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Trade Secret Pitfalls For The Hatch-Waxman Litigant

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Experienced Hatch-Waxman litigants are well familiar with the requirement that a generic drug manufacturer must provide a presuit offer of confidential access ("OCA") to its abbreviated new drug application when challenging an Orange Book-listed patent.[1] But many litigants do not give sufficient attention to the competitive risks associated with such access and how to best protect against misuse or allegations of misuse. Well-established principles of trade secret law provide critical guidance on developing strategies for minimizing liability while optimizing the protection and exploitation of what are often considered a company's most valuable assets — its trade secrets.


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The type of information that may be disclosed in connection with an OCA is often competitively sensitive and should otherwise be protectable as secrets under U.S. law. In addition to confidential technical and scientific information, generic drug manufacturers often (and perhaps without realizing) disclose confidential business information, such as the identities of active pharmaceutical ingredient suppliers, names of contacts at contract research organizations, and commercial details regarding ingredients and equipment used throughout the drug development process. The implications of disclosing or receiving business and technical information to or from a competitor can be significant and requires thoughtful consideration and careful planning.

The Hatch-Waxman Act has some built-in protections against misappropriation. For example, the act provides that any party receiving confidential information under an OCA can only use the information for the purpose of determining whether an action for infringement of the Orange Book-listed patent can be brought.[2] To that end, the act requires that the OCA contain restrictions as to access, use, and disposition of the information in the ANDA, akin to those that "would apply had a protective order been entered for the purpose of protecting trade secrets."[3] So in practice, drafting the OCA as a quasi-standalone protective order can help prevent misappropriation by confirming confidentiality obligations during and after the 45-day window for review. This should include assigning responsibility for who receives access to the ANDA, exactly how they are allowed to use information found in the ANDA, how that information is to be tracked and stored, and how the information is dealt with upon expiration of the review period.

In practical terms, the act's OCA requirement places both generic and innovator companies in unique

situations of differing vulnerabilities. For the generic company's part, it feels like a lopsided deal — handing over valuable secrets to a soon-to-be competitor in a marketplace where differentiating yourself is critical, usually followed by a lawsuit. A prudent strategy should, among other things, minimize the amount of competitive intelligence being delivered. This can be accomplished by careful consideration of what should and should not be redacted from the ANDA prior to giving access."[4] Even more important, as discussed in greater detail below, are the contractual aspects of the generic company's protection strategy.

Still, an OCA is in no way a windfall for the innovator, and they should be diligent and strategic in negotiating the terms of an OCA. Possessing a competitor's trade secrets can inject various levels of risk into the innovator's operations, including actual liability for misappropriation or allegations of misuse that can result in costly litigation. Here, part of the innovator's strategy should be to ensure that the personnel tasked with evaluating the ANDA under an OCA understand not only their limited objectives under the act, but also the considerable legal and ethical risks involved. Additionally, simply signing an OCA in the form presented by the generic company can be a serious mistake.

Thus, it is critical for both parties to have an understanding of the obligations created by an OCA, the basis of which will be rooted in the provisions if the OCA itself.

Persons Entitled to Access

Generic and innovator drug companies alike face a constant threat of misappropriation in the form of careless (or sometimes deliberate) employees with access to competitively sensitive information. This threat can originate in individuals given access to an ANDA under an OCA, and so it follows that access should only be given to those with a true need for it. To be sure, the act seemingly recognizes this potential threat and explicitly contemplates restrictions being placed on who may access the ANDA in order to evaluate possible infringement.

Here, the generic company should always give careful consideration to whether certain in-house counsel and outside counsel for the innovator company are competitive decision makers,[5] as disclosure to such individuals risks placing the generic at a competitive disadvantage. While not always competitive decision makers, outside counsel often advise on citizen petitions and other matters before the U.S. Food and Drug Administration that may have effect on the generic's regulatory and litigation positions. The generic should consider accounting for such individuals in the restrictions of its OCA. While many OCAs include a provision restricting access to outside counsel and their staff only, this standard limitation affords the generic company only some level of protection against misuse.

Other limitations that should be considered include: (1) limiting the number of outside counsel and staff who will be provisioned access; (2) requiring that each individual requesting access be identified in writing (including staff members); and (3) allowing for a period of time during which the OCA provider can object to any individuals identified as requesting access. Each of these limitations serves to further mitigate the risk of misappropriation and places the generic company in a better position to monitor whether the innovator performs as expected under the OCA.

In turn, a prudent innovator will identify what is at risk, and particularly what threats it faces in being subject to an OCA that restricts access to particular individuals. Oftentimes, in-house counsel for the innovator play an integral role in securing regulatory approval and/or planning enforcement of the patents at issue. When such counsel is in the best position to evaluate an ANDA for possible infringement, the innovator should consider challenging any provisions restricting access to outside

counsel only.[6] If those efforts fail, the innovator may consider seeking the entry of a protective order by the court that permits certain in-house counsel access. But risk management here is critical. In theory, the innovator has and likely is still working on technologies that may be similar to those disclosed in the generic company's ANDA. In addition to research and development, this work may include patent prosecution activities as well as proceedings that allow for amendments of patent claims, including inter partes review. Therefore, the potential for contamination is great, and once it occurs, it can be difficult to contain. For those and other reasons, the generic company often drafts OCA provisions that attempt to exclude certain counsel from accessing the ANDA and/or from having any involvement with patent prosecution matters on behalf of the innovator.

Whether to challenge a prosecution bar presents another strategic challenge for the innovator. On the one hand, those subject to the prosecution bar may be best suited to evaluate the ANDA and determine whether grounds exist for an infringement suit. On the other hand, anyone evaluating the ANDA while also carrying out prosecution activities will be forced to engage in a difficult game of mental gymnastics — keeping all of their known information properly walled off so that the generic's secrets are not mixed into the prosecution activities.[7] Once agreed to, failure to adhere to the prosecution bar can of course leave an innovator susceptible to a host of liabilities, including claims of trade secret misappropriation, breach of contract, and even criminal prosecution.

Generic counsel's vigilance and diligence with respect to monitoring who has had access to the ANDA under an OCA is a key driver in successfully protecting against misuse. Close management is required beyond the forty-five-day review period and can be critical during the pendency of litigation. Close attention should be paid to the innovators domestic and foreign prosecution activities and the individuals involved. In the case of suspicion, information regarding possible misuse may be gleaned from litigation materials, such as declarations and privilege logs. [8] Generally, courts will decide claims of misuse based on how something appears in context, particularly where perceived ethics are involved.

Thus, it should remain evident, even from the innovator's perspective, that only those deemed necessary for evaluating possible infringement should have be given access to an ANDA received under an OCA. The confidential information received should be apportioned appropriately and handled according to the provisions of the OCA and established company policies on the treatment of competitively sensitive information.

Defining Confidential Information Under an OCA

In addition to who has access, how the generic company defines what is to be treated as "confidential" under the OCA is critical. Here, the generic company should ensure that any provisions identifying what is considered confidential under the OCA are broad enough to cover all proprietary technology and business information. The innovator, in response, should consider whether attempting to force a narrower description from the generic company is advantageous. Challenging the sufficiency of provisions that define what is confidential can mitigate future risk from claims of misuse.

A further issue may arise if the generic company attempts to define confidential information under the OCA to include the notice letter's detailed statement. One way generic companies have tried to accomplish this is by "appending" the detailed statement to the end of the OCA (paginating the OCA and detailed statement consecutively) rather than including it in the notice letter. While perhaps clever, this approach is inconsistent with the act.[9] It follows that careful consideration must be given to exactly what information the generic plans on disclosing in its notice letter and detailed statement, regardless of the existence of an OCA.

Disposition of Information in the ANDA

In transactions such as OCAs, where secrets are disclosed and entrusted, procedures must be put in place to govern what happens to the confidential information when the review period ends. It is common for OCAs to contain disposition provisions calling for the return or destruction of all but one copy of the ANDA portions disclosed and documents that contain or were derived from information contained in the ANDA, regardless of whether a lawsuit is initiated. While seemingly innocuous upon first impression, an innovator should give real consideration to whether it truly needs to retain a single copy of the information covered by an OCA. Failing to return or destroy all of a competitor's confidential information (or otherwise comply with the OCA's disposition provisions) can create a continuous risk of a lawsuit claiming that the kept-information contaminated later innovative work. Similarly, the generic manufacturer should consider omitting any provision that gives the innovator a right to retain a single copy of its confidential information, in favor of a provision that requires the innovator to provide a written request showing good cause for future access. In either event, the generic should include specific and substantial penalties for any breach of the terms of the OCA.

Conclusion

It is clear that OCAs bring with them the competitive risks of misappropriation and inadvertent loss of sensitive information. Failure to recognize these realities can be detrimental, yet there is no one-size-fits-all approach to OCAs. Understanding the principles of trade secret law and management, and incorporating that understanding into their approach to OCAs, drug companies can reduce their liability and better position themselves to have influence and value in the global marketplace while also protecting their valuable trade secrets.

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[1] See 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc)

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

[3] Id.

[4] See 21 U.S.C.. § 355(j)(5)(C)(i)(III) ("[T]he application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.")

[5] The Federal Circuit has defined the term "competitive decisionmaking" as "shorthand for a counsel's activities, association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." U.S. Steel Corp. v. United States, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984).

[6] The innovator should request that the generic identify some basis, apart from their status as in-house counsel, for denying access. U.S. Steel Corp., 730 F.2d at 1469 (holding that status as in-house counsel cannot serve as the sole basis for denial of access to confidential information); but cf. R.R. Donnelley & Sons Co. v. Quark, Inc., No. C.A. 06-032-JJF, 2007 WL 61885, at *1 (D. Del. Jan. 4, 2007) ("[T]he risk of inadvertent disclosure cannot be overcome by the mere contention that access to confidential information is necessary for case management.")

[7] See generally, e.g., In re Deutsche Bank Trust Co. Ams., 605 F.3d 1373, 1378 (Fed. Cir. 2010) (citation and internal quotation marks omitted) ("[I]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well intentioned the effort may be to do so.").

[8] See, e.g., Galderma Labs. Inc. v. Amneal Pharms., LLC, C.A. No. 11-cv-1106-LPS, 2013 WL 6178234, at *1 (D. Del. Nov. 8, 2013) (ordering the production of documents related to defendants' unclean hands and breach of contract claims after in camera review of documents listed on plaintiffs' privilege log).

[9] See, e.g., Nycomed U.S. Inc. v. Tolmar, C.A. No. 10-cv-2635-KSH, 2011 WL 1675027, at *6 (D.N.J. Apr. 28, 2011).