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Legal Sidebar

Vanda Pharmaceuticals, Inc. v. United States: Fifth Amendment Takings Claims for Alleged Disclosures of Trade Secrets and Confidential Information

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In January 2025, the U.S. Court of Federal Claims entered final judgment for the government in a lawsuit brought by Vanda Pharmaceuticals, Inc. (Vanda) for alleged disclosure of confidential information and/or trade secrets by the U.S. Food and Drug Administration (FDA). This lawsuit raised a novel question regarding the viability of a Fifth Amendment takings claim for FDA's alleged disclosure of confidential or proprietary information during the approval process for new and generic drugs. The January 2025 opinion determined that Vanda had not successfully pled a takings claim based on the specific facts at issue, but left open the possibility that other disclosures by FDA could effectuate a taking in violation of the Fifth Amendment during the drug approval process. Vanda appealed the court's January 2025 decision, and the appeal remains pending.

Resolving if and when a pharmaceutical company can assert a takings claim against FDA—either on appeal or in a future litigation—could affect drug manufacturers' willingness to disclose information to FDA, as well as FDA's ability to communicate with generic drug manufacturers during the drug approval process to ensure generic drugs are safe, effective, and eligible for approval. If FDA changes its communication practices with drug manufacturers, or manufacturers are less willing to disclose information to FDA, it may become more difficult for both brand and generic drug manufacturers to obtain FDA approval and enter the marketplace. In turn, this could affect the availability of treatments for patients or the price at which such drugs are available.

Legal Background

Vanda claimed that FDA effectuated a taking of certain allegedly confidential information and trade secrets it provided to FDA as part of the approval process for two drugs. It alleged FDA improperly disclosed Vanda's confidential information and/or trade secrets to subsequent applicants seeking to introduce generic versions of those drugs. The legal framework for approving new and generic drugs for

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marketing in the United States, the legal nature of and protections surrounding trade secrets, and the Takings Clause inform Vanda's claims and the potential implications of the case for the drug approval process.

New Drug Applications and Abbreviated New Drug Applications

To market a new drug in the United States, the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a drug manufacturer first obtain FDA approval. The FD&C Act and FDA regulations outline the process for obtaining approval of new drugs. Generally, the new drug application (NDA) process requires the drug sponsor to submit data from clinical trials along with information about the drug itself, the manufacturing process, and proposed labeling for the drug. Among other things, the NDA submission must include the drug's chemical formula; specifications; how the drug works in the body; the amount of the drug needed to provide an effect; how the drug is absorbed, distributed, metabolized, and eliminated by the body; and the drug's indication (i.e., the diseases or conditions for which the drug would be used). Much of this information is confidential or proprietary and may qualify as a trade secret if the manufacturer takes steps to properly protect it. The FDA uses the information in the NDA to determine whether the drug meets the FD&C Act's requirements for approving a new drug as safe and effective for its proposed use.

For generic drugs, the Hatch-Waxman Act of 1984 amended the FD&C Act to allow generics to follow an abbreviated new drug application (ANDA) pathway that relies on FDA's prior approval of a new drug, referred to as a reference listed drug (RLD), to establish that the proposed generic is safe and effective. This abbreviated process often eliminates the need for generic manufacturers to conduct the lengthy and expensive clinical trials necessary for NDA approval. Instead, generics may rely on the data submitted by the NDA filer for the RLD to demonstrate safety and effectiveness. A generic drug may be approved if, among other things, the manufacturer demonstrates that the generic is pharmaceutically equivalent and bioequivalent to the RLD.

If FDA determines that an NDA or an ANDA does not meet the requirements for approval, FDA sends the sponsor a complete response letter explaining the deficiencies FDA identified in the NDA or ANDA and how they might be remedied.

Trade Secrets and Confidential Information

NDAs and ANDAs submitted to FDA may include trade secrets and other confidential information. A trade secret is a form of intellectual property generally defined as confidential information that has economic value as a result of it being secret and that the owner takes reasonable measures to protect from disclosure or discovery. Under both state and federal law, owners may bring civil actions against persons who "misappropriate" (i.e., improperly acquire, disclose, or use) the owner's trade secrets. Misappropriation does not include acquiring a trade secret through "fair and honest means," such as accidental disclosure by the owner, independent discovery, or reverse engineering.

Federal law prohibits the unauthorized disclosure of trade secrets or other confidential information by federal employees. FDA regulations further provide that trade secrets or confidential information submitted or divulged to FDA are not eligible for public disclosure.

Fifth Amendment Takings Claims

Vanda asserted that FDA allegedly effected a taking when it disclosed its trade secrets and confidential information in the drug approval process. The Takings Clause of the Fifth Amendment states that "private property [may not] be taken for public use without just compensation." To fall within the purview of the

Takings Clause, a taking of property for public use must be based on a governmental action that is authorized, or within the scope of a government agent's duties.

When the government physically takes possession of an interest in property (i.e., a per se taking), the government generally must compensate the property owner. In contrast, when a government action has an economic effect on one's property, compensation is required only when the regulation goes "too far" so as to amount to a "regulatory taking." In evaluating whether a government regulation amounts to a regulatory taking, courts generally apply a balancing test to evaluate the economic impact of the regulation on the owner, the character of the governmental action, and whether the challenged action interfered with the owner's reasonable investment-backed expectations as to its interests in the property.

Trade secrets, a form of intangible property, are protected under the Takings Clause. Due to their intangible nature, government interference with intangible property rights, such as trade secrets, often takes the form of an alleged regulatory taking, rather than a per se taking. That said, the Supreme Court has held that there is generally no Takings Clause violation if the property (including intangible property) was voluntarily exchanged for a governmental benefit.

The Supreme Court has recognized that the government may violate the Takings Clause by improperly disclosing a company's confidential data and trade secrets without just compensation. In *Ruckelshaus v. Monsanto*, the Supreme Court considered several provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and the effect of certain revisions of the statute and governing regulations that set up a mandatory pesticide registration procedure and allowed the U.S. Environmental Protection Agency (EPA) to disclose certain health, safety, and environmental data to qualified requesters. The Court determined that Monsanto had a cognizable property interest in the data it submitted to EPA. The Court further determined that no taking occurred when the statutory scheme in place at the time did not support a reasonable expectation that EPA would keep the data confidential. However, when Monsanto submitted data with a reasonable expectation that EPA would protect its trade secrets, unauthorized disclosure by the government without just compensation was a regulatory taking.

Vanda's Lawsuit Against FDA

Vanda is a biopharmaceutical company whose products include two FDA-approved brand-name drugs: Fanapt tablets, which are approved to treat schizophrenia, and Hetlioz capsules, which are approved to treat the circadian rhythm sleep disorder known as non-24-hour sleep-wake disorder. FDA's approval of these drugs and of subsequent generic versions of these drugs gave rise to the ongoing litigation.

As part of the approval process, Vanda submitted NDAs to FDA. According to the court's decision, Vanda's NDA for Fanapt included Vanda's proffered dissolution specification (i.e., the rate at which a drug is released in the body). In reviewing the application, FDA rejected Vanda's proposed dissolution specification and suggested an alternative specification based on the data in the application, which Vanda adopted. FDA then approved the NDA for Fanapt on May 6, 2009.

For Hetlioz, Vanda's NDA similarly proposed a dissolution specification, which FDA rejected after reviewing the data submitted by Vanda. FDA proposed an alternative dissolution specification, which Vanda adopted. Vanda's NDA for Hetlioz also contained allegedly confidential information regarding Vanda's manufacturing processes, including for detecting and controlling impurities in Hetlioz's active ingredient (tasimelteon) and for controlling the size of tasimelteon crystals in the drug product (known as micronization). FDA approved the NDA for Hetlioz on January 31, 2014.

Subsequently, two pharmaceutical companies filed ANDAs seeking approval to market generic versions of Fanapt, and two other pharmaceutical companies filed ANDAs seeking approval to market generic versions of Hetlioz. Vanda alleged that FDA improperly disclosed confidential information related to

Fanapt's dissolution specification and Hetlioz's dissolution specification, impurities analysis, and micronization to these competitors.

Specifically, Vanda alleged that FDA checked and relied on Vanda's dissolution specification when it rejected the dissolution specifications proposed by the generic competitors in the ANDAs. Vanda further alleged that FDA suggested that the generics adopt the dissolution specifications previously proposed by FDA and adopted by Vanda during the prior NDA processes. Vanda also alleged that FDA improperly disclosed information related to Hetlioz's impurities analysis and micronization by asking the generic manufacturers to submit data on detection of impurities and information on micronization. Vanda further alleged that following the generics' adoption of FDA's proposed dissolution specifications and submission of information on impurities analysis and micronization, FDA approved the generic companies' ANDAs.

Vanda filed suit in the Court of Federal Claims alleging that FDA's disclosures to the generic drug manufacturers violated the Takings Clause and breached an implied-in-fact contract. Vanda alleged that FDA disclosed Vanda's trade secrets to the generic drug companies and that this disclosure amounted to a per se taking of its property (or, in the alternative, a regulatory taking). It also claimed that FDA breached an implied-in-fact contract that was formed when Vanda submitted its NDAs to FDA, in which FDA promised to keep Vanda's information confidential.

In an earlier January 2024 decision, the Court of Federal Claims dismissed Vanda's breach of contract claim, but allowed Vanda's takings claim to proceed. The court rejected FDA's arguments that Vanda had failed to sufficiently allege a cognizable takings claim in its complaint. The court's opinion did not address what it dubbed the "more vexing" issue in the case because it was not raised by FDA—whether Vanda had a cognizable property interest in the dissolution specifications that FDA proposed and suggested that Vanda adopt during the NDA process. The court noted the potential practical consequences of holding that Vanda has a property interest in this information, such as potential adverse impacts on FDA's ability to provide assistance to generic drug companies and the risk that FDA may authorize inconsistent results.

Following this order, in April of 2024, FDA filed a motion for judgment on the pleadings, arguing that Vanda failed to sufficiently allege that it had a cognizable interest in the dissolution specifications. When considering a motion for judgment on the pleadings, the court applies "substantially the same test" as for a motion to dismiss—it assumes the plaintiff's well-pleaded allegations are true and determines whether the moving party is entitled to judgment as a matter of law.

The Court of Federal Claim's January 2025 Decision

In January 2025, the Court of Federal Claims issued a decision granting FDA's motion for judgment on the pleadings, holding that Vanda failed to plead a Fifth Amendment takings claim based upon the alleged disclosures of dissolution specifications, and impurities testing and micronization information.

The court rejected Vanda's takings claim with respect to the dissolution specifications because "logic dictates that the government cannot be credibly accused of taking information generated by a federal agency" and proposed to the applicant during the drug application process. An FDA regulation defines trade secret as "the end product of either innovation or substantial effort," and the court determined that the dissolution specifications did not satisfy either criterion because FDA came up with the specifications. The court distinguished the Supreme Court's decision in *Monsanto*, which held that the company had a property interest in the data the company disclosed to EPA, on the basis that the data in that case was completely generated by the company. Because FDA generated and recommended the dissolution specifications, the court found that they are not Vanda's trade secrets or confidential and proprietary information.

The court also determined that Vanda did not state a claim regarding the dissolution specifications because they did not have independent economic value resulting from their secrecy. According to the court, "generic manufacturers can determine, or at least approximate, the dissolution rate through independent lab testing," and this is "particularly true where, as here, the dissolution test method is publicly available for replication." Because no independent value was associated with the dissolution specifications, the court held that Vanda did not state a claim that FDA violated federal or state trade secret law. The court also pointed to practical issues associated with imposing liability on FDA for disclosing certain information to generic drug companies, noting that it would be difficult for FDA to "align dissolution specifications between generic and brand name drugs" without disclosing the NDA-approved dissolution specification to generic manufacturers.

With respect to the micronization information and impurities testing information, the court determined that the relevant information was already publicly available in a patent application filed by Vanda. According to the court, the inquiry the FDA posed to the generic drug companies did not "yield the improper disclosure of any novel or unknown part of Vanda's production process" because that information was already public. Once Vanda made the information public, its property right was extinguished, and the court therefore concluded that Vanda failed to plead a takings claim with respect to the micronization and impurities testing information.

Because Vanda failed to plead a claim, the court granted FDA's motion for judgment on the pleadings and entered judgment for FDA. In February of 2025, Vanda filed a notice of appeal, and the appeal is currently pending in the U.S. Court of Appeals for the Federal Circuit.

Considerations for Congress

Because the Court of Claims' opinion in *Vanda* is limited to the facts presented, the case does not answer whether a pharmaceutical company may ever successfully assert a takings claim against FDA for disclosing trade secret information during the drug approval process. The court's rationale rests on the specific facts at issue in this case—that FDA generated some of the data at issue and that the remaining information was previously included in a public filing. The court, therefore, did not decide whether a brand name drug company could state a claim against FDA for disclosing information in general. The possibility of FDA effectuating takings through the drug approval process raises potential issues of interest to Congress.

The issues raised in *Vanda* may be the subject of future litigation given FDA's recent actions in publicizing complete response letters, which FDA sends to a sponsor to explain any deficiencies in an NDA or ANDA to instruct on how to remedy those deficiencies. Historically, FDA had published complete response letters after granting the related drug application, as part of the action packages required to be posted online within 30 calendar days after approving a drug application in accordance with 21 U.S.C. § 355(l). Complete response letters associated with withdrawn or pending applications were not publicly released.

In July 2025, FDA announced that it published over 200 complete response letters associated with approved drug applications and put them in an openFDA database as part of its initiative "to modernize and increase transparency." Commentators reported that most of these letters were already public. In September 2025, FDA released 89 more complete response letters for pending or withdrawn drug applications and announced that it will release future complete response letters "promptly after they are issued to sponsors." Following this publication, on April 20, 2026, an anonymous pharmaceutical company filed a citizen petition requesting that FDA establish a clear process that provides sponsors with notice and an opportunity to respond to proposed disclosures of complete response letters associated with unapproved drug applications in order to prevent the release of confidential or trade secret information. The citizen petition points to several instances in which it claims FDA published confidential information

related to deficiencies in clinical data in a pending drug application, and it asserts that FDA's disclosure of this information may violate the Trade Secrets Act or constitute a taking in violation of the Fifth Amendment. The citizen petition also argues that 21 U.S.C. § 355(l) does not authorize disclosure of complete response letters for unapproved applications. FDA has not yet taken action on the pending citizen petition.

FDA published a "transparency roadmap" in October 2026, affirming its commitment to "being as forthcoming as possible about the scientific basis for its regulatory determinations" in complete response letters. FDA further addresses the publication of complete response letters in its legislative proposals for 2027, in which FDA requests that Congress amend the FD&C Act to "provide explicit authority" to "publicly disclose information on deficiencies in safety and efficacy data provided to a sponsor in complete response letters." The proposal argues that such disclosures "may make development more efficient for multiple stakeholders, as it could help others prevent similar deficiencies in their own development programs and marketing applications."

Congress may wish to clarify how trade secrets and other confidential information should be handled and what kinds of information related to a drug application can be publicly released or disclosed to a generic manufacturer or the public. Potential legislation could clarify the scope of 21 U.S.C. § 355(l), which requires the publication of action packages associated with approved drug applications, or may otherwise clarify confidentiality protections existing in current regulations or modify the manner in which any data submitted by a drug manufacturer may be used. Although the Takings Clause imposes some limits on Congress's power to legislate, Congress could amend existing legislation to avoid the need to provide just compensation to an entity by specifying for future new drug applications the expectation of confidentiality that a pharmaceutical company might have and striking a balance between the government benefit received as a result of any disclosure of trade secret information.

The Increasing Transparency in Generic Drug Applications Act, introduced in the 119th Congress as S. 1302 and H.R. 1843, would require FDA to inform generic drug manufacturers whether their proposed generic is qualitatively and quantitatively the same as the RLD, and, if not, disclose the ingredients and amounts of deviation that are not the same. The proposal further provides that any disclosures made are expressly authorized and would not violate the prohibitions on disclosure of trade secrets under 18 U.S.C. § 1905. Congress may wish to consider this or other potential legislation aimed at balancing the entry of generic drugs into the marketplace with incentives for brand name drug manufacturers to innovate and to disclose their data to FDA.

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