

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN NON-SHELLFISH DERIVED  
GLUCOSAMINE AND PRODUCTS  
CONTAINING SAME

Inv. No. 337-TA-668

2009 JUN 22 PM 3:47  
GFC OFFICE OF THE SECRETARY  
US ITC

**ORDER NO. 20: DENYING RESPONDENT NFT'S MOTION FOR SUMMARY DETERMINATION OF INVALIDITY**

(June 22, 2009)

On June 1, 2009, respondent Nantong Foreign Medicines & Health Products Co., Ltd. ("NFT") filed a motion for summary determination that claims 1-10 of U.S. Patent No. 7,049,433 ("the '433 patent") are invalid. (Motion Docket No. 668-022.) On June 11, 2009, complainant Cargill, Incorporated filed a response opposing the motion. On June 12, 2009, the Commission Investigative Staff ("Staff") filed a response supporting the motion in part. On June 18, 2009, NFT filed a motion for leave to file a reply, which is hereby GRANTED. (Motion Docket No. 668-028.)<sup>1</sup> On June 19, 2009, Cargill filed a response to NFT's motion for leave to file a reply.

In this investigation, Cargill asserts that NFT infringes claims 1-10 of the '433 patent. Claim 1 is an independent claim, and claims 2-10 are dependent claims that depend from claim 1. Claim 1 requires:

<sup>1</sup> In its reply brief, NFT raises a Polish patent (hereinafter "the Kocourek patent") as a piece of prior art. Because the Kocourek patent was not raised in NFT's original motion for summary determination or in the responses filed by Cargill and Staff, I will not consider the Kocourek patent in deciding NFT's motion. New arguments raised in reply are not proper. See *Certain Above-Ground Swimming Pools*, Inv. No. 337-TA-25, 1977 ITC LEXIS 8, at \*13-14 (Feb. 10, 1977) (holding that "any new issues raised for the first time in reply briefs which were not direct responses to discussions of the same issue or issues in the brief to which the reply was addressed" will not be considered).

1. A method of obtaining glucosamine from fungal biomass, the method comprising the steps of:

(a) providing the fungal biomass;

(b) reacting the fungal biomass in an acidic solution with an acid concentration of greater than 5 percent by weight at a reaction temperature greater than 80°C. for a reaction period of at least 4 hours to convert chitin in the fungal biomass to glucosamine; and

(c) separating the glucosamine from the acidic solution; wherein the method has a yield of glucosamine of greater than 50% of total chitin content of the fungal biomass.

NFT argues that a July 1983 paper in APPLIED & ENVIRONMENTAL MICROBIOLOGY by George C. Chen and Bruce R. Johnson, entitled “Improved Colorimetric Determination of Cell Wall Chitin in Wood Decay Fungi,” (hereinafter “Chen”) anticipates claims 1-6 of the ‘433 patent. NFT claims that “Chen discloses a method for obtaining glucosamine through the acid hydrolysis of fungal biomass from wood decay fungi.” (Mem. at 11.) NFT includes a declaration from its expert, Dr. Channing Robertson, which allegedly identifies where each claim element of claims 1-6 appears in Chen. (See Robertson Decl. at ¶¶ 35-38, Ex. 8.)

NFT claims that the combination of Chen and a 1997 paper in the RUSSIAN JOURNAL OF APPLIED CHEMISTRY by V. Yu. Novikov and A.L. Ivanoc, entitled “Synthesis of D(+)-Glucosamine Hydrochloride,” (hereinafter “Novikov”) renders claims 7-9 obvious. Claims 7-9 are each dependent on claim 1. NFT claims that Chen discloses all of the limitations from claim 1, and that Novikov discloses the additional limitations included in claims 7-9. NFT asserts that “there is no doubt that the combination of Chen and Novikov would have made claims 7-9 obvious to one of ordinary skill in the art at the time of the invention.” (Mem. at 17.) NFT supports its argument with a declaration from Dr. Robertson. (See Robertson Decl. at ¶¶ 40-44, Ex. 10.)

NFT claims that the combination of Chen and a 1998 article by Yang, entitled “Acidic Hydrolysis & Determination of Fungal Mycelium in Cereals,” (hereinafter “Yang”) renders claim 10 obvious. Claim 10 is dependent on claim 1. NFT claims that Chen discloses all of the limitations from claim 1, and that Yang discloses the additional limitation included in claim 10. NFT supports its argument with a declaration from Dr. Robertson. (See Robertson Decl. at ¶ 45, Ex. 12.)

NFT claims that it has put forward a strong *prima facie* case of obviousness with regard to claims 7-10. Citing *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007), NFT argues that Cargill cannot overcome the strong *prima facie* showing of obviousness with evidence of secondary considerations.

Cargill opposes NFT’s motion in its entirety. Cargill claims that Chen does not disclose the following claim elements of claim 1: (1) “fungal biomass;” (2) “separating the glucosamine from the acidic solution;” and (3) “a yield of glucosamine of greater than 50% of total chitin content of the fungal biomass.” (Resp. at 13-18.) Because claims 2-6 depend on claim 1, Cargill argues that Chen fails to anticipate any of claims 1-6 because it fails to disclose all the elements of any of those claims.

With regard to claims 7-10, Cargill argues that there was no apparent reason to combine the references identified by NFT, and that the art of producing glucosamine was unpredictable. (*Id.* at 20-22.) Cargill reiterates its arguments that Chen fails to disclose the limitations of claim 1. Cargill asserts that Novikov is directed to the separation and purification of glucosamine from purified shellfish chitin. Cargill claims that the hydrolysate in Novikov had 5% impurities and 95% glucosamine, as opposed to the 90% impurities and 10% glucosamine found in the hydrolysate of fungal biomass. (*Id.* at 23.) Cargill states that “[o]ne of ordinary skill in the art

would have no reasonable expectation that Novikov would achieve the same results by starting with a sample of fungal biomass.” (*Id.*) Cargill also argues that there was no reason to combine Chen and Novikov because Chen did not address separation of glucosamine from the fungal hydrolysate in the manner Novikov applied to shellfish. (*Id.* at 23-24.)

Cargill asserts that the combination of Chen and Yang do not disclose all of the elements of claim 10. (*Id.* at 24-25.) Further, Cargill asserts that Yang teaches away from using the genuses of fungi listed in claim 10. (*Id.*)

Staff supports NFT’s motion in part. Staff argues that no genuine issues of material fact exist with respect to whether Chen discloses all elements in claims 1-6. (Staff Resp. at 7-12.) Staff therefore supports NFT’s assertion that Chen anticipates claims 1-6. (*Id.*)

Staff does not support NFT’s motion with regard to claims 7-9. Specifically, Staff states that “NFT has failed to show how one of ordinary skill in the art would be motivated to combine [Chen and Novikov] particularly where the Chen Article is concerned with glucosamine obtained from a fungal biomass and Novikov is concerned with glucosamine obtained from shellfish.” (*Id.* at 12.)

Staff does not support NFT’s motion with regard to claim 10. Staff states that “a genuine issue of material fact exists with respect to whether one of ordinary skill would find some teaching or motivation in Yang and the Chen Article or in the field of art to combine these disclosures to reach the subject matter of claim 10.” (*Id.* at 13.)

## **I. Applicable Law**

Commission Rule 210.18 governs summary determination, and states, *inter alia*, that:

The determination sought by the moving party shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with

the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law.

19 CFR § 210.18(b).

The evidence “must be viewed in the light most favorable to the party opposing the motion...with doubt resolved in favor of the nonmovant.” *Crown Operations Int’l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). “Issues of fact are genuine only if the evidence is such that a reasonable [fact finder] could return a verdict for the nonmoving party.” *Id.* at 1375 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The trier of fact should “assure itself that there is no reasonable version of the facts, on the summary judgment record, whereby the nonmovant could prevail, recognizing that the purpose of summary judgment is not to deprive a litigant of a fair hearing, but to avoid an unnecessary trial.” *EMI Group North America, Inc. v. Intel Corp.*, 157 F.3d 887, 891 (Fed. Cir. 1998). “Where an issue as to a material fact cannot be resolved without observation of the demeanor of witnesses in order to evaluate their credibility, summary judgment is not appropriate.” *Sandt Technology, Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1357 (Fed. Cir. 2001) (Dyk, C.J., concurring). “In other words, ‘[s]ummary judgment is authorized when it is quite clear what the truth is,’ [citations omitted], and the law requires judgment in favor of the movant based upon facts not in genuine dispute.” *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1185 (Fed. Cir. 1993).

It is NFT’s burden to prove invalidity, and the burden of proof never shifts to Cargill to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). “Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. §

282, which can be overcome only through facts supported by clear and convincing evidence[.]”  
*SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006).

“A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.” *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). “Anticipation is a question of fact.” *SRAM Corp.*, 456 F.3d at 1357.

Section 103 of the Patent Act states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (2008).

“Obviousness is a question of law based on underlying questions of fact.” *Scanner Techs. Corp.*, 528 F.3d at 1379. The underlying factual determinations include: “(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness.” *Id.* (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are often referred to as the “*Graham* factors.”

## II. Analysis

### A. Claims 1-6

#### 1. The “Separating” Limitation

NFT and Dr. Robertson claim that Chen discloses the step of “separating the glucosamine from the acidic solution” when it states:

After cooling to room temperature, hydrolysates were filtered, and two 0.2-to 1-mil samples of filtrate were withdrawn and evaporated to dryness at 45 to 50°C under reduced pressure. The dry hydrolysates were then redissolved in distilled water to make a solution containing 5 to 15 µg of glucosamine hydrochloride per ml of solution.

(Robertson Decl. at Exs. 5, 8.) NFT asserts that “[a]fter reaction of the fungal biomass in hydrochloric acid, the prior art Chen reference takes samples of the hydrolysis solution and evaporates them ‘to dryness.’ It is indisputable that this evaporation step ‘separates the glucosamine from the acidic solution,’ which satisfies the language of claim 1.” (Reply at 6.)

Cargill asserts that Chen does not disclose the separating limitation. Cargill claims that the object of Chen was to develop a method of glucosamine that did not require separation of the glucosamine from the acid hydrolysate solution. (Resp. at 15-16.) Cargill argues that evaporating the solution to dryness, as disclosed in Chen, is not the same as separating the glucosamine from the acidic solution. As support, Cargill relies on the declaration of its expert, Dr. Samuel M. Hudson. Dr. Hudson states:

Chen never separated the glucosamine from the acid solution, but measured glucosamine liberated into a mixture of products of the acid hydrolysis reaction. Rather than separate the glucosamine from the acid solution, Chen merely dried (by evaporation) the entire acid solution, then redissolved the dried residue in water. Evaporating a solution to dryness, instead of partially evaporating to selectively isolate or crystallize components based on differing solubilities, will leave a mixture of heterogeneous products.

(Hudson Decl. at ¶ 23.)

I find that Cargill has raised a genuine issue of material fact regarding the separating limitation. Cargill asserts that the evaporation step in Chen does not constitute separating the glucosamine from the acidic solution, and supports that assertion with an expert declaration. (Resp. at 15-16.) Thus, the parties clearly dispute the facts regarding what Chen teaches, and whether or not the cited discussion in Chen discloses the “separating” requirement of claim 1. *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1345-1346 (Fed. Cir. 2001) (“What a prior art reference discloses in an anticipation analysis is a factual determination[.]”).

## 2. The “Yield” Limitation

NFT claims that the method disclosed in Chen has a yield of glucosamine of greater than 50% of the total chitin content of the fungal biomass, as required by claim 1. As evidence of this, NFT and Dr. Robertson point to the following passage from Chen: “[t]he chitin content of the cell walls was then calculated as the 1,4-anhydro-N-acetyl-2-deoxy-D-gucopyranose equivalent, with an adjustment of 7% for loss due to hydrolysis.” (Robertson Decl. at Exs. 5, 8.) NFT and Dr. Robertson claim that this passage demonstrates a yield of 93%. (*Id.* at Ex. 8.)

Cargill claims that the cited passage does not demonstrate a yield of glucosamine greater than 50% of the total chitin content of the fungal biomass. Dr. Hudson explains why he believes the cited passage in Chen does not demonstrate the claimed yield:

In short, Chen discloses the amount of liberated glucosamine and not the amount of glucosamine obtained. In addition, Chen fails to disclose the total chitin content in the ruptured and water-washed fungal cell walls. Without the amount of glucosamine obtained from the acid solution and the total chitin content of the fungal biomass, one of ordinary skill in the art cannot determine the yield of glucosamine as recited in subpart (c) of claim 1. In my opinion, the 93% recovery of the glucosamine referred only to the liberation of glucosamine into a mixture of products of the hydrolysis reaction. It does not measure glucosamine crystals obtained from the acid solution.

(Hudson Decl. at ¶ 24) (footnotes omitted.) Cargill argues that at the very least, the passage in Chen is ambiguous with regard to whether the disclosed process results in the claimed yield. (Resp. at 18.)

NFT responds by arguing that Cargill is improperly attempting to require that the yield be measured after all separation steps have taken place. (Reply at 7.) NFT asserts that the specification of the '433 patent demonstrates that yield measurements can be taken prior to completing the purification of the glucosamine. (*Id.*)

I find that Cargill has raised a genuine issue of material fact regarding the yield limitation. Cargill and its expert assert that the yield measured in Chen is not identical to the yield in claim 1 because, *inter alia*, Chen does not measure the chitin content of the starting material. (Resp. at 17-18.) Thus, the parties clearly dispute the facts regarding what Chen teaches, and whether or not the cited discussion in Chen discloses the yield requirement of claim 1. *Tegal Corp.*, 257 F.3d at 1345-1346.

### 3. Conclusion

Based on the competing views of the parties and their experts regarding (1) whether or not the evaporation step disclosed in Chen constitutes “separating the glucosamine from the acidic solution” from claim 1 of the '433 patent; and (2) whether or not Chen discloses a method resulting in a yield of glucosamine of greater than 50% of total chitin content of the fungal biomass, I find that there are genuine issues of material fact which preclude summary determination of anticipation of claims 1-6.<sup>2</sup>

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<sup>2</sup> Claims 2-6 are dependent on claim 1 and thus necessarily contain the disputed “separating” and “yield” limitations.

**B. Claims 7-10**

Each of claims 7-10 are dependent on claim 1. NFT argues that claims 7-9 are obvious based on the combination of Chen and Novikov. (Mem. at 17.) NFT argues that claim 10 is obvious based on the combination of Chen and Yang. (*Id.* at 17-18.) In the analyses for each of these claims, NFT relies solely on Chen to disclose all of the elements of claim 1. (Robertson Decl. at Exs. 10, 12.) Because I have found *supra* that there are genuine issues of material fact that preclude a finding that Chen discloses all elements of claim 1, summary determination of obviousness for claims 7-10 is not proper. 35 U.S.C. § 103; *CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (explaining that obviousness requires the disclosure of all claim limitations in the asserted prior art combination).

ORDER

Motion No. 668-022 is hereby DENIED.<sup>3</sup>

**SO ORDERED.**



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Robert K. Rogers, Jr.  
Administrative Law Judge

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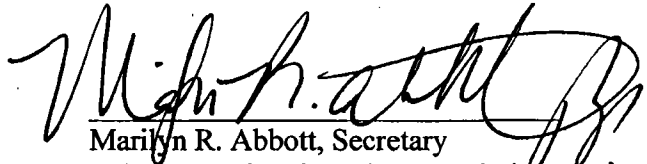
<sup>3</sup> The issues raised by the parties in their briefs but not discussed in this Order were not determinative in reaching my conclusions. They are not decided herein and may be argued in the normal course of the hearing process.

**CERTAIN NON-SHELLFISH DERIVED  
GLUCOSAMINE AND PRODUCTS  
CONTAINING SAME**

Inv. No. 337-TA-668

**PUBLIC CERTIFICATE OF SERVICE**

I, Marilyn R. Abbott, hereby certify that the attached **ORDER** was served upon **Kecia J. Reynolds, Esq.**, Commission Investigative Attorney, and the following parties via first class mail and air mail where necessary on **JUN 23 2009**



Marilyn R. Abbott, Secretary  
U.S. International Trade Commission  
500 E Street SW, Room 112A  
Washington, D.C. 20436

**FOR COMPLAINANT CARGILL, INCORPORATED:**

Reginald R. Goeke, Esq.  
**MAYER BROWN LLP**  
1909 K Street, N.W.  
Washington, DC 20006

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

**FOR RESPONDENTS ETHICAL NATURALS, INC.:**

G. Brian Busey, Esq.  
**MORRISON & FOERSTER LLP**  
2000 Pennsylvania Avenue NW, Suite 6000  
Washington, DC 20006-1888

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

**FOR RESPONDENTS NANTONG FOREIGN MEDICINES & HEALTH  
PRODUCTS CO., LTD and TIANCHENG INTERNATIONAL, INC. (USA):**

James C. Otteson, Esq.  
**WILSON SONSINI GOODRICH & ROSATI**  
650 Page Mill Road  
Palo Alto, CA 94304-1050

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

**RESPONDENTS:**

DNP International, Inc.  
12802 Leffingwell Ave., Bldg. E  
Sante Fe Springs, CA 90670

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

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**PUBLIC CERTIFICATE OF SERVICE PAGE 2**

Heather Hall  
**LEXIS - NEXIS**  
9443 Springboro Pike  
Miamisburg, OH 45342

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_

Kenneth Clair  
**THOMAS WEST**  
1100 Thirteen Street NW, Suite 200  
Washington, D.C. 20005

- Via Hand Delivery
- Via Overnight Mail
- Via First Class Mail
- Other: \_\_\_\_\_