

ANDA Access Negotiations May Affect Attorney Fee Liability

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When an applicant files an abbreviated new drug application with a Paragraph IV certification against Orange-Book-listed patents, the Hatch-Waxman framework requires the applicant to provide the patent owner and NDA holder with notice of the ANDA along with an offer for confidential access (“OCA”) to review the ANDA.[1] Under the framework, if the NDA holder brings an action for patent infringement within 45 days of receiving notice, it triggers a 30-month stay of U.S. Food and Drug Administration approval of the ANDA.[2]

Access to the ANDA under the OCA is meant to facilitate the NDA holder’s determination of “whether an action ... [for infringement] should be brought.”[3] To address any concern the ANDA applicant may have that the NDA holder will use information in the ANDA for purposes other than evaluating infringement — for example, to gain an undue advantage in the marketplace — the Hatch-Waxman statute requires that any person reviewing an ANDA under the OCA “review the application for the sole and limited purpose of evaluating possible infringement.”[4] Moreover, the statute provides that “[t]he document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.”[5]

Accordingly, ANDA applicants often include restrictions in their OCA similar to those found in a protective order. Such restrictions require that individuals receiving access to the ANDA under the OCA agree to refrain from certain activities that could allow for misuse of the ANDA information. For instance, the applicant may include a prosecution bar to address concerns that the NDA holder will use ANDA information in proceedings at the U.S. Patent and Trademark Office. That is, after reviewing the ANDA, the NDA holder could potentially seek new patents that address validity concerns but still read on the ANDA product, or the NDA holder could alter the scope of the Orange-Book-listed patent claims to

cover the ANDA product during inter partes review proceedings. Sometimes the applicant will include an FDA bar in the OCA to address concerns that information from the ANDA could be misused to file a citizen petition with the FDA to delay the challenged application's approval.[6]

If the NDA holder requests access to the ANDA, the request is considered to be an acceptance of the OCA including its restrictions.[7] Often, however, the NDA holder and the ANDA applicant will disagree on the restrictions in the OCA. An NDA holder can object to terms in an OCA that it finds to be unreasonably restrictive, but if it cannot come to an agreement with the ANDA applicant, it won't get access to the ANDA prior to filing its suit for patent infringement. In instances where the ANDA applicant has alleged noninfringement in its notice letter, the NDA holder should tread carefully because the U.S. Supreme Court's recent decision in *Octane Fitness* may create exposure to liability for attorneys' fees under 35 U.S.C. § 285. After *Octane Fitness*, failing to review the ANDA prior to filing a complaint may support finding a case exceptional where the ANDA product is ultimately determined not to infringe and such noninfringement is clear from the ANDA.

The Prefiling Investigation After *Octane Fitness*

Octane Fitness significantly lowered the standard for finding a case exceptional under 35 U.S.C. § 285. And, importantly for our purposes, inadequate prefiling investigation can form the basis for a finding of exceptional case and an award of attorneys' fees to the prevailing party.

35 U.S.C. § 285 is a patent-specific fee-shifting statute that provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." Prior to *Octane Fitness*, courts applied the *Brooks Furniture* standard to determine if a case was "exceptional" under the statute.[8] Under *Brooks Furniture*, cases were only found exceptional when defendants could prove by clear and convincing evidence that the patentee acted in subjective bad faith, and that the patentee's case was objectively baseless.[9]

Octane Fitness lowered this standard: Courts now consider the totality of the circumstances in evaluating exceptionality.[10] The most commonly cited ways to show exceptionality are: (1) establishing that the plaintiff failed to conduct an adequate prefiling investigation or to exercise due diligence before filing suit; (2) showing the plaintiff should have known its claim was meritless or lacked substantive strength; (3) evidencing the plaintiff initiated litigation to extract settlements from defendants who want to avoid costly litigation; (4) showing a party proceeded in bad faith; and (5) evidencing litigation misconduct.[11] And a combination of conduct creates the strongest case for finding a case exceptional and awarding fees.

No post-*Octane Fitness* cases directly address OCAs, but several cases evaluate the sufficiency of prefiling investigation under the new framework. These cases have required at least basic infringement analysis for prefiling investigation. For instance, in *Yufa*, the patentee filed suit without actually purchasing or evaluating the defendant's products for infringement. He instead relied on some advertisements and articles — none of which actually suggested that the accused product contained the claim limitations of the patented invention. The patentee also countered that he "tried to purchase" the accused devices, but was turned away as the company did not sell to individuals. Citing *Octane Fitness*, the court still found that the lacking pre-filing investigation "weigh[ed] in favor of finding that this case is exceptional,"[12] citing back to Rule 11 Federal Circuit precedent that an adequate prefiling investigation into infringement requires the patentee to interpret the patent claims and compare the accused device to those interpretations.

Patentees are not able to just check a box that they conducted some semblance of a pre-filing investigation. Their investigation must be complete. Kilopass somewhat oddly illustrates this concept: Kilopass received an opinion that suggested no literal infringement from one counsel. It then sought an opinion from different counsel which suggested it might be possible to advance a particular theory in litigation, but the firm would need to investigate further. Kilopass told them to cease work, but still relied on that incomplete initial opinion as a basis for the litigation and their infringement allegations. The court cited Octane Fitness and pointed to the lack of pre-filing investigation among other violations to award fees. [13]

Moreover, the pre-filing investigation must be meaningful. In the Chalumeau Power case, the plaintiff defended its infringement contentions, stating that it conducted a “thorough pre-filing investigation of each of the accused products” and “separately charted with relevant supporting technical documentation” each family of accused product. The court then asked for supporting documentation for their pre-filing investigation, but, upon this request, the plaintiff admitted that it didn’t vet every accused product family before filing suit. It provided a document analyzing infringement for one series of products — but that document was only five pages and one page was a cover page. Even though this constituted “some semblance” of a presuit investigation, the court found that it was lacking. This coupled with the “meager effort” put forth in the rest of the suit justified fees under Octane Fitness.[14]

Inadequate pre-filing investigation combined with litigation misconduct and “forging ahead” in a case that was “going nowhere” justified fees in Bayer. In Bayer the judge found only “one reasonable interpretation” for key issues in the case, and noted that Bayer’s arguments were based on “contorted theories and conjectural conclusions that did not trump reality and amounted to distraction.” It found that the “better and prudent course of action would have been to abandon the action” altogether.[15]

Prior to Octane Fitness, ANDA applicants had little recourse if an NDA holder brought suit despite having access to clear evidence of noninfringement in the applicant’s ANDA.[16] But post-Octane Fitness, ANDA applicants may be able to build a record, beginning with a refusal to conduct a pre-filing ANDA review, that bringing and maintaining meritless infringement allegations warrants finding a case exceptional under § 285. As the discussed cases indicate, pre-filing investigation must be meaningful, and forging ahead after conducting a cursory analysis and evaluation of the ANDA can still create an exceptional case.

What If the Proposed Restrictions in the ANDA Applicant’s OCA Are Unreasonable?

Filing suit without reviewing the ANDA may be justifiable if the terms of the OCA are not reasonable and the NDA holder at least tried to negotiate more reasonable terms. No cases directly address unreasonable OCA terms under the new exceptional case standard, but two pre-Octane Fitness cases approach the issue in the Rule 11 context.

In Cyclobenzaprine,[17] the plaintiffs refused to accept the defendant’s offer of access for being too restrictive. The plaintiff made several attempts to obtain ANDA access and was willing to observe the restrictions and limitations of the protective order in other member cases, but the defendant “rebuffed these efforts, and did not respond to plaintiff’s final request to receive the ANDA under Delaware Local Rule 26.2.”[18] The court found that filing without viewing the ANDA here “did not run afoul of Rule 11,” instead viewing the terms to be tantamount to a refusal by the defendant to provide access to the ANDA.

The Federal Circuit also considered the sufficiency of pre-filing investigation in the Rule 11 context in

Hoffmann-La Roche.[19] In Hoffman-La Roche, the NDA holder was concerned that the manufacture of the ANDA product would infringe its patents on a process for synthesizing a drug. After the parties conferred, the ANDA applicant provided a sample of the proposed ANDA product, but it would not disclose its manufacturing information. Based on the sample alone, the NDA holder was unable to ascertain whether the process of producing the ANDA product infringed its patent, so it filed suit for infringement. The Federal Circuit affirmed a denial of sanctions under Rule 11: “It is difficult to imagine what else Roche and Syntex could have done to obtain facts relating to Torpharm’s alleged infringement of their process patents. Torpharm has pointed to nothing else that it believes they could or should have done.”[20]

In these cases, the plaintiffs escaped Rule 11 sanctions despite filing suit without conducting a complete prefiling analysis. It is likely that, under the totality of the circumstances inquiry of Octane Fitness, when the ANDA applicant insists on unreasonable OCA restrictions and is unwilling to negotiate in good faith, filing suit without first reviewing the ANDA likely similarly will not contribute to case being found exceptional under Octane Fitness. It is worth noting, however, that these cases were decided prior to Octane Fitness and under the higher Rule 11 inquiry.

Litigants should look to protective order jurisprudence to evaluate whether OCA terms are acceptable. In the protective order context, disputes typically arise over the scope and duration of limitations on who can access designated material. Courts focus on the facts when resolving these issues: For example, when courts evaluate patent prosecution bars, they will consider the “extent and duration of counsel’s past history in representing the client before the PTO, the degree of the client’s reliance and dependence on that past history, and the potential difficulty the client might face if forced to rely on other counsel for the pending litigation or engage other counsel to represent it before the PTO.”[21]

So How Should ANDA Applicants and NDA Holders Navigate the OCA?

Octane Fitness’ standard is reasonableness, not bad faith, and parties should approach their negotiations over OCA restrictions with reasonableness in mind. NDA holders should at least try to negotiate OCA terms,[22] building a record that they made an effort such that it’s not unreasonable to refuse to review the ANDA under the conditions the ANDA applicant seeks to impose. A position that an OCA term is unreasonable should be grounded in actual harm or prejudice that the NDA holder may suffer if accepted. Such a position can be bolstered if similar terms proposed in protective orders have been found to be unreasonable. Outright refusal of an OCA without justification could lead to attorneys’ fees liability, particularly where the applicant’s notice letter has put the NDA holder on notice of noninfringement and reviewing the ANDA would have demonstrated that an infringement claim is meritless.

ANDA applicants too should start building a record early on for fee shifting — taking note of the NDA holder’s disinterest in negotiations. OCA restrictions should be crafted to provide reasonable protections of the ANDA applicant’s interests. Here too, the ANDA applicant should look to whether similar terms are found in protective orders. The key is to avoid putting unreasonable burdens in your terms, otherwise during an evaluation for fees, the NDA holder may be deemed to have been justified in refusing the OCA. And failure to evaluate an OCA presuit is only one factor in the exceptional case inquiry, so the ANDA applicant would do well to make a record of all instances of egregious conduct on the part of the NDA holder.

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[1] 21 U.S.C. § 355 (j)(5)(C)(i)(III).

[2] 21 U.S.C. § 355 (j)(5)(B)(iii).

[3] 21 U.S.C. § 355 (j)(5)(C)(i)(III).

[4] *Id.*

[5] *Id.*

[6] 21 C.F.R. § 10.30.

[7] 21 U.S.C. § 355 (j)(5)(C)(i)(III) (“A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract.”).

[8] *Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc.*, 393 F.3d 1378 (Fed. Cir. 2005) abrogated by *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014).

[9] *Id.* at 1381-1382.

[10] *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014) (“District courts may determine whether a case is “exceptional” in the case-by-case exercise of their discretion, considering the totality of the circumstances.”).

[11] *Bayer Cropscience AG v. Dow Agrosciences LLC*, No. CV 12-256 (RMB/JS), 2015 WL 1197436, at *4 (D. Del. Mar. 13, 2015); see also *TechRadium, Inc., v. FirstCall Network, Inc.*, No. CIV.A. 13-2641, 2015 WL 862326, at *6 (S.D. Tex. Feb. 27, 2015).

[12] *Yufa v. TSI Inc.*, No. 09-CV-01315-KAW, 2014 WL 4071902, at *3 (N.D. Cal. Aug. 14, 2014).

[13] *Kilopass Tech. Inc. v. Sidense Corp.*, No. C 10-02066 SI, 2014 WL 3956703, at *14 (N.D. Cal. Aug. 12, 2014).

[14] *Chalumeau Power Sys. LLC v. Alcatel-Lucent*, No. CV 11-1175-RGA, 2014 WL 4675002, at *2 (D. Del. Sept. 12, 2014).

[15] *Bayer CropScience AG v. Dow AgroSciences LLC*, No. CV 12-256 (RMB/JS), 2015 WL 108415, at *4 (D. Del. Jan. 5, 2015) report and recommendation adopted in part, No. CV 12-256 (RMB/JS), 2015 WL 1197436 (D. Del. Mar. 13, 2015).

[16] See, e.g., *Celgene Corp. v. KV Pharm. Co.*, No. CIV.A. 07-4819(SDW), 2008 WL 2856469, at *1-5 (D.N.J. July 22, 2008) (finding Plaintiff's pre-filing investigation sufficient under Rule 11 when Plaintiff filed an infringement suit after receiving an ANDA notice letter but without completing a pre-filing infringement analysis).

[17] *In re Cyclobenzaprine Hydrochloride Extended-Releases Capsule Patent Litig.*, 693 F. Supp. 2d 409, 416 (D. Del. 2010).

[18] Delaware Local Rule 26.2 reads:

If any documents are deemed confidential by the producing party and the parties have not stipulated to a confidentiality agreement, until such an agreement is in effect, disclosure shall be limited to members and employees of the firm of trial counsel who have entered an appearance and, where appropriate, have been admitted pro hac vice. Such persons are under an obligation to keep such documents confidential and to use them only for purposes of litigating the case.

[19] *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).

[20] *Id.* at 1364.

[21] *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1380-1381 (Fed. Cir. 2010).

[22] *Pure Fishing, Inc. v. Normark Corp.*, No. 10-2140, 2014 WL 5474589, at *4 (D.S.C. Oct. 28, 2014) (noting that bad faith is no longer required to support an award of fees but finding the plaintiff's position was not reasonable).
