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In *Thermolife v. GNC, et al.* (May 1), the Federal Circuit affirmed an "exceptional case" attorneys' fee award based on an insufficient pre-suit investigation into infringement where *only invalidity* was litigated and decided on the merits. This case emphasizes the need for an adequate pre-suit investigation regarding all allegations to be made.

In 2013, Thermolife (exclusive licensee) and Stanford University (patentee and licensor) sued several companies for infringement of patents relating to the administration of the amino acid arginine to increase endothelial nitric oxide production.[1] The cases were consolidated for pre-trial purposes and the parties stipulated to limit discovery to invalidity and unenforceability in a first phase and then, if necessary, proceed to infringement and damages in a second phase. Later, with the parties' consent, the court bifurcated the case for an initial trial on invalidity and unenforceability, postponing proceedings on infringement. The initial trial determined that all asserted claims were invalid over the prior art, which terminated the case on the merits.

Two of the defendants moved for attorneys' fees under § 285, asserting that Thermolife and Stanford had failed to conduct an adequate pre-suit investigation regarding infringement because the accused products did not contain sufficient arginine to meet the requirements of most of the asserted claims. Despite infringement not having been litigated or decided, the district court agreed with the defendants, found the case exceptional, and awarded about $1.2 million in attorneys' fees.[2] The Federal Circuit affirmed.

**No abuse of discretion to base attorneys' fee award on non-litigated issue.**

The Federal Circuit found no abuse of discretion by the district court in basing the exceptional case finding on an issue, infringement, that was "neither fully adjudicated nor even fully litigated before the judgment on the merits" regarding invalidity. Acknowledging that a non-litigated issue was an "unusual basis" for a fee award, and that the rationale for deference to the district court under the abuse of discretion standard was weaker where the district court did not have the more typical "distinctive familiarity with the issues relevant to fees due to its extensive work on the merits of the case," the Federal Circuit held that an inadequate pre-suit investigation of a non-litigated issue is nevertheless a legitimate basis for an exceptional case attorneys' fee award.

**No abuse of discretion in finding pre-suit investigation inadequate.**

The pre-suit investigation was inadequate because Thermolife and Stanford failed to (i) analyze and understand the limitations of the asserted claims, (ii) consider the publicly-available infringement evidence, or (iii) perform simple tests of the accused products.

*Claim Limitations*

Most of the asserted claims included limitations regarding the effect of the arginine administered, expressly requiring administration of sufficient arginine to increase the level of nitric oxide production.[3] Thermolife

[1] Endogenous nitric oxide is a potent vasodilator and is associated with potential health benefits and improvement in cardiovascular capacity. In general, the patents at issue relate to administering arginine in nutritional supplements to stimulate nitric oxide production.

[2] Order Granting Defendants' Applications for Attorneys' Fees (SD-Cal. Case No. 13-cv-651, January 18, 2018).

[3] *E.g.,* "an amount of L-arginine or its physiologically acceptable salt sufficient to increase the level of nitric oxide production in said human host" and an amount of arginine "sufficient to enhance endogenous endothelial [nitric oxide]." The Federal Circuit analyzed

and Stanford were either unaware of or disregarded scientific research publicly-available before they filed suit indicating that at least one gram of arginine was necessary to measurably elevate nitric oxide production. Indeed, Thermolife's and Stanford's own expert witness agreed that at least one gram of arginine was necessary to trigger the effect. A dependent claim included a range of arginine having a lower limit of half a gram, and on that basis Thermolife and Stanford argued that half a gram should be the lower limit. The Federal Circuit disagreed, finding that because the true – scientific – lower limit was one gram, the dependent claim merely had the effect of capturing the lower end of the range rather than establishing the limit of the lower end.

There were some claims that lacked the "effect" limitation and did not otherwise set a one gram lower limit on the amount of arginine administered. The Federal Circuit explained that even if assertion of those claims was justified, Thermolife and Stanford made no showing that "the burdens of this litigation were materially unaffected by the inclusion of all the other claims in this case" (*i.e.,* the claims including the one gram lower limit).[4] This is important: The pre-suit investigation being adequate as to one set of claims does not necessarily prevent an exceptional case finding where the pre-suit investigation was not adequate for another set of claims.

*Product Labels & Advertising*

Thermolife and Stanford either failed to read or disregarded the labels on the accused products. They did not dispute that "all the relevant products were publicly available," and the labels of many of the accused products indicated that they provided less than one gram of arginine in a serving while the labels of others indicated the absence of arginine in the product. The Federal Circuit concluded that "[t]hose deficiencies in labels either preclude an accusation of infringement or, at a minimum, strongly suggest a need for testing."

Thermolife and Stanford pointed to advertisements calling out nitric oxide-enhancing effects of the defendants' products, but the Federal Circuit said those advertisements were not a "reliable basis" upon which to assert infringement because Thermolife and Stanford (i) were "justifiably charged" with knowledge of the one gram minimum dose requirement, (ii) described the relevant portions of the advertisements as "bombastic," (iii) attacked the honesty of one of the defendant's executives, and (iv) raised an issue regarding an FDA warning about product adulteration received by another of the defendants. These factors, independently and collectively, suggest that Thermolife and Stanford knew, should have known, or believed that the advertisements were not accurate or reliable indicators of the arginine content of the products. Accordingly, Thermolife and Stanford were not justified in relying on the advertising to support their infringement allegations.

*Simple Testing*

Thermolife and Stanford failed to test the publicly-available accused products to determine their arginine content. Thermolife and Stanford did not dispute that they could have determined the amounts of arginine in the accused products by using a "simple test." The Federal Circuit explained that although testing is not necessarily required for an adequate pre-suit investigation, "[w]hether testing is necessary for a responsible

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the "effect" claims in terms of infringement rather than claim construction, framing the question as "a factual one about how human bodies operate" that asks "simply whether a particular amount being administered by the alleged direct infringer sufficed to produce the effect."

[4] The Federal Circuit amplified this point a bit later in the opinion: "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." It's not clear if the Federal Circuit intended to set a "fully prevail" standard for this type of situation – generally, one need not prevail on all claims or defenses to be a "prevailing party" under § 285. *See, e.g., SSL Services v. Citrix Systems,* 769 F.3d 1073, 1086-87 (Fed. Cir. 2014).

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." In this case, "given the deficiencies of the two possible alternatives to testing (product labels 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."

**Secondary basis helpful but not necessary for affirmance.**

The Federal Circuit stated that district court could have properly relied exclusively on the inadequate pre-suit investigation to find the case exceptional.[5] But the district court also cited a "pattern of misconduct" to support the attorneys' fee award. Thermolife and Stanford filed more than 70 suits and settled many of them for "seemingly small" amounts, a pattern of action the district court characterized as "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."

The Federal Circuit found that the pattern of conduct by Thermolife and Stanford did not amount, by itself, to the kind of litigation abuse that has supported exceptional case findings and attorneys' fee awards in cases like *SFA Sys., LLC v. Newegg Inc.,* 793 F.3d 1344 (Fed. Cir. 2015) and *Eon-Net LP v. Flagsar Bancorp,* 653 F.3d 1314 (Fed. Cir. 2011). However, in the context of Thermolife's and Stanford's filing suit "without carefully reviewing their claims," their pattern of conduct amounted to "irresponsible filing of infringement allegations [that] extended widely beyond the two cases before us." Thus, while not a sufficient independent basis for finding the case exceptional, the Federal Circuit explained that the district court's reliance on the plaintiffs' pattern of filing suit with inadequate pre-suit investigation "enhances the force of the deterrence policy" that underlies the exceptional case doctrine.

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Concluding thoughts:

- It is important to do your homework before filing a patent lawsuit, including all the claims you intend to present. Resist the temptation to remain willfully blind to problems in your case, and remember that including bad claims, whether or not they are ultimately litigated or adjudicated, can expose your client to § 285 attorneys' fees liability.
- The lessons of this and other pre-suit investigation cases apply equally to trade secret lawsuits – *e.g.,* it is critically important to clearly identify each allegedly misappropriated trade secret and marshal and analyze the evidence of misappropriation before filing suit.[6]
- Occasionally, clients and lawyers for various reasons[7] resist undertaking thorough pre-suit investigations. Despite the competition to attract and retain clients and the "go along to get along" culture often seen in lower-quality in-house legal departments, a lawyer is an officer of the court and has an independent ethical duty to adequately investigate potential claims, identify and analyze the relevant facts and law, and competently advise and protect their client.[8]

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[5] Slip op. at 26. "[W]e find no abuse of discretion in the district court's determination that plaintiffs failed to conduct an adequate investigation into infringement before filing suit" and [h]ad the district court deemed the matter exceptional on that basis, considering compensation and deterrence interests, we would find no abuse of discretion."

[6] *See, e.g.,* Cal Civ. Code §3426.4 and *FLIR Systems v. Parrish et al.,* 174 Cal.App.4th 1270 (Ct. App. Div 6 2009).

[7] *E.g.,* ignorance of the law and risks, cost, concern that the results will not support their or their boss's desire to sue or will undermine advice they've already given to their client or promises they've made, and sometimes just plain laziness.

[8] Of course, sometimes a client chooses not to follow your thorough and competent legal advice. That is the time to *walk away*.