

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 14-13131

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D.C. Docket No. 1:04-cv-03294-CAP

FEDERAL TRADE COMMISSION,

Plaintiff-Appellee,

CERTUSBANK, N.A.,

Plaintiff,

versus

NATIONAL UROLOGICAL GROUP, INC., et al.,  
d.b.a. Warner Laboratories,

Defendants,

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.,  
M.D. TERRILL MARK WRIGHT,  
Individually,

Defendants-Appellants.

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Appeals from the United States District Court  
for the Northern District of Georgia

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(May 5, 2015)

Before TJOFLAT, WILLIAM PRYOR, and BARKSDALE,\* Circuit Judges.

WILLIAM PRYOR, Circuit Judge:

In this appeal, we must decide whether the district court abused its discretion when it held Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, and Dr. Terrill Mark Wright in contempt for violating injunctions that prohibit them from making any representation about weight-loss products unless they “possess[] and rel[y] upon competent and reliable scientific evidence that substantiates the representation.” Hi-Tech, Wheat, Smith, and Wright submitted evidence to support the challenged representations and an expert declaration that the representations were substantiated by “competent and reliable scientific evidence.” But the district court refused to consider the evidence. The district court ruled that because it had required Hi-Tech, Wheat, Smith, and Wright to produce clinical trials to substantiate different representations about different weight-loss products in an

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\* Honorable Rhesa H. Barksdale, United States Circuit Judge for the Fifth Circuit, sitting by designation.

earlier stage of this litigation, they were collaterally estopped from presenting new kinds of evidence to satisfy the standard of “competent and reliable scientific evidence” and instead had to produce clinical trials to substantiate the challenged representations. After Hi-Tech, Wheat, Smith, and Wright failed to produce clinical trials to substantiate their representations, the district court held them in contempt. Because the district court misapplied the doctrine of collateral estoppel, we vacate and remand.

## **I. BACKGROUND**

We divide our discussion of the background in two parts. First, we discuss the initial litigation between the Federal Trade Commission and Hi-Tech, Wheat, Smith, and Wright. Second, we discuss the contempt proceedings that gave rise to this appeal.

### *A. Initial Litigation.*

In 2004, the Commission filed a complaint against Hi-Tech, Hi-Tech’s Chief Executive Officer, Wheat, Hi-Tech’s Senior Vice President, Smith, and Wright for violations of sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52. The Commission alleged that the defendants made unsubstantiated representations about two weight-loss products, “Thermalean” and “Lipodrene.” The Commission alleged that the defendants lacked adequate substantiation for

their representations that Thermalean “is an effective treatment for obesity,” “is equivalent or superior to the prescription weight loss drugs Xenical, Meridia, and Fastin in providing weight loss benefits,” “causes rapid and substantial weight loss, including as much as 30 pounds in 2 months,” and “causes users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, [and] decrease their stored fat by 300%,” and that Lipodrene “causes substantial weight loss, including as much as 125 pounds” and “enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%.”

In 2008, the district court granted summary judgment in favor of the Commission. The district court concluded that the defendants had violated the Trade Commission Act because they had not substantiated their representations with clinical trials of the weight-loss products instead of ingredients in the products. The district court entered a final judgment and permanent injunction against Hi-Tech, Wheat, and Smith, and a separate final judgment and permanent injunction against Wright based on his unsubstantiated endorsements of the products.

The injunctions prohibited the defendants from making any representation that a weight-loss product “causes rapid or substantial loss of weight or fat” or

“affects human metabolism, appetite, or body fat,” unless the defendants “possess[] and rel[y] upon competent and reliable scientific evidence that substantiates the representation.” The injunctions defined “competent and reliable scientific evidence” to mean “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.” The injunctions did not mention any requirement to produce clinical trials to substantiate weight-loss representations.

*B. Contempt Proceedings.*

After Hi-Tech, Wheat, Smith, and Wright continued to promote weight-loss products, the Commission moved the district court in 2011 to order Hi-Tech, Wheat, and Smith to show cause why they should not be held in contempt for making unsubstantiated representations about four products, “Fastin,” “Stimerex-ES,” “Benedrine,” and a reformulated version of “Lipodrene.” The Commission alleged that Hi-Tech, Wheat, and Smith lacked adequate substantiation for the following representations:

The “World’s Most Advanced Weight Loss Aid Ever Developed!” . . .  
(Fastin print ad);

“[A] Truly Extraordinary Weight Loss Product . . . Fastin is unlike anything you have ever tried before and will help you lose weight.” . . . (Fastin print ad);

A “Revolutionary Diet Aid Taking the Market by Storm!” . . . (Fastin product page, [www.hitechpharma.com](http://www.hitechpharma.com));

“[A] pharmaceutical-grade dietary supplement indicated for weight loss in extremely overweight individuals.” . . . (Fastin product packaging); . . .

An “EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID . . . WEIGHT LOSS [IS] YOUR DESIRED RESULT.” . . . (Fastin product packaging) . . .

“[I]s a revolutionary weight loss formula scientifically engineered to help people lose weight and feel great!” . . . (Lipodrene print ad);

Is “the benchmark standard for the weight loss industry.” . . . (Lipodrene product page, [www.hitechpharma.com](http://www.hitechpharma.com));

“[I]s the Gold Standard in the weight loss industry for one simple Reason . . . It Works!” . . . ;

“[W]ill cause rapid . . . weight loss with usage.” . . . (Lipodrene product packaging); . . .

“The World’s Most Advanced Weight Loss Aid Ever Developed!” [Lipodrene product packaging] . . .

Is an “Extreme Fat Burner.” . . . (Fastin print ad);

Is a “Novel Fat Burner.” . . . [Fastin print ad];

“[I]s the Gold Standard by which all Fat Burners should be judged.” . . . [Fastin print ad];

Is a “Rapid Fat Burner.” . . . (Fastin product packaging); . . .

Is a “Rapid Fat Loss Catalyst.” . . . (Fastin product packaging) . . .

A “Novel Fat Burner that Helps Melt Away Pounds.” . . . (Lipodrene print ad);

“[A] Fat Assassin unlike any other ‘Fat Burner.’” . . . [Lipodrene print ad];

“[T]he best fat-burner [sic] in existence.” . . . [Lipodrene print ad];

“[T]he ‘Gold Standard’ by which all fat loss products are judged.” . . . (Print ad for multiple Hi-Tech products including Lipodrene);

“Hi-Tech’s Flagship Fat Loss Product with 25 mg Ephedra Extract – Annihilate Fat.” . . . (Lipodrene product page, www.hitechpharma.com) . . .

“[T]he right move to strip away fat.” . . . [Lipodrene product page];  
...

“The Strongest Fat Burner/Energizer Ever Produced.” . . . (Benzedrine print ad); . . .

“[T]he most potent Fat Burner/Energizer known to man.” [Benzedrine print ad] . . .

Has “Unmatched Anorectic Activity to Manage Caloric Intake.” . . . (Benzedrine product page, www.hitechpharma.com); . . .

Is “the first anorectic supplement ever produced.” . . . (Benzedrine product packaging) . . .

“[U]ndeniably the most powerful, fat loss . . . formula ever created.” . . . (Print ad for multiple Hi-Tech products including Stimerex-ES);

“[T]he Strongest Fat Burner/Energizer to ever hit the market!” . . . (Stimerex-ES print ad); . . .

“The Ultimate Fat Burner Ever Created.” . . . (Stimerex-ES product page, [www.hitechpharma.com](http://www.hitechpharma.com)) . . .

“Curbs the Appetite!” . . . [Fastin ad] . . .

“Increases the metabolic rate, promoting thermogenesis (The Burning of Stored Body Fat).” . . . [Fastin ad]; . . .

“[H]as both immediate and delayed release profiles for appetite suppression, energy and weight loss.” [Fastin ad] . . .

Has “Unmatched Anorectic Activity to Manage Caloric Intake.” . . . (Benzedrine product page, [www.hitechpharma.com](http://www.hitechpharma.com)); and

Is “the first anorectic supplement ever produced.” . . . (Benzedrine product packaging).

The Commission also moved to hold Wright in contempt for his endorsement of Fastin.

In response, the defendants submitted evidence to support their representations and an expert’s declaration that the representations were substantiated by “competent and reliable scientific evidence,” but the district court refused to consider the defendants’ evidence. The district court explained, based on the “law of the case,” that “[t]he only evidence that will be relevant to show whether the defendants ‘possess[ed] and rel[ied] upon competent and reliable scientific evidence’ to substantiate any representation is the kind of evidence . . . previously adopted by the court.” In an earlier stage of the litigation, the district



court ruled that “some form of clinical trial must have been conducted on the product itself or an exact duplicate of the product to substantiate the defendants’ claims regarding the overall product.” Because the defendants had not produced clinical trials on the four products at issue in the contempt proceedings, the district court granted the motion to show cause. The district court later clarified that it based its ruling that only clinical trials could establish “competent and reliable scientific evidence” on the doctrine of collateral estoppel, instead of the “law of the case.”

After Hi-Tech, Wheat, Smith, and Wright failed to produce clinical trials on the weight-loss products, the district court held them in contempt for violating the injunctions. The district court held Hi-Tech, Wheat, and Smith jointly and severally liable for approximately \$40 million in sanctions, which equaled Hi-Tech’s gross receipts for the four products during the relevant time period. The district court also held Wright liable for \$120,000, which reflected the sum Hi-Tech paid him for endorsing Fastin during the relevant time period.

## **II. STANDARD OF REVIEW**

We review a sanction for civil contempt for abuse of discretion. *McGregor v. Chierico*, 206 F.3d 1378, 1383 (11th Cir. 2000). “A district court abuses its discretion if it applies an incorrect legal standard, applies the law in an

unreasonable or incorrect manner, follows improper procedures in making a determination, or makes findings of fact that are clearly erroneous.” *Citizens for Police Accountability Political Comm. v. Browning*, 572 F.3d 1213, 1216–17 (11th Cir. 2009).

### III. DISCUSSION

The district court abused its discretion when it held the defendants in contempt. The district court misapplied the doctrine of collateral estoppel when it refused to consider the defendants’ evidence of substantiation. Collateral estoppel “bars successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment, even if the issue recurs in the context of a different claim.” *Taylor v. Sturgell*, 553 U.S. 880, 892, 128 S. Ct. 2161, 2171 (2008) (internal quotation marks and citation omitted). We apply collateral estoppel only when four criteria are satisfied:

(1) the issue at stake is identical to the one involved in the prior litigation; (2) the issue was actually litigated in the prior suit; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding.

*Miller’s Ale House, Inc. v. Boynton Carolina Ale House, LLC*, 702 F.3d 1312, 1318 (11th Cir. 2012). To establish that an issue is not identical to one resolved in previous litigation, a party “need only point to one material differentiating fact that

would alter the legal inquiry,” *CSX Transp., Inc. v. Bhd. of Maint. of Way Emps.*, 327 F.3d 1309, 1317 (11th Cir. 2003). The defendants can easily do so because the level of substantiation the injunctions require for the representations at issue in the contempt proceedings is not “identical” to any issue the district court decided in the earlier litigation.

The issue decided in the earlier litigation involved different representations, different products, and the interpretation of a different legal standard from the issue the district court prevented Hi-Tech, Wheat, Smith, and Wright from litigating in the contempt proceedings. The district court previously ruled that Hi-Tech, Wheat, Smith, and Wright needed to produce clinical trials that substantiated their representations about Thermalean and an older version of Lipodrene under the Trade Commission Act. In the contempt proceedings, by contrast, the district court held that Hi-Tech, Wheat, Smith, and Wright were collaterally estopped from litigating the level of substantiation the injunctions require for different representations about Fastin, Stimerex-ES, Benzedrine, and the reformulated Lipodrene.

The differences between the issue decided in the previous litigation and the issue the defendants were prevented from litigating in the contempt proceedings “point to” at least “one material differentiating fact that would alter the legal

inquiry,” *id.* at 1317. The district court explained in the previous litigation that the “competent and reliable scientific evidence” standard imposed by the injunctions is “context specific” and “permits different variations . . . depending on what pertinent professionals would require for the particular claim made.” The district court further explained that “the size, duration or protocol of a scientific study, the number or type of scientific studies required to substantiate a claim, and the proper mechanism for extrapolating results from studies will obviously vary from circumstance to circumstance depending upon the expert evidence presented.” That the representations at issue in the previous litigation involved different products, referenced other weight-loss products by name, and were far more specific than those at issue in the contempt proceedings accordingly “alter[s] the legal inquiry,” *id.* The issue decided in the previous litigation is not “identical,” *Miller’s Ale House, Inc.*, 702 F.3d at 1318, to the issue the district court prevented the defendants from litigating in the contempt proceedings. The district court erred when it applied the doctrine of collateral estoppel.

Hi-Tech, Wheat, Smith, and Wright also argue that the district court erred by adopting a stricter standard for substantiation than the injunctions require and by relying on evidence of privileged communications, but those questions are premature. On remand, the district court must exercise its discretion to determine

the admissibility of any evidence offered by the Commission and by the contempt defendants and make findings about whether any evidence of substantiation, if admissible, satisfies the standard of the injunctions for “competent and reliable scientific evidence.” We hold only that the district court misapplied collateral estoppel when it barred Hi-Tech, Wheat, Smith, and Wright from presenting evidence to prove their compliance with the injunctions.

#### **IV. CONCLUSION**

We **VACATE** the order holding Hi-Tech, Wheat, Smith, and Wright in contempt and **REMAND** for further proceedings consistent with this opinion.

**UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT**

ELBERT PARR TUTTLE COURT OF APPEALS BUILDING  
56 Forsyth Street, N.W.  
Atlanta, Georgia 30303

Douglas J. Mincher  
Clerk of Court

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May 05, 2015

MEMORANDUM TO COUNSEL OR PARTIES

Appeal Number: 14-13131-FF  
Case Style: Federal Trade Commission v. Hi-Tech Pharmaceuticals, Inc., et al  
District Court Docket No: 1:04-cv-03294-CAP

**This Court requires all counsel to file documents electronically using the Electronic Case Files ("ECF") system, unless exempted for good cause.** Enclosed is a copy of the court's decision filed today in this appeal. Judgment has this day been entered pursuant to FRAP 36. The court's mandate will issue at a later date in accordance with FRAP 41(b).

The time for filing a petition for rehearing is governed by 11th Cir. R. 40-3, and the time for filing a petition for rehearing en banc is governed by 11th Cir. R. 35-2. Except as otherwise provided by FRAP 25(a) for inmate filings, a petition for rehearing or for rehearing en banc is timely only if received in the clerk's office within the time specified in the rules. Costs are governed by FRAP 39 and 11th Cir.R. 39-1. The timing, format, and content of a motion for attorney's fees and an objection thereto is governed by 11th Cir. R. 39-2 and 39-3.

Please note that a petition for rehearing en banc must include in the Certificate of Interested Persons a complete list of all persons and entities listed on all certificates previously filed by any party in the appeal. See 11th Cir. R. 26.1-1. In addition, a copy of the opinion sought to be reheard must be included in any petition for rehearing or petition for rehearing en banc. See 11th Cir. R. 35-5(k) and 40-1 .

Counsel appointed under the CRIMINAL JUSTICE ACT must file a CJA voucher claiming compensation for time spent on the appeal no later than 60 days after either issuance of mandate or filing with the U.S. Supreme Court of a petition for a writ of certiorari (whichever is later).

Pursuant to Fed.R.App.P. 39, costs taxed against appellee.

The Bill of Costs form is available on the internet at [www.ca11.uscourts.gov](http://www.ca11.uscourts.gov)

For questions concerning the issuance of the decision of this court, please call the number referenced in the signature block below. For all other questions, please call Janet K. Mohler, FF at (404) 335-6178.

Sincerely,

DOUGLAS J. MINCHER, Clerk of Court

Reply to: Jeff R. Patch  
Phone #: 404-335-6161

OPIN-1A Issuance of Opinion With Costs