IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MELINTA THERAPEUTICS, LLC, a Delaware company 44 Whippany Road Suite 280 Morristown, NJ 07960, and REMPEX PHARMACEUTICALS, INC., a Delaware corporation 44 Whippany Road Suite 280 Morristown, NJ 07960, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue SW Washington, DC 20201, and XAVIER BECERRA, *In His Official Capacity as Secretary of Health and Human Services,* U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201, and	Civil Action No. 1:22-cv-02190

ROBERT M. CALIFF, M.D.,
In His Official Capacity as Commissioner of Food and Drugs, United States Food and Drug Administration,
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

COMPLAINT

Plaintiffs Melinta Therapeutics, LLC and Rempex Pharmaceuticals, Inc. (together "Melinta") bring this action for declaratory, injunctive, and other relief against the U.S. Food and Drug Administration ("FDA"); the U.S. Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of Health and Human Services; and Robert Califf, M.D, in his official capacity as Commissioner of Food and Drugs, FDA.

The Federal Food, Drug, and Cosmetic Act ("FDCA") governs the pharmaceutical drug approval process for both innovator and generic drugs. In 1984, Congress amended the act through the Hatch-Waxman Amendments, which sought to strike a balance between inducing pioneering research and the development of new drugs and enabling competitors subsequently to bring generic copies of those drugs to market. *See Veloxis Pharms., Inc. v. FDA*, 109 F. Supp. 3d 104, 107 (D.D.C. 2015). A key component of that fundamental balance is a regime that requires generic drug companies to notify innovator drug companies of potential patent infringement by a proposed generic drug in order to allow the innovator to protect its patent rights in court *before* the generic receives FDA approval.

An applicant who files an "abbreviated new drug application," or ANDA, seeking FDA approval of a generic version of an innovator drug must expressly address patents that cover the innovator drug and explain specifically when FDA can approve the application in light of the patents. 21 U.S.C. § 355(j)(2)(A)(vii). One option to address an innovator patent is by including a "paragraph IV certification," which states "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A successful paragraph IV challenge can clear a patent obstacle to market. In addition, as part of the Hatch-Waxman regime, paragraph IV certification offers a significant incentive: "[T]he first company to file an ANDA containing a paragraph IV certification earns an 'exclusivity' period of 180 days, during which FDA may not approve for sale any competing generic version of the drug at issue." *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010). But this incentive comes with a risk: filing an application with a paragraph IV certification "constitutes an act of patent infringement." *Id.* (citing 35 U.S.C. § 271(e)(2)(A)).

An ANDA applicant that includes a paragraph IV certification must inform both the patent owner and the company that owns the new drug application ("NDA") for the innovator drug on which the generic drug piggybacks. 21 U.S.C. § 355(j)(2)(B). Receipt of this notice triggers a series of deadlines that are designed to inform the innovator companies and allow them to protect their rights. After the notice is received, the patent owner or innovator drug company has a 45-day window to sue the generic drug company for patent infringement in order to trigger a statutory stay.

21 U.S.C. § 355(j)(5)(B)(iii). If the NDA holder or patent owner sues during that 45-day period following receipt of notice, FDA must wait 30 months after the NDA holder and patent owner's receipt of notice before approving the ANDA, unless the ANDA applicant wins the suit sooner or the court shortens the 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii).

The ANDA applicant must amend its ANDA to provide documentation of the date of receipt of the required notice "by each person provided the notice." 21 C.F.R. § 314.95(e). For decades, FDA has accepted, as adequate documentation of "the date of receipt," "a [registered or certified mail] return receipt or a letter acknowledging receipt by the person provided the notice." 21 C.F.R. § 314.95(a), (e) (1994). Starting in 2016, FDA now also accepts as documentation of "the date of receipt" "signature proof of delivery by a designated delivery service." 21 C.F.R. § 314.95(e). An applicant may not rely on any other form of documentation to prove the date of receipt unless FDA has agreed to such documentation in advance. *Id.*

Here, Nexus Pharmaceuticals, Inc. ("Nexus") submitted an ANDA seeking approval to market a generic version of Melinta's innovator drug. Nexus's ANDA contained a paragraph IV certification stating that Melinta's patents were invalid or would not be infringed by Nexus's generic. But Nexus provided no registered or certified-mail return receipt, signature proof of delivery, or letter acknowledging receipt by Melinta at any point before March 31, 2021. Although Nexus purported to send notice to Melinta in December 2020—in the middle of an unprecedented global

pandemic and before vaccines were widely available—Melinta did not, in fact, receive notice of Nexus's paragraph IV certification until March 31, 2021.

On May 14, 2021, within 45 days of receipt of the notice, Melinta sued Nexus for patent infringement in the Northern District of Illinois. FDA is thus statutorily barred from making its approval of Nexus's application effective until October 1, 2023. Yet despite the ongoing litigation, FDA denied Melinta's citizen petition asking FDA to refrain from issuing any approval during the 30-month stay in a way that would violate its statutory commands. Shortly thereafter, in the afternoon on July 25, 2022, FDA disclosed publicly that it had approved Nexus's application on July 22, 2022. FDA's denial of Melinta's citizen petition and approval of Nexus's ANDA are inconsistent with the statutory scheme, violate its own regulations, and create a path for ANDA applicants to skirt important patent protections. Melinta respectfully requests that the Court set aside FDA's denial of Melinta's citizen petition and order FDA to withdraw its approval of Nexus's application or suspend the approval until the statutory stay expires. In support of its causes of action, Melinta avers as follows:

NATURE OF THE ACTION

1. This is an action to hold unlawful and set aside as arbitrary, capricious, an abuse of discretion, and contrary to law FDA's final decision approving Abbreviated New Drug Application ("ANDA") No. 214934 submitted by Nexus Pharmaceuticals, Inc. ("Nexus") seeking to market a purported generic form of Melinta's innovator drug Minocin® (minocycline) for Injection. The agency's decision—which would allow ANDA applicants to circumvent the notice requirements

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