IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

JAZZ PHARMACEUTICALS, INC.'S MOTION FOR A STAY PENDING APPEAL OR, IN THE ALTERNATIVE, A STAY PENDING APPLICATION TO THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") respectfully moves this Court to stay its Order And Judgment (D.I. 232, the "Order"), granting the renewed motion for partial judgment on the pleadings of Avadel CNS Pharmaceuticals LLC ("Avadel"). Jazz specifically seeks a stay pending appeal of the paragraph of the Order that directs Jazz "by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I) to submit to the FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®" "within fourteen (14) days from the date of this Order," (D.I. 232 at 1-2).

In the alternative (and at a minimum), Jazz respectfully moves for a temporary, one-month stay of that paragraph of the Order pending resolution of Jazz's application to the Federal Circuit for a stay pending appeal pursuant to Federal Rule of Appellate Procedure 8.

The grounds for this motion are set forth in Jazz's opening brief filed herewith.

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November 22, 2022

CERTIFICATION PURSUANT TO LOCAL RULE 7.1.1

Pursuant to D. Del. L.R. 7.1.1, the undersigned counsel hereby certifies that counsel for Plaintiff reached out to counsel for Defendant regarding the relief sought in the foregoing motion, and Defendant opposes the motion.

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

[PROPOSED] ORDER GRANTING JAZZ PHARMACEUTICALS, INC.'S MOTION FOR A STAY PENDING APPEAL OR, IN THE ALTERNATIVE, A STAY PENDING APPLICATION TO THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

At Wilmington this _____ day of _____, 2022, having considered Plaintiff Jazz Pharmaceuticals, Inc.'s motion for a stay of the Court's Order And Judgment (D.I. 232) granting the renewed motion for partial judgment on the pleadings of Avadel CNS Pharmaceuticals LLC pending resolution of Jazz's expedited appeal to the Court of Appeals for the Federal Circuit (the "motion");

IT IS HEREBY ORDERED that the motion is GRANTED.

_____
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 22, 2022, upon the following in the manner indicated:

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IN THE UNITED STATES DISTRICT COURT
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JAZZ PHARMACEUTICALS, INC.,	)	
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Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

**OPENING BRIEF OF JAZZ PHARMACEUTICALS, INC.
IN SUPPORT OF MOTION FOR A STAY PENDING APPEAL
OR, IN THE ALTERNATIVE, A STAY PENDING APPLICATION
TO THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL**

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November 22, 2022

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Jazz Pharmaceuticals, Inc. ("Jazz") respectfully moves this Court to stay its Order And Judgment (D.I. 232, the "Order"), granting the renewed motion for partial judgment on the pleadings of Avadel CNS Pharmaceuticals LLC ("Avadel"). Jazz specifically seeks a stay pending appeal of the paragraph of the Order that directs Jazz "by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I) to submit to the FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®" "within fourteen (14) days from the date of this Order," (D.I. 232 at 1-2).

In the alternative (and at a minimum), Jazz respectfully moves for a temporary, one-month stay of that paragraph of the Order pending resolution of Jazz's application to the Federal Circuit for a stay pending appeal pursuant to Federal Rule of Appellate Procedure 8.

SUMMARY OF ARGUMENT

This Court should stay the portion of its Order that requires Jazz to request that the FDA delist the '963 patent from the Orange Book pending Jazz's appeal of that Order. A stay will allow the Federal Circuit to address the questions of first impression that this appeal raises as to the scope of the delisting statute when applied to permissibly-listed patents, and it will preserve the availability of meaningful appellate relief. Individually, each of the following factors that this Court must consider strongly favors a stay—taken together, as they must be under the law of this Court and the Federal Circuit, they compel such relief.

First, this Court should issue a stay because Jazz is likely to prevail on novel questions of statutory construction regarding the applicability of the statutory counterclaim in 21 U.S.C. § 355(c)(3)(D)(ii)(I). That Jazz was permitted to list the '963 patent in the Orange Book prior to the Orange Book Transparency Act, a *prospective* statute passed in 2021, forecloses Avadel's application of the delisting counterclaim to the '963 patent. This is because the availability of the delisting remedy necessarily turns on whether the patent was permissibly listed in the first instance.

In other words, a patent that was permissibly listed in the Orange Book, as the '963 patent was, cannot be removed through the delisting counterclaim, because 21 U.S.C. § 355(c)(3)(D)(ii)(I) only authorizes the delisting of improperly-listed patents. At a minimum, because the scope of 21 U.S.C. § 355(j)(5)(C)(ii)(I) is a question of first impression for the Federal Circuit and will be reviewed *de novo* as a question of statutory construction, Jazz's appeal presents a substantial case on the merits.

Jazz is also likely to succeed on the merits because the Order is based on an erroneous assumption that claim construction of the '963 patent was dispositive of the counterclaim. Under the plain language of the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations from the U.S. Food and Drug Administration ("FDA"), the '963 patent is not subject to delisting even if the patent is construed as claiming a "system." There is no question that the patent continues to read on the FDA-required elements to assure the safe use of oxybate. Because the patent continues to read on the FDA-approved conditions of use, it is not subject to delisting whether it is construed as a method patent or a system patent.

Second, the equities strongly favor a stay of the Order to preserve Jazz's ability to obtain meaningful relief on appeal. Courts uniformly recognize the loss of the ability to obtain meaningful relief on appeal if the Order is not stayed as irreparable harm. To the extent that Jazz is forced to make the ordered submission to FDA, it is highly likely that FDA will remove the '963 patent from the Orange Book and vacate or expunge Avadel's patent certification. That bell cannot be unrung if the injunction is overturned on appeal.

The '963 patent provides exclusivity through June 17, 2023, just over seven months from now. That timing includes a six-month period of pediatric exclusivity granted after Jazz allocated significant resources to conduct studies in pediatric patients. The pediatric exclusivity, however,

only applies to patents listed in the Orange Book. *See* 21 U.S.C. § 355a(b)(1)(B). If Jazz is required to delist the '963 patent, then the pediatric exclusivity will evaporate, and the patent will no longer provide any exclusivity when it expires on December 17, 2022 (while the appeal is pending).

In addition, even if the appeal could be resolved before December 17, 2022, it is not clear that the patent could be "relisted" in the Orange Book in a way that would restore Avadel's patent certification and return parties to their current positions. Patents generally must be submitted to FDA for listing in the Orange Book within 30 days of issuance. *See, e.g.*, 21 C.F.R. § 314.53(c)(2)(ii), 314.53(d)(3). Avadel is likely to contend that "relisting" the '963 patent after a successful appeal would not comply with that requirement (because the patent issued in 2014) and accordingly claim to be under no obligation to certify to the relisted patent. *See* 21 C.F.R. §§ 314.53(d)(3), 314.50(i)(4). Such arguments would at least complicate Jazz's ability to recover the stay of approval that is currently in force.

Third, whereas Jazz will suffer irreparable harm if it is forced to comply with the Order, Avadel will not be harmed by a stay while the Federal Circuit decides Jazz's expedited appeal. Avadel's product is not marketable at this time. Rather, FDA still must complete additional steps in the approval process for Avadel's FT218 product, including by addressing whether the regulatory Orphan Drug Exclusivity ("ODE") afforded to Jazz's oxybate products (Xyrem® and Xywav®) bars approval of FT218 until 2027. Avadel's own strategic decisions also undermine any claim of harm it might assert. Avadel elected to seek FDA approval for its FT218 product via an abbreviated regulatory pathway by relying upon Jazz's innovative work with Xyrem®, and simultaneously refused to provide a patent certification with respect to the Orange Book listed '963 patent. Those decisions delayed resolution of its delisting counterclaim.

Finally, the public interest favors a stay to ensure the Order does not upset the policy considerations that Congress and the FDA weighed in implementing the Hatch-Waxman Act.

In the alternative, if this Court declines to stay its Order pending an appeal, the Court should issue a temporary stay for one month to give Jazz an opportunity to move the Federal Circuit to stay the Order pending appeal pursuant to Federal Rule of Appellate Procedure 8. Both this Court and the Federal Circuit grant such temporary stays to preserve the status quo and permit orderly appellate review of stay applications. Jazz would promptly brief the merits of the appeal during that time as well, such that a temporary stay would not delay the ultimate resolution of the appeal. Jazz respectfully submits that such a temporary stay would be appropriate here if the Court declines to issue a stay that would span the pendency of the appeal.

STATEMENT OF FACTS

On July 23, 2021, Avadel first moved for partial judgment on the pleadings as to its delisting counterclaim, which sought a mandatory injunction to direct Jazz to delist in the FDA's Orange Book the '963 patent. (*See* D.I. 21). That patent claims use of a computer-implemented system to address FDA-required Risk Evaluation and Mitigation Strategy ("REMS") conditions of using Xyrem® for treatment of narcoleptic patients according to its approved labeling. Jazz opposed the motion, arguing it should be denied because Jazz was either required or, at a minimum, permitted to list the patent in the Orange Book. (D.I. 43 at 8-9). This Court denied the motion on October 19, 2021, explaining that "there is a question as to whether Jazz was required to submit the '963 Patent for listing in the Orange Book," and that Avadel's "arguments depend in no small part on claim construction." (D.I. 55 at 5).

On June 23, 2022, after the parties had submitted claim construction briefing but before this Court had resolved those disputes, Avadel renewed its motion for partial judgment on the pleadings. (D.I. 118). Jazz opposed the motion, arguing (among other things) that FDA has

offered an alternative interpretation of section 355(c)(D)(ii)(I)(bb) that does not depend on patent-law definitions. *See* D.I. 153 at 9–10 (citing "FDA's Orange Book listing rules"); D.I. 155-1.

On November 18, 2022, this Court issued both its opinion (D.I. 229) and order (D.I. 230) on claim construction, and subsequently its opinion (D.I. 231) and the Order (D.I. 232) granting Avadel's renewed motion under Federal Rule of Civil Procedure 12(c) for a partial judgment on the pleadings as to Avadel's delisting counterclaim.

In the claim construction opinion as to the '963 patent, the Court concluded that the claims "are directed to systems and not to methods." (D.I. 229 at 14). The Court further determined that this claim construction "disposes of" Avadel's counterclaim because a patent that contains only system claims cannot be understood to claim "an approved method of using the drug," as that phrase appears in the FDCA. (D.I. 231 at 5.) The Court notably did not determine that the patent had been improperly listed in 2014. (*See id.* at 7 (stating that "the propriety of Jazz's initial listing" was "not relevant in view of 21 U.S.C. § 355(c)(3)(D)(ii)(I)").)

The accompanying Order directed Jazz "by mandatory injunction under 21 U.S.C. § 355(c)(3)(D)(ii)(I)," and "within fourteen (14) days from the date of this Order," "to submit to the FDA a request enclosing this Order to delete the '963 patent from the Orange Book entry for Xyrem®." (D.I. 232 at 1-2).

Jazz promptly filed its notice of appeal and the instant motion for a stay pending appeal to preserve the status quo.

ARGUMENT

Four factors guide the availability of a stay pending appeal: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Standard Havens*

Prod., Inc. v. Gencor Indus., Inc., 897 F.2d 511, 512 (Fed. Cir. 1990); *In re Revel AC, Inc.*, 802 F.3d 558, 571 (3d Cir. 2015) (applying same standard). However, "the four stay factors can effectively merge," such that a severe risk of irreparable injury reduces the showing of likelihood of success on the merits necessary for a stay to issue. *Standard Havens*, 897 F.2d at 513. Thus, "[w]hen harm to applicant is great enough, a court will not require 'a strong showing' that [the] applicant is 'likely to succeed on the merits.'" *Id.*; *see Merial Ltd. v. Cipla Ltd.*, 426 F. App'x 915, 915 (Fed. Cir. 2011) ("To obtain a stay, pending appeal, a movant must establish a strong likelihood of success on the merits, or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor."). All relevant factors support a stay pending appeal here. At the very least, all relevant factors support a temporary, one-month stay to give Jazz an opportunity to seek a stay pending appeal from the Federal Circuit.

I. THIS COURT SHOULD STAY ITS MANDATORY INJUNCTION PENDING APPEAL

A. Jazz Is Likely To Succeed On The Merits Of Its Appeal Or, At A Minimum, Presents A Substantial Case

1. Jazz's appeal is likely to succeed on the merits because the delisting statute, 21 U.S.C. § 355(c)(3)(D)(ii)(I), does not provide a basis to delist patents that, like the '963 patent, were appropriately included in the Orange Book under the law that applied at the time of their listing. The delisting provision must be read in conjunction with the statutory and regulatory provisions that authorize listings in the Orange Book in the first place. While the Orange Book Transparency Act of 2020 ("OBTA") amended 21 U.S.C. § 355(c)(2) to narrow the universe of patents that are appropriately listed, it did so only prospectively.

Accepting the Court's claim construction for this portion of its forthcoming appeal, Jazz was at least *permitted* to list the '963 patent in 2014 because the '963 patent does not fall into one of the categories that the FDA—in interpreting and implementing the Orange Book listing

statute—prohibited from being listed in 21 C.F.R. § 314.53(b)(1). Specifically, the relevant FDA regulation identified categories of patents that "must" be listed and then categories of patents that "must not" be listed. Because the two sets of categories are not exhaustive, the FDA necessarily left open other categories of patents as being listable. A "system" patent that claims one or more of the drug's approved conditions of use fell either into the category that must be listed or into the permissive category. Indeed, the "must not" categories consisted of only "process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates." 21 C.F.R. § 314.53(b)(1). Avadel has never argued, and this Court's Opinion did not find, that the '963 patent falls within those limited "must not" categories.

The OBTA then superseded FDA's regulation by amending section 505(c)(2) of the FDCA to provide that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph." 21 U.S.C. § 355(c)(2). As the Supreme Court has explained, had Congress thought the FDCA already included such a limitation, then "Congress would have not needed to enact these additional statutory references." *See Carcieri v. Salazar*, 555 U.S. 379, 392 (2009). In any event, there is also no dispute that the OBTA does not apply retroactively. The "express" language of 21 U.S.C. § 355(c)(2)—in particular, the phrase "shall not be"—unambiguously shows that Congress intended only prospective application. *Ghana v. Holland*, 226 F.3d 175, 182 (3d Cir. 2000) ("[E]very court of appeals to have considered the issue has concluded that the express language of § 1997e(a), which provides that 'no action shall be brought' until the prisoner exhausts administrative remedies, demonstrates Congress's intent that the exhaustion requirement apply only to new actions."). *See also* D.I. 153 at 16 (collecting authorities). Moreover, even if the statute were ambiguous (and it is not), there is no dispute that the Court would be compelled to find that the statute does not apply

retroactively because to do so would impair the preexisting rights of a party. *Apotex Inc. v. U.S. Food & Drug Admin.*, 414 F. Supp. 2d 61, 75 (D.D.C. 2006) ("retroactive applications of the law are not favored in the administrative law context").

2. Separately, Jazz is also likely to succeed on the merits because the Order mistakenly assumed that claim construction of the '963 patent settles the counterclaim question. There is no question that FDA has primary jurisdiction to interpret and execute the FDCA, including the portions of section 505 that govern the Orange Book. *See* 21 U.S.C. § 393(d)(2); *Wienberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). Where a REMS is required, FDA policy has been to allow REMS-related patents to be listed in the Orange Book as patents covering the drug's approved conditions of use. *See, e.g.*, 85 Fed. Reg. 33169, 33172 (Aug. 31, 2020) ("FDA is aware that some NDA holders have obtained patents claiming the way one or more of their REMS requirements have been implemented…. The prospect of NDA holders obtaining patents for REMS was also contemplated by Congress…."). For the past two years, FDA has been considering whether to change that policy. *See id.* at 33173 (requesting comments regarding "whether patents that claim how the sponsor has implemented a particular REMS requirement meet the statutory requirement for the type of patent information that is required to be submitted to FDA for listing in the Orange Book"); *see also* 85 Fed. Reg. 65819 (Oct. 16, 2020) (reopening the comment period); 86 Fed. Reg. 14450 (Mar. 16, 2021) (reopening the comment period again in light of the Orange Book Transparency Act). But, per its recent report to Congress, FDA remains undecided. *See generally* FDA, *The Listing of Patent Information in the Orange Book*, *available at* https://www.fda.gov/media/155200/download.

Until a change is made, REMS-related patents are properly included in the Orange Book, a point that was made clear in the related case in the District of Columbia. Writing as counsel for

FDA, the U.S. Department of Justice ("DOJ") emphasized that 21 C.F.R. 314.53(b)(1) was amended to make clear that patents claiming "a use other than an indication may be submitted for listing in the Orange Book." *Avadel CNS Pharmaceuticals, LLC, v. Becerra, et al.*, Case No. 22-02159, D.I. 28 at 17 n.9 (D.D.C., filed Aug. 30, 2022). At the hearing in that case, DOJ acknowledged that, although FDA is "considering [the] question of whether uses in the REMS document" should remain in the Orange Book, FDA's current policy is "**that they can be**." *Id.*, D.I. 40 at 83 (D.D.C. filed Oct. 13, 2022) (emphasis added). In light of the current policy of the expert federal agency with primary jurisdiction, Jazz is likely to persuade the Federal Circuit that the '963 patent was properly listed.

In its opinion, this Court reasoned that Jazz had offered no argument "that the '963 patent, construed as claiming systems," remains properly listed in the Orange Book.[1] (D.I. 231 at 6.) The Federal Circuit, however, is likely to conclude otherwise, given Jazz's argument regarding FDA's policy concerning REMS patents, which relies on an interpretation of the FDCA and its implementing regulations and avoids the assumption that terminology in the FDCA must have the same technical meanings that are applied under the Patent Act. *See* D.I. 153 at 9–10 (citing "FDA's Orange Book listing rules"); *see also Johnson v. United States*, 559 U.S. 133, 140 (2010) ("[W]e do not assume that a statutory word is used as a term of art where that meaning does not fit."). Relevant here, there is no reason to think that a patent containing system claims cannot read on "an approved method of using the drug" as that phrase appears in 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). To the contrary, there are several reasons to think it can.

[1] The Opinion also suggested that Jazz had previously suggested that construing the '963 patent as a system patent would be dispositive of the Orange Book listing question. (D.I. 231 at 6.) But Jazz contended that because Avadel's argument construed the '963 patent as a system patent, Avadel's argument required claim construction. (*See* D.I. 43 at 9–14.) But that does not mean that construing the '963 patent as a system patent is dispositive.

Start with plain language. Neither the FDCA nor its implementing regulations define "method," so a court "must interpret the word according to its ordinary meaning at the time Congress enacted" section 355(c)(D)(ii)(I)(bb). *Singh v. Attorney General*, 677 F.3d 503, 510 (3d Cir. 2012). In 2003, as today, the words "method" and "system" were synonyms, often used interchangeably in ordinary speech. *See Westfall v. City of Dunbar*, 517 S.E.2d 479, 482 (W. Va. 1999) ("[M]ethod … is synonymous with … system."); Black's Law Dictionary 57 (8th Ed. 2004) (an "accounting *method*" is a "*system* for determining income and expenses" (emphasis added)); *see also* System, *Webster's Third New International Dictionary* (2002) ("system" means "organized or established procedure or method"). There is no evidence that Congress meant the word "method" to import patent-law concepts into the FDCA. *See Heli-Coil Corp. v. Webster*, 352 F.2d 156, 167 (1965) (courts may assume that an undefined term "was not employed as a term of art").

Second, the controlling FDA regulation ***proves*** that patent law definitions ***cannot*** apply. 21 C.F.R. § 314.53(b)(1) states that "method-of-use patents" (also referred to as "patents that claim a method of use") must be submitted for listing in the Orange Book. Giving the word "method" its patent law definition would suggest that only process patents are eligible for inclusion in the Orange Book under this provision, as method claims are a subset of process claims. *See* 35 U.S.C. § 100(b) ("The term 'process' means process, art or method…."). Yet FDA's regulation affirmatively forbids the submission of process patents. *See* 21 C.F.R. § 314.53(b)(1) ("Process patents … are not covered by this section, and information on these patents must not be submitted to FDA."). The patent law definitions would therefore lead to an impossible contradiction: because

"method-of-use" patents would all be "process patents," sponsors would be simultaneously required to, and forbidden from, submitting them for listing in the Orange Book.[2]

Third, as Jazz previously explained, FDA has offered an alternative interpretation that does not depend on patent law definitions—unsurprisingly so, because FDA lacks patent expertise. (*See* D.I. 159 at 9–10 (citing "FDA's Orange Book listing rules"); *see also* Amicus Br. 18 (responding to Jazz's arguments).) As noted, the controlling statutory question is whether the patent claims an "approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). FDA's regulation provides that a patent does so when it claims, in whole or in part, "indications or other conditions of use for which approval is sought or has been granted in the NDA." 21 C.F.R. § 314.53(b)(1); *see id.* ("If the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted…."). In other words, FDA has interpreted the phrase "method of use" in the FDCA to simply mean "conditions of use." If a patent reads ***at all*** on a drug's approved conditions of use, it must be listed.

Here, the Federal Circuit is likely to conclude that Jazz was in fact *required* to list the '963 patent claims because the FDA itself characterized the REMS that the '963 patent claims as a "condition of use" for Xyrem®. (D.I. 153, Ex. B). Specifically, the Xyrem® label expressly provides that it "is available only through a restricted distribution program called the XYWAV and XYREM REMS because of the risks of central nervous system depression and abuse and

[2] This impossible contradiction would apply to all of the method claims described by the FTC as appropriately listed in the Orange Book, including "an innovative way of using a drug to treat a new condition" or "a new way to dose or administer a drug." Amicus Br. 17. If patent-law definitions apply to the FDCA and FDA regulations, those are all "process" claims that would be ineligible for listing per 21 C.F.R. § 314.53(b)(1).

misuse." (D.I. 153, Ex. B). The inclusion of this condition of use was expressly mandated by the FDA, which conditioned approval of Xyrem® on compliance with "the substance and procedures of all FDA regulations and *the specific restrictions on* distribution and *use* described below," including that "Xyrem is being approved with a Risk Management Program (RMP) that must include each of the following components" claimed under the '963 patent. (D.I. 153, Ex. A). And because the '963 patent claims a "condition of use," the Federal Circuit is likely to determine that Jazz was *required* to list the '963 patent under even Avadel's interpretation of the delisting statute, which recognizes the propriety of listing a "method of using the drug," *see* 21 U.S.C. §355(c)(3)(D)(ii)(I)(bb).

Fourth, the amicus brief filed by the Federal Trade Commission ("FTC") also indicates that the phrase "method of use" in the FDCA and FDA regulations does not incorporate the patent-law definition of "method" and instead refers to the drug's approved conditions of use. Thus, the FTC took "no position on the scope or claim construction of the '963 patent." Amicus Br. 2. The brief also suggests that the controlling question is whether a REMS patent claims "other conditions of use" within the meaning of 21 C.F.R. § 314.53(b)(1). *See* Amicus Br. 18-19. The FTC simply contends that REMS patents do not address conditions of use. *See id.* 19-20.

Although Jazz did not receive an opportunity to respond to the FTC amicus brief, the FTC's arguments are easily countered. To begin, the FTC placed undue weight on an inapposite case. *See* Amicus Br. 19 (quoting *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 22 n.24 (D.D.C. 2012)). Avadel offered the same argument in the D.C. case, but the DOJ corrected Avadel, pointing out that the *ViroPharma* precedent was not at all on point. *Avadel CNS Pharmaceuticals,*

LLC, v. Becerra, et al., Case No. 22-02159, D.I. 28 at 17–18 (D.D.C., filed Aug. 30, 2022).[3] The FTC nevertheless repeated Avadel's error in its amicus brief.

The FTC next errs by trying to distinguish between a drug's conditions of use and its conditions of approval. *See* Amicus Br. 19. However, FDA has never posited such a distinction, which in any event is plainly inconsistent with the FDCA. Section 505(d) sets out when FDA must deny approval, while section 505(e) sets out when FDA must withdraw approval. *See* 21 U.S.C. § 355(d)-(e). The two provisions were written and operate in parallel. *See Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 261 (D.C. Cir. 2020). The former defines approval in terms of the conditions of use proposed in the drug's labeling. 21 U.S.C. § 355(d)(1)-(3). The latter defines withdrawal in terms of the "conditions of use upon the basis of which the application was approved." 21 U.S.C. § 355(e)(1)-(2). Together, they show that a drug's conditions of use and the conditions of its approval are one and the same.

Finally, the FTC's argument cannot be squared with the new drug approval standard itself. Since at least 1941, FDA has viewed new drug approval as a scientific judgment that the benefits of a drug will outweigh its risks under its approved conditions of use. *See* Theodore Klumpp, *The Philosophy of the Food, Drug, and Cosmetic Act*, J. Am. Pharma. Assoc. 379, 382 (1941); *see also*

[3] Specifically, the *ViroPharma* plaintiff was arguing that it had obtained approval for a new condition of use (and thus earned a new regulatory exclusivity for an old antibiotic drug pursuant to 21 U.S.C. § 355(v)(3)(B)) simply by making minor changes to the drug's labeling. *See* 898 F. Supp. 2d at 14. The court acknowledged that the term "conditions of use" is used throughout the [FDCA] and in the FDA's regulations to unambiguously include a variety of aspects of a drug and its administration." *Id.* at 19. It simply held that the plaintiff's labeling changes did not arise to the level of changing the drug's approved conditions of use. *See id.* at 22. In a subsequent opinion, the court reiterated a drug's approved "conditions of use" reflect the core aspects of FDA's approval, which can then be "refined" and given "new details" by the product's approved "labeling." *ViroPharma, Inc. v. Hamburg*, 916 F. Supp. 2d 76, 80 (D.D.C. 2013). The case thus stands for nothing more than the proposition that not every labeling change represents a change to a product's approved conditions of use.

United States v. Rutherford, 442 U.S. 544, 556 (1979). Under that approach, a drug's conditions of use include those conditions that are relevant to FDA's benefit-risk judgment, including risk-mitigation conditions. For example, when FDA was establishing the predecessor program to REMS (known as "RiskMAPs"), the agency encouraged sponsors to adopt, as part of their risk management program, those "conditions of use most likely to confer benefits and to minimize particular risks." FDA, *Guidance for Industry: Development and Use of Risk Minimization Action Plans*, 6 (Mar. 2005), https://www.fda.gov/media/71268/download. Congress also followed this broad understanding of "conditions of use" when it enacted the REMS statute. Section 505-1 establishes that a REMS program must be included in an NDA only when a REMS program is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). Further, the more restrictive REMS elements (which are tellingly known as elements to assure safe ***use***) are defined by statute as the least burdensome precautions necessary to enable FDA to approve the drug. *See* 21 U.S.C. § 355-1(f)(1)(A), (f)(2)(C)-(D).

Because the '963 patent undeniably reads on the approved elements to assure the safe use of sodium oxybate, the patent necessarily reads on Xyrem®'s approved conditions of use. It follows that, under FDA's regulation and current policy, the '963 patent is appropriately listed in the Orange Book even if construed as a system patent.

Additionally, these issues—regarding the Orange Book Transparency Act and the interpretation of "an approved method of using the drug" under the FDCA—turn on questions of statutory construction, which "is a matter of law that [the Federal Circuit] review[s] *de novo*." *Hawkins v. United States*, 469 F.3d 993, 1000 (Fed. Cir. 2006). Accordingly, "a strong showing of irreparable harm combined with the Federal Circuit's *de novo* review" constitute the exceptional circumstances necessary to grant a stay pending appeal. *Butamax Advanced Biofuels LLC v. Gevo,*

Inc., No. CIV. 11-54-SLR, 2012 WL 2675232, at *2 (D. Del. July 6, 2012) ("[T]he court notes that a strong showing of irreparable harm combined with the Federal Circuit's *de novo* review . . . can be sufficient [to warrant a stay]."). Further, whether a patent that was permissibly listed in the Orange Book can be removed is a question of first impression, further favoring a stay to allow the Federal Circuit to bring to bear its expertise in resolving disputes pertaining to the Hatch-Waxman Act. *Jacobson v. Lee*, 1 F.3d 1251, at *5 (Fed. Cir. 1993) (unpublished) ("These are important questions, some of first impression, that deserve careful consideration by this court …. [T]o preserve these issues on appeal, we determine that a stay of execution of the April 14, 1993 judgment and injunction is appropriate.").

B. Jazz Will Be Irreparably Harmed Absent A Stay

Because Jazz has raised, at the very least, substantial legal questions for appeal, it is entitled to a stay of the Order if the equities tip in its favor. *See*, *e.g.*, *Standard Havens*, 897 F.2d at 516. Here, the equities as to Jazz overwhelmingly favor a stay.

Absent a stay of this Court's order pending appeal, the Federal Circuit will be unable to afford meaningful relief if it reverses the Order. The '963 patent currently provides exclusivity through June 17, 2023, with the inclusion of six-month pediatric exclusivity. That pediatric exclusivity, however, only applies to patents listed in the Orange Book. *See* 21 U.S.C. § 355a(b)(1)(B). If Jazz is required to delist the '963 patent, then the pediatric exclusivity will likely evaporate when the patent expires on December 17, 2022 (before the appeal proceedings could conceivably be completed). Accordingly, if Jazz were to delist that patent from the Orange Book within fourteen days as the Order requires, reversal of the Order on appeal would occur too late for Jazz to protect its pediatric exclusivity. That a stay is necessary to preserve any possibility of meaningful appellate relief strongly supports a stay pending appeal. *See Council on Am. Islamic Relations v. Gaubatz*, 667 F. Supp. 2d 67, 76 (D.D.C. 2009) (irreparable harm exists where, absent

relief, "the very rights [movant] seeks to protect will have been destroyed"); *Ctr. For Int'l Env't L. v. Off. of U.S. Trade Representative*, 240 F. Supp. 2d 21, 22 (D.D.C. 2003) (granting stay pending appeal where movants "have made a strong showing of irreparable harm because" immediate enforcement of the order "will render any appeal moot").

Indeed, stays pending appeal exist for precisely this situation, when "necessary to mitigate the damage that can be done during the interim period before a legal issue is finally resolved on its merits. The goal is to minimize the costs of error." *In re A & F Enterprises, Inc. II*, 742 F.3d 763, 766 (7th Cir. 2014). A stay of this Court's Order would minimize the costs of error by preserving the status quo, in which Jazz's patent remains listed in the Orange Book. *Providence J. Co. v. Fed. Bureau of Investigation*, 595 F.2d 889, 890 (1st Cir. 1979) (stay most favored "[w]here, as here, the denial of a stay will utterly destroy the status quo, irreparably harming appellants").

C. Any Harm That Avadel Will Suffer As A Result Of The Stay Is A Result Of Avadel's Own Decisions

Avadel will not suffer any harm as a result of the stay because Avadel's product, FT218, cannot be lawfully marketed even if Jazz delists the '963 patent. As an initial matter, Jazz has seven patents-in-suit that Avadel would infringe, and those patents must be adjudicated on their merits on an appropriately-developed record. Additionally, precisely because Jazz employed time-intensive and costly efforts to develop a new drug targeted toward a relatively small population, its oxybate products are subject to the protections of Orphan Drug Exclusivity ("ODE"). ODE is designed to provide the necessary incentive for the development and evaluation of new treatments for rare diseases, which is a key priority for the FDA. The FDA has not yet determined whether the ODE protection granted to Jazz's oxybate products precludes approval of Avadel's 505(b)(2) NDA until 2027. Indeed, the FDA's tentative approval letter to Avadel expressly states that it

"does not address whether any orphan drug exclusivity (ODE) recognized for Xyrem … or for Xywav … affects the approvability of Avadel's application." (D.I. 165-1 at 1 n.1).

In any event, Avadel cannot raise a cognizable harm that it will suffer as a result of the stay because any delay-related harm that Avadel will suffer is a result of its own decisions. *Cf. Abbott Lab'ys v. Diamedix Corp.*, No. 94-1345, 1994 WL 782247, at *2 (Fed. Cir. July 26, 1994) (explaining "concerns of expeditiously resolving this lawsuit now" are minimal where parties "exchanged correspondence concerning [the] alleged infringement for more than two years before the lawsuit was filed"). Specifically, significant delay is the result of Avadel's decision to seek FDA approval for its FT218 product via an abbreviated regulatory pathway by largely relying upon Jazz's innovative work with Xyrem®, while simultaneously refusing to provide a patent certification with respect to the Orange Book listed '963 patent. Avadel could (and should) have filed a patent certification for the '963 patent at least as early as December 2020 when it submitted its 505(b)(2) NDA.

D. The Public Interest Favors A Stay To Avert The Irrevocable Loss Of Patent Rights

Likewise, the public interest favors a stay. The Hatch-Waxman Act reflects a careful balancing of the need to encourage the research and development of new drugs with the benefit of sharing information through the Orange Book process to permit the development of generic versions. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (D.C. Cir. 2008) ("The goal of the Act is to better balance two competing interest in the pharmaceutical industry: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."); *see also Spectrum Pharms., Inc. v. Burwell*, 824 F.3d 1062, 1065 (D.C. Cir. 2016) ("Recognizing that [the pharmaceutical approval] process can be lengthy and expensive, . . . Congress crafted a statutory scheme that balances two

interests: innovation and affordability."); *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds) (noting the Hatch–Waxman Act "emerged from Congress' efforts to balance two conflicting policy objectives: 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"). Absent a stay, the Court's order would upset that balance by ordering the FDA to remove statutory protections for a patent without which the FDA would not have approved the drug. The Court's order has the potential to undermine the statutory scheme and therefore Congress's assessment of the appropriate balance between these competing interests. *See Biotech. Industry Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) ("We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude. Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts.") (cleaned up); *see also id.* at 1373 ("Congress, too, has acknowledged the central role of enhanced profits in the statutory incentive scheme it has developed.").

The public interest behind Congress's decision to enact pediatric exclusivity also favors a stay. *Cf. Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 646 (Fed. Cir. 2015) (discussing "encouragement of investment-based risk"). And, as explained *supra* at 15, Jazz's pediatric-exclusivity rights will likely be irrevocably lost absent a stay. For this reason, no countervailing interest in promoting competition shifts the public interest analysis: although "the public often benefits from healthy competition," "the public generally does not benefit when that competition comes at the expense" of an "investment-backed property right." *Id.* at 647.

II. IN THE ALTERNATIVE, THIS COURT SHOULD GRANT A ONE-MONTH STAY TO ALLOW TIME FOR JAZZ TO PETITION THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

At a minimum, this Court should grant a one-month stay while Jazz petitions the Federal Circuit to stay the injunction pending appeal. *See* Fed. R. App. P. 8(a); *see also Takeda Pharms. U.S.A., Inc. v. Mylan Pharms., Inc.*, 2020 WL 419488, at *3 (D. Del. Jan. 27, 2020), *aff'd*, 967 F.3d 1339 (Fed. Cir. 2020) (ordering defendant "to maintain the status quo" so plaintiff could "seek immediate relief" in the Federal Circuit); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 2008 WL 5351038, at *1 (D. Del. Dec. 22, 2008) (granting "temporary stay allowing the Federal Circuit to decide whether a permanent stay pending appeal should issue"). The Federal Circuit has granted such relief in numerous cases.[4]

At a minimum, a temporary, one-month stay should issue here to grant the Federal Circuit the opportunity to assess Jazz's basis for a full stay pending appeal. Because this appeal raises issues of first impression that will be subject to *de novo* review by the Federal Circuit, a temporary stay would allow that court to bring its expertise as to the Hatch-Waxman Act to bear on the questions of statutory interpretation raised by Jazz's appeal.

[4] *See, e.g.*, *DePuy Synthes Prods., Inc. v. Veterinary Orthopedic Implants, Inc.*, 990 F.3d 1364, 1367 (Fed. Cir. 2021); *Bio-Rad Lab'ys*, 967 F.3d 1353, 1362 n.2 (Fed. Cir. 2020); *Galderma Lab'ys, L.P. v. Teva Pharms.*, 799 F. App'x 838, 842 (Fed. Cir. 2020); *Dodocase VR, Inc. v. MerchSource, LLC*, 767 F. App'x 930, 933 (Fed. Cir. 2019); *Cont'l Serv. Grp., Inc. v. United States*, 722 F. App'x 986, 993 (Fed. Cir. 2018); *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 629 F. App'x 972, 975 (Fed. Cir. 2015); *Energy Recovery, Inc. v. Hauge*, 745 F.3d 1353, 1356 (Fed. Cir. 2014); *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1373 (Fed. Cir. 2012); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 424 F. App'x 952, 953 (Fed. Cir. 2011); *Fred Hutchinson Cancer Rsch. Ctr. v. BioPet Vet Lab, Inc.*, 412 F. App'x 308 (Fed. Cir. 2011); *Marine Plymer Techs., Inc. v. Hemcon, Inc.*, 396 F. App'x 686 (Fed. Cir. 2010); *Synqor, Inc. v. Artesyn Techs., Inc.*, 410 F. App'x 320, 321 (Fed. Cir. 2011); *NSK Corp. v. United States*, 422 F. App'x 885 (Fed. Cir. 2011).

And, while the equities favor a full stay of the Order pending appeal, the equities even more forcefully compel at least a temporary stay. A modest stay of 30 days for Jazz to seek stay relief from the Federal Circuit presents no risk of harm to Avadel. Conversely, denial of such a stay risks denying Jazz a meaningful opportunity even to seek emergency relief (i.e., a stay pending appeal) from the Federal Circuit. The Order requires Jazz to provide the FDA with the order requiring delisting of the '963 patent within 14 days pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I), which may not provide adequate time for the Federal Circuit to docket the appeal and grant an emergency stay, although Jazz intends to seek such relief on an expedited basis. Once Jazz has delisted the patent, no relief will be available on appeal enabling Jazz to relist the patent until the appeal is resolved in its entirety. Given the impending expiration of the '963 patent, that relief will either come too late for relisting to be possible, or result in the erroneous deprivation of a significant portion of the period of Orange Book exclusivity to which Jazz is entitled as patent holder.

CONCLUSION

For these reasons, this Court should stay the Order pending Jazz's appeal to the Federal Circuit or, at a minimum, stay the Order for one month so that the Federal Circuit will have a full opportunity to consider Jazz's appellate stay application in an orderly fashion.

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November 22, 2022

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 22, 2022, upon the following in the manner indicated:

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