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Takeaways For Generics After Octane And Highmark

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The generic pharmaceutical business is competitive.[1][2] Profit margins are typically a fraction of those for branded drug products.[3] The majority of those profits are often made in the 180 day limited exclusivity period[4][5][6] afforded the first abbreviated new drug application filer to successfully challenge patent(s) protecting a branded drug.[7] One of the earliest "legal" steps[8] toward becoming a first ANDA filer typically involves obtaining an opinion evaluating the claims of in-force patent(s), especially Orange Book[9] listed patents, covering a branded drug.[10] Opinions provide legal basis for a Paragraph (IV)[11] certification letter and subsequent litigation in which the generic attempts to show that patent(s) covering the branded drug are not infringed, are invalid and/or should not be enforced. A good opinion, in addition to increasing the likelihood of the generic prevailing in litigation or favorably settling the case,[12] also increases the probability that the generic will avoid fee shifting[13] and sanctions.[14] A good opinion can thus be worth its weight in gold.

When it comes to patent litigation, the American rule is that each litigant pays its own attorney's fees, win or lose.[15] Fee shifting is the exception to the American rule. 35 U.S.C. § 285 empowers courts to "shift" fees (e.g., to require the plaintiff to bear the defendant's attorney's expenses or vice versa) in "exceptional cases."[16] Previously, fee shifting in patent cases was decided under the standard articulated in Brooks.[17] Under Brooks, absent misconduct in securing the patent or in litigation, a case could be found exceptional, and fee shifting could be imposed, only if: (1) the litigation was brought in subjective bad faith and (2) the litigation was objectively baseless.[18] The fee-shifting standard has now been relaxed in two recent U.S. Supreme Court cases: Highmark[19] and Octane Fitness.[20]

The path to the Supreme Court in Highmark[21] began when Highmark Inc., sued Allcare Health Management System Inc., in federal court, seeking a declaratory judgment that Highmark's U.S. Patent No. 5,301,105 was invalid, unenforceable and that there was no claim infringement.[22] Allcare counterclaimed for patent infringement. Both sides filed motions for summary judgment and the district court entered a final judgment of noninfringement in favor of Highmark.[23] Moving for and winning on summary judgment is de facto becoming a necessary precursor for a fee-shifting award.

A summary judgment motion serves at least three purposes toward advancing a fee-shifting argument:

(1) the MSJ indicates that the moving party believes the opposing party's position is frivolous; (2) if successful, the MSJ limits litigation expenses because a full trial becomes unnecessary (timely disposition and lower total fees may favorably predispose a district court toward fee shifting); and (3) a district court's granting the MSJ can help lay the groundwork for finding a case to be worthy of fee shifting.[24]

After MSJ grant, Highmark moved for fee shifting and the district court granted Highmark's motion.[25] The district court determined that Allcare had engaged in arguably deceptive practices, maintained meritless infringement claims and asserted frivolous defenses.[26] The court awarded approximately $4.7 million in attorney's fees, $380,000 in expert fees and $210,000 in expenses.[27] The court's fee-shifting award is representative of what can happen when fees are shifted (i.e., in addition to their own costs, a litigant can be on the hook for an opponent's costs which can run well into seven figures).

On appeal, a circuit court affirmed the district court's exceptional case determination with respect to one claim, reversed with respect to another and found that "none of Allcare's conduct warranted an award of fees under the litigation-misconduct prong of Brooks Furniture."[28] The circuit circuit's review standard was de novo.[29]

The Supreme Court granted certiorari to determine "whether an appellate court should accord deference to a district court's determination that litigation is 'objectively baseless'."[30] Relying on the ordinary meaning of § 285, the Supreme Court held the Brooks standard to be "unduly rigid and inconsistent with the text of § 285."[31] In place of the Brooks standard, the Supreme Court held that an exceptional case "is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."[32] The court also held that "an appellate court should apply an abuse-of-discretion standard in reviewing all aspects of a district court's § 285 determination."[33] The court thus vacated the circuit court's judgment and remanded the case for further proceedings.[34]

Octane Fitness was decided on the same day as Highmark. Icon Health & Fitness Inc. sued Octane, alleging infringement of several claims of U.S. Patent No. 6,019,710.[35] Octane moved for and was granted summary judgment by the district court.[36] Octane then moved for fee shifting under § 285. The court denied Octane's motion because it did not meet the "objectively baseless" and "brought in subjectively bad faith" Brooks criteria.[37] Icon and Octane appealed, and the circuit court affirmed the district court's determinations.[38] The Supreme Court granted certiorari.

On appeal, the Supreme Court determined that the Brooks framework was "unduly rigid" and "impermissibly encumbers the statutory grant of discretion to district courts."[39] The high court, as in Highmark, held that "an 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated."[40] Emphasizing the fluid nature of its analysis, the court approvingly quoted that "'[t]here is no precise rule or formula for making these determinations,' but instead equitable discretion should be exercised 'in light of the considerations we have identified.'"[41] The high court also rejected the circuit's requirement that "patent litigants establish their entitlement to fees under § 285 by 'clear and convincing evidence.'"[42] Instead, the court held that the proper evidential standard was preponderance of the evidence because it is "generally applicable in civil actions" and it "allows both parties to 'share the risk of error in roughly equal fashion.'"[43] The case was reversed and remanded to the circuit court.

The Supreme Court's replacement of a "rigid" circuit court rule in Highmark and Octane Fitness with a

more flexible standard has ample precedent. For example, in Bilski,[44] the Supreme Court struck down the circuit's rigid "machine or transformation test" for patent eligibility as unduly rigid. Also, in KSR,[45] the Supreme Court replaced the circuit's rigid "teaching-suggestion-motivation" test with a more flexible, reason-based inquiry. Subsequent application of these more flexible standards resulted in an increase in the number of claims found to be not patent eligible or found to be obvious, respectively.[46] Accordingly, although the award of fee shifting — as an equitable remedy — should still be the exception, we anticipate that the frequency of fee shifting awards will increase post Highmark and Octane Fitness.

There is a history of fee shifting in generic pharmaceutical cases. For example, in Yamanouchi, attorney's fees were awarded to the prevailing branded manufacturer.[47] In addition to fee shifting, the generic in this case also (presumably) paid its own litigation expenses. In general, pharmaceutical patent litigation has been compared to horse racing (the sport of kings) because of its significant associated costs and the high stakes involved.[48] Shifted fees (and possibly sanctions and interest) and the lost opportunity to market a product can be painful base litigation cost multipliers. Opinions that make prima facie cases, and Paragraph (IV) letters based on these, can minimize fee-shifting risk.

The Supreme Court's recent Octane Fitness and Highmark decisions, thus, further raise the stakes for generic and branded manufacturers by increasing the potential for fee shifting. These decisions make it easier for district courts to shift the winning party's attorney fees — which can be reach into the millions of dollars — onto the losing party. At the same time, the decisions also limit circuit courts' ability to reverse a district court fee-shifting determination. Octane Fitness and Highmark thus further increase the value of a good opinion.

Below, we present nine recommendations for in-house generic pharmaceutical counsel that may decrease the risk of fee shifting (and sanctions) and increase the likelihood of prevailing in litigation, in a small molecule pharmaceutical patent Hatch-Waxman litigation.

Scrutinize Paragraph IV Certification Letters Well Before ANDA Filing and Sending

In the past, some generic pharmaceutical companies would file "bare bones" Paragraph (IV) certification letters with the idea of "sorting it out later" during and at the conclusion of pretrial discovery. This is not a recommended best practice. District courts can be reluctant to allow a generic to move away from legal positions asserted in its Paragraph (IV) certification letter. Also, where moving away from Paragraph (IV) certification letter legal positions is possible, asserting substitute legal arguments can signal to the district court that the case may be exceptional. It is recommended that generic in-house counsel carefully scrutinize Paragraph (IV) certification letters as the positions espoused in these letters are likely to be the positions the generic will assert at trial.

Do Not Cut Corners on Opinions

A good opinion is valuable. As discussed above, because generics' profit margins are typically a fraction of branded manufacturers' profit margins, there are incentives to save costs wherever possible, including on opinions which are generally expensive. As the Yamanouchi case shows, however, cost saving can be an expensive mistake if it results in cutting corners in the opinion that will be relied upon for a Paragraph (IV) certification letter and subsequent litigation.

Hire Experienced Outside Counsel Who are Technically and Legally Qualified

Formulating invalidity, noninfringement and inequitable conduct positions requires strong legal and technical skill sets. It is recommended that generic in-house counsel work with experienced outside counsel who have strength in all of these areas.

Be Actively Involved With Outside Counsel in the Creation of the Opinion

The best opinions arise out of a productive collaboration between generic in-house counsel and outside counsel. Work productively with outside counsel[49] to optimize the strength and accuracy of the opinion.

Make Sure All Elements of any Prima Facie Case are Present

Generics have been sanctioned and fee shifted for not making prima facie cases of invalidity and inequitable conduct which, in the district courts' (and the circuit courts') opinions, rendered their litigation baseless. When reviewing an opinion, for each asserted position, make sure all prima facie elements are present. Proactively discuss any questions regarding these with outside counsel.

Make Sure Contrarian Facts or Statements that May Appear in an Opinion are Addressed

In addition to making sure that opinions contain all elements of any prima facie case, it is recommended that generic in-house counsel also review the references relied upon in the opinion to make sure that the references do not contain scientific facts or statements that: (1) appear contrary to a position taken in the opinion; and (2) are not addressed in the opinion.

Get a Second Take if Something in an Opinion Seems "Off"

Generic in-house counsel are busy, often tracking up to 100 projects at a time in addition to attending meetings, corresponding with and managing outside counsel and internally counseling their management. Sometimes, after reading an opinion, significant questions may be raised in generic counsel's mind. Those significant questions may remain even after discussion(s) with outside counsel who drafted the opinion. When this is the case, generic in-house counsel should consider having the opinion reviewed by different outside counsel before proceeding to Paragraph (IV) certification and litigation.

Coordinate Litigation and Opinion Counsel as Early as is Practicable

Historically, moving litigation positions away from those taken in the Paragraph (IV) certification letter has been associated with fee shifting and sanctions. While advocating positions that are different from those in the Paragraph (IV) certification letter is sometimes justified and understandable (when permitted) because of, for example, new information unearthed in discovery, it is generally recommended to litigate based on positions outlined in the Paragraph (IV) certification letter. Coordination of litigation and opinion counsel can help insure that Paragraph (IV) certification letter positions are litigated.

Consider the Best Venue to Challenge Branded Patent(s)

Although ANDA actions are initiated in a district court, it may be advantageous to file an inter partes review at the U.S. Patent and Trademark Office. In an IPR, a patent does not enjoy a presumption of validity, claims are given their broadest reasonable interpretation and the standard to invalidate is

lower. Also, IPR administrative law judges are technologically savvy and the IPR process is typically quicker than litigating in district court.

Conclusion

To reduce the risk of fee shifting and sanctions — and increase the likelihood of prevailing in litigation — opinions should be drafted by experienced attorneys having demonstrated legal and scientific skill sets. Opinions should be drafted with the perspective and understanding that the opinions will be materially relied upon in litigation. Also, given the importance of opinions to litigation success and avoidance of fee shifting and sanctions, legal positions taken in opinions should be well-researched, tightly reasoned, clearly articulated and legally complete.

In this context, a stitch in time truly saves nine — cutting corners should be avoided. Opinions should be critically reviewed by in-house counsel and any questions raised by the review should be addressed before moving forward with Paragraph (IV) certification and litigation. If, after review and consultation, significant uncertainty remains regarding key portion(s) of the opinion, consider having a confidential, outside evaluation of the opinion conducted by a firm that did not author the opinion. Further, it is a best practice to coordinate opinion counsel and litigation counsel. Finally, determine if litigation at the USPTO is appropriate, and if so, when.

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[1] Generic pharmaceuticals fill 80 percent of U.S. prescriptions but consume just 27 percent of total drug spending. See “IMS Health, National Sales Perspectives, November 2011,” National Prescription Audit, December 2011.

[2] The top five generic pharmaceutical corporations (by unbranded generic prescriptions dispensed) are: Teva Pharmaceuticals USA, Mylan Labs Inc., Actavis, Sandoz and Lupin Pharma. See “The Industry”, Generic Pharmaceutical Association, available online at: http://www.gphaonline.org/about/the-industry.

[3] As of 2013, the average profit margin for generic pharmaceutical companies was 5.4 percent. In

contrast, the largest average profit margin for major branded drug manufacturers was 18.4 percent. See T. C. Wright, "The Average Profit Margin of Pharmaceuticals," azcentral, available online at: http://yourbusiness.azcentral.com/average-profit-margin-pharmaceuticals-20671.html.

[4] Section 505(j)(5)(B)(iv) of the Federal Food, Drug and Cosmetic Act establishes a 180-day period following the approval of an ANDA, during which U.S. Food and Drug Administration may not approve other ANDAs for the same drug product. Although commonly known as "180-day exclusivity", the 180-day exclusivity period is not truly "exclusive" as the new drug application holder, its distributors and its licensees continue to sell the originally approved drug product during the 180-day exclusivity period.

[5] If there are multiple ANDAs submitted on the same day as the first ANDA qualifying for 180-day exclusivity, they all share the 180-day exclusivity, thereby further depressing profits.

[6] As of 2011, 68 percent of generic drugs were launched without the 180-day exclusivity period. See "Frequently Asked Questions", Authorized Generics, available online at: http://www.authorizedgenerics.com/default.asp?contentID=29.

[7] "In general, most generic companies estimate that 60 to 80 percent of their potential profit for any one product is made during this [180 day] exclusivity period." D. F. Coughlin and R. A. Dede, "Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective", 25 Biotech. L. Rep. 525, 525-26 (2006).

[8] One of the earliest steps (legal and nonlegal) in getting a generic drug to market is finding a source of the active pharmaceutical ingredient in the branded drug product. See, e.g., B. Burck, "Preparing for Paragraph IV Patent Challenges," slide 18, available online at: http://thomsonreuters.com/business-unit/science/pdf/ls/newport_paragraphIV_webinar_slides.pdf.

[9] The Orange Book, also known as Approved Drug Products with Therapeutic Equivalence Evaluations, is maintained by the FDA and is available online at: http://www.accessdata.fda.gov/scripts/cder/ob/.

[10] These opinions are typically provided by outside law firms working in collaboration with generic pharmaceutical company in-house counsel.

[11] See 21 U.S.C. § 355(b)(2)(A)(iv).

[12] Some settlements result in reverse payments to the generic by the brand in return for the generic: (1) staying off of the market; and (2) agreeing to dispense with the lawsuit. The Supreme Court recently held that reverse payments are not presumptively unlawful, but are subject to a rule of reason analysis. See FTC v. Actavis, No. 12-416, 570 U. S. ____ (June 17, 2013), available online at: http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf .

[13] See 35 U.S.C. § 285.

[14] See Fed.R.Civ.P. 11.

[15] See Octane Fitness LLC v. Icon Health & Fitness Inc., 134 S. Ct. 1749, 1753 (2014).

[16] 35 U.S.C. § 285 recites: "The court in exceptional cases may award reasonable attorney fees to the prevailing party."

[17] See Brooks Furniture Manufacturing Inc. v. Dutailier International Inc., 393 F.3d 1378 (Fed. Cir. 2005).

[18] Id. at 1381.

[19] Highmark Inc. v. Allcare Health Management System Inc., 134 S. Ct. 1744 (2014).

[20] Octane Fitness LLC v. Icon Health & Fitness Inc., 134 S. Ct. 1749 (2014).

[21] Highmark Inc. v. Allcare Health Management System Inc., 134 S. Ct. 1744 (2014).

[22] Id. at 1747.

[23] Id.

[24] The authors are aware of no legal requirement to file for summary judgment as a prerequisite to being awarded fee shifting. Nevertheless, at the district court level, a motion for summary judgment preceded an award of fee shifting in Highmark. Further, a recent district court opinion, Stragent LLC v. Intel Corp., 11-cv-0421 (E.D. Texas 2014) (authored by Circuit Judge Timothy B. Dyk sitting by designation), highlights the apparent importance of motioning for summary judgment as a precursor to a fee shifting award.

Stragent's argument was certainly a weak one, but despite the alleged implausibility of Stragent's position, Intel never sought summary judgment of noninfringement on the basis of the limitation at issue. This suggests that Intel did not always view Stragent's infringement position as frivolous. There is little injustice in forcing Intel to bear its own attorney's fees for defending a claim it did not challenge on summary judgment. Disposing of a frivolous claim on summary judgment would avoid a trial and have the effect of saving both parties a substantial portion of their litigation costs.

[25] Highmark Inc. v. Allcare Health Management System Inc., 134 S. Ct. 1744, 1747 (2014).

[26] Id.

[27] Id.

[28] Id.

[29] Id.

[30] Id. at 1746.

[31] Id. at 1748.

[32] Id. at 1748, citation omitted.

[33] Id. at 1749. The court noted, at 1748, that traditionally the following standards of review apply: question standard of review; questions of law de novo; questions of fact clear error; and questions of discretion abuse of discretion.

[34] Id. at 1749.

[35] Octane Fitness LLC v. Icon Health & Fitness Inc., 134 S. Ct. 1749, 1755 (2014).

[36] Id.

[37] Id.

[38] Id.

[39] Id.

[40] Id.

[41] Id. at 1756.

[42] Id. at 1758.

[43] Id.

[44] See Bilski v. Kappos, 130 S. Ct. 3218 (2010).

[45] See KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007).

[46] For example, over "the five years since KSR was decided, the circuit court has reached a final determination of obviousness at a rate about 10 percent greater than during the 10-year period prior to the Supreme Court's grant of certiorari." J. Rantanen, "The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study", 16 Stan. Tech. L. Rev. 709, 751 (2013).

[47] See Yamanouchi Pharmaceutical Co. Ltd. v. Danbury Pharmacal Inc., 231 F.3d 1339 (Fed. Cir. 2000).

[48] When more than $25 million were at risk, the mean estimated total cost for a Hatch-Waxman patent infringement suit is about $7 million. See "Report of the Economic Survey", AIPLA, 37 (2013).

[49] Generic in-house counsel knows the product, API and synthetic route thereto better than anyone. Their input into the opinion is, for at least these reasons, invaluable.
