UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 21-691-GBW **NOTICE OF MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE***

PLEASE TAKE NOTICE that the Federal Trade Commission will move before the Honorable Gregory B. Williams, U.S.D.J., on November 10, 2022, for an Order granting leave to file a brief as *amicus curiae.*

PLEASE TAKE FURTHER NOTICE that in support of the motion, the Federal Trade Commission will rely on the attached memorandum of law. A proposed order has also been submitted with this motion.

Dated: November 10, 2022

Respectfully submitted,

/s/ Markus H. Meier

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MEMORANDUM IN SUPPORT OF THE FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE*

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The Federal Trade Commission respectfully moves for leave to file an *amicus curiae* brief in the above-captioned matter in connection with Defendant Avadel CNS Pharmacueticals, LLC's renewed motion for judgment on the pleadings as to its delisting counterclaim.[1] Avadel consents to the FTC's filing of an *amicus* brief. Commission staff consulted with counsel for Jazz Pharmaceuticals, Inc., but Jazz did not make a decision by the time of filing.

Avadel's motion raises the question of whether Jazz has properly listed U.S. Patent No. 8,731,963 ("the '963 patent") in the FDA's Orange Book. The types of patents that can be listed in the Orange Book are strictly limited by statute to those claiming a drug or a "method of using a drug." This limitation is important: As the Court is aware, listing a patent in the Orange Book and subsequently filing an infringement suit against a 505(b)(2) applicant like Avadel triggers an automatic 30-month stay of FDA approval for the competitor's product. When an Orange Book patent is appropriately listed, this stay reflects Congress's intent to provide brand pharmaceutical companies with an incentive to develop new drugs and new methods of treatment. But if a brand company obtains the stay by listing and enforcing a patent that does not meet the Orange Book criteria, this does not reflect the intended incentive and instead simply blocks competition that would lower health care costs and benefit patients. As a general matter, patents that claim only a distribution system do not meet the statutory requirements for listing in the Orange Book.

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court in assessing Avadel's motion to delist the '963 patent. The FTC is an independent agency charged by Congress with protecting the interest of consumers by enforcing competition and consumer protection laws.[2] It exercises primary responsibility over federal antitrust enforcement in the

[1] D.I. 118, June 23, 2022.

[2] 15 U.S.C. §§ 41–58.

pharmaceutical industry. The FTC has substantial experience addressing the impact of the Hatch-Waxman Act on competition in the pharmaceutical industry.[3] In addition to conducting investigations and enforcement actions in its role as a law enforcement agency, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues.[4] It has conducted numerous studies covering the pharmaceutical industry, including reports on competition under the Hatch-Waxman Act, which have been cited by numerous courts including the Supreme Court and the Third Circuit.[5] The FTC has also taken actions specifically related to improper Orange Book patent listings, including a study, an enforcement action, and an amicus brief.[6] In light of this expertise, as well as the FTC's mandate to protect competition and the public interest, we respectfully request that the Court accept the attached proposed *amicus* brief which explains the significant harm improper Orange Book listings can cause to consumers and outlines why REMS distribution patents do not meet the listing criteria.

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[3] *See, e.g. FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *Impax Labs., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc.*, 976 F.3d 327, 339 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015). For a fuller summary of the FTC's actions in the pharmaceutical industry, see *Overview of FTC Actions in Pharmaceutical Products and Distribution* (July 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/2022.07.12OverviewPharmafinalupdated.pdf.

[4] 15 U.S.C. § 46(b) (granting the FTC authority to gather information for industry-wide studies, apart from the Commission's authority to gather information related to specific discrete law enforcement investigations).

[5] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012) (citing an FTC study on generic pharmaceuticals); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) (citing an FTC study on the proper balance between competition and patent law); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765 n.20 (1976) (referring to an FTC study concerning drug price advertising restrictions); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208, 215 (3d Cir. 2012) (citing statistics from FTC studies on Hatch-Waxman patent litigation and settlement).

[6] *See* Generic Drug Entry Prior to Patent Expiration: An FTC Study, at 39-52 (2002); Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 (Oct. 2, 2002); Memorandum of Law of *Amicus Curiae* the Federal Trade Commission, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410-JGK (S.D.N.Y. Jan. 8, 2002) (Doc. No. 31).

The FTC would have submitted its proposed *amicus* brief in this matter earlier if that had been possible. Though "there is no rule governing the appearance of an *amicus curiae* in the United States District Courts,"[7] the FTC generally attempts to follow the timeline in Federal Rule of Appellate Procedure 29, which allows federal agencies to file an *amicus* brief within seven days of the principal brief of the party the agency is supporting. In this matter, however, the FTC did not become aware of the delisting dispute until after briefing was concluded, and we prepared the attached proposed brief as quickly as possible. Despite this timing, for the reasons described below, we nonetheless believe our proposed *amicus* brief would be useful to the Court in resolving the pending motion. We thus respectfully request that the Court grant the FTC leave to file its proposed *amicus* brief.

I. District Courts Have Broad Discretion to Appoint an *Amicus Curiae*

"District courts have broad discretion to appoint amicus curiae."[8] "Although there is no rule governing the appearance of an *amicus curiae* in the United States District Courts," some district courts in the Third Circuit have looked to the Federal Rules of Appellate Procedure for guidance in exercising their broad discretion.[9] As mentioned, in most circumstances Rule 29 allows federal agencies to file amicus briefs in the Court of Appeals as a matter of right. This reflects the fact that federal agencies offer a distinctive perspective: "governmental bodies,

[7] *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002).

[8] *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 555 (E.D. Pa. 1999) (quoting *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993)); *see also Avellino v. Herron*, 991 F. Supp. 730, 732 (E.D. Pa. 1998).

[9] *Alkaabi*, 223 F. Supp. 2d at 592.

acting as amicus curiae, possess unparalleled institutional expertise and constitute a valuable means of determining how the court's decision may affect the world outside its chambers."[10]

District courts in this Circuit have also applied a four-part standard that incorporates principles similar to Rule 29 as well as other factors.[11] These courts grant leave to participate as *amicus curiae* when: "(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." *See, e.g.*, *Liberty Res.*, 395 F. Supp. 2d at 209.

II. This Court Should Exercise Its Discretion to Accept the FTC's *Amicus* Brief

The FTC respectfully requests that the Court exercise its discretion to accept the attached proposed *amicus* brief because (1) the brief expresses both public and governmental interests of a federal agency charged with protecting consumers from unfair competition; (2) these interests are not currently represented before the Court; (3) the information proffered is useful and timely; and (4) the FTC is not partial to any specific outcome in the case.

First, the FTC is a federal agency representing the public interest with the goal of preserving competition and protecting consumers from violations of the antitrust laws. As outlined in the FTC's *amicus* brief, allegations that brand firms have inappropriately listed patents in the Orange Book to obtain a 30-month stay of competition may have serious long-term implications for *all* consumers, not just the private parties in this matter. Moreover, as an agency charged by Congress with enforcing competition laws, and as the primary antitrust enforcer in

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[10] Michael K. Lowman, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 AM. U. L. REV. 1243, 1261-62 (1992).

[11] *See, e.g.*, *Liberty Res., Inc. v. Philadelphia Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005) (citing *Sciotto*, 70 F. Supp. 2d at 555); Order, *Prof. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 3:11-cv-05479-JAP-LHG (D.N.J. Oct. 3, 2012) (Doc. No. 187).

the pharmaceutical industry, the FTC has a special interest in the interpretation of laws impacting generic drug competition. District courts consider these interests when granting motions for leave to federal agencies to participate as *amicus curiae*.[12]

Second, the FTC's interest, and the interest of consumers in general, may not be adequately represented by the private parties to this litigation because each of the parties is charged with representing its own interests. Unlike the parties, whose interests are focused on the outcome of this particular case, the Commission has broader interests in the proper use of the Orange Book listing process and the potential ramifications for consumers of prescription drugs when this framework is abused. The FTC's unique perspective as a government agency may aid the court in its analysis of the issues in this case.[13]

Third, the brief provides useful information based on the FTC's extensive knowledge of pharmaceutical competition. As described in the *amicus* brief, the FTC has a unique institutional perspective—based on years of study and empirical analysis of pharmaceutical markets—to offer the Court in its analysis of the competitive implications of the allegations raised in this case. The *amicus* brief outlines the relevant regulatory structure and explains how the regulatory issues involved affect competition and consumers. Given that oral argument on the delisting issue has

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[12] *See, e.g.*, *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995) (stating as a basis for accepting an *amicus* brief that "the EPA has a special interest in this litigation as it is the primary body responsible for administering and enforcing" the relevant law).

[13] *See, e.g., Avellino,* 991 F. Supp. at 732 (granting leave for motion to file *amicus* brief because it "will aid the Court in its understanding of the issues before it"). Several district courts in this circuit have accepted FTC *amicus* briefs on matters related to competition in the pharmaceutical industry. *See* Order, *Mylan Pharms., Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. June 24, 2014) (Doc. No. 30); Minute Entry for Proceedings Held Before Judge Noel L. Hillman, *Actelion Pharms. Ltd. v. Apotex Inc.*, No. 1:12-cv-5743-NLH (D.N.J. Oct. 17, 2013) (Doc. No. 92); Order, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-00995-WHW-MCA (D.N.J. Nov. 7, 2012) (Doc. No. 100); *but see* Order, *Prof. Drug Co., Inc. v. Wyeth Inc. (In re Effexor XR Antitrust Litig.)*, No. 3:11-cv-05479-JAP-LHG, (D.N.J. Oct. 3, 2012) (Doc. No. 187) (denying the FTC's motion for leave to file an *amicus* brief).

not yet taken place, we respectfully submit that our proposed brief is still timely and useful. As discussed above, there is no rule governing the timing of *amicus curiae* submission in federal district courts, and the Court has broad discretion to accept a brief whenever it believes one would be helpful. Though the parties' briefing has concluded, the Court and the parties would have an opportunity to address any issues raised by the FTC's brief during the upcoming November 15 hearing.

Fourth, the FTC is primarily interested in the development of the law in this area rather than the outcome in this case. The proposed *amicus* brief explains the FTC's views on the governing regulatory structure and argues that REMS distribution patents as a category do not meet the requirements for Orange Book listing. The brief 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. Thus, while the FTC is partial in the sense of its clearly expressed interest in protecting consumers, it is not partial in the sense of expressing a view on which party should ultimately prevail in the litigation.[14]

CONCLUSION

For the foregoing reasons, the FTC respectfully requests that the Court grant leave to file the attached *amicus curiae* brief.

[14] As Justice Alito observed when he sat on the Third Circuit, "it is not easy to envisage an amicus who is 'disinterested' but still has an 'interest' in the case." *Neonatology Assocs., P.A. v. Comm'r*, 293 F.3d 128, 131 (3d Cir. 2002) (citing Rule 29's requirement that an amicus must state its interest in the case). Then-Judge Alito concluded that requiring an *amicus* to be fully impartial "became outdated long ago."

Dated: November 10, 2022

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