PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 07-4352

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UNITED STATES OF AMERICA

v.

5 UNLABELED BOXES, more or less, of an article of food,
each box containing various quantities of 100 tablet bottles,
labeled in part: "Lipodrene Dietary Supplement 100ct.
25 mg ephedrine group alkaloids Manufactured for:
Hi-Tech Pharmaceuticals, Inc. Norcoss, GA
05121004EXP09/08"

v.

HI-TECH PHARMACEUTICALS, INC.,
Third Party Plaintiff

v.

(continued)

ANDREW C. VON ESCHENBACH, M.D.,
Commissioner of the U.S. Food and Drug Admimistration;
FOOD AND DRUG ADMINISTRATION;
MICHAEL O. LEAVITT, Secretary of the Department
of Health and Human Services;
DEPARTMENT OF HEALTH & HUMAN SERVICES,
Third Party Defendants

Hi-Tech Pharmaceuticals, Inc.,
Appellant

Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civil No. 06-cv-0027)
District Judge: The Honorable Nora Barry Fischer

Argued: October 23, 2008

Before: RENDELL, SMITH, Circuit Judges,
and POLLAK,* District Judge

(Filed: July 14, 2009)

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*The Honorable Louis H. Pollak, Senior District Judge of the United States District Court for the Eastern District of Pennsylvania, sitting by designation.

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(continued)

Andrew C. Von Eschenbach, M.D.,
Commissioner of the U.S. Food and Drug Administration;
Food and Drug Administration;
Michael O. Leavitt,
Secretary of the Department of
Health and Human Services;
Department of Health & Human Services.

OPINION OF THE COURT

POLLAK, District Judge.

This case concerns ephedrine alkaloids ("EDS"), substances that were marketed beginning in the early 1990s as dietary supplements to reduce weight and boost energy. In 2004, the Food and Drug Administration ("FDA") banned all supplements containing EDS after concluding that they present an "unreasonable risk of illness or injury" at all dose levels. Hi-Tech Pharmaceuticals, Inc., a maker of products containing EDS, challenges that determination.[1] As discussed below, we

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[1]This case was originally captioned with Andrew C. Von Eschenbach as Commissioner of the Food and Drug Administration and Michael O. Leavitt as Secretary of Health

conclude that Hi-Tech's challenge is precluded.

I.

A. Rulemaking Background

The Food, Drug, and Cosmetic Act ("FDCA") prohibits the "introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). In 1994, Congress amended the FDCA through the Dietary Supplement Health and Education Act, Pub. L. No. 103-417 (2000) ("DSHEA"), which sets guidelines for how FDA may regulate dietary supplements. FDA may declare that a dietary supplement is "adulterated" if it "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(a). The DSHEA also makes clear that the FDA bears the burden of proof in seeking to have a dietary supplement declared adulterated, as the section provides: "In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this

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and Human Services; the current Commissioner and Secretary are substituted for the former occupants of those positions pursuant to Federal Rule of Civil Procedure 25(d).

paragraph on a de novo basis." 21 U.S.C. § 342 (f).[2]

In 1995, FDA began examining EDS and in 1997 began to consider regulating dietary supplements containing EDS. 62 Fed. Reg. 30,678 (June 4, 1997). FDA sought comment on a proposed finding that a dietary supplement is adulterated if it contains 8 mg or more of EDS per serving, or if its labeling suggests usage resulting in a total daily intake of 24 mg or more of EDS. FDA received negative feedback on this proposal and in 2000 withdrew part of the proposed rule. 65 Fed. Reg. 17,474 (Apr. 3, 2000). Between 2000 and 2003, FDA released information on EDS and solicited other comments through notices to the public. In 2003, FDA published another notice, informing the public that FDA intended to consider whether EDS "present a 'significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.'" 68 Fed. Reg. 10,417 (Mar. 5, 2003).

FDA issued a final rule in 2004, declaring all EDS to be "adulterated" and therefore banned. FDA explained that it was acting based on "the well-known pharmacology of ephedrine

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[2]This scheme is in contrast with the burdens under the FDCA for drugs and devices, for which the manufacturer bears the burden of proving that the drug or device is safe before it may be marketed.

alkaloids, the peer-reviewed scientific literature on the effects of ephedrine alkaloids, and the adverse events reported to have occurred in individuals following consumption of dietary supplements containing ephedrine alkaloids." *Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*, 69 Fed. Reg. 6788-6854 (Feb. 11, 2004) (hereinafter "Final Rule").[3] The Final Rule represented the first time FDA banned an entire class of dietary supplements under the DSHEA.

FDA determined in the Final Rule that its burden to show unreasonable risk is met "when a product's risks outweigh its benefits in light of the claims and directions for use in the product's labeling, or if the labeling is silent, under ordinary conditions of use." FDA defined unreasonable risk to "represent[ ] a relative weighing of the product's known and reasonably likely risks against its known and reasonably likely benefits." In conducting this weighing, FDA evaluated the claimed benefits of EDS, including weight loss, enhanced

[3]The Rule is codified at 21 C.F.R. § 119.1 and provides: "Dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling, or if no conditions of use are recommended or suggested in the labeling, under ordinary conditions of use. Therefore, dietary supplements containing ephedrine alkaloids are adulterated under section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act."

athletic performance, and increased energy, against the known risks, including increased blood pressure and heart rate, and their consequences, such as increased risk of stroke and heart attack. FDA found that the "best clinical evidence for a benefit is for weight loss, but even there the evidence supports only a modest short-term weight loss, insufficient to positively affect cardiovascular risk factors associated with being overweight or obese." FDA concluded that the potential benefits of EDS did not outweigh the risks and therefore determined that EDS products were adulterated and must be banned.

B. The Two Litigation Proceedings

Hi-Tech filed a complaint challenging the Final Rule in the Northern District of Georgia on August 15, 2005.[4] Hi-Tech claimed that the Final Rule was issued in violation of the Administrative Procedures Act and that FDA failed to meet its burden to prove that supplements containing EDS present an

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[4]Hi-Tech stopped making EDS products once the Final Rule took effect. However, Hi-Tech resumed production after a district court in the District of Utah found problems with the rule and remanded it to FDA for further proceedings. *Neutraceutical Corp. v. Crawford*, 364 F. Supp. 2d 1310, 1321 (D. Utah 2005). That decision was later reversed by the Tenth Circuit, which upheld the Final Rule. *Neutraceutical v. Von Eschenbach*, 459 F. 3d 1033 (10th Cir. 2006), *cert. denied*, 127 S. Ct. 2295 (2007).

unreasonable risk. Hi-Tech's main claim was that FDA could not meet its burden of proving adulteration with a generally applicable rule for an entire class of substances, but was, instead, required to proceed on a product-by-product basis. On February 22, 2006, FDA sought forfeiture of EDS products, made by Hi-Tech, in the Northern District of Georgia. Hi-Tech, asserting an interest in the seized products, initiated its own action in the same court, and the two cases were consolidated.

In the meantime, FDA on January 9, 2006 initiated forfeiture proceedings in the District Court for the Western District of Pennsylvania against certain EDS products manufactured by Hi-Tech and located in that district. Hi-Tech filed a third-party complaint against FDA and challenged the Final Rule based on the same grounds it had asserted in its complaint in the Northern District of Georgia.

In both the Georgia and the Pennsylvania cases, Hi-Tech and the FDA filed cross-motions for summary judgment. The Georgia District Court granted summary judgment to the government on August 15, 2007. *Hi-Tech Pharms., Inc. v. Crawford*, 505 F. Supp. 2d 1341 (N.D. Ga. 2007). Hi-Tech filed a notice of appeal to the Eleventh Circuit on September 13, 2007. On October 15, 2007, the Pennsylvania District Court subsequently (and in part in relying on the Georgia decision) granted summary judgment to the government, upholding the Final Rule. That decision was appealed in the case at bar, in which Hi-Tech asks this court to invalidate the Final Rule.

However, before this court heard the appeal from the Western District of Pennsylvania, the Eleventh Circuit, on October 7, 2008, affirmed the decision of the Georgia District Court and upheld the Final Rule. *Hi-Tech Pharms., Inc. v. Crawford*, 544 F.3d 1187 (October 7, 2008). Argument was held in this case on October 23, 2008. Subsequent to argument in this case, Hi-Tech sought rehearing in the Eleventh Circuit, a request which was denied on January 5, 2009. Hi-Tech has not sought further review of the Eleventh Circuit's decision.

About a week after the Eleventh Circuit's decision and about a week before oral argument in this case, the government raised the possibility that review in this court was precluded by the Eleventh Circuit's decision. The parties presented argument on preclusion and, at the request of the panel, submitted supplemental briefing on the issue.

II.

FDA argues that, in view of the Eleventh Circuit's decision, res judicata or collateral estoppel should operate to bar Hi-Tech's arguments on this appeal.

Res judicata "requires a showing that there has been (1) a final judgment on the merits in a prior suit involving (2) the same claim and (3) the same parties or their privies." *EEOC v. United States Steel Corp.*, 921 F.2d 489, 493 (3d Cir. 1990). Collateral estoppel, on the other hand, requires of a previous

determination that "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citing *Henglein v. Colt Indus. Operating Corp.*, 260 F.3d 201, 209 (3d Cir. 2001)).

The parties use the terms "res judicata" and "collateral estoppel" nearly interchangeably, and neither side argues that using one or the other would meaningfully affect the analysis. Collateral estoppel customarily refers to issue preclusion, while res judicata, when used narrowly, refers to claim preclusion. This court has previously noted that "the preferred usage" of the term res judicata "encompasses both claim and issue preclusion." *Venuto v. Witco Corp.*, 117 F.3d 754, 758 n.5 (3d Cir. 1997).

A comparison of the parties and the issues makes the appropriateness of res judicata immediately apparent. The parties in the Eleventh Circuit are identical to the parties before this court. The claims are also identical. Hi-Tech contends that the claims are not the same because different EDS products were seized in Georgia than in Pennsylvania; therefore, Hi-Tech argues that because FDA must prove that each individual product is adulterated, the products seized in the Georgia action cannot be classified as the same as those seized in the Pennsylvania action. However, this argument is, in effect,

simply a reiteration of Hi-Tech's claims on the merits of this appeal. The argument, undertaking to counter the FDA's determination that the FDA could, via rulemaking, declare adulterated and ban an entire class of substances, is the exact argument the Eleventh Circuit rejected. Hi-Tech's brief to the Eleventh Circuit posed questions identical to those presented in Hi-Tech's brief to this court.[5] The Eleventh Circuit reached a

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[5]These identical questions are:

I. Whether the District Court erred in an enforcement proceeding brought by the Food and Drug Administration ("FDA") by deferring to the FDA's judgment rather than conducting a de novo review of the alleged adulteration of dietary supplement products manufactured by Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") as required by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), 21 U.S.C. § 342(f)?

II. Whether the District Court erred in holding that the FDA met its burden of proof under 21 U.S.C. § 342(f) to establish that dietary supplement products manufactured by Hi-Tech were adulterated under the conditions of use recommended by Hi-Tech where the FDA relied solely upon its own determination that all dietary supplements containing ephedrine alkaloids ("EDS") were adulterated regardless of dosage as set forth in the FDA's final rule declaring dietary supplements containing ephedrine alkaloids adulterated?

III. Whether the District Court erred in holding that the FDA final rule was such a logical outgrowth of the previous attempts to regulate EDS through various warning labels and dosage restrictions to provide the dietary supplement industry with sufficient notice under the Administrative Procedures Act that the FDA intended to ban an entire class of dietary supplements?

IV. Whether the District Court erred in holding that the FDA's final rule complied with the unambiguous congressional

judgment on the merits of these issues, concluding that the FDA is empowered to declare, through rulemaking, a class of substances adulterated and the "de novo review" requirement of the statute does not require the government to present additional proof of adulteration where there exists a validly-promulgated rule applicable to the product that is the subject of the enforcement action in question[6] This judgment on the merits in a case involving issues and parties identical to those in the case before this court meets the requirements for res judicata.

Hi-Tech argues, however, that the government has waived the res judicata defense by not asserting it until this "late hour." Hi-Tech correctly observes that FDA did not raise this issue as an affirmative defense in its answers in either the Pennsylvania or the Georgia litigation. But this is beside the point. Res judicata could not have been pleaded at those times, because, at the time the answers were filed, no final judgment had been rendered in either case. FDA did not argue that the Georgia action should have a preclusive effect on the Pennsylvania action until the Eleventh Circuit had affirmed the Georgia District Court's decision. But it should be noted that,

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mandate in DSHEA to treat dietary supplements as presumptively safe when the FDA employed a previously undisclosed and unauthorized analysis expressly reserved for drugs and medical devices but not dietary supplements which weighed any risks of EDS versus the known benefits of such supplements in order to declare EDS presented an unreasonable risk of illness or injury pursuant to 21 U.S.C. § 342(f)?

[6]The Eleventh Circuit also rejected as meritless for the reasons expressed by the District Court for the Northern District of Georgia Hi-Tech's remaining challenges to the Final Rule.

while the Georgia case was making its way to the Eleventh Circuit, FDA apprised both the Pennsylvania District Court and this court of the Georgia case's status.

FDA could probably have asked this court to give preclusive effect to the decision in the Northern District of Georgia without waiting for the Eleventh Circuit's decision, as the pendency of an appeal does not affect the potential for res judicata flowing from an otherwise-valid judgment. However, where, as in the situation here, "two or more cases wend toward judgment at differing speeds," early application of res judicata, though technically permissible, can create later problems if a first judgment, relied on in a second proceeding, is reversed on appeal. 18A Charles Alan Wright, et al., *Federal Practice and Procedure* 2d § 4433 at 71 (2002). The Restatement (Second) of Judgments, noting that a final judgment will customarily be given preclusive effect even though an appeal is pending, suggests, if possible, postponing decision on the question of preclusion in a second action until the appeal of the first judgment has been concluded. *Restatement (Second) of Judgments*, § 13, cmt. f. Any concerns about whether the Eleventh Circuit's decision is "sufficiently firm," *id.*, have now been allayed: Hi-Tech's appeals as of right have been exhausted, its petition for rehearing has been denied, and the time for it to seek Supreme Court review via certiorari has now elapsed.

Putting aside the question of waiver, this court also has an interest in the consistent application, where appropriate, of preclusion doctrines. Out of concern for judicial economy and respect for the conclusions reached by other courts considering the same issues, courts "have traditionally attached additional

importance to the application of res judicata principles." *Bechtold v. City of Rosemount*, 104 F.3d 1062, 1068 (8th Cir. 1997). "[I]n special circumstances," a court may even raise the issue of preclusion *sua sponte*. *Arizona v. California*, 530 U.S. 392, 412 (2000); *see* 18A Charles Alan Wright, et al., *Federal Practice and Procedure* 2d § 4405 n.10. That is not necessary here, where FDA raised the issue in advance of oral argument and the parties have addressed preclusion both at argument and in supplemental submissions.

Hi-Tech argues that, even if res judicata technically applies, its use in this case would be inconsistent with the congressional directives embodied in the DSHEA to "prove adulteration of a dietary supplement on a product-by-product basis." This argument is without merit, as it is merely another redundant invocation of Hi-Tech's main challenge to the validity of the Final Rule. Hi-Tech also argues that application of res judicata on issues of statutory interpretation would improperly "squelch[] the circuit disagreements that can lead to Supreme Court review." However, this concern–if assumed to have some weight–would be relevant only where the "differing [statutory] interpretations are developed in different cases, not in the same dispute" and where there is not mutuality of parties. *Holland v. Nat'l Mining Ass'n*, 309 F.3d 808, 815 (D.C. Cir. 2002); *United States v. Mendoza*, 464 U.S. 154, 160 (1984). In this case, the same dispute, between the same parties, that was before the Eleventh Circuit is now before this court, and there is no reason to permit re-litigation of issues already resolved.[7]

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[7]The Eleventh Circuit was in fact not the first circuit to address the validity of the Final Rule; the Tenth Circuit upheld the rule in *Neutraceutical v. Von Eschenbach*, 459 F. 3d 1033

III.

Hi-Tech has had two full opportunities to litigate its challenge to the Final Rule banning EDS, first in the Northern District of Georgia and then in the Western District of Pennsylvania. The Eleventh Circuit has evaluated Hi-Tech's claims and determined them to be without merit, and we will give that decision preclusive effect. Hi-Tech's appeal founders on the shoals of res judicata. Therefore, we will AFFIRM the Order of the District Court.

(10th Cir. 2006), *cert. denied*, 127 S. Ct. 2295 (2007). Hi-Tech was not a party to that case, as it was brought by a different EDS manufacturer.