IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW [redacted]

DEFENDANT AVADEL CNS PHARMACEUTICALS, LLC'S
REPLY IN SUPPORT OF ITS MOTION TO EXPEDITE CONSIDERATION OF ITS
RENEWED MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

The notion that Jazz—following a Court order to file a substantive response in two business days to Avadel's motion—now opposes prompt resolution of that fully-briefed motion speaks volumes about Jazz's real goal, which has always been delay. Avadel does not seek to burden this Court with a request for "extraordinary" relief. It simply requests the earliest possible resolution of a straightforward, fully-briefed motion that will end the ongoing substantial harm to Avadel while it is blocked from launching its novel narcolepsy product.[1] If anything, it is Jazz's opposition that is "extraordinary," if not unexpected. Jazz improperly listed, and to this day continues to maintain the listing of, the '963 patent in the Orange Book. Jazz's actions demonstrate that it is desperate to avoid a decision on Avadel's delisting motion. Each day that goes by benefits Jazz and harms Avadel. Indeed, Judge Noreika recognized the harm to Avadel and the urgency of addressing Avadel's motion when the Court ordered Jazz to respond to Avadel's 12(c) Motion on an expedited schedule. D.I. 151.

Jazz's criticisms of Avadel's request for expedited resolution of its delisting motion ring hollow and reflect nothing more than yet another fraught attempt to delay judgment.

First, Jazz will not be "prejudiced" by prompt resolution of Avadel's delisting motion. D.I. 165 at 1. Resolving that motion will materially advance the action, as Judge Noreika's Order expediting briefing recognized. And there can be no legitimate dispute that if the '963 patent is improperly listed in the Orange Book (which it is), the only "harm" Jazz will suffer is the removal of its patent from the Orange Book that should never have been listed in the first place. The only party who is prejudiced by further delay in resolution of this issue is Avadel.

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[1] Jazz's allegations that Avadel previously cried wolf in connection with the urgency of other motions is simply wrong. D.I. 165 at 2. Avadel asked the Court to set a scheduling order for a preliminary injunction motion that *Jazz* indicated it might file. Jazz inexplicably refused to cooperate. The only motion Avadel has asked the Court to expedite is its motion for judgment on the pleadings.

To be clear, the ongoing harm to Avadel is substantial.[2] Each day that goes by forces Avadel to [redacted] keeping its company in a constant state of readiness so that it is prepared to launch its product once it receives final FDA approval. Meanwhile, during time that could be spent launching and selling its product, Avadel is unduly kept off the market and unable to generate any revenue. Regardless of the "cash runway" Avadel has secured to keep the company afloat, it has nonetheless been forced to terminate half of its employees [redacted]. And the improper listing of the '963 patent continues to deny narcolepsy patients the benefit of Avadel's once-nightly oxybate treatment.

Second, Jazz's contention that claim construction is required for resolution of Avadel's delisting motion is simply wrong. D.I. 165 at 7. As Avadel's delisting motion and its request for expedited resolution make clear, Avadel's motion can be resolved in Avadel's favor under Jazz's proposed claim construction for the '963 patent, i.e., without having to address the merits of the parties' claim construction dispute. D.I. 162 at 4-5; D.I. 118 at 9-11. Alternatively, adopting Avadel's proposed claim construction for the '963 patent provides a second means of resolving the delisting motion in Avadel's favor. And if the Court prefers to first resolve the simple dispute of whether the claimed "computer-implemented system" is really a "method of using [a] drug," Avadel is happy to participate in a short *Markman* hearing on that issue if it would assist the Court. Jazz's contention that addressing the claim construction issue for the '963 patent is a prerequisite to deciding Avadel's delisting motion—much less its suggestion that all the claim construction

[2] While Avadel can plainly show that it is harmed by further delay, none of the case law Jazz cites establishes an irreparable harm standard for expediting consideration of an already briefed motion. As noted above, Judge Noreika implicitly recognized that the harm to Avadel warrants expedited briefing (D.I. 151), and Avadel respectfully submits that said harm also warrants expedited consideration.

issues in the case would need to be decided first—is untrue and raised for no other purpose than to delay resolution of Avadel's motion.

Third, Jazz's contention that the Court should undertake "consideration of Avadel's preliminary injunction motion" against the FDA is an irrelevant distraction. D.I. 165 at 1. The FDA case concerns entirely distinct legal issues from this dispute and does not provide any "context necessary" to adjudicate Avadel's Rule 12(c) Motion.[3] *Id*. That lawsuit challenges FDA's erroneous interpretation of the "use code" Jazz provided to the agency to allegedly describe the '963 patent, and the related determination by FDA that Avadel's REMS for its LUMRYZ product is covered by the use code. The improper use code, and FDA's faulty interpretation thereof, led to the FDA's decision requiring Avadel to provide a Paragraph IV certification to the '963 patent, which triggered the statutory stay. Here, by contrast, the issue is whether the *claims* of the '963 patent recite "a method of using [a] drug" that would justify its continued listing in the Orange Book.

Moreover, Jazz's suggestion that Avadel's delisting motion should be delayed because the Court's decision in the FDA suit could have some vague and undefined "significant impact" on this motion within an unknown timeframe is just more baseless hand waving from Jazz. D.I. 165 at 8. The possibility that Avadel will prevail on its request to compel FDA to move forward with approval of Avadel's NDA at some point in the future does not make Avadel's delisting motion irrelevant, or any less urgent. Jazz cites to no authority for the notion that a district court should decline to address a pending motion based on the possibility of some form of relief in an unrelated

[3] To the extent Jazz contends that the adjudication of the other patents in this case is also necessary "context" or should somehow prevent the relief Avadel is seeking, that suggestion is likewise baseless. *See* D.I. 165 at 2. The other six patents are not Orange Book-listed, do not give rise to the statutory stay of FDA approval, and are not the subject of Avadel's motion. That is, Jazz's other asserted patents do not prevent FDA approval or Avadel's market entry.

action. Conveniently, Jazz argued that the court in the FDA suit should reject Avadel's request for a preliminary injunction in that case because Avadel might obtain relief in *this* case by virtue of the same delisting counterclaim for which Jazz is now attempting to avoid resolution. *Avadel CNS Pharm., LLC. v. Becerra*, Case No. 1:22-cv-02159-APM, D.I. 24 at 17-18 (D.D.C). In short, Jazz would have *neither* court address Avadel's claims against FDA and Jazz.

Fourth, Jazz's speculation regarding FDA's consideration of Jazz's request for Orphan Drug Exclusivity ("ODE") does not make this motion any less pressing. FDA's Tentative Approval letter for Avadel's narcolepsy product explained that, consistent with FDA's prior communications with Avadel in June 2022 and 21 U.S.C. § 355(c)(3)(C), the final approval of the Avadel's 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." D.I. 165, Ex. 1 at 1-2. Jazz's speculation does not warrant further delay.

Finally, Jazz's assertion that Avadel brought the delay resulting from Jazz's improper listing of the '963 patent on itself by dedicating its resources to creating a once-nightly treatment for narcolepsy, or by not certifying to the '963 patent until it was required to do so by the FDA, is classic victim blaming. Avadel presumed that FDA would follow the law and appropriately understand that Avadel's proposed labeling does not implicate Jazz's use code and accept Avadel's patent statement (as it did for other Orange Book listed patents assigned to Jazz). In short, Jazz knowingly listed a patent directed to computer-implemented systems for distributing sodium oxybate in the Orange Book with no basis for doing so to improperly delay approval of Avadel's product. That is a problem of Jazz's design, not of Avadel's own making.

Jazz's opposition and continued attempts to forestall resolution of Avadel's delisting motion should be rejected. Jazz has not offered a single compelling reason why prompt resolution

is not appropriate. Avadel thus respectfully requests that the Court promptly decide Avadel's renewed motion for judgment on the pleadings (D.I. 117). In the alternative, Avadel requests a status conference at the Court's earliest convenience to discuss resolution of Avadel's motion, which Jazz has indicated it does not oppose. D.I. 165 at 3.

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on September 14, 2022 on the following counsel in the manner indicated below.

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