No. _____

In the Supreme Court of the United States

THERMOLIFE INTERNATIONAL LLC,

Petitioner,

v.

ANDREI IANCU, DIRECTOR, UNITED STATES PATENT AND TRADEMARK OFFICE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit violated the *Chenery* doctrine by making new factual findings in the first instance on appeal to affirm a decision of the Patent Trial and Appeal Board.

2. Whether the administrative patent judges of the Patent Trial and Appeal Board are unconstitutionally appointed "principal" officers whose decisions should be vacated and reheard by properly appointed officers regardless of when their appointments are challenged during appeal.

PARTIES TO THE PROCEEDINGS BELOW

Petitioner ThermoLife International LLC was the patent owner in proceedings at the United States Patent and Trademark Office, including before the Patent Trial and Appeal Board, and the appellant in the court of appeals.

Respondent Andrei Iancu, Director, United States Patent and Trademark Office, was the appellee in the court of appeals.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, petitioner ThermoLife International LLC states that it has no parent corporation and that no publicly held company owns 10% or more of its stock.

RELATED PROCEEDINGS

There are no proceedings directly related to this case within the meaning of Rule 14.1(b)(iii).

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

Page

APPENDIX

TABLE OF CONTENTS—Continued

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

CONSTITUTIONAL PROVISIONS AND STATUTES

TABLE OF AUTHORITIES—Continued

Page(s)

OTHER AUTHORITIES

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

PETITION FOR A WRIT OF CERTIORARI

ThermoLife International LLC ("ThermoLife") respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals (App. 1a-17a) is not published, but is available at 796 F. App'x 726. The court's denial of panel rehearing and rehearing en banc (App. 52a-53a) is not published. The final decision of the Patent Trial and Appeal Board (App. 18a-51a) is not published but is available at 2018 WL 2335128.

JURISDICTION

The court of appeals entered judgment on January 10, 2020 (App. 1a-17a) and denied ThermoLife's timely petition for panel rehearing and rehearing en banc on March 13, 2020 (App. 52a-53a). On March 19, 2020, this Court extended the time within which to file any petition for a writ of certiorari due on or after that date to 150 days from, *inter alia*, the order denying a timely petition for rehearing. Accordingly, the deadline for filing a petition for a writ of certiorari in this case is August 10, 2020. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Pursuant to this Court's Rule 14.1(f), the relevant constitutional and statutory provisions are set out in the appendix to this petition because of their length.

App. 54a-56a (reproducing U.S. Const. art. II, § 2, cl. 2; 35 U.S.C. § 6).

INTRODUCTION

1. The Federal Circuit violated this Court's bedrock *Chenery* doctrine. For nearly 80 years, this Court has held that courts of appeals may not resolve unaddressed factual disputes to affirm agency decisions. *See, e.g.*, *Gonzales v. Thomas*, 547 U.S. 183, 186 (2006) (per curiam); *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168-69 (1962); *SEC v. Chenery Corp.* ("*Chenery II*"), 332 U.S. 194, 196 (1947); *SEC v. Chenery Corp.* ("*Chenery I*"), 318 U.S. 80, 94 (1943). That "simple but fundamental rule" is firmly grounded in the constitutional separation of powers. *Chenery II*, 332 U.S. at 196. "Congress has exclusively entrusted … administrative agenc[ies]" to make factual determinations within their expertise, *not* the courts, which may only review those findings and affirm based on them. *Chenery I*, 318 U.S. at 88. The Federal Circuit disregarded that fundamental rule here.

The Patent Trial and Appeal Board (the "Board") revoked ThermoLife's patent rights to the blockbuster nutritional compound "creatine nitrate" based on a single report that the compound was purportedly produced in France over 160 years ago. But the Board failed to address clear scientific facts proving otherwise. For example, the record detailed how, based on now-known rules about chemical reactions and atomic molecular weights, the 160-year-old methods for purportedly making creatine

nitrate could not even *theoretically* produce the compound. The Federal Circuit should have remanded for the Board to correct that error and address those dispositive record facts. Instead, the court affirmed by curtly finding ThermoLife's interpretation of them to be "mere speculation" and "conjecture." App. 17a.

That *Chenery* violation is not an isolated aberration. The Federal Circuit makes such factual findings and substitutes its judgment for the PTO's with an alarming frequency that has sharply divided the court internally and generated extensive external criticism. Worse yet, this Court already addressed such administrative exceptionalism twenty years ago in *Dickinson v. Zurko*, 527 U.S. 150, 161-65 (1999), rebuking the Federal Circuit's improper expansion of its administrative review power to displace the PTO's factual findings. The Court's review is urgently needed to do so again.

2. The Court should also intervene because the Board's opinion was unconstitutional in the first instance. The three administrative patent judges ("APJs") that affirmed the revocation of ThermoLife's patent rights held office unconstitutionally under the Appointments Clause. The APJs were hired by the Secretary of Commerce (*see* 35 U.S.C. § 6(a)), but, as the Federal Circuit recently held in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1327 (Fed. Cir. 2019), *reh'g denied per curiam*, 953 F.3d 760 (Fed. Cir. 2020) (en banc), *petitions for cert. filed* (June 2020) (Nos. 19-1434, 19-1452, 19-1458), APJs are principal officers that must be appointed by the President with advice and consent of the Senate. Any decision by such

APJs should be vacated and remanded for full re-adjudication by constitutionally proper officers.

Addressing that violation of the Appointments Clause in all direct appeals (such as this one) is an important and pressing issue that deserves this Court's attention. The unconstitutional appointment of APJs has infected thousands of Board decisions that fall under the Federal Circuit's exclusive appellate jurisdiction to correct. Indeed, this Court's review has been sought in dozens of cases raising the same issues.[1] But the Federal Circuit has barred patentees like ThermoLife from raising the issue after opening briefing based on forfeiture principles. That is wrong—*Arthrex* was an intervening change in the law with clear retroactive effect. *See, e.g.*, *Curtis Publ'g Co. v. Butts*, 388 U.S. 130, 142-43 (1967) ("[T]he mere failure to interpose a [constitutional] defense prior to the announcement of a decision which might support it cannot prevent a litigant from later invoking such a ground."). Moreover, constitutional challenges raising significant structural concerns (like violations of the

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[1] *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 19-1204 ("*Arthrex I* Petition") (filed Apr. 6, 2020); *United States v. Arthrex, Inc.*, No. 19-1434 (filed June 25, 2020); *Sanofi-Aventis Deutschland GMBH v. Mylan Pharm. Inc.*, No. 19-1451 ("*Sanofi* Petition") (filed June 26, 2020); *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 19-1452 (filed June 29, 2020); *Arthrex, Inc., Petitioner, v. Smith & Nephew, Inc.*, No. 19-1458 ("*Arthrex II* Petition") (filed June 30, 2020); *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 19-1459 (filed June 30, 2020); *Duke Univ. v. Biomarin Pharm. Inc.,* No. 19-1475 ("*Duke* Petition") (filed July 2, 2020); *United States v. Image Processing Techs. LLC*, No. 20-74 (filed July 23, 2020); *Comcast Cable Commc'ns, LLC v. Promptu Sys. Corp.*, No. 20-92 (filed July 24, 2020).

Appointments Clause) cannot be automatically forfeited—they are even frequently addressed when raised in the first instance in this Court (as should be done here). *See Freytag v. Commissioner*, 501 U.S. 868, 878-80 (1991).

Review should be granted on this important question or the case held for resolution of related petitions raising this issue. *See supra* at n.1.

STATEMENT OF THE CASE

1. ThermoLife is one of America's leading innovators in nutritional science and first discovered a way to make, and a practical use for, the blockbuster nutritional compound "creatine nitrate." In 2010, ThermoLife was awarded United States Patent No. 7,777,074 (the "'074 patent") to secure its rights to that compound. *See* Pet'r C.A. Br. 13.

2. In 2011, two third parties petitioned the PTO to invalidate ThermoLife's patent through ex parte reexamination. *See* Pet'r C.A. Br. 14; Appx3005-06.[2] Ex parte reexaminations were established in 1980 and allow the reconsideration of issued patents. *See* Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 301 *et seq.*). They can be instituted directly by the PTO Director or based on a third party's request (as here). 35 U.S.C. §§ 303(a), 304. Patentees can amend challenged claims during reexamination. 35 U.S.C. § 305. If any existing or proposed claims are rejected, as here, patentees can appeal to the Board and then to the Federal Circuit. 35 U.S.C. §§ 134(b), 141(b), 142, 143, 144; 28 U.S.C. § 1295(a)(4)(A).

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[2] "Appx" refers to the appendix filed in the court of appeals.

3. After several years and two proceedings before the Board, all of ThermoLife's claims were ultimately confirmed in reexamination except for claim 6 to creatine nitrate. *See* Appx3130. The first trip to the Board focused on whether a treatise from 1914 ("Barger"[3]) anticipated (and thus invalidated) ThermoLife's claims. Barger stated a theoretical formula for creatine nitrate, but (critically) failed to disclose a way to make it—meaning Barger could not be an anticipatory reference.[4] During the reexamination, ThermoLife's claim 6 to creatine nitrate was originally allowed over Barger. Pet'r C.A. Br. 15. However, before the reexamination officially concluded, the PTO (without warning) developed a new theory—that Barger rendered claim 6 impermissibly obvious in light of certain modern references that supposedly showed modern chemists that making organic salts like creatine nitrate was a simple matter of (1) mixing with acid and then (2) evaporating that mixture. Pet'r C.A. Br. 15-16; Pet'r C.A. Reply Br. 24-25.[5] ThermoLife's experts—

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[3] George Barger, *The Simpler Natural Bases* (1914) ("Barger"); *see* Appx5062-64; Appx3809-15.

[4] For a prior art reference to anticipate a claimed invention under 35 U.S.C. § 102, the reference must disclose all of the claim limitations *and*, on its face, must enable the invention to be made and used. *E.g.*, *In re Brown*, 329 F.2d 1006, 1011 (C.C.P.A. 1964). That is, a purportedly anticipatory reference "'must be so particular and definite that from it alone, without experiment or the exertion of … inventive skill," a person of ordinary skill could "construct and use" the invention. *Id.* (citation omitted); *see also* Pet'r C.A. Br. 31-32.

[5] Unlike anticipation under 35 U.S.C. § 102, obviousness under 35 U.S.C. § 103 can rely on a combination of references

including an author of one of those modern references—explained that, to practicing chemists in the field, any such belief was "unreasonable" and "certainly not the case." Appx3494; *see* Pet'r C.A. Br. 16-17. Moreover, ThermoLife's method for making creatine nitrate is completely different. It begins with (1) mixing creatine with nitric acid, then (2) hydrating that solution, and then (3) crystallization (*not* evaporation, as in the prior art), including potentially under vacuum. *See* Appx34, 38 ('074 patent (1:48-64; 9:19-29)); Pet'r C.A. Reply Br. 19-20.

In light of ThermoLife's evidence, the PTO withdrew all obviousness rejections. *See* Pet'r C.A. Br. 17-18; Pet'r C.A. Reply Br. 24-25. Nonetheless, claim 6 was not allowed. Instead, the PTO insisted that Barger alone was enough to (once again) anticipate claim 6 because, regardless of whatever modern references taught or whatever practicing chemist PhDs said, mixing creatine with nitric acid and then evaporating was supposedly a simple and sure way to produce creatine nitrate. *See* Pet'r C.A. Br. 15-16, 18. *L'etat, c'est l'agence.*

4. ThermoLife appealed, and the Board affirmed—but not on the same grounds. *Ex parte ThermoLife Int'l, LLC*, No. 2015-005203, 2016 WL 406381 (P.T.A.B. Jan. 29, 2016). To show that chemists purportedly knew how to make creatine nitrate (the gap in the anticipation rejection), the Board pointed to two references from the 1800s that an APJ stumbled upon with a "quick Google search"

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that would render a claim invalid. *E.g.*, *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008).

(Appx5022) during the oral hearing: (i) a paper from 1854 by a French scientist "M. Dessaignes" ("Dessaignes"[6]); and (ii) a reference text from 1856 ("Gmelin"[7]), which simply repeated Dessaignes's claim nearly verbatim. *See* Appx4136-40; Pet'r C.A. Br. 18-20.

Dessaignes reported two ways for producing the "same" "nitrate of creatine" compound: (i) bubbling a "rapid current" of nitrous acid gas into water containing an unspecified amount of creatine (the "bubbling method"); or (ii) mixing 1.057 grams of creatine into a nitric acid and evaporating (the "mix-and-evaporate method") to produce 1.373 grams of the nitrate of creatine. Appx4150; *see* Appx3926-27; Pet'r C.A. Br. 19; Pet'r C.A. Reply Br. 15 n.5.

Finding Dessaignes on Google during oral argument was unnecessary. ThermoLife disclosed Dessaignes during the reexamination proceedings and the PTO (for good reason) had not relied on it. *See* Appx3796; Appx4003 (Barger alone was basis for rejection); Pet'r C.A. Br. 19 n.3. One of ThermoLife's experts (Dr. Chamberlin, the former chair of chemistry at UC Irvine) explained how Dessaignes was an archaic reference with reported processes and results that, to a modern chemist, "plainly rule out the creatine nitrate [Dessaignes] claims to have

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[6] M. Dessaignes, *Scientific and Medicinal Chemistry: Examination of some Products of the Transformation of Creatine*, *in* 12 The Chemical Gazette or Journal of Practical Chemistry 201-204 (1854); Appx4148-51.

[7] Leopold Gmelin, *Creatine*, *in* 10 *Hand-Book of Chemistry: Organic Compounds Containing Eight and Ten Atom of Carbon* 249-255 (Henry Watts, trans., 1856); Appx4153-60.

made." App3922; *see* Appx3920-30. In other words, Dessaignes could not, and did not, anticipate claim 6 because it did not enable a person of ordinary skill to make creatine nitrate. The following three scientific facts (the "Dispositive Facts") proved that to be true.

1. Chemists now know that Dessaignes's bubbling method always produces something *other than* creatine nitrate. Appx3927-30; Pet'r C.A. Br. 21-26, 44-46; Pet'r C.A. Reply Br. 9-11, 16-26.
2. Chemists now know that Dessaignes's mix-and-evaporate method also produces a different compound, creat*inine* nitrate. That happens because both steps of that process—mixing with an acid strong enough to cause a reaction and then evaporating the solution—dehydrate creatine into creat*inine*, which ensures only creat*inine* nitrate would result. Appx3695; Pet'r C.A. Br. 9, 20, 27-28, 44 n15, 46-47, 61; Pet'r C.A. Reply Br. 2, 19, 22-23.
3. And chemists now know (based on modern knowledge of atomic molecular weights) that Dessaignes's mix-and-evaporate method did "NOT yield the production of creatine nitrate" (Appx3930 (emphasis in original)) because 1.057 grams of creatine would produce 1.565 grams of creatine nitrate, not the 1.373 grams described in Dessaignes. Appx3927; Appx4150; Pet'r C.A. Br. 45-46; Pet'r C.A. Reply Br. 15 & n.5.

The Board did not address any of these facts. Nonetheless, it affirmed the rejection of claim 6 as anticipated because, according to the Board, Dessaignes's methods (which were recounted in

Gmelin) would enable chemists to make creatine nitrate. *See* Appx4135-40.

5. Because ThermoLife's patent claim was revoked on new grounds, prosecution was reopened. *See* Pet'r C.A. Br. 21. ThermoLife submitted additional expert declarations that repeated and expounded on Dr. Chamberlin's explanation that Dessaignes's methods were inoperable. *See id.* at 21-26; Appx4194-226. Despite that, the PTO maintained the Board's reasoning to reject claim 6, while also failing to address the Dispositive Facts. *See id.* at 26. ThermoLife again appealed to the Board.

6. Once again, the Board rejected claim 6 as anticipated. App. 18a-51a. And once again, the Board failed to substantively address the Dispositive Facts. *See id.* The Board ignored Dr. Chamberlin's detailed equations and extensive discussion proving that it was impossible for either of Dessaignes's methods—the bubbling method or the mix-and-evaporate method—to create creatine nitrate. *See, e.g.*, i*d.* at 33a. Instead, the Board declared, *inter alia*, that Dessaignes was "clear on its face" (*id.* at 37a) and the mix-and-evaporate method "constitute[d] a working example" because "Dessaignes [wa]s reporting the result of his personal experience" (*id.* at 41a).[8]

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[8] Personal experience does not make a process a "working example" under the law or logic. If it did, anyone could potentially stop innovation dead in its tracks by simply claiming to have personally discovered something first. *See* Pet'r C.A. Br. 46 n.17. In addition, despite ThermoLife's disclosed method for making creatine nitrate requiring

7. ThermoLife appealed to the Federal Circuit and repeatedly argued that the Dispositive Facts were "unrebutted" "clear facts and clear science" that were ignored by the Board and were irrefutable proof that Dessaignes's methods were inoperable and would not enable anyone to produce creatine nitrate. C.A. Oral Argument Recording at 11:51-12:27, 33:9-13;[9] *see id.* at 5:55-6:30, 6:44-8:35, 31:21-34:16 (highlighting the Dispositive Facts); Pet'r C.A. Br. 5-6, 9-11, 21-26, 27-29 43-48, 60-62 (same); Pet'r C.A. Reply Br. 2, 9-11, 16-26 (same). "At minimum," ThermoLife argued, the Board's critical oversight required remand for the Board to determine how creatine nitrate could have been anticipated in light of that clear factual proof to the contrary. Pet'r C.A. Br. 49 n.18; *see also* Pet'r C.A. Reh'g Pet. 2-15.

8. The Federal Circuit affirmed based on Dessaignes. *See* App. 9a (affirming based on Barger in light of Dessaignes's teachings or Dessaignes alone). In the court's view, the Board correctly held that "preparing creatine from Dessaignes would not have been beyond the skill of the ordinary artisan in 2007." App. 14a. The court did not discuss the Dispositive Facts. Instead, it found that ThermoLife's arguments that Dessaignes was not enabling—based on the Dispositive Facts—were

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hydrating a creatine/nitric acid solution and crystalizing, not evaporating, the Board also added that Dessaignes's mix-and-evaporate method was "substantially identical to the method taught by the '074 patent." App. 41a; *see* Pet'r C.A. Br. 47-48; Pet'r C.A. Reply Br. 2, 19-20.

[9] *Available at* http://www.cafc.uscourts.gov/oral-argument-recordings/search/audio.html?title=&f'ield_case_number_value=18-2189&field_date_value2%5 Bvalue%5D%5Bdate%5D=.

"mere speculation" and "conjecture." *Id.* at 17a. The court of appeals did not explain its reasoning for that factual conclusion, which was a basis for its affirmance. *See id.*

9. ThermoLife timely filed for panel and en banc rehearing, arguing, *inter alia*, that the panel's curt dismissal of the Dispositive Facts was improper under *Chenery*. Pet'r C.A. Rehearing Pet. 2-15. ThermoLife argued that the Federal Circuit could not make "determination[s] of fact" that the "[PTO] alone is authorized to make and which it has not made," which meant, for at least issues of fact (such as anticipation under 35 U.S.C. § 102), the court "must judge the propriety of [the PTO's] action solely by the grounds invoked by the agency"—"by what [it] did, not by what it might have done." *Chenery II*, 332 U.S. at 196; *Chenery I*, 318 U.S. at 88, 93-94; *see* Pet'r C.A. Reh'g Pet 2-3, 9-15. Rehearing was denied without opinion. App. 52a-53a.

10. While ThermoLife's appeal was pending, the Federal Circuit held that the hiring of APJs by the Secretary of Commerce violated the Appointments Clause (U.S. Const. art. II, § 2, cl. 2) because they are principal officers due to, *inter alia*, "[t]he lack of any presidentially appointed officer who can review, vacate, or correct [their] decisions" and the Secretary's "limited removal power." *Arthrex,* 941 F.3d at 1335. To remedy that violation, the court of appeals severed the statutory constraints on removing APJs and ordered rehearing at the Board before different APJs. *Id.* at 1335-40 (citing *Lucia v. SEC,* 138 S. Ct. 2044 (2018)). The Federal Circuit subsequently ordered identical rehearing in dozens of proceedings, which the PTO has stayed pending potential review by this Court. *See* General Order,

Arthrex, Inc. v. Smith & Nephew, Inc., 2020 WL 2119932, at *1 (P.T.A.B. May 1, 2020) (holding in abeyance dozens of cases remanded by the Federal Circuit pursuant to *Arthrex*).

The day after *Arthrex*, the Federal Circuit held in a precedential opinion that any Appointments Clause challenge regarding APJs was forfeited by parties that did not raise the issue in their opening brief (or sooner). *Customedia Techs., LLC v. Dish Network Corp.,* 941 F.3d 1173, 1174 (Fed. Cir. 2019) (per curiam); *see also Sanofi-Aventis Deutschland GmbH v. Mylan Pharm. Inc.*, 791 F. App'x 916, 928 n.4 (Fed Cir. 2019) (same), *petition for cert. filed* (June 26, 2020) (No. 19-1451). That incorrect ruling applied to ThermoLife, which filed its opening brief ten months prior to *Arthrex*.

REASONS FOR GRANTING THE WRIT

I. The Federal Circuit's Persistent Refusal To Adhere To The *Chenery* Doctrine Warrants Review

Time and again, this Court has rebuked Federal Circuit exceptionalism. *E.g.*, *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954, 967 (2017) (rejecting special rule for laches in patent cases); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1935 (2016) (rejecting special rule for enhancement of damages in patent cases); *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 548 (2014) (rejecting special standard for awarding attorney fees in patent cases); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006) (rejecting special standard for permanent injunctions in patent cases). It has even done so in the context of administrative review of PTO

decisions, which the Court has taught requires a "uniform approach of judicial review." *See Dickinson v. Zurko*, 527 U.S. 150, 154 (1999) (rejecting Federal Circuit "claim for an exception" to the "uniform approach to judicial review of administrative action").

The Federal Circuit has again gone astray. Here, the court ignored (without addressing or acknowledging) the *Chenery* doctrine when it upheld the Board's decision by making new factual findings in the first instance on appeal. That is an affront to the important "uniform approach to judicial review" of PTO decisions that this Court mandated in *Zurko*, 527 U.S. at 154, and upends the careful constitutional balance struck between executive agencies and the courts. It is nothing new, however. The Federal Circuit has repeatedly run afoul of the *Chenery* doctrine, despite numerous objections by many of the court's judges, scholars, and litigants alike. Only this Court can curtail the pernicious "variation and diversity" (*id.* at 155) that the Federal Circuit's exceptionalism is injecting into the review of Board decisions. Intervention is needed.

A. The Federal Circuit's *Chenery* Violations Are Important And Recurring

The Federal Circuit's violation of the *Chenery* doctrine merits this Court's intervention.

1. Chenery *Is A Critically Important Constitutional Safeguard*

The *Chenery* doctrine plays a critical role in maintaining the constitutional separation of powers. It reflects the careful balance that Congress struck to ensure that the best-equipped decision-makers are

finding facts (such as the Board, not the Federal Circuit). As this Court has explained, "Congress has exclusively entrusted administrative agenc[ies]" to make factual findings in the first instance within their expertise, whereas the courts may only review and affirm based on those agency findings. *Chenery I*, 318 U.S. at 88. "*Chenery*'s rule thus secures the separation of powers among the three branches" to best protect litigants' due process interests in their property and other rights when threatened by agency action. *Bhattarai v. Holder*, 408 F. App'x 212, 221 (10th Cir. 2011); *see also Church of Scientology of Cal. v. IRS*, 792 F.2d 153, 165 (D.C. Cir. 1986) (Silberman, J., concurring), *aff'd*, 484 U.S. 9 (1987); Richard E. Levy & Robert L. Glicksman, *Agency-Specific Precedents*, 89 Tex. L. Rev. 499, 504 (2011); Joshua I. Schwartz, *Administrative Law Lessons Regarding the Role of Politically Appointed Officials in Default Terminations*, 30 Pub. Cont. L.J. 143, 205 (2001); Kevin M. Stack, *The Constitutional Foundations of* Chenery, 116 Yale L.J. 952, 978-1000 (2007).

The separation of powers protected by the *Chenery* doctrine is clearly delineated when patent rights are at play. Congress delegated to the PTO all fact-finding authority over the decision to grant or deny a patent, which routinely requires resolving disputes over complex scientific facts. *See* 35 U.S.C. § 2; *Zurko*, 527 U.S. at 154-55; Amy R. Motomura, *Article: Rethinking Administrative Law's* Chenery *Doctrine: Lessons from Patent Appeals at the Federal Circuit*, 53 Santa Clara L. Rev. 817, 889 (2013) (discussing how "to grant or deny a patent is a function that most clearly fits within the PTO's delegate authority" assigned by Congress). Congress

gave the Federal Circuit exclusive jurisdiction to review the PTO's exercise of that authority within the confines of the APA. 28 U.S.C. § 1295(a)(4).

Here, for instance, whether the Dispositive Facts prove that the key prior art (Dessaignes) is not enabling is exactly the type of factual issue that Congress reserved for the PTO. *See* Pet'r C.A. Br. 31-32. Interpreting the Dispositive Facts requires an understanding of chemical laws and atomic molecular weights. And if the Dispositive Facts show as a matter of scientific fact that Dessaignes's methods are inoperable (they do), then the theoretical disclosure of creatine nitrate in the prior art was not enabled and ThermoLife's claim to the compound cannot be revoked. *See id.* at 31-32, 42-49; *see also supra* n.4. The Board failed to exercise its delegated authority to address that critical factual inquiry. Under the *Chenery* doctrine, the Federal Circuit was not at liberty to assume that authority in the first instance and declare as a factual matter that the Dispositive Facts are "mere speculation" and "conjecture." *See* App. 17a. That is precisely the unconstitutional judicial encroachment on executive power that *Chenery* prevents. Restoring that balance merits this Court's intervention.

2. The Federal Circuit's Chenery *Violations Have Created Persistent Intra-Circuit Conflict*

The Federal Circuit's wayward approach to the *Chenery* doctrine has sharply divided the court for years, generated extensive scholarly criticism, and prompted numerous requests for this Court's review.

Several Federal Circuit judges have protested the court's wanton violations of the *Chenery* doctrine when reviewing PTO decisions. For example, over a decade ago, Judges Moore, Newman, and Rader warned that the court was violating the *Chenery* doctrine by adopting a new ground for rejecting a patent and seemed to have a policy of "failing to review the decision the PTO has rendered" while "directing the examination" to decide "what alternative possible ground of rejection" should be enforced. *In re Comiskey*, No. 2006-1286, 2009 U.S. App. LEXIS 400, at *18-19, *26 (Fed. Cir. Jan. 13, 2009) (Moore, J., dissenting from rehearing en banc, joined by Newman & Rader, JJ.) ("*Comiskey* Dissent"). As those Federal Circuit judges put it, the court effectively became a "roving commission" that was "manag[ing] the examination process" rather than reviewing the PTO's decisions. *Id.* at *26; *see also* Paul R. Gugliuzza, *The Federal Circuit As A Federal Court*, 54 Wm. & Mary L. Rev. 1791, 1822-23 (2013) (discussing how *Comiskey* violated the *Chenery* doctrine).

Despite that warning, *Chenery* violations continue to fracture the court. For example, in *In re Aoyama,* Judge Newman dissented from the court's adoption of a new ground for rejecting a patentee's claim first invoked on appeal, protesting that the court's "*ab initio* decision" directly conflicted with the *Chenery* doctrine and "deprive[d] the applicant of the opportunity to contest th[e] new and procedurally final ground." 656 F.3d 1293, 1301-06 (Fed. Cir. 2011) (Newman, J., dissenting). The court, Judge Newman warned, did not even address the critical factual inquiry of whether an ordinary computer scientist would understand the patent to

disclose "a structural algorithm that could be routinely programmed" as the claims required, and, because of the *Chenery* violation, there was "no opportunity to develop a record on this aspect." *Id.* at 1305. That "def[ied] the requirements for appellate review of agency action" under the *Chenery* doctrine, which "[a]t a minimum," required the court to "remand[] to the PTO for interactive examination on this new ground." *Id.* at 1304-05.

Judge O'Malley sharply dissented on identical grounds in *In re Enhanced Security Research, LLC,* 739 F.3d 1347 (Fed. Cir. 2014) (O'Malley, J., dissenting). There, the court again "violate[d] the principles described in *Chenery* governing review of administrative agency determinations" by fact-finding on appeal. *Id.* at 1367. A key issue was whether a potentially invalidating prior art software reference disclosed the "use of severity assessments for blocking purposes." *Id.* at 1366. "The Board expressly found this teaching missing …." *Id.* Judge O'Malley urged the court to "not stray from the Board's reasoning" as required by *Chenery*, but it nonetheless accepted the PTO's new "alternative analysis" presented on appeal that the missing element was—contrary to the Board's finding—actually present in the prior art reference. *Id.* at 1365-66.

There have been numerous other examples over the years. *See, e.g.*, *In re Black*, 778 F. App'x 911, 923 (Fed. Cir. 2019) (O'Malley, J., dissenting) (arguing that the court's "discern[ing] [its own] grounds for the Board's rejection" violated the *Chenery* doctrine); *Knowles Elecs. LLC v. Iancu*, 886 F.3d 1369, 1384 (Fed. Cir. 2018) (Newman, J., dissenting) (arguing that the court's reliance on

"thirty-four newly selected pages … on appeal" from books "contain[ing] thousands of pages" violated the *Chenery* doctrine); *In re Huston*, 308 F.3d 1267, 1282 (Fed. Cir. 2002) (Prost, J., dissenting in part) (arguing that the court "chart[ing] an analytical course of its own" by finding a new motivation to combine on appeal violated the *Chenery* doctrine); *see also Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366-67 (Fed. Cir. 2016) (reversing Board decision after declaring that Board's factual finding could not be supported by anything in the record); *In re PODNERS, L.L.C.*, 337 F. App'x 901, 903-04 (Fed. Cir. 2009) (affirming invalidity on new grounds on appeal when "Board did not explain its conclusion in detail").[10]

Scholars have likewise repeatedly warned how "[t]he Federal Circuit continues to engage in agency-like adjudication" and "act[] like the head of an agency reining in wayward administrative law judges" when "sidestepping proper judicial review standards to allow for more hands-on review of PTO … appeals." Sapna Kumar, *The Accidental Agency?*, 65 Fla. L. Rev. 229, 232, 275 (2013); *see id.* at 268-78

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[10] The Federal Circuit's inconsistent approach to *Chenery* reaches beyond the PTO. *See, e.g.*, *McCarthy v. Merit Sys. Prot. Bd.*, 809 F.3d 1365, 1373 (Fed. Cir. 2016) (affirming on new grounds); *Turman-Kent v. Merit Sys. Prot. Bd.,* 657 F.3d 1280, 1291 (Fed. Cir. 2011) (Reyna, J., dissenting) ("[T]he majority adopts findings that go beyond the grounds stated by the Board," and "[t]his court should not serve to supplement that which the Board lacks in its determination."); *Allied Tech. Grp., Inc. v. United States*, No. 2010-5131, Pet. for Reh'g En Banc (Fed. Cir. July 15, 2011), 2011 WL 3290512 (arguing that the court affirmed agency decision on new grounds).

(discussing how the Federal Circuit has repeatedly "disregarded" the "*Chenery* decisions" and "fought against the confines of the APA" to "attempt to minimize deference to the PTO"); Amy R. Motomura, *Federal Circuit Deference: Two Regimes in Conflict*, 119 Penn St. L. Rev. 925, 975 (2015) (discussing how the Federal Circuit has "consistently demonstrated its unwillingness" to respect the PTO's findings and reasoning "in direct contravention of administrative law principles"); Motomura, 53 Santa Clara L. Rev. at 838-53 (discussing the Federal Circuit's struggle to adhere to the *Chenery* doctrine). As one put it, the Federal Circuit's policy of "exceptionalism" has spawned a "practice of, essentially, ignoring the [PTO] decision on review" so that "[t]he court thus acts not as an appellate court, reviewing the decision of an inferior tribunal, but as an agency administrator, dictating the issues the PTO must consider." Gugliuzza, 54 Wm. & Mary L. Rev. at 1823.

Numerous litigants have asked this Court to intervene to prevent the Federal Circuit from affirming Board decisions on new grounds, to no avail. *See, e.g.*, *Droplets, Inc. v. Iancu,* No. 17-1284, Petition for Writ of Certiorari (Apr. 3, 2018) ("*Droplets* Petition"); *Intermec, Inc. v. Alien Tech., LLC*, No. 16-1404, Petition for Writ of Certiorari (May 22, 2017) ("*Intermec* Petition"); *Merck & Cie v. Gnosis S.P.A.*, No. 16-125, Petition for Writ of Certiorari (July 25, 2016) ("*Merck* Petition"); *Packard v. Lee*, No. 14-655, Petition for Writ of Certiorari (Dec. 2, 2014) ("*Packard* Petition"); *Wang v. Plasmart, Inc.*, No. 12-616, Petition for Writ of Certiorari (Nov. 13, 2012) ("*Wang* Petition").

There is thus no reason to delay intervention on this important issue. Despite sharp internal dissent and external criticism, the Federal Circuit has repeatedly failed to correct course en banc and bring the court's administrative review practice back in line with *Chenery*. *See, e.g.*, App. 52a-53a; *Droplets* Petition 2; *Intermec* Petition 1; *Merck* Petition 9; *Packard* Petition 1; *Wang* Petition 1. The court's exclusive jurisdiction to review the Board's decisions has the potential to affect thousands of patents every year. *See* U.S. PTO, Trial Statistics: IPR, PGR, CMB 3 (Feb. 2020), https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2020_02_29.pdf ("PTO Trial Statistics") (IPR petitions alone to the Board since 2012 number over 10,000). This Court's review is warranted now to ensure that the Federal Circuit adheres to the uniform constitutionally mandated principles governing administrative review.

3. This Court Previously Intervened To Stop The Federal Circuit From Inflicting The Same Type Of Harm Caused By Chenery *Violations*

Over twenty years ago in *Zurko*, this Court recognized "the importance of maintaining a uniform approach to judicial review of administrative action" and intervened to "closely examine[] the Federal Circuit's claim for an exception to that uniformity" in reviewing PTO decisions. 527 U.S. at 154. There, the Federal Circuit erroneously held that it could review factual findings of the PTO under a laxer "clear[] error[]" standard, rather than the more-deferential (and APA-mandated) substantial-evidence standard, which impermissibly allowed the

court greater freedom to substitute its judgment for the PTO's. *See id.* at 154-55.

The Court should likewise intervene here to stop the "variation and diversity" (*id.* at 155) in the review of PTO decisions caused by the Federal Circuit's departure from the *Chenery* doctrine. Violating *Chenery* is even worse than the Federal Circuit's "claim for an exception" in *Zurko*. *Id.* at 154. Sidestepping *Chenery* does not just permit the Federal Circuit to afford slightly less deference to PTO findings, it allows the court to provide no deference at all and substitute its judgment wholesale. That virtually guarantees the harmful "variation and diversity" that this Court sought to prevent in *Zurko*—and the attendant due process violations that surely attend. *Id.* at 155. Indeed, here for example, the Federal Circuit never explained how the scientific Dispositive Facts that the Board overlooked could have been "mere speculation" or "conjecture" regarding enablement. App. 17a; *see also Arendi*, 832 F.3d at 1366 (fact analysis on appeal without substantive explanation).

Such uncertainty is particularly troubling in light of the Federal Circuit's exclusive jurisdiction to review PTO decisions. That exclusivity was designed to help ensure uniformity in the patent system and settle procedural expectations. *See, e.g.*, H.R. Rep. No. 97-312, at 23 (1981); Harold C. Wegner, *Federal Circuit Exclusive Appellate Patent Jurisdiction: A Response to Chief Judge Wood*, 13 Chi.-Kent J. Intell. Prop. 394, 397 (2014). Arbitrarily usurping the PTO's delegate fact-finding authority in contravention of *Chenery* does the opposite—it injects disorder, runs roughshod over due process, and erases settled expectations of

orderly administrative adjudication. That constitutional disarray warrants this Court's intervention.

B. This Case Is An Ideal Vehicle To Address The Federal Circuit's *Chenery* Violations

This is an ideal case to address the Federal Circuit's deviations from the *Chenery* doctrine. The *Chenery* violation here was clear and, if corrected, would restore ThermoLife's patent rights to creatine nitrate.

Unlike some *Chenery* violations that arguably concern mixed questions of law and fact, the question here, anticipation, is purely factual. *See, e.g.*, *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001) (blackletter law that anticipation is a pure factual question); *see also, e.g.*, *Droplets* Petition 9-12 (claim construction at issue, a mixed question of law and fact); *Arendi*, 832 F.3d at 1366 (first instance factual finding on appeal concerning obviousness, a mixed question of law and fact). The cornerstone of the Board's answer to that factual question in this case (and the Federal Circuit's affirmance) was that a chemist would know how to—and could—produce creatine nitrate from Dessaignes's mix-and-evaporate process described over 160 years ago. *See* App. 9a, 33a-51a. The Dispositive Facts, however, prove that to be scientifically false. The Federal Circuit's factual finding that such proof is "mere speculation" and "conjecture" (App. 17a) is thus contrary to *Chenery* and incorrect.

1. Dr. Chamberlin proved that, based on modern-known chemical processes, the bubbling method could not even theoretically produce creatine

nitrate. As he explained, it would be "impossible to produce the creatine nitrate salt [Dessaignes] claimed to be the product" (Appx3930) of the bubbling method—the chemical "reaction sequences" (Appx3927) now known to modern chemists resulting from that process (which Dr. Chamberlin diagramed in extensive detail, Appx3929), would *always* produce something other than creatine nitrate, even at intermediary stages (*see* Appx3928). Pet'r C.A. Br. 21-26, 44-46; Pet'r C.A. Reply Br. 9-11, 16-26. The Board never addressed that proof. But the import is clear—Dessaignes reported that the bubbling method made the "same compound" as the mix-and-evaporate process and that "same compound" was *not* creatine nitrate. Appx4150; *see* Pet'r C.A. Br. 19, 22-24, 44-45; Pet'r C.A. Reply Br. 10, 17-18.

2. The Dispositive Facts also proved that no modern chemist would (or could) make creatine nitrate using Dessaignes's mix-and-evaporate method.

As modern chemists now understand, it is not even theoretically possible for the mix-and-evaporate method to make creatine nitrate. Dehydrating creatine (e.g., by evaporation or otherwise) will produce creat*inine*, and mixing creatine into nitric acid strong enough to cause a reaction dehydrates the compound by abstraction of water. *See* Appx3695; Pet'r C.A. Br. 9, 20, 28, 44 n.15, 46-47, 61; Pet'r C.A. Reply Br. 2, 19, 22-23. The Board never addressed those facts. Yet they scientifically prove that both steps of Dessaignes's process (one—mix with nitric acid strong enough to cause a reaction; two—evaporate that mixture) ensure the production of creat*inine* nitrate, *not* creatine nitrate. *See id.*

The Dispositive Facts also conclusively prove that Dessaignes's mix-and-evaporate method actually did not work. As Dr. Chamberlin explained, applying modern knowledge of atomic molecular weights (which any modern chemist has), Dessaignes's reported weights for the product of his method (1.373 grams) did not match the weight required for creatine nitrate (1.565 grams). *See supra* at 9; Appx3927; *see also Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082-85 (Fed. Cir. 2008) (anticipation judged from perspective of modern artisan). Whatever that lighter product of the process was—such as creat*inine* nitrate, *see* Appx3695 (showing how creat*inine* has one less oxygen atom and two less hydrogen atoms)—chemists know that it did "NOT yield the production of creatine nitrate." Appx3930 (emphasis in original); *see* Pet'r C.A. Br. 45-46; Pet'r C.A. Reply Br. 15 & n.5.

If properly considered by the Board, those facts would resolve the validity question here and require reversing the revocation of ThermoLife's claim. Each independently proves—and together, overwhelmingly so—that Dessaignes's 19th-century methods could not and did not produce creatine nitrate and, thus, could not and did not anticipate. Put simply, something different is needed to produce creatine nitrate, something inventive, like the rehydration and crystallization steps that ThermoLife discovered through tireless research and disclosed in its patent. *See supra* at 7; Appx34, 38 ('074 patent (1:48-64; 9:19-29)).

The Board's failure to address those facts did not give the Federal Circuit the freedom to do so in the first instance on appeal and declare ThermoLife's explanations of their dispositive relevance to be

"mere speculation" and "conjecture." App. 17a. Just the opposite. Courts of appeals must not make "determination[s] of fact" that the "agency alone is authorized to make and which it has not made"—they must judge the agency "by what [it] did, not by what it might have done." *Chenery I*, 318 U.S. at 88, 93-94.

There is no question that the Federal Circuit violated that important principle when discarding the Dispositive Facts as factually unconvincing. And there is no doubt that the Federal Circuit's belief was factually (and logically) wrong. The clarity of those errors make this a particularly compelling vehicle to address the Federal Circuit's violation of the *Chenery* doctrine.

II. The Court Should Grant Review To Correct Decisions By Unconstitutionally Appointed APJs Whenever Challenged On Appeal

The APJs that approved the revocation of ThermoLife's claim to creatine nitrate held office unconstitutionally in violation of the Appointments Clause. The Court should grant review to address that important issue here, and in all similar direct appeals, and order rehearing by constitutionally appointed officers.

Alternatively, and at minimum, this petition should be held pending disposition of the numerous petitions raising this issue. *See supra* at n.1 (listing such petitions).

A. APJs Are Unconstitutionally Appointed

The Appointments Clause of the Constitution, U.S. Const. art. II, § 2, cl. 2, is a "significant structural safeguard[] of the constitutional scheme" that requires "principal" officers to be appointed by

the President with advice and consent of the Senate. *Edmond v. United States*, 520 U.S. 651, 659 (1997). APJs, however, are hired by the Secretary of Commerce in consultation with the Director of the PTO. 35 U.S.C. § 6(a). That would be permissible if they were "inferior" officers. *See Edmond*, 520 U.S. at 659. But they are not, as the Federal Circuit held in *Arthrex, Inc. v Smith & Nephew, Inc.*, 941 F.3d 1320, 1335 (Fed. Cir. 2019).

"[I]nferior officers are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Edmond*, 520 U.S. at 662. "The only two presidentially-appointed officers that provide direction to the USPTO are the Secretary of Commerce and the Director." *Arthrex*, 941 F.3d at 1329; *see* 15 U.S.C. § 1501; 35 U.S.C. §§ 1, 3(a). Neither provides sufficient direction and supervision for APJs to be considered inferior officers.

Other than general "policy direction," 35 U.S.C.§ 2(a), the Secretary provides no oversight except through the power of potential removal. However, that power (which the Director shares) is subject to the significant procedural and substantive limitations of Title 5, including restrictions on whether removal is justified for "efficiency of the service," timing of any removal, and independent review of cause and procedure by the Merit Systems Protection Board. *See Arthrex*, 941 F.3d at 1333 (citation omitted); 35 U.S.C. § 3(c); 5 U.S.C. § 7513(a)-(d). Nothing in those limited removal powers could make APJs inferior officers. *See Arthrex*, 941 F.3d at 1333-34.

Nothing within the Director's additional authority does either. The Director is "responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of trademarks." 35 U.S.C. § 3(a)(2)(A). The Director can also decide whether to institute certain petitions to be decided by APJs, can designate APJs' decisions as precedential or non-precedential after the fact, can assign APJs to certain three-APJ panels, and can join any such panel to provide a (minority) single vote. *See Arthrex*, 941 F.3d at 1331. But the Director (and the Secretary, for that matter) cannot direct how APJs should decide cases, cannot "review, nullify or reverse a final written decision issued by a panel of APJs," and cannot otherwise "modify a decision issued by APJs, even to correct legal misstatements." *Id.* at 1329, 1334. Once issued, only the Federal Circuit can exercise such review for final decisions of APJs if appealed, and the Director can only be a party to such an appeal. *See id.* at 1329; 35 U.S.C. §§ 6(c), 143; 28 U.S.C. § 1295(a)(4).

The Federal Circuit therefore correctly concluded that APJs are unconstitutionally appointed principal officers—they are greatly insulated from removal and have the unqualified "power to render a final decision on behalf of the United States" reviewable only by "courts of the Third Branch." *Edmond*, 520 U.S. at 665-66; *Arthrex*, 941 F.3d at 1329; *see also Lucia v. SEC*, 138 S.Ct. 2044, 2054 (2018); Gary Lawson, *Appointments and Illegal Adjudication: The America Invents Act Through A Constitutional Lens*, 26 Geo. Mason L. Rev. 26, 53-64 (2018).

It is immaterial whether APJs wield their unconstitutional power in reexamination

proceedings (as here) versus inter partes review proceedings (as in *Arthrex*). The "Director's authority over the Board's decisions is not meaningfully greater" in one versus the other, and the Director does not have "power to appeal the [APJs'] decision." *Virnetx Inc. v. Cisco Sys., Inc.*, 958 F.3d 1333, 1335 (Fed. Cir. 2020) (extending *Arthrex* to inter partes reexamination); *see In re Boloro Glob. Ltd.*, 963 F.3d 1380, 1381 (Fed. Cir. 2020) (same for ex parte reexaminations). And, in any event, "[i]f a special trial judge is an inferior officer for purposes" of some responsibilities, then "he is an inferior officer within the meaning of the Appointments Clause and he must be properly appointed." *Freytag v. Commissioner*, 501 U.S. 868, 882 (1991). Indeed, the Director has "conced[ed] that it follows under the reasoning of [*Freytag*], as understood in *VirnetX*, that 'APJs were principal officers for purposes of all governmental functions of their office.'" *Boloro*, 963 F.3d at 1381 (citation omitted).

B. Decisions By Unconstitutionally Appointed APJs Should Be Vacated For Rehearing By Proper Officers

The correct remedy for unconstitutional appointments of APJs is vacatur and subsequent rehearing by properly appointed officers. At Congress's choice, that could be either (i) APJs appointed by the President with advice and consent of the Senate or (ii) APJs whose decisions are subject to unrestricted review by the Director.

The Federal Circuit disagreed in *Arthrex* and simply severed the removal restrictions on APJs (contained in Title 5) so that they would be "removable at will." 941 F.3d at 1337-39. But that

did not cure the Appointments Clause violation. Removal at will does not somehow make APJs' decisions reviewable by a principal officer, like the Secretary or Director, and thus make them inferior officers without "final decision-making authority" for the United States. *Edmond*, 520 U.S. at 665; *see Arthrex II* Petition 15, 25-33; Lawson, 26 Geo. Mason L. Rev. at 62-63. Moreover, severance of Title 5 protections is contrary to Congressional intent: "removal protections were seen as essential to fair performance of the APJs quasi-judicial role," *Arthrex, Inc. v. Smith & Nephew, Inc.*, 953 F.3d 760, 771 (Fed. Cir. 2020) (Dyk, Newman, Wallach, Hughes, JJ., dissenting from denial of rehearing en banc), and Congress would not have "divested APJs of their Title 5 removal protections to cure any alleged constitutional defect in their appointment," *id.* at 781 (Hughes, Wallach, JJ., dissenting from denial of rehearing en banc). *See also Arthrex II* Petition 20-24. Proper course is vacatur and rehearing by properly appointed APJs, however Congress wishes to effect that.

C. The Unconstitutional Appointment Of APJs Is An Important Issue That Deserves Review

Proper adherence to the Appointments Clause in this context is "exceptionally important." *Arthrex*, 941 F.3d at 1326-27 (citation omitted). The Appointments Clause stands as "a bulwark against one branch aggrandizing its power at the expense of another branch" and "'preserves another aspect of the Constitution's structural integrity by preventing the diffusion of the appointment power.'" *Ryder v. United States*, 515 U.S. 177, 182 (1995) (quoting

Freytag, 501 U.S. at 878). It thus operates as a "significant structural safeguard[] of the constitutional scheme," *Edmond*, 520 U.S. at 659, and raises "important … separation of powers concerns," particularly in proceedings like those controlled by the Board, which commonly operate to extinguish patent rights in proceedings initiated by third parties (as here), *Arthrex*, 941 F.3d at 1326-27.

This issue "is critical to providing certainty to rights holders and competitors alike" and will have "wide-ranging effect on property rights and the nation's economy," potentially affecting thousands of patents. *Id.* at 1327; *see* PTO Trial Statistics at 3. Indeed, the Board has issued a blanket order holding in abeyance dozens of cases that were remanded by the Federal Circuit pursuant to *Arthrex*, General Order, 2020 WL 2119932, at *1, and there are numerous petitions pending before this Court, *see supra* at n.1.

The record here also confirms the importance of this issue. The Board had all of the Dispositive Facts before it, yet its APJs failed to consider them and approved the revocation of ThermoLife's patent right to creatine nitrate anyway. *See supra* at 8-9. That error (which was only compounded by the Federal Circuit's *Chenery* violation) was an affront to administrative and due process and demonstrates the need for proper advice and consent from the Senate (or proper review by the Director).

D. The Unconstitutionality Of APJs Cannot Be Forfeited Automatically And Warrants Review Whenever Raised On Appeal

The Federal Circuit correctly held that raising the unconstitutionality of APJs' appointments before the Board was unnecessary to seek relief on appeal. *Arthrex*, 941 F.3d at 1339. But immediately after *Arthrex*, the court erroneously held that any party that did not do so in its opening appellate brief (or sooner)—such as ThermoLife, which filed its opening brief ten months prior to *Arthrex*—had forfeited its right to do so. *Customedia*, 941 F.3d at 1174. That erroneous decision should not bar review or relief here (or in any direct appeal) for at least two independent reasons.

First, *Arthrex* should have been applied retroactively to any direct appeal pending when the opinion issued (such as ThermoLife's). "[W]hen the law changes while a case is on appeal," as it did when *Arthrex* issued while ThermoLife's appeal was pending, "the changed law applies" for all similar cases pending on direct review. *Sanofi-Aventis Deutschland GmbH v. Mylan Pharm. Inc.*, 791 F. App'x 916, 931 (Fed. Cir. 2019) (Newman, J., dissenting) (citing *Thorpe v. Housing Auth. of Durham*, 393 U.S. 268, 282 (1969)); *see id.* at 931-32 (explaining how *Arthrex* was a change in law and should have been applied retroactively); *Griffith v. Kentucky*, 479 U.S. 314, 323 (1987) ("[T]he integrity of judicial review requires that we apply [a case announcing a new] rule to all similar cases pending on direct review."); *see also Duke* Petition 21-22; *Arthrex I* Petition 27-33; *Sanofi* Petition 11-17. Federal courts have no "constitutional authority" to

disregard that principle and "treat similarly situated litigants differently." *Harper v. Va. Dep't of Taxation*, 509 U.S. 86, 97 (1993) (citation omitted).

That is especially true when, as here, it is a constitutional claim at issue. As this Court has held, "[t]he mere failure to interpose a [constitutional] defense prior to the announcement of a decision which might support it cannot prevent a litigant from later invoking such a ground." *Curtis Publ'g Co. v. Butts*, 388 U.S. 130, 142-43 (1967). The rigid rules of forfeiture should not have foreclosed the application of *Arthrex* as intervening law to ThermoLife's then-pending appeal before the Federal Circuit. *See also Sanofi* Petition 11-17 (discussing history and justification for such exceptions to ordinary rules of waiver and forfeiture); *Duke* Petition 20-22 (similar); *Arthrex I* Petition 27-32 (similar). This Court should so hold and dispose of this petition accordingly if the Appointments Clause issue in *Arthrex* is affirmed (here or otherwise) or review of it is denied.

Second, contrary to the Federal Circuit's holding, objections to violations of the Appointments Clause are not automatically forfeited. This Court should therefore exercise its discretion to directly review the Appointments Clause violation here, or, at minimum, correct the Federal Circuit's precedent that barred ThermoLife from seeking relief below, and remand accordingly.

The Appointments Clause does not stand on the same footing as personal constitutional rights. The Appointments Clause is a critical foundation for "the Constitution's structural integrity" that implicates "the strong interest of the federal judiciary in maintaining the constitutional plan of separation of

powers" by "preventing the diffusion of the appointment power.'" *Ryder*, 515 U.S. at 182 (1995); *Freytag*, 501 U.S. at 878-79. Violations of that "significant structural safeguard[] of the constitutional scheme," *Edmond*, 520 U.S. at 659, are too important to be lost to individual action or inaction—the "values of liberty and accountability protected by the separation of powers belong … to the Nation as a whole," *Wellness Int'l Network Ltd. v. Sharif*, 135 S. Ct. 1932, 1955 (2015) (Roberts, C.J., dissenting).

Thus, "notions of consent and waiver cannot be dispositive because the limitations serve institutional interests that the parties cannot be expected to protect." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 851 (1986); *see also June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2175 (2020) ("[E]ven truly forfeited or waived arguments may be entertained when structural concerns or third-party rights are at issue."). "Were such institutional interests … so easily waived, the affirmative requirements imposed by the Appointments Clause would effectively be rendered null and void." *Samuels, Kramer & Co. v. Commissioner*, 930 F.2d 975, 984 (2d Cir. 1991). Put simply, structural constitutional protections such as those embodied in the Appointments Clause cannot be forfeited automatically by not being raised in an opening brief to a court of appeals. *See also Sanofi* Petition 11-17; *Duke* Petition 20-22; *Arthrex I* Petition 27-32.

Indeed, this Court has routinely addressed important "nonjurisdictional structural constitutional objections … whether or not they were ruled upon below," including Appointments Clause

challenges raised for the first time in "'a supplemental brief upon a second request for review'" to this Court. *Freytag*, 501 U.S. at 878-79 (quoting *Glidden Co. v. Zdanok*, 370 U.S. 530, 536 (1962) (citing *Lamar v. United States*, 241 U.S. 103, 117-18 (1916))); *see also, e.g.*, *Nguyen v. United States*, 539 U.S. 69, 73, 80-81 (2003) (addressing structural challenge first raised in petition for writ of certiorari). As in those cases, the "constitutional challenge" here "is neither frivolous nor disingenuous"—the question is pressing and important, and the Appointments Clause violation is clear and goes to the "validity of … the proceeding that is the basis for this litigation," to which ThermoLife did not consent. *Freytag*, 501 U.S. at 879; *see supra* at 26-31. There also is little threat of "disruption to sound appellate process" since the Federal Circuit has already addressed the Appointments Clause issue numerous times, including when raised to the full court. *Freytag*, 501 U.S. at 879; *see Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995) ("[E]ven if this were a claim not raised by petitioner below, we would ordinarily feel free to address it since it was addressed by the court below" (emphasis removed)).

The Federal Circuit's blanket bar on parties challenging the unconstitutional appointment of APJs after opening briefing is contrary to that precedent. ThermoLife's right to raise its Appointments Clause challenge—either directly or by asserting *Arthrex* as a change in law—was not forfeited. This Court should correct that precedent or reach the Appointments Clause issue directly in its discretion. *See Freytag*, 501 U.S. at 879.

CONCLUSION

The petition for a writ of certiorari should be granted. In the alternative, it should be held pending disposition of related petitions (*supra* at n.1) and then decided accordingly.

Respectfully submitted,

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APPENDIX

TABLE OF CONTENTS

**UNITED STATES COURT OF APPEALS,
FOR THE FEDERAL CIRCUIT**

IN RE: THERMOLIFE INTERNATIONAL LLC,
Appellant

2018-2189

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 90/011,394, 90/011,869.

Decided: January 10, 2020

Before PROST, *Chief Judge*, TARANTO and STOLL, *Circuit Judges*.

PROST, *Chief Judge*.

ThermoLife International LLC appeals a decision from the Patent Trial and Appeal Board ("Board") from two merged ex parte reexamination proceedings of U.S. Patent No. 7,777,074 ("the '074 patent"). The Board found that claim 6, which was added during reexamination, is anticipated under 35 U.S.C. § 102(b).[1] For the reasons below, we affirm.

I

The '074 patent claims priority to an application filed in 2007 and is directed to various amino acid compounds. As relevant to this appeal, the '074 patent discloses nitrates of amino acid compounds. The specification teaches that "Nitrates are a class of

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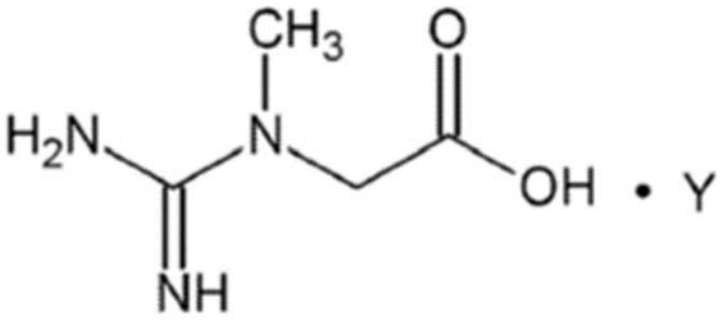
[1] Because the claim at issue in this case have effective filing dates prior to March 16, 2013, we apply pre-AIA § 102(b).

compounds that are salts of Nitric Acid (HNO_3) and at least comprise one Nitrogen atom and at three Oxygen Atoms (NO_3)." '074 patent col. 6 ll. 45–47.

Claim 6, which was added during ex parte reexamination of the '074 patent and is the only claim on appeal, is directed in part to nitrates of creatine. Claim 6 recites:

6. A Compound having the structure of:



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

J.A. 44.

Creatine is a nonessential amino acid or amino acid derivative that is naturally occurring in the human body and is commonly used in nutritional supplements. '074 patent col. 4 ll. 11–19. At the time of filing, it was known that creatine is capable of forming a number of salts by reaction with a number of acids. Claim 6 recites one such salt, creatine nitrate. *See* '074 patent col. 6 ll. 45–47.

The '074 patent teaches that creatine nitrate may be prepared by "combining nitric acid and Creatine, mixing with water, and leaving to crystallize." '074 patent col. 9 ll. 19–21. The specification does not state the chemical formula or the structural formula for

creatine nitrate. The specification does, however, identify the structural formula of creatine, which reveals that the chemical formula of creatine is $C_4H_9N_3O_2$. *See* '074 patent col. 4 ll. 1–9; *see also id.* at J.A. 44 (claim 6).

B

The '074 patent issued in 2010 with two claims. Two separate requests for ex parte reexamination were subsequently filed. These requests were merged into a single ex parte reexamination proceeding, during which the original claims of the '074 patent were cancelled and other claims, including claim 6, were added. Though all other newly added claims were allowed, claim 6 was finally rejected as anticipated under 35 U.S.C. § 102(b) over a prior art publication Barger.

Barger is a compendium of bases, and in relevant part, describes creatine and its structure. *See* J.A. 3809–815, 5063. Barger specifically teaches "[c]ompounds of creatine," including "[t]he nitrate, $C_4H_9O_2N_3 \cdot HNO_3$," and further describes creatine nitrate's properties.[2] J.A. 3812. Barger does not describe the structure of creatine nitrate or a method of making it.

ThermoLife appealed the examiner's rejection of claim 6 to the Board. *See In re ThermoLife Int'l LLC*, No. 2015-006203, 2016 WL 406381 (P.T.A.B. Feb. 1, 2016) ("*Board Decision I*"). ThermoLife argued that Barger is ambiguous and also that Barger is not enabling because it does not teach a method of preparing creatine nitrate. The Board disagreed, but

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[2] Barger, G., THE SIMPLER NATURAL BASES, R.H.A. Plimmer & F.G. Hopkins (eds.), "Monographs on Biochemistry," Longmans, Green & Co., London (1914).

nonetheless identified additional evidence to demonstrate that Barger is enabling. Specifically, the Board cited the prior art publication Dessaignes,[3] which predates Barger, for its disclosure of a method for preparing creatine nitrate. The Board additionally cited another prior art publication Gmelin[4] for a similar disclosure.

Dessaignes teaches methods of preparing the "nitrate of creatine," identifying the salt with the chemical formula "$C^8H^{18}N^6O^4$, $N^2H^2O^6$." *See* J.A. 4150. In one of these methods, Dessaignes states that creatine nitrate may be produced by "dissolving 1.057 gr. of crystallized creatine in nitric acid containing 0.447 gr. of $N^2H^2O^6$, and evaporating at 86° F." J.A. 4150. Dessaignes does not teach the structural formula of creatine nitrate.

The Board determined that "the salt described in Barger was conventionally made by dissolving crystallized creatine in the requisite quantity of nitric acid and allowing to crystallize by evaporation of the water, as evidenced by Dessaignes and Gmelin, identically to that described in the '074 patent." *Board Decision I*, at *6. The Board therefore concluded that Barger's teaching of creatine nitrate did not require a citation to, or a description of, how to make the salt. *Id.* (citing *Motorola, Inc. v.*

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[3] 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, 201–04 (June 1, 1854).

[4] Leopold Gmelin, "Creatine," HANDBOOK OF CHEMISTRY, Vol. 10: Organic Compounds Containing Eight and Ten Atoms of Carbon, pp. 249–55, Henry Watts, trs., printed for the Cavendish Society, London (1856).

Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed. Cir. 1997)). Because the Board had relied on new evidence to support its affirmance, it entered new grounds of rejection for claim 6: claim 6 is rejected under 35 U.S.C. § 102(b) as anticipated by: (a) Barger, as evidenced by Dessaignes and Gmelin, and (b) Dessaignes or Gmelin.[5]

ThermoLife elected to reopen prosecution as to the new grounds and submitted additional declarations and argument purporting to show that all three references, Barger, Dessiagnes, and Gmelin, are ambiguous and not enabling. The examiner, however, disagreed and finally rejected claim 6 on all grounds. ThermoLife again appealed to the Board.

In its second decision on appeal, the Board stated that the issue was whether "based on a preponderance of the evidence, has [ThermoLife] shown that the Examiner erred in maintaining the new grounds of rejection in light of further arguments and evidence of record . . . ?" *See In re ThermoLife Int'l LLC*, No. 2018-001029, 2018 WL 2335128, *3 (P.T.A.B. May 21, 2018) ("*Board Decision II*"). The Board answered in the negative, again rejecting ThermoLife's arguments that the references are ambiguous and not enabling. First, as to ambiguity, the Board found that each of the references, including Barger and Dessaignes, unambiguously identify creatine nitrate and disclose its chemical formula and

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[5] In *Board Decision I*, the Board expressly adopted all findings of the examiner in the final rejection and the examiner's answer in that appeal. *Board Decision I*, at 4. The Board's decision has not been vacated or otherwise reversed. The analysis and conclusions therein remain part of the prosecution history.

other physical properties. The Board expressly refuted ThermoLife's argument that Dessaignes teaches the incorrect chemical formula for creatine nitrate by doubling the number of atoms of each element in the formula. The Board stated that Dessaignes's formula "converts" to the correct formula. *Id.* at *8. The Board also stated that "[w]ithout sufficient evidence 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." *Id.*

The Board also expressly rejected ThermoLife's argument that Dessaignes is ambiguous due to potential inaccuracies in its disclosure or because of differences between the method of preparing creating nitrate taught in Dessaignes and the method taught by the '074 patent. The Board found that the method in Dessaignes is "substantially identical to that described in the '074 patent." *Id.* at *10.

Next, the Board found that ThermoLife had not met its burden to show that the asserted prior art is not enabling. *See id.* at *10–17 (citing *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012)). Specifically, the Board found that the record demonstrated that a skilled artisan as of the '074 patent's application in 2007 could have made creatine nitrate from Dessaignes's teaching without undue experimentation. The Board also rejected ThermoLife's argument that Dessaignes did not, in fact, make creatine nitrate, because as an initial matter, actual manufacture is not required to satisfy enablement. The Board further rejected ThermoLife's argument based on its finding that ThermoLife has not "conclusively shown" that Dessaignes's mixing process does not produce

creatine nitrate, or that the findings of Dessaignes are "necessarily inaccurate." *Id.* at *16, *17.

ThermoLife appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

Anticipation is a question of fact that considers whether a single reference describes the claimed invention "with sufficient precision and detail to establish that the subject matter existed in the prior art." *Wasica Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017) (quoting *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002)); *see also In re Hyatt*, 211 F.3d 1367, 1371 (Fed. Cir. 2000). As a matter of law, an ambiguous reference cannot anticipate a claim. *Wasica Finance*, 853 F.3d at 1284.

Once an examiner has shown a prima facie case of anticipation, because "a prior art printed publication cited by an examiner is presumptively enabling," the burden of proving that the prior art is not enabling shifts to the patent owner. *Antor Media*, 689 F.3d at 1288. Whether a prior art reference is enabled is a question of law based on underlying factual findings. *In re Morsa*, 803 F.3d 1374, 1376 (Fed. Cir. 2015). We review the Board's legal conclusions de novo and the Board's factual findings for substantial evidence. *Morsa*, 803 F.3d at 1376.

On appeal, ThermoLife argues that the cited prior art does not anticipate claim 6 of the '074 patent because the prior art does not expressly and unambiguously disclose the claimed invention. ThermoLife also argues that the cited prior art does not enable the claimed invention. We address each argument in turn.

A

ThermoLife argues that the prior art does not anticipate claim 6 of the '074 patent because each reference fails to expressly and unambiguously disclose the claimed invention. According to ThermoLife, the references do not teach anything relevant to the claimed creatine nitrate compound because they are designed to produce compounds with different formulas. We disagree. Substantial evidence supports the Board's determination that claim 6 is anticipated by at least Barger as evidenced by Dessaignes and by Dessaignes alone. Because we affirm with respect to these grounds, we do not reach ThermoLife's remaining arguments related to Gmelin.

Barger teaches the "nitrate" of creatine recited by claim 6. Barger further correctly reports the chemical formula of creatine nitrate ($C_4H_9N_3O_2 \cdot HNO_3$), which consistent with claim 6, identifies the chemical formula for creatine nitrate as creatine with nitric acid. *Compare* J.A. 3812 (Barger) *with* '074 patent col. 4 ll. 1–10, col. 6 ll. 45–47 *and* J.A. 44 (claim 6). Further still, Barger describes the properties of creatine nitrate, and Barger discloses the correct chemical formula and structural formula for creatine, one of creatine nitrate's starting materials.[6]

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[6] To the extent that ThermoLife argues that the Board's anticipation decision should be reversed because the Board copied the incorrect chemical structure of creatine from Barger into the body of the decision, we are not persuaded that this constitutes reversible error. The Board's statement that "Barger provides a chemical structure for creatine" is correct. *Board Decision II*, at *5; *see* also J.A. 5063. Additionally, throughout reexamination, the correct creatine structure from Barger was repeatedly cited by the examiner and those citations were

Though ThermoLife acknowledges that Barger's express disclosure of creatine nitrate "appears like it could match the claimed compound," ThermoLife nonetheless argues that the disclosed chemical formula "could just as easily refer to creatinine nitrate monohydrate or any other number of compounds." *See* Appellant's Br. 34; *see also id.* at 3. As the Board found, ThermoLife's argument is undermined by the clear description in Barger, which specifically identifies the disclosed chemical formula as being that of creatine nitrate and not another compound. *Board Decision II*, at *7. Substantial evidence supports the Board's finding that Barger unambiguously discloses creatine nitrate as recited by claim 6.

Like Barger, Dessaignes expressly teaches the "nitrate of creatine," which is the combination of creatine and nitric acid. J.A. 4150. Dessaignes identifies creatine nitrate with the chemical formula "$C^8H^{18}N^6O^4$, $N^2H^2O^6$," and Dessaignes specifically teaches a method for preparing creatine nitrate by mixing creatine and nitric acid. *Id.*

ThermoLife, however, argues that the Board erred in finding that Dessaignes's reported chemical formula, which doubles the number of each of the atoms, "converts" to the correct chemical formula. *Board Decision II*, at *8. According to ThermoLife, such conversion has "no place in chemistry." Appellant's Br. 50–51. But ThermoLife's argument

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adopted by the Board. *See e.g.*, *Board Decision I*, at *2. Moreover, as Barger has otherwise clearly identified creatine nitrate, it is not required to disclose its structure or the structure of its starting material in order to anticipate. *See In re Baranauckas*, 228 F.2d 413, 415 (C.C.P.A. 1955).

lacks evidentiary support. *See id.* In contrast, the Board's conclusion is supported by testimony offered by ThermoLife's own expert, Dr. Richard Chamberlin, with respect to another statement in Dessaignes. He stated that "[o]ne would assume that the '$N^2H^2O^6$' would mean two equivalents of nitric acid." *See* J.A. 3927, ¶ 23. Indeed, the chemical formula for creatine nitrate in Dessaignes is consistent with the correct ratio of one mole of creatine to one mole of nitric acid. *See* J.A. 4045. Substantial evidence supports the Board's finding that Dessaignes unambiguously discloses the correct chemical formula for creatine nitrate.

ThermoLife's remaining arguments that the Board erred in finding the prior art unambiguous are similarly unpersuasive. ThermoLife, for example, argues that while the prior art may disclose creatine nitrate, there "is no way to know whether the 'creatine' that the references refer to creatine as it is known today." Appellant's Br. 37. ThermoLife supports this argument with expert testimony by Dr. Trevor H. Levere, a chemistry historian, which the Board discounted because Dr. Levere is not capable of determining whether a chemist in 2007 would have been able to perform Dessaignes's mixing method without undue experimentation. *Board Decision II*, at *17. Citing Dr. Chamberlin, the Board also found that as of the time of the '074 patent's alleged invention in 2007, the art of salt formation was well-known, and that mixing crystallized creatine and nitric acid as described in Dessaignes would have required no more than routine experimentation. *Id.* We credit the Board's fact finding and determine that it is supported by substantial evidence.

ThermoLife also briefly argues that the Board legally erred in determining that the prior art is not ambiguous because in its view, the Board required ThermoLife to prove that the prior art was ambiguous by clear error, rather than by preponderant evidence. ThermoLife's only evidence that the Board applied an incorrect standard is the Board's lone statement that "[w]ithout sufficient evidence 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." *Id.* at *8 (emphasis added). Contrary to ThermoLife's suggestion, this statement does not apply to the Board's ultimate finding regarding whether the cited prior art unambiguously anticipates the prior art. Instead, the Board's statement is made in response to ThermoLife's specific argument that the prior art is ambiguous because it discloses incorrect chemical formulas, or otherwise contains errors, rendering the prior art ambiguous—the same argument considered above. *See id.*

The Board's decision shows that it correctly considered the ultimate question of whether the prior art unambiguously teaches the claimed invention. The Board framed the issues on appeal by asking whether the examiner's anticipation rejections should be maintained "based on a preponderance of the evidence." *Id.* at *3. Then the Board correctly applied the law. The Board explained that it was "unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous," because ThermoLife attempted to "undermine an express teaching [of the prior art] with no more than conjecture." *Id.* at *8. We agree.

The evidence demonstrates that the Board correctly found that both Barger and Dessaignes expressly disclose creatine nitrate as recited in claim 6, and also that neither Barger nor Dessaignes teaches incorrect formulas for creatine nitrate. These are factual findings that we review for substantial evidence. *See Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005) ("What a prior art reference discloses in an anticipation analysis is a factual determination . . . ."). Because Barger and Dessaignes do not include the errors alleged by ThermoLife, ThermoLife has not shown that the prior art is ambiguous by preponderant evidence.

On the facts of this case, therefore, we do not think that the Board's errant statement constitutes reversible error. We determine that to the extent that the Board incorrectly stated the preponderant evidence standard in a single statement, such error was harmless. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004) ("We have previously made clear that the harmless error rule applies to appeals from the Board just as it does in cases originating from district courts.").

Accordingly, we affirm the Board's decision that the prior art discloses a prima facie case of anticipation.

B

Because we determine that the Board correctly found a prima facie case of anticipation, we now turn to ThermoLife's argument that the prior art is not enabling. More particularly, ThermoLife argues that the prior art lacks enablement because in its view, the

prior art does not disclose a method of preparing creatine nitrate. *See Antor Media*, 689 F.3d at 1288.

With respect to Barger, in its first appeal to the Board during reexamination, ThermoLife argued that the reference was not enabling for failure to describe a method of making creatine nitrate. In response, the Board disagreed that Barger lacked enablement but also cited Dessaignes, among other references, as evidence that "Barger's teaching of creatine nitrate is the recitation of a material that was so conventional to organic chemists at the time of the invention that there was not need either for citation or for a description of how to make the salt." *Board Decision I*, at *6 (citing *Motorola*, 121 F.3d at 1472).

On appeal before this court, ThermoLife argues that Dessaignes does not cure the deficiency of Barger because it also is not enabling. According to ThermoLife, the preparation of a salt like creatine nitrate is complex and the method taught by Dessaignes would not teach a person of ordinary skill in 2007 to make creatine nitrate. ThermoLife also argues that Dessaignes does not teach the same method as the '074 patent, but instead discloses a different step for adding water. ThermoLife further argues that the method in Dessaignes may not make creatine nitrate at all, and that it is not possible to determine whether creatine nitrate was actually made based on the disclosures in Dessaignes.

ThermoLife made each of these arguments in its second appeal to the Board during reexamination. The Board correctly rejected each. *See Board Decision II*, at *10–17. For example, the Board found that preparing creatine nitrate from Dessaignes would not have been beyond the skill of the ordinary artisan in 2007 because the specific disclosures including the

amounts of creatine and nitric acid, as well as evaporation temperature, would have provided sufficient information to such an artisan to prepare creatine nitrate. *See id.*, at *13. Indeed, as the Board found, the directions in the prior art for preparing creatine nitrate are "substantially identical" to the method taught by the '074 patent. *See id.* at *12; *compare* '074 patent col. 9 ll. 19–21 (preparing creatine nitrate by "combining nitric acid and Creatine, mixing with water, and leaving to crystallize") *with* J.A. 4150 (Dessaignes) (preparing creatine nitrate by "dissolving 1.057 gr. of crystallized creatine in nitric acid containing 0.447 gr. of $N^2H^2O^6$, and evaporating at 86° F"). The amount of direction included in the '074 patent's specification is evidence of the knowledge in the art, and therefore, is also evidence of what amount of disclosure is required from the prior art to be enabling. *See Morsa*, 803 F.3d at 1378 ("There is a crucial difference between using the patent's specification for filling in gaps in the prior art, and using it to determine the knowledge of a person of ordinary skill in the art."); *see also Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 781 (1985) (noting that appellee's "own patent application does not undertake to tell anyone how to make the alloy it describes and seeks to patent. It assumes that those skilled in the art would know how").

To the extent that the method for preparing creatine nitrate in the '074 patent may not be completely identical to the prior art, i.e., mixing with water as compared to dissolving, the Board found that there was no evidence in the record to suggest that the difference would be "critical." *See Board Decision II*, at *12. Instead, the Board found that the '074 patent itself taught that the difference in the methods

would not be critical to preparing creatine nitrate. *Id.* (citing '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 . . . since many possible manufacturing processes and sequences of steps may be used to manufacture Amino Acid Compound implementations in a wide variety of forms."). We conclude that the Board's findings are supported by substantial evidence.

ThermoLife also argues that the Board's decision should be reversed or vacated because the Board improperly required it to demonstrate lack of enablement by clear error rather than by preponderant evidence. ThermoLife cites three sentences from the Board's decision as evidence that the Board applied the wrong standard in determining whether the prior art lacked enablement. First, ThermoLife cites the Board's statement that "[w]ithout sufficient evidence 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." *Id.* at *8. This is the same statement discussed above. As is clear from that discussion, the Board's statement is not related to whether the prior art is enabling, but instead relates to whether the prior art was ambiguous. We are not persuaded that the Board's statement in the context of ambiguity is relevant to the standard it applied during its separate discussion of whether the prior art is enabling.

ThermoLife additionally cites two other sentences from the Board's opinion that relate to enablement, but which nonetheless fail to prove that the Board committed reversible error. In these statements, the Board explained that ThermoLife has not

"conclusively shown Dessaignes' mixing process does not produce creatine nitrate," *id.* at *16, and that the Board was not persuaded "that the findings of Dessaignes are *necessarily* inaccurate," *id.* at *17 (emphasis in original). These statements, however, do not expressly demonstrate that the Board applied an incorrect standard, particularly where the Board had already correctly framed ThermoLife's burden for proving a lack of enablement in the immediately preceding paragraph. *Id.* at *16 ("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.") (emphasis added); *see also id.* at *3.

But even were we to assume that by using the words "conclusively" and "necessarily" the Board required more than preponderant evidence, we nonetheless do not find reversible error. Because enablement is a question of law, which we review de novo, on appeal we apply the Board's findings of fact to determine whether its ultimate legal conclusion is supported by preponderant evidence. *See Morsa*, 803 F.3d at 1376. Based on the record of this case, we conclude that it is.

The Board's fact finding establishes that the method taught by Dessaignes would enable a person of ordinary skill in the art to prepare creatine nitrate. *See Board Decision II*, at *10–17. The Board further found that based on the knowledge of the ordinarily skilled artisan in 2007, to the extent experimentation would be required to prepare creatine nitrate from Dessaignes's method (e.g., to determine the

concentration of nitric acid to use), such experimentation would have been no more than routine. *See id.* at *15, *17; *see also Morsa*, 803 F.3d at 1377; *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). And to the extent it would have been unclear whether creatine nitrate was in fact made, the Board found that the skilled artisan in 2007 would have had many methods for confirming the product. *Board Decision II*, at *15.

When the Board's findings of fact are taken together, ThermoLife's argument that Dessaignes's method would not have enabled an ordinarily skilled artisan in 2007 to prepare creatine nitrate is supported only by mere speculation. Such speculation or conjecture fails to show that, by a preponderance of the evidence, the prior art is not enabling. Accordingly, to the extent the Board applied the incorrect standard, on this record, such error is harmless and does not warrant reversal. *See In re Watts*, 354 F.3d at 1369.

We have considered ThermoLife's additional arguments and find them unpersuasive. For the above described reasons, we affirm the Board's decision that claim 6 is anticipated.

AFFIRMED

COSTS

The parties shall bear their own costs.

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL
AND APPEAL 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

I. STATEMENT OF CASE

ThermoLife International, LLC (hereinafter "Patent Owner"), the real party in interest[1] 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 6[2] under 35 U.S.C. § 102(b) as anticipated by

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[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

Barger,[3] as evidenced by Dessaignes[4] 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:

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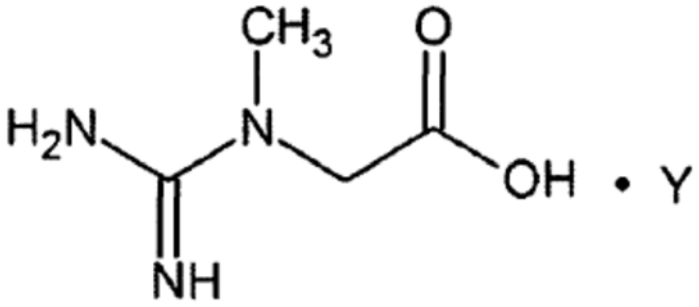
been confirmed as patentable by the Examiner. App. Br. 2; Advisory Action mailed July 23, 2014; Ans. 1.

[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").

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.

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. Chamberlin[6] 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

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[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.").

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 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. Chamberlin[8] 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

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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.").

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.

III. FINDINGS OF FACT

Dessaignes, 1854[10]

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

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[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).

> 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 mono hydrated nitric acid. The formula $C^8H^{18}N^6O^4$, $N^2H^2O^6$ requires 32.47 per cent. of $N^2H^2O^6$.

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 $N^2H^2O^6$, 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, 1856[11]

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 $C^8N^3H^9O^4$. Gmelin, 252.

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

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:

> *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.

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

Wislicenus[12], 1881

Wi1. Wislicenus states:

> Creatine crystalises in large, colourless, brilliant, short monoclinic prisms of the formula $C_4H_9N_3O_2$, 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, $C_4H_9N_3O_2$, HNO_3, crystalises in large colourless prisms.

Wislicenus, 423.

Wi2. Wislicenus further states that "Creatinine . . . is readily formed from creatine, with removal of water, by heating with dilute mineral acids; e.g. on

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

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° 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.

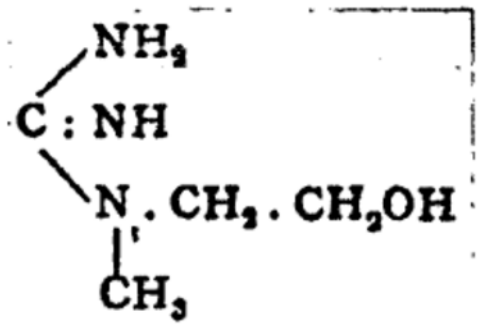
Ba3. Barger states that "[f]or our purposes a better practical definition is to describe a base as a substance which is precipitated by phosphotungstic acid. Adopting this criterion we consider creatinine to be a base but creatine not." Barger 6.

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.

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 x 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, crcatininc 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, Wi1, B1, Ba11) and that a nitrate of creatine was formed by mixing nitric acid and creatine and evaporating the water at 30° C, or 86° 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.").

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 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 other physical properties for both the starting creatine material and the nitrate of creatine. D1, D2, G1, G3, G4, Wil, 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 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 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

[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.

($C_4H_9N_3O_2$, 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 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 (GS), 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

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[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.

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 "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 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.*

lnterdigital 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 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 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." (D3) of "nitric acid" and evaporating at 86° F (30° C). D3, G4.[15]

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[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.

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 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 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 be capable of preforming Dessianges' 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 the in 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. ¶ **5**7 (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.

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.

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[16] There is an express teaching in the art that creatine easily dissolves in water (D2, G4), and thus the prior art would

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 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, Dessianges 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

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inform the skilled artisan as to the predictable solubility of creatine in water.

ammonia," and further properties of the precipitate), G4 ("small shining crystals" that recrystallize to "thick short prisms," "less soluble that the sulphate or hydrochlorate," "very sour taste," "decomposed by ammonia"), Wi1 ("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; 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.

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 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.

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[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 Dessianges 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.

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 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 Dessianges' 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

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

prior art expressly says is true. *In re Antor Media Corp.,* 689 F.3d at 1288.

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)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE: THERMOLIFE INTERNATIONAL LLC,
Appellant

2018-2189

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 90/011,394, 90/011,869.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES and STOLL, *Circuit Judges*[*].

PER CURIAM.

ORDER

Appellant ThermoLife International LLC filed a combined petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

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[*] Circuit Judge Moore did not participate.

The petition for rehearing en banc is denied.

The mandate of the court will issue on March 20, 2020.

FOR THE COURT

March 13, 2020
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

U.S. Const. art. II, § 2, cl. 2

Section 2.

* * *

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

35 U.S.C. § 6

§ 6. Patent Trial and Appeal Board

(a) IN GENERAL.—There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

(b) DUTIES.—The Patent Trial and Appeal Board shall—

(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

(2) review appeals of reexaminations pursuant to section 134(b);

(3) conduct derivation proceedings pursuant to section 135; and

(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

(c) 3-MEMBER PANELS.—Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

(d) TREATMENT OF PRIOR APPOINTMENTS.—The Secretary of Commerce may, in the Secretary's discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge's having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.