Protecting Trade Secrets Disclosed To The FDA

By **Douglas Nemec, William Casey and Tara Melillo** (February 13, 2018, 10:50 AM EST)

Douglas Nemec

William Casey

Tara Melillo

While intellectual property is a key value driver for most every company, in the life sciences industry, intellectual property is paramount. It provides for periods of market exclusivity and allows companies to differentiate their offerings from those of competitors. Given regulatory approval time lines that can take more than a decade and development costs that can exceed one billion dollars, strong intellectual property protection is necessary to ensure business viability. See, e.g., Costs to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion, Tufts Center for the Study of Drug Dev. (Nov. 18, 2014), here.

While maintaining intellectual property protection is critical, every company seeking U.S. Food and Drug Administration approval needs to disclose proprietary information, often including trade secrets, to gain that regulatory approval. These disclosures place a company's sensitive and valuable information in the hands of the FDA, which is responsible for maintaining its confidentiality. Such categories of information include formulations, manufacturing methods and processes, and clinical study reports, including clinical endpoints.

Recently, FDA Commissioner Scott Gottlieb gave a speech titled "Fostering Transparency to Improve Public Health" in which he discussed new FDA plans for increased transparency. Gottlieb discussed a program in which the FDA plans to select, redact and publicly post information from clinical study reports ("CSRs"), which are documents containing detailed information concerning methods and results of clinical studies. Information that the FDA plans to publish from these CSRs includes "the study report body, the study protocol and amendments, and the statistical analysis plan for each of the participating product's pivotal studies." Additionally, Gottlieb stated that the FDA is exploring whether it can publish complete response letters ("CRLs") related to clinical safety and efficacy with certain proprietary information redacted. CRLs, which are letters sent to an applicant informing them that the FDA will not approve an application to market a new drug, contain a list of deficiencies in an application and reflect the FDA's review of all data submitted in that application.

Given this increased focus on transparency from the FDA, life science companies should take a fresh look at the protections over trade secret information disclosed to the FDA, and be prepared to resist the disclosure of such information. Accordingly, this article summarizes the law surrounding trade secrets disclosed to the FDA[1] and steps that

companies can take to protect such information.

Trade Secrets

The Defend Trade Secrets Act ("DTSA")[2] defines trade secrets as:

> [A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, wither tangible or intangible, and wither or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if –
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> (A) the owner thereof has taken reasonable measures to keep such information secret; and
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> (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

18 U.S.C. § 1839. Information such as production and manufacturing methods and processes, formulations, quality analysis methods, clinical study reports and clinical trials has been held to be protectable trade secret information. E.g., Enteris Biopharma Inc. v. Clinical Pharmacology of Miami, 2015 WL 12085848, at *8–9 (S.D. Fla. Mar. 20, 2015).

Confidentiality of Trade Secret Information Submitted to the FDA

While the DTSA and various state laws define trade secrets broadly, the FDA has its own definition of a trade secret, which it defines as: "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." 21 C.F.R. § 20.61(a). For such information to be trade secret, "[t]here must be a direct relationship between the trade secret and the productive process." Id.

If trade secret data or information is disclosed to the FDA, it may be protected from disclosure so long as it is designated as exempt from disclosure within a reasonable time after submission or if the FDA has reason to believe that release of the information would result in competitive harm. 21 C.F.R. § 20.61 (c), (d), (f)(4). Designating information as exempt from disclosure does not guarantee its protection, as the FDA may independently decide that disclosure may be required and provide the submitter only 5 working days to object to a notice of planned disclosure. 21 C.F.R. § 20.61(e). Even if information is considered trade secret by the FDA, such information loses that status 10 years after submission. 21 C.F.R. § 20.61(d).

And although the FDA and the submitter may consider certain information to be trade secret, any member of the public may file a Freedom of Information Act ("FOIA") request seeking information from the FDA. Pursuant to FOIA Exemption 4, the FDA may "refuse disclosure of trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). There is a circuit split concerning the standard for whether information is confidential. The Second Circuit holds that "information is confidential if its disclosure would have the effect of either: (1) of impairing the government's ability to obtain information — necessary information — in the future, or (2) of causing substantial harm to the competitive position of the person from whom the information was obtained." Rozema v. U.S. Dep't of Health & Human Servs., 167 F. Supp. 3d 324, 338 (N.D.N.Y. 2016) (quoting Inner City Press/Community on the Move v. Bd. of Governors of Fed. Reserve Sys., 463 F.3d 239, 244 (2d Cir. 2006)) (quotation marks omitted). In contrast, the D.C. Circuit does not apply the "impairment" or "substantial competitive harm" test, instead allowing an agency to withhold information pursuant to

"FOIA Exemption 4 if it 'would customarily not be released to the public by the person from whom it was obtained.'" Rozema v. U.S. Dep't of Health & Human Servs., 167 F. Supp. 3d 324, 338 (N.D.N.Y. 2016) (quoting Critical Mass Energy Project v. Nuclear Reg. Comm'n, 975 F.2d 871, 878-79 (D.C. Cir. 1992) (en banc)).

If the FDA receives a request to disclose such information and denies that request, the requestor may challenge the FDA to defend the denial in court, and the FDA will require the submitter of the information to intervene to defend against the disclosure of that information. 21 C.F.R. § 20.55. If the submitter fails to intervene, the FDA may consider this failure in deciding whether to release the requested records. Id.

The Burden of Demonstrating that Information is Trade Secret Falls on the Company Attempting to Prevent Disclosure

Issues concerning the FDA's disclosures of trade secret information typically arise in one of two contexts: (1) as part of FOIA requests filed with the FDA, which are governed by the aforementioned laws, or (2) as information disclosed in discovery in competitor litigation and submitted to the court, usually under seal, which are governed by Federal Rule of Civil Procedure 26. While the facts and circumstances in these cases vary, the main theme running throughout these cases is that the burden is on the company to demonstrate that the disclosure of information identified as trade secret or confidential information would cause the business harm, and that merely conclusory statements will not meet that burden. See, e.g., King Pharms. Inc. v. Eon Labs Inc., 2010 WL 3924689, at *10 (E.D.N.Y. Sept. 28, 2010); Heeney v. Food & Drug Admin., 1999 WL 35136489, at *5 (C.D. Cal. Mar. 16, 1999).

FOIA Requests

In Heeney v. Food and Drug Administration, the FDA and Boston Scientific successfully justified the redaction of information sought by Heeney through a FOIA request by arguing that such information was either trade secret or privileged and confidential. 1999 WL 35136489, at *5. In support of the FDA's withholding of the documents, the FDA and Boston Scientific each provided Vaughn indices, which listed, for each document containing withheld information, "the page numbers where the redactions appear, a description of the document, a description of the redaction, and, as is required, the regulatory and statutory authority on which the FDA relies in withholding the information." Id. at *2. After finding that the declaration submitted by the FDA, which included the Vaughn indices, "supplies detailed information describing the purpose and need for each redaction" and that the declaration submitted by Boston Scientific "identify specific information in each document that Boston Scientific contends is confidential or trade secret," the court ruled that, with certain specific exceptions, "the redaction of information from Boston Scientific's § 510(k) file was proper under FOIA Exemption 4." Id. at *7, *9, *12.

In contrast, in cases where the rationale provided in support of maintaining confidentiality was conclusory, courts have ordered the publication of such information. In Public Citizen Health Research Group v. Food & Drug Administration, the court evaluated whether the FDA should disclose information in several investigational new drug applications ("INDs"). 185 F.3d 898 (D.C. Cir. 1999). With respect to four of the INDs, the court found that an affidavit submitted by Schering, the submitter of the INDs and intervenor in the action, in support of maintaining confidentiality over information contained therein was "sufficiently specific" to demonstrate that disclosure of that information would allow competitors to "pursue the same avenues of research and development" and "eliminate much of the time and effort that would otherwise be required to bring to market a [competitive] product." Id. at 905–06. However, the court found that an affidavit regarding a fifth IND contained only conclusory assertions that disclosure would have value to competitors, and on that basis required the FDA to release the IND. Id. at 906.

Motions to Unseal

Courts have undergone similar analyses, and come to similar conclusions, in evaluating motions to unseal documents filed under seal. For instance, in King Pharmaceuticals v. Eon Labs Inc., the court addressed whether information filed under seal should remain so. 2010 WL 3924689, at *1. Both the plaintiff and the defendant advocated for the sealing of their own confidential information. Id. at *7–14. Nevertheless, the court ordered the unsealing of the papers in their entirety based on the rationale that the parties failed to demonstrate that any of the information which they sought to keep under seal "contain [ed] any secret, proprietary information, the disclosure of which would injure" either of the parties. Id. at *12, *14.

Similarly, in Forst v. Smithkline Becham Corp., GlaxoSmithKline ("GSK") argued that certain documents should remain under seal because disclosure would: "allow competitors to show 'out of context snippets' of GSK correspondence to healthcare professionals and 'bias' them against GSK; give competitors 'insights into how GSK analyzes and interprets its clinical data'; allow competitors to use and/or exploit GSK's proprietary techniques for making labeling decisions in light of analyses of clinical trial data in their own dealings with the FDA; and, provide insight into GSK's 'internal decision-making processes.'" 639 F. Supp. 2d 948, 956–57 (E.D. Wis. 2009). The court rejected these arguments and made the documents public, finding that the information GSK sought to protect was either already publicly available or that GSK did not provide adequate explanation of how the information would allow competitors to "obtain economic value." Id. at 957.

Practice Pointers

Given the FDA's increasing focus on transparency, counsel for life sciences companies should take the following steps:

- Life science companies should redouble efforts to identify which materials in their FDA submissions are subject to FOIA exemption 4 and, to the extent possible, create files containing evidence for why that information is valuable and would injure the company if disclosed.
- In concert with focusing on the initial identification of confidential information in FDA submissions, life science companies should develop a periodic review system to analyze information previously submitted to the FDA and determine what information remains trade secret information and why that information is commercially valuable. If a life science company receives notice of the FDA's intent to disclose information, it will have only five days to respond, and such prior analysis will greatly enhance a company's ability to articulate what information ought not to be disclosed and why.
- In light of Commissioner Gottlieb's comments, life sciences companies should review past CSRs and CRLs to see what information in those documents they believe should be confidential. Companies should emphasize the importance of maintaining confidentiality over information that the FDA typically includes in CSRs and CRLs in future communications with the agency.
- In competitor cases alleging trade secret misappropriation, defendants should consider filing FOIA requests with the FDA to obtain documents containing the alleged trade secrets. Having the FDA take a position that information a defendant is alleged to have misappropriated is not trade secret could greatly benefit any defendant, and, because FOIA cases are typically resolved on summary judgment, a court may rule that there are no trade secrets at issue before a trial in any misappropriation action.
- Counsel representing a life sciences company in any litigation should be cautious about placing trade secret or proprietary information on the record under seal, as the decision to seal may be second guessed at a later date. When materials are

placed under seal, a nonconclusory statement of the reasons justifying sealing should also be placed on the record, even if the judge permitting sealing has a permissive attitude toward motions to seal.

Douglas R. Nemec is a partner with Skadden Arps Slate Meagher & Flom LLP in New York. William J. Casey is an associate at the firm's Palo Alto, California, office and Tara R. Melillo is a law clerk at the firm's New York office.

[1] We note that there have been relatively few recent decisions on these issues in recent years, but expect that may change as the FDA seeks to increase transparency.

[2] State laws concerning trade secrets vary, but DTSA's definition of a trade secret has significant overlap with the Uniform Trade Secret Act ("UTSA") definition of trade secret that has been adopted by many states. The UTSA defines a trade secret as: "'Trade secret' means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UTSA § 1(4).
