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Paper 51
Date: April 10, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NUSEED AMERICAS INC.,
Petitioner,

v.

BASF PLANT SCIENCE GMBH,
Patent Owner.

Case IPR2017-02176
Patent 7,777,098 B2

Before JO-ANNE M. KOKOSKI, JEFFREY W. ABRAHAM, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

# FINAL WRITTEN DECISION
*35 U.S.C. § 318 and 37 C.F.R. § 42.73*

# ORDER ON MOTION TO AMEND
*35 U.S.C. § 316(d) and 37 C.F.R § 42.121*

# I. INTRODUCTION

Nuseed Americas Inc. ("Petitioner") filed a Petition challenging claims 20–22 of U.S. Patent No. 7,777,098 B2 ("the '098 patent"). Paper 1 ("Pet."). On April 11, 2018, we instituted an *inter partes* review of all challenged claims, but not all grounds, raised in the Petition. Paper 16 ("Inst. Dec."). After the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), Petitioner filed an Unopposed Request for Rehearing, requesting that the Board institute on all of the challenges raised in the Petition. Paper 19, 1. On May 21, 2018, we granted Petitioner's Unopposed Request for Rehearing, and modified our Institution Decision to include all grounds raised in the Petition. Paper 22.

After institution, BASF Plant Science GmbH ("Patent Owner") filed a contingent Motion to Amend, proposing substitute claims 23–25.[1] Paper 25 ("Mot." or "Motion"). Subsequently, Petitioner filed an Opposition to Patent Owner's Motion (Paper 29, "Opp."), Patent Owner filed a Reply in Support of its Motion (Paper 36, "Reply"), and Petitioner filed a Sur-reply (Paper 39, "Sur-reply").

Petitioner filed a Motion to Exclude Evidence relating to the testimony of Dr. Jonathan Napier, Patent Owner's declarant. Paper 42 ("Mot. to Exclude"). Patent Owner filed an Opposition to the Motion to Exclude (Paper 44, "PO Opp."), and Petitioner filed a Reply to Patent Owner's Opposition (Paper 47, "Pet. Reply").

An oral hearing was held on December 4, 2018, and a transcript of the hearing has been entered into the record of the proceeding. Paper 50 ("Tr.").

[1] Patent Owner did not file a response to the Petition, and Petitioner did not file a reply.

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 20–22 of the '098 patent are unpatentable, and we deny Patent Owner's Motion to Amend with respect to proposed substitute claims 23–25.

### *A. Related Matters*

According to the parties, there are no related matters. Pet. 4; Paper 4, 2.

### *B. The '098 Patent*

The '098 patent was filed under the Patent Cooperation Treaty on February 23, 2005, and claims priority to a German patent application filed February 27, 2004, which is the earliest possible effective filing date for the challenged claims. Ex. 1001, at [22], [30].

The '098 patent is titled "Method for Producing Unsaturated ω-3 Fatty Acids in Transgenic Organisms." *Id.* at [54]. "Fatty acids with two or more double bonds are known as polyunsaturated fatty acids (PUFA or PUFAs)." Ex. 1002 ¶ 18.[2] The '098 patent explains that ω-3-PUFAs are "important components of human nutrition" that promote "development of the child brain, the functionality of the eyes, the synthesis of hormones and other signal substances, and the prevention of cardiovascular disorders, cancer and diabetes." Ex. 1001, 1:49–56. In contrast, ω-6-PUFAs "tend to have an adverse effect on" inflammatory processes associated with immunological diseases. *Id.* at 2:34–37. The ω-6-PUFAs "generally promote inflammatory reactions." *Id.* at 2:44–48. In

[2] Exhibit 1002 is a declaration by Randall J. Weselake, Ph.D.

short, "food having a high proportion of ω-3[, as opposed to ω-6, PUFA] has a positive effect on human health." *Id.* at 2:46–47.

Unfortunately, however, the human diet tends to be high in ω-6-PUFAs. *Id.* at 2:32–37. And, although certain desaturases can convert ω-6-PUFAs to ω-3-PUFAs, humans lack such desaturases. *Id.* at 4:4–6; Ex. 1002 ¶ 21. Accordingly, an object stated in the '098 patent is "to develop a process for the production of [ω-3- PUFAs] in an organism, advantageously in a eukaryotic organism, preferably a plant or a microorganism." Ex. 1001, 5:22–25. That process includes: (a) introducing, into the organism, at least one nucleic acid sequence that encodes an enzyme having ω-3-desaturase activity; and (b) culturing the organism under conditions that permit the production of ω-3-PUFAs. *Id.* at 5:25–45. According to the '098 patent, the ω-3-PUFAs "produced by this process are preferably $C_{18}$-, $C_{20}$- or $C_{22}$-fatty acid molecules with at least two double bonds in the fatty acid molecule, preferably with two, three, four, five or six double bonds." *Id.* at 22:50– 53.

A specific ω-3-desaturase gene described in the '098 patent is known as Pi-omega3Des. *Id.* at 47:19, Figs. 2–8. The '098 patent explains that Pi-omega3Des provides for "desaturation of docosatetraenoic acid (C22:4 ω-6-fatty acid) to docosapentaenoic acid (C22:5 ω-3-fatty acid)." *Id.* at 50:22–24, Fig. 7. The '098 patent identifies nucleic acid sequences that encode the Pi-omega3Des gene that are selected either from the sequence shown in SEQ ID NO:1, sequences derived from the amino acid sequences shown in SEQ ID NO:2 due to the degeneracy of the genetic code, or derivatives of the sequence shown in SEQ ID NO:1 that encode an amino acid sequence with a particular percentage identity to SEQ ID

NO:2. *Id.* at 7:66–8:12.

Claims 1–19, which are unchallenged in the Petition, explicitly recite or incorporate sequences encoding Pi-omega3Des. *Id.* at 59:11–60:43. Claims 20–22, which are challenged in the Petition, are not so limited. *Id.* at 60:44–59.

*C. The Challenged Claims*

Claims 20–22 are reproduced below.

> 20. A process for production of compounds comprising one or more C18-, C20-, and/or C22-polyunsaturated fatty acids in a transgenic organism comprising:
>
> a) introducing into an organism, at least one nucleic acid sequence which encodes an ω-3-desaturase that is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid, and
>
> b) culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids.
>
> 21. The process according to claim 20, wherein the one or more C18-, C20-, and/or C22-polyunsaturated fatty acids have at least two double bonds.
>
> 22. The process according to claim 20, wherein the transgenic organism is a transgenic microorganism or a transgenic plant.

Ex. 1001, 60:44–59.

*D. The Instituted Grounds of Unpatentability*

We instituted trial based on the following grounds of unpatentability:

| Reference(s) | Basis[3] | Claims Challenged |
|---|---|---|
| Mukerji (Ex. 1003)[4] | § 102(e) | 20–22 |
| Kang (Ex. 1004)[5] | § 102(b) | 20–22 |
| Mukerji and Kang | § 103(a) | 20–22 |

## II. ANALYSIS

### *A. Claim Construction*

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2017).[6] Absent a special definition for a claim term being set forth in the specification, claim terms are given their ordinary and customary meaning as would be understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed.

[3] Our citations to 35 U.S.C. §§ 102 and 103 are to their pre-AIA versions.
[4] U.S. Patent Application Publ. No. 2003/0196217 A1, published October 16, 2003.
[5] Kang, Zhao, et al., *Adenoviral Gene Transfer of Caenorhabditis Elegans n-3 Fatty Acid Desaturase Optimizes Fatty Acid Composition in Mammalian Cells*, PNAS, Vol. 98, No. 7, 4050–54 (2001).
[6] The Office recently changed the claim construction standard applicable to an *inter partes* review. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). The rule changing the claim construction standard, however, does not apply to this proceeding because Petitioner filed its Petition before the effective date of the final rule, i.e., November 13, 2018. *Id.* at 51,340 (rule effective date and applicability date), 51,344 (explaining how the Office will implement the rule).

Cir. 2007).

Neither party proposes an express construction of any term with regard to claims 20–22, and we determine that no express construction is required for these claims for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

*B. Principles of Law*

To prevail in this *inter partes* review of the challenged claims, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In an anticipation analysis, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826–27 (C.C.P.A. 1968).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). The question of obviousness is resolved

on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

We analyze the instituted ground of unpatentability in accordance with the above-stated principles.

### *C. Level of Ordinary Skill in the Art*

According to Petitioner:

> A person of ordinary skill as of the filing date of the '098 patent would have a Ph.D. in molecular biology, molecular genetics, biochemistry, or a related field, with at least three years of experience in molecular genetics or biology, plant genetics, or recombinant DNA techniques. Ex. 1002 ¶¶ 48-49. An individual need not have every qualification enumerated above and more experience can substitute for less education.

Pet. 13 (citing Ex. 1002 ¶¶ 48–49). Patent Owner does not substantively dispute Petitioner's definition, but contends that a person of ordinary skill in the art should also have experience in lipid biochemistry. Mot. 10 (citing Ex. 2040 ¶¶ 18–19).

We credit the testimony provided by the declarants for both parties and find that one of skill in the art would have a Ph.D. in one of molecular biology, molecular genetics, biochemistry, or a related field, with at least three years of experience in molecular genetics or biology, plant genetics, recombinant DNA techniques, or lipid biochemistry. Ex. 1002 ¶¶ 48–49; Ex. 2040 ¶¶ 18–19. This level of ordinary skill is reflected not only by the information presented by the parties, but also by the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

*D. Anticipation by Mukerji*

*1. Mukerji (Ex. 1003)*

Mukerji is directed to the identification and isolation of genes that encode enzymes involved in the synthesis of PUFAs. Ex. 1003 ¶ 1. In particular, Mukerji discloses "isolated polynucleotides encoding an omega-3 desaturase and a delta-12 desaturase, the enzymes encoded by the isolated polynucleotides, vectors containing the isolated polynucleotides, [and] transgenic hosts that contain the isolated polynucleotides that express the enzymes encoded thereby," as well as methods for producing the desaturase enzymes and using the enzymes to make polyunsaturated fatty acids. *Id.*, Abstract. Mukerji provides several examples to further illustrate the invention disclosed therein. *Id.* ¶¶ 148–256.

*2. Analysis*

Petitioner asserts that claims 20–22 are anticipated by Mukerji. Pet. 15–27. Specifically, Petitioner maps Example 5 of Mukerji to each step recited in claims 20–22. *Id.* at 18–26. Patent Owner did not file a response to the Petition, and, therefore, does not dispute the evidence or arguments presented by Petitioner. After reviewing the evidence of record, we agree with Petitioner that Mukerji discloses the limitations of claims 20–22, as discussed below.

Claim 20 recites "[a] process for production of compounds comprising one or more C18-, C20-, and/or C22- polyunsaturated fatty acids in a transgenic organism." Mukerji discloses methods for producing PUFAs, and Example 5 of Mukerji, titled "Expression of the Omega-3 DeSaturase Gene ("sdd17") from *Saprolegnia diclina* in Bakers' Yeast" (Ex. 1003 ¶ 199), discloses the production of C-18, C-20, and C-22 PUFAs. Ex. 1003 ¶¶ 200–213, Table 3, Abstract; Pet. 21–22.

Claim 20 also recites "introducing into an organism, at least one nucleic acid sequence which encodes an ω-3-desaturase." Mukerji generally discloses that "[t]he subject invention relates to the nucleotide and translated amino acid sequences of the ω3-desaturase" and that "the genes and their corresponding enzymes may be used in the production of polyunsaturated fatty acids." Ex. 1003 ¶ 50. Mukerji explains that the genes that encode an ω-3-desaturase enzyme can be introduced into a host cell through the use of a vector or construct, which is accomplished by methods known to those of ordinary skill in the art. *Id.* ¶¶ 91–92; Pet. 22–23. Additionally, in Example 5 of Mukerji, "Clone pRSP19, which contained the full-length omega-3 desaturase (sdd17) from *S. diclina* cloned into pYX242, was transformed into *Saccharomyces cerevisiae* [(Bakers' yeast)] (SC334) using the 'Alkali-Cation Yeast Transformation'-brand kit (BIO 101, Vista, Calif.)." Ex. 1003 ¶ 201.

Claim 20 requires that the encoded ω-3-desaturase "is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid." In Mukerji's Example 5, Mukerji discloses "[c]onversion of adrenic acid (22:4n-6) to DPA (22:5n-3)."[7] Ex. 1003 ¶ 206; Pet. 24. Mukerji also reports the enzyme activity of the sdd17 encoded protein product from Saprolegnia diclina in Tables 3 and 4, which show the enzyme desaturated C22:4 ω-6-fatty acid to yield the corresponding C22:5 ω-3-fatty acid. Ex. 1003 ¶¶ 209–211, Table 3 (4% conversion at 24° C), Table 4 (8.4% conversion at 15° C); Pet. 18–20.

[7] The "adrenic acid (22:4n-6)" and "DPA (22:5n-3)" mentioned in Mukerji may also be referred to, respectively, as C22:4 ω-6-fatty acid and C22:5 ω-3-fatty acid. *See* Ex. 1002 ¶ 19 ("The ω position is also denoted "n" such that ω-3 is often denoted n-3, and ω-6 is denoted n-6.").

Claim 20 also recites "culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids." Mukerji discloses that after a vector encoding an ω-3 desaturase is constructed and introduced into a host cell, "[t]he host cell is then cultured under suitable conditions permitting expression of the genes leading to the production of the desired PUFA, which is then recovered and purified." Ex. 1003 ¶ 92. Additionally, Mukerji discloses culturing transgenic *S. cerevisiae* in Example 5, and reports production of C20 and C22 PUFAs in the transgenic cultures in Tables 3 and 4. *Id.* ¶¶ 200–213; Pet. 24.

Claim 21 depends from claim 20 and recites "wherein the one or more C18-, C20-, and/or C22-polyunsaturated fatty acids have at least two double bonds." Mukerji discloses "enzymes [that] catalyze the introduction of a carbon-carbon double bond between a particular position within a fatty acid substrate. For example, the novel ω3-desaturase disclosed herein catalyzes the conversion of arachidonic acid (20:4n-6) to eicosapentaenoic acid (20:5n-3) . . . ." Ex. 1003 ¶ 1; *see also id.* ¶¶ 6, 53, 153, 200–213 (showing production of various double bonds); Pet. 25.

Claim 22 depends from claim 20 and recites "wherein the transgenic organism is a transgenic microorganism or a transgenic plant." Mukerji discloses the use of *Saccharomyces cerevisiae*, a yeast, which is a transgenic microorganism. Ex. 1003 ¶¶ 200–201; Pet. 25.

In view of the foregoing undisputed evidence, we find that Petitioner has established by a preponderance of evidence that Mukerji discloses every limitation of, and, therefore anticipates, claims 20–22.

*E. Remaining Grounds of Unpatentability*

Petitioner contends that Kang anticipates claims 20–22, and that claims 20–22 are unpatentable under 35 U.S.C. § 103 as obvious over the combined teachings of Mukerji and Kang. In view of our determination that Mukerji anticipates claims 20–22 based on undisputed evidence presented by Petitioner, we need not address these grounds.

## III. CONTINGENT MOTION TO AMEND

Patent Owner filed a Motion to Amend, seeking to replace original claims 20–22 with substitute claims 23–25.

*A. Proposed Substitute Claims*

Patent Owner proposes to substitute independent claim 23 for independent claim 20, and dependent claims 24 and 25 for dependent claims 21 and 22, respectively. Proposed substitute claim 23 is reproduced below, with brackets showing subject matter deleted from claim 20 and underlining showing the subject matter added to claim 20:

> 23. (Substitute for Claim 20) A process for production of compounds comprising one or more C18-, C20-, and/or C22-polyunsaturated fatty acids in a transgenic organism comprising:
>
> (a) introducing into an organism, at least one nucleic acid sequence which encodes [an] <u>one</u> ω-3-desaturase that is capable of desaturating <u>(1)</u> C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and <u>(2) C18:3 ω-6- fatty acid to C18:4 ω-3-fatty acid</u>, and
>
> (b) culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids.

Mot. 26 (Claims Listing). Proposed dependent claims 24 and 25 merely change

the dependency from original claim 20 to substitute amended claim 23. *Id.*

### *B. Asserted Prior Art*

#### *1. Covello I (Ex. 1012)*[8]

Covello I aims to "characterize the fatty acid desaturase produced by the *fat-1* gene from the nematode *Caenorhabditis elegans*." Ex. 1012, Abstract. Covello I expressed the enzyme in the yeast *Sacccharomyces cerevisiae*. *Id.* According to Covello I, the FAT-1 $\omega$-3 desaturase "acts on substrates of 16-20 carbons with a preference for $\omega$-6 fatty acids, and its regioselectivity was confirmed to be that of an $\omega$-3 desaturase." *Id.* Table 1 of Covello I depicts "[a] complete list of fatty acid substrates tested and the products of desaturation for *fat-1* expressed in yeast," which includes various C-16, C-18, and C-20 fatty acids. *Id.* at 3–4.[9]

#### *2. Kang (Ex. 1004)*

Kang is directed to modifying the fatty acid composition of mammalian cells. According to Kang, ω-3-fatty acids are "essential components required for normal cellular function and have been shown to exert many preventive and therapeutic actions," but "[t]he amount of *n*–3 PUFAs is insufficient in most Western people, whereas the level of *n*–6 PUFAs is relatively too high." Ex. 1004, 1.[10] Kang "tested whether the expression of *fat-1* gene in [rat] heart cells can lead to conversions of *n*–6 fatty acids to *n*–3 fatty acids and, thereby, a change in fatty acid

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[8] Covello et al., *Characterization of the Regiochemistry and Cryptoregiochemistry of a Caenorhabditis elegans Fatty Acid Desaturase (FAT-1) Expressed in Saccharomyces cerevisiae*, Biochemistry 39, 11948–11954 (2000).

[9] Citations to Exhibit 1012 are made to the page numbers provided by Petitioner in the bottom, right-hand corner.

[10] Citations to Exhibit 1004 are made to the page numbers provided by Petitioner in the bottom, right-hand corner.

composition." Ex. 1004, 3. Kang reports that

> [i]n the cells expressing the *fat-1* gene (*n*–3 desaturase), almost all kinds of n–6 fatty acids were converted largely to the corresponding *n*–3 fatty acids, namely, 18:2*n*–6 to 18:3*n*–3, 20:2*n*–6 to 20:3*n*–3, 20:3*n*–6 to 20:4*n*–3, 20:4*n*–6 to 20:5*n*–3, and 22:4*n*–6 to 22:5*n*–3.

*Id.* at 4 (referring to Table 1 and Figure 3). Based on this data, Kang concluded that "the *fat-1* gene can be expressed functionally in mammalian cells, and its expression could confer cells' capability of converting *n*–6 PUFAs to corresponding n–3 PUFAs, leading to a balanced *n*–6/*n*–3 ratio." *Id.*

*C. Patentability of the Substitute Claims*

Petitioner contends that substitute claims 23–25 are unpatentable under 35 U.S.C. § 102 as anticipated by either Covello I or Kang, and unpatentable under 35 U.S.C. § 103 as obvious in view of the combined teachings of Covello I and Kang. Opp. 9–22. Patent Owner challenges Petitioner's arguments and evidence. *See generally* Reply.

*1. The Parties' Arguments*

We begin with an analysis of Petitioner's argument that Covello I anticipates the substitute claims.

Substitute claim 23 recites "[a] process for production of compounds comprising one or more C18-, C20-, and/or C22-polyunsaturated fatty acids in a transgenic organism." Mot. 26 (Claims Listing). Petitioner contends that Covello I discloses this limitation because it teaches the expression of the FAT-1 $\omega$-3 desaturase in transgenic, cultured yeast cells, which acted on "substrates of 16-20 carbons with a preference for $\omega$-6-fatty acids." Opp. 13 (citing Ex. 1012, 3–4, Table 1; Ex. 1014 ¶ 80).

Petitioner further contends that Covello I expressly discloses "introducing into an organism, at least one nucleic acid sequence," as substitute claim 23 requires. *Id.* at 14. For this limitation, Petitioner directs us to the use of the *C. elegans* FAT-1 gene, a nucleic acid that encodes an *ω*-3-fatty acid desaturase, in the experiments of Covello I, and the successful construction of a recombinant yeast strain carrying the FAT-1 gene. *Id.* (citing Ex. 1012, 2–3; Ex. 1014 ¶ 81).

Petitioner also contends that the results reported in Covello I indicate "[f]or the yeast strains grown on media supplemented with 18:3(6,9,12) (*i.e.*, C18:3 ω-6-fatty acid), the desaturated 18:4(6,9,12,15) (*i.e.*, C18:4 ω-3-fatty acid) was evident only for the cultures expressing the *FAT-1* ω-3 desaturase." *Id.* (citing Ex. 1012, 3, Fig. 1, Table 1; Ex. 1014 ¶ 82). According to Petitioner, Covello I thus expressly discloses that the FAT-1 ω-3 desaturase is "capable of desaturating . . . C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid" as substitute claim 23 requires. *Id.*

Petitioner acknowledges that Covello I does not expressly address the conversion of C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid, also recited in substitute claim 23. *Id.* Petitioner contends, however, that Covello I also discloses an ω-3 desaturase capable of converting C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid based on "the application of the common knowledge of a person skilled in the art in view of the express teaching in *Kang* that the *FAT-1* ω-3 desaturase in fact desaturates C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid." Opp. 10–11 (citing, *inter alia*, *In re Preda,* 401 F.2d at 826), 15.

Petitioner asserts that the absence of information in Covello I regarding conversion of C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid is due to the fact that the experiments in Covello I did not include any C22:4 ω-6-fatty acids, and therefore Covello I "did not purport to test the full range of ω-6-fatty acids that

the *FAT-1* ω-3 desaturase was known to be capable of desaturating." *Id.* at 15. Petitioner also directs us to the statement in Covello I that "it seems reasonable to conclude that *C. elegans FAT-1* catalyzes the introduction of a cis double bond at the ω-3 position of a wide range of mono- and polyunsaturated fatty acid derivatives." *Id.* (citing Ex. 1012, 4).

Petitioner argues that Covello I reports the FAT-*1* ω-3 desaturase produces various C-18 and C-20 polyunsaturated fatty acids, and therefore discloses "culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22- polyunsaturated fatty acids" as recited in substitute claim 23. *Id.* at 16 (citing Ex. 1012, 2–3, 6, Fig. 1, Table 1; Ex. 1014 ¶¶ 80–85).

Substitute claim 24, which depends from substitute claim 23, requires that "the one or more C18-, C20-, and/or C22-polyunsaturated fatty acids have at least two double bonds." For this limitation, Petitioner again directs us to the statement in Covello I that "it seems reasonable to conclude that *C. elegans FAT-1* catalyzes the introduction of a cis double bond at the ω-3 position of a wide range of mono- and polyunsaturated fatty acid derivatives." *Id.* (citing Ex. 1012, 4).

Substitute claim 25, which depends from substitute claim 23, recites "wherein the transgenic organism is a transgenic microorganism or a transgenic plant." Petitioner argues that Covello I discloses the FAT-1 ω-3 desaturase conversion of ω-6 PUFAs to ω-3 PUFAs in both microorganisms and plants based on the experimental data of the FAT-1 ω-3 desaturase activity in transgenic yeast. *Id.* at 17 (citing Ex. 1012, 2; Ex. 1014 ¶ 87).

Patent Owner contends that Petitioner fails to demonstrate the prior art references disclose "introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase that is capable of desaturating

(1) C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and (2) C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid," as substitute claim 23 requires. *See, e.g.*, Reply 3. Specifically, Patent Owner argues that neither Covello I nor Kang expressly discloses a single ω-3 desaturase capable of desaturating *both* C22:5 ω-3-fatty acid and C18:4 ω-3-fatty acid in any organism. *Id.* at 1, 3. Patent Owner asserts that it is undisputed that there are gaps in Petitioner's prior art, namely Covello I "does not expressly address" the conversion of C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid, and Kang "does not expressly address" the conversion of C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid. *Id.* at 2 (citing Opp. 14, 18), 12 (citing Opp. 14, 18).

According to Patent Owner, Petitioner "attempt[s] to graft fat-1's capabilities from one system into another in order to meet the requirements of the substitute claims." *Id.* at 1. Patent Owner contends, however, that Petitioner's anticipation arguments are flawed because Petitioner assumes incorrectly that the FAT-1 ω-3 desaturase is capable of desaturating both C22:4 ω-6-fatty acid and C18:3 ω-6-fatty acid irrespective of the system it is in. *Id.* at 13.

Patent Owner asserts that the declarants for both parties agree that experimental data is important to a person of ordinary skill in the art to understand the desaturating capability of the FAT-1 ω-3 desaturase in different systems. *Id.* (citing Ex. 2058 ¶¶ 34–35); Mot. 8 (citing Ex. 2039, 68:22–69:5, 71:15–72:18; Ex. 2040 ¶ 48), 18 (citing Ex. 2039, 27:19–34). Patent Owner further asserts that Petitioner has presented no data to support its argument that the FAT-1 ω-3 desaturase is capable of desaturating C22:4 ω-6-fatty acid in Covello I's yeast, or that the FAT-1 ω-3 desaturase is capable of desaturating C18:4 ω-3-fatty acid in Kang's rat heart cells. Reply 3–4 (citing Opp. 14, 18;

Ex. 1014 ¶ 64; Ex. 2058 ¶¶ 8, 11–15; Ex. 2040 ¶¶ 69–72; Ex. 1004, 1, 3 (Fig. 3), 4; Ex, 1012, 3–4, Table 1); 12–13. Thus, a person of ordinary skill in the art "would not understand or have a reasonable expectation that fat-1 is capable of desaturating ***both*** DTA to DPA ***and*** GLA to SDA in a given organism." *Id.* at 2; *see also id.* at 13 (arguing that a person of ordinary skill in the art "would understand that confirmatory experimental data is necessary to understand fat-1's ability to convert [C18:3 ω-6-fatty acid] and [C22:4 ω-6-fatty acid] in either Covello I or Kang's systems").

Patent Owner further contends that experimental data showing that the FAT-1 ω-3 desaturase cannot convert C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid in its native organism undermines Petitioner's argument that C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid conversion is an inherent property of FAT-1. Reply, 4 (citing Ex. 2053); *see also id.* at 10–12 (arguing that Ex. 2055 further demonstrates that the FAT-1 ω-3 desaturase has different activity in different systems). In view of this data, Patent Owner argues that the functionalities of the FAT-1 ω-3 desaturase are system specific, i.e., the fact that the FAT-1 ω-3 desaturase converts a specific fatty acid in one system does not mean it will necessarily be able to do the same conversion in any other system. *Id.* at 2. Patent Owner thus concludes that "[w]ithout experimental data of both conversions in one system, [Petitioner] has not shown that either Covello I or Kang anticipates the '098 Patent." Reply 13.

In its Sur-reply, Petitioner contends that the "plain and ordinary meaning" of the "capable of" limitation in substitute claim 23 "requires no actual conversion of either [C22:4 ω-6-fatty acid] to [C22:5 ω-3-fatty acid] or [C18:3 ω-6-fatty acid ] to [C18:4 ω-3-fatty acid]. Nor [does it] require that any conversion

. . . must take place in the same transgenic organism." Sur-reply 1.[11] Instead, according to Petitioner, the claims require only that "the same ω-3-desaturase ***is capable of desaturating*** both DTA to DPA and GLA to SDA." *Id.* at 1–2. Petitioner contends that its plain and ordinary meaning interpretation "aligns with the prosecution history given that the applicants sought and obtained claims to other transgenic organisms despite disclosing data only in yeast of Pi-omega3Des desaturating activity." *Id.* at 2. According to Petitioner, the only actual conversion required by substitute claim 23 is "the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids." *Id.* Under this interpretation, Petitioner contends it is undisputed that Kang and Covello I each discloses that the FAT-1 ω-3 desaturase is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid, respectively. *Id.* at 2–4.

[11] We disagree with Patent Owner's contention that Petitioner presented a late claim construction argument in its Sur-reply. *E.g.*, Tr. 26:24–26. In its Opposition, Petitioner not only focused on the phrase "capable of" (*e.g.*, Opp. 7), but also presented its argument that Covello I anticipates the substitute claims based on the application of the common knowledge of a person of ordinary skill in the art would have had in view of Kang's teachings (*id.* at 10). Petitioner presented consistent arguments in its Sur-reply (*see, e.g.*, Sur-reply, 2–3) in response to Patent Owner's argument in the Reply specifying that the functionalities of the FAT-1 ω-3 desaturase are system specific (*e.g.,* Reply 1–2). Furthermore, as Petitioner notes, Patent Owner opposed additional briefing on claim construction, and we previously communicated to the parties that Petitioner could address claim construction issues in its Sur-reply. Tr. 47:1–7.

*2. Analysis*

The parties' dispute regarding whether Covello I anticipates substitute claims 23–25 centers on whether Covello I discloses the limitation of substitute claim 23 requiring "introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase that is capable of desaturating (1) C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and (2) C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid."[12]

It is undisputed that Covello I teaches expressing the FAT-1 ω-3 desaturase in the yeast *Saccharomyces cerevisiae* and therefore discloses "introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase," as recited in claim 23. Opp. 14; Ex. 1012, 1–3.

Based on the plain language of the claim, the next step in the anticipation analysis is to determine whether the FAT-1 ω-3 desaturase disclosed in Covello I is "capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid." *See Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1298 (Fed. Cir. 2014) ("Here, as in all aspects of claim construction, 'the name of the game is the claim.'") (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)); *Translogic*, 504 F.3d at 1257; *Wasica Finance GmbH v. Continental Auto. Sys.*, 853 F.3d 1272, 1281 (Fed. Cir. 2017) ("It is axiomatic that we will not narrow a claim term beyond its plain and ordinary meaning unless there is support for the limitation in the words of the claim, the specification, or the prosecution history.") (quoting *3M Innovative*

[12] Patent Owner does not dispute Petitioner's evidence and arguments regarding Covello I's disclosure of the remaining limitations of substitute claim 23, or the limitations in substitute claims 24 and 25. *See* Reply 3–13.

*Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1333 (Fed. Cir. 2013)).

On its face, substitute claim 23 refers only to the capability of an ω-3-desaturase to desaturate specific ω-3 fatty acids. The claim does not require the ω-3-desaturase to actually convert any C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid or any C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid. Indeed, counsel for Patent Owner acknowledged during the oral hearing that "[t]he claim does not require that the conversion actually happen." Tr. 24:6–8. Rather the claim requires introducing into an organism an ω-3-desaturase with certain abilities. This is consistent with the plain and ordinary meaning of the term "capable," which is defined as "[h]aving capacity or ability," and "[h]aving the ability required for a specific task or accomplishment." *The American Heritage Dictionary of the English Language*, available at https://ahdictionary.com/word/search.html?q=capable, last visited March 5, 2019.

The distinction between capability and actual conversion is reinforced by other language in the claim, namely the final step of the process, which requires "culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids." In contrast to the express requirement that the organism *produce* a C18, C20, or C22 fatty acid when cultured, when referring to the ω-3-desaturase, the claim instead requires that the ω-3-desaturase is *capable* of desaturating C22:4 and C18:3 ω-6-fatty acid. *See Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp.,* 533 F.3d 1362, 1371 (Fed. Cir. 2008) ("Different claim terms are presumed to have different meanings." (citation omitted)). The claim neither expressly requires that the ω-3-desaturase be responsible for the "production" of C18, C20, or C22 fatty acid, or that the "production" involves conversion of C22:4 ω-6-fatty acid to C22:5 ω-3-

fatty acid and C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid.

Furthermore, we disagree with Patent Owner that the "capable of" limitation in substitute claim 23 is system or organism specific. *See, e.g.*, Reply 2; Tr. 22:23–25 (counsel for Patent Owner arguing that "[t]he claim is in the context of one transgenic organism" and that Petitioner has "read the requirement of one transgenic organism out of the claim"). Although substitute claim 23 requires introducing the ω-3-desaturase "into an organism," there is no express language in the claim itself that limits the recited capabilities of an ω-3 desaturase to its capabilities within a single organism or system. And Patent Owner fails to direct us to intrinsic evidence sufficient to justify reading a limitation into substitute claim 23 that requires evaluating the capabilities of the ω-3-desaturase in a single system. *Wasica*, 853 F.3d at 1281.

Moreover, Patent Owner's interpretation would require that an ω-3 desaturase can be shown to have the recited capabilities only by providing evidence of actual conversions in the same system. This position, however, once again conflates the claim's distinction between capability and production/activity. Furthermore, it is inconsistent with the fact that the applicants sought and obtained claims generally directed to transgenic organisms despite disclosing data for the desaturating activity of Pi-omega3Des in yeast only. *See, e.g.*, Ex. 1001, 49:37–52:60; Sur-reply 2.

For all of the foregoing reasons, we give each term in substitute claim 23 its plain and ordinary meaning, such that "introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase that is capable of desaturating (1) C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and (2) C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid," means introducing an ω-3-desaturase into an

organism, wherein the ω-3-desaturase has the ability to desaturate C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid in at least one system, and the ability to desaturate C18:3 ω-6- fatty acid to C18:4 ω-3-fatty acid in at least one system.

It is undisputed that Covello I expressly teaches that the FAT-1 ω-3 desaturase is capable of desaturating C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid in the yeast *Saccharomyces cerevisiae*. Ex. 1012, 4, Table 1; Opp. 5; Reply 1; Sur-Reply 3. It is also undisputed that the same desaturase, the FAT-1 ω-3 desaturase, is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid in rat heart cells. Ex. 1004, 3–4; Opp. 5; Reply 1; Sur-Reply 3. In view of the plain and ordinary meaning of substitute claim 23, it is irrelevant that Covello I does not expressly discuss desaturation of C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid. Based on the teachings in Kang, a person of ordinary skill in the art would have understood that the properties of the FAT-1 ω-3 desaturase include the ability to desaturate C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid in at least one system. Thus, the undisputed evidence demonstrates that the FAT-1 ω-3 desaturase disclosed in Covello I is indeed "capable of" both conversions. *Preda*, 401 F.2d at 826–827.

We agree with Petitioner that Patent Owner's presentation of data demonstrating that the FAT-1 ω-3 desaturase cannot convert C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid in its native organism, and accompanying arguments (Reply 4–12; Ex. 2053; Ex. 2055), are not relevant to the question of whether Covello I anticipates substitute claim 23. First, Patent Owner's arguments again are based on equating capability with conversion activity in a particular system – which the claim does not expressly require, as discussed above. Second, Patent Owner ignores other evidence that demonstrates FAT-1 is capable of performing

that conversion in at least one system. *See, e.g.*, Ex. 1004, 3–4.

In view of the foregoing, we find Petitioner has demonstrated sufficiently that Covello I discloses "introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase that is capable of desaturating (1) C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and (2) C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid."

As noted above, Petitioner provides evidence showing that Covello I discloses the remaining limitations in substitute claim 23, namely "[a] process for production of compounds comprising one or more C18-, C20-, and/or C22-polyunsaturated fatty acids in a transgenic organism" and "culturing the organism under conditions which permits the production of one or more C18-, C20-, and/or C22-polyunsaturated fatty acids." Petitioner also presents evidence showing Covello I discloses the limitations in claims 24 and 25. Patent Owner does not contest this evidence. Therefore, after reviewing Petitioner's evidence, we agree that Petitioner has demonstrated Covello I discloses these limitations.

*3. Conclusion*

Accordingly, we find that Petitioner has demonstrated, by a preponderance of evidence, that Covello I anticipates substitute claims 23–25. Because we determine that substitute claims 23–25 are unpatentable over Covello I, we deny Patent Owner's Motion to Amend.

*4. Remaining Patentability Challenges*

In view of our determination that substitute claims 23–25 are unpatentable as anticipated by Covello I, we decline to address Petitioner's challenges that substitute claims 23–25 are unpatentable under 35 U.S.C. § 102 as anticipated by

Kang, and are unpatentable under 35 U.S.C. § 103 as obvious in view of Covello I and Kang.

*D. Alternative Analysis – 35 U.S.C. § 326 and 37 C.F.R. § 42.121*

The outcome here would not change even if we did agree with Patent Owner's proposed interpretation of substitute claim 23. In a motion to amend, a patent owner's proposed substitute claims must meet the statutory requirements of 35 U.S.C. § 326(d) and the procedural requirements of 37 C.F.R. § 42.121. *See* "Guidance on Motions to Amend in view of *Aqua Products*" (2017), available at https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf. Accordingly, Patent Owner must demonstrate that: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the original disclosure sets forth written description support for each proposed claim. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121; *see also Lectrosonics, Inc. v Zaxcom, Inc.*, Case IPR2018-01129, 01130 (PTAB February 25, 2019) (Paper 15) (precedential).

The written description requirement is contained in 35 U.S.C. § 112 ¶ 1, and reflects the prohibition of 35 U.S.C. § 316(d)(3) against adding new matter to the proposed amended claims. The test for sufficiency of written description is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Adequacy of written description is a

question of fact. *Id.* (citing *Ralston Purina Co. v. Far–Mar–Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

Compliance with the written description requirement will necessarily vary depending on the context, including the nature and scope of the claims, the complexity and predictability of the relevant technology, the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue. *Id.* (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357–59 (Fed. Cir. 2005)). While the written description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement. *Id.* at 1352 (citations omitted).

The ’098 patent issued from U.S. Patent App. No. 10/590,958 (“the ’958 Application”) and is the U.S. national stage entry of PCT App. No. PCT/EP2005/001865 filed on February 25, 2005. Ex. 1001, [21], [86]. The ’098 patent claims priority to German Patent App. No. 10 2004 009 458.6 filed on February 27, 2004 (“the ’458 Application”). *Id.* at [30]. According to Patent Owner, the ’958 and ’458 Applications are “substantively identical,” and support for claims 23–25 can be found in the original and priority application. Mot. 11.

Patent Owner argues that the ’958 and ’458 Applications provide support for the claim limitation of “introducing into an organism, at least one nucleic acid sequence which encodes one ω-3-desaturase that is capable of desaturating (1) C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and (2) C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid” based on the disclosure of Pi-omega3Des. *Id.* at 12.

According to Patent Owner, it is "undisputed that Pi-omega3Des converted, in relevant part, GLA (18:3 ω-6) to SDA (18:4 ω-3) and DTA (22:4 ω-6) to DPA (22:5 ω-3)." *Id.* Patent Owner further argues that the '958 and '458 Applications "provide details for culturing and growing transgenic microorganisms . . . and plants." *Id.* at 13 (internal citations omitted).

Patent Owner interprets the claim as requiring an ω-3-desaturase capable of desaturating ***both*** DTA to DPA ***and*** GLA to SDA in a given organism. Reply 2. To demonstrate this capability, Patent Owner requires experimental data confirming both conversions occur (i.e., activity/production) in the same organism. *Id.* at 2, 13.

The '958 and '458 Applications disclose expressing Pi-Omega3Des in yeast expression vector pYES3 (Ex. 2043, 55[13]; Ex. 2042, 64[14]), plant vector pSUN-USP (Ex. 2043, 56; Ex. 2042, 65), and transgenic oilseed rape plants and linseed plants (Ex. 2043, 61; Ex. 2042, 70–71). The '958 and '458 Applications provide data of conversion activity for Pi-omega3Des only in yeasts transformed with pYES3-Pi-Omega3Des. Ex. 2043 57–58, Figures 2–8; Ex. 2042, 66–68, Figures 2–8.

As Patent Owner acknowledges, the claims are neither limited to a single ω-3 desaturase, e.g., Pi-Omega3Des, nor limited to any particular transgenic organism, such as yeast expression vector PYES3. *See* Tr. 37:5–16, 39:3–9. The '958 and '458 Applications, however, lack any data demonstrating that Pi-

[13] Page numbers for this exhibit refer to the numbers appearing at the top-center of each page.
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> Omega3Des is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid when expressed in a transgenic organism other than pYES3. Although the '958 and '458 Applications discuss expressing Pi-Omega3Des in plants and seeds, there is no data in the applications regarding desaturation of fatty acids in these organisms. The '958 and '458 Applications also lack any data demonstrating that any other ω-3 desaturase is capable of desaturating C22:4 ω-6-fatty acid to C22:5 ω-3-fatty acid and C18:3 ω-6-fatty acid to C18:4 ω-3-fatty acid in the same organism, including pYES3. According to Patent Owner, the desaturation activity of an ω-3 desaturase in a particular system/organism is not something a person of ordinary skill in the art would know without having data. Reply 2, 13; s*ee also* Tr. 37:17–19 (counsel for Patent Owner arguing that "all omega-3 desaturases aren't the same, and they have different properties, which is why data is so important to show what conversions each of those desaturases are or are not capable of").

Under Patent Owner's interpretation of substitute claim 23, requiring desaturation data for each ω-3 desaturase in each organism, there is no evidence that the inventors had possession of the claimed subject matter, beyond Pi-Omega3Des in yeast, as of the filing date. Since the claims are not limited to Pi-Omega3Des or yeast, we find that there is no written description support for the full scope of the substitute claims under this interpretation. *See Ariad*, 598 F.3d at 1350 (finding no written description support where the claims "recite methods encompassing a genus of materials achieving a stated useful result, . . . [b]ut the specification does not disclose a variety of species that accomplish the result") (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed.

Cir. 1997)); *see also LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F. 3d 1336, 3147 (Fed. Cir. 2005) (holding that "a patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed"); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345–46 (Fed. Cir. 2000) (noting that the "scope of the right to exclude" must not "overreach the scope of the inventor's contribution to the field of art as described in the patent specification").

In view of this, Patent Owner fails to demonstrate its substitute claims, even under Patent Owner's interpretation and arguments, meet all of the statutory requirements of 35 U.S.C. § 326(d) and the procedural requirements of 37 C.F.R. § 42.121. We, therefore, deny Patent Owner's Motion to Amend under this alternative analysis as well.

## IV. MOTION TO EXCLUDE

Petitioner moves to exclude Exhibit 2040, the Declaration Dr. Jonathan Napier, and Exhibit 2058, the Reply Declaration of Dr. Napier.[15] Mot. to Exclude, 1. Petitioner contends that "Dr. Napier wrongly applies an improper standard for what a prior art reference teaches by requiring that only scientifically validated data are acceptable prior art or inherency teachings." *Id.* at 4. In response, Patent Owner argues that "Dr. Napier neither contests the prior art status of [Petitioner's] asserted references nor requires that such references contain scientifically validated data in order to qualify as prior art." PO Opp. 1. Because we did not rely on

[15] Petitioner separately identifies Dr. Napier's testimony in footnote 11 and paragraphs 43–45 of Exhibit 2058 in its Motion. We consider this part of Petitioner's request to exclude Ex. 2058 in its entirety.

Dr. Napier's testimony regarding the prior art in reaching our decision, we dismiss Petitioner's motion as moot.

## V. CONCLUSION

Based on the information presented, we conclude that Petitioner has shown by a preponderance of the evidence that claims 20–22 of the '098 patent are unpatentable under 35 U.S.C. § 102. Patent Owner's Motion to Amend is denied.

## VI. ORDER

For the reasons given, it is hereby

ORDERED that claims 20–22 of U.S. Patent 7,777,098 B2 are unpatentable under 35 U.S.C. § 102;

FURTHER ORDERED that Patent Owner's Motion to Amend is denied; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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