

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

Ex parte THERMOLIFE INTERNATIONAL, LLC.
Appellant

Appeal 2018-001029
Merged Reexamination Control 90/011,394 and 90/011,869
Patent 7,777,074 B2
Technology Center 3900

Before TONI M. SCHEINER, RICHARD M. LEBOVITZ, and
RAE LYNN P. GUEST, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*.

DECISION ON APPEAL

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

I. STATEMENT OF CASE

ThermoLife International, LLC (hereinafter “Patent Owner”), the real party in interest¹ of Patent 7,777,074 B2 (hereinafter the “’074 patent”), appeals under 35 U.S.C. §§ 134(b) and 306 from the new grounds of rejection, maintained by the Examiner, of claim 6² under 35 U.S.C. § 102(b) as anticipated by Barger,³ as evidenced by Dessaignes⁴ and Gmelin,⁵ or as anticipated by Dessaignes or Gmelin. App. Br. 1; Decision, mailed February 1, 2016 (“Decision”); Examiner’s Final Rejection, mailed September 28, 2016 (“Fin. Rej.”); Examiner’s Answer, mailed August 29, 2017 (“Ans.”). We have jurisdiction under 35 U.S.C. §§ 134(b) and 306.

The ’074 patent relates to various amino acid compounds, in particular, nitrates or nitrites of amino acid compounds. (’074 patent, col. 1, ll. 26–28).

Claim 6 is the only claim on appeal. Claim 6 was not an original claim of the ’074 patent, but was added during reexamination, and reads as follows:

¹ See Patent Owner’s Appeal Brief filed May 9, 2017 (hereinafter “App. Br.”) at 2.

² Claim 6 is the only remaining claim on appeal. Claims 1 and 2 have been cancelled, and claims 3, 4, 5, and 7–10 have been confirmed as patentable by the Examiner. App. Br. 2; Advisory Action mailed July 23, 2014; Ans. 1.

³ Barger, G., “Monographs on Biochemistry,” THE SIMPLER NATURAL BASES, R. H. A. 157–163, Plimmer & F. G. Hopkins (eds.) Longmans, Green & Co., London (1914) (“Barger”).

⁴ M. Dessaignes, “Scientific and Medicinal Chemistry: Examination of some Products of the Transformation of Creatine,” 12 (279) THE CHEMICAL GAZETTE OR JOURNAL OF PRACTICAL CHEMISTRY, 201–204, (June 1, 1854) (“Dessaignes”).

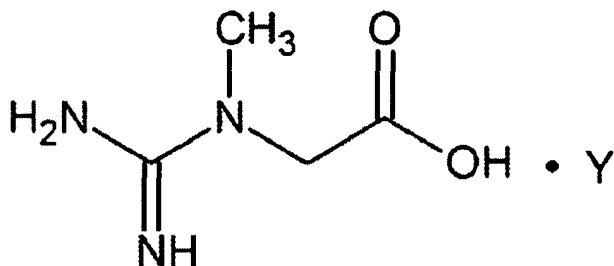
⁵ Leopold Gmelin, “Creatine,” Hand-Book of Chemistry, 10 ORGANIC COMPOUNDS CONTAINING EIGHT AND TEN ATOM OF CARBON, 249–255, Henry Watts, trs., Harrison and Sons for the Cavendish Society, London (1856) (“Gmelin”).

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

6. A Compound having the structure of:



wherein Y is selected from the group consisting of a Nitrate and a Nitrite.

Claims App'x, App. Br. 46.

It is undisputed that claim 6 is directed to a creatine nitrate or a creatine nitrite compound.

The '074 patent states that, when ingested, creatine nitrate provides enhanced nitric oxide production while providing improved vasodilation effects for better circulation and distribution of creatine in the body. *Id.*, col. 17, ll. 54–57.

II. BACKGROUND OF CASE ON APPEAL

This reexamination proceeding is based on two third-party requests for *ex parte* reexamination, one filed by Mr. Bruce W. Kneller and Mr. Richard Gaspari (Request for *Ex Parte* Reexamination, filed December 17, 2010) and one filed by Mr. Daniel Pierce and Mr. Richard Gaspari (Request for *Ex Parte* Reexamination, filed August 18, 2011). The two requests were merged into a single *ex parte* reexamination on March 30, 2012, retaining both of the reexamination control numbers for identification. A first Decision on Appeal (“Decision”) was issued on February 1, 2016, with a new ground of rejection including additional evidence that further supported the Examiner’s initial finding of anticipation.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

In our earlier Decision, we addressed Patent Owner's arguments that the sole applied prior art reference, Barger, which expressly teaches a "nitrate of creatine" is ambiguous and did not enable one skilled in the art to make creatine nitrate.

Decision 3. In setting forth this argument, Patent Owner relied on three declarations of Dr. Chamberlin⁶ and the testimony of Dr. Wolff.⁷ Decision 4.

Without agreeing that Barger is ambiguous or not enabling (*see* Decision 6 ("We are not persuaded that Barger is ambiguous or not enabled.")), the Decision included further evidence, Dessaignes and Gmelin, showing that Barger is enabling because substantially the same method used in the '074 patent to make creatine nitrate was known and thus need not have been expressly described in Barger. *See* Decision 9. A new ground of rejection was entered because new evidence was relied upon to address the specific arguments presented by Patent Owner. *See Honeywell Int'l. Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1358 (Fed. Cir. 2017) ("[a] new ground of rejection is not negated by the fact that the Board is responding to [a party's] argument.") (quoting *In re Biedermann*, 733 F.3d 329, 338 (Fed. Cir. 2013)). We did not reverse the Examiner's rejection, but agreed that, in light of the additionally applied evidence, the Examiner's rejection

⁶ The Declaration of Richard Chamberlin under 37 C.F.R. § 1.132, dated November 9, 2013, and entered into the record on November 12, 2013 (hereinafter "First Chamberlin Declaration" or "1st Chamberlin Decl."). The Supplemental Declaration of Richard Chamberlin, dated May 30, 2014, and entered into the record on June 2, 2014 (hereinafter "Second Chamberlin Declaration" or "2nd Chamberlin Decl.") (10 pages). The Second Supplemental Declaration of Richard Chamberlin, also dated May 30, 2014, and entered into the record on June 2, 2014 (11 pages) (hereinafter "Third Chamberlin Declaration" or "3rd Chamberlin Decl.>").

⁷ The Declaration of Dr. Manfred Wolff, dated November 8, 2013, and entered into the record on November 12, 2013 (hereinafter "Wolff Decl.>").

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

was sound. Because Dessaignes and Gmelin also expressly teach creatine nitrate and a process for making creatine nitrate that is substantially the same as that of the '074 patent, additional new anticipation grounds of rejection were entered based on these publications. Decision. 11.

Patent Owner reopened prosecution and submitted additional testimony by Dr. Chamberlin⁸ and new testimony of Dr. Levere.⁹ The Examiner was not persuaded by Patent Owner's arguments and evidence and maintained the Decision's new grounds of rejection. Final Rej.; Ans.

An oral hearing was held on March 7, 2018. A transcript of the hearing will be entered into the record in due course.

Accordingly, the issue before us is: based on a preponderance of the evidence, has Patent Owner shown that the Examiner erred in maintaining the new grounds of rejection in light of further arguments and evidence of record, namely the Fourth and Fifth Chamberlin Declarations and the Levere Declaration?

We answer this question in the negative and maintain the new grounds of rejection set forth in the Decision.

⁸ The Declaration of Richard Chamberlin under 37 C.F.R. § 1.132, dated March 30, 2016, and entered into the record on April 1, 2016 (hereinafter "Fourth Chamberlin Declaration" or "4th Chamberlin Decl."). The Declaration of Richard Chamberlin under 37 C.F.R. § 1.132, dated November 14, 2016, and entered into the record on November 28, 2016 (hereinafter "Fifth Chamberlin Declaration" or "5th Chamberlin Decl.").

⁹ The Declaration of Trevor H. Levere under 37 C.F.R. § 1.132, dated March 29, 2016, and entered into the record on April 1, 2016 (hereinafter "Levere Declaration" or "Levere Decl.").

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

III. FINDINGS OF FACT

Dessaignes, 1854¹⁰

D1. Dessaignes teaches that, in combining creatine with nitrous acid gas, “beautiful crystalline compounds with a strongly acid reaction” are formed that “consist of nitrate of creatine.” Dessaignes 203.

D2. Dessaignes describes two methods for making a “nitrate of creatine.”

The first is:

If a rapid current of nitrous acid gas be passed into water containing an excess of undissolved creatine, the latter is quickly dissolved, and a large quantity of small brilliant crystals afterwards make their appearance. These crystals, which may readily be obtained in thick short prisms by solution in warm water and cooling, consist of nitrate of creatine. Their solution, which has a very acid taste, is abundantly precipitated by ammonia. The precipitate, dissolved in hot water, furnishes on cooling small prisms, which effloresce at 212° F., and the solution of which is neutral with paper, and does not produce precipitates with chloride of mercury, chloride of zinc or nitrate of silver. These prisms, dried at 212° F. and analysed, furnished in 100 parts –

	Found.	Calculated (anhydrous creatine).
Carbon	36.77	36.64
Hydrogen	7.13	6.87
Nitrogen	32.18	32.06

I also determined the quantity of nitric acid in the nitrate of creatine, and found it to contain 32.36 per cent. of monohydrated nitric acid. The formula $C^8H^{18}N^6O^4$, $N^2H^2O^6$ requires 32.47 per cent. of $N^2H^2O^6$.

¹⁰ We refer to Dessaignes as reported in William Francis, 12 THE CHEMICAL GAZETTE OR JOURNAL OF PRACTICAL CHEMISTRY, No. 279, pp. 201–204 (June 1, 1854). Dessaignes, which was originally printed in German, is also of record in English as reported in John and Charles Watt, 1 THE CHEMIST, pp. 594–597 (1854).

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Dessaignes, 203.

D3. In the second method, “[t]he same compound was produced by dissolving 1.057 gr. of crystallized creatine in nitric acid containing 0.447 gr. of $\text{N}^2\text{H}^2\text{O}^6$, and evaporating at 86° F. The crystals were homogeneous, and weighed 1.373 gr. From calculation they should weigh 1.376 gr.” Dessaignes, 203.

Gmelin, 1856¹¹

G1. Gmelin describes the properties of creatine as follows: “White opaque mass. (Liebig.) Inodorous, without perceptible taste. (Chevreul.) Has a somewhat bitter taste, and scratches in the throat. (Liebig.) Neutral to vegetable colours. (Chevreul.)” and having the formula $\text{C}^8\text{N}^3\text{H}^9\text{O}^4$. Gmelin, 252.

G2. Gmelin states that

– 3. Creatine dissolved in strong nitric, sulphuric, phosphoric, or hydrochloric acid, is converted into cratinine by abstraction of 2HO , the cratinine then combining with the acid. (Liebig.) — But if these acids are dilute, the creatine remains unaltered, even after long boiling, and the solution in cold hydrochloric acid leaves, by spontaneous evaporation, crystals of pure creatine. (Liebig.)

Gmelin 252–253.

G3. Gmelin teaches

The colourless solution of creatine in nitric acid of sp. gr. 1.34 gives off nitrous fumes *when heated in the water-bath*, and leaves on evaporation a colourless residue [of nitrate of cratinine?], which dissolves in water, separates out therefrom in small granules, and does not precipitate bichloride of platinum. (Chevreul.)

Gmelin 253 (emphasis added; brackets in original).

G4. Gmelin also repeats the teachings of Dessaignes as follows:

¹¹ Watts, published in 1882, has substantially the same teachings as Gmelin.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Nitrate of Creatine. — 1. Obtained by dissolving crystallized creatine in the requisite quantity of nitric acid, and evaporating the solution at 30°. — 2. By passing a rapid stream of nitrous gas through water containing an excess of creatine in suspension. The creatine dissolves with tolerable rapidity, and a considerable quantity of small shining crystals of the nitrate are formed, which, when recrystallized by dissolving them in lukewarm water and cooling, form thick short prisms. This salt is less soluble in water than the sulphate or hydrochlorate. The solution has a very sour taste, and is decomposed by ammonia with precipitation of creatine. (Dessaignes.)”

Gmelin 254.

G5. Gmelin states that creatine “does not neutralize the weakest acid, even when added in vary large quantity. (Liebig.)” Gmelin 254.

Wislicenus¹², 1881

Wil. Wislicenus states:

Creatine crystalises in large, colourless, brilliant, short monoclinic prisms of the formula $C_4H_9N_3O_2 \cdot H_2O$, becoming cloudy at 100deg.C, with loss of the water of crystallization. It is soluble in 74 parts of cold, and considerably less boiling, water. It is insoluble in absolute alcohol and ether.

With the mineral acids creatine yields salts of acid reaction corresponding to those of glycocyamine, whose solutions can only be brought to unchanged crystallization at ordinary temperatures, being converted on heating into salts of creatinine.

Creatine nitrate, $C_4H_9N_3O_2 \cdot HNO_3$, crystalises in large colourless prisms.

Wislicenus, 423.

¹² Johannes Wislicenus, “Adolph Strecker's Short Text-Book of Organic Chemistry”, 423 KEGAN PAUL, TRENCH & CO., LONDON (1881).

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Wi2. Wislicenus further states that “Creatinine . . . is readily formed from creatine, with removal of water, by heating with dilute mineral acids; e.g. on evaporating a solution of creatine sulphate on the water bath, creatinine sulphate is left.” Wislicenus, 423.

Bloxam, 1895

B1. Creatine forms prismatic crystals easily soluble in hot water, but very sparingly in alcohol and ether. The crystals are $C_4H_9N_3O_2$, Aq. Creatine is neutral in reaction, but plays the part of a weak monacid base. *Creatine nitrate*, $C_4H_9N_3O_2$, HNO_3 crystallises in prisms. When the solutions of its salts are heated above $30^\circ C.$, they are converted into salts of creatinine, a stronger base containing H_2 and O less than creatine. Bloxam 656.

Barger, 1914

Ba1. Barger is a compendium of bases that can be derived from natural sources and is entitled “The Simpler Natural Bases.” Barger Title, 5.

Ba2. Barger identifies that “Many substances of physiological importance are at the same time acids and bases; those in which the basic character predominates have been included in this monograph.” Barger 5. Creatine is included in the monograph. Barger, vii (Table of Contents), 69–78, 157–163.

Ba3. Barger states that “[f]or our purposes a better practical definition is to describe a base as a substance which is precipitated by phosphotungstic acid.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

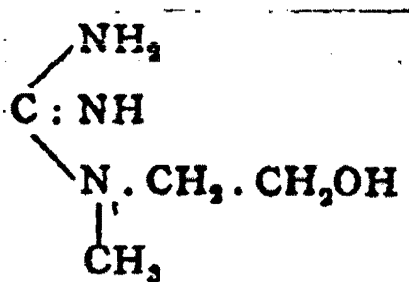
Adopting this criterion we consider creatinine to be a base but creatine not.”

Barger 6.

Ba4. Barger teaches that, in 1844, Liebig prepared creatine from the flesh of various animals, analyzed it and converted it into its anhydride which he named creatinine. Barger 69.

Ba5. Barger teaches that “Creatine and creatinine are interconvertible. The change from the former to the latter substance can be brought about quantitatively by heating with acid or even without a solvent (see appendix).” Barger 70.

Ba6. Barger provides a chemical structure for creatine as follows. Barger 78.



Ba7. Barger teaches forming creatinine from creatine by heating a dilute creatine solution containing 6–7 percent hydrochloric acid in a autoclave to 117° for forty-five minutes, by warming a 0.1 percent creatine solution for 3-4 hours on the water bath with 2.44 percent hydrochloric acid (twice its volume of normal hydrochloric acid), by adding an equal volume of normal hydrochloric acid and heating on the water bath for 3 hours or in the autoclave to 117–120° for 25 minutes, or by heating without a solvent in an autoclave for three hours at 4.5 atmospheres. Barger 158. Thus, Barger teaches all methods of forming creatinine from creatine require heating to at least 117°, even in the presence of acid.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Ba8. Barger describes the physical and chemical properties of both creatine and creatinine. Barger 158–159.

Ba9. Barger teaches that “The aqueous solution is neutral. The basic properties of creatine are very feeble (dissociation constant 1.81×10^{-11} at 40.2° , Wood [1903]) and its salts with mineral acids are hydrolysed by water.” Barger 158. Thus, Barger teaches that, although it is a feeble base, creatine forms salts with mineral acids.

Ba10. Barger explains that when creatine is “heated with dilute mineral acids, with water or by itself, creatinine is formed.” Barger 159.

Ba11. Barger teaches

Compounds of creatine.—The *nitrate*, $C_4H_9O_2N_3 \cdot HNO_3$, is less soluble than the hydrochloride or the sulphate. The compounds $C_4H_9O_2N_3 \cdot ZnCl_2$ and $C_4H_9O_2N_3 \cdot CdCl_2 \cdot 2H_2O$ are crystalline (Neubauer [1862, 2]). All these salts are hydrolysed by water.

Barger 160, first full ¶.

IV. ANALYSIS

There are multiple express teachings in the prior art of a nitrate of creatine (D1–D3, G4, W11, B1, Ba11) and that a nitrate of creatine was formed by mixing nitric acid and creatine and evaporating the water at $30^{\circ}C$, or $86^{\circ}F$. D3, G4. Express teachings in the prior art are initially presumed to be enabled. *In re Antor Media Corp.*, 689 F.3d 1282, 1289 (Fed. Cir. 2012) (“[D]uring patent prosecution, an examiner is entitled to reject claims as anticipated by a prior art publication or patent without conducting an inquiry into whether or not that prior art reference is enabling. As long as an examiner makes a proper prima facie case of anticipation by giving adequate notice under § 132, the burden shifts to the applicant to submit rebuttal evidence of nonenablement.”).

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

We have considered all of the evidence provided by Patent Owner purporting to show that these references are either ambiguous or not enabled. However, for the reasons discussed below, we are not persuaded that Patent Owner has overcome the new grounds of rejection set forth in the Decision.

Ambiguity

Patent Owner still contends that Barger is ambiguous and that Dessaignes and Gmelin create more ambiguity rather than clarify the ambiguity in Barger. App. Br. 9; Reply Br. 10. In particular, Patent Owner contends that Dessaignes or Gmelin do not establish that creatine nitrate salt is “the *only* possible resulting compound described by Barger.” App. Br. 11.

From at least the citations provided by Patent Owner, it has been held that an ambiguous reference does not, as a matter of law, anticipate a claim. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) (refusing to find claims anticipated when the prior art references were “unacceptably vague”); *see also In re Hughes*, 345 F.2d 184, 188 (CCPA 1965); *In re Turlay*, 304 F.2d 893, 899 (CCPA 1962) (“It is well established that an anticipation rejection cannot be predicated on an ambiguous reference.”). *Wasica Fin. GmbH v. Cont’l. Automotive Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017).

None of the cases cited by Patent Owner that describe the prior art as “ambiguous” involve a clear and express teaching in the reference that anticipates on its face. For example, in *Gore*, a claim directed to a paste-extruded PTFE product, having certain characteristics, was said not to be anticipated by two prior art references that teach paste-extrusion processes. *Gore*, 721 F.2d at 1554. The

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

teachings of the references are silent as to, and thus do not expressly teach, the particular characteristics of products produced from the processes taught. *Id.*

In *Hughes*, the claim to “pieced, interleaved-spiral core strips” was found not be anticipated by a prior art reference that described the core only as having the “identical position” or “relationship” as an original “wound core.” *Hughes*, 354 F.2d at 186. In other words, what was recited in the claims, i.e., a spiral core, was not expressly taught by the prior art in *Hughes*. *Id.* See also *Wasica*, 853 F.3d at 1284 (claim to “constant frequency” was not anticipated by prior art, where there was no express teaching in the art of a “constant frequency” as recited in the claims and evidence that the term “common frequency” might be an average frequency and not constant).

Similarly, *In re Brink*, 419 F.2d 914 (CCPA 1970), a claim reciting a fiber bed compressed to a bulk density within a recited range was found not to be anticipated by a prior art reference that did not expressly teach a bulk density for the fiber bed taught therein. *Brink*, 419 F.2d at 862–863. In *Turlay*, a claim to a cylinder block having “a single,” interpreted as one and only one, exhaust port was determined to not be anticipated because the reference’s figures in cross section could have equally conveyed one or two exhaust ports and there was no planar figure expressly showing the presence of only one exhaust port. *Turlay*, 304 F.2d at 899.

However, in the present case, Barger, Dessaignes, and Gmelin expressly teach a “nitrate of creatine” (Ba11, D2, G4), and these express teachings unambiguously anticipate the claimed composition, a nitrate of creatine, on their face. The express teaching is not vague or ambiguous, but clear and exact as to not only the name of the compound claimed, but also citing the chemical formula and

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

other physical properties for both the starting creatine material and the nitrate of creatine. D1, D2, G1, G3, G4, W11, B1, Ba5, Ba6, Ba8, Ba9, Ba10, and Ba11.

Patent Owner asserts that the ambiguity is found not in what is expressly taught by Barger, but in whether or not what is expressly taught is accurate. In particular, Patent Owner argues that “Barger may be disclosing alternative compounds” to creatine nitrate, and that the phrase “nitrate of creatine” is “just a name, without any substantive support in Barger that the claimed salt was ever actually or constructively reduced to practice.” App. Br. 11; *see* App. Br. 9, 15, 26, 27, 31, 32, 35, 37, 40, 41, and 44. Patent Owner relies on evidence that purports to show that Barger “*describes* a multitude of possible compounds” by the single express phrase “the nitrate of creatine” because there are “credible possible alternative compounds that *might* have been made.” App. Br. 12-15 (emphasis added) (citing various portions of Dr. Chamberlin’s First, Second and Third Declarations and Dr. Wolff’s Declaration). Yet, Barger describes only one compound expressly by the phrase “the nitrate of creatine,” (Ba11), as does Dessaignes and Gmelin. D2, G4. Patent Owner has not established that the name, itself, is ambiguous.

Patent Owner argues that the references are ambiguous because, although Dessaignes and Gmelin teach that creatine nitrate can be formed by combining creatine and nitric acid and evaporating at 30° C (D3, G4), Gmelin (and Watts) also teach that creatine dissolved in “strong” nitric acid is converted to creatinine then combined with the acid, and if dissolved in “dilute” acids “creatine remains unaltered” such that the solution retains “crystals of pure creatine.” PO App. Br. 15–18; Reply Br. 16–18; G2. According to Patent Owner, creatine nitrate is not a possible product with either “strong” or “dilute” acids, and, thus, a nitrate of

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

creatine is not possible by mere combination at all. PO App. Br. 18; Reply Br. 16–18.

We do not find these discrete teachings contradict or render ambiguous Dessaignes' mixing process. Gmelin's discussion of strong and dilute acids does not address specifically or disparage Dessaignes' particular process of making creatine nitrate by combining creatine and nitric acid and does not undermine the finding that the compound is anticipated. The teaching of creatine nitrate in Barger, Dessaignes, or Gmelin and the mixing process taught in Dessaignes and Gmelin are not ambiguous teachings, but clear on their face.

Regarding temperature, Patent Owner argues that the references are ambiguous because Gmelin (and Watts) teach that heating creatine results in converting creatine to creatinine. PO App. Br. 19; Reply Br. 15; G3. Patent Owner contends that evaporating at 30° C (86° F) would require heating the creatine and nitric acid solution and thus concludes that creatinine and the nitrate thereof are the only compounds that Dessaignes could have formed. *Id.* See also Fifth Chamberlin Decl. ¶ 15.

Again, we do not find these discrete teachings either contradictory or ambiguous. While they may show that the temperature at which creatine and nitric acid are combined is a result-effective parameter when making creatine nitrate, the parameters disclosed in the art do not teach or even suggest that that creatine nitrate cannot be made by combining creatine and nitric acid at 86° F, as taught by Dessaignes, and do not undermine the finding that the compound is anticipated. Indeed, nothing in the literature of record specifically indicates that creatine nitrate cannot be formed by mixing creatine and nitric acid and evaporating at 30° C. Rather, a preponderance of the evidence of record suggests that a much higher

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

temperature is necessary to convert creatine to creatinine. Wi1 (100 °C); B1 (“above 30 °C”); Ba7 (autoclave temperatures of at least 117 °C). In other words, a temperature requirement that is specifically taught in the prior art does not render the teaching of creatine nitrate in Barger, Dessaignes, or Gmelin ambiguous.

Patent Owner further contends that the references are ambiguous because not all of the references recite the correct formula for creatine nitrate, $C_4H_9N_3O_2$, HNO_3 , or they contain other errors. PO App. Br. 17, 30–38; Reply Br. 21–27. However, it appears that only Gmelin reports the formula for creatine nitrate incorrectly (G1 ($C^8N^3H^9O^4$, with 4 extra carbon atoms), while the other references, including Dessaignes report the formula correctly.¹³ D2 ($C^8H^{18}N^6O^4$, $N^2H^2O^6$, which converts to $C_4H_9O_2N_3 \cdot HNO_3$); Wi1 ($C_4H_9N_3O_2$, HNO_3); B1 ($C_4H_9N_3O_2$, HNO_3); and Ba11 ($C_4H_9O_2N_3 \cdot HNO_3$). We are not persuaded that Gmelin’s error in reproducing the formula stated in Dessaignes reflects ambiguity in the art, which expressly teaches creatine nitrate and a method for making creatine nitrate. The issue here is not whether a formula is correct or not, but whether the cited publications unambiguously teach creatine nitrate. Patent Owner attempts to undermine an express teaching with no more than conjecture. Patent Owner has failed to introduce adequate evidence that the claimed compound was not made, i.e., that the prior art on its face is factually incorrect. Without sufficient evidence

¹³ Patent Owner cites to other errors in the references cited by Barger, namely Neubauer, Liebig, and Volhard as evidence of unreliability of the formula in Barger. PO App. Br. 21, 23, and 30 (citing Lever Decl. ¶ 25). While indicating that it was difficult to get to the formula correct via elemental analysis available at the time of publication of these earlier references, errors in these references do not show ambiguity or error in the prior art teachings of creatine nitrate so relied upon. Moreover, Barger states the correct formula.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

to support a finding of clear error, we are unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous.¹⁴ The teaching of an incorrect formula in Gmelin is not evidence of ambiguity, particularly when Gmelin unambiguously names the compound that was produced and a process for making the claimed compound.

Patent Owner also argues that the references are ambiguous because Barger suggest that creatine is not a base (Ba3) and Gmelin teaches that creatine cannot neutralize the weakest acid even in large quantities (G5), and thus cannot disassociate in nitric acid to form creatine nitrate. PO App. Br. 13, 16–17; Reply Br. 19–21. We addressed the basic nature of creatine in our prior Decision on Appeal. Decision 6–7. We have nothing to add to these findings but note that Barger provides a dissociation constant indicating that creatine does dissociate in water. Ba9. We are not persuaded as to any ambiguity in the teachings of Barger or Gmelin regarding the weak basic nature of creatine.

Finally, Patent Owner contends that the references are ambiguous because they teach making the “same compound” or “same combination” using two different methods, and Patent Owner contends that because the gas bubbling method is ambiguous, the method for making the “same compound” or “same combination” must also be ambiguous. PO App. Br. 17–18, 30, and 32–35 (block quoting Fourth Chamberlin Decl. ¶¶ 12–24); Reply Br. 21, 23–24. In particular, the gas bubbling method taught by the prior art is said to be performed with

¹⁴ Even if the identification of the compound as “nitrate of creatine” is incorrect and Dessaignes never made creatine nitrate, the reference is not ambiguous; it is just wrong. An invention is anticipated if it “was ... *described in a printed publication*... more than one year prior to the date of application for patent in the United States.” 35 U.S.C. § 102(b) (2007). An error would still anticipate if the reference is sufficiently enabled to make what was described.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

“nitrous acid gas,” which Patent Owner argues is an ambiguous term, as it could mean several different gases. PO App. Br. 34 (quoting Fourth Chamberlin Decl. ¶¶ 16–17). Patent Owner further states that “a very skilled chemist” could not make creatine nitrate using the gas bubbling method taught by Dessaignes. Reply Br. 21 (Fourth Chamberlin Decl. ¶ 19), 32.

The rejection we set forth in the Decision does not rely on the bubbling method taught by Dessaignes and Gmelin. Decision 11. Rather, we rely on the second mixing method, which is expressly taught by Dessaignes (D3, G4) as teaching creatine nitrate. Decision 11 (comparing the mixing method to that of the ’074 patent). It is of no moment if the gas bubbling method is unclear in its teaching or if “a very skilled artisan” could not achieve creatine nitrate using the gas bubbling method. We give little weight to the actions of unnamed experimenters who have not testified on the record of their own first-hand knowledge of the steps taken during the alleged experiment. *Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997); *In re Michalek*, 162 F.2d 229, 231–232 (CCPA 1947) (“With respect to the experiments described in the affidavits it must be said that in a patent it is to be presumed that a process, if used by one skilled in the art, will produce the product alleged by the patentee and such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product”). *See also In re Reid*, 179 F.2d 998, 1002 (CCPA 1950) (“[T]he failures of experimenters who have no interest in succeeding should not be accorded great weight”).

Dessaignes’ second method was determined to be substantially identical to that described in the ’074 patent. Decision 11. Dessaignes expressly teaches making a nitrate of creatine by dissolving creatine in nitric acid and evaporating at

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

86° F (30° C). The description is clear on its face. We discuss in detail below why this description, even if dependent upon the nitric acid concentration, is an enabling teaching in the art.

Enablement

Patent Owner previously argued that Barger was not enabling because it did not teach a method of making creatine nitrate, only the existence thereof (which Patent Owner also disputed, as discussed below). Decision 3. However, in the Decision, we stated that which is known to those skilled in the art need not be expressly taught in a reference for it to be enabling. Decision 11 (citing *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 (Fed. Cir. 1997)). Thus, in the new ground of rejection, Dessaignes and Gmelin were relied upon as evidence that a process for making creatine nitrate was known in the art, establishing that Barger's teaching of the same compound was enabled. Decision 11. Patent Owners do not dispute that that which is known to those skilled in the art need not be expressly taught in a reference for it to be enabling. *See* PO App. Br. generally. Rather, Patent Owner contends that Dessaignes and Gmelin do not enable a skilled artisan to make creatine nitrate by the processes expressly taught therein, and thus, none of the references are enabled. PO App. Br. 15, 20–21.

“[A] prior art printed publication cited by an examiner is presumptively enabling barring any showing to the contrary by a patent applicant or patentee.” *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012). The burden thus shifts to Patent Owner to show that the reference is not enabling. *Id.* (“[I]t is procedurally convenient to place the burden on an applicant who is in a better position to show, by experiment or argument, why the disclosure in question is not

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

enabling or operative. It would be overly cumbersome, perhaps even impossible, to impose on the PTO the burden of showing that a cited piece of prior art is enabling. The PTO does not have laboratories for testing disclosures for enablement.”).

Initially, Patent Owner argues the express teaching of creatine nitrate is not “reliable” (i.e., what was made by Dessaignes might not be creatine nitrate as reported). PO App. Br. 18. Patent Owner’s argues that Dessaignes or Gmelin do not establish that creatine nitrate salt is “the *only* possible resulting compound described by Barger.” App. Br. 11.

However, in determining enablement, the product described in a prior art publication need not have actually been made to satisfy enablement. *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). The actual results may be prophetic or even not achievable at all by the writer at the time of the published document, provided that what is taught may be used by the skilled artisan to make the disclosed product at the time of claimed invention without undue experimentation. *See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) (“[A]dditional references used solely to show enablement of an anticipatory reference need not antedate that reference, but must show that the claimed subject matter was in possession of the public more than one year prior to the applicant’s filing date.”). Thus, Patent Owner’s argument that Dessaignes did not actually make, or is not conclusively shown to have made, creatine nitrate is not probative to the legal question of enablement.

Nor is a presumption of enablement overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. *In*

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

re Weber, 405 F.2d 1403, 1407 (CCPA 1969) (“We do not think that appellants’ mere showing that it is possible to operate within [the prior art’s] disclosure without obtaining his results is sufficient to overcome the strong presumption that the process of a patent if used by one skilled in the art will produce the results alleged by the patentee.”).

Rather, we consider whether a skilled artisan in 2007 could have made creatine nitrate from Dessaignes’ teaching (as repeated by Gmelin) without undue experimentation. “Enablement of prior art requires that the reference teach a skilled artisan—at the time of filing—to make or carry out what it discloses in relation to the claimed invention without undue experimentation.” *In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015).

Determination of whether the requisite amount of experimentation is undue may include consideration of:

(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).

Regarding the nature of the invention, the invention is directed to a nitrate or nitrite compound of creatine. Claim 6.

Regarding the amount of direction provided, Gmelin and Dessaignes teach substantially identical methods of making creatine nitrate. They describe a method of “dissolving” crystallized creatine in “the requisite quantity” (G4) or “0.447 gr.”

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

(D3) of “nitric acid” and evaporating at 86° F (30° C). D3, G4.¹⁵ Dessaignes is reporting the result of his personal experience, and thus Dessaignes’ teaching constitutes a working example.

We find the amount of guidance provided in the prior art to be substantial, particularly as the process described appears to be substantially identical to the method taught by the ’074 patent, which states that “[a]pplicants have cost-effectively synthesized Creatine Nitrate by combining nitric acid and Creatine, mixing with water, and leaving to crystallize.” ’074 patent, col. 9, ll. 19–21. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (lack of diagrams, flow charts, and other details in the prior art references did not render them nonenabling in view of the fact that applicant’s own specification failed to provide such detailed information, and that one skilled in the art would have known how to implement the features of the references).

Patent Owner further points out the differences between the process taught by the prior art and the process described in the ’074 patent, in that the ’074 patent mixes creatine and nitric acid then dilutes with water. PO App. Br. 17, 29–30; Oral Hearing Transcript 10:24–11:25, 28:1–8. However, Dessaignes teaches mixing creatine and aqueous nitric acid (D3, “dissolving”) and there is no evidence to suggest the order of adding water is critical. Indeed, the ’074 patent expressly states that the order of mixing materials is not critical. *See* ’074 patent, col. 15, ll. 49–59 (“[I]t will be understood that such manufacture is not limited to the specific order of steps or forms as disclosed. Any steps or sequences of steps of manufacture of implementations of an Amino Acid Compound in any form are

¹⁵ As noted above, we do not rely on the bubbling method described in these references. D2, G4. Thus, whether or not this method is enabling is not relevant to our analysis.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

given as examples of possible steps or sequences of steps or potential forms and not as limitations, since many possible manufacturing processes and sequences of steps may be used to manufacture Amino Acid Compound implementations in a wide variety of forms.”). Patent Owner asserts that the skilled artisan could only make creatine nitrate using knowledge gleaned from the ’074 patent (Reply Br. 10–11, 28, and 33) but have not demonstrated why the order of diluting with water is critical to the invention.

Regarding the state of the art, Patent Owner points out that the state of the art was “ancient.” PO App. Br. 22–23. Patent Owner cites extensively to the testimony of Dr. Levere, who is a historian with a specialty in history of chemistry, who provides a lengthy discussion of the limitations of mid-nineteenth century chemists and technology of the time, and where errors might be present in the 19th-century references. App. Br. 22–23 (citing Levere Decl. ¶¶ 10–29).

A reference is enabled if a skilled artisan would have been able to arrive at the claimed invention without undue experimentation *at the time of the invention*, not at the time of the references. While Dr. Levere describes where some errors may have existed in the prior art references, Dr. Levere states without clear explanation or evidence, that a skilled artisan in 2007 would not be capable of performing the process of mixing crystallized creatine with nitric acid and allowing it to evaporate at 86° F. Levere Decl. ¶¶ 9, 13, 22, and 33. We decline to give Dr. Levere’s testimony as to what a modern-day chemist would have been capable of making from the teachings in the references significant weight because Dr. Levere is not a modern-day chemist, but a historian. Levere Decl. ¶ 33 (“I am today a historian of chemistry, not a chemist.”). Dr. Levere has not provided any evidence as to the particular skills of a modern-day chemist, but only discusses what is

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

presented in the nineteenth century references in relation to the time period in which they were written. This evidence is not probative of whether a skilled artisan in 2007 would have been capable of performing Dessaignes' mixing method to make the claimed compound without undue experimentation.

At the time of the invention, in 2007, the art of salt formation from acids and bases was well-known and quite extensive. *See e.g.*, Fourth Chamberlin Decl. ¶¶ 16–20, 34–35 (describing what a modern-day chemist knows about oxidizing agents and nitration/nitrosation agents like nitric/nitrous acids and the knowledge and assumptions a skilled artisan would use in forming a salt with strong nitric acid). In fact, Dessaignes discloses specific amounts of each of creatine and nitric acid utilized to make the nitrate of creatine, as well as an evaporation temperature (D3). Patent Owner has not provided adequate evidence that following this specific guidance would not result in creatine nitrate, even if it were necessary to select a volume of acid in which to perform the mixing. Mixing crystallized creatine and nitric acid in the manner described in Dessaignes would require no more than routine experimentation by a skilled artisan.

Even if the chemical formula was wrong in 1854, the skilled artisan today would have at their disposal many methods for confirming the structure of the product produced by Dessaignes process. *See* Fourth Chamberlin Decl. ¶ 57 (discussing known ways to confirm identity “(which today would include melting point, elemental analysis, chromatographic analysis, NMR, IR, MS, X-ray crystallography). These rigorous standards have evolved into their present form over time as each technique listed became available.”). Patent Owner did not utilize such tools to prove Dessaignes was wrong, but merely attempts to undermine its express teaching with conjecture.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Regarding predictability in the art, Patent Owner points to the testimony of Dr. Chamberlin to support its contention that chemical reactions are unpredictable. App. Br. 24–25. Dr. Chamberlin testifies that “if the experimental parameters in the original publication are not carefully and completely specified” the result described therein is “profoundly unreliable.” *Id.* (citing First Chamberlin Decl. ¶ 16). However, Dr. Chamberlin has not explained how Dessaignes’ instructions for making creatine nitrate are not “carefully and completely specified.” Dr. Chamberlin describes “not knowing which of the many forms of a given salt was used in the original experiment can result in a misleading or completely erroneous conclusion.” *Id.* But Dessaignes does not use a salt as a reactant, and Dr. Chamberlin does not identify any lack of specificity in Dessaignes reagents (crystallized creatine and nitric acid). D3. As discussed above, a modern-day chemist would be capable of confirming the salt obtained by mixing crystallized creatine and nitric acid without undue experimentation. Dr. Chamberlin further testifies as to the unpredictability of solubility of a given crystal or crystallization behavior of compounds. PO App. Br. 25 (citing First Chamberlin Decl. ¶ 22).¹⁶ Again, Dr. Chamberlin does not speak to any lack of specificity in the process for making the compound or explain why a skilled artisan could not arrive at the compound taught by the prior art using the method steps specifically recited in the prior art.

As for the relative level of skilled artisan, Patent Owner asserts that the skilled artisan would not only need to be an organic chemist familiar with reactions of amino acids with mineral acids but also knowledgeable about the state of organic chemistry at the time of the

¹⁶ There is an express teaching in the art that creatine easily dissolves in water (D2, G4), and thus the prior art would inform the skilled artisan as to the predictable solubility of creatine in water.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

references so that she would be able to properly understand and judge the disclosures of the references.

PO App. Br. 23. However, salt formation from combining acid and bases in a simple titration is generally the subject of high school chemistry. Dessaignes' teaching of a single step of mixing one material with another is not complex organic chemistry – it's a mixing step, which can be performed without exceptional skill. Dessaignes teaches, in plain and clear language, a basic chemical concept not requiring significant chemical knowledge. While confirming the identity of a resulting salt indeed may be slightly more difficult, techniques used to confirm chemical compounds are well-known in the art and are taught at an undergraduate skill level. Moreover, Dessaignes describes numerous physical properties for the substance that he created, which would be observable without significant expertise. D2 ("thick short prisms," "very acid taste," "precipitated by ammonia," and further properties of the precipitate), G4 ("small shining crystals" that recrystallize to "thick short prisms," "less soluble than the sulphate or hydrochlorate," "very sour taste," "decomposed by ammonia"), W11 ("large colourless prisms").

Patent Owner does not address the quantity of experimentation necessary to arrive at the claimed invention, but only points out that "a very experienced chemist" could not perform the bubble method described by Dessaignes. PO App. Br. 24 (citing Fourth Chamberlin Decl. ¶ 19). As discussed above, it is the mixing method, not the bubbling method, that was cited in the Decision as being substantially identical to the method described in the '074 patent. Decision 11.

Patent Owner also argues that both the first and second methods are not enabled because the references suggest that creatine nitrate cannot be made with either a "strong" or "weak" acid. PO App. Br. 16–18, 30, and 43; Reply Br. 11;

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

G2. Indeed, Dessianges speaks to the grams of nitric acid and creatine, but not the volume of water in which they are dissolved to determine a final acid concentration. Even if concentration of nitric acid is a result-effective variable, we find no reason to conclude that varying nitric acid concentration for a skilled artisan in 2007 would constitute more than routine experimentation and does not undermine the finding that the compound is anticipated. In fact, varying concentrations is also a high school chemistry technique and would be routine for an ordinary artisan. A reference is not precluded from being enabled merely because the skilled artisan would have had to perform some experimentation, provided that the experimentation is not undue. *In re Morsa*, 803 F.3d at 1377. Moreover, “[s]killed workers would as a matter of course, in our opinion, if they do not immediately obtain desired results, make certain experiments and adaptations.” *In re Michalek*, 162 F.2d 229, 232 (CCPA 1947). In other words, a skilled artisan would have more than one opportunity to make adaptations within the instructions provided to arrive at creatine nitrate.

Thus, considering the above analysis of the *Wands* factors, we determine that the evidence supports a conclusion that the skilled artisan would have been capable of using the teachings of Dessaignes, even with routine variation in nitric acid concentration, to make creatine nitrate, as taught by the references. In other words, the skilled artisan would have had possession of the claimed creatine nitrate compound, as of the time of the invention. We determine based on a preponderance of the evidence that the prior art is enabling.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

What if Dessaignes did not, in fact, make creatine nitrate?

As noted above, in order to be enabling, the compound need not have been made to satisfy enablement. *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). Indeed, *In re Donohue*, has a fact pattern similar to the one at issue in this case: the examiner had made an anticipation rejection over a publication, which disclosed the claimed compound, in combination with two patents teaching a *general process* of making the particular *class* of compounds.¹⁷ *Donohue*, 766 F.2d at 532. Even though the authors of the publication in *Donohue* testified that had not actually synthesized the compound,¹⁸ the court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. *Id.* at 533–534. The method patents were evidence that the named subject matter of the primary reference, which disclosed every element of the invention (as does Barger) indeed “was in the public’s possession” at the time of the invention. *Id.* at 534. The court distinguished the case where a showing was made that *all attempts* to make the compounds using the prior art methods were unsuccessful. *Id.* at 533. We have no credible evidence of

¹⁷ The generic method patents relied on in *Donohue* are akin to the Examiner’s reliance on Rajkumar, Petrosyan, Terzyan, and Mostad, which teach generally how to make amino-acid nitrate salts from mixing the amino acid with nitric acid, even dilute nitric acid. Ans. 9–10. As the court in *Donohue* found the related general process sufficiently enabling a claim for a specific compound, *Donohue*, 766 F.2d at 534, we too could find the teachings of Rajkumar, Petrosyan, Terzyan, and Mostad sufficient. However, we need not turn to the more general class of amino acid nitrates cited by the Examiner because Dessaignes expressly and clearly provides a method to make the exact compound claimed.

¹⁸ We have no similar testimony from now long-dead Dessaignes to conclude that he did not actually perform what he asserts to have performed.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

record of a modern chemist's failed attempts to make creatine nitrate by the mixing method taught in Dessaignes.

Yet, Patent Owner contends that its evidence "cannot be dismissed by merely referencing *In re Donohue* and *In re Gleave* [, 560 F.3d 1331, 1338 (Fed. Cir. 2009) ("it is not 'necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.'" (quoting *Donohue*, 766 F2d at 533)]." Rather, Patent Owner argues that the credibility of the disclosed methods were not questioned in *Donohue* as they are here and that salt formation chemistry and the process taught by Dessaignes is less predictable than the preparation of antisense oligonucleotides from a sense sequence based on repeated cycles of phosphoramidite chemistry which was the known technology in *In re Gleave*. PO App. Br. 27–29. This argument dismisses the law requiring only that the product be taught and the procedure be enabling, and not that the product actually be made. Concerns about credibility of the method being capable of producing what is taught in the prior art are addressed through the above provided enablement analysis. If Patent Owner can establish, by preponderance of the evidence of record, that the skilled artisan cannot make what is alleged in the prior art using the steps taught in the prior art, only then is a presumed reliable prior art reference deemed to be unreliable and ineligible as an anticipatory reference as a matter of law. Patent Owner, despite any concerns about reliability of the resulting product, has not established based on a preponderance of the evidence that the skilled artisan is not enabled to make creatine nitrate using the mixing method described in Dessaignes without undue experimentation.

Moreover, we are not persuaded that Dessaignes is not reliable on its face or that Dessaignes did not make creatine nitrate. Patent Owner has identified every

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

possible error, possible idiosyncrasy, and possible incongruity in the prior art and in some art not even of record. Yet, Patent Owner still has not conclusively shown Dessaignes' mixing process does not produce creatine nitrate. On this record, Patent Owner has not attempted to reproduce Dessaignes' mixing process, which as discussed above can routinely be performed at various concentrations, to show an error in the process itself.¹⁹ Rather, Patent Owner contends that the burden has not properly shifted to require them to do so.

We disagree that the burden is not properly shifted to Patent Owner. We find the process taught by Dessaignes and that described in the '074 patent to be substantially identical. *See* Decision 11. The minimal difference between Dessaignes' method of mixing creatine and nitric acid and that of the '074 patent, namely the order of adding water, has not been shown to be substantially different. Patent Owner has not shown that the order of adding water is a critical to making creatine nitrate. Rather, the '074 patent indicates that the order of mixing is not critical. '074 patent, col. 15, ll. 49–59.

Because Dessaignes' mixing process on its face is simple and routine, we find the burden on Patent Owners to show that creatine nitrate cannot be made by mixing creatine with nitric acids of any concentration at 30° C, as described by Dessaignes, to be minimal and not overly burdensome. Yet, no such confirmation has been done on this record. The burden shift is appropriate because we do not have the resources of Patent Owner to confirm what the prior art expressly says is true. *In re Antor Media Corp.*, 689 F.3d at 1288.

¹⁹ Yet, Patent Owner allegedly attempted the likely more complicated bubbling experiment. Fourth Chamberlin Decl. ¶ 19.

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

Because of the age of the prior art, some inaccuracies *might* be present due to the lack of sophisticated equipment at the time, but we are not persuaded that the findings of Dessaignes are *necessarily* inaccurate. Supposition of error is not enough for Patent Owner to meet their burden to show lack of enablement or ambiguity in an otherwise express teaching in the prior art. *In re Weber*, 405 F.2d at 1407.

V. CONCLUSION

We conclude that Patent Owner has not overcome the new grounds of rejection of claim 6.

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this Decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1, 1.983.

AFFIRMED: 37 C.F.R. § 41.77(f)

Appeal 2018-001029

Merged Reexamination Control 90/011,394 and 90/011,869

Patent 7,777,074 B2

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