IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AVADEL CNS PHARMACEUTICALS, LLC
16640 Chesterfield Grove Road, Suite 200
Chesterfield, MO 63005

Plaintiff,

v.

XAVIER BECERRA, Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201;

ROBERT M. CALIFF, Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993; and

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Case No. 1:22-cv-2159

REDACTED

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Avadel CNS Pharmaceuticals, LLC ("Avadel") brings this suit against Defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services; the U.S. Department of Health and Human Services ("HHS"); Robert Califf, in his official capacity as Commissioner of Food and Drugs; and the U.S. Food and Drug Administration ("FDA"), and alleges as follows:

PRELIMINARY STATEMENT

1. Narcolepsy is a rare but serious chronic neurological disorder that affects the brain's ability to control sleep-wake cycles. People suffering from narcolepsy experience excessive daytime sleepiness and may experience uncontrollable episodes of falling asleep during the daytime. It is estimated that less than 200,000 Americans suffer from narcolepsy.

2. Although there is no cure for narcolepsy, certain types of medicine can treat some of its symptoms. One such drug is gamma-hydroxybutryate ("oxybate"), a central nervous system depressant that helps to induce deep, restful sleep.

3. Since 2002, oxybate has been marketed in the United States exclusively by Jazz Pharmaceuticals plc ("Jazz") under the brand name Xyrem, and, since 2020, Xywav. But a critical problem with Jazz's oxybate products is that they are immediate release formulations requiring two doses—one right before bedtime, and a second dose between two-and-a-half to four hours later—which necessitates people already suffering from a sleep disorder to set an alarm to forcefully awaken in the middle of the night to take the second dose.

4. Avadel is a biopharmaceutical company focused on researching and developing drugs to treat narcolepsy. For almost a decade, Avadel's focus has been on the development of LUMRYZ™, an innovative product that uses proprietary technology designed to enable dosing once before bedtime of sodium oxybate (a type of oxybate). That once before bedtime dosing regimen allows for improved patient safety, compliance, and quality of life by enabling patients to avoid setting an alarm to awaken in the middle of the night to take a second dose, thus offering the possibility of an uninterrupted night of restorative sleep.

5. To provide these benefits to patients, on December 15, 2020 Avadel submitted a new drug application ("NDA") for LUMRYZ to the U.S. Food and Drug Administration ("FDA" or the "Agency") pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act

("FDCA"), which provides streamlined pathways for approval of drugs that are based on the same active ingredient as—but which are not identical to—a previously approved drug.

6. To facilitate notice to owners of previously approved drugs that their intellectual property rights might be impacted by such an NDA, a Section 505(b)(2) applicant must file a "patent certification" or a "patent statement" regarding certain patents that relate to the previously approved drug. 21 U.S.C. §§ 355(b)(2)(A), (b)(2)(B).

7. Patent certifications are filed when an existing patent implicates the new drug, and filing a certification can cause mandatory delays in FDA's approval of the new drug; patent statements, by contrast, are filed when a patent does not implicate the new drug, and cause no approval delays. FDA instructs applicants to make this determination by reviewing FDA's "Orange Book," an FDA database that publishes certain summary information about patents associated with approved drugs.

8. With its NDA, Avadel submitted to FDA required information about potential overlap between the LUMRYZ NDA and patents held by Jazz. Jazz distributes Xyrem and Xywav pursuant to an FDA-mandated Risk Evaluation and Mitigation Strategy ("REMS"), which was designed by Jazz such that distribution occurs through a single, centralized pharmacy and database, to prevent misuse and diversion of oxybate—which has potential for abuse. Jazz also holds a patent that it alleges pertains to its single, centralized REMS drug distribution database, U.S. Patent No. 8,731,963 (the "Jazz REMS patent" or "'963 patent"), which it has filed under "use code" U-1110 in FDA's Orange Book.

9. LUMRYZ will also be distributed under a REMS, but Avadel has developed its own REMS system and will not use Jazz's. The LUMRYZ NDA accordingly included a "patent statement" affirming that the Jazz REMS patent, as described by Jazz's use code U-1110, does not

"claim[ ] a use for such drug for which the applicant is seeking approval," because Jazz's description of that patent in its use code U-1110 does not overlap with the LUMRYZ NDA. *See* 21 U.S.C. § 355(b)(2)(A).

10. 525 days after Avadel filed its NDA—and 221 days after FDA was required by law to render its final decision on the NDA—FDA instead rendered a final decision on only one discrete subcomponent of the LUMRYZ NDA, Avadel's patent statement to the '963 patent.

11. In a 16-page decision that "constitutes a final decision on the appropriateness of Avadel's section 505(b)(2)(B) [patent] statement" (the "Patent Decision"), FDA concluded that Jazz's use code U-1110 *does* describe a patent that "claims a use for such drug for which the applicant is seeking approval" through the LUMRYZ NDA, and ordered Avadel to "provide an appropriate patent certification under 21 CFR 314.50(i)(1)(i)" certifying to an overlap between the Jazz REMS patent, as described in Jazz's use code, and the LUMRYZ NDA.

12. FDA reasoned that because Jazz's use code describes the use of "a computer database in a computer system for distribution," and because the proposed LUMRYZ REMS will use four computer databases for distribution, Avadel must submit a patent certification certifying to the alleged overlap between the two.

13. The Jazz REMS patent does not expire until December 17, 2022, and Jazz has asserted an additional six months of "pediatric exclusivity" with respect to the '963 patent under 21 U.S.C. § 355a(b)(1)(B)(i)(II), until June 17, 2023. Accordingly, FDA's Patent Decision meant that the LUMRYZ NDA could not be approved immediately, at the soonest by July 22, 2022 (within 45 days of Avadel's relevant patent certification submissions), and potentially not until June 17, 2023, if Jazz were to sue Avadel for alleged infringement on the Jazz REMS patent as a result of FDA's mandated certification. *See* 21 U.S.C. § 355(c)(3)(C).

14. In response to FDA's Patent Decision, Avadel filed the FDA-ordered "patent certification" under protest on June 6, 2022, explaining its continued disagreement with FDA's decision that Jazz's use code describes a patent that "claims a use for such drug for which the applicant is seeking approval." *Id.* § 355(b)(2)(A).

15. On July 18, 2022, FDA issued a tentative approval of the LUMRYZ NDA (the "Tentative Approval"). A tentative approval is not a full, final, or effective approval of an NDA. Rather, a tentative approval provides that an NDA is approvable, provided that a future contingency is met that would permit the NDA to obtain final approval at a later time.

16. FDA's Tentative Approval explained that the final approval of the LUMRYZ NDA would be "made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of a paragraph IV certification" by July 22, 2022. FDA further clarified that "[i]f such a patent infringement action is brought prior to the expiration of 45 days . . . your application would be subject to a 30-month stay of approval . . . ."

17. On July 15, 2022, Jazz filed a lawsuit against Avadel for alleged infringement of the '963 patent in the United States District Court for the District of Delaware, case number 1:22-cv-00941-UNA. Due to FDA's Patent Decision and the resultant patent certification to the '963 patent under protest, this lawsuit triggered the stay identified by FDA.

18. That stay now precludes the immediate approval of the LUMRYZ NDA, as would have otherwise been possible in July 2022, until expiration of the '963 patent term and the related term of pediatric exclusivity in June 2023 (unless the stay is terminated earlier by, for example, delisting of the '963 patent from the Orange Book).

19. FDA's erroneous Patent Decision—coupled with Jazz's lawsuit—has caused and will continue to cause Avadel significant and irreparable harm. Avadel's business is solely

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.