Receipt number AUSFCC-8683145

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

VANDA PHARMACEUTICALS INC., Plaintiff, v. THE UNITED STATES OF AMERICA, Defendant.	Civ. No. 23-629 C

COMPLAINT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) brings this Complaint against Defendant the United States of America and alleges as follows:

NATURE OF THE ACTION

1. Vanda brings this action for the uncompensated taking of property in violation of the Fifth Amendment to the U.S. Constitution and for breach of an implied-in-fact contract.

2. Developing new pharmaceutical therapies that save and improve lives is a costly and time-consuming endeavor. Drug innovators invest millions of dollars and years (if not decades) of research and development in each new product. Hundreds of millions of Americans—and billions of people around the globe—benefit from these life-saving and life-changing drugs.

3. To fund their massive expenditures in research and development, innovators protect their novel creations through intellectual property. Absent such legal protections, manufacturers could not realize a return on their enormous investments. Intellectual property is thus the fuel of

the pharmaceutical development engine; without strong protections, the development of breakthrough new drugs would grind to a halt.

4. Drug researchers patent many of their inventions, securing the benefit of the patent bargain: Broad protections are provided for time-limited periods, while information is disclosed to the public.

5. Other intellectual property assets are maintained as trade secrets and other proprietary, confidential information. Drug developers maintain substantial confidential information related to the development, testing, and manufacturing of pharmaceutical products. Pharmaceutical innovators go to great lengths to protect the confidentiality of this information, ensuring that it is not publicly disclosed. This confidentiality is essential to allowing developers to realize a return on their enormous investments of money and time.

6. The complex (and in some respects highly arbitrary) regulatory approval necessary to market drugs in the United States greatly enhances the costs associated with commercializing a new product. Before a company can begin recouping its research and development costs, it must secure regulatory approval from the Food and Drug Administration (FDA) through the submission of a New Drug Application (NDA).

7. The FDA approval process involves the submission of hundreds (if not thousands) of pages of information, covering sensitive topics such as a drug's chemical composition, details relating to its manufacture and quality control, studies demonstrating a drug's safety and effectiveness, and much more. Many of these details constitute trade secrets and other confidential information that companies carefully protect to safeguard their extensive investments.

8. In recognition of the value of drug sponsors' confidential commercial information, FDA regulations and federal statutes strictly limit the extent to which the agency can disclose information submitted in an NDA to the public or to competing drug companies. These regulations prohibit the disclosure of confidential commercial information and trade secrets even after applications are approved. FDA has repeatedly confirmed this promise and obligation of confidentiality of drug sponsor information through its guidance and public statements.

9. Vanda submitted New Drug Application No. 022192 to FDA on September 27, 2007. This application sought approval to market Fanapt® for the acute treatment of schizophrenia in adults. Iloperidone is the active ingredient in Fanapt®.

10. Vanda submitted New Drug Application No. 205677 to FDA on May 31, 2013. This application sought approval to market Hetlioz® for the treatment of Non-24 hour sleep-wake disorder. Tasimelteon is the active ingredient in Hetlioz®.

11. Vanda's applications contained highly confidential information about its manufacturing processes for Fanapt® and Hetlioz®, much of which constituted trade secrets. Vanda supplied FDA this information in reliance on FDA's promise to maintain strict confidentiality of this information. To this day, details of the manufacturing process Vanda actually uses to manufacture the active ingredients for its drugs and those drugs' formulations remain strictly confidential.

12. Federal law authorizes generic drug manufacturers, after certain periods of patent and other exclusivities have elapsed, to seek marketing approval to sell generic versions of drugs. These generic manufacturers have done none of the innovative work required to develop the new drug: They have not developed the molecule or product at issue; they have not invested in

substantial and expensive pre-clinical and clinical research; and they have not navigated FDA's complex approval process to reach approval. Rather, generic manufacturers simply seek to mimic the branded company's product, relying on the groundbreaking scientific and clinical information painstakingly developed by the drug innovator.

13. In order to gain marketing approval, one of the few things a generic manufacturer must accomplish is to prove that its generic product meets the statutory requirement of bioequivalence. Congress has provided a calibrated way to enable this: An innovator pharmaceutical manufacturer must supply sample product to the generic on a commercially reasonable basis, which allows the generic to perform dissolution and bioequivalence testing on both the genuine product and its attempted clone. But Congress did *not* obligate a branded company to disclose its confidential information regarding the product's composition, its manufacture, or the testing results that the branded company performed.[1]

14. When a generic manufacturer wishes to market a clone of an innovator's branded product, the generic submits an Abbreviated New Drug Application (ANDA) to FDA. FDA then

[1] The secrecy of the branded product's dissolution testing is, among other things, an important anti-fraud tool. One large generic drug manufacturer, Ranbaxy USA Inc., the U.S. subsidiary of the then-giant generic manufacturer Ranbaxy Laboratories Limited, pleaded guilty to felony charges—and paid $500 million—in connection with massive fraud regarding dissolution and bioequivalence data. *See* Office of Public Affairs, *Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA*, DOJ (May 13, 2013) https://perma.cc/X8TX-2PGJ; *see also* Katherine Eban, *Bottle of Lies: The Inside Story of the Generics Drug Boom* (2019). To gain approval, generics must do their *own* dissolution and bioequivalence testing on the product, verifying that they in fact did the underlying tests.

reviews this submission, often resulting in discussions between FDA and the generic about steps the generic must take to achieve an approvable product.

15. FDA has previously acknowledged the impropriety of relying on and sharing data from a pioneer drug's application when considering whether to approve proposed generic drugs. Doing so violates a host of laws and regulations—and results in the unlawful disclosure of an innovator's confidential information.

16. FDA, however, has breached its confidentiality obligations with respect to Vanda. As documents Vanda has obtained detail, FDA blatantly and forthrightly relied on data in one of Vanda's drug applications and then disclosed that information to Vanda's competitors. All the while, FDA continued to refuse to release that same information to the public, on the basis that it constituted trade secret or confidential commercial information. And FDA's misconduct does not appear isolated: The material available thus far through public record requests demonstrates that FDA routinely directly or indirectly discloses confidential portions of drug sponsors' applications to competitors seeking to market generic knockoffs.

17. FDA's disclosure of Vanda's trade secrets and confidential commercial information to Vanda's competitors constitutes a taking under the Fifth Amendment for which Vanda has never received compensation. It also constitutes a breach of implied-in-fact contact, as a result of which Vanda has suffered substantial monetary damages.

PARTIES

18. Plaintiff Vanda Pharmaceuticals Inc., is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high-impact

unmet medical needs and improve the lives of patients. Vanda is incorporated in Delaware and maintains its principal place of business in Washington, DC.

19. Defendant is the United States, acting through its various authorized agencies and personnel, including, but not limited to, the United States Food and Drug Administration. Dr. Robert M. Califf is the current Commissioner of Food and Drugs—the head of FDA.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1491, which provides that "[t]he United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any act of Congress or any regulation of an executive department."

21. Venue is appropriate only in this Court because the claim is for more than $10,000. 28 U.S.C. § 1491(a)(1); *see U.S. Marine, Inc. v. United States*, 57 F.3d 1360, 1366 (Fed. Cir. 2013).

22. Vanda is not required to further exhaust any administrative remedies because there is no remedial administrative scheme in the Federal Food, Drug, and Cosmetic Act (FDCA) that would permit it to seek redress for FDA's unlawful disclosure of Vanda's trade secrets or any other unlawful takings. In the alternative, any such administrative procedure would be futile, as Vanda has already suffered harm due to FDA's unlawful disclosure.

BACKGROUND

23. Vanda is a small pharmaceutical company whose business model largely consists of acquiring compounds that other companies failed to develop into useful treatments, identifying

potential medical uses for them, devoting substantial resources to developing them, seeking FDA approval, and commercializing them.

24. Through this model, Vanda develops and markets innovative pharmaceutical products to address high-impact unmet patient needs. Two of its drugs are Fanapt® (iloperidone), an atypical antipsychotic, and Hetlioz® (tasimelteon), a circadian-rhythm regulator.

A. New Drug Applications.

25. Under the FDCA, to obtain marketing approval for a new drug, a drug sponsor must submit a New Drug Application to the FDA. See 21 U.S.C. § 355. And the drug sponsor must demonstrate by "substantial evidence," based on the sponsor's clinical trials and other supportive evidence, that the drug is safe and effective for its intended use. *Id*. § 355(d).

26. The pharmaceutical research and development process is both lengthy and expensive. Estimates suggest that it typically takes $2.6 billion and "at least ten years for a new medicine to complete the journey from initial discovery to the marketplace." Biopharmaceutical Research & Development: *The Process Behind New Medicines*, PhRMA at 1 (2015), perma.cc/PL5Y-YW7P.

27. An NDA must include "full reports" of clinical trials "which have been made to show whether [the] drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A)(i).

28. An NDA must also include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of [the] drug." 21 U.S.C. § 355(b)(1)(A)(iv).

29. The implementing regulations for the FDCA require that each NDA contain a "Chemistry, manufacturing, and controls" (CMC) section. 21 C.F.R. § 314.50(d)(1).

30. The CMC section of an NDA must contain "[a] full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form." 21 C.F.R. § 314.50(d)(1)(i).

31. The CMC section of an NDA must also contain "[a] list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; . . . a description of the manufacturing and packaging procedures and in-process controls for the drug product; the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including, for example, tests, analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration dating." 21 C.F.R. § 314.50(d)(1)(ii)(A).

32. Since at least 1987, FDA has published guidance concerning the information NDA applicants must include to satisfy the FDCA's manufacturing and controls requirements. Ctr. For

Drugs & Biologics, *Guideline for Submitting Documentation for the Manufacture of and Controls for Drug Products*, FDA (Feb. 1987), perma.cc/A82V-YJR8 ("Manufacturing Guidance").

33. FDA's Manufacturing Guidance provides that applicants should "submit a copy of the proposed or actual master/batch production and control records or a comparably detailed description." *Id.* at 4-5. The applicant must also "[d]escribe the manufacturing and packaging process for a representative batch, including a description of each production step, actual operating conditions, equipment to be utilized and points of sampling for in-process controls." *Id.*

34. FDA's Manufacturing Guidance also requires the identification of analytical methods. *Id.* at 6. Applicants must identify "[t]he significant chemical and physical parameters important to clinical response of the drug product." *Id.* at 6-7. Applicants must "demonstrate that the manufacturing, sampling, and control processes have been designed to provide a consistent product." *Id.* at 7.

35. As part of these requirements, FDA's Manufacturing Guidance mandates compliance with "regulatory specifications," which are "the defined limits . . . within which test results for a drug substance or drug product should fall when determined by the regulatory methodology." *Id.* at 8. "All drug products require assay and identity tests and specifications." *Id.* at 9. But "[a]dditional specifications or alternative analytical methods (e.g., tests for impurities, a stability indicating assay, a second identity test, etc.) may be required as necessary." *Id.*

36. For tablets, capsules, and other solid dosage forms, the FDA Manufacturing Guidance requires proof of compliance with regulatory specifications for: "(1) Uniformity of dosage units. (2) Rate of release of the active ingredient from the dosage form by methodology … (3)

Moisture content, where applicable... [and] (4) Softening or melting points for suppositories." *Id.* at 10.

37. Confidential manufacturing information is shared with FDA under an assurance that it will remain confidential. *See generally* Richard A. Epstein, *The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009*, 66 Food & Drug L.J. 285, 289-291 (2011).

38. Specifically, FDA regulations assure applicants that "[d]ata and information submitted or divulged to the Food and Drug Administration 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). Regulations also allow applicants to "designate part or all of the information in such records as exempt from disclosure." *Id.* § 20.61(d).

39. The Federal Trade Secrets Act also categorically prohibits agency employees from disclosing confidential information submitted to them in the course of their work for agencies. 18 U.S.C. § 1905; *see Demodulation v. United States*, 103 Fed. Cl. 794, 806-07 (2012) ("[T]he parties' 'tacit understanding' that the Government would not share Plaintiff's trade secrets is established by the fact that federal employees are prohibited by statute from disseminating trade secrets. *See* 18 U.S.C. § 1905."); *see also* 21 U.S.C. § 331(j).

40. Courts have expressly held that the Federal Trade Secrets Act "prohibits . . . public disclosure of application data." *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 141 n.7 (3d Cir. 1987).

41. FDA has emphasized that it may not rely on or disclose data from an underlying NDA when considering a related ANDA. Letter from Janet Woodcock, M.D., Director, CDER, to Katherine M. Sanzo, Esq. and Lawrence, S. Ganslaw, Esq., Morgan, Lewis & Bockius, LLP; Jeffrey B. Chasnow, Esq., Pfizer; Stephan E., Lawton, Esq. and Gillian R. Woollett, Ph.D., BIO; and William R. Rakoczy, Esq., Lord, Bissell & Brook, LLP, Docket No. FDA-2003-P-0014 (formerly 2003P-0408), PDN 1, at 10 n. 14 (Oct. 14, 2003) ("FDA may rely on its earlier conclusions regarding safety and effectiveness to whatever extent the conclusions are appropriate for the drug under review in the 505(b)(2) application. Although reliance on an FDA finding of safety and effectiveness for an NDA is certainly indirect reliance on the data submitted in the original NDA, reliance on the conclusions supported by that data is not the same as manipulating those data to reach new conclusions not evident from the existing approval."); *see also* Citizen Petition Denial Response from FDA CDER to Covington & Burling LLP (Abbot Laboratories), FDA-2012-P-0317, at 13 (Sept. 23, 2016); Epstein, *supra*, at 294-95 & nn. 47-48.

42. FDA has "conceded" in litigation "that it may not actually look at the data in" an approved NDA "when reviewing" an ANDA. *Epstein*, *supra*, at 294 (citing Federal Defendants' Motion for Stay of Proceedings at 3, *Pfizer v. FDA*, No. 03-2346 (D.D.C. Feb. 18, 2004).

43. FDA regulations prohibit it from disclosing "[m]anufacturing methods or processes, including quality control procedures" even after approval of an application. 21 C.F.R. § 314.430(g)(1).

44. The primacy of confidentiality in FDA's review process is in part a recognition that "health regulation should not distort the competitive balance between two firms that would

otherwise exist in the absence of regulation." Epstein, *supra*, at 291. "FDA's power is granted for specific purposes, and its coercive power should be exercised only for the purposes for which it was granted." *Id.* at 292. FDA "should not be pressed into service as a roaming veto power over existing property rights." *Id.*

45. Pharmaceutical manufacturers, including Vanda, rely on this confidentiality obligation when they disclose highly valuable, confidential information to FDA. Drug developers invest millions upon millions in the development of each new molecule, and this investment turns in large part on the exclusivity that confidentiality helps supply. Developers thus have extensive, investment-backed expectations that, when they share confidential information with FDA, FDA will maintain this information in the utmost confidence and secrecy.

46. FDA's guarantees of confidentiality are material in that they significantly inform what confidential material sponsors, including Vanda, submit and when and how they submit it.

47. Pharmaceutical manufacturers, including Vanda, consider the viability of their intellectual property rights and the corresponding effect on their ability to recoup their investments when deciding whether to develop new drugs and/or to submit those drugs for FDA approval.

48. Indeed, a "governmental guarantee" of confidentiality—which is present here—necessarily provides "the basis of a reasonable investment-backed expectation." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1011 (1984).

B. Abbreviated New Drug Applications

49. As described above, FDA's regulatory approval process for new drugs is lengthy and expensive.

50. Congress passed the Hatch-Waxman Amendments "to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbot Labs. V. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *accord Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("The Hatch–Waxman Act was accordingly a compromise between two competing sets of interests: those of innovative drug manufacturers, who had seen their effective patent terms shortened by the testing and regulatory processes; and those of generic drug manufacturers, whose entry into the market upon expiration of the innovator's patents had been delayed by similar regulatory requirements.").

51. The Amendments created a new mechanism—the Abbreviated New Drug Application (ANDA)—by which generic manufacturers could obtain accelerated, less burdensome approval by piggybacking off the pioneer drug's NDA. *See* 21 U.S.C. § 355(j).

52. The ANDA provision "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). Instead, generic manufacturers need only submit "information to show that the new drug is bioequivalent to the listed drug" and that the labeling, route of administration, dosage form, and strength is the same. 21 U.S.C. § 355(j)(iii)-(v).

53. The FDCA's ANDA provisions specify that one ground for rejection of an ANDA is if "the methods used in, or the facilities and controls used for, the manufacture, processing, and

packaging of the drug are inadequate to assure and preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(j)(4)(A).

54. FDA thus requires that ANDAs conform to the same CMC requirements as NDAs. 21 C.F.R. § 314.94(a)(9) (stating that an ANDA "must submit" "[t]he information required under § 314.50(d)(1).").

55. The FDCA specifies the precise and limited manner in which brand drug sponsors must cooperate with attempts by generic manufacturers to copy their drugs. A sponsor must, for example, provide "sufficient quantities of" its product "on commercially reasonable, market-based terms." 21 U.S.C. § 355-2(b)(1). The statute does not require brand drug sponsors to provide information about its manufacturing processes or the composition of its drugs beyond that which is already publicly available.

56. Congress's desire to facilitate generic drugs was thus not absolute. Its goal was to allow the expedited creation of generic drugs while respecting the intellectual property rights of companies that develop pioneer drugs. Generics were allowed to enter the market only after the expiration or invalidation of relevant patents, and pioneer drug sponsors were not required to disclose trade secrets about their manufacturing processes to teach the generics exactly how to copy their drugs. Nor could Congress have directed a taking of drug innovators valuable intellectual property without providing just compensation.

FACTUAL ALLEGATIONS

A. Vanda's NDA for Fanapt®

57. Fanapt® is among a class of drugs known as atypical antipsychotics. Fanapt® helps patients suffering from schizophrenia (particularly those who have not benefitted from other anti-psychotic therapies) think more clearly, feel less nervous, and experience fewer hallucinations.

58. Iloperidone is the active ingredient in Fanapt®.

59. Vanda licensed iloperidone from a large pharmaceutical company that tried, but failed, to develop it into a useful FDA-approvable therapy.

60. On September 27, 2007, after years of development work and clinical trials, Vanda submitted NDA 022192 to FDA seeking approval to market Fanapt® for the acute treatment of schizophrenia in adults.

61. FDA approved Fanapt® on May 6, 2009.

62. Vanda's Fanapt® NDA contained sensitive and highly confidential details about its manufacturing process for Fanapt®, including its synthesis of iloperidone. Additionally, the NDA contained sensitive and highly confidential details about the formulation of Fanapt®.

63. The Fanapt® NDA, for example, contained a proposed "dissolution specification" that indicated how much of the label-listed iloperidone drug must dissolve by a specified point after administration in order for the drug to be safe and effective.

64. The dissolution specification contained in the Fanapt® NDA is the result of significant research expenditures by Vanda.

65. The details of Vanda's manufacturing process for Fanapt® and the composition of Fanapt® are not public and are not readily ascertainable by any member of the public.

66. Vanda is the owner of all rights, title, and interest in several patents that grant it various exclusive rights with respect to the making, using, offering for sale, and selling of iloperidone and in the method for using and process for making iloperidone, including patents relating to the use of iloperidone to treat schizophrenic patients.

67. Vanda has devoted millions of dollars and many years into the research, development, and regulatory approval of Fanapt®.

B. Vanda's NDA for Hetlioz®

68. Hetlioz® is among a class of drugs known as melatonin receptor agonists, which bind to and activate receptors in the brain for melatonin, a hormone that regulates the sleep cycle.

69. Tasimelteon is the active ingredient in Heltioz®.

70. Vanda licensed tasimelteon from a large pharmaceutical company that tried, but failed, to develop it into a useful, FDA-approvable therapy.

71. On May 31, 2013, after years of development work and clinical trials, Vanda submitted NDA 205677 to FDA seeking approval to market Hetlioz® to treat non-24-hour sleep-wake disorder (Non-24), a condition in which an individual's circadian rhythms become misaligned with the 24-hour day.

72. FDA approved Vanda's Hetlioz® NDA on January 31, 2014. FDA also granted Vanda's request for orphan drug designation. Since 2014, Vanda has marketed tasimelteon under the brand name Hetlioz®.

73. Vanda's Hetlioz® NDA contained sensitive and highly confidential details about its manufacturing process for Hetlioz®, including its synthesis of tasimelteon and the composition of Hetlioz®.

74. In the Hetlioz® NDA, for example, Vanda explained its process for detecting and controlling for impurities in tasimelteon.

75. The impurities present in the synthesized drug product and the levels at which those impurities are present vary greatly depending on the particulars of the relevant manufacturing process.

76. The specific impurities that Vanda controls for, the levels at which those impurities are controlled, and the methods by which those impurities are controlled have actual or potential economic value as a result of their secrecy. This information is the result of significant research expenditures by Vanda, and is a core part of its confidential manufacturing process for Hetlioz®.

77. The specific impurities that Vanda controls for, the levels at which those impurities are controlled, and the methods by which those impurities are controlled are the subject of reasonable efforts to maintain their secrecy. Vanda has not publicly disclosed this information except where required under the FDCA.

78. Vanda's NDA also includes highly confidential information about the methods through which it controls the size of tasimelteon crystals in its drug product. The need to do so and the methods actually used to do so are not widely known or readily ascertainable.

79. The details of Vanda's overall manufacturing process for tasimelteon and the composition of Heltioz® are not public and not readily ascertainable by any member of the public.

80. Vanda is the owner of all rights, title, and interest in several patents that grant it various exclusive rights with respect to the making, using, offering for sale, and selling of tasimelteon and in the method for using and process for making tasimelteon, including patents relating to the use of tasimelteon to treat SMS patients.

81. Vanda has devoted millions of dollars and many years into the research, development, and regulatory approval of Hetlioz®.

C. FDA's review and approval of ANDAs

82. FDA has considered and approved several ANDAs for generic copies of both iloperidone and tasimelteon.

1. Iloperidone ANDAs

83. To date, FDA has reviewed and approved at least five ANDAs seeking permission to market generic versions of Fanapt®.

84. On information and belief, Lupin Limited and/or Lupin Pharmaceuticals, Inc. submitted ANDA No. 206890 on or about May 8, 2014.

85. On information and belief, FDA issued a tentative approval for Lupin's ANDA on August 25, 2021. FDA issued a final approval for Lupin's ANDA on May 5, 2022.

86. On information and belief, Roxane Laboratories Inc. submitted ANDA No. 205480 in 2013.

87. Ownership of ANDA No. 205480 "transferred from Roxane Laboratories Inc. to" West-Ward Pharmaceuticals Corp. *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*, 887 F.3d 1117, 1122 n.3 (Fed. Cir. 2018).

88. FDA issued a tentative approval for West-Ward's ANDA on November 22, 2017.

89. On information and belief, FDA has never finally approved West-Ward's ANDA.

90. On information and belief, Taro Pharm Inds. Ltd. submitted ANDA No. 207098.

91. On information and belief, FDA issued a final approval for Taro's ANDA on July 22, 2019.

92. On information and belief, Inventia submitted ANDA No. 207231.

93. On information and belief, FDA issued a final approval for Inventia's ANDA on November 28, 2016.

94. On information and belief, Alembic Pharms. LTD submitted ANDA No. 207409.

95. On information and belief, FDA issued a tentative approval of Alembic's ANDA on or about July 2, 2018.

96. On information and belief, FDA has never finally approved Alembic's ANDA.

97. Vanda obtained information relating to FDA's review of Lupin's iloperidone ANDA (No. 206890) through a FOIA request submitted to FDA. On March 27, 2023, Vanda submitted a FOIA request seeking the final approval letter, the approved label, any bioequivalence review produced during FDA's evaluation, and any other readily available materials relating to Lupin's ANDA. On April 12, 2023, FDA produced 143 pages of responsive records to Vanda.

98. During its review of Lupin's iloperidone ANDA, FDA sent Lupin notice of a deficiency. In that notice, FDA informed Lupin that its proposed dissolution specification was not acceptable, and requested that Lupin "acknowledge" a specified "FDA-recommended dissolution method and specification":

BIOEQUIVALENCE DEFECIENCY TO BE PROVIDED TO THE APPLICANT
(PROCESSED BY BIO-PM)
EASILY CORRECTABLE DEFICIENCY-10 (ECD-10).

ANDA: 206890

APPLICANT: Lupin Limited

DRUG PRODUCT: Iloperidone Tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg

The Division of Bioequivalence (DB) has completed its review of the dissolution testing portion of your submission acknowledged on the cover sheet. The review of the bioequivalence (BE) studies and the waiver requests will be conducted later.

Your dissolution testing using the FDA-recommended method is acceptable. However, your proposed specification, NLT (b)(4)% (Q) in (b)(4) minutes, is not acceptable. Please acknowledge the following FDA-recommended dissolution method and specification:

USP Apparatus:	II (paddle)
Rotational Speed:	50 rpm
Temperature:	37°C ± 0.5°C
Media:	0.1 N Hydrochloric Acid
Volume:	500 mL
Specification:	NLT (b)(4)% (Q) dissolved in 30 minutes

Sincerely yours,

{See appended electronic signature page}

Ethan M. Stier, Ph.D. R.Ph.
Director
Division of Bioequivalence II
Office of Generic Drugs
Center for Drug Evaluation and Research

(Lupin FOIA Response at 142).

99. The dissolution specification in an NDA or ANDA is an important component of the manufacturing process. Solid oral dosage forms (such as tablets and capsules) must make the active drug bioavailable at a consistent rate in order to guarantee safety and efficacy.

100. On information and belief, "NLT [b4]% (Q) dissolved in 30 minutes" means that not less than a redacted percentage of the label-approved active drug must be dissolved into the media after 30 minutes under the specified dissolution method.[2]

101. In the Division of Bioequivalence Dissolution Review conducted as part of FDA's review of Lupin's ANDA, the FDA reviewer explained the origin of FDA's substitute dissolution specification:

[2] When FDA provided Vanda this material pursuant to a FOIA request, it redacted certain information on the basis of 5 U.S.C. § 552(b)(4), which authorizes the government to withhold from a FOIA requestor "trade secrets and commercial or financial information obtained from a person and privileged or confidential." FDA's designation of this information as (b)(4) confidential thus confirms FDA's own awareness of the confidentiality of this sort of information. In discovery, Vanda will seek unredacted copies of these documents—subject to any protective order—in order to further demonstrate FDA's unlawful disclosure of confidential information.

II.2 Dissolution Method As Posted on the FDA Website

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Iloperidone	Tablet	II (Paddle)	50	0.1 N Hydrochloric Acid	500	5, 10, 15, 30, 45, & 60 minutes	08/5/2010

Specification (firm's proposed): NLT (b)(4)% (Q) in (b)(4) minutes
Specification (from RLD): NLT (b)(4)% (Q) in 30 minutes[1]

Reviewer's Note: the reviewer checked the NDA Annual report for the above mentioned specification for the RLD[2]

(Lupin FOIA Response at 125).

102. On information and belief, "RLD" means "reference listed drug"—in this case, Fanapt®.

103. The footnotes on this page make clear that the "Specification (from RLD)" was taken directly from the Fanapt® NDA:

[1] DARRTS: NDA-022192: REV-CLINPHARM-01(General Review): 07/10/2008: JACKSON, ANDRE J
[2] DARRTS: NDA-022192: New/Annual Report with PMR/PMC Status: Annual Report-3: 06/29/2012

(Fanapt FOIA Response at 125).

104. On information and belief, DAARTS is the "Document Archiving, Reporting, and Regulatory Tracking System," which is FDA's archival system of record for internal application files. And NDA-022192 refers to Vanda's NDA for Fanapt®, including FDA's review of the information that Vanda submitted.

105. FDA made similar disclosures to Inventia.

106. Vanda obtained information relating to FDA's review of Inventia's iloperidone ANDA (No. 207231) through a FOIA request submitted to FDA. On March 27, 2023, Vanda submitted a FOIA request seeking the final approval letter, the approved label, any bioequivalence review produced during FDA's evaluation, and any other readily available materials relating to Inventia's ANDA. On April 20, 2023, FDA produced 143 pages of responsive records to Vanda.[3]

107. During its review of Inventia's iloperidone ANDA, FDA sent Inventia notice of a deficiency. In that notice, FDA informed Inventia that its proposed dissolution specification was not acceptable, and requested that Inventia "acknowledge" a specified "FDA recommended dissolution method and specification":

[3] Counsel for Vanda received FDA's response on physical media by mail on May 1, 2023.

BIOEQUIVALENCE DEFICIENCIES TO BE PROVIDED TO THE APPLICANT
(PROCESSED BY BIO-PM)

ANDA: 207231

APPLICANT: Inventia Healthcare Private Limited

DRUG PRODUCT: Iloperidone Tablets1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg

The Division of Bioequivalence I (DBI) has completed its review of the dissolution testing portion of your submission acknowledged on the cover sheet. DB will review the fasting and fed BE studies and waiver requests later.

Your dissolution testing data are acceptable; however, your proposed specification is too liberal and not acceptable. Please acknowledge the following FDA recommended method and specification for your test product:

USP Apparatus:	II (paddle)
Rotational Speed:	50 rpm
Temperature:	37°C ± 0.5°C
Media:	0.1 N Hydrochloric Acid
Volume:	500 mL
Specification:	NLT (b)(4)% (Q) dissolved in 30 minutes

The bioequivalence comments provided in this communication are comprehensive as of issuance. However, these comments are subject to revision if additional concerns raised by chemistry, manufacturing and controls, microbiology, labeling, other scientific or regulatory issues or inspectional results arise in the future. Please be advised that these concerns may result in the need for additional bioequivalence information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

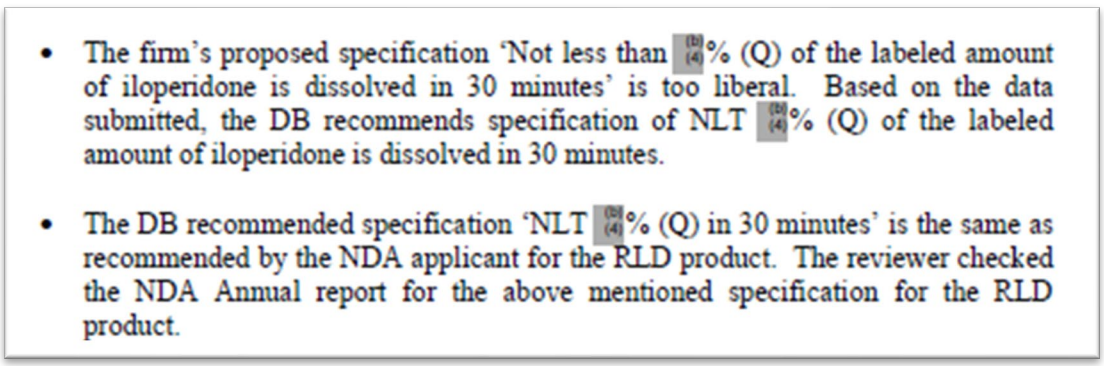
Sincerely yours,

{See appended electronic signature page}

Wayne I. DeHaven, Ph.D.
Acting Director, Division of Bioequivalence I
Office of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

(Inventia FOIA Response at 55).

108. In the Division of Bioequivalence Dissolution Review conducted as part of FDA's review of Inventia's ANDA, the FDA reviewer made clear that the recommended dissolution specification was derived from Vanda's Fanapt® NDA:



- The firm's proposed specification 'Not less than [b](4)% (Q) of the labeled amount of iloperidone is dissolved in 30 minutes' is too liberal. Based on the data submitted, the DB recommends specification of NLT [b](4)% (Q) of the labeled amount of iloperidone is dissolved in 30 minutes.
- The DB recommended specification 'NLT [b](4)% (Q) in 30 minutes' is the same as recommended by the NDA applicant for the RLD product. The reviewer checked the NDA Annual report for the above mentioned specification for the RLD product.

(Inventia FOIA Response at 53).

109. Despite its disclosures to Lupin and Inventia, FDA continues to regard the sponsor's proposed dissolution specification as trade secret and confidential even after an NDA is approved.

110. In the Clinical Pharmaceutical Biopharmaceutics Review FDA published as part of the publicly available approval package for Fanapt®, for example, FDA redacted the proposed dissolution specification as trade secret and/or confidential commercial information:

Item 3

Dissolution Method and Specification (from OCP's review of July 10, 2008) – for convey to the Sponsor:

The dissolution method and specification for all strengths of the immediate release tablets should be:

Apparatus 2 (rotating paddle)
500 ml 0.1 N HCl
50 rpm rotation speed.
Q= ——— in 30 minutes

b(4)

(Fanapt Clinical Biopharmaceutics Review at 4).

111. FDA regulations prohibit it from disclosing "[m]anufacturing methods or processes, including quality control procedures" even after approval of an application. 21 C.F.R. § 314.430(g)(1).

112. FDA's direction to Lupin and Inventia constitutes a disclosure of Vanda's proposed dissolution specification. The recipients of the deficiency notices would have understood that FDA adopted and was communicating to it information contained in the Fanapt® NDA.

113. The result of FDA's approach to the dissolution specification is that it is willing to provide the confidential information directly to Vanda's competitors without notification to Vanda, but unwilling to provide it publicly.

114. FDA has historically emphasized the difference between reliance on the public fact of NDA approval and reliance on actual data contained in the NDA:

> [14] When FDA approves a stand alone NDA submitted under section 505(b), the approval is based on the data and information submitted in the application. Later approvals under section 505(j) of duplicates or minor modifications to this listed drug will rely on the Agency's conclusions that a drug with those specific characteristics (e.g., active ingredient, strength, dosage form, conditions of use) was previously found to be safe and effective. Similarly, when reviewing a 505(b)(2) application that relies in part on the earlier approval of a listed drug, FDA may rely on its earlier conclusions regarding safety and effectiveness to whatever extent the conclusions are appropriate for the drug under review in the 505(b)(2) application. Although reliance on an FDA finding of safety and effectiveness for an NDA is certainly indirect reliance on the data submitted in the original NDA, reliance on the conclusions supported by that data is not the same as manipulating those data to reach new conclusions not evident from the existing approval. For example, if the NDA for the listed drug contained studies indicating that the drug may be effective for indications X and Y, but the listed drug is not approved for use Y, a 505(b)(2) applicant could not rely on those
>
> studies to get approval for indication Y; it could only rely on the fact that the Agency found the drug to be effective for use X.

(Woodcock Letter, 2003P-0404-CP1, at 10-11 n.4); *see also* Epstein, *supra*, at 294-95 & nn. 47-48).

115. In subsequent litigation, FDA has admitted that it is inappropriate for it to base its approval decisions on information contained in the RLD's NDA:

> During the course of preparing its Citizen Petition response to Pfizer's scientific challenge to NDA 21-435 and collecting the administrative record for the response, FDA became aware that a first line reviewer made reference to certain studies of Pfizer's in the documentation of his review of NDA 21-435. In light of this discovery, FDA determined that it should reevaluate whether the approval of NDA 21-435 was based upon data from appropriate sources. Thus, on February 5, 2004, FDA issued an Administrative Stay of Approval (attached as Exhibit D) pending its reevaluation of the source of the data FDA relied on in approving NDA 21-435. If FDA determines upon reevaluation that the approval of NDA 21-435 is appropriate, FDA will promptly complete its Citizen Petition response to Pfizer's scientific challenge to FDA's approval of NDA 21-435 and will lift the Administrative Stay.

Motion for Stay of Proceedings at 3, *Pfizer v. FDA*, No. 03-cv-2346 (D.D.C. Feb. 18, 2004).

116. FDA's reliance on Vanda's NDA for the dissolution specification during its review of Lupin and Inventia's ANDAs is directly contrary to its publicly stated approach to ANDA review.

117. At the time FDA disclosed Vanda's dissolution specification to Lupin and Inventia, it was not generally known to or ascertainable by the public. A drug's dissolution profile cannot be ascertained simply from knowledge of the drug's formulation. Accurate and supportable conclusions about dissolution profile and appropriate dissolution specifications can only be made by reliance on data from dissolution testing. That is why FDA relied on Vanda's data, provided in its NDA, when communicating with Lupin.

118. At all times, the dissolution specification was the subject of reasonable efforts by Vanda to maintain its secrecy.

119. As an integral part of Vanda's manufacturing process, the dissolution specification had economic value to Vanda (and to its competitors) from its secrecy. The dissolution specification is a core component of Vanda's processes for ensuring that its drugs are consistent, safe, and effective.

120. Because dissolution rate is correlated with physical properties of solid oral dosage forms, disclosure of the dissolution specification also discloses confidential information about the viscosity of the drug formulation, and thus confidential information about the formulation itself.

121. Disclosure of the confidential dissolution specification would greatly accelerate Vanda's competitors' efforts to copy the formulation of Fanapt®.

122. The dissolution specification constitutes a trade secret under relevant state and/or federal law.

123. Apart from whether the information at issue qualifies for protection as a trade secret, FDA's maintenance of information as confidential—an express condition upon which Vanda and other drug manufacturers provide information to FDA—creates a cognizable property interest under District of Columbia, Maryland, and/or federal law. *See Carpenter v. United States*, 484 U.S. 19, 26 (1987) ("Confidential business information has long been recognized as property."); *id*. ("'[I]nformation acquired or compiled by a corporation in the course and conduct of its business is a species of property to which the corporation has the exclusive right and benefit, and which a court of equity will protect through the injunctive process or other appropriate remedy.'" (quoting

3 W. Fletcher, Cyclopedia of Law of Private Corporations § 857.1, p. 260 (rev. ed. 1986)); *Formax, Inc. v. Hostert*, 841 F.2d 388, 390 (Fed. Cir. 1988) ("[C]onfidential business information is property."); *see also Cleveland v. United States*, 531 U.S. 12, 19 (2000). Indeed, the Maryland Court of Special Appeals has relied on *Carpenter* for the conclusion that "confidential business information constitutes property of the company and that its premature and improper disclosure can constitute a misappropriation of corporate property." *Alleco, Inc. v. Harry & Jeanette Weinberg Found., Inc.*, 639 A.2d 173, 180 (1994), *aff'd* 665 A.2d 1038 (1995). *See also Maryland Metals, Inc. v. Metzner*, 282 Md. 31, 38, 382 A.2d 564, 568 (1978) (distinguishing claims between misappropriation of "trade secrets and confidential information"); *Allan M. Dworkin, D.D.S., P.A. v. Blumenthal*, 551 A.2d 947, 949 (1989) (similar).

124. Information need not qualify as a trade secret for it to qualify as property protected under the Takings Clause. *Cf. United States v. Mahaffy*, 693 F.3d 113, 135 (2d Cir. 2012) ("Information may qualify as confidential under *Carpenter* even if it does not constitute a trade secret."); *United States v. Hager*, 879 F.3d 550, 555 (5th Cir. 2018) ("Although state law is a valid source for defining the scope of property rights protected by federal laws, it is not the sole source."); *id.* (placing emphasis on the use of "such as" in the holding from *Monsanto* that "property interests.... are created and their dimensions defined by existing rules or understandings that stem from an independent source *such as* state law" (quoting *Monsanto*, 467 U.S. at 1001)); *United States v. Yates*, 16 F.4th 256, 265 (9th Cir. 2021) (recognizing "a property right in trade secrets *or* confidential business information" (emphasis added)).

125. FDA's disclosure of Vanda's dissolution specification was without Vanda's express or implied consent.

126. FDA's disclosure of Vanda's trade secret and/or confidential commercial information to Vanda's competitors eliminated or greatly reduced the value of Vanda's intellectual property.

127. Vanda has suffered significant economic damage and irreparable losses to consumer goodwill due to FDA's disclosure of its trade secret and/or confidential information.

128. Vanda had no awareness of FDA's wrongful disclosure to Lupin until April 12, 2023, when it received a FOIA response from FDA. And Vanda categorically could not have learned of this information any time prior to May 2022.

129. That is, the documents detailing FDA's disclosures to Lupin were definitely unavailable to the public (including Vanda) until at least May of 2022. FDA categorically refuses to release information relating to pending or otherwise unapproved applications. 21 C.F.R. § 314.430(d)(1) ("[N]o data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter.").[4] Vanda thus had

[4] Indeed, Vanda has filed litigation against FDA to obtain access to FDA reviews of its *own* pending submissions to FDA. Vanda recently prevailed in that litigation. *Vanda Pharms., Inc. v. Food & Drug Admin.*, No. 22-CV-938 (CRC), 2023 WL 2645714 (D.D.C. Mar. 27, 2023). Throughout that litigation, FDA maintained its position that information of this sort was forbidden from release "under the deliberative process privilege." *Id*. at *1. But this litigation addressed solely prohibition from release under (b)(5), addressing the deliberative process privilege and related privilege grounds. It does not establish that a third party may obtain FDA reviews or related documents of not-yet-approved drugs submitted by *other* entities.

no way of knowing that FDA disclosed its trade secrets or confidential commercial information to Lupin prior to May of 2022, when FDA approved Lupin's ANDA. And even then, it took Vanda filing a FOIA request to learn this information.

130. On information and belief, FDA's reliance on the pioneer drug NDA in evaluating ANDAs is not limited to these disclosures.

131. On information and belief, FDA made similar disclosures of data drawn from the Fanapt® NDA during its review of the other iloperidone ANDAs.

2. Tasimelteon ANDAs

132. To date, FDA has reviewed and approved three ANDAs seeking permission to market generic versions of Hetlioz®.

133. On information and belief, Teva Pharmaceuticals submitted ANDA No. 211601 to FDA on or about January of 2018. FDA received the ANDA on January 31, 2018.

134. FDA issued a tentative approval for Teva's ANDA on September 27, 2021. FDA issued a final approval for Teva's ANDA on December 12, 2022.

135. On information and belief, Apotex Corp. submitted ANDA No. 211607 to FDA on or about January of 2018. FDA received Apotex's ANDA on January 31, 2018.

136. FDA issued a tentative approval for Apotex's ANDA on February 3, 2020. FDA issued a final approval for Apotex's ANDA on December 20, 2022.

137. On information and belief, MSN Pharmaceuticals Inc. submitted ANDA No. 211654 to FDA on or about January of 2018. FDA received the ANDA on January 31, 2018.

138. FDA issued a tentative approval for MSN's ANDA on May 28, 2020. FDA issued a final approval for MSN's ANDA on January 12, 2023.

139. Like with the Lupin and Inventia iloperidone ANDAs, FDA sent correspondence to tasimelteon ANDA applicants concerning their proposed dissolution specification.

140. On information and belief, in a Discipline Review Letter signed by Astrid Inniss on July 16, 2018, FDA rejected Teva's proposed dissolution specification. Instead, FDA asserted that "[b]ased on test bio-lot dissolution data, the dissolution acceptance criterion of 'not less than [b4]% (q) of label claimed amount of Tasimelteon dissolved in 15 min' is recommended."[5] FDA instructed Teva to "[u]pdate the drug product specification table and other relevant section of [the] ANDA accordingly."

141. On information and belief, in a Discipline Review Letter signed by Astrid Inniss on July 12, 2018, FDA rejected Apotex's proposed dissolution specification. Instead, FDA asserted that "[b]ased on test bio-lot dissolution data, the dissolution acceptance criterion of 'not less than [b4]% (q) of label claimed amount of Tasimelteon dissolved in 15 min' is recommended."[6] FDA instructed Apotex to "[u]pdate the drug product specification table and other relevant section of [the] ANDA accordingly."

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[5] Vanda obtained the discipline review letters sent to Teva in response to a request submitted on March 14, 2023. FDA designated that request as Request No. 2023-2013 and produced 12 responsive pages on April 19, 2023, along with a response letter dated April 4, 2023.

[6] Vanda obtained the discipline review letters sent to Apotex in response to a request submitted on March 14, 2023. FDA designated that request as Request No. 2023-2002 and produced 19 responsive pages on April 19, 2023, along with a response letter dated April 6, 2023.

142. On information and belief, FDA's rejection of Apotex and Teva's proposed dissolution specifications and substitution of a different specification was based on information drawn from Vanda's Hetlioz® NDA.

143. On information and belief, FDA's insistence that Apotex and Teva modify their dissolution specifications would have been understood to indicate that the replacement specification was based on information drawn from Vanda's Hetlioz® NDA.

144. Additionally, when FDA "determines that [it] will not approve [an] application or abbreviated application in its present form," the agency "will send the applicant a complete response letter" (CRL). 21 C.F.R. § 314.110(a). A CRL "reflects FDA's complete review of the data submitted in an original application or abbreviated application." 21 C.F.R. § 314.110(a)(2). The CRL "will describe all of the specific deficiencies that the agency has identified in an application or abbreviated application" and will "[w]hen possible . . . recommend actions that the applicant might take to place the application or abbreviated application in condition for approval." 21 C.F.R. § 314.110(a)(1), (3).

145. During its review of Apotex's ANDA, FDA issued a CRL on July 12, 2018.[7]

[7] The CRL was submitted as a public trial exhibit during prior litigation between Vanda and Apotex concerning patents relating to tasimelteon. *See Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-651, JTX-071 (D. Del. 2022).

146. During its review of Teva's ANDA, FDA issued a CRL to the drug manufacturer who produces the tasimelteon used in Teva's ANDA product on July 12, 2018.[8]

147. In its CRL to Apotex, FDA highlighted five impurities that "are possible impurities of the drug substance reported in patent US20170190683A1." FDA asked Apotex to "clarify whether the current related substances analytical method is capable of detecting and quantifying these impurities" and to "provide supporting data including LOD, LOQ, and linearity." It further instructed Apotex to "control these impurities in the drug substance release specification at justified limits, or provide justification as to why controls are not needed."

148. FDA made a similar demand in a CRL to Teva's tasimelteon manufacturer. There, FDA called out Impurities "4 and 7" as "possible degradants of the drug substance" and also pointed to "impurities 2, 3, 5, and 6" as impurities "reported in patent US20170190683A1." FDA instructed Teva's manufacturer to "clarify whether the current related substances analytical method is capable of detecting and quantifying these impurities," to "provide supporting data including LOD, LOQ, and linearity," and to "control these impurities in the drug substance specification at justified limits, or provide justification as to why controls are not needed."

149. US20170190683A1 (the "Impurities Patent Application") is a patent application covering "[a] process for preparing a batch of highly purified, pharmaceutical grade tasimelteon"

[8] The CRL to Zhejiang Ausun Pharmaceutical Co. Ltd. was submitted as a public trial exhibit during prior litigation between Vanda and Apotex concerning patents relating to tasimelteon. *See Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-cv-651, PTX-153 (D. Del. 2022).

which "comprises analyzing a batch of tasimelteon synthesized under GMP conditions for the presence of one or more identified impurities." The Impurities Patent Application was published by the U.S. Patent and Trademark Office on July 6, 2017.

150. The Impurities Patent Application discloses seven listed impurities. *Id.* at 2. Impurities 1, 2, 3, 5, and 6 "may be by-products of certain steps of the synthesis of tasimelteon." "[I]mpurities 4 and 7 may be degradation products."

151. The Impurities Patent Application was eventually approved on September 11, 2018. The Impurities Patent was submitted to FDA on November 17, 2020, and was subsequently listed in the Orange Book. The Orange Book is an index maintained by FDA of patents provided by sponsors of approved NDAs that relate to their approved drugs.

152. The impurities listed in the Impurities Patent Application are specific to the manufacturing process disclosed in the Application. Different manufacturing processes for tasimelteon will result in the presence or absence of different impurities.

153. In fact, Apotex indicated in its CRL response that certain of the impurities identified in the Impurities Patent Application do not or cannot occur in its manufacturing process.

154. Nothing in the Impurities Patent Application discloses which portions of the Application match the methods listed in Vanda's NDA for Hetlioz® for the commercial manufacture of tasimelteon.

155. The filing of a patent application does not disclose that a patentee actually practices the patent. *King Instruments Corp. v. Perego*, 65 F.3d 941, 949 (Fed. Cir. 1995) ("A patentee need not make, use, or sell an invention to gain patent protection.").

156. Even if the Impurities Patent Application discloses portions of Vanda's manufacturing process, the overall process as a combination of those disclosed elements remains a confidential trade secret. *DSMC, Inc. v. Convera Corp.*, 479 F. Supp. 2d 68, 78 (D.D.C. 2007) ("Even if individual elements are known to the public, a trade secret can exist in a unique combination of those otherwise publicly available elements.").

157. FDA has continued to recognize that Vanda's manufacturing process, including the impurities for which Vanda controlled and the mechanisms it used to do so, is confidential even after approval of Vanda's NDA. For example, FDA redacted impurity information as confidential and/or trade secret in the administrative correspondence and chemistry review that it published as part of the action package for approval for Hetlioz®.

158. FDA's reference to the Impurities Patent Application would be understood to its intended recipients as an indication that Vanda does, in fact, practice the impurities patent.

159. Further, FDA's reference to the Impurities Patent Application and insistence that applicants control for some of the seven listed impurities (or provide an explanation for failure to do so) constitutes a disclosure that the manufacturing process disclosed in the Impurities Patent Application is substantially similar to Vanda's actual commercial manufacturing process for tasimelteon.

160. Additionally, FDA's reference to the Impurities Patent Application and insistence that applicants control for some of the seven listed impurities (or provide an explanation for failure to do so) constitutes a disclosure that Vanda practices the Impurities Patent Application (and the later-granted Impurities Patent).

161. FDA's reference to the Impurities Patent Application and insistence that applicants control for some of the seven listed impurities (or provide an explanation for failure to do so) constitutes a disclosure of Vanda's confidential commercial information and trade secrets.

162. Further, FDA disclosed to at least one of competitors of Vanda that, during the manufacturing process, tasimelteon "may be subject to micronization." In its CRL to Apotex, FDA queried Apotex whether its "drug substance may be subject to any particle size reduction." FDA thus implicitly, if not expressly, disclosed that a generic *should* use micronization techniques when manufacturing tasimelteon. Irrespective of Vanda's manufacturing process, that disclosure constitutes an improper disclosure of Vanda's confidential information that was supplied to FDA. Indeed, FDA could not inform Teva and Apotex directly of Vanda's manufacturing process; it cannot circumvent its confidentiality obligations through indirect questions or suggestions, as those themselves qualify as disclosures.

163. FDA's disclosure of Vanda's trade secret and confidential information was without Vanda's express or implied consent.

164. At the time FDA disclosed Vanda's trade secret and/or confidential commercial information, FDA knew or had reason to know that it acquired the underlying information from Vanda under circumstances giving rise to a duty to maintain its secrecy and/or limit its use.

165. FDA's disclosure of Vanda's trade secrets to Vanda's competitors and confidential information erases or substantially decreases their value.

* * *

166. FDA's disclosures here are even more egregious than the facts of *Monsanto*, in which the Supreme Court found an unconstitutional taking. 467 U.S. at 1016. Like FDA's regulations here, EPA between 1972 and 1978 provided guarantees that confidential information would be kept secret. *Id.* at 1010. "This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation." *Id.* In 1972, Congress amended FIFRA to allow EPA "to consider data submitted by one applicant . . . in support of another application pertaining to a similar chemical." *Id.* at 992. Recognizing the problem with this regime, Congress conditioned this use on the subsequent applicant's "offer[] to compensate the applicant who originally submitted the data." *Id.* The Court explained that the statute created a "mandatory data-licensing scheme" in which compensation would be provided to the owner of the trade secrets through an arbitration process. *Id.* While FIFRA envisioned compensation by the recipient of the confidential information, FDA's regime does not. *Id.* at 1013-14. Thus, while the scheme in *Monsanto* might have resulted in a taking, FDA's disclosure certainly does. The lack of a parallel compensation process, especially against the backdrop the well-established legal landscape following *Monsanto*, is conclusive evidence that Congress did not intend for disclosure in the FDCA context. And either way, the lack of compensation makes any disclosure regime in the FDCA context even *less* constitutionally permissible.

CLAIMS FOR RELIEF

COUNT I

Uncompensated Taking in violation of the Fifth Amendment

167. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-166 as though fully set forth herein.

168. The Fifth Amendment provides that private property cannot "be taken" by the Government "for public use without just compensation." U.S. Const. Amend. V.

169. Vanda possessed cognizable property rights in the protectable trade secrets and other confidential information that it owns. Specifically, information about Vanda's manufacturing process for tasimelteon and iloperidone—including its dissolution specifications, manufacturing processes, and details of its control of various impurities—constitute protectable trade secrets. That Vanda does in fact practice the Impurities Patent in its manufacture of tasimelteon is also a trade secret. These facts also constitute confidential information.

170. The Supreme Court has held disclosure of a trade secret can constitute a taking for purposes of the Fifth Amendment. *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1001-04 (1984).

171. Similarly, the Fifth Amendment protects against disclosure of a party's protected confidential information, regardless of whether it qualifies as a trade secret. All confidential information a drug developer provides to FDA under a reasonable expectation that it will be kept confidential qualifies as property, the improper disclosure of which is actionable. Here, regardless of whether FDA disclosures of Vanda's information qualifies as misappropriation of trade secrets, it surely qualifies as disclosure of confidential information.

172. At all times, the trade secret and confidential information disclosed to FDA was kept secret by Vanda. Vanda employs industry-standard measures to safeguard its proprietary information.

173. Vanda's trade secrets and confidential commercial information, as relevant here, had significant economic value, including (and especially) to Vanda's competitors such as Lupin, Inventia, Apotex, and Teva. The information that constitutes those trade secrets and confidential information was the product of significant expenditure of Vanda's time and resources.

174. Vanda's trade secrets and confidential commercial information had value as a result of their secrecy, as evidenced by their commercial value to Vanda's competitors.

175. Upon information and belief, and as alleged above, the United States took Vanda's proprietary information and, via duly authorized actions of Government personnel, provided it to others, including Vanda's competitors without payment of just compensation to Vanda.

176. The United States did not have express or implied consent to appropriate or disclose Vanda's proprietary information apart from the limited purpose of evaluating Vanda's related applications.

177. To the extent that FDA has conditioned access to the U.S. pharmaceutical market on a sponsor's forfeiture of its intellectual property (including trade secrets and other confidential commercial information), that imposition constitutes an unconstitutional condition that itself qualifies as a taking. *See, e.g.*, *Kaiser Aetna v. United States*, 444 U.S. 164, 172 n.7 (1979); *Nollan v. California Coastal Comm'n*, 483 U.S. 833 n.2 (1987); *Philip Morris v. Reilly*, 312 F.3d 24, 46-47 (1st Cir. 2002) (holding that imposing disclosure requirements in exchange for "allowing a

manufacturer to simply sell its legal product" is unconstitutional). *See generally* Epstein, *supra*, at 301-313. Such a regime is also inconsistent with congressional mandates to safeguard trade secret and confidential commercial information.

178. The United States, at the time of the disclosures, knew or should have known that its knowledge of Vanda's proprietary information was acquired under circumstances giving rise to a duty to maintain their secrecy or limit their use.

179. Though FDA "does not have explicit statutory authority to regulate drug prioritizing," the agency nonetheless attempts to do so by prioritizing and incentivizing the approval of generics. Agata Dabrowska, Cong. Rsch. Serv. IF11075, *FDA and Drug Prices: Facilitating Access to Cheap Drugs* (Jan. 17, 2019). On information and belief, FDA's unlawful and uncompensated disclosure of Vanda's trade secrets and/or confidential information was in furtherance of its goal of altering the market by favoring generics.

180. FDA's disclosures of Vanda's confidential commercial information and trade secrets to Vanda's competitors has erased or substantially diminished their value.

181. As a direct and proximate result of the United States' taking of Vanda's proprietary information, Vanda has suffered monetary damages in excess of millions of dollars.

COUNT TWO

Breach of Implied-in-Fact Contract

182. Vanda hereby incorporates and re-alleges the foregoing paragraphs 1-181 as though fully set forth herein.

183. An implied-in-fact contract was created when Vanda revealed trade secrets and confidential commercial information to FDA and thereby imposed on FDA an obligation to maintain the confidentiality of Vanda's trade secrets and confidential commercial information without providing compensation to Vanda or seeking Vanda's consent.

184. Statutes and regulations constitute a standing, unambiguous offer by FDA to receive new drug applications (including required trade secret and confidential commercial information) on the condition that FDA will respect the confidentiality of that information.

185. Vanda unambiguously accepted FDA's standing offer by submitting its NDA for Hetlioz® and Fanapt®.

186. FDA's guarantee of confidentiality was material to Vanda's decision to submit its NDA for Hetlioz® and Fanapt®.

187. FDA breached this implied-in-fact contract by failing to maintain Vanda's trade secrets and confidential commercial information in confidence and by in fact disclosing those trade secrets and confidential commercial information to Vanda's competitors.

188. As a direct and proximate result of FDA's breach of the implied-in-fact contract, Vanda has been irreparably harmed and suffered significant financial damage.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor and that the Court:

1. Declare that FDA's disclosure of confidential commercial information contained in an NDA to ANDA applicants constitutes a taking for purposes of the Fifth Amendment to the United States Constitution;

2. Declare that the United States has taken Vanda's proprietary information without providing just compensation in violation of the Fifth Amendment to the United States Constitution;

3. Declare that the United States has breached an implied-in-fact contract by failing to maintain the confidentiality of Vanda's trade secret and confidential commercial information;

4. Award to Vanda just compensation and/or damages for the taking and breach in an amount to be determined at trial;

5. Award Vanda its costs and reasonable attorney's fees incurred in this action to the extent allowable under any applicable law; and

6. Award Vanda such other and further relief as the Court may deem just and proper.

Dated: May 1, 2023

Respectfully submitted,

/s/ Paul W. Hughes
Paul W. Hughes
Andrew A. Lyons-Berg (*pro hac vice* forthcoming)
Charles Seidell (*pro hac vice* forthcoming)
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