In the United States Court of Federal Claims

FOR PUBLICATION

No. 23-629C
(Filed: January 18, 2024)

VANDA PHARMACEUTICALS, INC.,	)
Plaintiff,	)
v.	)
UNITED STATES,	)
Defendant.	)

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OPINION AND ORDER

BONILLA, Judge.

This case presents novel issues of first impression, including whether a brand pharmaceutical company can assert a viable Fifth Amendment takings claim and/or a breach of an implied-in-fact contract based upon a government official's alleged disclosure–intentional or inadvertent–of claimed trade secrets and confidential commercial information to competitors seeking Food and Drug Administration (FDA)

approval of generic drugs. Pending before the Court is defendant's motion to dismiss the complaint for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the United States Court of Federal Claims (RCFC). Specifically, defendant maintains plaintiff fails to allege a cognizable takings claim; the alleged contract is, at best, implied-in-law which is outside this Court's jurisdiction; and plaintiff's claims involving one generic manufacturer are time-barred. For the reasons set forth below, defendant's motion is DENIED-IN-PART and GRANTED-IN-PART.

BACKGROUND[1]

Vanda Pharmaceuticals, Inc. (Vanda) is an international biopharmaceutical company that researches, develops, and markets high impact medications to address unmet medical needs.[2] Founded in 2003, the corporation is headquartered in Washington, DC and maintains a self-described business model of "acquiring compounds that other companies failed to develop into treatments, identifying potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them." ECF 1 at 6–7. At issue in this case are two brand name drugs developed by Vanda: Fanapt® (iloperidone) tablets approved to treat schizophrenia in adults and Hetlioz® (tasimelteon) capsules approved to treat the circadian rhythm sleep disorder known as non-24-hour sleep-wake disorder. The FDA approved Vanda's New Drug Applications (NDAs) relating to Fanapt® and Hetlioz® on May 6, 2009, and January 31, 2014, respectively. In the years since, the FDA considered and approved several Abbreviated New Drug Applications (ANDAs) for generic versions of the brand name drugs. Vanda's lawsuit focuses on the information FDA officials purportedly shared with manufacturers of these generics in evaluating and approving their applications.

I. Drug Approval Process

To market drugs in the United States, pharmaceutical companies must secure approval from the FDA for each new product pursuant to the Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an

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[1] In resolving defendant's motion to dismiss, the facts are largely drawn from plaintiff's complaint, corroborating administrative proceedings appended to defendant's dispositive motion (cited and quoted in plaintiff's complaint), and undisputed publicly available information. *See Dimare Fresh, Inc. v. United States*, 808 F.3d 1301, 1306 (Fed. Cir. 2015) (In evaluating a complaint for sufficiency under RCFC 12(b)(6), the court is "not limited to the four corners of the complaint. [The court] may also look to 'matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record.'") (citations omitted); *Bitscopic, Inc. v. United States*, 166 Fed. Cl. 677, 696 (2023) (In assessing an RCFC 12(b)(1) motion to dismiss, "[t]he court is not limited to the pleadings to assure itself of its jurisdiction; it may 'inquire into jurisdictional facts' to confirm jurisdiction.") (quoting *Rocovich v. United States*, 933 F.2d 991, 993 (Fed. Cir. 1991)).

[2] *See* https://perma.cc/DS79-PV8H (last viewed Jan. 17, 2024).

application filed [in accordance with this Act] is effective with respect to such drug."). The FDCA outlines the extensive data and information manufacturers must provide the Secretary of the Department of Health and Human Services (delegated to the FDA) in an NDA to amply demonstrate consumer safety and effectiveness and gain FDA approval of a new drug. *See id.* § 355(b)(1)(A)(i)–(viii). In addition to the statutory requirements, by regulation, NDAs must include information on a product's chemistry, manufacturing, and controls, a meticulous technical review of the drug's manufacturing procedures, and "the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including . . . acceptance criteria relating to . . . dissolution rate . . . ." 21 C.F.R. § 314.50(d)(1)(i)–(ii)(a). Of relevance to the brand name and generic drugs developed here is the requirement for dissolution specifications, which refer to the rate at which a drug dissolves into the body.

The FDA publishes a list of new drugs approved for safety and effectiveness in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), along with their associated patents and exclusivity information. *See Janssen Pharmaceutica, N.V. v. Apotex*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (citing 21 U.S.C § 355(b)(1), (c)(2) & (j)(2)(A)(i)). Drugs approved by the FDA, and included in the Orange Book, are referred to as "listed drugs." *See id.* "Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product."[3]

The research and development phases and ensuing FDA approval process for a new drug is expensive and time consuming.[4] To incentivize pharmaceutical research and development, as well as scientific and medical advancements, a pioneer or brand name drug manufacturer generally receives a statutory period of market exclusivity following FDA approval. Further protecting their intellectual property, manufacturers typically secure patents issued by the United States Patent and Trademark Office (USPTO), including patents listed in the Orange Book, which, in some cases, impact the timing of relevant generic drugs entering the market. The time afforded a brand drug to market exclusivity does not always run concurrently with germane patent terms. Beyond market exclusivity and patent terms, as relevant to this case, certain data and information in NDA disclosures (e.g., trade secrets, manufacturing methods and processes, production and sales distribution) are kept confidential unless previously disclosed to the public. *See* 21 C.F.R. § 314.430(g).

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[3] *See* https://perma.cc/QLQ7-JPY4 (last viewed Jan. 17, 2024).

[4] According to a 2015 report published by the Pharmaceutical Research and Manufacturers of America (PhRMA), on average, pharmaceutical manufacturers spend $2.6 billion over the course of more than a decade to bring a new drug to market. *See* https://perma.cc/WMZ4-YHAA (last viewed Jan. 17, 2024); *cf. Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (describing FDA approval process alone as "long, comprehensive, and costly").

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, 21 U.S.C. § 355(j), to balance the vital public policy interest of encouraging new scientific development with competitors' ability to bring inexpensive generic copies to the marketplace. *See Caraco Pharms. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) ("The goal of the [Hatch-Waxman] Act is to [strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.") (quotations omitted). Under the Act, upon filing an ANDA, the timing of generic drug approval may be subject to patent and market exclusivity protections, and the ANDA must provide appropriate patent certifications or statements for each patent listed in the Orange Book.[5]

Employing the ANDA process, generic competitors may bypass much of the costly and time-consuming research and development brand manufacturers undergo. *See* 21 U.S.C. § 355(j); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) ("The ANDA applicant can substitute bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application."). Through an ANDA, a competitor can secure FDA approval by demonstrating that the proposed generic shares the same active ingredients and bioequivalence as the brand name drug. In doing so, competitors must provide data establishing the administration, dosage, and strength of the generic is comparable to the brand name drug. Through the streamlined ANDA process, generics effectively piggyback off the pioneer's proven research and development and due diligence from manufacturing, testing, and approving the brand name drug.

By statute, the unauthorized disclosure of trade secrets and confidential and proprietary information by federal government officials who obtain that information in the course of their official duties or employment is expressly prohibited. 18 U.S.C. § 1905. Governing FDA regulations pointedly state: "Data and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." 21 C.F.R. § 20.61(c); *accord id.* § 314.430(g) ("The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public . . . or they relate

[5] An ANDA applicant must certify or state: (1) the patent information is not listed in the Orange Book (Paragraph I certification); (2) the patent listed in the Orange Book has expired (Paragraph II certification); (3) the date the patent will expire (Paragraph III certification); and/or (4) that an Orange Book-listed "patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the [generic] drug" (Paragraph IV certification). *See Report to Congress: The Listing of Patent Information in the Orange Book* at 8–9 (last viewed Jan. 17, 2024). Although not relevant to deciding the issues before this Court, as discussed *infra*, the parties engaged in Paragraph IV certifications and resulting ANDA patent infringement litigation related to the brand and generic drugs discussed herein.

to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information . . . : (1) Manufacturing methods or processes, including quality control procedures."). These protections are intended to promote full and transparent engagement between drug manufacturers and the FDA throughout the application and approval process. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1010–11 (1984) (nondisclosure protections afforded under the Trade Secrets Act, 18 U.S.C. § 1905, are intended to protect "reasonable investment-backed expectation[s]").

II. Vanda's Brand Name Drugs

Vanda filed NDA No. 022192 for Fanapt® on September 27, 2007. In reviewing the application for the brand name drug, the FDA rejected Vanda's proffered dissolution specification and instead proposed an alternative specification (i.e., a rate of not less than Q where "Q = [b4%] in 30 minutes for all strengths of the Tablet").[6] Vanda adopted the FDA's proposed dissolution rate and the agency approved Fanapt® as safe and effective for consumers on May 6, 2009.

The FDA similarly rejected Vanda's proffered dissolution specification for Hetlioz®, included in NDA No. 205677 and filed on May 31, 2013. In reviewing Vanda's application, the agency found that "[t]he proposed dissolution criterion is not supported by the data and is not acceptable."[7] As with Fanapt®, the FDA proposed an alternative specification for dissolution of Hetlioz® (i.e., a rate of not less than Q where "Q = [b4%] at 15 minutes").[8] Of note, Vanda's NDA included claimed confidential information regarding the manufacturer's processes for detecting and controlling impurities in Hetlioz®'s active ingredient (i.e., tasimelteon) as well as "the methods through which it controls the size of tasimelteon crystals in its drug product," otherwise known as micronization. ECF 1 at 17. Following Vanda's adoption of the FDA's proposed dissolution rate, the FDA approved Hetlioz® as safe and effective on January 31, 2014.

III. Claimed ANDA Disclosures and Parallel Litigation

Vanda's claims arise from the FDA's alleged engagement with four competitors who filed ANDAs seeking approval to bring generic versions of Fanapt® and Hetlioz® to market. More specifically, Vanda alleges FDA officials disclosed the brand

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[6] *See* https://perma.cc/V9YV-9PSN at 41 (last viewed Jan. 17, 2024). The specific dissolution rates the FDA recommended to Vanda for each brand name drug and, later, to the generic manufacturers, detailed *infra*, were classified "Trade Secret / Confidential" and redacted from the record presented in this matter using a "b4" designation. Because the parties stipulate the percentage values identified herein as "b4" are identical for the respective brand name drugs and generics, disclosure of the specific dissolution rates is therefore unnecessary to resolve this motion.

[7] *See* https://perma.cc/AGW8-W4DU at 152 (last viewed Jan. 17, 2024).

[8] *Id.* at 153.

pharmaceutical company's confidential trade secret information in correspondence with the following competitors: Lupin Limited and/or Lupin Pharmaceuticals (Lupin), Inventia Healthcare Private Limited (Inventia), Teva Pharmaceuticals (Teva), and Apotex Corporation (Apotex). The alleged disclosures, summarized below, relate to proposed dissolution specifications, impurities analysis, and micronization.

Lupin submitted ANDA No. 206890 for generic Fanapt® (iloperidone) on May 8, 2014. Rejecting Lupin's proposed dissolution specification, the FDA explained, "[t]he firm's proposed specification . . . is too broad and not supported by their data and therefore not acceptable." ECF 7-2 at 1. Instead, the FDA proposed the same specification for dissolution the agency recommended and approved for Fanapt® (i.e., a rate of not less than [b4]% (Q) dissolved in 30 minutes). *Id.* at 2. A contemporaneous note confirms that an FDA official consulted the June 29, 2012 annual report produced for Fanapt® in determining what dissolution specification to recommend to Lupin. ECF 7-2 at 2 ("Reviewer's Note: the reviewer checked the NDA Annual report for the above mentioned specification for the [reference listed drug].") (footnote omitted). Following Lupin's adoption of the FDA's proposed dissolution rate, on May 5, 2022, its generic was formally approved as safe and effective.

Within two weeks of Lupin's application, on May 21, 2014, Inventia submitted ANDA No. 207231 for generic Fanapt® (iloperidone). Rejecting Inventia's proposed dissolution specification as "too liberal and not acceptable," *see* ECF 7-1 at 16, the FDA again recommended a dissolution rate of not less than [b4]% (Q) dissolved in 30 minutes. Internal records note the FDA's proposed specification "is the same as recommended by the NDA applicant for the [reference listed drug] product." *Id.* at 14. As in Lupin's review, the FDA official consulted the annual report produced for Fanapt® in determining what dissolution specification to recommend to Inventia. *See id.* ("The reviewer checked the NDA Annual report for the above mentioned specification for the [reference listed drug] product."). Following Inventia's adoption of the FDA's proposed dissolution rate, its generic was approved as safe and effective on November 28, 2016.

In the interim, in January 2018, Teva submitted ANDA No. 211601 for generic Hetlioz® (tasimelteon). The FDA rejected Teva's proposed dissolution specification, instead recommending the specification the agency previously proposed and approved for Hetlioz® (i.e., a rate of not less than [b4]% (Q) dissolved in 15 minutes). Citing Vanda's U.S. Patent Application No. 20170190683A1 (Highly Purified Pharmaceutical Grade Tasimelteon) (published July 6, 2017),[9] the agency also

[9] The USPTO granted Vanda's patent (U.S. Patent No. 10,829,465 B2) on November 10, 2020. The abstract provides: "A process for preparing a batch of highly purified, pharmaceutical grade tasimelteon comprises analyzing a batch of tasimelteon synthesized under [good manufacturing practice (GMP)] conditions for the presence of one or more identified impurities." *See* https://perma.cc/8FEV-3W6L at 1 (last viewed Jan. 18, 2024).

inquired whether the generic manufacturer was capable of detecting, quantifying, and controlling specified impurities in the drug and, if so, instructed Teva to produce supporting data including limits of detection and quantification and linearity. Following Teva's adoption of the FDA's proposed dissolution rate, and the company's submission of the requested impurity information, its generic was approved by the FDA as safe and effective on December 12, 2022.

Concomitantly, Apotex submitted ANDA No. 211607 for generic Hetlioz® (tasimelteon) in January 2018. As with Teva's application, the FDA rejected Apotex's proposed dissolution specification and recommended the brand name drug rate of not less than [b4]% (Q) dissolved in 15 minutes. Likewise, the FDA instructed Apotex to clarify its capabilities related to detecting, quantifying, and controlling specified impurities in the drug and, if applicable, instructed Apotex to produce supporting data including limits of detection and quantification and linearity. The FDA also inquired whether its generic drug was "subject to any particle size reduction," suggesting "tasimelteon 'may be subject to micronization.'" ECF 1 at 38. On December 20, 2022, following Apotex's adoption of the FDA's proposed dissolution rate, and the manufacturer's submission of the requested impurity data and micronization information, its generic was approved by the FDA as safe and effective.

Regarding the FDA's review of these ANDAs, Vanda alleges the agency improperly disclosed its trade secrets by offering recommendations to the generic competitors and thus breached its duty of confidentiality. More specifically, Vanda alleges the FDA's communications regarding dissolution rates, impurities, and micronization to the ANDA applicants revealed Vanda's confidential manufacturing information and caused economic injury to the company.[10] In sum, the generic ANDAs and FDA's alleged disclosures of confidential trade secrets, include:

Competitor	Pioneer Model	ANDA Submitted	FDA's Alleged Disclosures	FDA Approval
Lupin	Fanapt® (Iloperidone)	May 8, 2014	• Dissolution Rate	May 5, 2022
Inventia	Fanapt® (Iloperidone)	May 21, 2014	• Dissolution Rate	Nov. 28, 2016
Teva	Hetlioz® (Tasimelteon)	Jan. 2018	• Dissolution Rate • Impurities Inquiry	Dec. 12, 2022
Apotex	Hetlioz® (Tasimelteon)	Jan. 2018	• Dissolution Rate • Impurities Inquiry • Particle Size/ Micronization Inquiry	Dec. 20, 2022

[10] Throughout its complaint, Vanda also references additional competitors seeking to bring generic versions of Fanapt® and Hetlioz® to market, including: Alembic Pharmaceuticals Ltd., MSN Pharmaceuticals Inc. (MSN), Roxanne Laboratories Inc. n/k/a Hikma Labs Inc. (transferred to West-Ward Pharmaceuticals Corp.), and Taro Pharmaceutical Industries Ltd. However, at this time, Vanda has not alleged any improper FDA disclosures to these generic manufacturers.

Following the FDA's approval of the generic competitors' ANDAs, Vanda initiated ANDA patent infringement suits against the companies in federal district court.[11] Prior to commencing this action against the United States on May 1, 2023, Vanda also filed a number of civil suits against the FDA in federal district court.[12]

DISCUSSION

I. Standards of Review

This Court's statutorily prescribed jurisdiction to adjudicate claims and grant relief requires an affirmative waiver of sovereign immunity. *United States v. Testan*, 424 U.S. 392, 399 (1976). When the Court's authority to entertain a cause of action is challenged or otherwise called into question under RCFC 12(b)(1), the onus is on plaintiff to present preponderant evidence that jurisdiction is proper. *Reynolds v. Army & Air Force Exch. Serv.*, 846 F.2d 746, 748 (Fed. Cir. 1988). In evaluating the jurisdictional propriety of a claim, the Court is "obligated to assume all factual allegations to be true and to draw all reasonable inferences in plaintiff's favor." *Henke v. United States*, 60 F.3d 795, 797 (Fed. Cir. 1995) (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974); *Catawba Indian Tribe v. United States*, 982 F.2d 1564, 1568–69 (Fed. Cir. 1993)).

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[11] *See, e.g.*, *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-651, 2022 WL 17593282 (D. Del. Dec. 13, 2022) (judgment entered for defendants Teva and Apotex following four-day bench trial), *aff'd*, No. 23-1247, 2023 WL 3335538, at *2 (Fed. Cir. May 10, 2023), *pet'n for cert. docketed*, __ U.S.L.W. __ (U.S. Jan. 17, 2024) (No. 23-768); *Vanda Pharms., Inc. v. Lupin Ltd.*, No. 15-1073 (D. Del.) (voluntarily dismissed following settlement wherein Lupin deferred commercialization of generic product until Nov. 2, 2027); *Vanda Pharms., Inc. v. Inventia Healthcare PVT. LTD.*, No. 15-921 (D. Del.) (case remains pending despite confidential stipulation wherein Inventia has not launched or commercialized generic drug); *see also* https://perma.cc/4WDE-ZFPS at 18–19 (Vanda's Quarterly Report (Form 10-Q) for the period ending March 31, 2022, noting the above-referenced confidential stipulation with Inventia and non-exclusive licensing agreement with MSN and Impax Laboratories, LLC to manufacture and market MSN's generic version of Hetlioz®) (last viewed Jan. 17, 2024).

[12] *See, e.g.*, *Vanda Pharms., Inc. v. FDA*, No. 23-1674 (D.D.C.) (Freedom of Information Act (FOIA) litigation remains pending); *Vanda Pharms., Inc. v. FDA*, No. 23-1673 (D.D.C.) (same); *Vanda Pharms., Inc. v. FDA*, No. 22-938 (D.D.C.) (summary judgment granted in favor of plaintiff in FOIA litigation); *Vanda Pharms., Inc. v. FDA*, No. 23-280 (D.D.C.) (Administrative Procedures Act (APA) challenge to FDA's decision to approve Teva's ANDA of generic Hetlioz® remains pending); *Vanda Pharms., Inc. v. FDA*, No. 22-3808 (D.D.C.) (FOIA litigation remains pending); *Vanda Pharms., Inc. v. FDA*, No. 22-3807 (D.D.C.) (same); *Vanda Pharms., Inc. v. FDA*, No. 22-3413 (D.D.C.) (same); *Vanda Pharms., Inc. v. FDA*, No. 22-3052 (D.D.C.) (FOIA litigation voluntarily dismissed following settlement); *Vanda Pharms., Inc. v. FDA*, No. 22-2775 (D.D.C.) (APA challenge to FDA's alleged failure to issue a decision on Vanda's December 2018 Supplemental NDA for Hetlioz® and delay in scheduling a hearing remains pending); *Vanda Pharms., Inc. v. FDA*, No. 22-1432 (D.D.C.) (summary judgment for defendant in APA challenge to FDA's decision denying Vanda "Fast Track" designation for tradipitant–a drug to treat gastroparesis); *Vanda Pharms., Inc. v. FDA*, No. 22-1405 (D.D.C.) (FOIA litigation voluntarily dismissed following settlement).

In turn, when considering a motion to dismiss for failure to state a claim under RCFC 12(b)(6), courts "must accept as true all the factual allegations in the complaint and . . . indulge all reasonable inferences in favor of the non-movant." *Sommers Oil Co. v. United States*, 241 F.3d 1375, 1378 (Fed. Cir. 2001) (citations omitted). "A trial court should not dismiss a complaint for failure to state a claim unless it is beyond doubt that the plaintiff can prove no set of facts which would entitle him to relief." *Id.* (quotation marks omitted) (quoting *Hamlet v. United States*, 873 F.2d 1414, 1416 (Fed. Cir. 1989)). Assertions of legal conclusions are not credited during this assessment, and the complaint must include nonconclusory factual allegations setting forth a plausible–as opposed to merely a conceivable–claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)).

II. Fifth Amendment Taking (Count I)

The government seeks dismissal of plaintiff's Fifth Amendment takings claim (Count I) under RCFC 12(b)(6), principally citing Vanda's claims that FDA officials violated governing statutes and regulations generally prohibiting the disclosure of trade secrets and confidential commercial information. Upon this ground, defendant avers Vanda's claims of *ultra vires* conduct fails to plead a viable taking under the law of this circuit. The government further contends that any surviving constitutional claim should be limited to a regulatory taking, citing Vanda's failure to adequately plead a per se taking. Relatedly, the government maintains Vanda failed to adequately plead the requisite economic harm or interference with the company's reasonable investment-backed expectations. For the following reasons, the Court denies the government's motion to dismiss Count I of Vanda's complaint.

A. Unauthorized v. Unlawful

As recently stated by this Court in *Darby Development Co. v. United States*,

> To assert a viable takings claim against the United States, the government action in issue must be duly authorized by Congress. Where . . . a federal agency's actions are not authorized, the actions "may be enjoinable, but they do not constitute [a] taking effective to vest some kind of title in the government and entitlement to just compensation in the owner or former owner."

160 Fed. Cl. 45, 51–52 (2022) (citations omitted), *appeal docketed*, No. 22-1929 (Fed. Cir. June 24, 2022). Although seemingly counterintuitive, unlawful acts are not per se unauthorized for purposes of engaging in a Fifth Amendment takings analysis.

In *Del-Rio*, the United States Court of Appeals for the Federal Circuit distinguished an unauthorized government act for which a takings claim is legally

infirm from an authorized government act later deemed unlawful which may constitute a compensable taking, explaining:

> In a case such as this one, in which the alleged taking consists of regulatory action that deprives a property-holder of the enjoyment of property, government agents have the requisite authorization if they act within the general scope of their duties, *i.e.*, if their actions are a "natural consequence of Congressionally approved measures," or are pursuant to "the good faith implementation of a Congressional Act[.]" The principle underlying this rule is that when a government official engages in *ultra vires* conduct, the official "will not, in any legal or constitutional sense, represent the United States, and what he does or omits to do, without the authority of Congress, cannot create a claim against the Government 'founded upon the Constitution.'"
>
> In holding that *ultra vires* conduct cannot give rise to a Fifth Amendment taking, the courts have drawn an important distinction between conduct that is "unauthorized" and conduct that is authorized but nonetheless unlawful. Merely because a government agent's conduct is unlawful does not mean that it is unauthorized; a government official may act within his authority even if his conduct is later determined to have been contrary to law.

146 F.3d at 1362 (citations omitted). As in *Del-Rio*, where the challenged agency action involved the Department of the Interior's review and approval of mining leases, *see id.* at 1360, the FDA's review and approval of NDAs and ANDAs falls squarely within the scope of the federal agency's statutorily authorized duties, even if certain acts taken during the review process are ultimately found to be unlawful. *Id.* at 1362–63; *compare, e.g.*, *Darby Dev.*, 160 Fed. Cl. at 51–55 (Fifth Amendment takings claim failed as a matter of law because the Centers for Disease Control and Prevention lacked the requisite authority to issue contested nationwide residential eviction moratoria to combat the spread of COVID-19). As such, the Court must deny defendant's motion to dismiss on this basis.

B. Proprietary Interest

The more vexing issue in this case is whether Vanda can assert a cognizable property interest in the alternative dissolution specification the FDA proposed to Vanda during the approval process. Although the FDA generated the alternative dissolution specifications in evaluating Vanda's data, it is not axiomatic that the alternative data points became Vanda's trade secrets or confidential commercial information simply because the company adopted them. After all, Vanda was incentivized to accept the FDA counterproposal to expedite approval and bring its branded drugs to the marketplace. Similar inquiries must be asked regarding whether and to what extent the FDA is precluded from inquiring about a generic

manufacturer's impurity detection and micronization capabilities simply because Vanda addressed them in their NDA.

Consideration should also be given to the potential consequences of crediting Vanda's proprietary claims. Such a ruling may adversely impact (or preclude altogether) the FDA's ability to provide other brand name and generic manufacturers with comparable assistance. As raised by the Court during oral argument, without comparing the data and information of an approved NDA to the proposed data and information included in a generic's ANDA under review, the FDA may authorize inconsistent results. In that case, Vanda might claim the FDA improvidently delayed the brand name product to market or, in the alternative, hastened the generic drug's review and approval. The FDA could also reject a generic's proposed dissolution specification previously accepted for a brand manufacturer or another generic, subjecting the agency to accusations of delaying a generic drug's approval.

For now, these theoretical issues must wait. As highlighted by Vanda at oral argument (and conceded by the government), defendant effectively waived these issues for purposes of the pending dispositive motion. *See* ECF 14 at 10 n.3 ("To be clear, we reserve the right to contest Vanda's alleged property interest in any of the information at issue if this case proceeds beyond the pending motion, including Vanda's alleged property interest in the dissolution specifications that FDA provided to Vanda."). The parties must address these issues as this case proceeds.

C. Per Se v. Regulatory Taking

Vanda alleges the FDA's disclosure of the brand manufacturer's trade secrets and confidential commercial information to competitors "substantially diminished their value," ECF 1 at 42, and infringed upon Vanda's "right to exclude" generics from the market. ECF 11 at 29. Such claims strongly suggest Vanda is pursuing a regulatory takings claim under *Monsanto*, 467 U.S. at 986, as opposed to a per se invasion. *See 767 Third Ave. Assocs. v. United States*, 48 F.3d 1575, 1580 (Fed. Cir. 1995) ("A taking may occur as a result of a regulatory action that is neither a physical invasion nor a physical restraint.") (later citing *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922) ("The general rule at least is that while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking.")). If true, Vanda's constitutional claim, valued "in excess of millions of dollars," ECF 1 at 42, must be assessed under the three-part test articulated in *Penn Central Transportation Co. v. City of New York*: (1) the "economic impact of the regulation on the claimant"; (2) "the extent to which the regulation has interfered with distinct investment-backed expectations"; and (3) "the character of the governmental action." 438 U.S. 104, 124 (1978).

Notwithstanding the Court's first impression, Vanda seeks to assert in the first instance a per se invasion of the brand manufacturer's trade secrets and confidential commercial information and alternatively claim a regulatory taking. While Vanda is

correct that the government's infringement of its right to exclude can certainly constitute a per se taking, *Cedar Point Nursery v. Hassid,* 594 U.S. __, 141 S. Ct. 2063 (2021)–which Vanda relied heavily upon at oral argument–is readily distinguishable from this case. In *Cedar Point*, the government infringed upon the landowners' real property by allowing union representatives to physically enter the land on a regular cadence to engage workers in union activities. *See* 141 S. Ct. at 2074. The Supreme Court held that the physical nature of the union's presence on the land constituted an invasion of the property, since union representatives could "traverse it at will." *See id.* Although Vanda may have the right to exclude others from its trade secrets and confidential commercial information, the Court is nevertheless unconvinced that *Cedar Point*'s ultimate holding extends to intangible property interests as plaintiff alleges. However, in light of the uncertainty of Vanda's cognizable interest in the claimed FDA-generated trade secrets and confidential proprietary information, as discussed *supra*, it is premature to resolve this issue now.

III. Breach of Contract (Count II)

To resolve defendant's dispositive motion as to Count II of Vanda's complaint, the Court must address the true nature of the alleged contract at issue in this case, regardless of the legal obligations Vanda attributes to the FDA. If, as alleged in the complaint, Vanda's NDA submissions created implied-in-fact contracts with the FDA, any breach of those agreements would fall within this Court's jurisdiction. In contrast, the Court lacks jurisdiction over Count II if the alleged contractual relationship is implied-in-law as the government avers. *City of Cincinnati v. United States*, 153 F.3d 1375, 1377 (Fed. Cir. 1998) ("Implied-in-fact contracts, which are within the jurisdiction of the Court of Federal Claims, differ significantly from implied-in-law contracts, which impose duties that are deemed to arise by operation of law and are outside the jurisdiction of the Court of Federal Claims.") (citing cases).

As summarized by the Federal Circuit in *City of Cincinnati*:

> An implied-in-fact contract is one founded upon a meeting of the minds, which, although not embodied in an express contract, is inferred, as a fact, from conduct of the parties showing, in the light of the surrounding circumstances, their tacit understanding. Like an express contract, an implied-in-fact contract requires (1) mutuality of intent to contract; (2) consideration; and, (3) lack of ambiguity in offer and acceptance. When the United States is a party, a fourth requirement is added: The government representative whose conduct is relied upon must have actual authority to bind the government in contract.

Id. (citations and quotation marks omitted). Vanda avers the FDA maintains a statutory "standing offer" to review NDAs (and ANDAs), which Vanda accepted by submitting NDAs for Fanapt® on September 27, 2007, and Hetlioz® on May 31, 2013. According to Vanda, the drug manufacturer's worldclass data and application fees

are exchanged in consideration for the government's confidential review and potential approval of the brand name drugs. As discussed *supra*, the requisite contractual authority and asserted confidentiality requirements are presumably codified in the statutory and regulatory scheme.

In support of the claimed implied-in-fact contract, Vanda primarily relies upon the Federal Circuit's decision in *Airborne Data, Inc. v. United States*, 702 F.2d 1350 (Fed. Cir. 1983) (per curiam). In that case, the Federal Circuit affirmed the trial court's conclusions that a company's submission of an unsolicited proposal for a government contract–which included trade secrets and a confidentiality restriction–formed an implied-in-fact contract to safeguard the confidential information, breached when the receiving agency used the company's proposal to solicit bids from third parties for similar services. *Id.* at 1352–53. Vanda also cites a decision by this Court's predecessor in *Research, Analysis, & Development, Inc. v. United States*, 8 Cl. Ct. 54 (1985). This case similarly involved a company's submission of an unsolicited proposal for a military contract–including proprietary information and a confidentiality statement–ultimately compromised when the Air Force published the proprietary information in seeking comparable technological proposals from third parties. *Id.* at 56–57. Finding the material facts indistinguishable from *Airborne Data*'s binding precedent, the trial court in *Research Analysis* likewise found an implied-in-fact confidentiality contract was consummated and subsequently breached. *Id.* at 61.

The implied-in-fact contractual relationships in *Airborne Data* and *Research Analysis* are readily distinguishable from the facts in this case. Put simply, there is a clear difference between: (a) submitting a proposal seeking a government contract with a particular federal agency; and (b) filing an application for regulatory approval to bring a product to market as required by federal law. *Compare Airborne Data*, 702 F.2d at 1352–53 *and Research Analysis*, 8 Cl. Ct. at 56–61 *with Perry v. United States*, 149 Fed. Cl. 1, 17–20 (2020) (inventor's submission of patent applications to the USPTO does not consummate a contract claim within the jurisdictional authority of the Court of Federal Claims, warranting dismissal under RCFC 12(b)(1); alternatively, "any attempt to construe the relationship between the USPTO and a patent applicant as contractual is legally implausible on its face," subject to dismissal under RCFC 12(b)(6)), *aff'd*, No. 20-2084, 2021 WL 2935075 (Fed. Cir. July 13, 2021) (per curiam).

At most, any claimed disclosure of Vanda's purported trade secrets or confidential commercial information is a failure to duly adhere to the legal confidentiality requirements imposed by statute and regulation rather than a breach of an implied-in-fact contract. Vanda's characterization notwithstanding, Count II must be dismissed as either an implied-in-law contract outside the Court's jurisdiction or an improvidently pleaded claim that is facially implausible as a matter of law.

IV. Time-Barred Claims

The government finally argues that any claims related to Inventia are time-barred and should be dismissed. The Court agrees. "A claim under the Tucker Act, 28 U.S.C. § 1491, . . . must be brought 'within six years after such claim first accrues.'" *Adera v. United States*, No. 22-1074, 2023 WL 3768645, at *2 (Fed. Cir. June 2, 2023) (quoting *Katzin v. United States*, 908 F.3d 1350, 1358 (Fed. Cir. 2018) (citing 28 U.S.C. § 2501)). Otherwise, the claim is time-barred and must be dismissed for lack of jurisdiction. *John R. Sand & Gravel Co. v. United States*, 457 F.3d 1345, 1354 (Fed. Cir. 2006) ("Pursuant to 28 U.S.C. § 2501, claims brought in the Court of Federal Claims under the Tucker Act are 'barred unless the petition thereon is filed within six years after such claim first accrues.'"), *aff'd*, 552 U.S. 130 (2008). A claim first accrues "when all the events have occurred which fix the alleged liability of the defendant and entitle the plaintiff to institute an action." *Hopland Band of Pomo Indians v. United States*, 855 F.2d 1573, 1577 (Fed. Cir. 1988); *Conner v. United States*, No. 23-1316, 2023 WL 5011753, at *2 (Fed. Cir. Aug. 7, 2023) (citing *Goodrich v. United States*, 434 F.3d 1329, 1333 (Fed. Cir. 2006) (citations omitted)). In this case, the FDA's alleged disclosure of Vanda's claimed trade secrets and confidential commercial information to Inventia took place on or before November 28, 2016, when the generic drug was approved. Yet Vanda failed commence this action until May 1, 2023–over five months after the six-year jurisdictional deadline.

In an effort to salvage the Inventia-based claims, Vanda now seeks to invoke the accrual suspension rule. "[S]trictly and narrowly applied," the rule is triggered only when a plaintiff can demonstrate the government "concealed its acts," resulting in plaintiff's lack of awareness, or the alleged injury was "'inherently unknowable' . . . at the time the cause of action accrued." *Ingrum v. United States*, 560 F.3d 1311, 1314–15 (Fed. Cir. 2009) (citing cases); *accord Welcker v. United States*, 752 F.2d 1577, 1580 (Fed. Cir. 1985) (quoting *Japanese War Notes Claimants Ass'n v. United States*, 373 F.2d 256, 358–59 (Ct. Cl. 1967)). Relevant here, "[t]he phrase 'inherently unknowable' has been construed to mean that the factual basis for the claim is 'incapable of detection by the wronged party through the exercise of reasonable diligence.'"[13] *Texas Nat. Bank v. United States*, 86 Fed. Cl. 403, 414 (2009) (quoting *Ramirez-Carlo v. United States*, 496 F.3d 41, 47 (1st Cir. 2007)); *accord Young v. United States*, 529 F.3d 1380, 1384 (Fed. Cir. 2008) ("According to the accrual suspension rule, 'the accrual of a claim against the United States is suspended, for purposes of 28 U.S.C. § 2501, until the claimant knew or should have known that the claim existed.'") (quoting *Martinez v. United States*, 333 F.3d 1295, 1319 (Fed. Cir. 2003)).

Vanda contends it first became aware of the FDA's purported disclosures to Inventia on or about April 20, 2023, when the FDA responded to Vanda's March 27, 2023 FOIA request related to the generic manufacturer's ANDA approval. But Vanda

[13] Vanda does not allege the FDA took any steps to conceal its actions.

is silent as to its decision to wait six years and four months after Inventia's drug approval to submit its FOIA request or otherwise inquire about the generic's ANDA. Considering Vanda commenced directly related ANDA litigation against Inventia on October 13, 2015–over a year before the ANDA was approved and made public–this time gap is particularly notable here.[14] *See Vanda Pharms., Inc. v. Inventia Healthcare PVT. LTD.*, No. 15-921 (D. Del. filed Oct. 13, 2015). Additionally, upon approval of Inventia's ANDA on November 28, 2016, the information Vanda ultimately secured through its FOIA request was "immediately available for public disclosure." *See, e.g.*, 21 C.F.R. § 314.430(e) ("After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. . . . (7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application . . . ."). Lastly, the Federal Circuit has squarely rejected attempts to invoke the accrual suspension rule based solely on additional information received through Privacy Act and FOIA requests after the six-year statute of limitations expired. *See Adera*, 2023 WL 3768645, at *4.

For these reasons, Vanda's assertion that the alleged FDA disclosures to Inventia were incapable of detection prior to November 28, 2022–within six years of the generic's FDA approval–rings hollow. Accordingly, the company's claims relating to Inventia are time-barred.

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss (ECF 7) is **DENIED-IN-PART** and **GRANTED-IN-PART** as follows: defendant's motion to dismiss Count I (Fifth Amendment taking) is **DENIED**; and defendant's motion to dismiss Count II (breach of contract) and plaintiff's claims involving Inventia are **GRANTED**. In accordance with RCFC 12(a)(4)(A)(i), defendant shall file an answer on or before February 1, 2024.

It is so **ORDERED**.

Armando O. Bonilla
Judge

[14] As noted *supra*, although Vanda and Inventia have reportedly settled the ANDA litigation, the district court matter remains pending.