# United States Court of Appeals for the Federal Circuit

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**THERMOLIFE INTERNATIONAL LLC, BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,**
*Plaintiffs-Appellants*

**v.**

**GNC CORPORATION, GENERAL NUTRITION CENTERS, INC., GENERAL NUTRITION CORPORATION,**
*Defendants*

**HI-TECH PHARMACEUTICALS, INC., VITAL PHARMACEUTICALS, INC,**
*Defendants-Appellees*

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2018-1657, 2018-1666

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Appeals from the United States District Court for the Southern District of California in Nos. 3:13-cv-00651-JLS-MDD, 3:13-cv-00830-JLS-MDD, 3:13-cv-01015-JLS-MDD, Judge Janis L. Sammartino.

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Decided: May 1, 2019

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ROBERT J. GAJARSA, Latham & Watkins LLP, Washington, DC, argued for plaintiff-appellant ThermoLife International LLC. Also represented by GABRIEL BELL;

GREGORY BLAIN COLLINS, ERIC HULL, CARA MOLLY LOUISE ROGERS, Kercsmar & Feltus PLLC, Scottsdale, AZ.

WILLIAM P. ATKINS, Pillsbury Winthrop Shaw Pittman LLP, McLean, VA, argued for plaintiff-appellant Board of Trustees of the Leland Stanford Junior University. Also represented by BENJAMIN LEE KIERSZ.

ROBERT F. PARSLEY, Miller & Martin PLLC, Chattanooga, TN, argued for defendant-appellee Hi-Tech Pharmaceuticals, Inc. Also represented by DAVID M. BARNES.

FRANCIS DIGIOVANNI, Drinker Biddle & Reath LLP, Wilmington, DE, argued for defendant-appellee Vital Pharmaceuticals, Inc. Also represented by MICHAEL CURT LAMBERT, THATCHER RAHMEIER; MARC KESTEN, Vital Pharmaceuticals, Inc., Parkland, FL.

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Before TARANTO, BRYSON, and STOLL, *Circuit Judges.*

TARANTO, *Circuit Judge.*

ThermoLife International, LLC exclusively licensed four patents from the Board of Trustees of the Leland Stanford Junior University. It filed infringement suits, asserting selected claims of four patents, against numerous defendants, including Hi-Tech Pharmaceuticals, Inc. and Vital Pharmaceuticals, Inc. After Stanford became a co-plaintiff of ThermoLife's, a bench trial was held involving Hi-Tech, Vital, and a trio of companies from the GNC family as defendants (all other defendants having settled). The district court held all asserted claims invalid. That ruling ended the cases on the merits and is not at issue here.

Before us is the court's later grant of Hi-Tech's and Vital's motions for attorney's fees under 35 U.S.C. § 285, which authorizes an award of fees to a prevailing party (like Hi-Tech and Vital) in "exceptional" cases. The district

court found the cases exceptional, but not based on an assessment of the validity position taken by plaintiffs ThermoLife and Stanford or how they litigated validity. Rather, the court relied on its conclusion that plaintiffs were unjustified in alleging infringement in the first place, having failed to do an adequate pre-filing investigation.

ThermoLife and Stanford appeal the district court's award of fees, challenging the determination that these were "exceptional" cases, not the amounts the court awarded after finding the cases exceptional. We recognize that these are unusual cases in that the basis for the fee award had nothing to do with the only issues litigated to reach the judgment on the merits: Infringement had not been adjudicated in reaching the final judgment, and even discovery on infringement had been postponed early in the proceedings so that validity could be litigated first. Nevertheless, we see no abuse of discretion in the district court's determination of exceptionality based on plaintiffs' inadequate pre-suit investigation of infringement in these and related cases. We therefore affirm.

## I

### A

Stanford owns U.S. Patent Nos. 5,891,459, 6,117,872, 6,646,006, and 7,452,916, which claim methods and compositions involving the amino acids arginine and lysine, to be ingested to enhance vascular function and physical performance. *See*, *e.g.*, '459 patent, Abstract. The '459 patent, the '916 patent, and the relevant claims of the '006 patent share a priority date of June 11, 1993, and expired on June 11, 2013. The '872 patent has a priority date of June 23, 1998, and expired on June 23, 2018. All asserted claims of the '459, '872, and '916 patents are method claims, whereas all asserted claims of the '006 patent are composition claims.

Claim 1 of the '459 patent, the only claim of that patent asserted against Hi-Tech and Vital, includes a requirement of efficacy in producing physiological results. It recites:

> 1. A method of improving vascular NO activity of the vascular system of a human host by enhancing endothelial NO, said method comprising:
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> administering orally as a dietary supplement to said host in accordance with a predetermined regimen a prophylactic dose in *an amount sufficient to enhance endogenous endothelial NO, L-arginine or L-arginine hydrochloride*, as other than a natural food source and in the absence of other amino acids and polypeptides as other tha[n] dietary supplements, to enhance the level of endogenous NO in the vascular system.

*Id.*, col. 26, lines 39–49 (emphasis added). As originally filed, claim 1 included L-arginine and all physiologically acceptable salts thereof, but it was amended during prosecution to exclude salts other than L-arginine hydrochloride.

Claim 1 of the '872 patent requires particular amounts of identified amino acids. It reads:

> 1. A method for enhancing physical performance of a mammal prior to said physical performance, said method comprising:
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> administering to said mammal prior to said physical performance as the active ingredient an amino acid composition consisting of at least one amino acid selected [from] the group consisting of *arginine* and lysine of *at least about 60 mg/kg/day* within 24 h of said physical performance.

'872 patent, col. 11, line 55, through col. 12, line 6 (emphasis added).[1] Claims 4 and 5 depend on claim 1 and thus also require at least about 60 mg/kg/day of arginine or lysine. *Id.*, col. 12, lines 11–16. Claims 7, 8, and 12 all require "at least about 2 g per day" of arginine or lysine. *Id.*, col. 12, lines 19–31, 45–51. Claim 10 depends on claim 7 and additionally requires "about 2 to 12 g per day" of arginine or lysine. *Id.*, col. 12, lines 34–36.

Claim 1 of the '916 patent includes both efficacy and amount requirements for L-arginine or any physiologically acceptable salt (not just the hydrochloride salt). It reads:

> 1. A method of enhancing nitric oxide production comprising orally administering to a human host in need thereof a composition comprising L-arginine or a physiologically acceptable salt thereof, wherein (i) said composition includes *an amount of L-arginine or its physiologically acceptable salt sufficient to increase the level of nitric oxide production in said human host* and (ii) said composition is a dietary or food supplement or a pharmaceutical composition in a form suitable for oral administration selected from the group consisting of a pill, a powder, a liquid, and a capsule, wherein said administering provides a daily amount ranging from *1 to 12 grams of L-arginine or its physiologically acceptable salt* and wherein the composition further comprises at least one additional compound associated with production of nitric oxide other than L-arginine or a physiologically acceptable salt thereof.

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[1] For a 150-pound person, 60 mg/kg/day is about 4 grams per day. Unlike claim 1 of the '459 patent, this claim is not limited to L-arginine or its hydrochloride salt.

'916 patent, col. 26, lines 38–53 (emphases added). Claim 2, another independent claim, and claim 6, which depends on claim 2, likewise require both "an amount of L-arginine or its physiologically acceptable salt sufficient to increase the level of nitric oxide production" and "a daily amount ranging from 1 to 12 grams of L-arginine or its physiologically acceptable salt." *See id.*, col. 26, lines 54–67; *id.*, col. 28, lines 6–8.

Standing apart from the other asserted claims are three claims of the '006 patent, which claim compositions comprising L-arginine and any physiologically acceptable salt but do not include either amount or efficacy requirements. Claim 3 reads:

> 3. A composition comprising *L-arginine or a physiologically acceptable salt thereof* and at least one additional compound associated with production of nitric oxide other than L-arginine or a physiologically acceptable salt thereof, said composition excluding other amino acids which are not precursors of nitric oxide, wherein said composition is in a form suitable for oral administration selected from the group consisting of a pill, a powder, a liquid, and a capsule.

'006 patent, col. 27, lines 40–47 (emphasis added). Claim 5, another independent claim, and claim 14, which depends on claim 5, similarly do not, on their face, contain any amount or efficacy limitations. *See id.*, col. 27, lines 52–61; *id.*, col. 28, lines 20–22.

B

Stanford originally granted exclusive licenses to the '459, '872, '006, and '916 patents to Cooke Pharma, Inc., which eventually became Unither Pharma, Inc. In 2002 and 2003, Unither and Stanford filed several infringement suits involving some of those patents in the Northern District of California. One of those cases resulted in a

November 2005 district court decision that construed "amount sufficient" in the '459 patent to mean "an amount typically administered to a subset of mammalian organisms for the purpose of the administration." *Unither Pharma, Inc. v. Daily Wellness Co.*, No. 02-cv-05284, 2005 WL 6220096, at *10 (N.D. Cal. Nov. 30, 2005). Unither terminated its license with Stanford in September 2012.

Some months later, in February 2013, Stanford exclusively licensed the four patents to ThermoLife. From March 19, 2013, to December 11, 2013, ThermoLife filed a total of eighty-one infringement suits, including suits against Hi-Tech and Vital, in the Southern District of California. Although separate suits were filed, *see* 35 U.S.C. § 299 (broadly requiring separate filings), the district court, beginning in August 2013, consolidated the cases before it for pre-trial purposes. Eventually, in January 2015, Stanford was added as a plaintiff, through the filing of an amended complaint against all defendants, to resolve a dispute about ThermoLife's standing to proceed alone.

ThermoLife alleged that Hi-Tech and Vital each directly infringed the four patents—for the composition claims, by making or selling the accused products, and for the method claims, by administering the accused products to end users—and also indirectly infringed, by inducing or contributing to end users' directly infringing use of the accused products. ThermoLife pointed to Hi-Tech's and Vital's labels and advertisements in support of its allegations. ThermoLife sought damages, including enhanced damages, and injunctive relief. The January 2015 amended complaint is similar.

Pursuant to applicable local rules for patent cases, ThermoLife notified the defendants of specific infringement contentions shortly after the suits were filed. In its December 12, 2013 amended infringement contentions, ThermoLife identified specific Hi-Tech products and the corresponding allegedly infringed patent claims: Anavar

('459 patent—claim 1); NO Overload ('459 patent—claim 1; '872 patent—claims 1, 4, 5, 7, 8, 10, 12; '916 patent—claims 1, 2, 6); Zencore Plus ('459 patent—claim 1; '006 patent—claims 3, 5); Mesomorph (APS Nutrition) ('006 patent—claim 3); SizeMatters (HealthSource) ('459 patent—claim 1; '006 patent—claims 3, 5, 14); and StaminaRx ('459 patent—claim 1; '006 patent—claims 3, 5, 14). The same day, ThermoLife made more limited allegations against Vital products: AEX NO ('872 patent—claim 12; '916 patent—claims 1, 2, 6); and NO Shotgun V3, NO Shotgun MHF-1, and NO Synthesize ('459 patent—claim 1).

By January 2014, with dozens of cases before it, the district court had set a schedule in which discovery was to begin for claim construction, invalidity, unenforceability, and standing—but not for infringement. In March 2014, the parties filed a joint report stating that they had agreed to "phased discovery": "discovery should be coordinated and initially limited to issues concerning standing, claim construction, patent invalidity and/or unenforceability." J.A. 215. "If necessary," the report added, "discovery should then proceed as issues unique to each Defendant and each case, namely[,] infringement and damages." *Id.* The report explained that "[t]his will facilitate the fair and efficient conduct of discovery and dispositive motion practice in this matter, and will alleviate the burden of excessive and potentially unnecessary discovery on all parties in this matter." *Id.* The district court was aware of the agreed-on procedure.

In December 2014, the district court construed several terms in the asserted claims. *ThermoLife Int'l, LLC v. Myogenix Corp.*, No. 13-cv-651, 2014 WL 12160740 (S.D. Cal. Dec. 2, 2014). It did not construe "an amount sufficient to enhance endogenous endothelial NO," as used in claim 1 of the '459 patent, or any other limitations of the asserted claims regarding the amount of arginine to be administered. *See id.* at *11–12.

On July 29, 2015, defendants moved for summary judgment on invalidity, contending that all asserted claims of all four patents were invalid. In December 2015, the district court denied summary judgment, concluding that there were genuine disputes of material fact as to the invalidity of all asserted claims. *ThermoLife Int'l, LLC v. Myogenix Corp.*, No. 13-cv-651, 2015 WL 11237635, at *20 (S.D. Cal. Dec. 8, 2015). Shortly thereafter, with the parties' agreement, the court bifurcated the proceedings: A consolidated trial on invalidity and unenforceability would be held; and if necessary, separate proceedings on infringement would follow.[2]

The district court held a bench trial on invalidity from August 1 to August 8, 2016.[3] In September 2016, the court held that all asserted claims of all four patents were invalid for anticipation or obviousness. *ThermoLife Int'l, LLC v. Myogenix Corp.*, No. 13-cv-651, 2016 WL 5118525, at *25 (S.D. Cal. Sept. 21, 2016). For instance, the court found that claim 1 of the '459 patent was anticipated by U.S. Patent No. 5,217,997 (Levere), which discloses using L-arginine to treat high-vascular-resistance disorders such as hypertension. *Id.* at *9 (citing J.A. 5306–16).

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[2] The "Defendants" listed in the jointly filed agreement to that process are Hi-Tech, Vital, and three GNC entities, plus eight more firms: Kingfisher Media LLC; NBTY, Inc.; Novex Biotech, LLC; Nutrex Research, Inc.; Solgar, Inc.; United States Nutrition, Inc.; Vitamin World, Inc.; and 6S, Inc. d/b/a Bodystrong.

[3] By the time of trial, the only remaining defendants were Hi-Tech, Vital, and the three GNC entities. Only validity was tried, as unenforceability was dropped before trial.

C

On October 12, 2016, Hi-Tech and Vital (but not the GNC entities) moved for attorney's fees under 35 U.S.C. § 285. Rhetoric aside, they made two related arguments for exceptionality that are relevant here.[4] Their main argument was that plaintiffs did not conduct an adequate pre-suit investigation into infringement, an investigation that would have revealed that the accused products did not infringe claim 1 of the '459 patent, the only claim Hi-Tech and Vital specifically discussed. One premise of the argument was that the accused products all contained less than one gram of L-arginine (or its hydrochloride salt) per serving.[5] The other premise was that plaintiffs' own validity expert made clear in his 2015 deposition testimony and

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[4] Hi-Tech and Vital also made two other arguments for exceptionality: They briefly relied on their victory on validity; and as to infringement, they asserted that some accused products fell outside claim 1 of the '459 patent because those products contained amino acids prohibited by the claim. The district court did not rest its exceptional-case determination on either of those bases. We note that Hi-Tech and Vital generally adopted each other's arguments, though certain contentions were product-specific.

[5] Specifically, Hi-Tech submitted a declaration stating that its accused products do not "contain 1 gram or more of L-Arginine or L-Arginine hydrochloride." J.A. 10716–17. Vital submitted two such declarations, the first stating that one of its accused products "never contained L-arginine or L-arginine hydrochloride" and that two of its accused products "always contained less than 500 milligrams of L-arginine per serving." J.A. 10506–07. Vital's second declaration revised that figure downward, stating that the latter two accused products "always contained[] less than 5 milligrams of L-arginine" or L-arginine salts per serving. J.A. 11586.

2016 trial testimony that studies published before these suits were filed showed that amounts of L-arginine less than one gram were ineffective to enhance nitric oxide production (being too small an increase over the regular human intake of arginine). *See* J.A. 10456, 10461–63. Based on those premises, Hi-Tech and Vital argued that plaintiffs would have discovered that the accused products did not infringe had they read the labels on the accused products and conducted simple tests before suing. In their secondary argument, Hi-Tech and Vital broadened their focus and accused plaintiffs of filing many suits, without adequate investigation, simply to try to extract nuisance-value settlements.

Plaintiffs ThermoLife and Stanford jointly responded. They did not deny that the accused products were publicly available, and they neither denied the existence of simple tests to determine the accused products' composition nor asserted that they had conducted any such tests. While noting that Hi-Tech and Vital focused entirely on claim 1 of the '459 patent, to the exclusion of the other patents at issue, plaintiffs did not discuss any other claims to show why they differed as to the adequacy of the pre-suit investigation. Plaintiffs denied the accusation that they sued just to extract settlements and argued that there was insufficient record information to support the speculation that the settlements were for mere nuisance values.[6]

The district court held oral argument on the attorney's fees motions on February 9, 2017. After Hi-Tech argued the inadequacy of the pre-filing investigation by plaintiffs' *counsel*, plaintiffs sought permission to file a declaration to

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[6] Plaintiffs did not contend before the district court that Stanford should be distinguished from ThermoLife with respect to whether there was a reasonable pre-filing investigation. We therefore treat them the same, and we focus on the filing of the cases in 2013.

address the argument, which they said was new. The court provisionally allowed plaintiffs to file such a declaration, but said that Hi-Tech and Vital, in responding, could argue that the declaration should be stricken. On February 16, 2017, plaintiffs submitted a declaration from their lead counsel, Mr. Woods, who described the pre-filing investigation that he and his co-counsel undertook. Hi-Tech and Vital jointly responded.

In April 2017, the district court issued its decision on the motions for attorney's fees. *ThermoLife Int'l, LLC v. Myogenix Corp.*, No. 13-cv-651, 2017 WL 1235766 (S.D. Cal. Apr. 4, 2017) (*Fees Op.*). The court began by striking the Woods declaration. The court explained that plaintiffs could have presented the same information in their initial opposition to the attorney's fees motions, that the declaration went beyond providing facts about their counsel's pre-filing investigation, and that Hi-Tech and Vital had no opportunity to conduct discovery regarding the new statements and arguments. *Id.* at *2–3.

On the merits of the attorney's fees requests, the court first found that plaintiffs had conducted an inadequate pre-filing investigation, resulting in objectively unreasonable infringement contentions. *Id.* at *4–7. The court focused entirely on claim 1 of the '459 patent, as the parties had done in their filings. It found that plaintiffs' validity expert testified that less than one gram of arginine would not enhance NO production. *Id.* at *6. The court found that either plaintiffs did not examine the accused products' *labels* before filing or, if they did, they ignored clear label indications of less than one gram of L-arginine (or its hydrochloride salt) for some of the accused products. *Id.* at *5. The court found that, aside from any (unclear) reliance on labels, plaintiffs relied only on the defendants' advertising statements, even while disparaging the statements as "bombastic." *Id.* at *6 (quoting J.A. 11060, 11062 (plaintiffs' response)). At least in light of the label information and the tension between such information and defendants'

advertising statements, the court concluded, this was a case in which it was unreasonable to dispense with (undisputedly available) testing to identify ingredients and their amounts in the accused products, which were "publicly available." *Id.* at *5–6. And although plaintiffs noted that some accused products contain compounds that are not themselves L-arginine (or its hydrochloride salt), as recited in claim 1 of the '459 patent, but result in L-arginine when dissolved in water pursuant to label instructions, the court found that even those products did not lead to the one gram required for efficacy. *Id.* at *6 (citing, *e.g.*, J.A. 11586). The court thus found "strong evidence that had Plaintiffs conducted any reasonable pre-filing investigation, they would have been on notice that at least some of the products in this litigation could not have infringed." *Id.* at *7.

When the court turned to Hi-Tech and Vital's secondary argument, it found that plaintiffs "only list one marketed product, sales of which never amounted to more than 300 units," and "brought suit under three patents that expired several months after ThermoLife agreed to purchase the licenses." *Id.* The court also found that plaintiffs "settled early with many of the defendants in this lawsuit for seemingly small dollar amounts" and "have filed numerous infringement suits." *Id.* The court then built into its finding on this aspect of the matter a notion of irresponsibility in the bringing of the many suits: "[T]he pattern of action here is indeed one that strongly suggests Plaintiffs brought suit against many defendants *without carefully reviewing their claims* as a calculated risk that might yield nuisance-value settlements." *Id.* (emphasis added).

The court summarized its conclusions: Plaintiffs' "pre-filing investigation was severely lacking, thus resulting in frivolous claims and the objective unreasonableness of certain infringement contentions"; plaintiffs' "motivation was seemingly to extract nuisance-value settlements from a large number of defendants"; and "awarding fees here will advance compensation- and deterrence-oriented goals." *Id.*

at *8. Under the totality of the circumstances, the court ruled, "this case is exceptional," justifying a fee award. *Id.*

Plaintiffs filed a motion for reconsideration of the district court's decision, including new evidentiary material. The district court struck the new material, which could have been supplied earlier, and rejected each of plaintiffs' arguments for changing the result of the April 2017 fees opinion. *ThermoLife Int'l, LLC v. Myogenix Corp.*, No. 13-cv-651, 2017 WL 4792426, at *9 (S.D. Cal. Oct. 24, 2017) (*Reconsideration Op.*). In February 2018, the district court awarded $903,890.13 to Hi-Tech and $406,131.76 to Vital for attorney's fees and expenses, including pre- and post-judgment interest.

ThermoLife and Stanford appeal the district court's exceptional-case determination. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## II

A court "in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. An exceptional case is one that, under the totality of the circumstances, "stands out from others with respect to the substantive strength of a party's litigating position" or "the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014).

We review a district court's grant of attorney's fees under § 285 for abuse of discretion. *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 572 U.S. 559, 561 (2014). A district court abuses its discretion when it makes "a clear error of judgment in weighing relevant factors or in basing its decision on an error of law or on clearly erroneous factual findings." *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302, 1306 (Fed. Cir. 2017) (citing *Highmark*, 572 U.S. at 563 n.2). A district court must "provide a concise but clear explanation of its reasons for the fee

award." *Hensley v. Eckerhart*, 461 U.S. 424, 437 (1983); *see In re Rembrandt Techs. LP Patent Litig.*, 899 F.3d 1254, 1276 (Fed. Cir. 2018); *see also AFGE Local 3599 v. EEOC*, 920 F.3d 794, 799–800 (Fed. Cir. 2019) (discussing fees in agency context). We generally "give great deference to the district court's exercise of discretion in awarding fees." *Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1307 (Fed. Cir. 2018).

We conclude that the district court in this case acted within its discretion in determining, on the limited arguments plaintiffs made in response to the fee motions, that plaintiffs did not conduct an adequate pre-suit investigation into infringement by Hi-Tech and Vital. That determination would suffice to support the exceptional-case determination. And we read the district court's additional discussion of plaintiffs' filing of numerous suits on the patents at issue here as itself ultimately resting on the same lack of adequate pre-suit investigation, not simply on ThermoLife's limited product sales, the expiration dates of three of the four patents, the number of suits filed, or the amounts of the settlements. For those reasons, we affirm the exceptional-case determination.

A

We begin with three issues that confirm the propriety of the district court's focus on the inadequate-investigation question.

1

We see no abuse of discretion in the district court's striking of the Woods Declaration. The district court explained that the declaration was untimely: plaintiffs were on notice of the need to address the adequacy of their pre-filing investigation, an issue that does not neatly segregate counsel from client, and so plaintiffs could and should have put forth the information contained in the Woods Declaration in their initial opposition to the motions for attorney's

fees. The court also explained that Hi-Tech and Vital did not have an opportunity to conduct additional discovery in response to the facts and arguments raised in the declaration. *Fees Op.*, 2017 WL 1235766, at *2–3. Those are sufficient reasons for striking the declaration.

2

Nor do we see an abuse of discretion in the district court's resting its exceptional-case determination on an examination of an issue—infringement, and specifically the basis for alleging infringement—that was neither fully adjudicated nor even fully litigated before the judgment on the merits. In *Lumen View Technology LLC v. Findthebest.com, Inc.*, we held that a district court did not abuse its discretion in finding the case exceptional because "[t]he allegations of infringement were ill-supported," even though non-infringement had not been adjudicated before the asserted claims were invalidated. 811 F.3d 479, 481–83 (Fed. Cir. 2016). This is an unusual basis for fees, and we have emphasized the wide latitude district courts have to *refuse* to add to the burdens of litigation by opening up issues that have not been litigated but are asserted as bases for a fee award. *Spineology, Inc. v. Wright Med. Tech., Inc.*, 910 F.3d 1227, 1230 (Fed. Cir. 2018). As a practical matter, moreover, one stated rationale for deference—the district court's distinctive familiarity with the issues relevant to fees due to its extensive work on the merits of the case—is weaker when the award of fees rests on a basis not meaningfully considered before fees were sought after the merits were resolved. Also, a fuller explanation of the court's assessment of a litigant's position may well be needed when a district court focuses on a freshly considered issue than one that has already been fully litigated. But we have been given no persuasive reason for holding that such a basis for fees is a legally impermissible one.

To be sure, due process and other procedural rights must be respected in deciding the exceptional-case

question as a precondition to awarding fees against a losing party. *In re Rembrandt Techs.*, 899 F.3d at 1275–76. And more process may well be needed on a fees motion when the issue presented as a basis for fees has not previously been litigated. But we have been pointed to no denial of plaintiffs' procedural rights in adjudicating the exceptional-case question in this matter. Plaintiffs did not request a hearing, they had an opportunity to meet the contentions made in the fees motion, and they have made no concrete persuasive argument for what discovery was needed and requested but denied.

3

Nor are we prepared to say that Hi-Tech and Vital must be denied a fee award, if one is otherwise justified, just because they did not give early notice of the defects in plaintiffs' infringement assertions that later became the basis for the fee award. Recently, we have stressed that one consideration that can and often should be important to an exceptional-case determination is whether the party seeking fees "provide[d] early, focused, and supported notice of its belief that it was being subjected to exceptional litigation behavior." *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1181 (Fed. Cir. 2018). Here, the record before us does not reflect Hi-Tech's or Vital's provision of that kind of notice with respect to the amount-of-arginine issue, whether by filing a motion under Federal Rule of Civil Procedure 11 or otherwise. *Cf.* J.A. 11051 n.2 (plaintiffs noting in opposing fees: "If Defendants thought Plaintiffs' infringement case was meritless from day one, they likely would have sent Rule 11 notices at some point in the last three-and-a-half years, rather than wait until the case was closed . . . .").[7] Nevertheless, we see

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[7] Suggesting that it gave such notice, Vital points to a December 2014 email from ThermoLife's counsel, apparently responding to an assertion by Vital that three of its

no basis for finding the fee award in this matter to be an abuse of discretion because such notice was missing.

The § 285 standard is a flexible one within the framework and guidelines established by governing precedents. We have held that the lack of the early notice described in *Stone Basket* can support a denial of attorney's fees, *see Stone Basket*, 892 F.3d at 1181–83, and that the presence of such notice, followed by continuation of litigation, can be a factor in justifying an award of attorney's fees, *see Nat'l Oilwell Varco, L.P. v. Omron Oilfield & Marine, Inc.*, 676 F. App'x 967, 973 (Fed. Cir. 2017). But we have not held that such notice is rigidly required. And here, there is reason to avoid what would amount to a retroactive imposition of a rigid notice requirement. Plaintiffs' suits against a large number of defendants, involving numerous products and several patents and claims, reasonably led not only to coordination among numerous defendants but to the agreement of all parties, for efficiency, to give priority to the common issue of validity so that even discovery as to party-specific issues like infringement could be postponed. In these circumstances, we think that the district court did not abuse its discretion in not treating lack of early notice by Hi-Tech and Vital as a bar to fees if, as the court determined, plaintiffs failed to undertake an adequate pre-filing

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accused products did not infringe the asserted claims of the '459 patent because they contained citrulline malate, a salt of another amino acid, as an active ingredient. *See* J.A. 11589. But that observation does not concern the amount-of-arginine issue on which the fee award rested here. It concerned the separate claim limitation forbidding certain other amino acids, which raised an issue—subject to a claim construction that presents an obstacle to Vital's position, *see* J.A. 4275—that the district court did not decide in its fees decision. *See supra* note 4.

investigation to support their infringement allegations against Hi-Tech and Vital.

B

We see no abuse of discretion in the inadequate-investigation determination.

1

Although plaintiffs now contend that the district court improperly restricted its attention to claim 1 of the '459 patent, we see no reversible error in that respect. As we have noted, plaintiffs in the district court made only a couple of passing references to the fact that Hi-Tech and Vital focused their fees motion entirely on that one claim, but they made no argument showing how the basis for their infringement allegations was stronger for the other asserted claims than for the '459 patent's claim 1. In the absence of any such showing, we cannot fault the district court for not separately assessing the reasonableness of plaintiffs' pre-suit investigation as to the other asserted claims.

In this regard, it is worth noting that plaintiffs accused three of Vital's products of infringing only the '459 patent's claim 1 and a single Vital product of infringing the asserted '872 and '916 patent claims. The latter all contain amount and/or efficacy requirements. As to Hi-Tech, plaintiffs alleged that most of the accused products infringed the '459 patent's claim 1, one infringed the asserted '872 and '916 patent claims, and several infringed the '006 patent's claims 3, 5, or 14 (one product was not accused of any infringement outside the '006 patent). Although the '006 patent claims stand out from the others at issue (in not containing amount or efficacy limitations), plaintiffs made no showing in the district court, and make no showing in this court, that even if assertion of the '006 patent claims was justified, the burdens of this litigation were materially unaffected by the inclusion of all the other claims in this

case. The district court thus acted properly in limiting its focus to claim 1 of the '459 patent.

2

The district court committed no error in finding that one gram of L-arginine (or its hydrochloride salt) was required for infringement of that claim. To begin with, contrary to plaintiffs' contention in this court, that finding is not a matter of claim construction, but of infringement. The claim requires L-arginine or L-arginine hydrochloride in "an amount sufficient to enhance endogenous endothelial NO." '459 patent, col. 26, lines 44–45. The claim phrase, which was not construed in this case, requires an amount that produces a specified effect, so the question of infringement for that limitation was simply whether a particular amount being administered by the alleged direct infringer sufficed to produce the effect.[8]

That question is a factual one about how human bodies operate. It is not a question about what was believed about the body's operation at the time of issuance of or application for the patent. Contrary to plaintiffs' contention, it is immaterial that claim 20 of the '459 patent, which depends on claim 1, adds a restriction that the dosage be "in the range of 0.5−10 g." '459 patent, col. 28, lines 43−47. All

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[8] Under the 2005 construction in *Unither*, the question for infringement would be whether an administered amount is "an amount typically administered . . . for the purpose of" achieving the specified effect. *Unither*, 2005 WL 6220096, at *10. That question, too, focuses on an amount to achieve the effect, and it is generally to be expected that typical administration would come to reflect what science revealed as the amount needed for the effect. Plaintiffs have not shown that the *Unither* construction applies here or would make a material and favorable difference to the analysis.

that dependent-claim language covers, by its terms, is any amount that both falls within the specified range and also meets the efficacy requirement: it does not declare that all amounts in the range meet the requirement. Plaintiffs suggest that the language tends to suggest that applicants believed in 1993 that, as a matter of science, the low end of the claimed range would have the required efficacy. But applicants' belief, when applying for the patent or later, does not control the answer to the efficacy question posed directly by the claim language. Science does.

The district court thus properly focused on whether, when plaintiffs sued in 2013, they had done an adequate investigation of whether the accused products were being administered in amounts that would produce the claimed effect. The district court found that one gram was needed for that purpose. That finding had adequate support in the record.

The deposition and trial testimony given by ThermoLife's validity expert provides such support. In the deposition, the expert described knowledge available before the 2013 filing of these cases:

> [A]ll the studies that were performed after Dr. Cooke's initial study and that showed an increase in nitric oxide utilized doses higher than 1.5 to 2 grams per day in a chronic dosing, whereas several studies that have been published and claimed that L-arginine is ineffective in increasing nitric oxide were using doses of 1 to 1.5 grams and below.

J.A. 10456. Asked "[y]ou said showed 1 gram was ineffective; is that correct?," he replied, "1 gram and below was ineffective." *Id.* "Q: According to studies? A: Yes." *Id.* At trial, he was asked: "And administering 1 gram or less of a supplement is not going to affect the arginine—excuse me, is not going to meaningfully affect the arginine level in one's plasma, correct?" J.A. 10463. He answered: "That's

correct." *Id.* The district court committed no clear error in finding one gram necessary for the claimed efficacy.

Finally, given this evidence, we see no error in the district court's attribution to plaintiffs of knowledge of the one-gram minimum. Their expert testified that this minimum was revealed in the public literature. It is not an abuse of discretion in these circumstances to fault plaintiffs for failing to learn this public-literature information before bringing suit, whether by hiring an expert or otherwise.

3

The district court also committed no reversible error in determining that plaintiffs did not conduct adequate investigations to apply the one-gram minimum to the accused products. Importantly, it was not disputed in the district court that "all the relevant products were publicly available." *Fees Op.*, 2017 WL 1235766, at *5. Nor was it disputed that plaintiffs could have determined the amounts of L-arginine or its hydrochloride salt (in the recommended servings of the accused products) by performing what Vital characterized as a "simple test." J.A. 10537; *see also* J.A. 10710 (Hi-Tech's motion). Nor, finally, does the record reveal that plaintiffs performed such a test.

We have explained that testing of an accused product is not *necessarily* a required part of an adequate pre-filing investigation. *See Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1338 (Fed. Cir. 2007) (testing not required where high obstacles to testing); *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1302–03 (Fed. Cir. 2004) (testing unnecessary for purposes of Rule 11 and § 285 where the product labels, among other things, supported infringement). Whether testing is necessary for a responsible accusation of infringement necessarily depends on the availability of the products at issue, the existence and costs of testing, and whether other sufficiently reliable information exists. Here, given the deficiencies of the two possible alternatives to testing (product label ingredient lists

and product advertising), we see no error in the district court's determination that this matter was one in which there was no adequate substitute for simple testing of publicly available products.

The district court noted that there was some, though slim, evidence that plaintiffs examined the labels of the accused products. *Fees Op.*, 2017 WL 1235766, at *5; *Reconsideration Op.*, 2017 WL 4792426, at *6; *see* J.A. 10187 (deposition testimony of ThermoLife's president). But the court agreed with Vital and Hi-Tech that the labels of at least some, perhaps many, of the accused products made clear that they did not contain one gram of L-arginine or its hydrochloride salt in a serving. *Fees Op.*, 2017 WL 1235766, at *5–7. The evidence supports that determination.

The label of Vital's NO Synthesize does not list L-arginine or its hydrochloride salt as an ingredient at all. J.A. 10509.[9] The labels of other accused products list L-arginine but in amounts that preclude one gram per serving. For instance, Hi-Tech's Stamina Rx, Zencore Plus, and SizeMatters products list L-arginine as an ingredient, but all the listed ingredients together total 550, 325, and 550

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[9] In the fees proceeding, plaintiffs observed that the label lists di-L-arginine malate, a non-hydrochloride salt of L-arginine, though without listing an amount, J.A. 10509, and plaintiffs asserted that this ingredient would dissociate to form L-arginine "when the powder product is mixed with liquid as instructed on the label," J.A. 11065. But there is no evidence that plaintiffs had this view of infringement in mind before suing: it is not reflected even in the amended infringement contentions. *See* J.A. 6257–58. Had plaintiffs investigated, they might have found, as stated in Vital's evidence credited by the district court, that the amount was less than 5 milligrams per serving. *See Fees Op.*, 2017 WL 1235766, at *6 (citing J.A. 11586).

milligrams per serving, respectively. *See* J.A. 10721; J.A. 10736; J.A. 10739. The Zencore Plus and SizeMatters labels instruct users to take one or two servings, but reaching the one-gram minimum of L-arginine is impossible (325 milligrams times 2, total ingredients for Zencore Plus) or quite unlikely (550 milligrams times 2, total ingredients for SizeMatters) with two servings. Those deficiencies in labels either preclude an accusation of infringement or, at a minimum, strongly suggest a need for testing.

To be sure, other accused products have labels that do not arithmetically preclude more than one gram of L-arginine or its hydrochloride salt per serving. *See*, *e.g.*, J.A. 10513 (Vital's NO Shotgun V3 product contained L-arginine as one of several ingredients totaling 9660 milligrams per serving). Those product labels, however, do not identify the amount of L-arginine or its hydrochloride salt, so they can reasonably be deemed insufficient to support an allegation of infringement where, as here, a simple test on easily acquired products was available to resolve the issue. Moreover, even if some allegations of infringement were made with an adequate basis, inclusion of numerous allegations not made with such a basis might so increase defense costs, and alter the litigation or settlement of the responsible allegations, that such inclusion may weigh in favor of exceptionality when the defendants end up fully prevailing.

Ingredient lists on the labels aside, plaintiffs also relied for their pre-filing investigation on what may be described as advertising by the defendants for their products—including the non-ingredient portions of labels. In some circumstances, a potential infringer's public assertions about its products may supply, or help to supply, a reliable basis for a patent owner to allege infringement. *See Q-Pharma*, 360 F.3d at 1302–03 ("Because Q-Pharma obtained a sample of the accused product, reviewed Jergens' statements made in the advertising and labeling of the accused product, and, most importantly, compared the claims of the

patent with the accused product, we conclude that its claim of infringement was supported by a sufficient factual basis."). But the nature and setting of the assertions can significantly affect their reliability for that purpose. Here, the district court properly found that defendants' advertising claims were no substitute for simple testing.

Plaintiffs have not pointed to advertisements that assert the inclusion of more than one gram of L-arginine or its hydrochloride salt. Advertisement claims to NO-enhancement effects, made in disregard or ignorance of the knowledge (available by 2013) that one gram was needed, may properly be found not to be a reliable basis for plaintiffs, justifiably charged with such knowledge, to assert infringement in 2013. In addition, in the fees proceeding, plaintiffs themselves characterized Hi-Tech's statements in the non-ingredient portions of its labels as "bombastic." J.A. 11060; *see* J.A. 11062; *Fees Op.*, 2017 WL 1235766, at *6. Plaintiffs also attacked the probity of Hi-Tech's president, J.A. 11063–64, and stated that Vital was warned by the Food and Drug Administration about product adulteration, J.A. 11067 n.8. *See Fees Op.*, 2017 WL 1235766, at *6. In these circumstances, we see no reversible error in the district court's determination that plaintiffs could not reasonably rely on the advertising at issue for these products as a substitute for simple testing.

4

At oral argument in this court, ThermoLife's counsel sought to undermine the one-gram-minimum premise of the district court's decision by pointing to statements in the defendants' January 2015 invalidity contentions that "any amount of L-arginine inherently enhances nitric oxide

production." Oral Arg. at 12:58–13:56 (citing J.A. 10421).[10] We note that those contentions are preceded by extensive disclaimers that some or all invalidity contentions are made on a mere assumption of the truth of plaintiffs' infringement contentions (*i.e.*, the December 2013 amended infringement contentions). *See* J.A. 10209. But we do not further address this argument, which is either an assertion that defendants are barred from disputing what plaintiffs should have known about required L-arginine amounts before filing or an invocation of evidence that plaintiffs never cited to the district court on that issue, much less said was significant. No matter how characterized, the argument comes too late, not having been made to this court in plaintiffs' opening briefs and not having been presented to the district court. *See*, *e.g.*, *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1355 (Fed. Cir. 2018); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006). We will not disturb the district court's exercise of discretion on such a basis.

For those reasons, we find no abuse of discretion in the district court's determination that plaintiffs failed to conduct an adequate investigation into infringement before filing suit.

B

Had the district court deemed the matter exceptional on that basis, considering compensation and deterrence interests, we would find no abuse of discretion. *See Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*, 876 F.3d 1372, 1377 (Fed. Cir. 2017) (affirming attorney's fees award based on the exceptional weakness of the patentee's arguments, citing deterrence policy); *Lumen View*, 811 F.3d at

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[10] Vital attached the invalidity contentions to its fees motion to support its brief argument that plaintiffs' validity position made this matter exceptional. J.A. 10532.

481, 483 (affirming fee award based on "ill-supported" allegations of infringement). The district court, however, did not draw a bottom-line exceptionality conclusion after finishing its discussion of the Hi-Tech and Vital cases. It continued with its analysis, addressing the full range of cases filed by plaintiffs and finding a "pattern of action"—specifically, a pattern of misconduct—that, together with the discussion tied to the Hi-Tech and Vital cases, supported the ultimate exceptional-case determination. *Fees Op.*, 2017 WL 1235766, at *7.

Plaintiffs challenge the significance of four enumerated findings made by the district court in reaching its pattern-of-misconduct determination. Considered alone, those findings would not support a pattern-of-misconduct finding. But those findings do not stand alone. The district court's "pattern" determination ultimately is tied to the finding that plaintiffs failed to conduct an adequate pre-suit investigation into infringement. Because, as we have explained, we see no reversible error in that finding, we reject plaintiffs' challenge to the ultimate "pattern" determination and affirm the exceptional-case ruling.

In the first two findings at issue, the district court noted that plaintiff ThermoLife was at best a very small seller of nutritional-supplement products (we assume that Stanford is not a seller of such products at all) and that plaintiffs brought these suits just a few months before three of the patents were to expire. *Id.* We do not consider what role such facts might play in resolving other patent-law issues, such as the appropriate remedy where infringement is found, or even whether they might bear on an exceptional-case determination resting on a different basis from the one the district court in this case adopted. Here, what the district court found was a pattern of misconduct, and these two facts do not tend to support such a finding. One of the four patents had five years left on its term, and even for the three that would soon expire, six years' worth of damages for past infringement were potentially

available under 35 U.S.C. § 286. Moreover, the patent statute does not restrict enforceable patent rights to those who practice the patent, to the exclusion of research institutions and their exclusive licensees engaged to perform needed enforcement activities in which the inventors, or research institutions, may lack expertise or experience. *See Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 424–25 (1908); *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 703 (Fed. Cir. 2008); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995); *cf. eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006) (rejecting categorical exclusion of non-practitioners from injunctive remedy).

The more significant findings by the district court were that plaintiffs brought many suits and settled many for "seemingly small" amounts. *Fees Op.*, 2017 WL 1235766, at *7. But even those findings do not show misconduct without the additional evidence of inadequate pre-suit investigation.

"[A] pattern of litigation *abuses* characterized by the repeated filing of patent infringement actions *for the sole purpose of forcing settlements*, with no intention of testing the merits of one's claims, is relevant to a district court's exceptional case determination under § 285." *SFA Sys., LLC v. Newegg Inc.*, 793 F.3d 1344, 1350 (Fed. Cir. 2015) (emphases added); *see Eon-Net LP v. Flagsar Bancorp*, 653 F.3d 1314, 1324–28 (Fed. Cir. 2011) (relying on litigation misconduct and baseless infringement assertions). We have emphasized, however, that filing a large number of suits does not, by itself, justify an inference of such an improper motive. *SFA Sys.*, 793 F.3d at 1351 ("The mere existence of these other suits does not mandate negative inferences about the merits or purpose of this suit."). A patent might apply in similar fashion to the activities of numerous persons, such as numerous sellers of similar products, and a patentee may have a legitimate interest in pressing reasonably grounded claims against all or many

of them, whether to obtain compensation or to deter disregard of these or other patent rights or for other reasons. *See Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 858 F.3d 1371, 1375 (Fed. Cir. 2017) (distinguishing legitimate "motivation to implement the statutory patent right by bringing suit based on a reasonable belief in infringement" from motivation "to harass or burden an opponent"); *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (recognizing deterrence value of enforcement actions). As a procedural matter, moreover, Congress has required separate suits in circumstances like the one before us. 35 U.S.C. § 299.[11]

Similarly, "there is no minimum damages requirement to file a patent infringement case," and "[a]sserting seemingly low damages against multiple defendants—or settling with defendants for less than the cost of litigation—does not necessarily make a case 'exceptional' under § 285." *AdjustaCam, LLC v. Newegg, Inc.*, 861 F.3d 1353, 1361 (Fed. Cir. 2017). A patent plaintiff may be able to distribute common costs over many suits, making each suit worthwhile even on its terms, let alone as a deterrent to others who might disregard the plaintiff's patent rights. The economics of such cost-distribution is familiar from the related context of class actions. *See*, *e.g.*, *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1632 (2018) ("[C]lass actions can enhance enforcement by spreading the costs of litigation . . . ." (internal quotation marks and alteration omitted)).

As for settlement amounts, a low figure might simply reflect the small size of an individual defendant's potential liability. Indeed, the figure may result from what the

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[11] To the extent that the district court here referred to plaintiffs' filing of suits on other patents, *see Fees Op.*, 2017 WL 1235766, at *7 (noting that ThermoLife filed 117 cases in 2013), it cited nothing to suggest the unreasonableness of any of those other suits.

Supreme Court has recognized as the normal, legitimate settlement calculus, which includes consideration of litigation costs: a prediction of the amount of liability, "discounted by its probability, plus the transaction costs of further litigation." *Evans v. Jeff D.*, 475 U.S. 717, 734 (1986); *see Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1369 (Fed. Cir. 2017). A court must therefore be cautious in inferring bad faith from the "small dollar amounts" of settlements, which is all the district court in this case found, without further findings about, for example, the value of the claims. *Fees Op.*, 2017 WL 1235766, at *7.

For those reasons, and noting the fact that plaintiffs pressed their claims to judgment through extensive litigation on the merits, we agree with plaintiffs that the four findings whose significance plaintiffs criticize on appeal would not, standing alone, show "litigation abuses" or "the repeated filing of patent infringement actions for the sole purpose of forcing settlements, with no intention of testing the merits of [the] claims." *SFA Sys.*, 793 F.3d at 1350. In other words, those findings would not themselves establish misconduct in the form of imposing burdens solely to extract "nuisance-value settlements." *Fees Op.*, 2017 WL 1235766, at *7.

We nevertheless reject plaintiffs' argument that the "pattern" portion of the district court's opinion infects the ultimate determination of exceptionality. The four findings we have discussed do not stand alone. What the district court found is a "pattern of action" by plaintiffs of bringing "suit against many defendants *without carefully reviewing their claims*." *Id.* (emphasis added). The district court, which oversaw the full group of more than six dozen suits, thus viewed the inadequacy of plaintiffs' pre-filing investigation as extending beyond the two suits against Hi-Tech and Vital to the group more generally. Plaintiffs have not shown reversible error in that finding if, as we have

concluded, there is no reversible error in the inadequate-investigation finding as to the Hi-Tech and Vital suits.

The "pattern" part of the district court's opinion thus rests on a finding, which we accept, that plaintiffs' irresponsible filing of infringement allegations extended widely beyond the two cases before us. The remainder of the discussion in the "pattern" portion of the district court's opinion may add nothing significant to that finding, but it does not undermine the finding. On that basis, which enhances the force of the deterrence policy as applied here, we see no abuse of discretion in the ultimate determination of exceptionality.

III

For the foregoing reasons, we affirm the district court's judgment.

**AFFIRMED**