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'S OPPOSITION TO THE FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE*

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Regulations

Rules

Other Authorities

Jazz Pharmaceuticals, Inc. ("Jazz") respectfully opposes the untimely motion for leave to file a brief as *amicus curiae* filed by the Federal Trade Commission ("FTC") in connection with the renewed motion for judgment on the pleadings by Avadel CNS Pharmaceuticals, LLC ("Avadel") as to its delisting counterclaim.

As the FTC acknowledges, it is left to this Court's discretion whether to accept the FTC's proposed *amicus* filing. *Wortham v. KarstadtQuelle AG*, 153 F. App'x 819, 827 (3d Cir. 2005). Because there is no Federal Rule of Civil Procedure on point, district courts are guided by Rule 29 of the Federal Rules of Appellate Procedure in determining whether to grant a motion seeking to file an *amicus* brief. *U.S. v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). Specifically, district courts in this Circuit typically consider whether: "(1) the petitioner has a 'special interest' in the particular case; (2) the petitioner's interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the petitioner is not partial to a particular outcome in the case." *Liberty Resources, Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005).

In this case, the Court should deny the FTC's motion, first and foremost, because it is extraordinarily untimely. The FTC inexcusably filed its motion with just one full business day remaining before the hearing on the delisting motion, long after briefing had closed and after the parties had already submitted their final slides for their hearing presentations. Avadel filed its delisting counterclaim a year-and-a-half ago; there was no last-minute development that justified the FTC seeking leave to file an *amicus* at this late hour. The FTC does not contend otherwise. In addition, the motion should be denied because the FTC fails to satisfy any of the other factors considered by trial courts. Indeed, on its own terms, the FTC's brief (which, the FTC

acknowledges, it composed in haste, D.I. 222-1 (herein "Mot.") at 3), has little direct relevance to the factual and legal issues that are currently before the Court.

I. THE FTC'S MOTION SHOULD BE DENIED AS UNTIMELY

As an initial matter, the FTC's motion should be denied because it is extraordinarily untimely. The parties have been briefing the delisting issue on the public docket for at least 18 months. But the FTC did not file its motion until 72 days after the close of briefing on Avadel's renewed delisting motion, and with just one full business day remaining before the upcoming November 15 hearing on the motion. While the FTC asserts that Jazz should be prepared to respond to its 21-page proposed *amicus* brief at the hearing, Mot. at 6, the FTC fails to acknowledge that the parties had already submitted their final hearing slides, pursuant to the Court's order (D.I. 212), before the FTC filed its belated motion. At this late stage, with the hearing slides finished and preparation for the hearing in the final stages, it would be unfair to require Jazz to try to address the FTC's proposed *amicus* brief at the hearing.[1]

Were this an appellate court, where motions for leave to file *amicus* briefs are granted much more liberally, the FTC's motion would likely be deemed untimely. As the FTC acknowledges (Mot. at 3), Rule 29 of the Federal Rules of Appellate Procedure permits federal agencies to file motions as of right, but only when they do so within ***7 days*** of the principal brief of the party the agency is supporting. Here, Avadel's principal brief on the renewed Rule 12(c) motion was filed on June 23, 2022. D.I. 118. The FTC filed its motion ***140 days*** later.

[1] Nor did the FTC mitigate this prejudice to Jazz by notifying Jazz of its intent before the eleventh hour. The FTC notified Jazz of its intent to file an *amicus* brief only on November 9, 2022, the day before it filed for leave to submit. But the FTC's decision to file, the brief itself, and the FTC's associated press release (*see infra* at 8) were clearly underway before then.

The FTC's extreme untimeliness is even more disqualifying here in district court, where *amicus* briefs are less appropriate than in appellate courts. "Courts in this Circuit have found that participation as *amicus* at the level of the trial court, as opposed to the appellate court, 'is rather more the exception than the rule.'" *Wayne Land & Mineral Grp., LLC v. Del. River Basin Comm'n*, 2016 WL 7256945, at *1 (M.D. Pa. Dec. 15, 2016) (citing *Abu-Jamal v. Price*, 1995 WL 722518, at *1 (W.D. Pa. Aug. 25, 1995)). This is because, "[a]t the trial level, where issues of fact as well as law predominate, the aid of *amicus curiae* may be less appropriate than at the appellate level, where such participation has become standard procedure." *Alkaabi*, 223 F. Supp. 2d at 592 n.16 (quoting *Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985)).

Nor can the FTC justify its delay. The FTC states that it "would have submitted its proposed *amicus* brief in this matter earlier if that had been possible." Mot. at 3. But nothing made it impossible for the FTC to submit a timely request.[2] The FTC states it "did not become aware of the delisting dispute until after briefing was concluded." Mot. at 3. But that speaks only to the FTC's lack of attention to this case. Avadel first moved to delist the '963 patent in July 2021. D.I. 21. The Court decided the original delisting motion three months later, on October 19, 2021. D.I. 55. Avadel then renewed its motion on June 23, 2022. D.I. 118. The parties then spent months briefing the renewed motion (D.I. 118, dated June 23, 2022; D.I. 157, dated August 30, 2022), followed by more briefing on the motion to expedite. D.I. 162. All of these filings are

[2] The FTC's filings in other matters illustrate that it is capable of seeking leave as *amicus* in a timely manner. *See, e.g.*, in *Takeda Pharms. Co. v. Zydus Pharms., (USA) Inc.*, Case No. 18-1994 (D.N.J.), where the FTC filed a motion for leave to appear as *amicus curiae*, D.I. 42 (June 6, 2018), two days after the principal brief for which the *amicus* brief offered support, D.I. 38 (June 4, 2018).

public, with many covered in the legal and industry press.[3] Each gave any interested party ample notice that the parties were briefing a delisting motion.

That the FTC did not pay any attention to these proceedings does not mean it was not possible for it to have done so, as the FTC contends. Rather, its lack of attention highlights that the issues relevant to this delisting motion are not within the FTC's core competency. As discussed further below, in fact, the U.S. Food & Drug Administration ("FDA") is the agency with far more expertise and interest regarding the issues actually before this Court. The FDA has paid ample attention to this matter and related matters, and has already made its views, which favor Jazz's position, known.

II. THE FTC'S MOTION SHOULD ALSO BE DENIED UNDER THE OTHER APPLICABLE FACTORS

While the untimeliness of the motion should be decisive, the FTC's motion also fails to satisfy the other factors considered by trial courts in deciding whether to grant leave for the filing of timely *amicus* briefs.

First, the FTC fails to demonstrate a special interest in the case. The FTC states that its goals are "preserving competition and protecting consumers from violations of the antitrust laws." Mot. at 4. Yet it fails to connect these goals to relevant issues currently before the Court. Although the ostensible purpose of the FTC's brief is to "assist the Court in assessing Avadel's motion to delist the '963 patent," Mot. at 1, the FTC expressly "takes no position on the scope or claim

[3] *See, e.g.*, "Jazz Pharms., Inc. v. Avadel Pharms. Plc," *JD Supra* (Feb 4, 2022), https://www.jdsupra.com/legalnews/jazz-pharms-inc-v-avadel-pharms-plc-9623401/ (reporting on the Court's denial of Avadel's original delisting motion); *see also* Edited Transcript of AVDL.OQ Earnings Conference Call, August 9, 2022, available at https://finance.yahoo.com/news/edited-transcript-avdl-oq-earnings-120000838.html (Avadel discussing this litigation on earnings call, noting it had "filed a motion in the U.S. District Court for the District of Delaware to delist the REMS patent from the FDA's Orange Book on June 23").

construction of Jazz's '963 patent, nor does it take any view as to whether the '963 patent claims more than a REMS distribution system such that it would qualify for listing." Mot. at 6. This concession is unsurprising, given that the FTC lacks expertise in claim construction. Yet these are two of the key substantive issues that will determine the '963 patent's proper listing.

Moreover, to the extent the FTC wishes to express a position on whether a REMS patent can cover an approved method of using a drug, it is intruding on the province of the FDA. The FDA, not the FTC, is the federal agency that is charged with implementing the Hatch-Waxman Act's statutory scheme. The FDA created the Orange Book in 1980, *see* 45 Fed. Reg. 72582 (Oct. 31, 1980), and Congress has delegated responsibility for implementing the Food, Drug, and Cosmetic Act, including the Hatch-Waxman Amendments, to the FDA. *See* 21 U.S.C. § 393(d)(2). Moreover, the FDA has promulgated a binding regulation defining when patents must, and must not, be submitted to the FDA for inclusion in the Orange Book. *See* 21 C.F.R. § 314.53(b). The FDA is also the agency with special expertise in approved methods of use and interpreting the statutory language and regulations regarding which patents can be listed in the Orange Book. *See* 21 C.F.R. § 314.2 (explaining that the FDA's Orange Book regulations are "intended to establish an effective system for FDA's surveillance of marketed drugs").

The FDA has conducted extensive investigations into these matters. For example, it is the FDA, and ***not*** the FTC, that recently solicited comments regarding which types of patents should be eligible for listing in the Orange Book, including on the specific question of whether "patents associated with an established REMS" should be eligible. 85 Fed. Reg. 33169, 33173 (June 1, 2020) (establishing Docket No. 2020-N-1127). Subsequently, the FDA has twice reopened the docket for additional comments: first on its own accord, 85 Fed. Reg. 65819 (Oct. 16, 2020), and then in response to the specific mandate of the Orange Book Transparency Act of 2020, 86 Fed.

Reg. 14450 (Mar. 16, 2021). *See* Pub. L. 116-290 § 2(e) (requiring the FDA to "solicit public comment regarding the types of patent information should be included, or removed from, the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(7))"). In its recent report to Congress, the FDA noted that the comments it received "reflected a range of different and sometimes competing views." FDA, *The Listing of Patent Information in the Orange Book* at 20-21, available at https://www.fda.gov/media/155200/download. Meanwhile, the FTC did not participate in those proceedings or file any comments.

The FDA also expressed its views in the parallel court proceeding before Judge Mehta in the District of Columbia, *Avadel CNS Pharmaceuticals, LLC, v. Becerra, et al.*, Case No. 22-02159 (D.D.C.). Writing as counsel for the FDA, the U.S. Department of Justice ("DOJ") emphasized that the FDA's regulations, including 21 C.F.R. 314.53(b), are intentionally broad so that patents claiming "a use other than an indication may be submitted for listing in the Orange Book." *Id.*, D.I. 28 at 17 n.9 (Aug. 30, 2022). At the hearing, in reference to the open docket and report to Congress mentioned above, the DOJ stated that the FDA is currently "considering [the] question of whether uses in the REMS document" should remain listed in the Orange Book and represented to Judge Mehta that the FDA's position has long been "that they can be." *Avadel CNS Pharmaceuticals, LLC, v. Becerra, et al.*, Case No. 22-02159 (D.D.C.), D.I. 40, at 83 (Oct. 13, 2022). Thus, whatever the FTC's interest in this case, it makes no attempt to account for the views of the FDA, which has much more experience and expertise in the issues implicated by this dispute. In sum, the FTC simply lacks a special interest that would warrant allowing it to appear as *amicus*.

See, e.g., *Prof'l Drug Co. v. Wyeth Inc.*, 2012 WL 13172911 (D.N.J. Oct. 2, 2012) (denying leave for the FTC to file an *amicus* brief).[4]

Second, the FTC fails to demonstrate that its interests are not already competently represented in this case. The FTC states that it wishes to comment on the possible competitive implications of purported erroneous Orange Book listings, Mot. at 4, but Avadel, which is represented by competent counsel, has already advanced the same position. *See, e.g.*, D.I. 118 at 10-11 (discussing the 30-month stay triggered by its Paragraph IV Patent Certification).

Third, the FTC has failed to demonstrate that its *amicus* brief would be useful to the Court because the FTC, by its own admission, does not directly engage with the most relevant issues. The FTC acknowledges that it "takes no position on the scope or claim construction of Jazz's '963 patent, nor does it take any view as to whether the '963 patent claims more than a REMS distribution system such that it would qualify for listing." Mot. at 6. The FTC's avoidance of the substantive and fact-bound issues that the Court must grapple with illustrates why district courts in particular often observe that the aid of *amicus curiae* is unnecessary. *See, e.g.*, *Alkaabi*, 223 F. Supp. 2d at 592 n.16; *Wayne Land & Mineral Grp., LLC*, 2016 WL 7256945, at *1.

[4] Further underscoring the FTC's lack of informed experience, the FTC argues that the FDA has explained that "conditions of use" are "those that encompass 'how a drug is used [], to whom it is prescribed[], [or] for what purposes[].'" D.I. 222-3 at 19 (alteration in original) (quoting *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 22 n.24 (D.D.C. 2012)). But that is not the position that the FDA took in the case before Judge Mehta, where it explained that its statement in the "unrelated litigation" in *ViroPharma* "related to an interpretation of 'condition of use' in the context of 21 U.S.C. § 355(v)(3)(B), which bars three-year new clinical investigation exclusivity for certain antibiotic drugs as to 'any condition of use for which the drug . . . was approved before October 8, 2008.'" *See Avadel CNS Pharmaceuticals, LLC v. Becerra, et al.*, Case No. 22-2159 (D.D.C.), D.I. 28 at 17 (Aug. 30, 2022). The FDA further explained that the "'other condition of use' language was added [to the regulations at issue in this litigation (including 21 C.F.R. § 314.53)] to broaden the relevant uses beyond just indications." *Id*.

Fourth, the FTC has shown that it is excessively partial to the outcome in this case. Indeed, although the FTC's *amicus* brief makes no substantive statement about the merits of Avadel's motion, the FTC issued a press release on the same day that it filed its motion accusing Jazz of "[a]buse of FDA 'Orange Book' [l]isting [p]rocedures" and advocating for the '963 patent to be delisted.[5] Moreover, in this press release, the FTC erroneously stated that it had "***filed*** an amicus brief" with this Court—treating this Court's decision on the FTC's motion for ***leave to file*** its *amicus* brief as a mere formality.[6] That the FTC apparently considered its untimely filing to be part of a broader public relations effort reflects that it is significantly partial to a particular outcome in this case.

The FTC's partiality is also reflected in its failure to review the facts of this case in a careful or balanced way. As just one example, the FTC appears to believe that Jazz filed its patent infringement suit relating to the '963 patent only ***after*** Avadel had filed a Paragraph IV certification, and thus that the original filing triggered a 30-month stay of Avadel entering the

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[5] FTC, "FTC Amicus Brief Challenges Abuse of FDA 'Orange Book' Listing Procedures to Block Drug Competition," November 10, 2022, available at https://www.ftc.gov/news-events/news/press-releases/2022/11/ftc-amicus-brief-challenges-abuse-fda-orange-book-listing-procedures-block-drug-competition ("Jazz's '963 patent appears to cover only a method for distributing Xyrem under a REMS program. After listing it in the Orange Book, Jazz filed a patent infringement lawsuit against Avadel, triggering a 30-month stay and blocking final FDA approval of Avadel's competing narcolepsy drug.").

[6] *Id*. (stating that "[t]he Federal Trade Commission filed an amicus brief with the U.S. District Court for the District of Delaware in the case of *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*" and making no mention of its motion for leave) (emphasis added). Furthermore, the same day the FTC filed its motion and issued a press release regarding this matter, it issued another press release on a new policy statement titled "FTC Restores Rigorous Enforcement of Law Banning Unfair Methods of Competition." FTC, "FTC Restores Rigorous Enforcement of Law Banning Unfair Methods of Competition," November 10, 2022, available at https://www.ftc.gov/news-events/news/press-releases/2022/11/ftc-restores-rigorous-enforcement-law-banning-unfair-methods-competition.

market. *Id.* In fact, Jazz filed its original patent infringement claim relating to the '963 patent ***before*** Avadel certified, at a time when the suit caused ***no stay***. D.I. 1 (filed May 12, 2021).

As another example, the FTC mistakenly suggests that the '963 patent is the only remaining issue for Avadel to address before receiving final approval from the FDA. D.I. 222-3 at 11. In fact, the FDA has yet to decide whether Jazz's Orphan Drug Exclusivity for Xyrem and Xywav ***separate and apart*** from the '963 patent precludes final FDA approval of Avadel's 505(b)(2) application. D.I. 153-1, Ex. C. at 1 n.1. The FTC's proposed filing contains other inaccuracies as well, which Jazz would need to correct if the FTC's motion for leave were granted. Because the motion is untimely, however, and because the FTC has failed to satisfy the other factors for the exceptional step of filing an *amicus* brief at the trial court level, the FTC's motion should be denied.

III. CONCLUSION

The Court should deny the FTC's motion for leave to file a brief as *amicus curiae* because it is extraordinarily untimely and because the FTC has failed to demonstrate that it satisfies the other factors considered by trial courts in this context. In the alternative, if the Court grants the FTC leave to file a brief as *amicus curiae*, Jazz respectfully submits that fairness dictates that Jazz, as the party against whose position the brief would be submitted, be permitted an opportunity to file a written response. Specifically, Jazz requests leave to file a responsive brief no longer than ten pages within ten days.

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November 14, 2022

CERTIFICATE OF SERVICE

I hereby certify that on November 14, 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 14, 2022, upon the following in the manner indicated:

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