

No. 20-150

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In the  
**Supreme Court of the United States**

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THERMOLIFE INTERNATIONAL LLC,

*Petitioner,*

v.

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

*Respondent.*

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

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**REPLY BRIEF FOR PETITIONER**

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## INTRODUCTION

The Director’s cursory brief in opposition confirms that review is warranted. He does not dispute the importance of either question presented. Instead, he musters only two purported reasons for denying review: (i) there was no *Chenery* violation here; and (ii) ThermoLife forfeited its Appointments Clause challenge just like the unsuccessful petitioner in *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 19-1204 (filed Apr. 6, 2020) (the “*Arthrex I* Petition”). Neither has merit.

First, it is clear that the Federal Circuit violated the *Chenery* doctrine in this case. The Director’s suggestion that the court of appeals affirmed the Board’s existing factual rejection of the Dispositive Facts is simply wrong. The portions of the Board’s opinion that the Director cites to substantiate that theory do not address the Dispositive Facts. That is because the Board never actually considered them—only the Federal Circuit did, when unconstitutionally declaring them in the first instance on appeal to be “mere speculation” and “conjecture.” App. 17a.

Second, despite any purported forfeiture (there was none, *see* Pet. 32-35), the Director agrees that this Court can address ThermoLife’s Appointments Clause challenge in its “discretion” (Opp. 10 (citation omitted)). Such discretion is due here for the reasons discussed in the petition. *See* Pet. 35. And the unsuccessful *Arthrex I* Petition does not change that fact. That petition exclusively requested that this Court create a bright-line rule that the Federal Circuit’s Appointments Clause decision in *Arthrex* had to apply to all pending cases. That would be justified (*see* Pet. 26-31), but setting such new

precedent is not necessary here. Unlike the *Arthrex I* Petition, ThermoLife’s petition also independently requests that this Court cure the Appointments Clause violation in this case directly by exercising its discretion regardless of any forfeiture. Pet. 35. That would not require setting new precedent or necessitate further substantive proceedings if this Court affirms in the consolidated *Arthrex* proceedings (*United States v. Arthrex, Inc.*, No. 19-1434 (filed June 25, 2020); *Smith & Nephew, Inc. v. Arthrex, Inc.*, No. 19-1452 (filed June 29, 2020); *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 19-1458 (filed June 30, 2020) (collectively, the “*Arthrex* Proceedings”).

The Court should intervene to put an end to the Federal Circuit’s penchant for violating the *Chenery* doctrine or hold the petition for summary disposition in its discretion after conclusion of the *Arthrex* Proceedings.

## ARGUMENT

### I. The Federal Circuit’s Violation Of The *Chenery* Doctrine Warrants Review

The Director does not dispute that the Federal Circuit is violating the *Chenery* doctrine with an alarming frequency that warrants review. Because he cannot. The Federal Circuit has paid haphazard lip service to the *Chenery* doctrine for decades, repeatedly violating the separation of powers by trampling on the PTO’s fact-finding power. *See* Pet. 16-21. In the rare case where the Federal Circuit has done so to affirm PTO decision-making (like here), it is understandable that the Director might not object. But the Federal Circuit has no congressional mandate to revoke a patentee’s rights by “directing the examination” merely because the Director of the PTO

happens to not object. *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 denial of rehearing en banc, joined by Newman & Rader, JJ.). Scholars, the bar, and the Federal Circuit's own judges have repeatedly tried to stop that unconstitutional encroachment on executive power. Pet. 16-21. Those attempts have failed. This Court's intervention on this undisputedly important and recurring issue is thus desperately needed—just like it was to stop similar harm in *Zurko* two (long) decades ago. *See* Pet. 21-22.

Despite his implicit concession about the importance of this issue, the Director insists that there is a roadblock to review: no *Chenery* violation purportedly occurred here because the Federal Circuit did not address the Dispositive Facts in the first instance on appeal. Opp. 7-9. Instead, according to the Director, the Board “fully considered” those scientific facts, “including petitioner’s arguments (Pet. 23-26)” concerning them, and specifically “rejected them based on the evidence in the record before it.” Opp. 7-8. So, the Director contends in turn, the Federal Circuit merely confirmed that “the Board had ‘correctly rejected each’ of those arguments” based on the “substantial evidence in the record”—a supposedly “factbound” decision inapt for review. *Id.* at 8-9 (citation omitted).

That narrative, however, is spun from whole cloth. The Board never considered and rejected the Dispositive Facts. It never made *any* substantive factual findings regarding *any* of the Dispositive Facts or ThermoLife’s arguments concerning them. *See* Pet. 9-10, 23-25. The only support that the Director advances for his account is a bare string cite

to eight pages of the Board’s opinion without quotation or further explanation. Opp. 8 (citing Pet. App. 33a-34a, 39a-44a). But nothing in those pages indicates that the Board “fully considered” and “rejected” the Dispositive Facts and ThermoLife’s arguments concerning them. Opp. 7-8; *see* Pet. App. 33a-34a, 39a-44a (discussing different arguments and record evidence); *see also* Pet. 9-10, 23-25.

Each of those Dispositive Facts (which the Director tacitly concedes needed to be addressed by the Board, *see* Opp. 7-8) irrefutably proves that Dessaignes’s methods would not, and did not, produce creatine nitrate.<sup>1</sup> But the issue here is not whether

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<sup>1</sup> The Dispositive Facts were a critical part of “the record as a whole” (Opp. 7) that the Director tacitly concedes had to be considered here. For instance, they definitively prove that ThermoLife’s process for making creatine nitrate is not “substantially identical” to Dessaignes’s mix-and-evaporate method, as the Board believed and the Director touts. Pet. App. 37a, 41a; Opp. 8. The Dispositive Facts irrefutably establish that the mixing and evaporation in Dessaignes’s method would dehydrate creatine and therefore produce only *creatinine* nitrate. *See* Pet. 9, 24. ThermoLife’s method overcomes that dehydration (and thus avoids the creation of *creatinine* nitrate) by: (i) *rehydrating* the initial nitric acid/creatine mixture with water (an additional step Dessaignes never performed), and (ii) then *crystallizing* the resulting mixture (rather than dehydrating it further through evaporation, as Dessaignes did). *See* Pet. 7; Pet’r C.A. Reply Br. 2, 19-20; *see also* Pet’r C.A. Br. 47. Those inventive differences are why ThermoLife’s process works—and, as the Dispositive Facts prove, Dessaignes’s methods did not. Pet. 7, 9, 24-25; *see also* Pet’r C.A. Br. 48; Pet’r C.A. Reply Br. 2, 19-20, 23-24. Those differences are legally significant too. Transforming a non-functional prior-art method into a new functional one by adding or changing steps raises a question of obviousness under 35 U.S.C. § 103, and ThermoLife overcame every obviousness rejection advanced by the PTO. *See* Pet. 7; Pet’r C.A. Br. 59; Pet’r C.A. Reply Br. 24-25, 27-30.

those facts and testimony actually establish that the prior art was not enabled (even though they do). What matters is that the Board failed to consider them and, instead of remanding to correct that error, the Federal Circuit took upon itself to reject the Dispositive Facts as “speculation” and “conjecture” in the first instance. That is not “factbound” substantial evidence review of the Board’s decision, as the Director suggests (at 7-9)—it is new fact-finding by the court of appeals in clear violation of the *Chenery* doctrine.

The Director does not dispute that *Chenery* violations, and the Federal Circuit’s well-known habit of committing them, is an important and pressing issue that warrants this Court’s intervention. Review therefore should be granted on the first question presented.

## **II. The Court Should Grant Review To Correct The Appointments Clause Violation Here**

The Director does not dispute that the Appointments Clause issue is an important one that should be addressed by this Court. Instead, the Director argues that ThermoLife “forfeited its Appointments Clause challenge in this case” by not raising it “before the Board or the court of appeals.” Opp. 9-10.

But the Director presents no argument to establish that ThermoLife forfeited its rights by not presenting the Appointments Clause issue to the Board. See Opp. 10. And the theory is wrong. See Pet. 32-34; *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1326-27 (Fed. Cir. 2019), *cert. granted*, --- S. Ct. ----, 2020 WL 6037208, at \*1 (U.S. Oct. 13, 2020) (granting review of Appointments Clause issue but



denying review of whether the same was not forfeited when raised first on appeal).

Nor is review inappropriate because the Appointments Clause challenge was not raised before the Federal Circuit. Constitutional decisions like *Arthrex* should extend to all cases on direct review. *See* Pet. 32-35. And ThermoLife did not request that relief below because the Federal Circuit's binding precedent definitively barred it from doing so. Pet. 13, 32 (discussing *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1173 (Fed. Cir. 2019) (per curiam)). That does not mean, as the Director contends, that ThermoLife is asking the Court to hold that the Federal Circuit "was *required* to apply *Arthrex sua sponte* in a case where no party had raised the issue." Opp. 10. It simply means that ThermoLife chose to challenge the Federal Circuit's draconic forfeiture precedent in this Court, rather than unnecessarily seeking futile reconsideration of that precedent below. *See* Pet. 32.

The Director also claims that denial should "follow[] *a fortiori* here" because this Court denied the *Arthrex I* Petition, which likewise challenged *Customedia*. Opp. 11. But ThermoLife's petition is different. The *Arthrex I* Petition exclusively requested that the Court overrule *Customedia* to create a bright-line rule that the Federal Circuit had to extend *Arthrex* to all pending cases. *See Arthrex I* Pet. 32-33. ThermoLife's petition, however, also independently requests that this Court exercise its discretion directly to cure the Appointments Clause violation in this case without creating any such bright-line rule (which the Director agrees the Court can do). Pet. 35 ("This Court should correct [*Customedia*] or reach the Appointments Clause issue

*directly in its discretion.*” (emphasis added)); Opp. 10 (agreeing that this Court can address even ostensibly forfeited Appointments Clause challenges in its “discretion” (citation omitted)). Avoiding the *Customedia* issue altogether in that discretionary manner would allow the Appointments Clause violation to be cured in this case without any additional proceedings if the Court affirms the unconstitutionality of administrative patent judges’ appointments in the *Arthrex* Proceedings.

The Director curtly implies that such discretion is unwarranted because it should be reserved for “rare cases.” Opp. 10 (citing *Freytag v. Commissioner*, 501 U.S. 868, 879 (1991)). But the Director does not explain why this is not such a case. *Id.* It clearly is. As the petition discussed, the standards this Court has traditionally applied to determine such “rar[ity]” are all found here. Pet. 35. Namely, the Appointments Clause challenge is meritorious and important and has already been decided by the Federal Circuit. *See id.* And the Appointments Clause violation also goes to the heart of the proceeding at issue. *See id.* Indeed, the Board’s clear error in failing to consider the Dispositive Facts is the type of harm that the Appointments Clause was designed to prevent through proper oversight or appointment. Pet. 30-31, 35.

This Court should exercise its discretion to directly remedy the Appointments Clause violation here. At minimum, the petition should be held for disposition after conclusion of the *Arthrex* Proceedings.

**CONCLUSION**

The petition for a writ of certiorari should be granted. In the alternative, it should be held pending disposition of the *Arthrex* Proceedings and then decided accordingly.

Respectfully submitted,

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