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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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On January 18, 2024, the U.S. Court of Federal Claims denied, in part, the government's motion to dismiss 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 raises 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. Resolution of this question could affect drug manufacturers' willingness to fully 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 affect both brand and generic drug manufacturers' ability 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 claims that FDA effectuated a taking of the confidential information and/or trade secrets it provided to FDA as part of the approval process for two drugs. It alleges 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 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.

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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 and 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 propriety and may be kept by the manufacturer as trade secrets if properly protected. 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.

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 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 the FDA are not eligible for public disclosure.

Fifth Amendment Takings Claims

Vanda has asserted a takings claim in connection with its allegation that FDA 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 "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 this intangible nature, government interference with intangible property rights, such as trade secrets, often takes the form of alleged regulatory takings, rather than per se takings. That said, the Supreme Court has held that it generally does not violate the Takings Clause 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. It 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 was a regulatory taking when it did not receive just compensation in return.

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 have given rise to the ongoing litigation.

As part of the approval process, Vanda submitted NDAs to FDA. According to the court's order, 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 alleges 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 alleges 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 alleges 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 alleges 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 alleges that FDA disclosed Vanda's trade secrets to the generic drug companies and that this disclosure amounts to a per se taking of its property (or, in the alternative, a regulatory taking). It also claims 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.

The Court of Federal Claims' Decision

In its January 2024 decision, the Court of Federal Claims addressed the government's motion to dismiss the case. At the motion-to-dismiss stage, the court must accept Vanda's allegations in its complaint as true and evaluate whether these allegations state a plausible takings claim that would entitle it to relief. The court partially denied the government's motion to dismiss, allowing Vanda's takings claim to proceed and dismissing Vanda's breach of an implied-in-fact contract claim. The court concluded that Vanda had sufficiently alleged a cognizable takings claim in its complaint to warrant further proceedings. Although future proceedings will determine whether Vanda can ultimately succeed on the merits based on the facts at issue in this case, the court's decision to allow this case to proceed suggests that other pharmaceutical manufacturers may be able to successfully bring a takings claim in similar contexts.

In assessing Vanda's taking claim, the court first considered the requirement that a viable takings claim be based on a government action that is "duly authorized by Congress." In its motion, FDA argued that, because Vanda's complaint alleged that FDA's disclosures violated its own regulations and federal statutes protecting trade secrets (which must be accepted as true at the motion-to-dismiss stage), FDA's disclosures to the generic drug companies were illegal and therefore could not have been "authorized by Congress." The court rejected this argument, reasoning that it is possible for a government official's unlawful act to constitute authorized action if the official is acting within the general scope of his or her duties. It ultimately held that "the FDA's review and approval of NDAs and ANDAs falls squarely within the scope of the federal agency's statutorily authorized duties."

While FDA did not challenge whether Vanda had a cognizable property interest in the dissolution specifications, and therefore effectively waived the issue for purposes of the motion to dismiss, the court provided some initial thoughts on the legal and policy considerations for this "more vexing" issue in the case. Although the court left the question undecided, it questioned whether Vanda could claim a property interest in a specification that it ultimately adopted but that FDA had come up with and proposed during the drug approval 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 generics and the risk that FDA may authorize inconsistent results.

Finally, though recognizing it would be premature to resolve at this stage due to the uncertainty about the cognizable property interest, the court briefly considered Vanda's argument that FDA's alleged disclosure constituted a per se taking because it interfered with its right to exclude others from using its trade secret information. The court noted that the nature of Vanda's claims "strongly suggest . . . a regulatory takings claim under *Monsanto*" but that Vanda had alleged a per se taking as its primary claim and raised the regulatory takings claim in the alternative. In support of its per se taking argument, Vanda relied on the Supreme Court's opinion in *Cedar Point Nursery v. Hassid*, which had found a per se taking based on interfering with the property owner's right to exclude when the government allowed union representatives to physically enter private property. Although the court felt that *Cedar Point* was "readily distinguishable" from the alleged disclosures of intangible property, the court declined to decide the issue at this stage given the uncertainty of Vanda's property interest.

Considerations for Congress

Regardless of whether Vanda succeeds on its claim, the court allowing the takings claim to proceed past the motion to dismiss signifies that it could be possible for a pharmaceutical company to successfully assert a takings claim against FDA for disclosing trade secret information during the drug approval process. The possibility of FDA effectuating takings through the drug approval process raises potential issues of interest to Congress.

Final resolution of this case could affect the manner in which FDA communicates with generic drug manufacturers during the ANDA process. If the court ultimately decides that FDA did violate Vanda's Fifth Amendment rights, it could constrain FDA's communication with generic drug manufacturers during the drug approval process, impacting its ability to ensure generic drugs are safe, effective, and eligible for approval. Finding a taking in this context could slow or reduce the number of generic drugs that FDA approves, which could affect generic competition and drug prices for consumers.

If the court ultimately holds that FDA did not unlawfully take Vanda's property, there could be a chilling effect on drug manufacturers' willingness to fully disclose confidential information to FDA. This effect could be mitigated by the fact that FDA approval is a necessary step for drug manufacturers to sell drugs in the United States, which requires manufacturers to disclose relevant drug information and may be the only avenue for capitalizing on the confidential information.

Congress may wish to clarify how trade secrets and other confidential information should be handled in connection with FDA's review of ANDAs and communications with generic competitors. Potential legislation could clarify the 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 can avoid the need to provide just compensation to an entity by specifying 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 118th Congress as S. 775, appears intended to alter FDA's communication with generic drug manufacturers during the generic drug approval process. As drafted, the bill would require FDA to inform generic drug manufacturers whether their proposed generic is qualitatively and quantitatively the same as the RLD and, if not, require disclosure of the ingredients and amounts of deviation that are not the same. The bill 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. If enacted, the bill would essentially nullify claims similar to Vanda's from pharmaceutical companies going forward and clarify the property interests and confidentiality protections applicable to information submitted by drug manufacturers to FDA during the drug approval process. Congress may wish to consider this or other potential legislation aimed at balancing the entry of generic drugs into the marketplace and incentives for brand-name drug manufacturers to innovate and to disclose their data to FDA.

Author Information

Dorothy C. Kafka
Legislative Attorney

Christina L. Shifton
Section Research Manager

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