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# Generics Need Sword, Shield For 'Exceptional' Patent Case

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Generic drug companies marketing in the U.S. have particularly rough going these days. The year 2013 saw substantial new Generic Drug User Fee Amendments "user fees" levied on generics for access to the U.S.Food and Drug Administration. The same year brought the U.S. Supreme Court's Actavis decision: Now the Federal Trade Commission can sue generics for structuring pharma litigation settlements such that the generic company receives something of value from the brand.

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Now comes 2014, bringing yet another development of concern to generic drug companies with finite resources litigating in the U.S. On April 29, the Supreme Court ruled essentially unanimously in a pair of cases that the requirements for awarding a party (often the brand drug company) exceptional-case attorney fees and costs have become too strict. Octane Fitness LLC v. Icon Health & Fitness Inc., 134 S. Ct. 1749 (2014); Highmark Inc. v. Allcare Health Mgmt. Sys., 134 S. Ct. 1744 (2014).

In other words, brands may find it easier to get exceptional-case fees and costs from generics. Generics — already struggling at the margin to maximize their litigation budgets — need to get a firm grip on this development so that they can avoid paying these fees, and maybe even turn the tables on their adversaries!

So what are the requirements for a finding of an exceptional case? The provision is one of most bare-bones in the entire patent statute: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285.

This reverses the standard "American Rule," i.e., each party bears its own fees and costs. The "English Rule" — the prevailing party is awarded fees and costs — is said by many to discourage the fighting of meritorious lawsuits by parties that can't afford to lose them. And the Hatch-Waxman Act governing brand-generic pharma litigations aims to encourage generics to challenge vulnerable brand patents, because such invalidation of bad patents benefits society as a whole. See, e.g., 149 CONG. REC. at 16104 (Sen. Orrin Hatch, R-Utah, recently discussed the congressional intent for Hatch-Waxman exclusivity to provide an incentive to generics for early patent challenges.)

In order to effect a balance to the competing interests, the Court of Appeals for the Federal Circuit had adopted a set of requirements for a finding of an exceptional case: Either (1) Grievous misconduct during litigation or (2) litigation (i) brought in subjective bad faith and (ii) objectively baseless (no reasonable litigant could expect success). Checkpoint Sys. Inc. v. All-Tag Security SA, 711 F.3d 1341 (Fed. Cir. 2013).

With that set of requirements, courts had awarded attorney fees — sometimes big ones — to brand drug companies in Hatch-Waxman litigations.

One prominent case was Takeda Chemical Indus. Ltd. v. Mylan Labs Inc., 459 F. Supp. 2d 227 (S.D.N.Y. 2006), aff'd 549 F.3d 1381 (Fed. Cir. 2008). The court awarded the brand a two-defendant combined $16.8 million fees and costs on the basis that the case was exceptional. In particular, the court had found (1) a rush by Mylan to position itself obtain first-to-file exclusivity despite not having obtained a legal opinion for its notice-letter theories; (2) objectively baseless presuit notice letters by Mylan and Alphapharm, which misidentified the closest prior art/lead compound and contained other errors, and failed to address commercial-success secondary considerations relevant to obviousness; (3) "ever-shifting" litigation positions (Mylan and Alphapharm abandoned their original invalidity theories, for instance adopting a new lead compound for obviousness). Id. at 235–46. Thus the court found the entire litigation both baseless and infected by misconduct, and awarded the brand the entirety of its requested fees and costs.

But generic patent challengers themselves have successfully used the 35 U.S.C. § 285 exceptional-case provision as a sword against the brands.

In AstraZeneca AB v. Dr. Reddy's Labs. Ltd., No. 07 Civ. 6790(CM), 2010 U.S. Dist. LEXIS 32883 (S.D.N.Y. March 30, 2010), the patent suit concerned a patented process for making omeprazole magnesium having 70% crystallinity in its final product. Astra itself tested DRL's samples and found no evidence of infringement. Despite that finding, Astra kept pushing on many fronts for more and more discovery, arguing that such a large amount of discovery was de rigueur in Hatch-Waxman cases. Finally, to avoid summary judgment, Astra concocted a baseless claim construction that was directly contradicted by the intrinsic patent record. Id. at *4–*9, *13–*15, *17, *20–*22.

In a stinging finding, the court stated, "It was obvious from very early that plaintiffs had brought and were maintaining this lawsuit in a desperate effort to keep any competing product from hitting the shelves — even if the competing product was not an infringing product." Id. at *2–*3. Finding the case exceptional ("frivolous"), the court awarded attorney fees and costs to the generic. See also In re Cyclobenzapine Hydrochloride Extended Release Capsule Patent Litigation (D. Del. Jan. 12, 2012) (granting attorney fees where brand continued litigation even after confirming no infringement (no recited plasticizer) in order to "police against possible reformulations").

Against the background of these awards, the Supreme Court replaced the existing standard for finding exceptional case, and lowered the quantum of proof from clear-and-convincing to preponderance-of-the-evidence: An exceptional case "is simply one that 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, 134 S. Ct. at 1756, 1758. One could be forgiven for seeing the replacement of the statutory-provision language — "exceptional" — with "stands out" as lying south of useful.

The ruling certainly appears to expand what could qualify as an exceptional case. And the companion case underscores the eerie, thin-ice feeling. Having rejected the earlier subjective/objective framework,

the Supreme Court ruled that, rather than appellate application of de novo/clear-error review, “an appellate court should apply an abuse-of-discretion standard in reviewing all aspects of a district court’s § 285 determination.” Highmark, 134 S. Ct. at 1749. Such deference will allow more trial court awards to stand.

What’s a generic to do in light of the changed exceptional-case playing field? Obviously, don’t “stand out” is the rule now. But what are such a rule’s limits in the Hatch-Waxman context?

We can get a wee bit of comfort from a case in which the brand moved for exceptional-case fees and failed. Shire LLC v. Amneal Pharms. LLC, Civ. A. No. 11-3781, 2014 U.S. Dist. LEXIS 85369 (D.N.J. June 23, 2014). There the court found that the filing of an abbreviated new drug application was merely a technical act of infringement, and that the safe-harbor provision of the Hatch-Waxman Act was broad. Id. at *26–*28.

The court then found that all substantive and procedural activities — including the signing of a supply contract between a defendant supplier and ANDA defendants covering future sales of the subject compound — were “the kinds of things Defendants in these cases typically do when they seek to market a generic version of a pharmaceutical protected by patents.” Id. at *25–*26, *27–*28. Notably, the court contrasted the conduct in a seminal, willful-infringement, case that involved “a wholly unjustified ANDA certification and misconduct during the litigation.” Id. at *26 (citing Yamanouchi Pharm.Co. v. Danbury Pharmacal Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000)). Accordingly, not “standing out” means “keeping it typical.”

In the end, we believe that best practices involve a close read of pre-Octane and Highmark cases, with the understanding that it may be easier — for both sides of the "v." — now to obtain exceptional-case awards. The core dos and don’ts from these earlier cases are these:

- Do ensure that the notice letter and all supporting opinions are timely researched and prepared, and that they adequately and accurately provide the required detailed fact and legal bases that underlie them — in particular, courts will wonder about prior art that the defendant ought to have known about as part of presuit due diligence.

- Do address, if there’s an obviousness theory, secondary considerations; do not take the position that a discussion of, e.g., commercial success, isn’t appropriate prior to discovery.

- Do mind your adversary’s (mis)conduct: If, for instance, the plaintiff does not abandon a position, or indeed the litigation as a whole, once there’s a decision or discovery that is fatal to a material part of plaintiff’s case — continuing in the face of such a development can be litigation misconduct, and the generic can get its fees and costs.

- Don’t switch legal theories without a very good explanation of why the abandoned theory was reasonable presuit.

- Don’t beat a dead horse if, e.g., the Markman ruling kills your case: you may only incur further, exceptional-case, exposure.

And always bear in mind the bottom line underlying all of these points: To avoid exceptional-case fees and costs, don't stand out!

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***Disclosure: At a previous firm, the author worked on behalf of Alphapharm Pty. Ltd. on the Takeda case discussed herein.***