 was taken from a previous run. *See* RX-154C.

As Mr. Zong testified, although certificates such as that associated with Fremd No. 127 have blanks for certain information to be filled in,

. He knows of cases in which

. Zong Tr. 1079-1081, 1097-1100.

Indeed, an examination of the certificate in question (CX-38C) strongly indicates that such an event occurred in this instance. The person who filled out the form

. On the certificate, there is a line for: As respondents pointed out, on many other such certificates,

. *See* RX-204C. However, in the case of this certificate there is the entry: CX-38C. Clearly, the person filling out the form

. Given the fact that the certificate was being used for such purposes, it cannot be found that

. It is more probable that

.

Complainants argue that Fremd No. 127 could not have originated because the level of sulfate detected of over

14,000 ppm would mean

. *See* Complainants' Post-Hr'g Br. at 9. Respondents point out, though, that other tests of the ASK in question which were run in-house by Nutrinova showed sulfate results that were 12,070; 8,780; 9,220; 7,310; and 10,725 ppm. Indeed, a precise sulfate measurement could not be made of the material contained in Fremd No. 127 because, in the words of the Nutrinova laboratory, the sample was "not homogenous." RX-253C ("Probe nicht homogen." *** "Präzision: 000").

As Dr. Walters testified, the non-homogeneity of the acesulfame potassium that went into Fremd No. 127 indicates that it was probably a mixture of ASK crystals and crystals. *See* Walters Tr. 1179. In his testimony relating to the sulfate and fluoride content in Sanhe's ASK, Mr. Qiu made certain assumptions in order to perform his calculations, including the assumption that the material was dissolved evenly in solution. *See* Qiu Tr. 910. Consequently, given what is known about the non-homogeneous nature of the ASK used to test Fremd No. 127, and its counterpart tested in the Nutrinova laboratory, it cannot be found that Mr. Qiu's calculations were in error or that based on the sulfate testing, the ASK in Fremd No. 127 was made by the '629 process.

Respondents' evidence concerning fluoride is also consistent with the process. It is undisputed that fluoride is a by-product left behind during the process, yet that will remove

fluoride from the finished ASK product. A question is raised, though, concerning

.

Respondents' expert, Dr. Walters, elaborated upon the testimony of Mr. Qiu concerning

. Dr. Walters confirmed that

, and that

. He testified in part, as follows:

BY MR. HNATH:

Q Yes. It' been suggested that older Sanhe samples have higher sulfate and fluoride below the detection limit, and that more recent samples have

. In your opinion, does that show that Sanhe used an infringing process in the past?

A No, it shows really nothing about the process for synthesizing the ASK. It goes much more to the way that the ASK was purified. It shows that very different methods were used to purify those two samples.

Q Can you explain what you mean?

A Yes. The material that they are producing now has . The material with a very high level of sulfate and undetectable fluoride clearly came from the material that Mr. Qiu described making very early in the process,

.

Q And how would that process affect the sulfate level?

A Again, can I use the easel to illustrate?

JUDGE HARRIS: Yes.

THE WITNESS: The material Mr. Qiu described very early in the process

. And he had tried

. So that material already would have had

Now, in order to

He testified that there was

And again, he took this material,

So this material now has

> In fact, the testing labs reported that the material was not homogenous, so I think it's likely that he had a mixture of ASK crystals and crystals in there.

Walters Tr. 1178-1179; *see* RPX-41C (illustrating testimony).

Thus, the used by Sanhe produced a that, although synthesized through process, had a low fluoride level.

Consequently, one cannot draw any reasonably certain conclusions about the nature of the process used to make ASK by relying primarily on an analysis of the quantities of sulfate and fluoride by-products found in an ASK sample, since the amounts of such by-products are greatly influenced by the purification process used. In this case, there was a major change in the purification process. Prior to , which would have resulted in a final product with a high sulfate level and a low fluoride level. After , Sanhe changed to a substantially different purification process that . *See, e.g.*, FF IV 79-83.

In addition to issues relating to sulfate and fluoride, an issue was also raised concerning , a compound that complainants found in samples of acesulfame potassium (ASK) manufactured by "third parties," i.e., Chinese companies other than respondents in this investigation. Those third-party samples also contained .

Respondents argue that the deposition testimony of certain witnesses for complainants, viz. Drs. Lipinski, Dettmeier and Topp, establishes that the presence of in a sample of an ASK product indicates that a process other than the '629 process was used. Furthermore, inasmuch as many of the third-party samples containing also contain relatively , it is argued that complainants' own witnesses and tests confirm that can be found in acesulfame potassium made by a process other than the '629 process.[36] *See* Respondents' Post-Hr'g Br. at 23 n.1; Respondents' Post-Hr'g Br. at 2; Respondents' PFF 297-298.

It is not disputed that high levels of were found in third-party samples of ASK products. *See* RX-255C. Furthermore, it does not appear to be disputed that inasmuch as

. *See* RX-256C (Walters Decl.), ¶ 3.

However, complainants and the Commission Investigative Staff dispute the significance attributed by respondents to the test results showing in third-party samples.

---

[36] The discussion above shows it is unnecessary to rely on a factor such as to show that the '629 process was not used by Sanhe, inasmuch as the mere presence of , with or without fluoride, does not establish which process was used to synthesize the acesulfame molecule.

It is argued, *inter alia*, that the deposition testimonies of Drs. Lipinski, Dettmeier and Topp, when read in context, do not establish a link between and non-infringing processes, and that an experiment performed for Nutrinova (CX-194C) shows that in certain circumstances may indicate that the '629 process was used. In particular, it is argued that the preferred embodiment of the '629 patent calls for the use of

. *See* Mem. of Complainants Regarding Ex. RX-255C and Mot. to Admit Exs. CX-191C to CX-201C into the Record at .5-6.

As indicated in the Background section of this Initial Determination, a substantial portion of the evidence relevant to the issue and the ASK products of third parties was admitted after the close of the hearing. Many of the documents submitted can be accorded little if any weight, and are of marginal relevance. For example, it is not clear exactly how long the and under exactly what conditions before the test was performed to determine whether had been

---

. Mem. of Complainants Regarding Ex. RX-255C and Mot. to Admit Exs. CX-191C to CX-201C into the Record at 6; Topp Tr. 526.

formed. It is not clear how such a would relate to carrying out the claimed elements of the '629 patent. Perhaps most importantly, it has not been established that the third-party companies in China used a similar to Nutrinova's experiment. Furthermore, the contained in RX-105C/SX-5C, which is supposed to provide , appears to contain hearsay, and to have been written at an unspecified time by an unnamed author.

The most informative evidence of record concerning the issue is the testimony of complainants' witnesses, upon which the subsequent arguments and proffers of evidence are based.

During his deposition, Dr. Lipinski was asked a series of questions concerning impurities in ASK and what their presence would indicate about the manufacturing process, including . It is evident from his testimony that he is not an expert in how ASK is made, and that he does not have well-developed theories of his own about ASK impurities and by-products. Nevertheless, he did know that others at Hoechst or Nutrinova had theories concerning impurities such as . Dr. Lipinski's testimony is as follows:

> Q. What would the presence of fluoride indicate in a sample of ASK?
>
> A. We believe this was an indication of fluorine containing starter materials.
>
> Q. Are you familiar with how ASK is made?

A. To some extent, but it's not my area of expertise.

Q. Are you familiar with the purification process?

A. Not in detail.

Q. Are you aware that the more you purify a sample of ASK the lower amount of trace impurities will be in the final product?

A. That's what I would expect.

Q. More purification would mean less fluoride?

A. I don't know what behavior of fluoride in purification is.

Q. How about sulfate, in general would more purification lead to less sulfate?

A. I can't state that either because I don't know the behavior of sulfate in purification.

Q. If you could look at the first page there, there are a number of different compounds listed.

A. Yes.

Q. The first is . Why were you interested in having the samples tested for that?

A.

Q.

A.

Q. What does the presence of that impurity indicate about the process, to your understanding?

A. At the present moment I don't know.

Q. Have you had discussions with people at Nutrinova or Hoechst?

A. Yes.

Q. What are some of the theories advanced as to what that compound would indicate about the process?

A. At that time we believed it would indicate a different manufacturing route.

Q. Which route did you believe it would indicate?

A. The use of .

Q. What type of process would use

A.

Q. Is that the CSI process?

A. No, that's a different one.

Q. Why were you interested in testing for ?

A. I think that is listed in one of the pharmacopoeias as an impurity with a limit.

Q. What would that tell you about process used to make the sample, if anything?

A. For the time being, I don't know anything.

Q. Did you have a theory at one time as to what that would indicate?

A. No.

RX-19C (Lipinski Dep. Designations) Tr. 112-115.

Thus, according to Dr. Lipinski's testimony, at one time (apparently when third-party testing was done) Nutrinova believed that

However, by the time of Dr. Lipinski's deposition, it appeared that

Nutrinova no longer took that view.

Dr. Dettmeier provided the most technical detail of how might be found in a sample of acesulfame potassium. He testified, as follows:

RX-257C (Dettmeier Dep. Designations) Tr. 298-299 (attached to respondents' Mot. No. 403-50 as Ex. 2).

Dr. Dettmeier's testimony is similar to that of Dr. Lipinski in some respects, such as the fact that the theories at Nutrinova concerning have been subject to change. Dr. Dettmeier's testimony seems to be that the presence of may depend upon more than one factor, and further that can provide a "hint," at the process used.

Dr. Topp was also questioned about and other impurities during his deposition. An important consideration concerning Dr. Topp's testimony is that despite his extensive experience working for Hoechst (which included the manufacture of ASK under Hoechst's FSI process) he does not consider himself to be an expert in the area of analytical test results, nor do complainants offer him as someone having such expertise.[38] *See* Mem. of Complainants Regarding Ex. RX-255C and

---

[38] Dr. Topp studied organic chemistry at the University of Göttingen in Germany, and then entered a one-year post doctoral program at Ohio State University in Columbus, Ohio. Topp Tr. 460. In November of 1969, he commenced 8 years of work in research and development at Hoechst AG, after which he became production manager at a plant for side-chain chlorination. Next, he was assistant to the head of the organic chemicals division for 2 years. For a year and a (continued...)

Mot. to Admit Exs. CX-191C to CX-201C into the Record (quoting CX200C (Topp. Dep. Designations) Tr. 208).

Dr. Topp's testimony concerning is as follows:

---

[38](...continued)
half he was production manager in an ethylene oxide plant. This was followed by one year and a half as an assistant to a member of the Hoechst Board. Topp Tr. 460-461. Dr. Topp's responsibilities included overseeing the design and placement of chemical reactors within chemical plants. Topp Tr. 462. He became responsible for the acesulfame potassium plant in 1986, when Hoechst was using its old FSI process (which Hoechst continued to use until the second half of 1987). Topp Tr. 462. In 1992, he became a department head. In 1995, when Hoechst reorganized to create new business units, he became responsible for the unit concerned with food ingredients. When Nutrinova was founded in 1997, Dr. Topp stayed with Hoechst, and at the time of the hearing his retirement was imminent. Topp Tr. 460-461.

RPX-13C (Topp Dep. Designations) Tr. 264-265.

Dr. Topp's testimony was unequivocal in that he would not expect to be found in ASK that was produced according to the '629 patent, whereas it would be found after the FSI process and possibly after the ASF process. It appears from the testimony of Drs. Dettmeier and Lipinski, quoted above, that at one time those were the beliefs generally held at Nutrinova. As also seen from the Dettmeier and Lipinski testimony, those beliefs changed as it was learned that the presence of may depend on more factors than originally considered by Nutrinova. Indeed, as discussed above, Nutrinova now argues that it has discovered a factor, i.e., . Upon learning of Nutrinova's latest research and theory, Dr. Topp revised his views concerning to match those of Nutrinova. *See* CX-199C (Topp Decl.), ¶ 7-8.

Consequently, due to his lack of expertise, Dr. Topp's testimony, whether in deposition or at the hearing, cannot provide useful information concerning an analysis of or any other impurity found in finished ASK products.

In summary, the presence of may indicate the use of a process that does not infringe the '629 patent. Yet, it cannot be found that the mere presence of ,

indicates which process was used.[39] In this case, it is not clear why the third-party samples contain , and what effect, if any, the presence of that compound in the third-party samples could have on an analysis of the Sanhe process.

Possible Conversion of Respondents' Production Facility

As discussed above, complainants argue that respondents have changed their process for the manufacture of acesulfame potassium. Part of the basis for complainants' argument is their assertion that although the infringing process was not being run during the plant inspection conducted in this investigation, respondents' production facility can readily be converted to run the infringing process. They argue that "there was nothing to hinder Respondents from modifying their production facility from the '629 process to the inspected process during the period [from] October 15, 1997 when the Complaint was filed until April 20-21, 1998, when the plant inspection occurred." Complainants' Post-Hr'g Br. at 11.

Complainants' expert, Dr. Dettmeier, testified that he could easily convert the Sanhe ASK reactor vessels to produce ASK by the '629 process, which uses SO_3. *See* Dettmeier Tr. 608-611. He testified that

---

[39] In addition, complainants' conclusion that the third-party samples with must have been made by the '629 process must also be rejected. As discussed in detail throughout this section, the presence of sulfate without fluoride does not necessarily establish use of the '629 process.

it would take him only about one week to convert the Sanhe plant from an SO_3 process to the process that he observed when he was at the Sanhe facility. *See* Dettmeier Tr. 612-614. In fact, in Dr. Dettmeier's opinion the features of the Sanhe plant

. *See* Dettmeier Tr. 614-615.

Respondents do not appear to dispute the fact that the Sanhe facility could run the '629 process, and that at least from a physical standpoint a conversion to the '629 process would be fairly easy to accomplish. Indeed, in response to a question from complainants' counsel concerning conversion of the Sanhe plant to the '629 process, given the arrangement of the vessels currently there, respondents' expert answered: "I think everyone agrees that these are very generic-type reactors, so certainly it's possible that that could be done. There's no reason why that would be impossible, physically impossible." Walters Tr. 1194.

Nevertheless, respondents take issue with complainants' arguments concerning conversion of the Sanhe facilities primarily on two grounds. Respondents argue first that it is irrelevant whether Sanhe *could* practice the '629 process; and second, several other factors apart from the physical configuration of the plant would prevent Sanhe from making a conversion to the '629 process in only a week or a matter of months. *See* Respondents' Reply at 5-6. Both of these points raised by respondents have merit.

To say that infringement could have occurred does not, of course, imply or prove that it has. The record is clear that much more than simple physical conversion of a plant is required to run a new process for the manufacture of a product such as acesulfame potassium. For example, conservatively speaking, it took Sanhe many months of experimentation to begin production of acesulfame potassium using the process, even after Mr. Qiu had decided to use the process which was . *See, e.g.*, Qiu Tr. 876-890. Given Sanhe's limited resources, it is unclear whether Mr. Qiu could in fact convert the Sanhe facility from a '629 process to process in the timetable suggested by complainants.

In summary, the generic nature of the reactors and other features of the Sanhe facility in China do not constitute significant evidence in determining whether Sanhe infringes the '629 patent.

The Lack of Corrosion in Sanhe's Production Vessels

Complainants argue that although the vessels used by Sanhe are well-suited to run the '629 process, they are not suitable for the process because . The Commission Investigative Staff makes similar arguments.

The corrosion argument is based on testimony and other evidence offered primarily through Dr. Topp. Dr. Topp testified that he was surprised to see vessels used at Sanhe, and to find no major corrosion. Topp Tr. 491-495. Consequently, after the inspection, he supervised an experiment to confirm his understanding that corrosion should have been present in Sanhe's reactor vessel 2 (R2).

Dr. Topp personally prepared a mixture of

. He placed rods into the solution. After 20 hours in the solution, the rods showed significant signs of corrosion. Dr. Topp calculated the corrosion rate on the at 47.6 millimeters per year. He then ran a second test that included

to see if corrosion takes place in vapor and condensation phases. He calculated corrosion rates of 6.6 millimeters per year for the vapor phase, and 3.2 millimeters per year for the condensation phase. The corrosion of the samples from the solution and vapor phases was evident upon a visual inspection of the samples, which were brought into the hearing. *See* Complainants' Post-Hr'g Br. at 11-12; Topp Tr. 510-515, 552; CPX-3C; CX-64C.

Respondents reject the corrosion argument and the tests set forth by complainants. They point out that the Sanhe process had been operating for over a year in the reaction vessels viewed at the Sanhe plant, and there was no sign of corrosion from the process. *See* Walters

Tr. 1169-1170; Qiu Tr. 962-963.

Respondents argue while they do use process, the reason that Sanhe's vessels have not undergone significant corrosion is that is not produced in sufficient quantities in vessels R1 or R2 to cause corrosion, and that . It is also argued that during his experiment with rods, Dr. Topp did not accurately duplicate the conditions in Sanhe's reactor vessels.

As discussed below, the evidence shows that respondents are correct in their assertion that complainants failed to duplicate the Sanhe's conditions in their corrosion test, and furthermore, the process used by Sanhe does not in fact form a significant amount of so as to cause corrosion in the reactor vessels.

Some of the most illustrative evidence concerning the corrosive or non-corrosive nature of the solution found in Sanhe's vessel R2 was in the form of a sample of the solution which had been stored in for a considerable period of time. While Dr. Topp may have tried to duplicate such a solution, these containers were subject to the actual solution used at Sanhe during the inspection, and it is undisputed that Sanhe was not running the '629 process during the plant inspection.

On April 21, 1998, during the Sanhe plant inspection, samples were taken out of the vessels. These samples had been sitting in for over two months by the time of the hearing. According to Dr. Topp's theory concerning the solution used in R2, there should have

been signs of corrosion in the . Indeed, depending on the type of used in the relatively thin containers brought to the hearing room, one might have expected the containers to have been completely corroded through. Yet, unlike the rods that Dr. Topp placed in his test solution, the containing the Sanhe solution showed no signs of corrosion at all. *See* RPX-5(a); RPX-5(B); Topp Tr. 561-565; Walters Tr. 1170; Qiu Tr. 962-963.

The lack of corrosion is not surprising, given the fact that tests performed by Sani-Pure on samples from vessel R2 show the presence of very little in solution. In one sample, the level of was measured at , and in another the level was .[40] With that amount of , corrosion would be approximately .001 millimeters per year at most. At that rate, vessels such as R2 would sustain very little corrosion damage. Dr. Walters calculated that given the available in the samples given to Sani-Pure, it would take 1,000 years for large containers such as the Sanhe reactors to corrode; and he testified that given the actual pH and temperature used in Sanhe's reaction, the corrosion rate would be even slower.[41] Walters

---

[40] The amount of may be even less. Another laboratory (Metuchen Analytical) found the level to be . *See* RX-154C.

[41] Dr. Topp testified that it would be impossible to obtain a sample from Sanhe's reactor vessel with , given the Sanhe process. *See* Topp Tr. 1294-1296. However, as discussed in detail, *infra*, it is clear that Dr. Topp was not fully informed concerning crucial aspects of the Sanhe process, and that his own experiments failed to replicate the conditions in Sanhe's reactor

(continued...)

Tr. 1170-1174; RPX-40.

As explained by Dr. Walters and Mr. Qiu, since the in the R1 and R2 vessels form , the solution has a low level of . Furthermore, the remains in solid form, and therefore is not capable of being converted .[42] In contrast, in Dr. Topp's experiment all the fluoride was in solution. Walters Tr. 1174-1175; Qiu Tr. 963-968.

There were other important differences brought out at the hearing that may explain the differences between Dr. Topp's test results and the effect that the reactions actually have on the reactors in Sanhe's facilities, as well as upon the containers brought to the hearing in which samples of the contents of the vessels were stored. *See* Topp 6 Tr. 1285-1306; RPX-25C.

One of the most crucial differences concerns . Mr. Qiu testified in his deposition that Sanhe uses

---

[41](...continued)
vessels. In contrast, Dr. Walters and Mr. Qiu provided persuasive testimony concerning the in the reactor vessels, based upon an accurate understanding of the Sanhe process. *See, e.g.*, Walters Tr. 1174-1175; Qiu Tr. 963-968.

[42] Before Dr. Topp performed his experiment, Mr. Qiu stated that , was formed in the Sanhe process. For example, although Mr. Qiu avoided some questions during the Sanhe plant inspection, in response to questions from complainants about the reactions taking place, he wrote an equation indicating that . Mr. Qiu told the visitors during the inspection that the solid material precipitating out of vessel R2 was . Indeed, the diagram of the facility drawn by Dr. Dettmeier after the inspection, which memorializes some of what he observed and what he was told, shows a path for Topp Tr. 508; CX-72C.

, and it is well-known that vessels are the standard for reactions involving the use of .[43] Topp Tr. 551, 1285-1286. Yet, Dr. Topp ran his experiments by adding in a much higher concentration of . Dr. Topp admitted that

. Therefore, it is possible that, as Mr. Qiu testified, used by Dr. Topp in his experiments reacts very differently from used by Mr. Qiu at Sanhe, and may have had a corrosive effect . *See* Topp Tr. 1291-1294; Qiu Tr. 971-975.

Complainants point out that the portion of Mr. Qiu's deposition in which he testified concerning was designated by respondents as "Confidential/Trade Secret-Highly Sensitive," and therefore not available to Dr. Topp before he conducted his experiments. They argue that Mr. Qiu had made prior inconsistent statements concerning used in his process, and that the Protective Order prevented them from informing Dr. Topp of the Mr. Qiu's latter testimony.[44] Complainants'

---

[43] Mr. Qiu explained at the hearing that .

[44] Respondents admit that Mr. Qiu's declaration submitted in support of their April 17, 1998 motion for summary determination read . They argue that the reference to was the result of a (continued...)

Reply Br. at 12 & n.4.

As explained, *supra*, in the Background portion of this Initial Determination, the Protective Order was modified. *See* Order No. 6. This modification was made to accommodate complainants, who sought to use current and former in-house technical personnel in connection with respondents' confidential discovery and hearing testimony. The administrative law judge modified the Protective Order over respondents' objections to allow complainants greater latitude to use in-house personnel than would normally be permitted.[45] However, certain highly secret areas of the Sanhe process were still to be segregated from the confidential information provided to Nutrinova personnel, such as Dr. Topp. Such highly secret Sanhe information was still available to complainants' counsel and any qualified outside expert retained by

---

[44](...continued)
typographical error, and that his testimony was corrected during his deposition. *See* Respondents' Reply to the Proposed Findings of Fact and Conclusions of Law of the Complainants at 49-50.

[45] Drs. Dettmeier and Topp are or have been affiliated with Hoechst, of which Nutrinova is a wholly owned subsidiary. The administrative law judge modified the Protective Order to permit these experts to view confidential business information after a representation by counsel that independent experts with appropriate knowledge were either non-existent or difficult to find. However, based upon the evidence, including the prior art, it does appear that independent experts in this field were available. Had the administrative law judge known of the availability of experts in this field, he would not have modified the Protective Order in the manner requested by complainants. *See* ALJ Ex. 2C (Transcript of Mar. 5, 1998 Telephone Conf.)

complainants, such as Dr. Stalick.[46]

It is unclear why no attempt was made to declassify or reduce the level of secrecy attached to the portion of Mr. Qiu's deposition concerning before Dr. Topp performed his experiment. Nor is it clear why complainants selected Dr. Topp to perform the experiment (rather than Dr. Stalick) and to offer the experiment into evidence when complainants' counsel and Dr. Stalick had access to all the discovery concerning information, and it was known that Dr. Topp did not. The result is that Dr. Topp's experiment cannot be assumed to have the reliability that such an experiment might have had if complainants had chosen to offer an experiment designed by someone who had access to all relevant discovery and evidence concerning the Sanhe process.

In addition to the question of , another problem with Dr. Topp's experiment lies in the fact that the concentration of used in the experiment differed from the ratio in the Sanhe process. That could have affected corrosion rates. Nor did the experiment take into account the fact that Mr. Qiu uses in the Sanhe process. Finally, although Dr. Topp ran his

---

[46] Dr. Stalick received a Ph.D. in organic chemistry from Northwestern University in 1969. He taught for one year at San Jose State University. He was then awarded a fellowship at Ohio State, where he did postdoctoral research for Melvin Newman. In 1972, he accepted a position as assistant professor at George Mason University. In 1976 he was promoted to associate professor with tenure, and in 1987, was made a full professor. Dr Stalick was accepted in this investigation as an expert in synthetic organic chemistry. Stalick Tr. 690-693.

experiment at , that is not necessarily the temperature at which Sanhe's process is run.[47] Topp Tr. 1300-1303; Qiu Tr. 971-974.

The evidence shows that the solution found in Sanhe's reactor vessels does not corrode their at a rapid rate. Although Sanhe uses process, the is precipitated in such a manner as to prevent the formation of an appreciable level of corrosion-causing . Although complainants, under Dr. Topp's supervision, ran a test in an effort to show that the process which Sanhe claims to use would corrode at a rapid rate, the test which was performed did not duplicate the Sanhe process adequately so that the test results (including corroded rods) are not useful in drawing any conclusion about the Sanhe process.

Complainants' Argument That Respondents' Alleged Process "Does Not Make Chemical Sense"

Complainants argue that respondents claim to use a process which "makes no chemical sense," viz.: a process in which

. *See, e.g.*, Complainants' Post-Hr'g Br. at 13-15.

According to complainants, this process creates unnecessary steps

---

[47] Sanhe makes sure that the temperature of its reaction vessels does not exceed , yet there is no assurance that the reaction occurs at . Qiu Tr. 974.

; lowers yield; and creates another impurity, , which has to be removed, in addition to the that is already present. Complainants argue that the only reason why respondents perform this is to appear, albeit unsuccessfully, to be using the process, but still have present in the end product.

It is argued that respondents' claimed method makes no sense from a pure yield basis because the '629 process has a yield of at least 70% while the yield of respondents' alleged process is . Thus, complainants assert that respondents have an obvious incentive to practice the '629 process, and it is simply not credible to suggest that respondents are actually practicing a process with a yield.

Finally, in a related argument, complainants argue that contrary to respondents' assertions, it is implausible for

In addition, the Commission Investigative Staff argues that there are discrepancies in respondents' explanations concerning in China. They also argue given respondents' alleged process, of ASK have been produced that have not been accounted for. OUII Post-Hr'g Br. at 25-27.

The question presented by the arguments of complainants and the Commission Investigative Staff is not one simply of whether Sanhe's

process is illogical or inadvisable; the question is whether the process that Sanhe claims to use is so illogical that Sanhe must have used the '629 process, and would do so again after the factory inspection.

The administrative law judge has determined that the record does not support a finding that respondents have fabricated a story about the Sanhe process. Rather, the evidence supports the claims made by respondents concerning the development and use of process. Furthermore, the evidence cited by complainants in support of the argument that the Sanhe process does not make "chemical sense" does not support a finding that Sanhe's process is illogical or nonsensical, and certainly does not rise to the level that one can conclude that Sanhe has lied about its process.

Mr. Qiu's laboratory notebooks going back to detail his experiments using as a purification method, and his reasons for selecting method over another method, such as one that uses . RX-203C at R000640-0658; Qiu Tr. 886-888; FF IV 46-63.

Respondents' expert explained that the method that Sanhe currently uses to purify ASK is not an "illogical" method for purification. It is a sensible reaction that separates ASK from by-products of the reaction. *See* Walters Tr. 1159-1160.

Dr. Walters testified that after , the resulting mixture is a very complex reaction mixture that has various by-products, all of which . Walters Tr. 1160; RPX-39C. In the reaction vessel (referred

to by Mr. Qiu as vessel "R8" and by Dr. Topp as vessel "R1"), the contents include

. Walters Tr. 1161-1162; RPX-39C. In order to

. Walters Tr. 1161-1162.

Next,

. Walters Tr. 1161-1162.

Walters Tr. 1161-62; RPX-39C.

Walters Tr. 1162-1163.

After the

. Walters Tr. 1162-1163.

Walters Tr. 1162-1163.

In order to

.[46] Walters Tr. 1163-1164.

Mr. Qiu provided detailed testimony at the hearing concerning Sanhe's decision to use . He testified that the purification method he developed enables Sanhe to

. Furthermore, Sanhe's purification method allows

---

[46] Complainants' witnesses testified that Sanhe's would result in approximately a loss of yield. Topp Tr. 543-546; Dettmeier Tr. 648-649.

. Qiu Tr. 844-849; RPX-26C; RPX-27C.

In addition, the chemicals used in Sanhe's method are . *See* Topp. 546; Dettmeier Tr. 649.

For these reasons, Sanhe

[49]

The evidence establishes that Sanhe's is not "illogical" as argued by complainants. Moreover, there is no indication that it was put forth by respondents in connection with this investigation either as a mere argument or as a temporary practice to deceive the Commission or to create an illusion of consistency between an alleged process and the test results of respondents' acesulfame potassium. Rather, the Sanhe process has been shown to be the result of long-term research and planning in order to meet Sanhe's need for a relatively inexpensive and safe way to make a marketable acesulfame potassium product.

---

[49]

the chemical process

Reuschling Tr. 341-344.

With respect to the question of overall yield, and complainants' argument that it is not economically feasible to practice a process that results in a yield, it must be observed that the record is sparse at best on the actual overall yield of Sanhe's process or on the question of Sanhe's economic viability. It did not appear that complainants had conducted a detailed analysis on that question, and did not intend to raise it as an issue. Nor did respondents have the opportunity to offer relevant testimony. *See, e.g.*, Topp Tr. 547. Consequently, there is insufficient evidence to find that Sanhe's reported yields are too low to be credible.

A question has also been raised as to whether, according to the Commission Investigative Staff's calculations, there are of ASK that are not accounted for under Sanhe's arguments and testimony. Although the issue was not the subject of detailed briefing or evidence, it appears that the discrepancies between the parties' calculations involve the molecular weight of ASK. The molecular weight of ASK is approximately , thereby accounting for the in question. *See* Respondents' Reply Br. at 10; Qiu Tr. 983-984.

Finally, there is the question of whether or not it is believable that Sanhe

, as well as apparent inconsistencies in respondents' statements concerning

.

Mr. Qiu testified that Sanhe

. Qiu Tr. 878-980. Such an arrangement is often called "toll manufacturing." A toll manufacturer will perform a process on-site. This is a common practice throughout the world. Topp Tr. 578.

It appears that Mr. Qiu's relationship with his toll manufacturer may not be customary, as least in comparison with how such processing is done in Europe. Mr. Qiu did in fact testify that in this case he has not told the toll manufacturer the chemicals that are reacted. Qiu Tr. 978-979. Complainants do not believe that such a relationship is possible.

However, Mr. Qiu testified that

is not made for immediate sale in China. Thus, he must contract

. Nevertheless, he is wary of

. Therefore, he has not disclosed the reactants . In order to assure that the processing with is done correctly and safely, Mr. Qiu has visited the manufacturer, and told the company to install certain equipment. He has worked with technical personnel and other workers, and directed the processing himself. Thus, although it is strictly true that Mr. Qiu has not revealed the chemicals , it also appears that Mr. Qiu is in fact largely responsible for the running of the

. Qiu Tr. 878-980.

With respect to , Mr. Qiu made it clear that there is great concern in China over . He did, however, testify that he received a small sample for his own laboratory experiments. *See* Qiu Tr. 980-981. Based on the lack of reliable evidence concerning the manufacture and use in China, except for the evidence provided by Sanhe, there is insufficient evidence to show an inconsistency between on an industrial scale, and Mr. Qiu receiving a small laboratory sample.

Respondents' Purchases of Raw Materials

In their main post-hearing brief, complainants argue that their expert, Dr. Stalick, examined the raw material receipts produced by respondents in discovery and determined that the receipts did not support a claim of continuous use of process since , but rather supported the conclusion that respondents likely had made acesulfame potassium by the '629 process based upon . Specifically, Dr. Stalick concluded that during the period , respondents did not purchase chemicals necessary to manufacture or to make acesulfame potassium by process . It is alleged that two weeks after the complaint was filed, however, purchasing of all four

products resumed. Complainants' Post-Hr'g Br. at 15.

Complainants further argue that in this period in question , respondents purchased . Dr. Stalick concluded that, at a minimum, this was enough for respondents to have manufactured acesulfame potassium by the '629 process. According to complainants, respondents purchased , and one of the pre-complaint samples, Fremd No. 127, that shows high sulfate and no fluoride, was accompanied by a certificate of analysis indicating that it was manufactured . Complainants contend that respondents were only able to attack this argument by producing, at the last minute, receipts for raw materials that allegedly fill in the gaps in Dr. Stalick's calculations. It is argued that the newly produced receipts are highly suspect. Complainants' Post-Hr'g Br. at 16.

Respondents argue that the raw materials purchased by Sanhe are consistent with their use of a process that has as a starting material and . Respondents' Post-Hr'g Br. at 24-25. It is argued that before Dr. Stalick submitted his exhibits for hearing concerning Sanhe's raw material purchases, the additional receipts were produced that showed there was in fact no gap in Sanhe's raw material purchases, including receipts for . Respondents add that there is nothing unusual about its purchases of , inasmuch as Dr. Stalick and Mr. Qiu both testified that . Respondents' Reply Br. at 11-12.

Mr. Qiu testified that there are many receipts stored at his company, and it took a lot of work to produce all receipts covering his raw material purchases. He testified that he originally thought he could produce only receipts sufficient to show what materials were being used. He stated that during his deposition, complainants' counsel raised the issue of production of all receipts. So, he cut short his planned stay in the United States, returned to China, and produced the rest of the receipts immediately. Qiu Tr. 943-944.

The discovery requests at issue called for documentation broader than the documents Mr. Qiu initially produced. By the time of his deposition he understood his obligation to produce all his receipts, and he quickly acted to remedy the situation before the commencement of the hearing. It is possible that the late production of this information prejudiced complainants. Therefore, complainants were offered the opportunity to reopen the record after conclusion of the hearing at respondents' expense. Complainants declined this offer. If they had accepted, the question of raw material purchases is an area in which the administrative law judge would have received additional evidence and argument.

The need for additional information is particularly apparent with respect to arguments made by complainants in their reply brief, in the Commission Investigative Staff's briefs, and addressed in the supplemental briefing accepted after the replies were filed. Complainants and the Commission Investigative Staff argue that even if

the belatedly produced receipts are taken into account, Sanhe did not purchase enough to make the of ASK that Sanhe claims it made.[50] It is argued that at lest were needed to obtain of ASK, and Sanhe's receipts show the purchase of only . *See* Complainants' Reply Br. at 10-11.

Although respondents do not dispute the purchase of [51] they contest the assertion that having purchased only Sanhe could not use its process to produce of ASK.

First, respondents point out that the other parties do not take into consideration the fact that not all of Sanhe's resulted from a process based on . Mr. Qiu testified that for a period in the , he tried to make . Qiu Tr. 936-937. Indeed, it was established at the hearing that can be used to make . *See* Qiu Tr. 936-937; Stalick Tr. 826.

Second, according to respondents, the calculations of complainants and the Commission Investigative Staff assume a yield of when Sanhe

---

[50] In responses to discovery requests, respondents represented that Sanhe produced of acesulfame potassium during the period from . *See* CX-101.

[51] Respondents rely on the invoices contained in CX-98C to prove the purchase of . Respondents argue that the Commission Investigative Staff failed to take those invoices into account. They argue that this explains why the Commission Investigative Staff was able to confirm the purchase of only . *See* Respondents' Mot. No. 403-48 at 4; OUII Reply Br. at 5.

makes ASK when in fact

the record shows .

Respondents rely upon a (RX-131C)

in which Sanhe said its yield , as well as the

deposition testimony of Mr. Qiu. Mr. Qiu's relevant deposition

testimony is as follows:

> BY MR. SCHILL:
> Q: Mr. Qiu, as recall statements in some, many of your documents, that you had - Sanhe is making a calculation that
>
> ;
>
> is that a correct understanding?
>
> A: That's correct. That's a general number. We don't know . Oh, we don't know
>
> Q: In other words, when you produce at your plant, you don't analyze it before you use it in the next step?
>
> A: Yes, I told you that this morning. As I said, we're . We don't yet have the capability to analyze it.
>
> Q: Okay. Do you maintain
> to check to see
>
> ?
>
> A: In fact, the whole process from this
> to the end, we've never been able very carefully to measure. Sometimes I have
>
> .
>
> When the is added, I
>
> . So it's very difficult to say ultimately
> . So only after a long period of time of using I'm able to make a kind of an estimate as to .

Q: And is your estimate that you are achieving
?

A: If it comes out well, then it's
, more or less. This is a more or less question.

Q: Is that for this kind of commercial process?

MR. HNATH: Objection to the question as vague and ambiguous.

THE WITNESS: I have no idea if this is
. The technology that I', using now has a
. Yeah. I think if we continue to make modifications
.

BY MR. SCHILL:
Q: When he said that it,
Mr. Qiu?

A: We hope that we can
.

Q: Is there a goal to reach,
?

A: I hope that it will be
.

RX-258C (Qiu Dep.) Tr. 205-208.

Respondents compared their calculations in which the yield of ASK in order to show the substantial increase in number of tons of ASK that would be produced over an equation in which a yield is used. *See* Respondents' Mot. 48 at 3-6.

Based upon the record currently before the administrative law judge, it is not possible to determine precisely how much ASK Sanhe could have obtained before final purification, given the purchase of

. It is clear that Sanhe had in its possession a sufficient amount of , to make ASK. However, in order to use Sanhe's receipts to make a precise calculation such as the parties have offered, additional evidence concerning the raw materials purchases and related factual testimony would have to be received. It is expected that a complete record would have been obtained if the record had been reopened to address raw material receipts for which were produced late in discovery. However, as the record stands at present it is inconclusive as to whether Sanhe's raw material purchases prevented or enabled Sanhe's production of of acesulfame potassium.

Conclusion As to Alleged Infringement of the '629 Patent

Upon consideration of all the evidence adduced in this investigation, the administrative law judge cannot conclude that Mr. Qiu and Sanhe have misrepresented the Sanhe process and that Sanhe has instead practiced the process of the '629 patent. Mr. Qiu's demeanor was credible and forthcoming. His testimony was lengthy and detailed. His frequent explanations of technical detail and his reliance on mathematical formulae and illustration were impressive, and would have left him extraordinarily vulnerable to impeachment had he lied. Such impeachment did not occur.

Respondents did more than deny complainants' allegations. Respondents presented detailed and cohesive information concerning the

development and industrial use of Sanhe's process. In addition to the testimonial evidence presented through Mr. Qiu and Mr. Zong, respondents also produced voluminous documentary evidence covering Mr. Qiu's efforts to design the Sanhe process, and to practice of the process in the Sanhe plant. His laboratory notes and the Sanhe workshop documents are too extensive and detailed to conclude that they were fabricated for the purpose of this litigation.

The testimony and documentary evidence provided by Mr. Qiu and Sanhe were enhanced by the testimony of their expert, Dr. Walters. Dr. Walters' background made him an especially persuasive witness. As discussed above, his educational training and work experience qualified him as an expert in sweeteners and high-potency sweeteners, including the chemistry and biology of sweeteners. He has had particularly relevant experience with high intensity, artificial sweeteners similar to acesulfame potassium. He is well-informed as to their development, and as to their commercial production and use.[52] *See* Walters Tr. 1124-1129.

As an expert witness, Dr. Walters was able to elucidate further key factual testimony of Mr. Qiu. He was able to provide insight into difficulties encountered in starting production under processes such as

---

[52] Dr. Walters is the listed inventor on patents in the field of high-potency sweeteners. His book, *Sweeteners: Discovery, Molecular Design and Chemoreception* received the platinum award from the Agricultural and Food Chemistry Division of the American Chemical Society. *See* Walters Tr. 1124.

Sanhe's process as well as the process of the '629 patent. He also provided detailed testimony about the chemistry involved in the process described by Mr. Qiu. As in the case of Mr. Qiu, Dr. Walters was vigorously cross-examined, and the bases for his opinions and statements were closely tested. However, his testimony was not impeached. *See, e.g.*, Walters Tr. 1168-1228.

Consequently, it has not been demonstrated by a preponderance of the evidence that respondents have infringed the '629 patent. Indeed, the evidence of record supports respondents' claim that Sanhe has not practiced the '629 process in the production of acesulfame potassium.[53]

C. The '068 Patent

As discussed in detail in connection with the validity issue, the claims of the '068 patent cover blends of acesulfame potassium with other sweeteners.

One claim construction issue has been raised by the parties with respect to the '068 patent, which as discussed in detail in this section, is relevant to some alternative findings made by the administrative law judge. The issue is whether the claims of the '068

---

[53] In addition to the lack of proof that Sanhe has used SO_3 for ring closure, it has not been shown that Sanhe's process has operated within the parameters specified in the dependent claims of the '629 patent. For example, it has not been shown that Sanhe uses SO_3 "in a molar excess of up to about 20-fold, preferably about 3- to 10-fold, in particular about 4-to 7-fold, relative to the acetoacetamide-N-sulfonic acid (salts)." *See* CX-5 ('629 Patent) at col. 18, lines 57-60.

patent cover blends of acesulfame potassium with non-high-potency sweeteners.

Complainants offer a broader interpretation of the patent claims (which would include such blends) than that offered by respondents or the Commission Investigative Staff. However, the administrative law judge finds that the claims do not cover certain mixtures which include non-high-potency sweeteners. *See* RX-233C at 6.

The primary claim language at issue is the transitional phrase "consists of," which is found in independent claim 1.[54] Complainants contend that one should ignore the presence of any non-high-potency sweetener that may be found in a mixture that also includes one of the expressly recited binary combinations of sweetener mixtures. *See* Complainants' Post-Hr'g Br. at 37-41.

However, the transition phrase "consists of" has been found in other cases to be a restrictive transition phrase. *See Doxorubucin*, 20 U.S.P.Q. 1603, 1608 (U.S. Int'l Trade Comm'n 1991)("We find that he [the ALJ] correctly found "consists of" to be a restrictive transition phrase and that he correctly defined the other two terms."); *Certain Slide Fastener Stringers and Machines and Components Thereof*, Inv. No. 337-TA-85, 216 U.S.P.Q. 907 (U.S. Int'l Trade Comm'n 1981)(closed nature of claim "consisting of" applies to chemical and non-chemical cases).

Complainants rely upon the decisions in *Special Metals Corp. v*

---

[54] The claims of the '068 patent are printed, *supra*, in the section of this Initial Determination on patent validity.

Teledyne Indus., 215 U.S.P.Q. 698 (W.D.N.C. 1982), *aff'd*, 717 F.2d 124 (4th Cir. 1983) (vacated based upon a voluntary dismissal) ("*Special Metals*"), and *Hoskins Mfg. v. General Electric Co.*, 212 F.2d 422 (N.D. Ill. 1913), *aff'd*, 224 F. 464 (7th Cir. 1915) ("*Hoskins*") to support their contention that one can and should ignore the presence of natural sweetener agents in sweetener mixtures when determining infringement of the '068 patent. *See* Complainants' Post-Hr'g Br. at 40-41. However, these decisions do not support Complainants' contentions.

The *Special Metals* and *Hoskins* cases are factually distinguishable from the instant investigation. In those cases, the application claims upon which the asserted claims were based had used the open transitional term "comprising" and not the closed term "consisting of." *See Special Metals*, 215 U.S.P.Q. at 701; *Hoskins*, 212 F.2d at 425. The application claims were amended at the insistence of the PTO on the grounds of undue breadth. Further, in each of those cases, the accused products would have been literally within the scope of the application claims prior to the substitution of "consisting of" for "comprising." *Special Metals*, 215 U.S.P.Q. at 701-02; *Hoskins*, 212 F. at 428.

In each of the foregoing decisions, the courts gave greater breadth to the phrase "consisting of" than the PTO traditionally does but it appears that they only did so because of actions during the prosecution history. In those cases, the transitional phrase was changed at the insistence of the examiner and not because of the existence of prior art that would have prevented issuance of a claim

using the term "comprising".

In contrast to the cases cited by complainants, the original claim language of the '068 patent contained the transitional phrase "consisting of" and not the term "comprising." Thus, the issue of a modification during prosecution that confronted the courts above is not present here. Additionally, although the application claims here would have covered artificial sweetener mixtures containing three or more artificial sweeteners, the claims would not have encompassed a combination that included a non-artificial sweetener.[55] Thus, since the apparent bases upon which the courts construed the transitional phrase in *Special Metals* and *Hoskins* are not present here, the Staff submits that those decisions do not support Complainant's contentions, and the administrative law judge concurs.

In addition, Complainants cite to certain proposed findings of fact that identify sorbitol (which is used by foreign and domestic manufacturers with acesulfame potassium) as a suitable "bulking agent," while ignoring other references that identify sorbitol, sugar, mannitol, glycerol and other natural sweeteners as suitable sweetening agents. *See* CX-29, col. 2, lines 53-56; RX 6, col. 1, lines 39-37; RX 7, col. 1, lines 71-75; and RX 8, col. 3, lines 35-39. Further, sugar (sucrose) is the "gold standard," against which each sweetener is compared. *See*,

---

[55] No ruling is made specifically with respect to sorbitol, if and when it is used as a bulking agent. For a discussion of sorbitol, *see* notes 58 and 59, *infra*.

e.g., Complainants' PFF 1018-1022. However, under complainants' construction, sugar is simply a bulking agent that should be ignored if present in a mixture. *See, e.g.*, Complainants' Post-Hr'g Br. at 39; Complainants' PFF 1382-1387 (which relate to two blends: one which consists of 25% ASK, 15% aspartame and 60% sucrose, and the other which is 25% ASK, 15% aspartame and 60% fructose). Finally, several of the references cited by the Examiner during prosecution of the '068 patent expressly disclose that mixtures of sugar and a specific artificial sweetener led to synergy.[56]

Moreover, the specification of the '068 patent refers to the prior art's use of mixtures of artificial and *natural* sweeteners. *See* CX 1 ('068 Patent), col. 1, lines 30-37. The term "natural sweetener" generically includes, *inter alia*, sucrose, fructose, sorbitol, and maltose. SX 1; SX 2 at 4; SX-3. Furthermore, unlike the specification of certain prior art references cited by complainants, the specification of the '068 patent does not contain any language that either expressly or impliedly excludes natural sweetening agents (i.e., sucrose,

---

[56] For example, in the Crosby patent (RX 8), the specification states: "They [claimed artificial sweeteners] may be used alone or as the primary sweetener in a composition, or they may be one of *several* sweeteners in the final composition; *sucrose or another natural sweetener* or another synthetic sweetener also being added." RX 8, col. 3, lines 35-39 (emphasis added). In the Shlatter patent (RX 7), the specification states: "Combinations of the dipeptide sweetening agents with *sugar* or synthetic sweeteners such as saccharin likewise can be incorporated into consumable materials of this invention. Lesser amounts of *each* sweetener are, furthermore, required as a synergism effected by such combination." RX 7, col. 1, lines 71-75.

fructose, sorbitol or mannitol) from the scope of the term "sweetener mixture." Finally, with the exception of the applicants' reference to Horowitz as solely teaching "diluents to increase bulk"[57] (RX 4, col. 6, lines 4-7), the applicants' reference to the other cited references that disclose sugar as an element of the "sweetener mixture" merely stated that such references taught mixtures of synthetic and *natural* sweeteners.

As demonstrated above, the applicants for the '068 patent expressly noted the presence of natural sweetening agents in sweetener mixtures and expressly excluded such materials from the scope of the '068 patent. Therefore, the presence of natural sweeteners in a "sweetener mixture" cannot be considered to constitute a "'minor amount[s] of material . . . recognized as conventional in the art . . .'" that can, or should be disregarded as urged by complainants. *See* Complainants' Post-Hr'g Br. at 41. In view of the foregoing, complainants' proposed construction of the scope of the claims of the '068 patent so as to ignore the presence of any natural sweetening agent is erroneous. The claims must be properly construed not to cover blends of acesulfame potassium with non-high-potency sweeteners such as sugar.[58]

---

[57] Horowitz (RX 4) states, *inter alia*, that natural sweeteners such as sugar and sorbitol are suitable for use as diluents. RX 4, col. 6, lines 4-7.

[58] Sorbitol is a sweetener belonging to the class of sugar alcohols. It has half the sweetness of sugar. *See* Lipinski Tr. 72-73. According to complainants, it should be ignored when it is

(continued...)

The briefing filed by the parties after the hearing concerned two products: 1) a product called "Tianjutang," a blend of acesulfame potassium and other sweeteners, which has not been sold in the United States; and 2) the acesulfame potassium made by Sanhe which has been imported, offered for sale and/or sold by Sanhe and the other respondents.

In their briefs accusing respondents of infringement, complainants first presented their arguments with respect to Tianjutang. Furthermore, the arguments with respect to Tianjutang involve alleged direct infringement, while those with respect to the imported Sanhe acesulfame potassium involve the added legal concept of induced infringement. Thus, Tianjutang is discussed first below. In addition, for the purposes of the discussion concerning alleged infringement of the '068 patent, the patent shall be assumed *arguendo* to be valid inasmuch as only a valid patent may be infringed.

Alleged Infringement with Respect to "Tianjutang"

It appears that Tianjutang is a sweetener product that Sanhe has begun marketing in China, and further that Sanhe has applied for patent

---

[54] (...continued)
used as a bulking agent. Complainants further argue that when combined with a high-potency sweetener the contribution of sorbitol cannot be noticed. The question of whether sorbitol when so used is within or without the patent claims has not been litigated, and the administrative law judge makes no finding with respect thereto. *See, infra*, the discussion of Tianjutang.

protection in China for this product. It appears from discovery responses provided by respondents and from the parties' briefs that according to the Chinese patent application, Tianjutang may consist of a blend of acesulfame potassium, aspartame and/or sorbitol,[59] with the percentage of each constituent ranging from 0% to 100%. It appears that the Chinese patent application provides examples or "implementations" in which all three constituents are used in varying proportions. *See, e.g.*, CX-136C; CX-130; Complainants' Post-Hr'g Br. at 36; Complainants' PFF 1392; Respondents' PFF 330; Respondents' Reply to Complainants' PFF at 105. Respondents' witnesses testified that Tianjutang samples

. Qiu Tr. 987; Zong Tr. 1072-1073. According to Mr. Qiu, the Tianjutang samples that have been distributed in China consisted of three ingredients, i.e., acesulfame potassium, aspartame, and sorbitol.[60] Qiu Tr. 988.

Complainants argue that respondents seek to import Tianjutang, and

---

[59] Sorbitol can be used in applications where sugar provides important functions, including providing bulk to a recipe. *See* Lipinski Tr. 72-73. There is disagreement among the parties as to whether sorbitol acts a sweetener when used in conjunction with a high-intensity sweetener such as acesulfame potassium, and whether it could affect the taste of a mixture containing acesulfame potassium.

[60] It is not clear why the amount of sorbitol would be relatively small compared to the high-potency sweeteners in Tianjutang and other consumer products if it is merely a bulking agent that does not contribute to taste. Perhaps the answer to this question is clear to those in the art, but the record does not contain an adequate explanation.

that Tianjutang infringes the '068 patent literally and under the doctrine of equivalents. Complainants devote a substantial portion of their briefing to their argument that the addition of sorbitol to Tianjutang does not place the product outside the claims of the '068 patent. *See, e.g.*, Complainants' Post-Hr'g Br. at 36-43.

Respondents argue that although Tianjutang has been marketed only overseas, they would like to market Tianjutang in the United States, and therefore seek a ruling that it does not infringe any claim of the '068 patent. They further argue that a blend with three sweeteners, especially when one of them is sorbitol, cannot infringe the '068 patent. *See* Respondents' Post-Hr'g Br. at 41-44.

The Commission Investigative Staff argues that the claims of the '068 patent do not cover mixtures of three components, and that Tianjutang cannot infringe the '068 patent either literally or under the doctrine of equivalents. OUII Post-Hr'g Br. at 34.

In considering the arguments and the record concerning Tianjutang, the administrative law judge finds that there are two interrelated and overriding issues. The first is that the evidentiary record concerning Tianjutang is not complete because questions pertaining to Tianjutang were not fully litigated; and the second is that Tianjutang is not properly a part of this investigation.

The record contains statements from respondents as to what Tianjutang samples in China have purportedly contained. However, although the parties do not agree on the proportions, all parties agree

that under the Chinese patent, Tianjutang could consist of various proportions of acesulfame potassium, aspartame and/or sorbitol. It also appears that if the Chinese patent application adequately defines what Sanhe means by "Tianjutang," a Tianjutang mixture could contain 0% acesulfame potassium or only two ingredients.

There is no evidence that Tianjutang has ever been imported, sold for importation or sold after importation. Thus, the record relating to Tianjutang is perhaps understandably deficient since it was not genuinely litigated.

Therefore, it is impossible for the administrative law judge to make a finding as to exactly what respondents might import under the name "Tianjutang," and to make prospective findings of law and of fact to the effect that such a product would or would not infringe the '068 patent.

Indeed, pursuant to the statutory requirements of section 337, the Commission instituted this investigation "to determine whether there is a violation of 19 U.S.C. § 1337(a)(1)(B) in the importation into the United States, the sale for importation, or sale within the United States after importation of certain acesulfame potassium or blends and products containing same by reason of infringement" of the '629 or the '068 patent. 62 Fed. Reg. 62071 (1997). Therefore, under the statutory provisions of section 337 and the notice of investigation, this investigation does not cover a product that has never been imported, sold for importation or sold after importation.

Respondents, in their reply brief, pointed out that "Tianjutang has not been made, used or sold by anyone in the United States." Respondents' Reply at 19 (emphasis in original). However, in respondents' main post-hearing brief, they argued that a ruling should be made with respect to Tianjutang, for the reasons set forth by the administrative law judge in *Certain Diltiazem Hydrochloride and Diltiazem Preparations*, Inv. No. 337-TA-348, Order No. 31 (Nov. 16, 1993). *See* Respondents' Post-Hr'g Br. at 41.

The principles relied upon by the administrative law judge in Order No. 31 in *Diltiazem Hydrochloride* are not applicable in this case. In *Diltiazem Hydrochloride*, one of the respondents filed a motion for partial summary determination that its "alternate" process for the manufacture of bulk diltiazem did not infringe the patent-in-suit. Complainants filed a motion to strike the motion for partial summary determination on jurisdictional grounds, arguing that the respondent sought an advisory opinion that was not proper pending final Commission action in the underlying investigation. The administrative law judge did not concur that the respondent sought an advisory opinion, and denied the motion to strike.

Unlike the question involving Tianjutang, in *Diltiazem Hydrochloride*, the administrative law judge stated that the alternate process at issue was in fact covered by the notice of investigation and had been an issue in the investigation. Among the factors cited by the administrative law judge were that the complainants stated in their

complaint that they would rely on all research and development conducted by the respondents (which necessarily included the respondents' "alternate" process), and that the respondent represented that the "very sample of diltiazem which formed the basis for the discussion of [the respondent's] diltiazem in the amended complaint . . . was manufactured by the alternate process." *Diltiazem Hydrochloride*, Order No. 31 at 2. The administrative law judge further considered the fact that according to the respondent, it could at any time switch back to its alternate process, which had been used only one year before. Thus, it was concluded that it would have been an inefficient use of the Commission's resources to deny consideration of the respondent's motion for partial summary determination "concerning a product which has been imported into the United States, formed a part of the basis for the complaint . . . and which apparently remains accused by complainants." *Id.* at 3

None of the factors supporting the administrative law judge's ruling in *Diltiazem Hydrochloride* is present in this investigation with respect to Tianjutang. There is no evidence that Tianjutang has ever been imported or sold for importation, or that it formed a basis for the complaint. Under these circumstances, Tianjutang cannot even be "accused" of infringement in the legal sense. If Tianjutang is ever sold for importation or imported, it would have to form the basis of a new investigation, which could develop the record as to the precise characteristics of the accused product.

Accordingly, for the reasons discussed above, no finding is

entered as to any infringement or non-infringement of the '068 patent by "Tianjutang."

Alleged Induced Infringement with Respect to Respondents' Acesulfame Potassium

Section 271(b) of the Patent Act provides that "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b).

Complainants argue that respondents have actively induced companies located in the United States to infringe the '068 patent. Complainants' Post-Hr'g Br. at 43 (citing 35 U.S.C. § 271(b)). They point out that induced infringement may be proven by direct or circumstantial evidence. Complainants' Post-Hr'g Br. at 43-44 (citing, *inter alia*, *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987) and *Brantingson Fishing Equip. Co. v. Shimano American Corp.*, 8 U.S.P.Q.2d 1669, 1675 (Fed. Cir. 1988)).

Complainants allege that despite knowledge of the '068 patent, respondents continued to solicit customers and to encourage blending of the accused acesulfame potassium with aspartame. It is argued that given the substantial commercial use in the United States of acesulfame potassium in blends within the ratios of the '068 patent (i.e., approximately 78%), and respondents' solicitation to some of Nutrinova's largest customers that do blend within the patented ratios, there is

sufficient evidence of direct infringement to support a finding of induced infringement. It is argued that the fact that non-infringing uses exist cannot change the fact that respondents have induced infringement. Complainants' Post-Hr'g Br. at 44-49.

Respondents argue that the evidence does not support a finding that respondents knowingly induced infringement of the '068 patent. They argue that acesulfame potassium has substantial non-infringing uses, and that the mere suggestion to blend cannot induce infringement. They also argue that there is no evidence of direct infringement. Respondents' Post-Hr'g Br. at 28-40.

The Commission Investigative Staff argues that the record does not contain any evidence that any entity in the United States uses respondents' ASK in any blend that is within the scope of the claims of the '068 patent. It is argued that complainants have failed to offer direct evidence that the small amounts of accused ASK imported to date have been used by any domestic entity in a manner that constitutes infringement of the '068 patent, and, *inter alia*, that the circumstantial evidence does not support a finding of direct infringement. *See, e.g.*, OUII Post-Hr'g Br. at 34-35.

As held by the Commission, induced infringement requires a finding that: "(1) there has been an act of direct infringement; (2) the accused infringer actively induced a third party to infringe the patent; and (3) the accused infringer knew or should have known that his actions would induce infringement." *Certain Flash Memory Circuits and Products*

Containing Same, Inv. No. 337-TA-382, USITC Pub. 3046, Comm'n Op. on the Issues Under Review and on Remedy, the Public Interest, and Bonding, at 11 (July 1997)(citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990)).

As discussed in detail below, the administrative law judge has determined that induced infringement cannot be found in this investigation for at least the reason that neither direct nor circumstantial evidence establishes that any act of direct infringement has occurred in the United States involving respondents' acesulfame potassium. *See Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986)("Absent direct infringement of the patent claims, there can be neither contributory infringement . . . nor inducement of infringement.").

Complainants refer to many instances of alleged solicitation for sales or suggestions to blend. Indeed, they argue that it is impossible to know all the persons and companies solicited or to whom brochures and samples have been provided by respondents. However, when challenged by respondents and the Commission Investigative Staff on the issue of direct infringement, complainants, in their reply, were unable to point to any direct evidence of specific direct infringement. However, complainants focused their arguments relating to circumstantial evidence primarily on two companies, i.e., Wrigley and Coca-Cola. *See* Complainants' Reply Br. at 23-25. Indeed, if the record cannot support a finding of infringement by these two companies it certainly cannot

support such a finding with respect to companies about which even less is known.

Complainants did not offer evidence that respondents told Wrigley or Coca-Cola to blend their acesulfame potassium in an infringing manner. Nevertheless, complainants argue that inducement was knowing. They rely on the fact that one of respondents' representatives, JRS's Ms. Jane Xu, testified at her deposition that although she did send information to Coca-Cola about her company, she did not send Coca-Cola any written product information about acesulfame potassium because she knew it would be unnecessary to do so. *See* Complainants' Reply at 23; Complainants' PFF 1556. An examination of Ms. Xu's testimony shows that she did not recall what she sent to Coca-Cola, and that she probably did not send a "spec sheet." There is in fact no evidence that Ms. Xu ever discussed blending or provided any blending information to Coca-Cola. RPX-42C (Xu Dep.) Tr. 260-261.

Complainants reason that respondents did not have to tell companies like Coca-Cola or Wrigley to blend their acesulfame potassium because these are cases in which the infringer's intended use would have been readily apparent. *See* Complainants' Reply at 23 (quoting *Mendenhall v. Astec Indus.*, 13 U.S.P.Q.2d 1913, 1954 (E.D. Tenn. 1988)). They argue that Wrigley received three kilograms from three different lots of respondents' acesulfame potassium, and that Coca-Cola received one kilogram. Further, they argue that:

> Given that these companies regularly use

> Complainants' acesulfame potassium in blends covered by the '068 patent, it is entirely logical to conclude that the test performed by these companies included blending to determine whether the performance of Respondents' acesulfame potassium in a typical usage was satisfactory. Certainly, Wrigley's would not have needed three kilograms if it were mere testing for compliance with production specifications.

Complainants' Reply Br. at 25.

However, the record does not permit the drawing of any such conclusion. It is pure speculation to say that Wrigley and Coca-Cola necessarily blended respondents' acesulfame potassium and did so in a manner that infringed the '068 patent. Even if both companies do blend ASK for their consumer products in a manner that is covered under the '068 patent -- an issue that is not conceded by respondents or the Commission Investigative Staff -- there is no reason to conclude that they did so with respondents' ASK.[61] There is, for example, no evidence

---

[61] If it had been established that Wrigley or Coca-Cola in fact blended respondents' ASK in ratios covered by the '068 patent, there may have been an act of direct infringement. The experimental use doctrine which excepts one from liability for patent infringement has been narrowed over the years, and now it is recognized not to apply when practice of a patent claim was "solely for business reasons and not for amusement, to satisfy idle curiosity, or strictly philosophical inquiry." *See Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984); *see also* Chisum, § 16.03[1][c] at 16-110 (The Federal Circuit's holding in *Roche* has been understood to mean that experiments of a purely intellectual character are to be distinguished from experiments designed to adapt an invention to pecuniary and business uses.). Of course, it still would have to be determined whether the particular formulations used by Wrigley or Coca-Cola fell under the claims of the '068 patent. This question is disputed among the parties, especially in view of the fact that the

(continued...)

concerning the testing protocols used by Wrigley or Coca-Cola. There is no evidence that they considered using respondents' acesulfame potassium in their current brand-name products, or some other existing products.[62] There is no evidence as to what actually happened to all of the 4 kilograms of ASK in question. Perhaps some was destroyed because only a small portion was needed. Perhaps Wrigley wanted three kilograms from different productions because it was checking for homogeneity and consistency of production. The answers to these questions are simply not known.

The lack of evidence concerning Wrigley, Coca-Cola and other domestic companies is particularly noteworthy because it is clear that evidence relating to these companies is crucial to complainants' infringement case, and domestic companies such as Wrigley and Coca-Cola are amenable to service in the United States.[63] A question is raised

---

[61](...continued)
sweetening mixtures in Wrigley products have at times consisted of three or four components, some of which are not high-potency sweeteners. *See* OUII Reply Br. at 17; RX-232.

[62] It is undisputed that acesulfame potassium may be used alone as a sweetener. *See* CX-1 ('068 Patent) at col. 1.

[63] Although acesulfame potassium has been used by Coca-Cola for soft drinks available in foreign countries, including Canada, *see, e.g.*, RX-232C, it has not been shown that Coca-Cola used it in their U.S. products. However, complainants rely upon evidence relating to Ms. Xu's contacts with Coca-Cola headquarters in the United States. (Ms. Xu contacted Coca-Cola in Atlanta Georgia.) *See* RPX-42C (Xu Dep.). Consequently, it appears that the testing of Sanhe ASK was conducted in the United States. Indeed, infringement could only take place if the alleged blends were made in the United States.

then as to why the Commission is left to speculate upon what happened to the accused acesulfame potassium, when discovery methods were readily available to complainants had they chosen to provide evidence to the Commission concerning possible use of accused ASK by Wrigley, Coca-Cola, or any other domestic company.

Complainants argue that it is known that Wrigley and Coca-Cola performed tests on respondents' acesulfame potassium. The evidence cited by complainants is the deposition testimony of Ms. Xu. However, the evidence shows that it is largely unreliable hearsay, and at best suggests that the tests were only performed for characteristics such as purity and consistency, rather than for blended taste. *See* Complainants' Reply Br. at 25 (citing Complainants' PFF 1544-50, 1562).

With respect to Wrigley, Ms. Xu testified that she contacted a Wrigley's representative, who asked for acesulfame potassium samples from three different lots. Ms. Xu responded to that request by obtaining samples from Sanhe. RPX-42C (Xu Dep.) Tr. 238.

Subsequently,

. She testified as follows:

> Q. After you sent the sample to Wrigley's did you hear from Wrigley's again before you personally went out to Illinois in August?
>
> A. I believe
>
> . That, you know, is the conversation, and
> . You know, that back-forth, that kind of conversation.

Q. I'm sorry, I'll a little confused.

A. Okay, you're asking me the communication.

Q. Right, and
?

A. Right, .

MR. HNATH: Wait, wait, there's confusion. Listen to the question very carefully.

Q. I'm trying to ask,
?

A. Yes.

Q. What is it she had said ?

A. She said .

Q. What do you mean by the, to your understanding, what did she mean by the lab test?

A. The lab test, the result, whatever they do, the test.

Q. Was it your understanding, therefore, that she was saying
?

A. Right.

Q. And did she call you to tell you that or did you contact her after few days or a week after you had sent the sample?

A. I believe every time, you know, we always follow up.

Q. Do you know what kind of test Wrigley ran?

A. I don't know.

Q. So when she said to you, based on your follow-up call, that what did you

say to her?

A. I said I don't know

.

Q. Did she indicate

?

A. Well, she was saying

.

Q. Did you then contact Sanhe and tell them Wrigley's comment?

A. Yes.

Q. And what happened next?

A. They said

.

Q. So Sanhe did not

before you went --

A. No.

Q. -- there in August 1997?

A. No.

RPX-42C (Xu Dep.) Tr. 239-241.[64]

Ms. Xu simply did not know exactly what type of testing Wrigley performed on the Sanhe acesulfame potassium. If anything, Ms. Xu's

---

[64] Although

. *See* PRX-42C (Xu Dep.) Tr. 241-241, 289-290.

testimony might lead one to believe that Wrigley performed laboratory testing to determine the purity and consistency of the sample. In her testimony about Wrigley's testing, Ms. Xu made no mention of blending or of taste, yet it is clear she was under the impression that there had been laboratory testing of the Sanhe ASK. In any event, it is impossible to conclude that Wrigley blended the Sanhe ASK, and did so in a manner that was covered by the claims of the '068 patent.[65]

With respect to Coca-Cola, Ms. Xu testified that sometime after June 1997, following a conversation with a representative of Coca-Cola, she sent an approximately one kilogram sample of ASK to Coca-Cola for testing. She testified that large companies usually want samples of that size rather than small packets. According to her recollection, sometime in September of 1997, she contacted Coca-Cola again and was told that the sample had been tested and "approved." There is no indication in Ms. Xu's testimony or elsewhere in the record as to what her understanding was of the term "approved," or what that term meant when used by Coca-Cola's representative. *See* RPX-42C (Xu Dep.) Tr. 265-272.

Ms. Xu testified that she informed the representatives at both

---

[65] Even if Wrigley blended respondents' acesulfame potassium with other sweeteners, it is not clear that any blend made by Wrigley would necessarily be covered by any claims of the '068 patent. For example, it is known that Wrigley's products have contained blends of ASK with non-high-potency sweeteners. *See, e.g.*, RX-56C; RX-232C. As discussed, *supra*, such blends may not be within the scope of the patent claims.

Wrigley and Coca-Cola that she would name them in connection with investigation. It appears that those individuals were not deposed, or if they were, that their depositions were not relied upon by complainants to prove their case of infringement. Nor was there any effort to determine precisely what Wrigley and Coca-Cola did with all the Sanhe acesulfame potassium that was provided to them. Given the fact that the activities of Wrigley and Coca-Cola are crucial to complainants' infringement case, and that complainants have requested the Commission to find that Wrigley and Coca-Cola have infringed the '068 patent, it would have been helpful for complainants to offer testing documents from these companies into evidence and to call witnesses from these companies to testify at the hearing. As the record stands, the administrative law judge cannot enter a finding of patent infringement by Wrigley, Coca-Cola or any other domestic entity.

Based upon the record and the arguments of the parties, complainants have failed to prove by a preponderance of the evidence that respondents have induced infringement of the '068 patent.

Although the record does not permit a finding of induced infringement of the '068 patent, there is evidence relating to other elements of complainants' inducement charge against respondents. The evidence concerning the other elements was disputed by the parties. Nevertheless, a number of relevant facts relating to those other elements were established during this investigation, and the administrative law judge has made a series of Findings pertaining to the

other elements of complainants' induced infringement charge. *See* FF IV 148-230.

The facts relevant to the second and third elements of induced infringement under section 271(b) that were enumerated in *Flash Memories* and which were set forth above in this section of the Initial Determination (i.e., whether the accused infringer actively induced a third party to infringe the patent, and whether the accused infringer knew or should have known that his actions would induce infringement), must be viewed against the legal standards of knowledge and intent.

As held by the Federal Circuit in *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988), "[a]lthough section 271(b) does not use the word 'knowing,' the case law and legislative history uniformly assert such a requirement . . . While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." Indeed, in the Commission's cases, it has been required that "the person inducing the infringement 'actively' and knowingly aided and abetted another's direct infringement of the patent," and that "the defendant have some knowledge of the patent as well as the nature of his acts and their consequences." *Certain Surveying Devices*, 208 U.S.P.Q. 36, 44 & n. 58 (U.S. Int'l Trade Comm'n 1980). *See* Chisum, § 17.04[2], at 17-70 (citing, *inter alia, Water Technologies*, 850 F.2d at 668, and *Surveying Devices*, 208 U.S.P.Q. at 44 n.58).

The evidence in this case does not support a finding that the

respondents knowingly aided and abetted infringement, or otherwise actively induced infringement. For example, there is no evidence that respondents had knowledge of the '068 patent until May 1997. After that time, respondents modified their brochures, albeit imperfectly, to remove any suggestion of blending, even though they had never specifically mentioned the sweeteners and ratios recited in the claims of the '068 patent. Furthermore, the only evidence of discussions concerning the blending of acesulfame potassium with other sweeteners occurred between respondents' representatives and complainants' private investigator. The investigator never actually blended any acesulfame potassium. She held herself out both as a potential customer and as an independent consultant in the food industry who had questions about acesulfame potassium. It is not clear from the record who brought up the subject of blending (i.e., one of respondents' representatives or the investigator), or what if anything respondents thought the investigator was going to do with the very general information that their representative imparted to the investigator during the brief conversations.

Even though circumstantial evidence may be used to demonstrate induced infringement, it is noteworthy that on the subject of alleged induced infringement, the record contains very little evidence that an act of infringement was actively induced by the respondents. Perhaps that was because there was no proof of any act of direct infringement of the '068 patent.

V. DOMESTIC INDUSTRY

Section 337(a)(1)(B), which is asserted against respondents in this investigation, applies "only if an industry in the United States, relating to the articles protected by the patent. . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2).

The parties have stipulated to the existence of a domestic industry with respect to both the '629 patent and the '068 patents at issue in this investigation. *See* Complainants' Post-Hr'g Br. at 49; CX-8C (Stip.); FF Section V.

Findings of Fact

I. Background

1. Acesulfame potassium is sometimes referred to as acesulfame-K or ASK. ALJ Ex. 1, Tutorial Tr. 7, 10-14.

2. The four basic tastes are: sweet, salty, sour, and bitter. ALJ Ex. 1, Tutorial Tr. 11.

3. Sugar (i.e., sucrose or saccharose) is the standard by which to judge the taste of any other sweetener. ALJ Ex. 1, Tutorial Tr. 11, 14, 21.

4. The term "taste intensity" refers to the strength of taste perception. "Taste quality" refers to the aspect contributing to the overall perception of taste. "Taste liking" refers the acceptance of a certain taste profile by people, including the preference of one taste over other. ALJ Ex. 1, Tutorial Tr. 14.

5. Sweeteners can be divided into three categories: sugar, bulk sweeteners, and intense sweeteners. ALJ Ex. 1, Tutorial Tr. 12.

6. Sugars are metabolized in the human body and provide energy. ALJ Ex. 1, Tutorial Tr. 12.

7. Bulk sweeteners are metabolized into the body, but do not normally provide the same amount of energy as sugars. The sweetness level of bulk sweeteners is lower than sugars. ALJ Ex. 1, Tutorial Tr. 12.

8. Intense sweeteners are much stronger in sweetness than the other

two categories. They are either not converted into energy in the human body at all, or if they do, their energy contribution is insignificant. ALJ Ex. 1, Tutorial Tr. 12-13.

9. All non-sugar sweeteners have other tastes in addition to sweetness, and thus, they fall short of exactly matching the taste of sucrose. ALJ Ex. 1, Tutorial Tr. 21.

10. Intense sweeteners deliver a sweet taste at a much lower concentration than sucrose. ALJ Ex. 1, Tutorial Tr. 14.

11. The term "additivity" when applied to mixtures of sweeteners means that when mixing two or more components together, the mixture would be as strong as the sum of the taste intensities of the components. ALJ Ex. 1, Tutorial Tr. 15.

12. "Synergism" occurs when one mixes two or more components and the mixture is sweeter than one would expect on the basis of the sum of the taste intensities of the components. ALJ Ex. 1, Tutorial Tr. 15. This phenomenon involves sweetness enhancement, and is sometimes referred to as "quantitative synergism." ALJ Ex. 1, Tutorial Tr. 21.

13. Whether a sweetener mixture will be additive or "hyperadditive" (i.e., synergistic) depends upon the specific mixture. Currently, it is not always possible to predict with certainty whether the effect of mixing sweeteners will be additive or synergistic, or -- in rare cases -- antagonistic such that there is taste suppression. *See* ALJ Ex. 1, Tutorial Tr. 15, 109-110.

14. If synergy is the result of a blend, then one can use less sweetener and thereby reduce the cost of making the food product. If one blends sweeteners together, it may be possible to get an improvement in taste quality. In that case, there is "qualitative synergism." ALJ Ex. 1, Tutorial Tr. 21.

15. By blending, one may achieve a better temporal profile for the sweetener blend. ALJ Ex. 1, Tutorial Tr. 110-111.

16. One common way to measure sweetness is to evaluate sweeteners and the effects of sweetener blends with "equal-sweetness matches." This involves a taste test in which there are beverages whose concentration of sweetness is not known to a group of panelists. In fact, there may be sugar solutions that start as low as one percent (which is hardly sweet). They proceed through 10 percent (which is the sweetness of many sugar-sweetened beverages); and range as high as 15 percent. The panelists are asked to try each solution, and to select which solution tastes as sweet as a test product. From this data, the scientist can determine which solution is the sweetness reference that is the same sweetness as the product. ALJ Ex. 1, Tutorial Tr. 22-23, 105.

17. Taste panels may also be used to understand the many sensations of sweetness experienced by individuals. A taste panel consists of a group of people trained to recognize the different sensory characteristics. The panelists try the products and discuss among themselves the characteristics that they perceive to obtain

agreement from the group as a whole. ALJ Ex. 1, Tutorial Tr. 24-25.

18. To create a report card for sweeteners, panelists will try each sweetener then rate the sweetener on each set of characteristics, typically on a scale of 1 to 9, or 1 to 100. Then, after the taste tests are completed, a "spider plot" is created, where the attributes that the panelists have used are presented on paper as spokes. ALJ Ex. 1, Tutorial Tr. 25-27. For example, the attributes which are plotted might include characteristics of "off-flavor," mouth drying, bitter aftertaste, pure sweetness, etc. ALJ Tutorial Tr. 25.

19. "Spider plots" are an easy way to understand the quality profile of different products. To the degree that the profiles look alike, the products have similar quality of tastes. To the degree that the spider plots look different from each other, there will be radically different tastes of the samples. ALJ Ex. 1, Tutorial Tr. 27.

20. Taste quality includes the aspect of time. The aspect of quality is influenced by how fast the taste rises when the substance is in contact with the tongue and how fast the taste perception declines when the product is in the mouth. Sucrose has a very specific time-intensity profile, with a fairly fast onset of sweetness yet is not too lingering. ALJ Ex. 1, Tutorial Tr. 29.

21. Time intensity has an important role. It is a significant factor

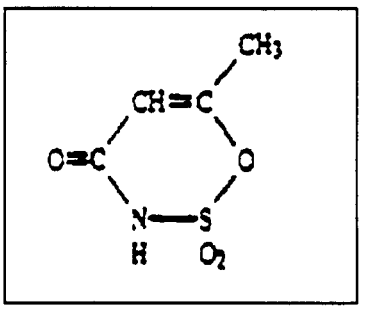
for sweetener blends, especially for acesulfame and aspartame. ALJ Ex. 1, Tutorial Tr. 30.

22. "Taste liking" can also be measured. For example, in a head-to-head preference test, people are offered two products and asked which is the sample they personally prefer. Subjects may also be asked to rate a product on a scale ranging, for example from a score indicating dislike to a score indicating a product that is liked extremely. ALJ Ex. 1, Tutorial Tr. 30-31.

23. Acesulfame potassium, the sweetener at issue in this investigation is made of organic molecules. ALJ Ex. 1, Tutorial Tr. 35.

24. Organic chemistry is defined as the chemistry of carbon-containing compounds. Common elements present in these compounds include hydrogen, nitrogen, oxygen and sulfur. ALJ Ex. 1, Tutorial Tr. 35.

25. Acesulfame potassium is the potassium salt of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide, a molecule of which is represented in the '629 patent, as follows:



CX 5 ('629 Patent) at col. 1, lines 11 through 19.

26. In synthetic organic chemistry, one looks for different ways to make particular molecules, such as the acesulfame potassium molecule. ALJ Ex. 1, Tutorial Tr. 96.

27. The '629 patent at issue in this investigation claims a process for synthesizing acesulfame, including the potassium salt thereof. CX 5.

28. Acesulfame is only one of over 11 million organic compounds. One way in which organic compounds are categorized is by generalities called "functional groups." Functional groups are based upon the way in which a series of molecules may react, and also the site on a molecule at which a chemical reaction is expected to occur. ALJ Ex. 1, Tutorial Tr. 35, 43.

29. Of the 11 million organic compounds known, there are only about 15 or 16 functional groups. ALJ Ex. 1, Tutorial Tr. 37.

30. Focusing on functional groups is particularly useful when working with large molecules that may have only one functional group. ALJ Ex. 1, Tutorial Tr. 44. However, there may be more than one functional group present in the same molecule. ALJ Ex. 1, Tutorial Tr. 53.

31. Cyclic compounds have rings structures. ALJ Ex. 1, Tutorial Tr. 41-42.

32. A double bond is two bonds between each carbon atom. ALJ Ex. 1, Tutorial Tr. 44.

33. D-glucose is the most common sugar in nature. It is the sugar that is found in all types of carbohydrates, and in cellulose. ALJ Ex. 1, Tutorial Tr. 49.

34. D-fructose is the sugar from fruits. ALJ Ex. 1, Tutorial Tr. 49.

35. Nature makes the compounds of D-glucose and D-fructose in chains, but when they are put in water, they cyclize. They become a cyclic compound. ALJ Ex. 1, Tutorial Tr. 49.

36. Nature tends to cyclize six-membered and five-membered rings. Glucose is a six-membered ring, and fructose is a five-membered ring. They are also quite commonly found within nature. ALJ Ex. 1, Tutorial Tr. 49.

37. Glucose and fructose can come together in a reaction to form sucrose, table sugar. ALJ Ex. 1, Tutorial Tr. 49-50.

38. Heterocyclic rings replace one of the carbon atoms with a hetero atom. The typical heteroatoms found in heterocyclic chemistry are nitrogen, sulfur, and oxygen. ALJ Ex. 1, Tutorial Tr. 51.

39. Heterocyclic rings are niacin, cytosine, and acesulfame potassium. ALJ Ex. 1, Tutorial Tr. 51.

40. Ketones constitute a functional group which has two forms: a "keto" form, and an "enol" form. The keto derives its name from "ketone," a carbonile group attached to carbon atoms. The enol form means that there is a functional group called an "ene," indicating a relationship to an alkene, which is the carbon-carbon double bond. And the "ol," indicates a relation to

alcohol. The two forms are in equilibrium with one another. As a reaction occurs on one form, equilibration occurs until all of it basically reacts. ALJ Ex. 1, Tutorial Tr. 59-60, 65, 97-98.

41. The "reagents" or "reactants" are the starting materials in a process. ALJ Ex. 1, Tutorial Tr. 99.

42. The result of a first reaction is an intermediate which serves as the reagent or staring materials for the second reaction, and so forth until the desired product is obtained in the final step. ALJ Ex. 1, Tutorial Tr. 99.

43. "Solvents" is a liquid used to dissolve things and make it easy for a reaction to take place. Solvents may also assist in controlling temperature, as in the case of liquids that help to disperse heat, i.e., to speed up cooling. ALJ Ex. 1, Tutorial Tr. 100.

44. "By-products" are those substances formed during a reaction that are not the desired product of the reaction. Similarly, impurities which may appear in a reaction are substances that are not desired. ALJ Ex. 1, Tutorial Tr. 99. For example, if an intermediate does not react completely, or if side reactions occur, impurities are created. ALJ Ex. 1, Tutorial Tr. 99-100.

45. After a desired reaction is run and a final product is obtained, by-products and other impurities must be removed. Several methods are commonly used to separate the desired product. ALJ Ex. 1, Tutorial Tr. 101.

46. If the by-products are solid and the desired product is dissolved in a liquid, filtration might be used. Liquids can often be separated based upon differences in boiling point, and thus distillation might be used. Extraction is another method, and it is based upon differences in solubility and the formation of layers, as, for example, in the case of oil and water. ALJ Ex. 1, Tutorial Tr. 101-102.

47. Finally another method of purification is the separation of materials based on differential solubility in a one-solvent system through crystallization and recrystallization. For example, if one has collected a solid reaction product that contains an impurity, one might dissolve all the solid material in a solvent, typically often with the application of heat. Then, as the solution is cooled, material that is less soluble will tend to crystallize, while material that is more soluble, such as water, will tend to stay dissolved. Crystallization can be repeated, although it is rare to get everything to crystallize completely. ALJ Ex. 1, Tutorial Tr. 102-103.

48. A condensation reaction is defined as a reaction of two components giving off, generally a small molecule, most often water, but it can be HCL or other types of molecules. ALJ Ex. 1, Tutorial Tr. 52-53.

49. If aspartic acid is combined with a methyl ester of phenylalanine, the same type of reaction as with amino bonds

occurs where there is a loss of water. The end product in this situation is aspartame. ALJ Ex. 1, Tutorial Tr. 54.

50. Aspartame is a compound that is referred to as Nutrasweet. It is a dipeptide because there are two amino acid units connected together. ALJ Ex. 1, Tutorial Tr. 54.

51. One can make the same product by more than one method in organic chemistry. ALJ Ex. 1, Tutorial Tr. 56.

52. An intermolecular reaction is an example where two different molecules react with each other. ALJ Ex. 1, Tutorial Tr. 56.

53. Acesulfame potassium salt is easy to break up. If it is put in acid, it goes to the NH compound. If it is put in excessive KOH, it goes to the potassium compound. ALJ Ex. 1, Tutorial Tr. 61.

54. Acetic anhydride reacts with water to give two molecules of acetic acid. The H goes to the oxygen, which remains with one of the molecules of acetic acid. The OH goes to the carbon of the other one, to give this molecule of acetic acid. Basically, the anhydrides adds water to produce the diacids, or the two acid compounds. But this is a reversible reaction. ALJ Ex. 1, Tutorial Tr. 62.

55. As various types of acids are heated together, they will lose water and form anhydrides. ALJ Ex. 1, Tutorial Tr. 62.

56. Just as carboxylic acids can be formed from organic anhydrides, so too can phosphoric or sulfuric acids be formed from inorganic anhydrides. ALJ Ex. 1, Tutorial Tr. 63.

57. Anhydrides like to pick up water, and hence, reactions that give off water are many times aided by putting an anhydride in to do that. ALJ Ex. 1, Tutorial Tr. 63.

58. Sulfur trioxide, one of the molecules talked about in the making of acesulfame potassium, is an anhydride of sulfuric acid. ALJ Ex. 1, Tutorial Tr. 63.

59. ASF refers to a starting material, amino sulfanile fluoride. ALJ Ex. 1, Tutorial Tr. 64.

60. Four-membered rings are very reactive. Diketene, a four-membered ring, as a consequence is a very reactive molecule. ALJ Ex. 1, Tutorial Tr. 64.

61. Acids are defined as molecules that donate protons. Bases are defined as molecules that accept protons. Typical acids are hydrochloric acid, hydrofluoric acid, and acesulfame in its proteinated form. ALJ Ex. 1, Tutorial Tr. 66.

62. Examples of bases are sodium hydroxide, ammonium, and sodium bicarbonate. ALJ Ex. 1, Tutorial Tr. 66-67.

63. In general, an acid will react with a base. It will undergo a reaction to produce salt plus water. ALJ Ex. 1, Tutorial Tr. 67.

64. Hydrochloric acid plus sodium hydroxide produces sodium chloride, which is known as table salt, plus water. ALJ Ex. 1, Tutorial Tr. 67.

65. Acesulfame acid reacts with potassium carbonate to produce acesulfame potassium plus carbon dioxide and water. ALJ Ex. 1,

Tutorial Tr. 68.

66. It is impossible to measure out one molecule of a substance. It is too small to see and to work with. ALJ Ex. 1, Tutorial Tr. 69.

67. One mole equals the amount of grams of a substance divided by its molecular weight. ALJ Ex. 1, Tutorial Tr. 70.

68. One mole of any substance will contain 6.02 x 1023 (23 is the exponent) molecules of that particular material. ALJ Ex. 1, Tutorial Tr. 70.

69. The molecular weight of a molecule is determined by adding together the numbers at the bottom of each element on the Periodic Table. ALJ Ex. 1, Tutorial Tr. 70.

70. Percent yield is defined as equal to the part divided by the whole times 100. The part is the amount of product that was actually obtained. The whole is the amount that one could possibly have obtained. ALJ Ex. 1, Tutorial Tr. 74.

71. Different starting materials and a variety of reactants can be used to produce the same product. ALJ Ex. 1, Tutorial Tr. 75.

72. In a laboratory, stirred vessels are normally constructed with glass linings. However, the actual materials used depend on the condition that occurs in the reactor. ALJ Ex. 1, Tutorial Tr. 82.

73. A stirred vessel normally has a motor which stirs the materials inside. ALJ Ex. 1, Tutorial Tr. 83.

74. With stirred vessels, another reaction can be run as soon as the stirred vessel has been cleaned. This can occur in a matter of a few hours. ALJ Ex. 1, Tutorial Tr. 85.

75. Phase separation means that if you have two liquids which are not soluble, they can be separated. ALJ Ex. 1, Tutorial Tr. 86.

76. If the construction material is not stable against the surrounding conditions, ones says that the material corrodes. Corrosion is an important concept in the chemical industry because if any part of the vessel corrodes, it will stop working properly. ALJ Ex. 1, Tutorial Tr. 88-89.

77. Corrosion of construction materials is an important factor that a company must consider in developing processes. ALJ Ex. 1, Tutorial Tr. 91.

78. The terms "glass lined vessels" and "enamel lined vessels" are synonymous. ALJ Ex. 1, Tutorial Tr. 92.

79. It is common for there to be production flexibility in a pilot plant, as well as in a production plant. ALJ Ex. 1, Tutorial Tr. 94.

II. Importation and Sale

1. Respondents have imported and distributed and/or sold in the United States on a limited basis samples of acesulfame potassium manufactured by respondent Hangzhou Sanhe Food Additives Factory. Tr. 145 (Stip.).

2. Respondent Dingsheng, Inc. obtained the acesulfame potassium it distributed in the United States from respondent Sanhe Food Company, Ltd. RPX-43 (G. Zong Dep.) at 68.

3. A , ordered of acesulfame potassium from JRS, but because JRS did not have sufficient inventory, JRS needed to receive an air-shipment of supply from Sanhe. RX-42C (Xu Dep. at 124).

4. A of acesulfame potassium was sent to JRS by Sanhe in August 1997. CX-112C, CX-116C.

5. On August 14, 1997, JRS sent of acesulfame potassium. CX-115C.

6. On June 30, 1997, Jane Xu sent a product sample of acesulfame potassium, along with a Certificate of Analysis of the sample. RX-42C (Xu Dep. at 203-204), CX-108C.

7. On July 21, 1997, Jane Xu sent of acesulfame potassium. CX-119C.

8. Accompanying the July 21, 1997 letter, was a certificate of analysis, that states that the was manufactured on June 5, 1997. CX-119C.

9. Also accompanying the July 21, 1997 letter was a copy of JRS's Company Information sheet, which states that JRS is a subsidiary of Sanhe and that Sanhe is a subsidiary of Wahaha. CX-119C. Ms.

Xu testified that she uses the term "subsidiary" to indicate that JRS was a distributor of Sanhe products. RPX-42 (Xu Dep.) Tr. 57-60.

10. Dr. Lipinski of Nutrinova was in Atlanta, Georgia at the end of June 1998, attending the Institute of Food Technologists (IFT) trade show. Lipinski Tr. 100.

11. Several thousand persons attended the IFT show in Atlanta in June 1998, where Nutrinova and respondents were among the companies with booths. Lipinski Tr. 100.

12. Dr. Lipinski was sent to the IFT show to collect information on new developments in the food industry, particularly generic acesulfame potassium. Lipinski Tr. 100.

13. At the show, there are booths with product samples available for taking. It is possible to pass by and take a sample of a product or sample food with a new ingredient. Promotional material is also on display. One can often freely take the promotional materials or food samples. Lipinski Tr. 100.

14. Respondents' booth this year at the IFT show had information available about acesulfame potassium. Lipinski Tr. 101.

15. Dr. Lipinski picked up from respondent's booth a sample (CPX-21) of the sweetener acesulfame potassium, which included analytical and specification data indicating that the source of the sample was Dingsheng Incorporated. Dr. Lipinski kept the sachet in his custody until he turned it over to counsel. Lipinski Tr.

102-103, CPX-21.

16. The sample (CPX-21) included the phone and fax number of Dingsheng. Lipinski Tr. 102, CPX-21.

III. Validity

1. The specification of the '068 patent describes the task facing the inventors and the resolution of that task, as follows:

> A known advantageous sweetener is acetosulfame, (generic name: acetosulfame-potassium salt), which is the potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazine-4-one-2,2-dioxide. Its sweetness is about 80 to 250 times that of saccharose (cane or beet sugar) [cf. table 1, page 143 of the journal "Chemie in unserer Zeit," No. 5 (1975)]. The sweetness of this sweetening agent is evolved very rapidly and fades only very slowly. The after taste is insignificant and can be noticed only in rather high concentrations. Thus acetosulfame could be suitably used alone for the sweetening of food, pharmaceuticals, cosmetics and animal feed. Nevertheless, it was desirable to improve especially its saccharose-like taste; acetosulfame is very sweet, like all the other synthetic sweeteners, but its quality of sweet taste differs from that of saccharose. The sweet taste of saccharose, however, sets the standard for the evaluation of all sweeteners, as has been mentioned above.
>
> The task of the present invention was, consequently, to improve the saccharose-like taste of acetosulfame.
>
> This task could be solved according to the invention by mixing acetosulfame with further known artificial sweeteners. The present invention, consequently, relates to a sweetener mixture having an improved saccharose-like taste and consisting of
>
> (a) acetosulfame and
>
> (b) at least a further artificial sweetener, selected especially from the class of the aspartyl peptide esters, the sulfamate sweeteners, the

sulfimide sweeteners and the dihydrochalcone sweeteners.

CX-1 ('068 Patent) at col. 1, lines 38-68.

2. Saccharose is sucrose. Walters Tr. 1133.

3. The '068 patent issued in 1979, based upon an application filed in the United States in 1977, with a foreign application priority date of 1976 (Germany). CX-1.

4. A person of ordinary skill working in the relevant art in the mid-1970s would have been someone working for a university or a food company, or possibly in the government, with a Bachelor's degree, typically in food science or food chemistry, and possibility a Master's degree or Ph.D. This individual would typically have had five to ten years of experience. Walters Tr. 1129-1130.

5. By the mid-1970s, a number of high potency sweeteners had been already used or sold. Saccharin had been in use for a long time, and dulcin had been in use for a period of time until it fell out of use in the 1960s. Cyclamate was discovered in 1937 and used until the 1960s. Acesulfame had been discovered in 1965 and was being intensely studied by the mid-1970s. Walters Tr. 1130.

6. RX-11 contains a German article, "Der Süßungsgrad von Dulcin und Saccharin," by Dr. Theodor Paul, from the journal *Chemiker Zeitung*, which was published in 1921. The exhibit also contains an abstract of the article in English, which was published in

Chemical Abstracts in 1921, and which summarizes the key points of the article.

7. The Paul article describes the blending of dulcin and saccharin, the two high potency sweeteners that were known at that time. Although dulcin was no longer in use by the mid-1970s, the information contained in the Paul article would have been known to one of ordinary skill. Furthermore, one of ordinary skill would have been interested in its structure and taste. Walters Tr. 1130-1131.

8. The Paul article indicates that the taste of the mixed solution is "more pleasant" than that of saccharin alone. RX-11.

9. Respondents' expert, Dr. Walters, testified as follows:

> Q And what would one of ordinary skill have understood to be meant by the phrase "more pleasant"?
>
> A More pleasant than the taste of saccharin alone would mean that it tastes better, and the standard for a sweet taste is sucrose.
>
> Q Why was sucrose the standard for sweet taste?
>
> A Sucrose is the sweetener we're most accustomed to, that's table sugar, so that's what we're accustomed to. If we have a sweetener that tastes different from that, we consider it not as good.

Walters Tr. 1131.

10. The Paul article also shows that when one blends the two, there is synergy, i.e., an increase in the level of sweetness beyond what you would expect based on the individual concentrations

alone. RX-11; Walters Tr. 1130-1131.

11. RX-23 is a paper published in 1955 in the *Journal of the American Pharmaceutical Association* by Vincent and a group of co-workers from Abbott Laboratories, including Fred Helgren. The article deals with the combination of cyclamate plus saccharin. RX-23; Walters Tr. 1132. A number of tests were conducted with ratios ranging from 1:10 to 10:1. "[I]t was concluded that the 10:1 ratio of cyclamate to saccharin is most satisfactory from the standpoints of minimizing off taste and of emphasizing desirable qualities of sweetness." CX-23 at 443.

12. RX-23 would have taught one of ordinary skill in the art in the mid-1970s that blending saccharin and cyclamate would create synergy. Moreover, a higher level of sweetness was observed. Furthermore, the article notes that a majority of the tasters commented on the "clean, sweet taste" of the combination. The phrase "clean, sweet taste" means less of the "off" tastes of saccharin and cyclamate, and therefore a taste which is more like sucrose than either sweetener alone. RX-23; Walters Tr. 1133.

13. In addition, RX-23, the Vincent article, states with respect to the tasters reporting a "clean" and sweet taste that "a surprising number volunteered that those are the sucrose solutions in this series, when it was the combination they had tasted." This means that many of the panelists thought that the combination tasted like sucrose, that is, had a more

saccharose-like taste. RX-23 at 445; Walters Tr. 1133.

14. RX-25 is an article entitled "A Novel Method for the Utilization of Artificial Sweeteners," from a Japanese food science journal, published in 1964 by workers at Ueno Pharmaceutical Company. In this article, the authors discussed combinations of saccharin and dulcin. RX-25; Walters Tr. 1134.

15. RX-25 discusses various binary blends of high potency sweeteners: dulcin, saccharin and cyclamate. In RX-25, the authors state that:

> It has been said that when a number of seasoning agents are blended together, mutual defects are eliminated the greater the number blended, and a particular flavour emerges. The same is true for artificial sweeteners. It is well known that when two or more types of sweeteners are mixed, there is not a mere summation of the respective sweetness. The sweetness contained will be greater than this, and furthermore, a delicious sweetness is produced.

RX-25 at 12-13.

16. One of ordinary skill would interpret the phrase "delicious sweetness" to mean that the taste is more like sucrose, since sucrose was the standard those of ordinary skill in the art were trying to achieve in blending sweeteners. RX-25; Walters Tr. 1134-1135.

17. RX-17 is a Japanese article on sweeteners that was edited by Takeo Yamane, and published in 1966.

18. At the top of page 216, the article (RX-17) states as follows:

> It has long been recognized from experience that

> when sweeteners are used together, the level of sweetness is increased synergistically, and in the case of synthetic sweeteners, too, when these are used with each other or when they are used along with sugar or some other such sweetener, the level of sweetness is considerably raised in comparison to the sum of the levels of sweetness when used individually.

RX-17; Walters Tr. 1135.

19. The Yamane article further notes that "in particular, by the combined use of synthetic sweeteners, *it is clear there is a reduction in the bitterness or unpleasant taste which is their particular disadvantage.*" By "synthetic sweeteners," the authors are referring to high potency sweeteners. RX-17 at 216-17 (emphasis added); Walters Tr. 1136-1137.

20. As in the case of the Ueno article, the Yamane article would have taught someone of ordinary skill in the art that by blending sweeteners, one can reduce the amount of bitter or unpleasant or off tastes and create a taste that is better, and therefore more like sucrose. *See* Walters Tr. 1137.

21. RX-20 is a Japanese patent to Yamaguchi and others, which was published in 1972. According to the patent, "[t]he present invention relates to a method of enhancing the potency and improving the taste quality of artificial sweeteners." The patent deals with blends of aspartame with other high potency sweeteners, including saccharin and cyclamate. RX-20; Walters Tr. 1137.

22. According to RX-20, as a result of investigations into the taste characteristics of aspartame, "the present inventors have discovered that if APM [aspartame] is mixed with saccharin or cyclamic acid (cyclamate), sweetness is markedly enhanced by synergistic action between the inherent sweetness of the two components, and at the same time, the unpleasant taste which is a characteristic of artificial sweeteners is eliminated by this mixing, and the quality of the taste is dramatically improved." RX-20.

23. RX-20 would have taught one of ordinary skill in the art in the mid-1970s working in the sweetener area that by blending aspartame with other high potency sweeteners, one can improve the taste quality. RX-20; Walters Tr. 1138.

24. RX-11, RX-17, RX-20, RX-23 and RX-25 were not before the Patent Office during the prosecution of the '068 patent. *See* CX-1; Walters Tr. 1138.

25. The prior art cited by respondents and relied upon by Dr. Walters in his expert testimony at the hearing deals specifically with blends of high potency sweeteners. Walters Tr. 1138-1139.

26. Collectively, the prior art would have taught one of ordinary skill in the mid-1970s that there were four high potency sweeteners that had been studied up to that point (i.e., saccharin, aspartame, cyclamate and dulcin), and six possible pairs of sweeteners that could be considered. Out of those six

possible pairs of sweeteners, five had been evaluated and all five of showed not only synergy, but more importantly, improved taste, i.e., made the taste more sucrose-, or "saccharose-" like. *See* Walters Tr. 1139.

27. Based on what was known about structure activity relationships, if saccharin showed synergy and improved taste, then it was very likely that acesulfame potassium would also show synergy and improved taste when blended with other high potency sweeteners. Walters Tr. 1140.

28. One of ordinary skill in the art in the mid-1970s would have expected similar structures to behave similarly. Walters Tr. 1140.

29. RX-176 ("Structure-Taste Relationships of Some Dipeptides"), RX-183 ("Aspects of Functional Groups and Flavor"), RX-184 ("Dependence of Relative Sweetness on Hydrophobic Binding") and RX-192 ("Relationship Between Taste and Structure in Some Derivatives of Meta-Nitaniline") are typical structure activity studies showing the relationship between taste and chemical structures. These studies show that one of ordinary skill in the art in the mid-1970s would have been familiar with these types of studies, and would have considered the structure of acesulfame potassium when considering its taste and the effect that it may have in a blend. Walters Tr. 1141-1143.

30. In a 1973 paper by Clauss and Jensen of Hoechst describing

acesulfame, they noticed the similarity in structure between saccharin and acesulfame, and made an analog of their acesulfame structure which was as close in structure as possible to saccharin. RX-29; RPX-38; Walters Tr. 1145.

31. An "analog" refers to a small change in chemical structure, such as changing only a few atoms in a complex molecule, so that one can still recognize the similarity between the two compounds. Walters Tr. 1147. It was recognized in the 1970s that in complex structures sometimes even a small change will result in a loss of sweet taste, yet a small change in another portion of the molecule will not have a large effect on taste. Walters Tr. 1147-1148, 1207-1209; CX-40; CX-185.

32. It would have been obvious to one of ordinary skill in the art in the mid-1970s that if saccharin has the effect of producing synergy with other sweeteners, and has the effect of producing better taste qualities with other sweeteners, then it was highly likely that acesulfame potassium would produce similar results when blended with other sweeteners. Walters Tr. 1146.

33. By the mid-1970s, saccharin had been shown to have both synergy and improved taste qualities when blended with other sweeteners. Walters Tr. 1146-1147.

34. Dr. Lipinski could not remember when he began working on the claimed invention, which sweeteners he first tried to blend with acesulfame potassium, or what contributions listed co-inventor

Erich Lück made to the claimed invention. His laboratory notebooks have been lost or destroyed. *See* RPX-19C (Lipinski Dep. Designations) Tr. 48, 55-61, 69-70; Lipinski Tr. 120.

35. Dr. Lipinski admitted that at the time the application for the '068 patent was filed, there had been no experiments to determine which ratios of sweeteners would produce the best results, and in fact, the applicants did not know which ratios would produce the best taste when blending sweeteners. Lipinski Tr. 116-120; RPX-19C (Lipinski Dep. Designations) Tr. 72-73, 79-80.

36. In the mid-1970s, one could have determined the best ratios for blending sweeteners through a set of experiments that could be done with a taste panel, having them taste different ratios of the sweeteners. Walters Tr. 1151; Moskowitz Tr. 306-307.

37. One of ordinary skill in the art would have known how to do this type of taste test. Most of the larger food companies already had facilities to do this sort of testing, with trained panels already in place. This type of taste test is very straightforward and would take perhaps one or two weeks. Walters Tr. 1152.

38. Sucrose is the gold standard for sweeteners. *See* Walters Tr. 1155.

39. The ratios found in the specification and the claims appear to be based on experiments that he ran at Hoechst, especially since the ratios are found in the Examples disclosed in the patent

application. *See* CX-2; CX-1.

IV. Infringement

The '629 Patent

1. Dr. Walters' educational and professional background are summarized in his resume, RX-46(A).

2. Dr. Walters earned a Bachelor of Science degree in Pharmacy from the University of Wisconsin in 1974, and a Ph.D. in Medicinal Chemistry from the University of Kansas in 1978. Medicinal chemistry involves the synthesis and testing of analogs and drugs to understand how the structure of a drug molecule affects its activity. Walters Tr. 1122.

3. After receiving his Ph.D., Dr. Walters did post-doctoral work for a year and a half at Indiana University, where he studied the structure of proteins and glucoproteins. In 1979, he went to work in the basic flavor chemistry department of Kraft Foods in Glenview, Illinois, where he studied taste components. Walters Tr. 1123.

4. As part of his work at Kraft, Dr. Walters participated in several kinds of taste panels, evaluating flavors of food products, and also expert taste panels where they developed vocabulary to describe particular kinds of tastes. Walters Tr. 1123.

5. In 1982, Dr. Walters went to work for the G.D. Searle Company, the pharmaceutical company which discovered aspartame in 1965.

Late in 1982, Dr. Walters became involved in helping to prepare a plan for research on a new sweetener at Searle. Walters Tr. 1123.

6. Dr. Walters is listed as a co-inventor on two patents for a series of high potency sweeteners developed during his work at Searle and NutraSweet. Walters Tr. 1124; RX-50, RX-51.

7. In the mid-1980s, Monsanto bought the Searle company and shortly after that made the NutraSweet business into a separate business unit. At NutraSweet, Dr. Walters was involved in the discovery of new high potency sweeteners. He did computer modeling studies to understand structure-activity relationships among high potency sweeteners and helped design new structures which the chemists in the lab would synthesize and test. Walters Tr. 1125.

8. While at NutraSweet, Dr. Walters was promoted to the position of group leader, directing the research of a group of synthetic chemists who were making high potency sweeteners. Walters Tr. 1125.

9. While at the NutraSweet company, Dr. Walters was also very involved in taste panel studies. He personally ran a number of informal taste panels in the laboratory to evaluate new sweeteners which were synthesized in the lab, and served as the liaison person between his department, which synthesized the compounds, and NutraSweet's sensory evaluation group, which evaluated new sweeteners. Walters Tr. 1125-1126.

10. While at NutraSweet, Dr. Walters had experience with a pilot plant facility which chemists in his group used from time to time to make chemicals. Walters Tr. 1126.

11. Based on his supervision of chemists who were making high potency sweeteners, as well as his review of literature on high potency sweeteners, Dr. Walters is very familiar with the chemistry of high potency sweeteners. Walters Tr. 1126-1127.

12. Dr. Walters has published over 40 scientific publications, about half of which deal with sweeteners and sweetness, including high potency sweeteners. He is also the editor of a book entitled "Sweeteners: Discovery, Molecular Design and Chemoreception" which discusses the discovery of sweeteners and how to go about designing new high potency sweeteners and, on a biochemical level, how sweetness is detected. This book received the platinum award from the Agricultural and Food Chemistry Division of the American Chemical Society. Walters Tr. 1126-1127.

13. Dr. Walters has also given over 40 research presentations, approximately half of which deal with sweeteners and sweetness. In addition, he has given a number of invited lectures at universities and various companies dealing with sweetness. Walters Tr. 1128.

14. In 1991, Dr. Walters left NutraSweet to join the biochemistry department at the Finch University of Health Sciences at the Chicago Medical School, where he has been teaching biochemistry

to medical students. He has continued to do research in sweeteners, including the mechanisms of sweet and bitter taste and how they interact. Walters Tr. 1128.

15. At the hearing, Dr. Walters was accepted as a expert in sweeteners and high potency sweeteners, including the chemistry and biology of sweeteners. Walters Tr. 1128-1129.

16. Prior to the filing of their complaint, complainants obtained samples from respondents JRS International, Inc. and WYZ Tech, Inc. of imported acesulfame potassium manufactured by the Sanhe respondents. When the samples were received by complainants, they were assigned the internal designations Fremd No. 127 (JRS) and Fremd No. 128 (WYZ). Samples Fremd No. 127 and No. 128 were each divided into two parts. One part was kept in Nutrinova's laboratory, and the other was sent for testing. Klug Tr. 399-400.

17. Testing was performed for Nutrinova by Institut Fresenius in Germany, a well-regarded laboratory that, among other things, performs independent chemical analyses. Klug Tr. 400.

18. Dr. Klug, Nutrinova's Director of Quality and Integrated Management Systems, visited Institut Fresenius, discussed the standards and analyses to be applied to the testing, and supplied the samples to the Institut for testing. Klug Tr. 383-402.

19. The tests performed on the samples taken for complainants during the plant inspection were performed by Sani-Pure Laboratories of

Saddle River, New Jersey. *See* Stalick Tr. 758.

20. Dr. Dettmeier studied organic chemistry and completed his studies in 1968 with a doctorate degree. After completing his education, Dr. Dettmeier started to work as a chemist in a company owned by Hoechst AG. His job at that time was to develop processes and products in the field of organic chemistry. Dettmeier, Tr. 590.

21. Dr. Dettmeier then accepted a position as an assistant to a member of the board of Hoechst AG who was responsible for research and development. Following that assignment, Dr. Dettmeier went back to the Division of Organic Chemicals. He stayed there as a leader of the laboratory for a year. At the end of 1974, Dr. Dettmeier was named a group leader. One year later, Dr. Dettmeier was given responsibility for the whole department that worked with organic chemicals. The department included about 100 chemists, engineers, and a small group responsible for analytical chemistry. A pilot plant and laboratories were part of the department. Dettmeier Tr. 590-91.

22. Dr. Dettmeier was recently employed by the Swiss company, Clariant, and retired from Clariant on June 30, 1998. Dettmeier Tr. 589.

23. Nutrinova asked Dr. Dettmeier whether, in his opinion, one can identify processes by analyzing by-products. He answered that based on his experience at Hoechst, in general it was possible to do so. Nutrinova also asked whether he could identify processes

for making acesulfame potassium by analyzing by-products. Dr. Dettmeier reviewed his own knowledge concerning acesulfame potassium processes, including the FSI process (which was developed by Hoechst) and the '629 process, and also conducted a literature search of all known processes described in patents. He also considered the availability of raw materials, the handling of intermediates, and other variables. Dettmeier Tr. 604.

24. Having finished his research into the question posed by Nutrinova, Dr. Dettmeier was able to conclude that there are two categories of production processes: "one was processes which start with fluoride containing intermediates for starting materials, and the other group of processes which use SO_3 as a cyclization agent." Dettmeier Tr. 604-605. Dr. Dettmeier further answered that "[i]f one has the chance to identify processes by analyzing the by-products, then the best chance one would have [is] to look at the traces of fluoride and sulfates." Dettmeier Tr. 605.

25. Dr. Walters testified on direct as follows:

> Q Now, Dr. Walters, do you have an opinion about whether Complainants' test results of Sanhe samples are evidence that Sanhe has used a different process in the past?
>
> A Yes, I do.
>
> Q What is your opinion?

A My opinion is that based on simply on fluoride and sulfate levels, you really can't say anything at all about the process that was used.

Q What does the level of fluoride tell you?

A Well, the fluoride level tells you if there is fluoride present, it tells you that there's a good probability that the ASK was made with a fluorene containing reagent, something like ASF or FSI, but if the fluoride is absent, you don't know whether it's because the '629 process was used or whether it's absent because the material was simply purified to the point that fluoride is not there anymore.

Q What about sulfate, what does the presence of sulfate tell you?

A I think sulfate is even less useful in this respect, because we've seen samples from the FSI process that contain sulfate, we've seen that in the process that Sanhe uses, sulfate is there because they have used , so it has nothing to do with the '629 process. And in fact, the '629 samples that Hoechst analyzed had the lowest level of sulfate of any.

Q Where have we seen evidence of sulfate in the FSI samples?

A One of the old Hoechst samples that was analyzed contained sulfate.

Q And what would the lack of sulfate tell you?

A Again, lack of sulfate doesn't tell you much, because you don't know the reason that it's absent, you don't know if it was absent because of the process not involving sulfate, you don't know whether it's absent because it was simply purified to the point that the sulfate is not detectable anymore.

Q Now, Dr. Walters, it's been suggested that the older Sanhe samples had higher sulfate and lower

fluoride and the more recent samples have , and that that's evidence that Sanhe used a different process in the past. Do you agree with that?

A No.

Q Why not?

That's --

MR. SCHILL [for Complainants]: Objection, your Honor; there's lack of foundation for this. It's not lower -- it's not lower fluoride. There's no fluoride.

JUDGE HARRIS: Or un --

MR. HNATH [for Respondents]: Low or no fluoride.

JUDGE HARRIS: Undetectable.

MR. HNATH: Undetectable, yes.

JUDGE HARRIS: So the question is modified. Do you want to restate it?

BY MR. HNATH:
Q Yes. It's been suggested that older Sanhe samples have higher sulfate and fluoride below the detection limit, and that more recent samples have

. In your opinion, does that show that Sanhe used an infringing process in the past?

A No, it shows really nothing about the process for synthesizing the ASK. It goes much more to the way that the ASK was purified. It shows that very different methods were used to purify those two samples.

Walters Tr. 1175-1177.

26. Samples of Hoechst '629 acesulfame potassium had undetectable concentrations of both sulfate and fluoride. However, three

samples of Hoechst's FSI acesulfame potassium had detectable fluoride, and sulfate was detected in two of the Hoechst FSI samples. In the September test, a value of 30 ppm for sulfate was reported. In October, the values of 10, and less than 10 were reported. These values are relatively small in that they were at or near the level of detection for the tests that were performed in September and October on complainants' behalf, and they were smaller than those reported for respondents' products which, according to Dr. Dettmeier, were roughly about 300 ppm. Klug Tr. 427-432; Dettmeier Tr. 641-644; CX-48C; CX-49C.

27. Dr. Dettmeier testified concerning an early step in the Hoechst FSI process that starts with the reaction product

Thus, according to Dr. Dettmeier, the

used to make FSI "could be the source for the sulfate." Distillation is used in Hoechst's FSI process as a means of purification. Although FSI can be distilled, sulfate cannot. Therefore, Dr. Dettmeier expected that "traces" or "minor amounts" of sulfate would be found in the distillate. Dettmeier Tr. 641-644; CX-78C.

28. Mr. Qiu received a degree in 1985 from Zhejiang Industrial

University, where his courses included chemistry, organic chemistry, chemical engineering, mathematics, high polymer materials, metallic and non-metallic materials, and corrosion theory. His studies in the area of corrosion included electro-chemical corrosion, metal and material corrosion and anti-corrosion, non-metal corrosion materials and coating. Qiu Tr. 837-838.

29. As an honors graduate Mr. Qiu was able to obtain employment at Zhejiang Chemical Industrial Institute, which is one of the largest institutes of its kind in China with over 1,000 researchers and 7 separate departments. Qiu Tr. 838-839.

30. While at the Institute, Mr. Qiu began work in relating to food additives, including acesulfame potassium. Qiu Tr. 840, 874.

31. The first thing in developing an ASK method that Mr. Qiu did was to conduct a literature search in order to understand the characteristics of ASK and its market potential. He also studied the different known ways of making ASK in the world. Qiu Tr. 874-875.

32. In his literature search, Mr. Qiu identified seven different methods for making ASK. These seven methods are summarized in RPX-24C. RPX-24C; Qiu Tr. 875-876.

33. Two of the processes for making ASK involved use of as a raw material. Mr. Qiu concluded that even though the patent on this

route had expired, the materials used to make were dangerous, and therefore he did not choose these methods. Qiu Tr. 875.

34. The third route for making ASK used as a starting material. Mr. Qiu recognized that the key to this route was to successfully make . The patent on making ASK using has also expired. Qiu Tr. 875.

35. The fourth route that Mr. Qiu studied used as a starting material to make ASK. However, this route did not use . Mr. Qiu concluded that this method might involve , and therefore did not chose this method. He was concerned that could be dangerous. The patent on this method had also expired. Qiu Tr. 876.

36. The fifth route which Mr. Qiu considered used as a starting material to make ASK. However, this process used as a reactant and was covered by valid patents. Therefore, Mr. Qiu did not select this method. Qiu Tr. 876.

37. The sixth route which Mr. Qiu considered used for ring closure. This method was patented in China and many other countries in the world, and therefore, he did not select this route. Qiu Tr. 876.

38. The seventh route which Mr. Qiu studied used as a starting raw material. This route had a patent application pending in China, so it was not selected. Qiu Tr. 876.

39. Based on his analysis of the various processes that could be used and his experience, Mr. Qiu concluded that the key to making ASK was making . Qiu Tr. 876.

40. The seven different routes which Mr. Qiu considered are summarized in the Report to the government in China, which Mr. Qiu prepared at a later time. Qiu Tr. 877.

41. Most of Mr. Qiu's literature searches were done manually. RX-199C is part of his literature search relating to the making of ASK. RX-198C is a printout of a computer search which Mr. Qiu generated relating to the making of ASK. Qiu Tr. 877; RX-199C; RX-198C.

42. The literature in RX-199C concerning the making of ASK was gathered together starting in approximately . Qiu Tr. 878.

43. After Mr. Qiu did his literature search for methods of making ASK, he searched for different methods of making . RX-200C includes different references which Mr. Qiu located concerning the making of . This search was done in . RX-200C; Qiu Tr. 878.

44. Mr. Qiu attempted to make .
He attempted to make using this method in the lab, but his lab experiment failed.

(RX-199C at R000225). RX-199C; Qiu Tr. 878.

45. After Mr. Qiu was unsuccessful , he did an intensive search on other ways to make

. RX-200C; Qiu Tr. 878.

46. RX-203C consists of Mr. Qiu's work notes with regard to how to make and how to make ASK. RX-203C; Qiu Tr. 878-79.

47. Mr. Qiu's is described in his work notes. The took place in . RX-203C at R000659-0671; Qiu Tr. 879-80.

48. In addition, one of the raw materials used in the , was very difficult to make and very expensive. Qiu Tr. 880.

49. After Mr. Qiu's , he did extensive reading about the making of , including the literature search identified earlier. Based on the materials and literature that he reviewed, the availability of raw materials in China, and his analysis, experience and judgment, Mr. Qiu selected the method to make that is the method currently being used by Sanhe. Qiu Tr. 881.

50. Once Mr. Qiu had selected a method, he conducted lab experiments for . Those experiments are described in RX-203C at R000620-0639. The experiments took place in . RX-203C; Qiu Tr. 881-83.

51. Mr. Qiu used the laboratory in Sanhe's factory to conduct his experiment, even though he was not an employee of Sanhe. He conducted these experiments in his spare time. Very few people

supported him, because there were few people at Sanhe who had chemical technical knowledge and no one who had any experience in chemical engineering. Two individuals assisted him, but what they did was under Mr. Qiu's supervision. Qiu Tr. 883-884.

52. Once Mr. Qiu had succeeded in making , he then did laboratory experiments relating to making ASK . The difficulty was not in how to make the reaction happen, since there was only one reaction available. Instead, the key to making ASK was

. Qiu Tr. 886.

53.

Qiu Tr. 886.

54. Mr. Qiu's work notes (RX-203C at R000640-0658) describe his experiments for making ASK between and . RX-203C; Qiu Tr. 886-887.

55. Mr. Qiu's lab notes describe why he chose in order to . The use of is described, for example, at RX-203C at R000641. RX-203C; Qiu Tr. 887-888.

56. The use of , is described in the literature. This technique is described, for example, in

RX-199C; Qiu Tr. 888-890.

57. Mr. Qiu concluded, however, that it was not appropriate to use

. In addition,

. On the other hand,

. Qiu Tr. 888-889.

58. In addition,

. Qiu Tr. 889.

59.

. CX-83; Topp, Tr. 1273-1279; Reuschling, Tr. 347-348.

60. Mr. Qiu also considered

. In addition,

. Therefore, using was not considered suitable. Qiu Tr. 889.

61. For these reasons, Mr. Qiu chose to use . Mr. Qiu had a large range of choices with regard to . Qiu Tr. 889; RPX-28C.

62. Mr. Qiu had not seen the use of described anywhere in the literature. This is a method which he developed based on his own analysis. Qiu Tr. 890-891.

63. After Mr. Qiu completed his experiment with , the next step was to determine how to . Mr. Qiu's experiments relating to are described in his work notes, RX-203C at R000643. RX-203C; Qiu Tr. 891.

64. At the close of his experimentation, Mr. Qiu became an employee of Hangzhou Sanhe Food Additives Factory in , at which time he and Sanhe's Director, Mr. Zong, began their concerted efforts to take Sanhe's production of ASK from the laboratory stage to the pilot plant stage. Qiu Tr. 884, 892; Zong Tr. 1063-1064.

65. Although Sanhe has produced a substantial amount of acesulfame potassium , the company

. Qiu Tr. 922-925; RX-201C.

66. Construction of the pilot plant began some time in and was completed about . Acesulfame potassium was first made at the pilot facility some time in . Qiu Tr. 896-897.

67. In the first few months of the pilot experiment, the acesulfame potassium manufactured by Sanhe , which is undesirable in acesulfame potassium. Qiu Tr. 898

68. One possible cause of . Qiu Tr. 897.

69. In addition, . He thought that this would . Therefore, in the early stages of the pilot experiment, . It was only later that he realized . Qiu Tr. 897-898.

70. In order to . He also considered . Qiu Tr. 898-899.

71. Mr. Qiu searched the literature and found that . Therefore, he tried .

Qiu Tr. 899-900.

72. During the hearing, Mr. Qiu illustrated the method in which he

. *See* Qiu Tr. 901-902; RPX-29C; RPX-30C.

73. He described the process in which

. Qiu Tr. 901-902.

74. The term "ASH" refers to the sweetener acid itself, without the potassium. ASH may be neutralized, for example with potassium hydroxide, and turned into acesulfame potassium. In certain processes, ASH and ASK may be converted back and forth. *See, e.g.*, Reuschling Tr. 331-332, 352.

75.

. At the time Mr. Qiu used this method

. He testified that

Although Mr. Qiu

. Qiu Tr. 902; *see* Walters Tr. 1178-1179.

76. During the pilot experiment phase, approximately of acesulfame potassium was processed

. Qiu Tr. 900.

77. In the initial stages of the pilot experiment, the workers had to be trained, and were acting directly under Mr. Qiu's instructions. In , as the workers began to have more familiarity with the process, the factory formally set up the acesulfame potassium workshop, and the workers were required to keep workshop records. Qiu Tr. 903-04.

78. The workshop process records refer to the purification method which Mr. Qiu described in his testimony,

. *See* RX-205(A)C at R001405-412 ; Qiu Tr. 905-906.

79. In , Mr. Qiu started using . The product made using . Therefore, there was no need to continue to use . Qiu Tr. 906-907.

80. With respect to fluoride content, Mr. Qiu testified that . Thus, the fluoride content in early samples of Sanhe's product would be expected to be very low, since the product . Qiu Tr. 908-910, 1029; RPX-31C and RPX-32C.

81. Mr Qiu testified that initially, . Qiu

Tr. 910-911.

82.

. Therefore, using this process, it would be expected that the amount of fluoride would be very small or not detectable. Qiu Tr. 910-911; RPX-31C, RPX-32C, and RPX-33C.

83. Dr. Walters confirmed that , and that . He testified in part, as follows:

> BY MR. HNATH:
>
> Q Yes. It' been suggested that older Sanhe samples have higher sulfate and fluoride below the detection limit, and that more recent samples have : In your opinion, does that show that Sanhe used an infringing process in the past?
>
> A No, it shows really nothing about the process for synthesizing the ASK. It goes much more to the way that the ASK was purified. It shows that very different methods were used to purify those two samples.
>
> Q Can you explain what you mean?
>
> A Yes. The material that they are producing now has . The material with a very high level of sulfate and undetectable fluoride clearly came from the material that Mr. Qiu described making very early in the process, .
>
> Q And how would that process affect the sulfate level?

A Again, can I use the easel to illustrate?

JUDGE HARRIS: Yes.

THE WITNESS: The material Mr. Qiu described very early in the process

. And he had tried

. So that material already would have had

Now, in order to

He testified that there was

And again, he took this material,

So this material now has

In fact, the testing labs reported that the material was not homogenous, so I think it's likely that he had a mixture of ASK crystals and crystals in there.

Walters Tr. 1178-1179; *see* RPX-41C (illustrating testimony).

84. Although certificates such as that associated with Fremd No. 127 have blanks for certain information to be filled in,

. He knows of cases in which

. Zong Tr. 1079-1081, 1097-1100.

85. An examination of the certificate in question (CX-38C) strongly indicates that such an event occurred in this instance. The person who filled out the form

. On the certificate, there is a line for:

As respondents pointed out, on many other such certificates,

. *See* RX-204C. However, in the case of this certificate

there is the entry: CX-38C.

86. Tests of the ASK in Fremd No. 127 which were run in-house by Nutrinova showed sulfate results that were 12,070; 8,780; 9,220; 7,310; and 10,725 ppm. However, a precise sulfate measurement could not be made of the material contained in Fremd No. 127 because, in the words of the Nutrinova laboratory, the sample was "not homogenous." RX-253C ("Probe nicht homogen." "Präzision: 000").

87. As Dr. Walters testified, the non-homogeneity of the acesulfame potassium that went into Fremd No. 127 indicates that it was probably a mixture of ASK crystals and crystals. *See* Walters Tr. 1179.

88. In his testimony relating to the sulfate and fluoride content in Sanhe's ASK, Mr. Qiu made certain assumptions in order to perform his calculations, including the assumption that the material was dissolved evenly in solution. *See* Qiu Tr. 910.

89. . *See* RX-255C.

90. Inasmuch as is the acesulfame molecule in which one

. *See* RX-256C

(Walters Decl.), ¶ 3.

91. Complainants do not

. Mem. of Complainants Regarding Ex. RX-255C and Mot. to Admit Exs. CX-191C to CX-201C into the Record at 6; Topp Tr. 526.

92. Dr. Lipinski is not an expert in how ASK is made, and does not have well-developed theories of his own about ASK impurities and by-products. Nevertheless, he did know that others at Hoechst or Nutrinova had theories concerning impurities such as

. Dr. Lipinski's testimony is as follows:

> Q. What would the presence of fluoride indicate in a sample of ASK?
>
> A. We believe this was an indication of fluorine containing starter materials.
>
> Q. Are you familiar with how ASK is made?
>
> A. To some extent, but it's not my area of expertise.
>
> Q. Are you familiar with the purification process?
>
> A. Not in detail.
>
> Q. Are you aware that the more you purify a sample of ASK the lower amount of trace impurities will be in the final product?
>
> A. That's what I would expect.
>
> Q. More purification would mean less fluoride?
>
> A. I don't know what behavior of fluoride in purification is.

Q. How about sulfate, in general would more purification lead to less sulfate?

A. I can't state that either because I don't know the behavior of sulfate in purification.

Q. If you could look at the first page there, there are a number of different compounds listed.

A. Yes.

Q.

A.

Q.

A.

Q. What does the presence of that impurity indicate about the process, to your understanding?

A. At the present moment I don't know.

Q. Have you had discussions with people at Nutrinova or Hoechst?

A. Yes.

Q. What are some of the theories advanced as to what that compound would indicate about the process?

A. At that time we believed it would indicate a different manufacturing route.

Q. Which route did you believe it would indicate?

A. The use of

.

Q. What type of process would use

?

A. .

Q.

A.

Q.

A.

Q.

A.

Q.

A.

RX-19C (Lipinski Dep. Designations) Tr. 112-115.

93. Dr. Dettmeier testified as follows:

Q.

A.

RX-257C (Dettmeier Dep. Designations) Tr. 298-299 (attached to respondents' Mot. No. 403-50 as Ex. 2).

94. Dr. Topp does not consider himself to be an expert in the area of analytical test results, nor do complainants offer him as someone having such expertise. *See* Mem. of Complainants Regarding Ex. RX-255C and Mot. to Admit Exs. CX-191C to CX-201C into the Record (quoting CX200C (Topp. Dep. Designations) Tr. 208).

95. Dr. Topp's testimony concerning is as follows:

Q.

A.

Q.

A.

Q.

A.

Q.

A.

Q.

A.

Q.

A.

RPX-13C (Topp Dep. Designations) Tr. 264-265.

96. Upon learning of Nutrinova's latest research and theory, Dr. Topp revised his views concerning to match those of Nutrinova. *See* CX-199C (Topp Decl.), ¶ 7-8.

97. It took Sanhe many months of experimentation to begin production of acesulfame potassium using the process, even after Mr. Qiu had decided to use the process which was

. *See, e.g.*, Qiu Tr. 876-890.

98. After the Sanhe plant inspection, Dr. Topp supervised an experiment to confirm his understanding that corrosion should have been present in Sanhe's reactor vessel 2 (R2). He personally prepared a mixture of

. He placed rods into the a solution. After 20 hours in the solution, the rods showed significant signs of corrosion. Dr. Topp calculated the corrosion rate on the at 47.6 millimeters per year. He then ran a second test that included to see if corrosion takes place in vapor and condensation phases. He calculated corrosion rates of 6.6 millimeters per year for the vapor phase, and 3.2 millimeters per year for the condensation phase. The corrosion of the samples from the solution and vapor phases was evident upon a visual inspection of the samples, which were brought into the hearing. *See* Complainants' Post-Hr'g Br. at 11-12; Topp Tr. 510-515, 552; CPX-3C; CX-64C.

99. On April 21, 1998, during the Sanhe plant inspection, samples were taken out of the vessels. These samples had been sitting in for over two months by the time of the hearing. According to Dr. Topp's theory concerning the solution used in R2 there should have been signs of corrosion in the . Indeed, depending on the type of used in the relatively thin containers brought to the hearing room, one might have expected the containers to have been completely corroded through. Yet, unlike the rods that Dr. Topp placed in his test solution, the containing the Sanhe solution showed no signs of

corrosion at all. *See* RPX-5(a); RPX-5(B); Topp Tr. 561-565; Walters Tr. 1170; Qiu Tr. 962-963.

100. Tests performed by Sani-Pure on samples from vessel R2 show the presence of very little in solution. In one sample, the level of was measured at , and in another the level was . With that amount of , corrosion would be approximately .001 millimeters per year at most. At that rate, vessels such as R2 would sustain very little corrosion damage. Dr. Walters calculated that given the available in the samples given to Sani-Pure, it would take 1,000 years for the large containers such as the Sanhe reactors to corrode; and he testified that given the actual pH and temperature used in Sanhe's reaction, the corrosion rate would be even slower. Walters Tr. 1170-1174; RPX-40.

101. Tests run by Metuchen Analytical of Edison, New Jersey found in Sample No. C38447-8.

102. Dr. Duerr (Metuchen Analytical's president) who supervised testing for respondents in connection with this litigation, has Bachelor's, Master's and Ph.D. degrees from MIT. He is a registered professional engineer in the State of New Jersey and a certified chemist, as recognized by the American Institute of Chemists. Dr. Duerr testified that Metuchen Analytical is registered with the FDA and is inspected by the FDA every two years. Metuchen has at least 10 years of experience using

selective ion electrodes for fluoride analysis like those used in the testing performed for respondents, and have probably done 100 analyses using this equipment over those years. Metuchen has done work for major corporations such as Johnson & Johnson, and Proctor & Gamble. RPX-18C (Duerr Dep.) Tr. 9-10, 79-81. Sani-Pure's Mr. Schnitzer testified that Dr. Duerr has a very good reputation in the testing field. CPX-14C (Schnitzer Dep.) Tr. 72.

103. Inasmuch as the in the R1 and R2 vessels form , the solution has a low level of in the solution. Furthermore, the remains in solid form, and therefore is not capable of being converted . In Dr. Topp's experiment all the was in solution. Walters Tr. 174-1175; Qiu Tr. 963-968.

104. In response to questions from complainants about the reactions taking place, Mr. Qiu wrote an equation indicating that . Mr. Qiu told the visitors during the inspection that the solid material precipitating out of vessel R2 was . Indeed, the diagram of the facility drawn by Dr. Dettmeier after the inspection, which memorializes some of what he observed and what he was told, shows a path for Topp Tr. 508; CX-72C.

105. Mr. Qiu testified in his deposition that Sanhe uses . vessels are the standard for

reactions involving the use of . Topp Tr. 551, 1285-1286. Yet, Dr. Topp ran his experiments by adding in a much higher concentration of . Dr. Topp admitted that

. Therefore, it is possible that, as Mr. Qiu testified, used by Dr. Topp in his experiments reacts very differently from used by Mr. Qiu at Sanhe, and may have had a corrosive effect . *See* Topp Tr. 1291-1294; Qiu Tr. 971-975.

106. Mr. Qiu explained at the hearing that the

Qui Tr. 969-971.

107. The concentration of used in Dr. Topp's experiment differed from the ratio in the Sanhe process. That could have affected corrosion rates. Nor did the experiment take into account the fact that Mr. Qiu uses in the Sanhe process. Finally, although Dr. Topp ran his experiment at , that is not necessarily the temperature at which Sanhe's process is run. Topp Tr. 1300-1303; Qiu Tr. 971-974.

108. Sanhe makes sure that the temperature of its reaction vessels does not exceed , yet there is no assurance that the reaction

occurs at . Qiu Tr. 974.

109. Based on the evidence of record, there is no reason why vessels in Sanhe's plant would show signs of corrosion. Further, since vessels corrode when exposed to air, it is normal for them to be painted. *See* Qiu Tr. 975-977.

110. Dr. Topp's experiment does not account accurately represent the Sanhe process. Topp. Tr. 1300-1303.

111. Dr. Topp does not know the yield of Sanhe's reaction or what percentage are formed. Topp. Tr. 556-557.

112. Mr. Qiu's laboratory notebooks going back to detail his experiments using as a purification method, and his reasons for selecting method over another method, such as one that uses . RX-203C at R000640-0658; Qiu Tr. 886-888; FF IV 46-63.

113. In the Sanhe process, after , the resulting mixture is a very complex reaction mixture that has various by-products, all of which . Walters, Tr. 1160; RPX-39C.

114. In the reaction vessel (Mr. Qiu's vessel R8 and Dr. Topp's vessel R1), the contents include . Walters Tr. 1161-1162; RPX-39C. In order to

Walters

Tr. 1161-1162.

115. Next,

. Walters

Tr. 1161-1162.

116.

Walters, Tr. 1161-62;

RPX-39C.

117.

Walters, Tr. 1162-1163.

118. After the

Walters Tr. 1162-1163.

Walters

Tr. 1162-1163.

119. In order to

. Walters Tr. 1163-1164.

120. The purification method Mr. Qiu developed enables Sanhe to

Furthermore, Sanhe's purification method allows

. Qiu Tr. 844-849; RPX-26C; RPX-27C.

121. The chemicals used in Sanhe's method are .

See Topp. 546; Dettmeier Tr. 649.

122. Sanhe

in Sanhe's process. Qiu Tr. 878-980.

123. A "toll manufacturer" performs a process on-site. This is a common practice throughout the world. Topp Tr. 578.

124. Mr. Qiu has not

. Qiu Tr. 978-979.

125.

is not made for immediate sale in China. Thus, Mr. Qiu must contract

. Nevertheless, he is wary of

. Therefore, he has not disclosed the reactants . In order to assure that the processing with is done correctly and safely, Mr. Qiu has visited the manufacturer and told the company to install certain equipment. He has worked with technical personnel and other workers, and directed the processing himself. Thus, although it is strictly true that Mr. Qiu has not revealed the chemicals to , it also appears that Mr. Qiu is in fact largely responsible for the running the . Qiu Tr. 878-980.

126. Although there is concern in China over , Mr. Qiu received a small sample for his own

laboratory experiments. *See* Qiu Tr. 980-981.

127. can be used to make . Qiu Tr. 936-937; Stalick Tr. 826.

128. In responses to discovery requests, respondents represented that Sanhe produced of acesulfame potassium during the period from . *See* CX-101.

129. Mr. Qiu testified that for a period in the , he tried to make . Qiu Tr. 936-937.

130. In a Sanhe said its yield . RX-131C.

131. During his deposition, Mr. Qiu's testified as follows:

> BY MR. SCHILL:
> Q: Mr. Qiu, as recall statements in some, many of your documents, that you had - Sanhe is making a calculation that
>
> ; is that a correct understanding?
>
> A: That's correct. That's a general number. We don't know . Oh, we don't know
>
> Q: In other words, when you produce at your plant, you don't analyze it before you use it in the next step?
>
> A: Yes, I told you that this morning. As I said, we're . We don't yet have the capability to analyze it.
>
> Q: Okay. Do you maintain to check to see
>
> ?

A: In fact, the whole process from this to the end, we've never been able very carefully to measure. Sometimes I have

. When the is added, I

. So it's very difficult to say ultimately . So only after a long period of time of using I'm able to make a kind of an estimate as to .

Q: And is your estimate that you are achieving ?

A: If it comes out well, then it's , more or less. This is a more or less question.

Q: Is that for this kind of commercial process?

MR. HNATH: Objection to the question as vague and ambiguous.

THE WITNESS: I have no idea if this is . The technology that I', using now has a . Yeah. I think if we continue to make modifications .

BY MR. SCHILL:

Q: When he said that it, Mr. Qiu?

A: We hope that we can .

Q: Is there a goal to reach, ?

A: I hope that it will be .

RX-258C (Qiu Dep.) Tr. 205-208.

132. The government in China

. Sanhe needed approval from the local government . Qiu Tr. 892.

133. Thus, in , Sanhe had to submit to the local Chinese government an appraisal of its

. That appraisal is contained in RX-196C. The recommendation was made for Sanhe to . Qiu Tr. 892-893, 895.

134. The appraisal report states that is used as a raw material in the production of acesulfame potassium. Qiu Tr. 893.

135. The appraisal report that . Qiu Tr. 893-894.

136. The appraisal report says that Sanhe used . However, in his laboratory experiment Mr. Qiu actually used . Qiu Tr. 894-895.

137. Mr. Qiu later used . Qiu Tr. 894.

138. Appraisal documents, such as RX-196C, are open to the public in China. Mr. Qiu believes that there are many industrial spies in China. Qiu Tr. 894-895.

139. The purpose of the appraisal report was to evaluate Sanhe's process of making acesulfame potassium . Qiu Tr.

895.

140. The Liu Bao facility is part of Sanhe. Sanhe supplemented its discovery to include the Liu Bao address. A "Sanhe" sign is displayed at the Liu Bao plant. Zong Tr. 1113-1114; RPX-3C; RPX-4C.

141. Dr. Stalick has never used in an industrial setting. Stalick Tr. 801.

142. Dr. Stalick is not an expert about the safety precautions that need to be taken when using in an industrial setting. Stalick Tr. 801.

143. Mr. Qiu testified that in preparation for the plant inspection, Sanhe bought new safety suits so that they would be available to visitors instead of the old ones previously used by plant workers. Qiu Tr. 867.

144. Mr. Qiu testified that the government ordered Sanhe to paint the plant in preparation for the inspection. Qiu Tr. 867.

145. The fact that parts of the Sanhe plant had been recently painted, and that new safety suits were being used during the plant inspection is not probative of whether the Sanhe plant had recently been modified or whether Sanhe was attempting to conceal evidence. There are simple and plausible explanations for such recent modifications. *See* Qiu Tr. 867.

146. One reviewing the literature relating to would not know which of the published methods would work best. Nor would one know

exactly how to implement those methods in a laboratory or a pilot plant. Qiu Tr. 878-879; Stalick Tr. 801-802.

The '068 Patent

147. Sorbitol is a sweetener belonging to the class of sugar alcohols. It has a sweetness which is approximately half that of sugar. It can be used in applications where sugar provides important functions, including providing bulk to a recipe. *See* Lipinski Tr. 72-73.

148. CX-118C is a letter dated April 29, 1997, from Robert Hammer, patent counsel for Hoechst Food Ingredients, a U.S. subsidiary of Hoechst AG. The letter was addressed to Jane Xu of JRS. The letter concerns the '068 patent. CX-118C.

149. Nutrinova first learned that respondents were distributing acesulfame potassium in the U. S. market from a trade show organized by the Institute of Food Technologies (IFT) in New Jersey. Lipinski Tr. 83.

150. Nutrinova received documents and a sample from the New Jersey IFT show. Lipinski Tr. 83.

151. As is common at IFT shows, during the June 1998 show, Dr. Lipinski walked by and picked up the information and the samples from respondents' booth, which are considered available for the taking. Lipinski Tr. 104.

152. On document CPX-21A, which was obtained at the June 1998 IFT

trade show, there is a section that was obscured by white tape at the bottom of the first column and top of the second column. Lipinski Tr. 105; CPX-21A.

153. When the document CPX-21A is held up to the light, the obscured words can be read. Lipinski Tr. 105; CPX-21A.

154. During the Orlando and Edison, New Jersey IFT trade shows, Jane Xu collected business cards of potential customers. RX-42 (Xu Dep.) Tr. 177-178.

155. CX-106C contains in response to Interrogatory No. 6 a list of companies to whom Jane Xu/JRS distributed samples of acesulfame potassium. Jane Xu maintains that she reviewed the Amended Responses and that the representations contained therein are true. RX-42C (Xu Dep.) Tr. 220-221; CX-106C.

156. JRS sent samples of acesulfame potassium

. RX-42C (Xu Dep.) Tr. 181-182.

157. Jane Xu called . RX-42C (Xu Dep.) Tr. 183.

158. Jane Xu also contacted . RX-42C (Xu Dep.) at 187-188.

159. Ms. Sacks had two conversations with each person. Sacks Tr. 166.

160. Ms. Sacks understood that Ms. Hu was representing Dingsheng when she spoke with her. Sacks Tr. 166.

161. When Ms. Sacks received a package from Ms. Hu, the label read WYZ Tech on it. Sacks Tr. 166.

162. CX-36C, p.3 contains handwritten notes that Ms. Sacks took during her first conversation with Jane Xu from JRS, dated September 3, 1997. Sacks Tr. 166; CX-36C.

163. Ms. Sacks took these notes because it is the ordinary procedure at IGI to take notes during an interview or conversation. Sacks Tr. 166.

164. The notes are not a transcript of the conversation, rather they contain some significant points that were made during the discussion. Sacks Tr. 166-167.

165. Ms. Sacks asked Ms. Xu for some information on an alternative to aspartame, and Ms. Xu then told Ms. Sacks about acesulfame potassium, blending and prices. Sacks Tr. 167.

166. Ms. Sacks told Ms. Xu that she was an independent consultant in the food industry, who was doing a taste test concerning baked goods. She also told Ms. Xu that she represented a potential customer. Sacks Tr. 167.

167. Ms. Xu told Ms. Sacks, possibly in response to questions from Ms. Sacks, that acesulfame potassium does not have an aftertaste, it is stable in heat, and there is a better flavor if acesulfame potassium is blended with sugar or aspartame. Sacks Tr. 167-168, 188-189.

168. They also discussed pricing, and Ms. Xu said that blending could cut down costs. Sacks Tr. 168.

169. The conversation lasted less than 15 minutes. Sacks Tr. 168.

170. Ms. Xu requested that Ms. Sacks send a fax requesting a sample of acesulfame potassium, and that after such fax was received Ms. Xu would send the sample. Sacks Tr. 168.

171. CX-31C is a memorandum that Ms Sacks wrote on September 3, 1997, that sets out her discussion with Ms. Xu, as required by IGI's standard business practice. Sacks Tr. 168; CX-31C.

172. At the bottom of CX-31, Ms. Sacks notes that she attempted to contact Dingsheng. Sacks Tr. 168, CX-31C.

173. The memorandum is consistent with Ms. Sacks handwritten notes, albeit not a precise transcript of the conversation. Sacks Tr. 169.

174. The memorandum reflects that Ms. Xu said that acesulfame potassium had the best flavor when blended with sugar or aspartame, as well as Ms. Xu's recommendation to blend to cut down costs. Sacks Tr. 169; CX-31C.

175. Those comments are consistent with Ms. Sacks's memory of the conversation. Sacks Tr. 169.

176. CX-30C is a copy of the fax that Ms. Sacks sent Ms. Xu requesting a sample. Sacks Tr. 169-170; CX-30C.

177. The confirmation sheet indicates that the fax successfully transmitted. Sacks Tr. 171; CX-30C.

178. Ms. Sacks had a second conversation with Ms. Xu later in September, the exact date of which she did not recall. Sacks Tr. 172.

179. CX-36C are Ms. Sacks's handwritten notes taken about that second conversation, which took place September 17, 1997. Sacks Tr. 172-73; CX-36C.

180. Ms. Xu told Ms. Sacks that acesulfame potassium is used in Jell-O, chewing gum, and some other products. She said she could not give references because she was short of staff, and would not have time to contact the customers to get permission. Sacks Tr. 173; CX-36C.

181. In 1993, it was public knowledge that Kraft General Foods (Jell-O) and other companies blended acesulfame potassium with aspartame in their products. CX-188.

182. At some point in the conversation, Ms. Xu told Ms. Sacks that JRS does not supply Coca-Cola in the United States because Ace-K is not approved for beverages. Sacks Tr. 173; CX-36C.

183. It is standard IGI procedure to take notes during a conversation, which is the same procedure that Ms. Sacks followed with her second conversation with Jane Xu. Sacks Tr. 173.

184. CX-32C is a memorandum written on September 8, 1997 to Larry Shatzer of Foley and Lardner discussing the site surveys that were completed on JRS and Dingsheng, as well as discussing the first two contacts that Ms. Sacks had with JRS and Dingsheng. Sacks Tr. 174; CX-32C.

185. Ms. Sacks wrote this memorandum because it is IGI procedure to write a report to the client providing them with all information

to date. Sacks Tr. 174.

186. Ms. Sacks wrote this memorandum personally, basing it on the information she had available at the time. Sacks Tr. 174.

187. Page 4 of the memorandum under the heading "Inquiries" describes conversations that Ms. Sacks had with Jane Xu and Jane Hu. Sacks Tr. 174-175; CX-32C.

188. The conversation described with Jane Xu of JRS in the memorandum is an accurate representation of the discussion that took place with Mr. Xu on September 3, 1997, even though it may not contain all the points covered in the conversation. Sacks Tr. 175.

189. In the memorandum there is information regarding Ms. Xu's comments about blending acesulfame potassium to the effect that Ms. Xu stated that acesulfame potassium could be blended with other sweeteners to reduce costs and that acesulfame potassium had the best flavor when blended with sugar or aspartame. Sacks Tr. 175; CX-32C.

190. CX-37C is a memorandum that Ms. Sacks wrote to Larry Shatzer of Foley and Lardner on September 18 that sets out the site survey for WYZ Tech and also Ms. Sacks's follow-up inquiry with JRS and Dingsheng. Sacks Tr. 176, CX-37C.

191. The information conveyed in the memorandum marked CX 37 regarding Ms. Sacks's second conversation with Ms. Xu is a summary of the conversation she had with her, although again it may not contain all of the points discussed in the conversation. Sacks Tr.

176-177.

192. In preparing this memorandum about her second conversation with Ms. Xu, Ms. Sacks based her comments on her handwritten notes that she had taken during the conversation and also recollections that she had. Sacks Tr. 177.

193. After Ms. Sacks second conversation with Ms. Xu, Ms. Sacks had no further contact with Ms. Xu. Sacks Tr. 177.

194. CX-36C, page 4 contains handwritten notes that Ms. Sacks took concerning her first contact with Dingsheng and of her first conversation with Jane Hu. Sacks Tr. 177; CX-36C.

195. Ms. Sacks called the number that she had for Dingsheng and was later called back by Jane Hu. Sacks Tr. 177.

196. During the course of Ms. Sacks's conversation with Ms. Hu, Ms. Hu described acesulfame potassium and told Ms. Sacks the negatives of aspartame and also told her about the price, as well as the benefit of blending acesulfame potassium with aspartame to get a better effect. Sacks Tr. 178; CX-36C.

197. This information is contained in Ms. Sacks's handwritten notes that were written throughout her conversation with Ms. Hu. These notes are not a complete transcript of the conversation, but rather just reflect the main points of the conversation. Sacks Tr. 178.

198. CX-32C is Ms. Sacks's September 8, 1997 memorandum to Larry Shatzer of Foley and Lardner reflecting her conversation with Ms.

Hu from Dingsheng. The memorandum may not have all the points of the conversation in it, but it is a summary discussed during the conversation. Sacks Tr. 178-179, CX-32C.

199. In the memorandum, there is no mention of Ms. Hu's comments about blending even though they are indicated in Ms. Sacks handwritten notes. Sacks Tr. 179; CX-32C.

200. Ms. Sacks has a recollection of discussing blending with Ms. Hu. Sacks Tr. 179.

201. In the conversation, Ms. Sacks discussed obtaining a sample and gave Ms. Hu her address over the phone. Sacks Tr. 179-180.

202. Ms. Sacks had a follow up conversation with Ms. Hu the same day that Ms. Sacks contacted Jane Xu the second time. Sacks Tr. 182.

203. Pages 1 and 2 of CX-36C are Ms. Sacks handwritten notes that she took during her follow up conversation with Jane Hu. Sacks Tr. 183; CX-36C.

204. In that conversation, Ms. Sacks discussed with Ms. Hu any references that she might have from customers and also any products Ms. Hu knew that contained acesulfame potassium so that Ms. Sacks could sample them. Sacks Tr. 183.

205. During the conversation, Ms. Hu said that acesulfame potassium is used in candy such as roll-up candies and that she had seen it used by small bakeries at a convention in Florida that she had been to. Sacks Tr. 183; CX-36C.

206. Ms. Hu told Ms. Sacks that she could not provide her with any

references because it was a new product for them and they did not yet know the market. Sacks Tr. 183; CX-37C.

207. CX- 37C is a September 18, 1997 memorandum written to Larry Shatzer of Foley and Lardner from Ms. Sacks that is a summary of Ms. Sacks's follow-up conversation with Jane Hu. Sacks Tr. 183-184; CX-37C.

208. CX-37C is a summary of Ms. Sacks second conversation with Jane Hu, although it might not contain every single point that she discussed with Ms. Hu. Sacks Tr. 184.

209. In preparing CX-37C, Ms. Sacks based her statements on her handwritten notes and the recollections she had of her conversation with Ms. Hu. Sacks Tr. 184.

210. After Ms. Sacks second conversation with Ms. Hu, she did not have any further contact with her. Sacks Tr. 184.

211. On the exhibit marked CX-31C, Ms. Sacks believes that the memo only suggests that she was the first to bring up pricing and not that she was the first to bring up blending. Sacks Tr. 195-196.

212. The page in CX-131C relating to acesulfame potassium contains a section entitled Excellent Synergy, which reads: "Use of Acesulfame K with other non-nutritive sweeteners can result in synergistic effect. The level of perceived sweetness becomes greater than the sum of the parts. As a result, as much as 20-40% less total sweetener may be requid [sic] to achieve the desired sweetness level." CX-131C.

213. For the Orlando IFT show in June 1997, Jane Xu recommended to Gary Zong that the Excellent Synergy language be blocked out because of the April 29, 1997 letter that JRS had received from Robert Hammer of Hoechst stating that the brochure's suggestion of blending with other non-nutritive sweeteners could be an infringement of Nutrinova's (Hoechst's) patent. RX-42C (Xu Dep.) Tr. 139; CX-118C.

214. Upon receipt of the Hammer letter (CX-118C), Ms. Xu faxed a copy to Gary Zong. RX-42C (Xu Dep.) Tr. 140, 163.

215. Gary Zong orally replied

. RX-42C (Xu Dep.) Tr. 140, 163-164.

216. Ms. Xu did not consult an attorney about the representations set forth in Mr. Hammer's letter. RX-42C (Xu Dep.) Tr. 140-141.

217. In speaking with Mr. Zong, Ms. Xu recommended that for the upcoming Orlando IFT show that JRS (and Dingsheng/WYZ Tech.) block out the language in the brochure concerning Excellent Synergy. RX-42C (Xu Dep.) Tr. 141.

218. Ms. Xu recommended blocking out the language because

RX-42C (Xu Dep.) Tr. 142.

219. Jane Xu distributed copies of the acesulfame potassium page of

the brochure with the Excellent Synergy language unobscured at the Edison, New Jersey IFT show. RX-42C (Xu Dep.) Tr. 143.

220. The Edison, New Jersey IFT show was in March or April 1997. RX-42C (Xu Dep.) Tr. 146.

221. At the June IFT show in Orlando, Dingsheng provided all copies of promotional materials, including the acesulfame potassium page with the Excellent Synergy language blocked out. RX-42C (Xu Dep.) Tr. 149.

222. Present at the Orlando IFT trade show were Jane Xu, Gary Zong and Jane Hu of WYZ Tech. at the same booth. RX-42C (Xu Dep.) Tr. 150.

223. At both trade shows, JRS had samples of acesulfame potassium available. RX-42C (Xu Dep.) Tr. 153.

224. The samples were a small amount (e.g., one teaspoon or so) in a small, zip-lock bag. RX-42C (Xu Dep.) Tr. 154.

225. At the Edison, New Jersey IFT show, Ms. Xu spoke with Andres Lotz of Nutrinova (Hoechst). RX-42C (Xu Dep.) Tr. 158.

226. The Hoechst employee who took a few samples and informed Ms. Xu that JRS might be violating a Hoechst patent. RX-42C (Xu Dep.) Tr. 159-162.

227. Ms. Xu and Mr. Lotz spoke after the Edison, New Jersey IFT show about setting up a possible meeting. A meeting was never arranged. However, JRS received the April 29, 1997 letter from Robert Hammer. RX-42C (Xu Dep.) Tr. 160.

228. After speaking with Mr. Lotz, Ms. Xu did not contact Mr. Gary Zong about the contents of her conversation(s). RX-42C (Xu Dep.) Tr. 163.

229. Ms. Xu subsequently received a call from someone at Hoechst regarding Mr. Hammer's letter, and she suggested the caller contact Sanhe directly. RX-42C (Xu Dep.) Tr. 164-165.

230. Over 100 of the 209 blends listed on RX-56C (Sunett Product List) are outside the scope of the '068 patent. RX-56C; Lipinski Tr. 133-135.

V. Domestic Industry

1. Complainants have made significant investments in plant and equipment with respect to the patents at issue at their Somerset, New Jersey facility. These investments include: an approximately square foot facility, and at least to construct and equip a sensory laboratory, a formulation laboratory and a pilot plant laboratory as detailed in paragraphs 7.2 to 7.8 of the complaint, as amended. CX-8C.

2. Complainants have invested a significant amount in labor and capital at their Somerset New Jersey facility as detailed in paragraphs 7.2 to 7.12 of the complaint, as amended. This investment includes employees dedicated to acesulfame potassium. These employees include full time employees working in research and development on acesulfame potassium.

Four of these employees have advanced degrees, including Ph.D. degrees and one with a Masters Degree in the areas of food science and technology. CX-8C.

3. Complainants carry out significant research and development with respect to the patents at issue in their Somerset, New Jersey facility as detailed in paragraphs 7.2 through 7.9 of the complaint, as amended. This research and development includes working directly with customers to create blend recipes or formulas for each customer's products. Many of complainants' customers could not use acesulfame potassium without the assistance of complainants' research and development staff. CX-8C.

4. Complainants carry out significant activities related to obtaining regulatory approval for acesulfame potassium at their Somerset, New Jersey facility as detailed in paragraphs 7.9 and 7.10 of the Complaint, as amended. Complainants have invested over over the last three years in testing costs, technical support costs, expert and legal consulting fees and other expenses directly related to obtaining regulatory approval for acesulfame potassium in the United States. CX-8C.

5. Complainants have granted either express or implied licenses to all of their customers in the United States under U.S. Patent No. 4,158,068. CX-8C.

6. Complainants acesulfame potassium sold in the United States is

manufactured by a process covered by one or more claims of U.S. Patent No. 4,695,629. CX-8C.

7. Complainants and their customers in the United States practice blending of acesulfame potassium with other non-nutritive sweeteners within the scope of one or more claims of U.S. Patent No. 4,158,068. CX-8C.

CONCLUSIONS OF LAW

1. The Commission has personal jurisdiction over the parties and subject matter jurisdiction over this investigation. *See* Op. at 2-3.

2. There have been importations and sales after importation of accused products. *See* Op. at 22.

3. It has been established by clear and convincing evidence that the claims of the '068 patent are invalid for obviousness under 35 U.S.C. § 103. *See* Op. at 45.

4. It has not been established that the claims of the '068 patent are invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶ 1. *See* Op. at 47.

5. It has not been established that respondents have infringed any claim of the '629 patent. *See* Op. at 117-119.

6. It has not been established that respondents have induced infringement of the '068 patent. *See* Op. at 141-143.

7. The domestic industry requirement of section 337 is satisfied. *See* Op. at 144.

8. There is no violation of section 337.

INITIAL DETERMINATION AND ORDER

Based on the foregoing opinion, findings of fact, conclusions of law, the evidence, and the record as a whole, and having considered all pleadings and arguments as well as proposed findings of fact and conclusions of law, it is the administrative law judge's INITIAL DETERMINATION ("ID") that no violation of § 337 exists in the importation or sale of certain acesulfame potassium and products containing same by reason of infringement of claims 1, 2, 3, 4 or 5 of U.S. Letters Patent 4,695,629, or claims 1 or 2 of U.S. Letters Patent 4,158,068.

The administrative law judge hereby CERTIFIES to the Commission this ID, together with the record of the hearing in this investigation consisting of the following:

1. The transcript of the hearing, with appropriate corrections as may hereafter be ordered by the administrative law judge; and further,

2. The exhibits accepted into evidence in this investigation as listed in the attached exhibit lists.

In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential by the administrative law judge under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are

signatories to the Protective Order (Order No. 1 *as modified by* Order No. 6) issued by the administrative law judge in this investigation, and the Commission investigative attorney. To expedite service of the public version, counsel are hereby ORDERED to serve on the administrative law judge by no later than November 30, 1998, a copy of this ID with those sections considered by the party to be confidential bracketed in red.

Pursuant to 19 C.F.R. § 210.42(h), this ID shall become the determination of the Commission unless a party files a petition for review pursuant to § 210.43(a) or the Commission, pursuant to § 210.44, orders on its own motion a review of the ID or certain issues herein.

Sidney Harris
Administrative Law Judge

Issued: November 20, 1998

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	)	
	)	
CERTAIN ACESULFAME POTASSIUM AND BLENDS AND PRODUCTS CONTAINING SAME	)	Investigation No. 337-TA-403
	)	
	)	
	)	

Order No. 23: Denying Complainants' Motion No. 403-26 for Sanctions

On May 12, 1998, complainants Nutrinova Nutrition Specialties and Food Ingredients GmbH and Nutrinova, Inc. filed their Motion of Complainants for Sanctions Against Respondents for Failure to Comply with Discovery Orders. Motion Docket No. 403-26.

On May 22, 1998, respondents Hangzhou Sanhe Food Company Ltd., Hangzhou Sanhe Food Additives Factory, Dingsheng Inc., WYZ Tech, Inc., and JRS International, Inc. filed their opposition to complainants' motion for sanctions.

On May 27, 1998, complainants filed a motion for leave to reply (Motion Docket No. 403-28), and a reply. Motion No. 403-28 to reply is GRANTED.

On May 28, 1998, the Commission Investigative Staff filed its response, which supports in part and opposes in part complainants' motion for sanctions.

The parties have filed numerous additional pleadings concerning

complainants' motion for sanctions, including: a report from complainants filed on June 5, 1998; a statement from respondents filed on June 5, 1998; a motion for leave to reply (Motion Docket No. 403-33),[1] and a reply filed on June 8, 1998; a memorandum from respondents filed on July 22, 1998; and a post-hearing submission from complainants filed on July 29, 1998.

At issue in complainants' motion for sanctions and the subsequent related pleadings is the question of whether respondents failed to comply in a timely manner with certain portions of Order No. 4 ("Compelling Production of Documents, Answers to Interrogatories and Inspection of Plant Facilities") and Order No. 5 ("Order Implementing Order No. 4").

As described by complainants in their motion for sanctions, the compelled discovery at issue consists of voluminous documents falling into four categories: (1) Workshop Processing Records; (2) Batch Reports; (3) Construction and Equipment Installation Plans, Drawings and Invoices; and (4) Invoices for the Processing of [

]

Having considered the pleadings filed in connection with complainants' motion for sanctions, as well as the relevant testimony of witnesses and arguments of counsel presented during the hearing in this investigation, the administrative law judge has determined that

---

[1] Respondents' Motion No. 403-33 to reply is GRANTED.

respondents did in fact fail to comply with certain portions of Orders No. 4 and No. 5 in a timely manner. The administrative law judge does not find, as argued by respondents, that much or all of the discovery at issue was compelled only under a later discovery Order. Rather, it is found that many documents responsive to Orders No. 4 and No. 5, and the underlying discovery requests, were produced late. Most if not all of the discovery at issue was produced substantially after the February 20, 1998 due date established by Order No. 5 for interrogatory responses and document production.

Pursuant to 19 C.F.R. § 210.33(b) and (c),[2] complainants

---

[2] Commission Rule 210.33(b)-(c) provides as follows:

> (b) *Non-monetary sanctions for failure to comply with an order compelling discovery.* If a party or an officer or agent of a party fails to comply with an order including, but not limited to, an order for the taking of a deposition or the production of documents, an order to answer interrogatories, an order issued pursuant to a request for admissions, or an order to comply with a subpoena, the administrative law judge, for the purpose of permitting resolution of relevant issues and disposition of the investigation without unnecessary delay despite the failure to comply, may take such action in regard thereto as is just, including, but not limited to the following:
>
> (1) Infer that the admission, testimony, documents, or other evidence would have been adverse to the party;
>
> (2) Rule that for the purposes of the investigation the matter or matters concerning the order or subpoena issued be taken as established adversely to the party;

(continued...)

[2] (...continued)

(3) Rule that the party may not introduce into evidence or otherwise rely upon testimony by the party, officer, or agent, or documents, or other material in support of his position in the investigation;

(4) Rule that the party may not be heard to object to introduction and use of secondary evidence to show what the withheld admission, testimony, documents or other evidence would have shown;

(5) Rule that a motion or other submission by the party concerning the order or subpoena issued be stricken or rule by initial determination that a determination in the investigation be rendered against the party, or both; or

(6) Order any other non-monetary sanction available under Rule 37(b) of the Federal Rules of Civil Procedure. Any such action may be taken by written or oral order issued in the course of the investigation or by inclusion in the initial determination of the administrative law judge. It shall be the duty of the parties to seek, and that of the administrative law judge to grant, such of the foregoing means of relief or other appropriate relief as may be sufficient to compensate for the lack of withheld testimony, documents, or other evidence. If, in the administrative law judge's opinion such relief would not be sufficient, the administrative law judge shall certify to the Commission a request that court enforcement of the subpoena or other discovery order be sought.

(c) *Monetary sanctions for failure to make or cooperate in discovery.* (1) If a party, or an officer, director, or managing agent of the party or person designated to testify on behalf of a party fails to obey an order to provide or permit discovery, the administrative law judge or the Commission may make such orders in regard to the failure as are just. In lieu of or in addition to

(continued...)

request the imposition of both non-monetary and monetary sanctions.[3]

With respect to non-monetary sanctions, complainants request that a default judgment be entered against respondents to the effect that respondents infringe U.S. Patent No. 4,695,629, which is one of the

---

[2] (...continued)

> taking action listed in paragraph (b) of this section and the extent provided in Rule 37(b)(2) of the Federal Rules of Civil Procedure, the administrative law judge or the Commission, upon motion or sua sponte under § 210.25, may require the party failing to obey the order or the attorney advising that party or both to pay reasonable expenses, including attorney's fees, caused by the failure, unless the administrative law judge or the Commission finds that the failure was substantially justified or that other circumstances make an award of expenses unjust. Monetary sanctions shall not be imposed under this section against the United States, the Commission, or a Commission investigative attorney.
>
> (2) Monetary sanctions may by imposed under this section to reimburse the Commission for expenses incurred by a Commission investigative attorney or the Commission's Office of Unfair Import Investigations. Monetary sanctions will not be imposed under this section to reimburse the Commission for attorney's fees.

19 C.F.R. § 210.33 (b)-(c).

[3] The administrative law judge concurs with the Commission Investigative Staff that complainants' motion for sanctions does not establish an adequate basis for the imposition of monetary sanctions. It has not been established that respondents' tardy production of discovery has resulted in significant added expenses, e.g., a second plant inspection or the taking of deposition testimony that would not otherwise have been necessary. However, for the reasons discussed in detail, *infra*, additional costs may yet be incurred by complainants in order to cure prejudice resulting from respondents' tardy production of discovery, and respondents may be required to pay those costs.

patents at issue in this investigation. In the alternative, it is requested that numerous adverse inferences be drawn against respondents, and that respondents be precluded from introducing into evidence any documents subject to Order No. 4 which were produced after February 20, 1998.

When relevant documents are produced but were not made available until after the date required by an Order compelling their production, the sanction that most likely would be imposed in the usual case is one of evidence preclusion, or possibly the drawing of inferences which would make the introduction of certain evidence useless. By precluding respondents from relying on the subject documents it would ordinarily be the case that a message of deterrence would be sent to respondents and future litigants, and complainants would be relieved of any prejudice they might otherwise suffer as a result of late production.

However, the documents at issue in this case are of such a material nature to this investigation that preclusion of evidence could potentially be tantamount to a judgment in complainants' favor, or could result in an initial determination that relies heavily on adverse inferences and deliberately excludes and ignores evidence which is highly probative of core infringement issues.

When considering the imposition of sanctions under Federal Rule of Civil Procedure 37, upon which Commission Rule 210.33 is in large part based, it has been recognized that the exclusion of "critical

evidence" is an "extreme sanction," not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995); *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977); *Dudley v. South Jersey Metal*, 555 F.2d 96, 99 (3d Cir. 1977).

Furthermore, "[i]n considering a Rule 37 sanction, the court is compelled to examine all pertinent circumstances of the case. *** Additionally, the court must keep in mind the sound social policy of deciding cases on their merits and against this policy, balance considerations of sound judicial administration and the need to deter parties from abusing the discovery process." *Transportes Aereos de Angola v. Ronair, Inc.*, 104 F.R.D. 482, 508 (D. Del. 1985)(citing, *inter alia*, *Davis v. Williams*, 588 F.2d 69 (4th Cir. 1978)).

The policy to decide cases on their merits is heightened in this investigation because of the requirement of the Administrative Procedure Act to make a complete record, and because this investigation is not aimed solely at providing relief to a private party but rather at making findings upon which to base governmental action, which must be consistent with the public interest.

In this case, the documents at issue purport to disclose information concerning the raw materials and intermediaries used by respondents, and the actual formulation and manufacture of substantial

amounts of the accused acesulfame potassium. Such information, if reliable and adequately explained, is strong evidence of whether or not respondents infringe the '629 patent. Indeed, it can hardly be doubted that a record of how a product was actually manufactured is superior to deduction concerning which process was used based upon circumstantial evidence. Furthermore, the documents at issue were the subject of inspection by the administrative law judge at the hearing and were used on direct and cross-examination by the parties. Despite some suggestion from complainants to the contrary, there is no indication that the documents at issue lack authenticity.

Under these circumstances, respondents' actions or inactions would have to be particularly egregious, and the prejudice to complainants would have to be particularly severe, in order for the administrative law judge to nullify or ignore such critical evidence by ordering evidence preclusion or the imposition of adverse inferences that are possibly contrary to the evidence. While it has been shown that complainants have suffered at least a substantial amount of prejudice, egregious conduct on respondents' part has not been established.

It appears from the pleadings and testimony of the witnesses that a number of factors combined to result in respondents' tardiness. Especially at first, despite instructions from respondents' counsel, respondents' employees in China who had custody of the documents at issue did not fully appreciate the necessity of producing all

information and documents responsive to discovery requests and orders, or the penalties for failing to comply fully and promptly with orders compelling discovery. In large part, this was due to linguistic, cultural and legal differences between the United States and China, as well as the inexperience of respondents with litigation, especially litigation in the United States.

It also appeared from respondents' hearing testimony that they were hampered by a lack of supporting personnel. Indeed, it appeared that responses to requests for discovery, including the task of locating and sending documents to counsel in the United States, was carried out exclusively or primarily by only two individuals, i.e., Dr. Qiu, whose primary concerns are ordinarily the technical aspects of product development and the daily production activities of the Sanhe plant in Hangzhou, and Mr. Zong who is a factory executive and a government cadre assigned to Sanhe. *See* Zong Tr. 1066, 1083-1084, 1090-1093. It further appeared that the delays in production were influenced by the need to spend a significant amount of time obtaining permission from the government authorities to produce trade secrets under the Protective Order for the purposes of this investigation, and also to arrange for a plant inspection by complainants.[4]

---

[4] The government in China at first denied permission to conduct a plant inspection involving opposing counsel and foreign experts, and additional intercession by Mr. Zong along with a request from the administrative law judge was required for the inspection to go forward. Respondents represent that they are unaware of any other (continued...)

Indeed, there was evidence presented at the hearing that the local government, and to a certain extent the national Chinese government, have a stake in the Sanhe respondents, and that the Sanhe respondents are subject to governmental supervision. *See, e.g.,* Zong Tr. 1064, 1115. Certain aspects of the Sanhe respondents' operations are deemed state secrets by the Chinese government and severe penalties attach to the unauthorized distribution of such secrets. These facts had a direct effect on the availability of timely discovery in this investigation. For example, the workshop processing records, which are of crucial importance in this investigation, could not be discussed with United States counsel and could not be released without the specific approval of the local government. Mr. Zong was required to intercede personally in order for the workshop records to be produced. *See* Opp. of Respondents to Complainants' Motion for Sanctions at 5-6; Zong Tr. 1074-1079; RX 209; RX 151.

The problems and concerns facing Dr. Qiu and Mr. Zong caused them to prioritize their efforts, and clearly they made decisions that resulted in discovery arriving too late to be used properly by the other parties. Unilateral decisions about what to produce and when to produce it are not excused, and respondents through their counsel should have sought relief from the administrative law judge and possibly even a continuance of the proceedings, rather than

---

[4] (...continued)
such inspection in China as part of U.S. patent litigation.

compounding problems by making late production to complainants who were also burdened with discovery requests and their own hearing preparations.

It also did appear to the administrative law judge that respondents' employees were slow to provide full disclosure of the required documents due to their desire to protect their secrecy and the competitive position of their businesses. These are tendencies among litigants and companies which, although apparently universal in their nature, cannot ordinarily be excused. However, when sovereign governments are involved experience teaches that delays are usual. The administrative law judge finds no basis upon which to conclude that respondents' reluctance to produce everything required of them and the ensuing delays were premised on bad faith, a plan to deceive either complainants or the Commission, or a flagrant disregard of discovery orders.

Although all of the documents were eventually produced, some of the critical documents were not produced until quite late in the investigation. For example, respondents admit that the workshop processing records, the batch reports, certain invoices pertaining to raw materials, and invoices relating to [ ] in the manufacturing process were not produced to complainants until late May and early June, 1998. Consequently, documents crucial to complainants' case were not made available for the commencement of analysis until just days or a few weeks before hearing exhibits and

prehearing statements were due.

Although complainants and the Commission Investigative Staff were able to cross-examine respondents' witnesses at the hearing on the documents at issue, complainants and the Commission Investigative Staff have argued that severe prejudice resulted from respondents' late production of critical documents. In particular, complainants' witnesses, including complainants' witness Dr. Stalick, had to prepare for the hearing and to prepare several exhibits without the benefit of all relevant evidence. This not only hampered complainants' experts but also denied the administrative law judge the opportunity to learn how complainants' experts would have analyzed critical evidence and presented their arguments had they been fully informed of the facts to which they were entitled.

As discussed above, the administrative law judge has determined not to exclude relevant evidence from the case or to draw inferences that render the evidence a nullity. Although courts often find themselves compelled to sanction litigants for the types of delays and prejudice caused by respondents, the administrative law judge does not find it to be in the public interest to disregard the large amount of probative, reliable evidence that is now available and which, to a certain extent, was used at the hearing.

Complainants must be offered the opportunity to reopen the record and, if necessary, to present additional facts and arguments relevant to respondents' belatedly produced documents. This will cure the

prejudice caused by the late production of the discovery, and it will allow the administrative law judge to make a complete record by making sure that all parties have had an adequate opportunity to present their analyses of the more recently obtained evidence.

Therefore, if complainants desire a further opportunity to address any of the evidence at issue in their motion for sanctions, the administrative law judge would consider a prompt proposal to reopen the evidentiary record. Such a proposal should consist of specific descriptions of prejudice occasioned by respondents' tardy production of discovery, as well as specific proposals to cure or ameliorate the prejudice on the record.

Inasmuch as the need to reopen would arise from respondents' late production of critical evidence in this investigation, complainants cannot be made financially liable for the reopening of the record. Therefore, the administrative law judge would also consider proposals for respondents to bear the costs incurred by complainants in reopening the record.

Accordingly, to the extent discussed above, respondents' Motion No. 403-26 is DENIED.[5]

---

[5] Since the filing of complainants' motion for sanctions, respondents offered several exhibits into evidence based on documents reflecting the subject matters covered by complainants' motion, i.e, RX-210C, RX212C through RX-225. Most of these exhibits consist of, or are based largely on, documents that were not produced in a timely manner. In the case of RX-224, it appears that the document was not produced in advance of the underlying exhibit. Complainants moved at

(continued...)

By August 21, 1998, each party shall submit to the office of the administrative law judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version thereof. The parties' submissions may be made by facsimile and/or hard copy. By the aforementioned date, any party seeking to have any portion of this document deleted from the public version must submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information. The parties' submissions concerning the public version of this document need not be filed with the Commission Secretary.

Sidney Harris
Administrative Law Judge

Issued: August 14, 1998

---

[5] (...continued)
the hearing to strike these exhibits. Inasmuch as the administrative law judge has determined not to preclude evidence covered by complainants' motion for sanctions, the exhibits will not be rejected or stricken from the evidentiary record.