NO. 19-1445

In the
Supreme Court of the United States

HI-TECH PHARMACEUTICALS, INC., corporation; JARED WHEAT, individually and as officer of the corporation; STEPHEN SMITH, individually and as officer of National Urological Group, Inc., and National Institute for Clinical Weight Loss, Inc.; NATIONAL UROLOGICAL GROUP, INC., d.b.a. Warner Laboratories, et al.; THOMASZ HOLDA, individually and as officer of the corporations, et al.,

Petitioners,

v.

FEDERAL TRADE COMMISSION; CERTUSBANK, N.A.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF FOR PETITIONERS

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October 9, 2020

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REPLY BRIEF

The FTC concedes that the injunction here didn't include the standard the court later incorporated in imposing $40-million contempt sanctions. It concedes that Federal Rule of Civil Procedure 65(d) requires an injunction to "state its terms specifically" and "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained." And it concedes that injunctions must be specific to support contempt sanctions. Those concessions answer the question presented: Contempt sanctions cannot stand when the underlying injunction didn't contain the standard supposedly violated. The government thus poses a different question—whether Petitioners had extratextual notice of what the district court would ultimately require—to argue no harm, no foul. Moreover, it contends, the issue is waived, the splits in caselaw best ignored, and the dispute too factbound for review. None of that is true.

The first contention fails because both the purported waiver and the lack of specificity stem from the same original sin: The fact that the injunction didn't include the standard the government later sought to enforce. The responsibility for that falls at the government's feet—it sought the injunction and subsequent sanctions. Nevertheless, it would flip the burden of proof to petitioners, forcing them to predict evolving positions. Second, left unaddressed, those splits over waiver and specificity encourage agency overreach. Third, these issues are legal, not factual, because the government concedes that the standard the court applied isn't in the injunction.

The government would excuse this failure by contending Petitioners had notice that cost-prohibitive, product-specific, randomized clinical trials ("RCTs") were required to substantiate its product claims. They didn't, but regardless, Rule 65(d)—which is "no mere extract from a manual of procedural practice," but "a page from the book of liberty," *H.K. Porter Co. v. Nat'l Friction Prods.*, 568 F.2d 24, 27 (7th Cir. 1977) (as amended)—contains no exception for enjoined parties' subjective understanding of what standards might later be read into an injunction. And yet the government's approach uses the policies behind that rule to eviscerate its plain language. Before the trial court's decision and the Eleventh Circuit's affirmance, no court had allowed the FTC to import new standards into its injunctions to support sanctions. No court, this one included, should.

A. Background

Three factual points in the Brief in Opposition require correction. First, the FTC's position changed over time (though the injunction didn't). Second, neither the initial enforcement order nor subsequent discussions with counsel[1] put Petitioners on notice that the FTC would reinterpret the injunction to reflect that change—and seek contempt sanctions based on it. Third, Petitioners could raise specificity on contempt—as they did consistently—without challenging the injunction's validity when it was first

[1] The government alleges "voluminous evidence" of notice, but relies on only these two items. BIO 8. Regardless, these lie outside the injunction and cannot supply the lacking specificity.

entered because the party seeking sanctions must *always* show specificity.

1. As the government concedes, the injunction required only "competent and reliable scientific evidence." Doc. 945 at 57:21-24. But the government doesn't acknowledge that the FTC's own experts disagreed among themselves about what that standard required. Doc. 945 at 55:6-56:24, 74; Doc. 946 at 34:17-39:12, 121:10-122:3; Doc. 952 at 155:6-157:8, 158:1-4. BIO 2. The government's ultimate position, adopted and upheld below, was that those claims must be supported by:

> independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate end points are collected over an appropriate period of time … conducted on the product itself.

App. 49-50, 223. This new standard—the same applied to prescription drugs—wasn't in the injunction. Importing it, as the court did, conflicts with DSHEA, FTC guidance, and other courts' decisions. Pet. 7-8, 9, 14-15, 20-21 & n.4.

The government's suggestion that this new standard wasn't a change in position is wrong. It was, both here where the court allowed it, and in other cases where courts have not. Pet. 8, 22-23 (discussing cases).

2. a. The government tries to justify rewriting the injunction based on the district court's decision in the initial enforcement action. That action concerned

different claims about different supplements,[2] for which, the court held, Hi-Tech needed "well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials [RCTs] … on the product itself." App. 316. But it *didn't* apply that standard in the injunction. Rather, it held that "[d]ifferent scientific evidence is required for different claims impacting different products," "different claims require different substantiation," and *future* efficacy claims, including about other products, should be substantiated by "competent and reliable scientific evidence." App. 279-80.

b. The government also excuses the injunction's failure to specify that only product-specific RCTs would suffice because some of Wheat's lawyers warned him that the government and court might try (incorrectly) to interpret the injunction accordingly (with respect to different claims). BIO 5-6. They did, as the record shows. But Hi-Tech, believing its subsequent claims adequately substantiated under the competent-and-reliable-scientific-evidence standard actually in the injunction, wasn't required to predict the FTC's overreach or risk relieving the government of its burden to prove specificity. *E.g.*, Doc. 332-3 at 84, 86; Doc. 476-4 at 27, 34.

3. a. Once the FTC sought sanctions, Hi-Tech argued that the injunction, which never mentioned RCTs (let alone required them) violated Rule 65(d) and was insufficiently specific to support sanctions. Doc. 346 at 14-21; Doc. 396 at 2-15. The district court

[2] Both the initial action and the contempt proceedings involved the name Lipodrene, but those products differed. App. 5.

nonetheless adopted the FTC's new rule—established through expert opinion, not the injunction itself or positive law. On appeal, the Eleventh Circuit did not reach Hi-Tech's Rule 65(d) argument because it was raised too early and was "premature"—the opposite of waiver.[3] App. 38. On remand, Petitioners repeatedly objected that the injunction didn't contain the FTC's new standard. Doc. 876-1 at 3-8; Doc. 883 at 8-12; Doc. 959 at 4-8; Doc. 963 at 1-17; Doc. 965 at 10-19, 31-37 & n.14. Neither court below held otherwise; rather, they excused the failure based on notice and waiver, respectively.

B. This Court should grant certiorari

1. a. There was no waiver. Like the Eleventh Circuit, the government relies entirely on a single seventy-one-year-old decision, *McComb v. Jacksonville Paper Co.*, 336 U.S. 187 (1949), to wrongly argue waiver. This misreads *McComb*, contradicts this Court's subsequent case law, and places a burden on enjoined parties that, in many cases (including this one), no party can meet. The respondent in *McComb* was enjoined from violating the Fair Labor Standards Act's minimum-wage, overtime, and recordkeeping provisions, but the injunction didn't "compute the weekly and monthly amount ... due each employee." *Id.* at 194. It couldn't, because the court had no idea how many non-overtime and overtime hours employees would work. Because FLSA "provide[d] the formula by which the amounts

[3] The Eleventh Circuit's position leaves Petitioners in a Catch-22, where the first appellate court to consider kill-the-company contempt sanctions concluded it was *too early* to rule on specificity, and the second that it was *too late*.

can be simply computed"—down to the hour and cent—there was no doubt about what the injunction required. *Id.* Here, by contrast, the injunction could've required RCTs, but instead incorporated a standard that, per the FTC's own guidance, had "no fixed formula for the number or type of studies required[.]" Doc. 876-4 at 14.

The government's reading of *McComb* makes Rule 65(d) meaningless and *McComb* impossible to reconcile with *International Longshoremen's Association v. Philadelphia Marine Trade Association*, 389 U.S. 64 (1967), *Schmidt v. Lessard*, 414 U.S. 473 (1974) (per curiam), and *Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto Truck Drivers*, 415 U.S. 423 (1974). Perhaps recognizing this, the government tries vainly to distinguish them. True, in *International Longshoremen's*, 389 U.S. at 70-71, and *Schmidt*, 414 U.S. at 476 n.1, the parties *did* seek judicial clarification; but Petitioners here had no reason to think the government would later assert that "competent and reliable scientific evidence" meant RCTs and only RCTs. Second, this Court in *Granny Goose*, 415 U.S. at 444, *did* interpret the temporary restraining order on its way to vacatur, holding that the order didn't give "notice of what the injunction actually prohibits."

McComb didn't hold that an enjoined party must predict the future and object immediately to any ambiguity, even unforeseeable ones. *Cf. Barry v. Coombe*, 26 U.S. 640, 652 (1828) (distinguishing patent and latent ambiguity). Nor could Hi-Tech have known that the government would interpret the

standard that *was* in the injunction contrary to its own guidance.

b. Multiple splits in authority warrant review. As an initial matter, this Court shouldn't deny certiorari because the opinion is unpublished. This Court regularly reviews unpublished opinions,[4] and the FTC can still cite those decisions as persuasive authority to defend an approach that other courts have rejected.

This case also directly implicates a broader circuit split. Other circuits have consistently held that contempt cannot stand where an injunction doesn't clearly encompass the challenged conduct. *E.g.*, *Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir. 1971). Thus, defendants can challenge an injunction's specificity in contempt proceedings. *E.g.*, *Russell C. House Transfer & Storage Co. v. United States*, 189 F.2d 349, 351 (5th Cir. 1951).

The government attempts to distinguish every case Hi-Tech cites, claiming they say nothing about waiver. Of course they don't, and that's exactly the point: Waiver doesn't apply. The FTC had the burden of showing by clear and convincing evidence that the injunction was specific and unambiguous. App. 11. By finding waiver, the Eleventh Circuit improperly eliminated that obligation. This error stems from the fact that the government, like the Eleventh Circuit,

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[4] At least four such cases are currently set for argument: *Torres v. Madrid*, 769 F. App'x 654 (10th Cir.), *cert. granted*, 140 S. Ct. 680 (2019); *Salinas v. U.S. R.R. Ret. Bd.*, 765 F. App'x 79 (5th Cir. 2019), *cert. granted*, 140 S. Ct. 813 (2020); *United States v. Borden*, 769 F. App'x 266 (6th Cir. 2019), *cert. granted in part*, 140 S. Ct. 1262 (2020); *Niz-Chavez v. Barr*, 789 F. App'x 523 (6th Cir. 2019), *cert. granted*, 207 L. Ed. 2d 169 (2020).

confuses the injunction's *validity*—which must be raised when the injunction is issued—with *specificity*, which must be proved in contempt proceedings. *E.g.*, *Polo Fashions v. Stock Buyers Int'l*, 760 F.2d 698, 700 (6th Cir. 1985) (while "the validity of the injunction is not an issue in … contempt [proceedings]," specificity is).

The government also suggests that Circuit splits exist only when cases conflict in every possible application. BIO 12 ("[T]he court of appeals did not hold that defendants can *never* challenge the specificity of an injunction in contempt proceedings."); BIO 13 ("[N]one of those decisions held that the doctrine of waiver is categorically inapplicable in contempt proceedings."). That's both wrong and irrelevant: The injunction entered against Hi-Tech is impermissibly ambiguous, and in any Circuit other than the Eleventh and Federal Circuits, Hi-Tech could have litigated that challenge on the merits.

2. The Circuits disagree whether a district court's deciding a previously waived issue confers the right to appeal the issue under 28 U.S.C. § 1291. The government tacitly concedes the split's existence but discounts its importance. BIO 15-16. But it's not merely "the circuit courts' procedural rules" at stake, BIO 16 (cleaned up), and nothing the government cites suggests that litigants' rights should be overlooked merely because a "procedural" rule does the damage.

The government also claims this Court should ignore this issue because of waiver. BIO 13-16. But waiver isn't a serious obstacle here because the district court didn't find waiver. It spent 40 pages finding the injunction sufficiently specific without

once mentioning "waiver" or "forfeiture." App. 69-104, 117, 150 n.29. It understood Petitioners' failure to object to the injunction's non-specificity about RCTs when it was entered not as waiver, but as evidence that Petitioners knew what was required, whether or not it appeared in the injunction. App. 73-74, 85-86, 97-99. And it didn't find "the absence of a timely appellate challenge dispositive." App. 86. The government doesn't even argue that the Eleventh Circuit's holding otherwise was *right*, just that it was *reasonable*. BIO 14. It was neither.

Throughout the contempt proceedings, Petitioners *did* press specificity. The Eleventh Circuit and the government contend that not anticipating this issue and contesting the injunction's specificity *when it was first entered* relieved the government of its burden of proving specificity in subsequent contempt proceedings. No case supports such a conclusion. In fact, courts expressly consider Rule 65(d) specificity arguments in contempt proceedings. *See, e.g.*, *Gates v. Shinn*, 98 F.3d 463, 471-72 (9th Cir. 1996) (vacating contempt because consent decree was not "specific in terms" as Rule 65(d) requires). And of course, the party seeking sanctions bears the burden of proof. *Rosenstiel v. Rosenstiel*, 278 F. Supp. 794, 803 (S.D.N.Y. 1967).

Far from presenting a factbound barrier to review, the Eleventh Circuit's ruling begs for review. It's Kafkaesque—an unpublished affirmance of a $40-million contempt sanction imposed based on a standard not in the injunction, and affirmed based on an alternative ground the district court never mentioned. *Cf. Plumley v. Austin,* 135 S. Ct. 828, 831

(2015) (Thomas, J. & Scalia, J., dissenting from denial of certiorari).

Nor is this some intra-circuit squabble, as the government supposes, just because *Hi-Tech Pharmaceuticals, Inc. v. HBS International Corp.*, 910 F.3d 1186, 1194 (11th Cir. 2018), is to the contrary. BIO 16. The Circuits disagree both internally and with each other, and that calls for review. Certiorari is warranted to resolve the split and to clarify that an issue not pressed but unreservedly passed on by a district court is appealable of right under 28 U.S.C. § 1291.[5]

3. On the merits, the government contends that notice based on matters outside the injunction can substitute for the specificity Rule 65(d) requires. That impermissibly elevates the policies behind Rule 65(d) over its plain text.

The government argues that Rule 65(d) is satisfied because the words "competent and reliable scientific evidence," App. 244, appear in the injunction, and that they should be read to require RCTs based on the district court's summary judgment ruling. But that order imposed one standard for the claims before it, and the injunction another going forward. That deliberate choice of two different standards cannot be squared with the government's argument that they are in fact the same; and in any

[5] The government calls "inapposite" the analogy to granting certiorari where state courts passed on issues not pressed. BIO 14; Pet. 29. Of course those cases are not controlling—no one has suggested otherwise—but they explain how an unraised issue can (and should) be reviewed where the court has nonetheless weighed in.

event, Rule 65(d) says "other documents" cannot supply missing specificity. Any other result creates an extratextual exception that swallows the rule.

As the government acknowledges, the injunction defined "[c]ompetent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." App. 234. Hi-Tech hired experts in clinical research, nutrition, exercise physiology, weight-loss medicine, and pharmacology, and submitted over 100 publications, including peer-reviewed studies analyzing each product's active ingredients, as well as double-blind, placebo-controlled RCTs for materially identical products. Doc. 368 at 19-25.

The government argues that "the level of specificity that petitioners appear to demand is not practical for many injunctions." BIO 19. But even if practicality could trump due process, Rule 65(d), and contempt requirements, the injunction here could've easily required RCTs, as the FTC has elsewhere. Pet. 30-33 (collecting cases). It didn't. *Cf. Mohamad v. Palestinian Auth.*, 566 U.S. 449, 456 (2012) (applying basic interpretive principle that different words mean different things). As every other court to consider the issue held, that choice precludes the FTC from seeking sanctions for violating standards never incorporated in the underlying injunction. Pet. 22-23.

The government's fall-back argument, that subjective knowledge provides the otherwise-lacking

textual specificity, also fails. Like the Eleventh Circuit, the government points to no case upholding sanctions where the underlying injunction was insufficiently specific. That's because only the Eleventh Circuit has held that courts can look to the enjoined parties' subjective understanding to cure specificity that's lacking. This Court should grant certiorari to resolve that split.

b. The government asserts that "[t]he district court did not clearly err when it found that petitioners lacked competent and reliable scientific evidence." BIO 21. That's false, but the district court's legal error—looking beyond the injunction to supply the specificity it lacked—calls out for further review.

4. Finally, the government asserts that *Liu v. SEC's* limitation, 140 S. Ct. 1936 (2020), "does not apply to civil contempt proceedings." BIO 22. Citing *McComb*, it argues that courts can order "full remedial relief" on contempt. 336 U.S. at 193. The question isn't what remedy the court can order, but what remedy the FTC is statutorily empowered to seek. Agencies "literally [have] no power to act ... unless and until Congress confers power upon [them]." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). The government gives no reason why the FTC can seek greater damages in a contempt proceeding than in enforcement actions concerning the same conduct.[6]

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[6] This Court recently granted certiorari in *FTC v. Credit Bureau Center, LLC*, 937 F.3d 764 (7th Cir. 2019), and *AMG Capital Management, LLC*, 910 F.3d 417 (9th Cir. 2018), to address limits on the FTC's equitable authority in enforcement actions (S. Ct. Case Nos. 19-825 and 19-508). All these cases

CONCLUSION

Contempt proceedings shouldn't be a game of three-card monte where agencies can belatedly choose the cards that serve them best. This Court should grant certiorari.

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involve administrative overreach—there in enforcement actions and here in contempt proceedings. This Court ought not hand the FTC a "permission slip for the arrogation of power" in either context. *Decker v. Nw. Envt'l Def. Ctr.*, 568 U.S. 597, 620 (2013) (Scalia, J., concurring in part and dissenting in part).

Respectfully submitted,

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