held by the individual defendants and Diversified.

This is not to condone defendants' actions, which were not consistent with standards of behavior to which honorable people aspire. But plaintiff easily could have protected itself against such behavior by negotiating for provisions in the Settlement Stipulation that would have foreclosed Prairie from issuing any new shares without plaintiff's approval or, perhaps, given plaintiff preemptive rights. It is not for the Court to rewrite a contract entered into by a presumably sophisticated investor with the assistance of counsel.

#### Conclusion

The motion to enforce the settlement is denied.

SO ORDERED.



# MARTEK BIOSCIENCES CORPORATION, Plaintiff,

v.

NUTRINOVA INC., Nutrinova Nutrition Specialties & Food Ingredients GMBH, and Lonza, Ltd., Defendants.

Civil Action No. 03-896 GMS.

United States District Court, D. Delaware.

Oct. 30, 2007.

**Background:** Patentee sued competitors, alleging infringement of its patents relating to process for production of microbial products with a high concentration of highly unsaturated fatty acids and processes for growing microorganisms. Judgment

was entered on jury verdict finding jury competitors had wilfully infringed patents, and that patents were valid. Competitors filed motions for judgment as a matter of law (JMOL), and patentee filed motion for permanent injunction.

**Holdings:** The District Court, Gregory M. Sleet, Chief Judge, held that:

- accused process for making nutritional fatty acid that employed sodium hydroxide literally infringed patent directed to a method for growing microorganisms;
- (2) patentee was not estopped from claiming that sodium hydroxide was a "nonchloride sodium salt" or its equivalent;
- (3) substantial evidence supported jury's finding that competitor willfully infringed patent;
- (4) patents were not invalid as anticipated by publication, which was created after the priority date based on prior application;
- (5) evidence was insufficient to support jury's findings rejecting competitor's lack of enablement defense; and
- (6) entry of a permanent injunction to enjoin competitor's further infringement of patents was warranted.

Motions granted in part and denied in part.

## 1. Federal Civil Procedure \$\sim 2142.1\$

A court may render judgment as a matter of law after the moving party is fully heard on an issue at trial, if there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue. Fed.Rules Civ.Proc.Rule 50, 28 U.S.C.A.

#### 2. Federal Civil Procedure \$\sim 2608.1\$

To prevail on a renewed motion for judgment as a matter of law (JMOL) fol-

lowing a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied by the jury's verdict cannot in law be supported by those findings. Fed. Rules Civ.Proc.Rule 50(b), 28 U.S.C.A.

#### 3. Federal Civil Procedure \$\sim 2608.1\$

For purposes of a renewed motion for judgment as a matter of law (JMOL) following a jury trial, "substantial evidence" is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review. Fed.Rules Civ. Proc.Rule 50(b), 28 U.S.C.A.

See publication Words and Phrases for other judicial constructions and definitions.

#### 4. Federal Civil Procedure \$\sim 2609\$

In assessing the sufficiency of the evidence, on a renewed motion for judgment as a matter of law (JMOL) following a jury trial, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. Fed. Rules Civ.Proc.Rule 50(b), 28 U.S.C.A.

#### 5. Federal Civil Procedure \$\sim 2608.1\$

The appropriate inquiry on a renewed motion for judgment as a matter of law (JMOL) following a jury trial is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. Fed.Rules Civ.Proc.Rule 50(b), 28 U.S.C.A.

#### 6. Federal Civil Procedure \$\sim 2609\$

A court considering a renewed motion for judgment as a matter of law (JMOL) following a jury trial may not determine the credibility of the witnesses nor substitute its choice for that of the jury between conflicting elements of the evidence. Fed. Rules Civ.Proc.Rule 50(b), 28 U.S.C.A.

#### 7. Patents \$\sim 226.6\$

A patent infringement analysis entails two steps: (1) claim construction to determine the scope of the claims, followed by (2) determination of whether the properly construed claim encompasses the accused device.

#### 8. Patents \$\infty\$314(5)

Claim construction is a matter of law for the court to decide, while the determination of infringement of the patent is a question of fact.

#### 9. Patents \$\infty\$226.6

To establish literal infringement of a patent, every limitation set forth in a claim must be found in the accused process, exactly.

#### 10. Patents \$\sim 229\$

Accused process for making nutritional fatty acid that employed sodium hydroxide literally infringed patent directed to a method in which microorganisms obtained from a saline environment were grown in fermentor with a culture medium containing non-chloride sodium salt; although source of sodium hydroxide used in accused process could not identified, expert opined that sodium hydroxide was a non-chloride sodium salt, and once a salt was identified as a "non-chloride sodium salt" it did not matter how the salt was actually made in every instance.

#### 11. Patents \$\sim 237\$

A device that does not literally infringe a claim may nonetheless infringe if there is equivalence between those elements of the accused product and the claimed elements of the patented invention.

#### 12. Patents \$\sim 237\$

Infringement under the doctrine of equivalents must be established on a limitation-by-limitation basis.

Cite as 520 F.Supp.2d 537 (D.Del. 2007)

#### 13. Patents \$\sim 237\$

A court must take a special vigilance against allowing the doctrine of equivalents to eliminate completely the individual elements of the patented invention.

#### 14. Patents \$\sim 237\$

An element of an accused device is equivalent to an element of the patented invention if the differences between them are insubstantial.

#### 15. Patents \$\sim 237\$

An accused product infringes under the doctrine of equivalents if the element in the accused device performs substantially the same function in substantially the same way to obtain the same result as the claim limitation.

#### 16. Patents \$\sim 230, 237

Whether the "insubstantial differences" test or the "triple identity" test is applied, the essential inquiry under the doctrine of equivalents remains the same: whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention.

#### 17. Patents \$\sim 314(5)\$

A determination of infringement under the doctrine of equivalents is a factual matter normally reserved for a factfinder.

## 18. Patents \$\iiint 314(5)\$

Although infringement under the doctrine of equivalents is generally considered a question of fact, that does not in and of itself preclude directing judgment in favor of the accused infringer; there is a triable issue of fact only if the evidence is such that a reasonable jury could resolve the question in favor of the patentee.

#### 19. Patents \$\sim 312(4)\$

Just as with literal infringement, under the doctrine of equivalents, a patentee must prove by a preponderance of the evidence that each element of the patent, or its substantial equivalent, exists in the accused device.

#### 20. Patents \$\sim 312(6)\$

Patentee offered sufficient evidence from which the jury could have reasonably found that accused process for making nutritional fatty acid met the "reduced fermentor corrosion" element of patent directed to a method in which microorganisms obtained from a saline environment were grown in fermentor with a culture medium, including expert testimony that accused process was less corrosive than the hypothetical culture medium, because it contained less chloride ions than the hypothetical cultural medium and that no testing was necessary because one in the art could readily do a comparison of accused process to the hypothetical culture medium.

#### 21. Patents \$\infty\$ 314(5)

Prosecution history estoppel, which precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter that has been relinquished during prosecution of its patent application, is a legal question for the court.

#### 22. Patents \$\infty\$168(2.1)

Prosecution history estoppel may result from a number of events, including a narrowing amendment made to overcome a rejection or arguments made to the patent examiner to procure allowance of claims.

#### 23. Patents \$\infty\$168(2.1)

Argument based estoppel applies only when a patentee evinces a clear and unmistakable surrender of subject matter.

#### 24. Patents \$\infty\$168(2.1)

To determine whether there has been a clear and unmistakable surrender of subject matter, for purposes of invoking argument-based estoppel, a court must objectively determine whether a competitor would reasonably believe that the patent applicant had surrendered the relevant subject matter.

#### 25. Patents €=168(3)

Patentee's arguments during prosecution of application for patent directed to a method in which microorganisms obtained from a saline environment were grown in fermentor with a culture medium containing non-chloride sodium salt did not amount to an unequivocal surrender of subject matter and, thus, patentee was not estopped from claiming that sodium hydroxide was a "non-chloride sodium salt" or its equivalent.

#### 26. Patents \$\sim 227\$

In determining wilfulness, the primary consideration is whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe that it had the right to act in the manner that was found to be infringing of the patent.

#### 27. Patents \$\sim 227\$

In patent infringement action, wilfulness requires not merely minimally tolerable behavior, but prudent, and ethical, legal, and commercial actions.

#### 28. Patents \$\infty\$ 312(8)

Substantial evidence supported jury's finding that competitor willfully infringed patent directed to a method in which microorganisms obtained from a saline environment were grown in fermentor with a culture medium, including evidence that competitor continued to ship into the United States thousands of pounds of nutritional fatty acid made by accused process, after it had notice of patent and in spite of its statements to patentee regarding its switching the sodium salt in its culture medium.

#### 29. Patents €=110

To gain the benefit of the filing date of an earlier application under the Patent Act, each application in the chain leading back to the earlier application must comply with the written description requirement. 35 U.S.C.A. § 120.

#### 30. Patents \$\sim 99\$

To show that one is "in possession" of what is claimed as of the filing date sought, the applicant must describe the invention, with all of its claimed limitations, and not only that which makes it obvious.

#### 31. Patents \$\sim 99\$

While it is not necessary for a patent applicant to describe the claimed subject matter in the same terms as used in the claims, the specification must contain an equivalent description of the claimed subject matter.

## 32. Patents \$\iiint 314(5)\$

Whether a patent complies with the Patent Act's written description requirement is an issue of fact. 35 U.S.C.A. § 112(1).

## 33. Patents \$\infty\$66(1.24), 110

Patent relating to process for production of microbial products with a high concentration of highly unsaturated fatty acids was entitled to the filing date of earlier application for patent, which disclosed every limitation of subsequent patent claims, and, as such, subsequent patent was not invalid as anticipated by publication, which was created after the priority date

## 34. Federal Civil Procedure \$\sim 2602\$

A post-verdict motion for judgment as a matter of law may not be made on grounds not included in the earlier motion. Fed.Rules Civ.Proc.Rule 50(a, b), 28 U.S.C.A.

# 35. Patents \$\iiin\$ 323.3

Competitor's terse mention of "1.08 grams per liter" element of patent directed to process for growing microorganisms in a section of the brief supporting preverdict motion for judgment as matter of law (JMOL) that was devoted to a discussion of the "60% sodium ion concentration" element was not sufficiently specific to preserve that argument for its postverdict JMOL motion. Fed.Rules Civ.Proc.Rule 50(a, b), 28 U.S.C.A.

#### 36. Patents \$\sim 62(1), 110

Expert's testimony provided sufficient evidence from which the jury could have reasonably found that the "60% sodium ion concentration" element of patent directed to processes for growing one strain of euryhaline microorganisms was disclosed in earlier application, such that patentee was entitled to the priority date of earlier application and patent was not invalid as anticipated by documents which were created after earlier application's priority date.

# 37. Patents €=112.5

The party seeking to invalidate the patent has the burden to prove by clear and convincing evidence that the patent is not enabled. 35 U.S.C.A. § 112.

#### 38. Patents ≈99

A patent must set forth a sufficient basis for a person of ordinary skill in the art to conclude that practicing the invention will produce the claimed results. 35 U.S.C.A. § 112.

## 39. Patents \$\sim 99\$

To meet the Patent Act's enablement requirement, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. 35 U.S.C.A. § 112.

#### 40. Patents \$\sim 99\$

Factors to consider in determining whether the experimentation required would be undue, for purposes of the Patent Act's enablement requirement, include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. 35 U.S.C.A. § 112.

#### 41. Patents \$\sim 314(5)\$

Although the question of undue experimentation entails many factual considerations, enablement, for purposes of the Patent Act, is ultimately a question of law. 35 U.S.C.A. § 112.

#### 42. Patents \$\sim 312(6)\$

Given expert's uncontroverted testimony that patent directed to processes for growing one strain of euryhaline microorganisms "absolutely and equivocally" did not teach one of skill in the art to practice the invention without undue experimentation, evidence was insufficient to support jury's findings rejecting competitor's lack of enablement defense. 35 U.S.C.A. § 112.

## 43. Injunction <sup>∞</sup>9

A plaintiff seeking a permanent injunction must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

#### 44. Patents \$\sim 317\$

Entry of a permanent injunction to enjoin competitor's further infringement of patents relating to process for production of microbial products with a high concentration of highly unsaturated fatty acids and process for growing microorganisms was warranted; patentee suffered irreparable harm because of competitor's infringement of patentee's right to exclude others from practicing patents, having paid approximately \$60 million to acquire company and its patents, competitor was patentee's only competitor, and patentee's legal remedies were not adequate to compensate it for the infringement. U.S.C.A. § 283.

### Patents \$\sim 328(2)\$

5,130,242, 5,130,242, 6,451,567, 6,607,-900. Cited.

#### Patents \$\sim 328(2)\$

5,340,594. Valid.

#### Patents \$\sim 328(2)\$

6,410,281. Infringed.

John G. Day, Steven J. Balick, Tiffany Geyer Lydon, Ashby & Geddes, Wilmington, DE, for Plaintiff.

Christine B. Chua, Pro Hac Vice.

Gidon Stern, Pro Hac Vice.

- 1. Subsequent to bringing this lawsuit, Lonza Ltd. acquired all of the assets of Nutrinova Inc. and Nutrinova Nutrition Specialties & Food Ingredients GMBH that relate to the subject matter of this lawsuit. Accordingly, the court will refer to the defendants simply as "Lonza."
- 2. The parties subsequently stipulated to a dismissal of the inequitable conduct claim.

George Pazuniak, Womble Carlyle Sandridge & Rice, Wilmington, DE, for Defendants.

## **MEMORANDUM**

GREGORY M. SLEET, Chief Judge.

#### I. INTRODUCTION

The plaintiff, Martek Biosciences Corporation ("Martek"), filed the above-captioned action against Nutrinova Inc. and Nutrinova Nutrition Specialties & Food Ingredients GMBH <sup>1</sup> (collectively, "Lonza" or the "defendants") on September 23, 2003, alleging infringement of United States Patent Nos. 6,607,900 (the "'900 patent") and 6,451,567 (the "'567 patent") by Lonza's activities with regard to its docosahexaenoic acid ("DHA") product, produced by microalgae and marketed under the brand names DHActive™, Nutrinova® DHA, and Lonza DHA. In subsequent amendments to the complaint and answer, as well as stipulations of dismissal, Martek added and removed patents from the lawsuit. As a result, the following patents remained asserted by Martek: the '567 patent, U.S. Patent No. 5,340,594 (the "'594 patent"), and U.S. Patent No. 6,410,-281 (the "'281 patent") (collectively, the "patents-in-suit").

Lonza asserted the defenses of invalidity under 35 U.S.C. §§ 102, 103, and 112. Lonza also asserted the defense of inequitable conduct.2 The court held a Markman hearing and issued an order construing the disputed terms of the patents-insuit on December 12, 2005.3 A jury trial

3. The parties requested supplemental claim construction briefing on the term "nonchloride sodium salt," which the court granted. On October 2, 2006, the court issued a Supplemental Claim Construction Order (D.I.239) construing the disputed term.

commenced on October 10, 2006. During trial, Martek and Lonza properly moved for judgment as a matter of law ("JMOL") pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. The court reserved ruling on all JMOL motions.

On October 23, 2006, the jury returned a unanimous verdict on all claims in favor of Martek. The jury found that Lonza infringed the asserted claims of the '281, '594, and '567 patents,<sup>4</sup> and that its infringement of the patent was willful. The jury also upheld the validity of the '594 and '567 patents. The court entered judgment on the verdict on October 24, 2006.

Following the jury's verdict, Lonza filed three renewed JMOL motions pursuant to Federal Rule of Civil Procedure 50(b): (1) a motion for JMOL that the '281 patent is not infringed by Lonza's Process No. 2 and not willfully infringed; (2) a motion for JMOL that the '594 patent claims are invalid; and (3) a motion for JMOL that the '567 patent claims are invalid. Martek filed a motion for JMOL that Lonza's Process No. 2 literally infringes the claims of the '281 patent, and a motion for a permanent injunction. For the following reasons, the court will deny Lonza's JMOL motion regarding the '281 patent, deny Lonza's JMOL motion regarding the '594 patent, and grant in part and deny in part Lonza's JMOL motion regarding the '567 patent. The court also will grant Martek's JMOL motion regarding the '281 patent and Martek's motion for a permanent injunction.

# II. BACKGROUND OF THE TECHNOLOGY

Martek develops and sells products from microalgae, including nutritional fatty acids, such as the omega–3 fatty acid DHA. This case involves three of Martek's

**4.** Martek asserted claims 1, 3, and 7 of the '594 patent, claims 1, 4, 5, 7, 10, 11, and 14

patents relating to DHA. DHA is a major and essential structural fatty acid, necessary for the development of organs including the eye retina, the brain, and the heart. The human body produces DHA in only limited quantities, creating a need in the medical science community to find alternate sources of DHA or develop processes to produce it. Martek recognized this need and developed microalgae processes to make DHA and products relating to its processes. The three patents-in-suit all relate to the same field of invention, which Dr. Robert Barclay ("Dr.Barclay"), the inventor, describes as relating to: "heterotrophic organisms and a process for culturing them for the production of lipids with high concentrations of omega-3 highly unsaturated fatty acids ('HUFA') suitable for human and animal consumption as food additives or for use in pharmaceutical and industrial products." ('594 patent col. 1, ll. 25-30; '567 patent col.1, ll. 45-51; '281 patent, col. 1, ll.38-43.)

More particularly, the '594 patent is directed to a food product with a high concentration of omega-3 HUFAs, which includes microorganisms characterized by having a high concentration of fatty acids of which a high percentage are omega-3 HUFAs. ('594 patent, col. 4, 11. 54–59.) In addition or alternatively, the food product can include omega-3 HUFAs extracted from the microorganisms of the order Thraustochytriales, namely, Thraustochytrium or Schizochytrium. (Id. at col. 4, ll. 59-63.) The microorganisms or extracted omega-3 HUFAs are then incorporated with additional food material, which may be either animal food or human food. (Id. at 63-67.) For example, the harvested whole-cell microbial product can be added to processed foods as a nutritional supple-

of the '567 patent, and claims 17, 31, 41, and 47 of the '281 patent.

ment, or to fish and animal feeds to enhance the omega-3 highly unsaturated fatty acid content of products produced from these animals. (*Id.* at Abstract.) The lipids containing these fatty acids can also be extracted and used in nutritional, pharmaceutical, and industrial applications. (*Id.*)

The '567 and '281 patents are directed to processes for growing the microflora Thraustochytrium, Schizochytrium, and mixtures thereof, which includes the growing of the microflora in a culture medium containing non-chloride containing sodium salts, particularly sodium sulfate. ('567 patent Abstract; '281 patent Abstract.) In addition, a significant portion of the sodium requirements of the fermentation are supplied as a non-chloride containing sodium salt. ('567 patent, col. 2, ll. 26-28; '281 patent, col. 2, ll. 15-17.) The processes disclosed in the '567 and '281 patents are particularly useful in commercial production because the chloride content in the medium can be significantly reduced, thereby avoiding the corrosive effects of chloride on fermentation equipment. ('567 patent, col. 2, 11. 28-32; '281 patent, col. 2, 11. 17-21) The inventions of the '567 and '281 patents also are particularly useful for production of food products for use in aquaculture. ('567 patent, col. 2, l. 32-34; '281 patent, col. 2, ll. 21–23.)

The inventions disclosed in the '567 and '281 patents share the above-discussed similarities, but are also different. Specifically, the '567 patent discloses and claims a fermentation process for producing lipids from euryhaline microorganisms that have two characteristics: (1) the capacity for high lipid production, or high long chain omega-3 fatty acid production, and (2) the ability to grow and produce in low salinity environments even though originating from saline environments. The '281 patent discloses and claims a process for growing microorganisms in a fermentation

medium which contains a non-chloride sodium salt, so that fermentor corrosion is reduced. The invention is based on the discovery that the microorganisms can grow in a medium that provides the source of sodium needed by the microorganisms in the absence of a significant amount of chloride, which can corrode the fermentor.

## III. STANDARD OF REVIEW

[1-6] Pursuant to Federal Rule of Civil Procedure 50, a court may render judgment as a matter of law after the moving party is fully heard on an issue at trial, if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Walter v. Holiday Inns, Inc., 985 F.2d 1232, 1238 (3d Cir. 1993) (citation omitted). If the court denies a motion for JMOL during trial, the motion may be renewed within ten days of entry of judgment in the case. R.Civ.P. 50(b). To prevail on a renewed motion for JMOL following a jury trial, a party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed.Cir.1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed.Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d. at 893. In assessing the sufficiency of the evidence, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. Id.; Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. The appropriate inquiry is Cir.1997). whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed.Cir. 1998). The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin–Elmer Corp.*, 732 F.2d at 893.

#### IV. DISCUSSION

# A. Martek's and Lonza's Renewed JMOL Motions Regarding Infringement of the '281 Patent

In two motions presently before the court, Martek and Lonza challenge several of the jury's findings regarding infringement of the '281 patent. More particularly, Martek contends that asserted claims of the '281 patent are literally infringed by Lonza's Process No. 2, while Lonza contends that the '281 patent is not infringed by its Process No. 2, and not willfully infringed by its Process No. 1. As previously discussed, the asserted claims of the '281 patent are directed to a method in which microorganisms obtained from a saline environment are grown in a fermentor with a culture medium. One of the primary inorganic ions in the medium is sodium provided in the form of a non-chloride sodium salt. Martek has asserted only dependent claims against Lonza. Claim 1, however, is a representative claim containing all of the elements that Martek asserted for infringement purposes, as well as all of the elements that the parties dispute in their respective motions, and reads:

- 1. A method for reducing corrosion of a fermentor during growth of microorganisms in a saline fermentation medium, said method comprising:
- obtaining microorganisms from a saline environment;
- 5. For clarity, the court has highlighted those claim elements on which the parties base

growing the microorganisms in the fermentor comprising a culture medium in which one of the primary inorganic ions is sodium which is provided in the form of a nonchloride sodium salt, wherein the culture medium contains a chloride concentration of less than about 3 grams chloride per liter of culture medium, and wherein the culture medium containing the non-chloride sodium salt as the primary source of sodium results in reduced fermentor corrosion compared to the culture medium containing sodium chloride as the primary source of sodium

('281 Patent Claim 1.) 5 The court construed the term "non-chloride sodium salt" to mean "an ionic compound produced by the reaction of a sodium base and a nonchloride acid." (D.I. 239 ¶ 1.) The court construed the term "corrosion" to mean "the culture medium causes less chemical wearing of the vessel in which the microorganisms are grown as compared to the level of chemical wearing away to a vessel caused by a culture medium comprising sodium chloride as the primary source of sodium." (D.I. 101 ¶ 8.) The court further construed the term "culture medium" to mean "the material in which the microorganisms grow." (Id. ¶7.) With these constructions in mind, the court turns to the parties' arguments.

## 1. Literal Infringement

[7–9] A patent infringement analysis entails two steps: "(1) claim construction to determine the scope of the claims, followed by (2) determination of whether the properly construed claim encompasses the accused device." Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed.Cir.1998) (citations omitted). The first step, claim

their arguments.

construction, is a matter of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The second step, the determination of infringement, is a question of fact. Bai, 160 F.3d at 1353. "To establish literal infringement, every limitation set forth in a claim must be found in [the] accused [process], exactly." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed.Cir. 1995). At trial, Martek had the burden of proving literal infringement by a preponderance of the evidence. See, e.g., id.; Braun Inc. v. Dynamics Corp., 975 F.2d 815, 819 (Fed.Cir.1992).

- [10] The jury found that Martek did not meet its burden on literal infringement with respect to Lonza's Process No. 2. Martek contends that the jury's finding was in error, because it was not supported by sufficient evidence. Specifically, Martek contends that, given the facts before it, the jury could not have arrived a the conclusion that the sodium hydroxide used in Lonza's Process No. 2 does not literally
- 6. Preliminarily, the parties dispute what claim term or terms are at issue as a result of the jury's findings. Martek argues that because the jury found that Lonza's Process No. 2 infringed the patent under the doctrine of equivalents, and the only issue in the '281 patent that concerned the doctrine of equivalents was whether sodium hydroxide is a "non-chloride sodium salt," it may be inferred that the jury found that the use of sodium hydroxide in Lonza's Process No. 2 does not literally meet the claim element, but does meet the element under the doctrine of equivalents. In response, Lonza argues that there were two claim elements at issue: (1) the "nonchloride sodium salt" element, and (2) the "reduced fermentor corrosion" element. According to Lonza, there was no credible evidence that Lonza's Process No. 2 met either the "non-chloride sodium salt" element or the "reduced fermentor corrosion" element. The court is persuaded by Martek's argument for several reasons. First, the jury instructions agreed to and submitted by the parties instructed the jury to consider the

meet the "non-chloride sodium salt" element of the '281 patent. Having reviewed all of the evidence adduced at trial, the court is persuaded by Martek's argument. Dr. Daniel I.C. Wang ("Dr.Wang"), Martek's expert, opined that sodium hydroxide is a non-chloride sodium salt. To support his opinion, Dr. Wang testified that the reaction of sodium oxide and water "perfectly" fits the court's construction of the term "non-chloride sodium salt." (Trial Transcript ("Tr.") at 251:11 -253:3; 254:4-5; 254: 19–20.) Using literature available to one of skill in the art, namely Grant & Hack's Chemical Handbook ("Grant & Hack's"), Dr. Wang testified that sodium oxide is defined as "a reagent and a strong base." (Id. at 252:10-16.) Dr. Wang further testified, again with citation to Grant & Hack's, that water is a weak acid, "strictly from a chemistry point of view." (Id. at 252:17-253:3.) Finally, Dr. Wang testified that the reaction of sodium oxide and water produces sodium hydroxide, which is an ionic compound.<sup>7</sup> (Id. at 254:4-5; 254:19-20.)

- doctrine of equivalents only in determining whether sodium hydroxide is an equivalent of a non-chloride sodium salt. (See D.I. 268, at 23-25.) That is, the jury instructions did not instruct the jury to consider whether the "reduced fermentor corrosion" element was infringed under the doctrine of equivalents. Additionally, Martek only presented doctrine of equivalents evidence on the "non-chloride sodium salt" element of the '281 patent. Finally, Lonza's "reduced fermentor corrosion" argument is inconsistent with the jury's finding that Lonza's Process No. 1, which is carried out in the same type of fermentors as Lonza's Process No. 2, literally infringes the "reduced fermentor corrosion" element of the '281 patent.
- 7. Lonza also introduced evidence that sodium hydroxide is a non-chloride sodium salt, namely, the prosecution history of the '281 patent. In corresponding with the Patent and Trademark Office (the "PTO") during the course of prosecuting what would become the

Lonza argues that the evidence is sufficient to support the jury's verdict, because Dr. Wang could not testify as to the source of Lonza's sodium hydroxide, and that sodium hydroxide could be made by many different processes. In making this argument, Lonza reads the court's claim construction too narrowly. The court agrees with Martek that such a strained interpretation of the claim construction would lead to absurd results, in that whether or not one infringes the asserted claims would depend on which vendor one used to purchase its non-chloride sodium salt. The court further finds that, although Dr. Wang could not testify as to the source, i.e. vendor, of Lonza's sodium hydroxide, he did testify unequivocally that once a salt is identified as a "non-chloride sodium salt" it does not matter how the salt is actually made in every instance. (Tr. at 330:1-333:25.) This testimony was uncontroverted and unchallenged by Lonza.

Lonza did not adduce any testimony to challenge Dr. Wang's demonstration that sodium hydroxide met the "non-chloride sodium salt" element. In fact, the only testimony Lonza cites in its opposition brief is Dr. Thomas Veach Long's ("Dr. Long") testimony as to why Lonza utilized sodium hydroxide in its fermentation process. This is irrelevant for purposes of infringement, however, as all that an infringement analysis entails is a comparison of the accused process, here Lonza's Process No. 2, to the claim elements. In the present case, Martek put forth sufficient evidence with respect to the "non-chloride sodium salt" element, in the form of Dr. Wang's testimony, that was essentially unchallenged by Lonza. Therefore, because

'281 patent, the patentee distinguished a cited prior art reference and told the PTO that "the nonchloride sodium salt [of the prior art reference] is the well-known base, sodium hydroxide, which is added to increase pH, and not to substitute for chloride salts." (DTX

the court finds no legally sufficient evidentiary basis for a reasonable jury to conclude that Lonza's Process No. 2 does not literally infringe the '281 patent, the court will grant Martek's motion.

# 2. Infringement under the Doctrine of Equivalents

[11–13] A device that does not literally infringe a claim may nonetheless infringe "if there is equivalence between those elements of the accused product and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Infringement under the doctrine of equivalents must be established on a limitation-bylimitation basis. See id. at 29, 117 S.Ct. 1040 (stating that, "the doctrine of equivalents must be applied to the individual elements of the claim, not to the invention as a whole."). Moreover, the court is mindful that it must take a "special vigilance against allowing the concept of equivalents to eliminate completely" the individual elements of the patented invention. Id. at 40, 117 S.Ct. 1040.

[14–16] An element of an accused device is equivalent to an element of the patented invention if the differences between them are insubstantial. *Id.* at 39, 117 S.Ct. 1040; *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316–17 (Fed.Cir. 1999); *Dawn Equip. Co.*, 140 F.3d at 1014. Alternatively, the accused product infringes under the doctrine of equivalents if the element in the accused device performs substantially the same function in substantially the same way to obtain the

615, at 129.) Thus, in pointing out that sodium hydroxide was added in the particular prior art reference not as a substitute for chloride salts, but to increase pH, the patentee acknowledged that sodium hydroxide is a non-chloride sodium salt. same result as the claim limitation. See Warner-Jenkinson, 520 U.S. at 39, 117 S.Ct. 1040; Zelinski, 185 F.3d at 1316–17; Dawn Equip. Co., 140 F.3d at 1016. Whether the former, the "insubstantial differences" test, or the latter, the "triple identity" test is applied, the essential inquiry remains the same: "[d]oes the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" Warner-Jenkinson, 520 U.S. at 40, 117 S.Ct. 1040.

[17–19] A determination of infringement under the doctrine of equivalents is a factual matter normally reserved for a fact finder. Sage Products, Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir. 1997). Although infringement under the doctrine of equivalents is generally considered a question of fact, that does not in and of itself preclude directing judgment in favor of the accused infringer. There is a triable issue of fact only if the evidence is such that a reasonable jury could resolve the question in favor of the patentee. Dawn Equip. Co., 140 F.3d at 1017 (reversing district court and granting judgment for defendant where devices were not substantially the same) (citing Warner-Jenkinson, 520 U.S. at 39 n. 8, 117 S.Ct. 1040). Finally, just as with literal infringement, the patentee must prove by a preponderance of the evidence that each element of the patent, or its substantial equivalent, exists in the accused device. See Lemelson v. United States, 752 F.2d 1538, 1551 (Fed.Cir.1985).

Lonza's motion challenges the jury's finding that its Process No. 2 infringes the '281 patent under the doctrine of equivalents. Lonza provides three arguments as to why the jury's verdict cannot stand: (1) Martek did not offer sufficient evidence that Lonza's Process No. 2 results in "reduced fermentor corrosion" as required by

the '281 patent claims; (2) Martek did not offer sufficient evidence that sodium hydroxide is a "non-chloride sodium salt;" and (3) prosecution history estoppel bars Martek from arguing that sodium hydroxide is a "non-chloride sodium salt" or its equivalent. The court addresses only Lonza's first and third arguments, because its discussion and conclusion regarding Martek's JMOL motion for literal infringement disposes of Lonza's second argument.

Lonza contends that Martek did not produce any evidence that its Process No. 2 results in "reduced fermentor corrosion" as required by all of the '281 patent claims. In making its contention, Lonza cites to the court's claim construction of the term "reduced fermentor corrosion" and concludes that "[t]o show 'less chemical wearing of the vessel,' Martek must have proffered comparison tests between Process No. 2 and a 'culture medium containing sodium chloride as the primary source of sodium." (D.I. 283, at 3.) Lonza also cites to several cases to support its proposition that Martek could only prove infringement of the "reduced fermentor corrosion" element by having conducted comparison tests. Lonza further argues that, because Martek did not conduct any comparison testing, the entirety of Martek's proffered evidence as to infringement of the '281 patent amounts to the "unsubstantiated opinions" of two expert witnesses, Dr. Wang and Dr. David Duquette ("Dr.Duquette"). (Id.)

[20] The court disagrees and finds that Martek offered sufficient evidence from which the jury could reasonably find that Lonza's Process No. 2 met the "reduced fermentor corrosion" element of the '281 patent claims. For example, both Drs. Wang and Duquette testified that the literature was clear that increasing the amount of chloride in a culture medium increases the corrosion of a fermentor composed of

304 stainless steel. (Tr. at 267:11-25; 1169:25–1170:8: 1173:17–25.) In addition, both Drs. Wang and Duquette compared the culture medium of Lonza's Process No. 2, which contains sodium chloride and sodium hydroxide, with the hypothetical culture medium described in the patent that contains sodium chloride as the primary source of sodium. (Id. at 269:9–17; 1169:2-13; 1172:13-24.) Both Drs. Wang and Duquette reached the same conclusion in conducting their comparisons: Lonza's Process No. 2 is less corrosive than the hypothetical culture medium, because it contains less chloride ions than the hypothetical cultural medium—specifically about 1/3 less chloride ions. (Id. at 270:5-271:3; 1172:14-1173:16.) Dr. Duquette also testified that, based on his experience and the general literature of corrosion, no testing was necessary because one in the art could readily do a comparison of Lonza's Process No. 2 to the hypothetical culmedium. (Tr. at 1169:19-22; 1173:17–25.) As previously indicated, the

8. Additionally, the court finds that the cases cited by Lonza do not support the proposition that "Martek must have proffered comparison tests between Lonza's Process [No.] 2 and a 'culture medium containing sodium chloride as the primary source of sodium," " to demonstrate reduced fermentor corrosion. In Summit Tech., Inc. v. Nidek Co., Ltd., 363 F.3d 1219 (Fed.Cir.2004), the court affirmed a grant of JMOL because the plaintiff offered no evidence to establish that the defendant's device met a certain claim element. 363 F.3d at 1228, 1230. In contrast, here, the court has concluded that Martek adduced sufficient evidence in the form of expert testimony. Similarly, in Naturopathic Labs. Int'l, Inc. v. Dermal Research Labs., Inc., 415 F.Supp.2d 1007 (W.D.Mo.2006), the district court found that the evidence produced was not sufficient to sustain the jury's infringement verdict. See PharmaStem Therapeutics, Inc. v. ViaCell, Inc., No. C.A. 02-148 GMS, 2004 WL 2127192, at \* 11 (D.Del. Sept.15, 2004) (finding that the plaintiff's expert did not review or analyze any of the defendants' alleged infringing products and that her opinions were not court finds that the testimony of Drs. Wang and Duquette provided sufficient evidence to support the jury's determination.<sup>8</sup>

[21–24] Lonza next contends that Martek should be estopped from claiming that sodium hydroxide is a "non-chloride sodium salt" or its equivalent, because it clearly and unmistakably surrendered that subject matter in its arguments during prosecution of the '281 patent. Prosecution history estoppel is a legal question for the court. Insituform Techs. v. Cat Contracting, 99 F.3d 1098, 1107 (Fed.Cir. 1996), cert. denied, 520 U.S. 1198, 117 S.Ct. 1555, 137 L.Ed.2d 703 (1997). "Prosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter that has been relinquished during prosecution of its patent application." Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1376 (Fed. Cir.1999); see Salazar v. Procter & Gam-

based on any methods or procedures of science, or her specific expertise in the field); Nisus Corp. v. Perma-Chink Sys., Inc., 327 F.Supp.2d 844, 861 (E.D.Tenn.2003), aff'd, 128 Fed.Appx. 156 (Fed.Cir. May 6, 2005) (granting summary judgment because the plaintiff did not produce sufficient evidence). Notably, in none of these cases did the Federal Circuit or district courts hold that a plaintiff must proffer comparison testing or any other testing to demonstrate infringement.

Finally, W.L. Gore & Assoc., Inc. v. Garlock, Inc., 842 F.2d 1275 (Fed.Cir.1988) is distinguishable, because the district court in that case, acting as factfinder, rejected the plaintiff's expert's opinion. Here, the jury has already accepted the testimony of Martek's experts regarding infringement, as well as their opinions that no testing is required for the "reduced fermentor corrosion" element to be met. Thus, the court is not free to simply reject the opinions of Martek's experts, but rather, must apply the JMOL standard, as it has already done in determining that Martek's evidence was sufficient to support the jury's verdict

ble Co., 414 F.3d 1342, 1344 (Fed.Cir. 2005). This preclusion may result from a number of events, including a narrowing amendment made to overcome a rejection or arguments made to the patent examiner to procure allowance of claims. Id. Argument based estoppel applies, however, only when a patentee must "evince[s] a clear and unmistakable surrender of subject matter." AquaTex Indus. v. Techniche Solutions, 419 F.3d 1374, 1382 (Fed. Cir.2005) (quoting *Pharmacia*, 170 F.3d at 1377). To determine whether there has been such surrender, a court must objectively determine "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1457 (Fed.Cir.1998).

[25] In the present case, the court finds that the patentee's arguments during prosecution of the '281 patent application did not amount to an unequivocal surrender of subject matter. Turning to the prosecution history of the '281 patent, Dr. Barclay, the patentee, distinguished the prior art because the art was directed to recovering various products from brine solutions, not reducing corrosion of a fermentor during fermentation of microorganisms. (DTX 615, at 127.) In doing so, Dr. Barclay explained that his invention was a method directed to successfully fermenting microorganisms from a saline environment in a low chloride medium containing a non-chloride sodium salt. (Id. at 128.) Dr. Barclay further distinguished the prior art by noting that it "do[es] not replace chloride with non-chloride sodium salt, but rather add[s] the base (sodium hydroxide) to adjust the pH of the brine, which is principally sodium chloride. This is a direct teaching away from the present invention." (Id. at 129) (emphasis in original). Thus, Dr. Barclay's arguments distinguished the prior art based on the fact that it taught a medium or brine that was principally sodium chloridea chloride containing sodium salt whereas his invention taught a non-chloride sodium salt. Indeed, Dr. Barclay's entire invention revolved around successfully fermenting microorganisms in a low chloride medium containing a non-chloride sodium salt. (Id. at 128) ("The single most critical deficiency of the references, even if combined, is that they do not disclose or suggest that microorganisms from a saline environment can be successfully fermented in a low chloride medium containing a non-chloride sodium salt. Surprisingly, the present inventor has not only discovered that such fermentation is possible, but that lipid production may even be increased!").

Moreover, Dr. Barclay acknowledged that sodium hydroxide is a non-chloride sodium salt in the following statement to the examiner: "Additionally, the non-chloride sodium salt is the wellknown base, sodium hydroxide, which is added [to the brine in the prior art reference to increase pH, and not to substitute for chloride salts." (Id. at 129.) Given the arguments and statements in the prosecution history, the court concludes that Martek did not clearly and unmistakably surrender subject matter. Thus, prosecution history estoppel does not bar Martek from asserting infringement under the doctrine of equivalents.

#### 3. Willful Infringement

[26, 27] Finally, Lonza contends that Martek failed to prove by clear and convincing evidence that Lonza's Process No. 1 willfully infringed the '281 patent. More particularly, Lonza argues that the record indicates that it wanted to license a strain of microorganisms that were not disclosed in Martek's patent applications, and that it switched process from a non-chloride sodium salt to a chloride sodium salt after it

received notice of Martek's '281 patent. In determining wilfulness, "the primary consideration is whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe that it had the right to act in the manner that was found to be infringing." *SRI Int'l v. Advanced Tech. Labs., Inc.,* 127 F.3d 1462, 1464–65 (Fed.Cir.1997) Furthermore, the law requires not merely "minimally tolerable behavior," but "prudent, and ethical, legal and commercial actions." *Id.* 

[28] In the case before the court, there was sufficient evidence from which the jury could conclude that the defendants failed to meet such a standard. For example, Martek notified Lonza of its potential infringement of the '281 patent in May 2003. (Tr. at 537:5-10; PTX 233.) After receiving notice of the patent, Lonza decided to change its process for making DHA by substituting sodium chloride in the culture medium of Process No. 1 for sodium sulfate, the preferred non-chloride sodium salt of the '281 patent. (Tr. at 555:23-556:7; 539:2-6.) In August 2003, Lonza then responded to Martek's notice letter, indicating that the '281 patent was not impacted by its activities, because it did not use a non-chloride sodium salt. (Id. at537:16-20.) Martek took Lonza's word and did not include the '281 patent in its original complaint filed against Lonza, because it believed that Process No. 1 would not infringe the '281 patent if Lonza was using sodium chloride. (Id. at 538:2-13.) Lonza's answer to the complaint stated that it only used sodium chloride in its process. (Id. at 538:14–18.)

Subsequent to filing the lawsuit, Martek learned that Lonza was using sodium sulfate in Process No. 1 and amended its

 According to Lonza, the parties agree that Dr. Barclay's Canadian PCT application WO 91/07490, published on May 30, 1991, and Dr. Barclay's U.S. Patent No. 5,130,242, publishcomplaint to include the '281 patent. (Tr. at 539:7-9.) Lonza's answer to the amended complaint also stated that the only sodium salt in its processes was sodium chloride. (Id. at 539:12-14.) Even though Lonza had notice of Martek's '281 patent and in spite of its statements to Martek regarding its switching the sodium salt in its culture medium, Martek offered evidence that Lonza continued to ship into the United States DHA made by Process No. 1. Martek offered both testimonial and documentary evidence that Lonza imported into the United States 4,000 pounds of DHA made by Process No. 1 between 2003 and 2005. (See id. at 540:7-13; PTX 236-37.) Based on the foregoing, the court concludes that substantial evidence supports the jury's finding that Lonza willfully infringed the '281 patent. Therefore, the court will deny Lonza's motion for judgment as a matter of law.

# C. Lonza's Renewed JMOL Motions Regarding Anticipation of the '594 and '567 Patents

Lonza filed separate, but related, JMOL motions on the issue of anticipation of the '594 and '567 patents. In both motions, Lonza contends that the dispositive issue before the court on validity is whether the '594 and '567 patent claims are entitled to the benefit of Dr. Barclay's original 1988 patent application, U.S.App. 07/241,410 (DTX 607), filed on September 7, 1988 (the "1988 application"). Specifically, Lonza contends that the written description of the 1988 application does not support one limitation of the '594 patent and two limitations of the '567 patent.

ed on July 14, 1992, are prior art if the '594 and 567 patent claims are not entitled to the benefit of the 1988 application.

[29-32] "In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571 (Fed. Cir.1997). Section 112 of the patent statute describes what must be contained in the patent specification. Among other things, it must contain "a written description of the invention, and of the manner and process of making and using it...." 35 U.S.C.  $\S$  112  $\P$ 1. The Federal Circuit has held that the written description requirement mandates an applicant to provide a description that "reasonably conveys" to one skilled in the art that the inventor was in possession of what is claimed as of the filing date sought. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed.Cir.1991) (citation omitted). In order to show that one is "in possession," the applicant must describe the invention, with all of its claimed limitations, and not only that which makes it obvious. Lockwood, 107 F.3d at 1572. Further, while it is not necessary for the applicant to describe the claimed subject matter in the same terms as used in the claims, "the specification must contain an equivalent description of the claimed subject matter." Id. (citing Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed.Cir.1995)). Whether a patent complies with the written description requirement is an issue of fact. Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 1324 (Fed.Cir.2002) (citation omit-Thus, the court must determine whether the jury's verdict that the written description requirement has been met by the 1988 application is supported by substantial evidence. See Wang Labs., Inc. v.

**10.** For clarity, the court has highlighted those claim elements on which Lonza bases its ar-

Toshiba Corp., 993 F.2d 858, 865 (Fed.Cir. 1993).

## 1. The '594 Patent

The application for the '594 patent was filed on July 10, 1992. The '594 patent issued on August 23, 1994. Claim 1, the only independent claim of the '594 patent, reads:

## 1. A food product, comprising:

- a) lipids extracted from a fermentation process for growing microorganisms selected from the group consisting of microorganisms of the genus Thraustochytrium, microorganisms of the genus Schizochytrium and mixtures thereof, wherein said microorganisms are capable of effectively producing lipids containing mixtures of omega–3 and omega–6 highly unsaturated fatty acids under conditions comprising:
  - i) salinity levels less than salinity levels found in seawater;
  - ii) a temperature of a least about 15°C; and
  - b) food material.

('594 patent Claim 1.) <sup>10</sup> Lonza contends that the written description of the 1988 application does not support the "mixtures" embodiment recited in Claim 1 of the '594 patent. More specifically, Lonza argues that the claim element "mixture" of "microorganisms of the genus Thraustochytrium, [and] microorganisms of the genus Schizochytrium" is not supported by the 1988 application.

[33] Conversely, Martek asserts that implicit in the jury's verdict that the '594 patent claims are entitled to the filing date of the 1988 application, is the finding that the 1988 application sufficiently discloses all limitations of the asserted '594 patent

guments.

claims. Martek further argues that the record supports the jury's finding that the specification of the 1988 application discloses Thraustochytrium, Schizochytrium, and mixtures thereof. The court agrees with Martek and finds that the record supports the jury's conclusion that the '594 patent is entitled to the filing date of the 1988 application. For example, Dr. Wang testified that the 1988 application "fully disclosed" all the claims of the '594 patent. (Tr. at 1058:23-1059:6.) Dr. Wang further testified that the 1988 application discloses "[m]ixing lipids of the invention with food material, and ... the lipids extracted from Schizochytrium, and Thraustochytrium, and mixtures thereof." (Id. at 1059:14-19.) More specifically, Dr. Wang pointed to portions of the 1988 application containing the disclosure of microorganisms of the genus Thraustochytrium and Schizochytrium. (*Id.* at 1060:13–1064:17.)

Dr. Wang also pointed to a portion of the 1988 application upon which he relied, in part, in reaching his conclusion that it disclosed mixtures of microorganism strains (Tr. 1064:19-1067:9): "Nitrogen limitation (to induce higher lipid production) can therefore be carried out in a much smaller reactor, or the cells from several reactors consolidated into one reactor." (DTX 607, at 26.) Dr. Wang explained, as one of skill in the art, how the disclosure teaches that the microorganisms discussed in the specification could be mixed together and lipids extracted from the mixture. (See Tr. at 1064:18-1067:9; 1125:10-1126:19.) Finally, Dr. Wang testi-

11. Lonza makes much of what it terms Martek's "limited disclosure" in the 1988 application—that is, its view that the entire validity of the '594 patent rests on one clause in the 1988 application. Because the court has found that the evidence is sufficient to entitle Martek to the September 7, 1988 priority date, the court need not address this argument. Nevertheless, the court notes that

fied that the 1988 application's specification disclosed mixing lipids of the invention with food material: The 1988 application "says the cells can also be broken or lysed ... Schizochytrium ... and the lipids extracted into vegetable or edible oil. Just remember now, in this case, vegetable and edible food oil[s] are food materials. These are extracted lipids into a food material." (Id. at 1059:7-1060:12.) Based on foregoing, the court concludes that there is sufficient record evidence to support the jury's finding that the '594 patent is entitled to the filing date of the 1988 patent, because it discloses every limitation of the '594 patent claims.11 As such, the '594 patent is not invalid as anticipated by Dr. Long's PCT publication, since that document was created after the September 7, 1988 priority date and, therefore, is not prior art to the '594 patent.

## 2. The '567 Patent

The application for the '567 patent was filed on December 14, 1999. The '567 patent issued on September 17, 2002. Claim 1 is the only independent claim of the '567 patent and reads:

- 1. A process for producing lipids comprising:
- (a) growing euryhaline microorganisms in a fermentation medium, wherein said euryhaline microorganisms are capable of producing about 1.08 grams per liter of the fermentation medium per day of long chain omega–3 fatty acids per 40 grams of sugar per liter of the fermentation medium at a sodium ion

whether a disclosure is limited or broad is of no moment in a written description analysis, as the only requirement of section 112 is for an applicant to provide a description that "reasonably conveys" to one skilled in the art that the inventor was in possession of what is claimed as of the filing date sought. *Vas—Cath Inc.*, 935 F.2d at 1563.

concentration in the fermentation medium of 60% seawater; and

(b) extracting lipids from said euryhaline microorganisms.

('567 patent Claim 1.) <sup>12</sup> Lonza contends that the 1988 application does not support two elements of the '567 patent, namely the "1.08 grams per liter" and the "sodium ion concentration of 60% seawater" elements. Martek asserts in response that the court should deny Lonza's motion for two reasons: (1) Lonza has waived any argument on the "1.08 grams per liter" element, because that position was not presented in its pre-verdict Rule 50(a) JMOL motion; and (2) Lonza fails to meet the demanding legal standard required to justify the grant of JMOL.

[34] Because Martek has raised a waiver argument, the court must first determine whether Lonza has properly preserved its position on the "1.08 grams per liter" element. Federal Rule of Civil Procedure 50(a) provides that a JMOL motion "may be made at any time before the case is submitted to the jury[,]" and "must specify the judgment sought and the law and facts that entitle the movant to the judgment." The purpose of a Rule 50(a) motion is to inform the opposing party of the challenge, afford that party an opportunity to cure any defects in proof, and allow the court to dispose of any issues without submission to the jury. SeeDuro-Last, Inc. v. Custom Seal, Inc., 321 F.3d 1098, 1105 (Fed.Cir.2003); Fed. R.Civ.P. 50(b) Advisory Committee Notes to the 2006 Amendments. If the court does not grant the JMOL motion, Rule 50(b) permits a party to renew the motion. "A post-verdict motion may not be made on grounds not included in the earlier motion." Duro-Last, 321 F.3d at 1105-06;

**12.** For clarity, the court again has highlighted those claim elements on which Lonza bases

Mosley v. Wilson, 102 F.3d 85, 90 (3d Cir.1996) ("A motion for judgment as a matter of law rendered after trial must be made on grounds that were previously asserted in a motion for directed verdict prior to submission of the case to the jury."); Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1172–73 (3d Cir.1993) ("A motion for judgment as a matter of law pursuant to Rule 50(b) must be preceded by a Rule 50(a) motion sufficiently specific to afford the party against whom the motion is directed with an opportunity to cure possible defects in proof which otherwise might make its case legally insufficient."); Fed.R.Civ.P. 50(b) Advisory Committee Notes to the 2006 Amendments ("Because the Rule 50(b) motion is only a renewal of the preverdict motion, it can be granted only on grounds advanced in the preverdict motion.").

[35] Here, Lonza filed a pre-verdict Rule 50(a) motion for judgment as a matter of law that the '567 patent claims are invalid as anticipated (D.I.258), as well as a brief supporting its Rule 50(a) motions and setting forth its invalidity arguments with respect to the '567 patent. (See D.I. 260, at 5-11.) Having considered Lonza's brief and the arguments set forth therein, the court concludes that Lonza did not properly preserve its argument regarding the "1.08 grams per liter" element. Lonza's brief does contain a section titled "The '567 Patent is Not Entitled to the 1988 Priority Date of the '410 Application." Nevertheless, absent from that section is any argument regarding the "1.08 grams per liter" element. Rather, that section of Lonza's brief sets forth in detail an argument that the 1988 application does not support the "60% sodium ion concentra-

its arguments.

tion" element of claim 1 of the '567 patent. Lonza's argument includes many citations to the testimony of its expert, Dr. Long. The argument concludes with the following passage:

Based on this evidence, Dr. Long concluded that the Example 9 in the [1988] application did not support the claims of the '567 patent. This analysis was also confirmed by Lonza's expert Dr. Owen Ward.... Let me just ask you [Dr. Ward] a very brief question, if you could bring up that slide with Claim 1 of the '567 patent. Dr. Ward, is there any disclosure in the earliest patent applications filed by Dr. Barclay of that limitation, 1.08 grams per liter? No, there is not.

(D.I. 260, at 10.) Lonza asserts that the above-cited passage sufficiently raised the "1.08 grams per liter" element. The court is not persuaded and finds that Lonza's terse mention <sup>13</sup> of "1.08 grams per liter" in a section of the brief devoted to a discussion of the "60% sodium ion concentration" element is not sufficiently specific to preserve that argument for its Rule 50(b) motion. Accordingly, the court addresses only Lonza's argument regarding the disclosure of the "60% sodium ion concentration" element in the 1988 application.

[36] Lonza contends that the written description of the 1988 application does not support the "60% sodium ion concentration" element recited in Claim 1 of the '567 patent. The jury's verdict on the issue of priority benefit was for Martek. Thus, Lonza bears the burden of demonstrating that the jury's verdict was not supported by substantial evidence. In this instance, the court finds that Lonza has not met its burden, because the record supports the

**13.** In sharp contrast, Lonza devotes the majority of its Rule 50(b) brief (D.I.285), more than 9 pages, to its arguments regarding the

jury's finding that the "60% sodium ion concentration" element is disclosed in the 1988 application. The issue at trial with respect to this limitation was whether one of skill in the art would know by reading the disclosure of the 1988 application that the glutamate disclosed in Example 9 was monosodium glutamate. Dr. Wang testified unequivocally that the "glutamate" in Example 9 is monosodium glutamate. Specifically, Dr. Wang focused on the following language from Example 9: "glutamate had been increased to 40 g/l [grams/liter]," and testified that, based on solubility, the glutamate had to be sodium glutamate. (Tr. at 1070:3-1072:22.) Dr. Wang explained that the solubility of the medium was important, and that one could not put 40 grams of glutamic acid into solution because its solubility is only 8.64 grams per liter. (Id. at 1071:18-1072:22.) Thus, according to Dr. Wang's testimony, it was readily apparent to one skilled in the art that, based on the solubility of glutamic acid verses sodium glutamate, the glutamate in Example 9 of the 1988 application is monosodium glutamate. (Id.)

Dr. Wang also testified, by discussing the sodium concentration present in Figure 7, that the "glutamate" disclosed in Example 8 of the 1988 application is monosodium glutamate. (*Id.* at 1074:5–1076:24.) Dr. Wang then concluded, based on his reading of the 1988 application as a whole, that "this glutamate here [in Examples 8 and 9] really means sodium glutamate." (*Id.* at 1076:24.)

Finally, Dr. Wang explained that, knowing that the glutamate in Example 9 is monosodium glutamate, one of skill in the art could calculate the value of 60 percent salinity by first adding up the sodium concentrations in the fermentation medium,

"1.08 grams per liter" element, and spends little more than 2 pages discussing the "60% sodium ion concentration" argument.

i.e. the sodium concentration from the sodium chloride, sodium carbonate, and the sodium glutamate, which totals 6.4 grams per liter of sodium. (Id. at 1077:10-1078:11.) Dr. Wang then multiplied the salinity of seawater, or 10.7 grams per liter of sodium, by 60 percent, which yielded 6.4 grams per liter of sodium. (Id. at 1078:12-1078:24.) Based on these calculations, Dr. Wang concluded that the sodium in Example 9 of the 1988 application (which is also Example 8 of the '567 patent) "comes out exactly equal to 60 percent [the salinity] of seawater." (Id. at 1078:22-24.) The court concludes that this testimony provided sufficient evidence from which the jury could reasonably find that Martek was entitled to the priority date of the 1988 application. Thus, the '567 patent is not invalid as anticipated by Barclay's Canadian PCT application and Barclay's U.S. Patent No. 5,130,242, since these documents were created after the September 7, 1988 priority date and, therefore, are not prior art to the '594 patent.

# D. Lonza's Renewed JMOL Motion Regarding Lack of Enablement of the '567 Patent

[37-41] Lonza next moves for JMOL on its lack of enablement defense. Although not entirely clear from its briefing on the issues, Lonza appears to argue that the '567 patent claims are of a vast and indeterminate scope. Put differently, Lonza argues that the '567 patent discloses one strain of euryhaline microorganisms, without disclosing where to find other microorganisms. As such, Lonza contends that the '567 patent is not enabled. The party seeking to invalidate the patent has the burden to prove by clear and convincing evidence that the patent is not enabled. Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1469 (Fed.Cir.1993). To be enabled, a patent must satisfy the requirements of 35 U.S.C. § 112, which states in pertinent part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. Thus, a patent must set forth a sufficient basis for a person of ordinary skill in the art to conclude that practicing the invention will produce the claimed results. See In re Cortright, 165 F.3d 1353, 1355 (Fed.Cir.1999). To meet the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation." In re Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993) (quoting In re Vaeck, 947 F.2d 488, 495 (Fed.Cir. 1991)). Factors to consider in determining whether or not the experimentation required would be undue include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed.Cir.1988). Although the question of undue experimentation entails many factual considerations, enablement is ultimately a question of law. Id. at 735, 737.

[42] Here, the jury found for Martek on enablement and, implicit in its verdict, is a finding that Lonza did not prove by clear and convincing evidence that one skilled in the art could not practice the claims of the '567 patent without undue experimentation. The question presented, therefore, is whether there was sufficient evidence to support the jury's finding. The court concludes that there was not.

Lonza provided two experts on the issue enablement, Dr. David Porter ("Dr.Porter") and Dr. Owen P. Ward ("Dr. Ward"). During his direct examination, Dr. Ward discussed, with reference to the eight Wands factors, why the claims of the '567 patent were not enabled. Specifically, he testified that "a very large number" of euryhaline microorganisms are potentially covered by Claim 1 of the '567 patent. (Tr. at 1013:22–1014:1) (addressing the eighth Wands factor). Dr. Ward then testified that it would take "an enormous amount of research" to find a euryhaline microorganism that would meet the limitations of Claim 1. (Id. at 1014:14-1014:19) (addressing the first Wands factor). Dr. Ward also explained that Dr. Barclay did not teach how to "find, select out, and evaluate the range or organisms" claimed. (Id. at 1015:12-21) (addressing the second Wands factor). With respect to the third Wands factor, Dr. Ward testified that only one working example, S31 in Example 8, was present in the '567 patent. (Id. at 1015:22-1016:5.) Dr. Ward also testified that the invention was a complex biotechnology invention that involved much unpredictability among microorganisms and their properties. (Id. at 1016:6-25) (addressing the fourth and seventh Wands factors). With respect to the fifth and sixth Wands factors, Dr. Ward testified that "there is no way that the prior art teaches that [which Dr. Barclay did not provide in the '567 patent,]" and that the skill in the art was not such as to eliminate the need for better teachings. (Id. at 1017:8–13.) Based on his application of the Wands factors, Dr. Ward concluded that the '567 patent "absolutely and equivocally" does not teach one of skill in the art to practice the invention without undue experimentation. (*Id.* at 1017:14–18.)

To rebut Dr. Ward's testimony on direct examination, Martek presented no witnesses, but presently relies on Dr. Ward's testimony elicited during cross-examination. According to Martek, Dr. Ward's testimony on cross-examination conflicted with his testimony during direct examination. The court disagrees. Although Martek may have attempted to make Dr. Ward contradict himself, it did not succeed in that effort. Indeed, Martek cites to some of Dr. Ward's testimony that could arguably be considered as contradictory when taken out of context and read alone. For example, Martek points out that Dr. Ward acknowledged that Dr. Barclay's screening method could potentially screen thousands of strains of organisms in one or two days. (D.I. 301, at 30-31.) Martek, however, omits from its citation a key portion of Dr. Ward's testimony on cross-examination, in which he testifies that Dr. Barclay's screening process is a different process from what is claimed in Claim 1 of the '567 patent. (Tr. at 1027:10-17.) Dr. Ward additionally testified that:

"Dr. Barclay, with that particular screening method, will not be able to identify all of the euryhaline microorganisms which could produce the lipids under these conditions [the claimed conditions] or, indeed, test them, because different tests will achieve different results here. And a test under one condition-for example, if you just vary the pH, you will find different organisms. And if you vary the temperature, you will find different organisms. This is a very important point. I have worked for 30 years in microbiology. And there are far more euryhaline organisms than that simple test. He did not teach how to achieve the matter of that claim."

(*Id.* at 1027:18–1028:5.) Given Dr. Ward's uncontroverted testimony, which is the only evidence that Martek provides in making its enablement argument, the court finds that the evidence was insufficient to support the jury's findings on that issue. Accordingly, the court will grant Lonza's renewed JMOL motion on the issue of enablement.

# E. Martek's Motion for a Permanent Injunction

[43] Martek's motion requests the court to issue a permanent injunction enjoining Lonza from further infringement of the patents-in-suit. A district court "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 126 S.Ct. 1837, 1839, 164 L.Ed.2d 641 (2006). A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.  $Id.^{14}$ 

**14.** In *eBay*, the Supreme Court rejected the categorical rules applied by the district court and the Federal Circuit respectively: (1) that a patentee's willingness to license its patents and lack of commercial activity in practicing the patents is enough to establish that the patentee would not suffer irreparable harm absent a permanent injunction; and (2) that a patentee's "statutory right to exclude alone justifies [a] general rule in favor of permanent injunctive relief." *eBay*, *Inc. v. MercExchange*, *L.L.C.*, 126 S.Ct. at 1840. The Court then

[44] Turning to the four-factor test, the court finds that entry of a permanent injunction with respect to the '594 and '281 patents is warranted.<sup>15</sup> The court first concludes that Martek has suffered irreparable harm because of Lonza's infringement of Martek's right to exclude others from practicing the '594 and '281 patents. Here, Martek paid approximately \$60 million to acquire Omega Tech, Inc. and its patents, which include the '594 and '281 patents. (D.I. 305, Ex. A  $\P\P$  2–4.) In addition, Lonza is Martek's only competitor in the vegetarian DHA market for adult foods and beverages, and is targeting Martek's customers in that industry. (Id. ¶ 18.) License and supply agreements with food and beverage manufacturers are long-term. (*Id.* ¶ 19–20.) Accordingly, Martek expects to exclude Lonza from marketing and selling DHA food and beverages in order to increase its value by securing contracts with companies in the adult food and beverage industry. Based on these circumstances, Martek has suffered irreparable harm. Martek will continue to suffer such harm if Lonza is not enjoined from infringing the '594 and '281 patents, as it is likely to lose market share that it may not be able to recapture.

The court next finds that legal remedies are not adequate to compensate Martek for the infringement of the '594 and '281 patents. The statutory right to exclude represents a tangential benefit associated

held that district and appellate courts should exercise their discretion "consistent with traditional principles of equity," in determining whether a permanent injunction should issue. *Id.* at 1841.

**15.** Because the court has determined that Martek did not sufficiently prove that the '567 patent is enabled, the request for a permanent injunction as to this patent is moot.

Cite as 520 F.Supp.2d 537 (D.Del. 2007)

with patent rights that cannot be quantified in monetary damages. Fisher-Price, Inc. v. Safety 1st, Inc., 279 F.Supp.2d 526, 528 (D.Del.2003) (citation omitted). Indeed, as previously mentioned, Lonza is Martek's only competitor in the food and beverage vegetarian DHA market, and Martek has a right to exclude its rival from using its proprietary technology. Novozymes A/S v. Genencor Intern., Inc., 474 F.Supp.2d 592, 613 (D.Del.2007).

The balance of hardships also favors Martek. While DHA represents only a small percentage of Lonza's total business, Martek's primary source of revenue is the sale of nutritional oils, including DHA. (D.I. 305, Ex. A ¶¶7; D.I. 305, Ex. J.) Additionally, Lonza makes no argument with respect to this factor. Thus, it appears as though Lonza agrees that the balance of hardships tips in Martek's favor.

Finally, Lonza has presented no evidence nor made any argument that a permanent injunction would harm the public. Moreover, as this court has previously explained, "it is almost redundant to note the substantial interest in enforcing valid United States patents, while the court perceives no countervailing harm to the public [—such as that the infringing products are medically necessary or that their removal from the stream of commerce would harm the public-] in granting the requested injunctive relief." Fisher-Price, F.Supp.2d at 528. Accordingly, after having analyzed the four factors articulated in eBay, the court concludes that Lonza

16. In opposing Martek's motion for a permanent injunction, Lonza argues that the court should delay entering an injunction until the appeal process has ended. Lonza's request, however, is not supported by any argument or analysis of the four criteria a movant must show to receive a stay, namely: "(1) a strong showing that he is likely to succeed on the

should be enjoined from infringing the '594 and '281 patents. 16

## IV. CONCLUSION

For the reasons set forth herein, Martek's renewed JMOL motion regarding literal infringement of the '281 patent is granted; Lonza's renewed JMOL motion that the '281 patent is not infringed by Lonza's Process No. 2 and not willfully infringed is denied; Lonza's renewed JMOL motion regarding anticipation of the '594 and '567 patents is denied; Lonza's renewed JMOL motion regarding lack of enablement of the '567 patent is granted; and Martek's motion for a permanent injunction is granted in part with respect to the '594 and '281 patents and denied in part as moot with respect to the '567 patent.

#### **ORDER**

For the reasons set forth in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

- 1. Martek's Motion for Judgment as a Matter of Law that the Asserted Claims of the '281 Patent are Literally Infringed by Lonza's Process No. 2 (D.I.280) is GRANTED.
- 2. Lonza's Motion for Judgment as a Matter of Law that the '281 Patent is not Infringed by Lonza's Process No. 2 and is not Willfully Infringed (D.I.282) is DENIED.
- 3. Lonza's Motion for Judgment as a Matter of Law that the '567 Patent Claims are Invalid (D.I.284) is GRANTED in part

merits; (2) irreparable harm to the movant absent a stay; (3) substantial injury to the other parties interested in the proceeding; and (4) no harm to the public interest." Fisher-Price, 279 F.Supp.2d at 529. As such, it appears to the court that Lonza has abandoned this argument; therefore, the court need not address it.

and DENIED in part. The motion is GRANTED as to Lonza's lack of enablement defense with respect to the '567 patent and denied in all other respects.

- 4. Lonza's Motion for Judgment as a Matter of Law that the '594 Patent Claims are Invalid (D.I.286) is DENIED.
- 5. Martek's Motion for a Permanent Injunction (D.I.304) is GRANTED in part and DENIED in part as moot. The motion is GRANTED with respect to the '594 and '281 patents and denied as moot with respect to the '567 patent. The court will enter Martek's Amended Proposed Order of Permanent Injunction with the following modification: Martek shall remove all paragraphs and references to the '567 patent from the Amended Proposed Order and resubmit it within five (5) days of the date of this Order.
- 6. Martek's Motion for Leave to File a Surreply (D.I.315) is DENIED as moot.



Sally L. BOULANGER, Plaintiff,

v.

Michael J. ASTRUE,<sup>1</sup> Commissioner of Social Security, Defendant.

Civ. No. 06-333 SLR.

United States District Court, D. Delaware.

Oct. 30, 2007.

**Background:** Claimant appealed from a decision of the Commissioner of Social Security denying her application for disabili-

1. On February 12, 2007, Michael J. Astrue replaced Jo Anne B. Barnhart as Commis-

ty insurance benefits. Parties filed crossmotions for summary judgment.

**Holdings:** The District Court, Sue L. Robinson, J., held that:

- substantial evidence supported the ALJ's determination that claimant's treating physician's opinion was not entitled to controlling weight in determining claimant's residual functional capacity, and
- (2) hypothetical that the ALJ posed to the vocational expert in social security disability provided the vocational expert with enough information to properly answer the hypothetical.

Defendant's motion granted.

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In the context of judicial review of social security disability claim, a single piece of evidence will not satisfy the substantiality test if the Commissioner ignores, or fails to resolve, a conflict created by countervailing evidence; nor is evidence substantial if it is overwhelmed by other evidence, particularly certain types of evidence. Social Security Act, § 205(g), 42 U.S.C.A. § 405(g).

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Where the countervailing evidence consists primarily of the social security disability claimant's subjective complaints of disabling pain, the Commissioner must consider the subjective pain and specify his reasons for rejecting those claims and support his conclusion with medical evidence in the record.

sioner of Social Security.