IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 22-941-GBW

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MEMORANDUM OPINION

May 24, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE

Pending before the Court is (1) Plaintiff Jazz Pharmaceutical Inc.'s partial motion to dismiss Defendant Avadel CNS Pharmaceutical, Inc.'s antitrust counterclaims (D.I. 21), (2) Jazz's motion for leave to file a supplemental brief in support of that motion to dismiss (D.I. 48), (3) Jazz's motion to stay pending resolution of Jazz's partial motion to dismiss (D.I. 49), and (4) Jazz's motion to stay pending final resolution of the validity of U.S. Patent No. 11,147,782 (the '782 patent) (D.I. 80). For the reasons set forth below, the Court denies Jazz's partial motion to dismiss, denies Jazz's motion for leave to file a supplemental brief in support of its motion to dismiss (collectively, the "motions to dismiss"), and denies Jazz's motion to stay the action pending resolution of Jazz's partial motion to dismiss. The Court will defer ruling on Jazz's supplemental motion to stay pending final resolution of the validity of the '782 patent until a timely point after the parties' hearing on Jazz's motion for a permanent injunction (*see* C.A. No. 21-691 (the "Related Case"), D.I. 587) against Avadel's future infringement of the '782 patent.

I. BACKGROUND

Jazz has filed two actions against Avadel in this District alleging that Avadel's product, LUMRYZ, infringes U.S. Patent No. 8,731,963 (the "'963 patent"). D.I. 22 at 1. Jazz filed the first of those actions in 2021. After Jazz filed that action, Avadel filed a Paragraph IV certification in connection with its new drug application (NDA) for LUMRYZ certifying that the '963 patent was invalid or that LUMRYZ does not infringe that patent. *Id.* Avadel also moved

to delist the '963 patent from the Orange Book.[1] *Id.* The Court granted that motion after finding that "the claims of the '963 patent are directed to systems, not methods." *Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC*, 2022 WL 17083873, at *8 (D. Del. Nov. 18, 2022). In 2022, Jazz filed the instant action. D.I. 22 at 1. That filing triggered an automatic 30-month stay of the FDA's ability to authorize Avadel's NDA for LUMRYZ because it occurred after Avadel's Paragraph IV certification. *See* D.I. 25.

In response, Avadel filed counterclaims against Jazz in the instant action, alleging that Jazz violated Section 2 of the Sherman Act by improperly listing the '963 patent in the Orange Book, and that Jazz continues to violate Section 2 of the Sherman Act by refusing to delist that patent. *Id.* at 2. Jazz disagrees, and, in its motions to dismiss, argues that Avadel has not sufficiently stated a claim for violation of Section 2 of the Sherman Act because (1) Jazz had a reasonable basis for listing the '963 patent, and (2) Jazz's filing of this action was protected litigation under *Noerr-Pennington*. *Id.* at 2-4.

Jazz also argues, in its motion to stay and its supplemental motion to stay, that Avadel lacks antitrust standing because (1) Jazz's product, XYREM, barred Avadel's entry into the marketplace because of Jazz's product's orphan drug exclusivity (ODE), and (2) the '782 patent barred Avadel's entry into the marketplace because LUMRYZ infringes that patent. *See* D.I. 50; D.I. 80.

In the Related Case, Jazz asserted the '782 patent and U.S. Patent No. 10,758,488 (the '488 patent) against Avadel. Related Case, D.I. 578. Avadel stipulated to infringement of the '782 patent, but did not stipulate to infringement of the '488 patent. The parties proceeded to a

[1] The '963 patent is a REMS-related (risk evaluation and mitigation strategies) patent directed to a system and method for distributing sensitive drugs.

jury trial in that case. The jury found that Avadel did not infringe the '488 patent and that the '488 and '782 patents are not invalid. *Id.* Following the verdict, Jazz moved for a permanent injunction in the Related Case and asks the Court to enjoin Avadel from making, using, or selling LUMRYZ for patients who, at the time of the injunction, have not been prescribed LUMRYZ. As of the entry of this Opinion, that motion is pending and fully briefed. Related Case, D.I. 587.

II. LEGAL STANDARD

A. Motion to Dismiss

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." Fed. R. Civ. P. 8(a)(2). Such a claim must plausibly suggest "facts sufficient to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). "A claim is facially plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). But the Court will "'disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.'" *Princeton Univ.*, 30 F.4th at 342 (quoting *Davis v. Wells Fargo*, 824 F.3d 333, 341 (3d Cir. 2016)). Under Rule 12(b)(6), the Court must accept as true all factual allegations in the Complaint and view those facts in the light most favorable to the plaintiff. *See Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 351 (3d Cir. 2020).

B. Section 2 of the Sherman Act

Liability under Section 2 of the Sherman Act requires "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). Monopoly power is the ability to control prices and exclude competition in a given market. *Id.* at 571, 86 S.Ct. 1698. If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power. *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 380 (3d Cir. 2005).

III. DISCUSSION

A. The Court Finds That Avadel Has Adequately Alleged An Antitrust Injury For Purposes Of Its Claim Under Section 2 Of The Sherman Act.

Jazz argues that Avadel has not stated a claim under Section 2 of the Sherman Act because Avadel has not plausibly alleged that Jazz "lacked any reasonable basis for submitting the '963 patent for listing in the Orange Book." D.I. 22 at 10. Jazz contends that it had a reasonable basis for listing the '963 patent, and its reasonable basis for listing the '963 patent compels dismissal of Avadel's claims under Section 2 of the Sherman Act, because imposing liability in such a case "would create conflicts between antitrust law and the Hatch-Waxman regulatory scheme." D.I. 22 at 13. Avadel disagrees, and contends that (1) Jazz's defense is an affirmative defense that Avadel is not required to address at this stage, and (2) Jazz's defense requires it to show that its listing of the '963 patent in the Orange Book was both "reasonable" and "in good faith." D.I. 25 at 5.

1. Avadel Is Not Required To Plead That Jazz Lacked A Reasonable Basis For Listing The '963 Patent To State A Claim Under Section 2 Of The Sherman Act.

Avadel does not have to allege that Jazz lacked a reasonable basis for listing the '963 patent to state a claim under Section 2 of the Sherman Act. *See, e.g., United Food and Com. Workers Local 1776 & Participating Emps. Health and Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 137–38 (2d Cir. 2021) (plaintiffs are "not required to aver that 'the listing decision was unreasonable' in order to allege a monopolization claim").

Jazz cites *Organon Inc. v. Mylan Pharm., Inc.*, 293 F. Supp. 2d 453 (D.N.J. 2003), for the proposition that Avadel must adequately allege that Jazz listed the '963 patent in bad faith to successfully state a claim under Section 2 of the Sherman Act. The Court is not convinced. In *Organon*, the plaintiff argued that defendant violated Section 2 of the Sherman Act by improperly listing its patent in the Orange Book because the FDA does not permit the listing of "off-label uses." *Id.* at 459. The *Organon* court found that (1) listing a patent in the Orange Book is not *Noerr-Pennington*-protected petitioning activity, and (2) the defendant did not list its patent "improperly," because it had a reasonable basis for doing so. *Id.* at 457-460. This Court, however, cannot clearly discern the reasoning of *Organon* because the court in *Organon* did not explain why a defendant's reasonable basis for listing means that such a listing was "proper."[2]

[2] The basis for the court's decision in *Organon* is somewhat ambiguous. The court in that case found that the defendant in that case "had a reasonable basis for the submission" because "its reading would not have been inconsistent with the broad language" of the relevant statute. *Organon*, 293 F. Supp. 2d 453, 460. This Court is unclear whether the court in *Organon* (1) found that defendant's listing was permitted under the relevant statute, or (2) declined to determine whether defendant's listing was permitted under the relevant statute because it would have been permissible under a "reasonable" (but not necessarily correct) interpretation of that statute. For the purpose of the Court's analysis, the Court assumes that the court in *Organon* declined to determine whether the defendant in that case was statutorily permitted to list its patent in the Orange Book since that is the interpretation of *Organon* that Jazz appears to advance. *Cf. In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 373 (S.D.N.Y. 2019) (interpreting *Organon* in that fashion); *cf. In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 13 (1st Cir. 2020) (holding that a reasonable and in good faith attempt to adhere to regulatory obligations is a legitimate antitrust

See id.; *In re Actos*, 417 F. Supp. 3d at 373. The court in *Organon* found that 21 C.F.R. 314.53(b) was susceptible to two reasonable interpretations, and that defendant would have been permitted to list its patent under one of those interpretations. *Organon*, 293 F. Supp. 2d at 457-460. However, the court in *Organon* did not resolve whether defendant's interpretation was correct. *Id.* Thus, this Court can only guess that the court in *Organon* found that an antitrust claimant who asserts a claim against a defendant for improperly listing its patent in the Orange Book must show that defendant's decision to do so was both (1) not supported by law, and (2) not supported by a reasonable interpretation of the law. *Id.* This Court declines to adopt that rationale, however, because a defendant's decision to list its patent in the Orange Book is not "petitioning activity" entitled to *Noerr-Pennington* immunity.[3] *Id.* at 458. Accordingly, this Court is not persuaded that an antitrust claimant seeking to allege a violation of Section 2 of the Sherman Act must plead the additional threshold allegation that a defendant's decision to list its patent in the Orange Book was unreasonable. *In re Actos*, 417 F. Supp. 3d at 373.

Jazz also cites to *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 964 (S.D. Ohio 2010). Jazz argues that the court in *Kroger* dismissed a plaintiff's claim under Section 2 of the Sherman Act because that plaintiff's claim relied on conclusory allegations of bad-faith patent listing. D.I. 22 at 15. Thus, Jazz argues that adequately pleading the bad faith listing of a patent is necessary for Avadel to state a claim under Section 2 of the Sherman Act. *Id.* However, one of the issues in *Kroger* was whether the defendant had obtained its patent via inequitable conduct at the PTO. *Kroger*, 701 F. Supp 2d at 943. Thus, the plaintiff in *Kroger* argued that defendant

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defense). If, instead, the court in *Organon* found that the defendant in that case was statutorily permitted to list its patent in the Orange Book, *Organon* is distinguishable because this Court has found that Jazz was not permitted to list the '963 patent.

[3] *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 526-527 (D.N.J. 2004), which relied on *Organon*, is similarly unpersuasive.

had violated Section 2 of the Sherman Act by "enforcing the fraudulently procured [] patent by submitting it to the FDA for listing in the FDA's Orange Book and by filing and prosecuting patent infringement actions." *Id.* at 964. However, in the underlying patent infringement action in *Kroger*, the court ruled that defendant's patent was valid and enforceable. *Id.* at 943. Therefore, when the court in *Kroger* explained that defendant's listing of its patent in the Orange Book was not done in bad faith (i.e., because its patent was valid and enforceable), the court did so to explain why the patent litigation filed by the defendant in *Kroger* was not "objectively and subjectively baseless"—thus rendering the defendant immune from liability under *Noerr-Pennington*. *See id.* at 964. Specifically, in *Kroger*, defendant's patent litigation suit was not "sham litigation" because defendant's patent was valid and defendant prevailed on infringement at trial. *Id.* at 943. Thus, this Court is not convinced that *Kroger* stands for the proposition that an antitrust claimant seeking to allege a violation of Section 2 of the Sherman Act must plead the additional threshold allegation that defendant listed its patent in the Orange Book in bad faith.[4]

2. Avadel Adequately Alleged That Jazz Lacked A Reasonable Basis For Listing The '963 Patent In The Orange Book.

Also, the Court would not dismiss Avadel's complaint even if Avadel were required to plead that Jazz lacked a reasonable basis for listing the '963 patent in the Orange Book to state a claim under Section 2 of the Sherman Act. The Court finds that Avadel has plausibly alleged that Jazz lacked a reasonable basis for listing the '963 patent in the Orange Book. Avadel contends that Jazz knew, or should have known, that it was not required to list the '963 patent. D.I. 25 at 9. For example, Avadel contends that Jazz should have known that the '963 patent did

[4] *Astra Aktiebolag v. Kremers Urban Dev. Co.*, 2001 WL 1807917, at *1 (S.D.N.Y. Oct. 26, 2001), which dealt with patent misuse, is inapposite because patent misuse requires a showing of bad faith and improper purpose. *Id.*

not qualify for listing because—as the Court found in its Order directing Jazz to delist the '963 patent (an Order that the Federal Circuit affirmed, *Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC*, 60 F.4th 1373, 1378-1381 (Fed. Cir. 2023))—the '963 patent does not claim the "the active pharmaceutical ingredient in XYREM, the formulation or composition of XYREM, or a method of using XYREM." *Id.* Moreover, Avadel contends that legislation passed by Congress after Jazz's listing of the '963 patent in the Orange Book to prevent companies from using REMS requirements to "block or delay" the entry of new pharmaceuticals shows that Jazz's listing of the '963 patent was done in error and that Jazz continues to commit a violation of Section 2 of the Sherman Act by failing to delist the '963 patent. *Id.*; *see* 21 U.S.C. § 355-1(f)(8).

In response, Jazz contends that it had a reasonable basis for concluding that it was required to list the '963 patent. For example, Jazz argues that the FDA's policy in 2014 (when Jazz listed the '963 patent), was that uses in the REMS document could be included in the Orange Book. D.I. 28 at 2. Counsel for the FDA explained in *Avadel CNS Pharma., LLC v. Becerra, et al.*, C.A. No. 22-12159 (D.D.C.), that the FDA has "been considering this question of whether uses in the REMS document can be used for method-of-use patents, [and] the position of the agency has been that they can be." D.I. 22, Ex. A at 83. Further, Jazz argues that this Court was the first court to find that REMS patents were not listable in the Orange Book. *Id.* at 12. Also, Jazz argues that its REMS for XYREM (i.e. the systems claimed in the '963 patent) are a method of using, or a "condition of use" of, XYREM because the FDA approved that drug on the condition that it would be used according to the specific restrictions on distribution and use described [in the REMS]." *Id.* at 12.

The Court finds that there is a genuine dispute of material fact regarding whether Jazz had a reasonable basis to conclude that it was required to list the '963 patent. The Court and the

Federal Circuit have considered and rejected Jazz's arguments that the '963 patent is listable under 21 C.F.R. § 314.53(b)(1). *Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC*, 60 F.4th 1373, 1378-1381 (Fed. Cir. 2023) ("Jazz misreads the regulation describing method-of-use patents. Section 314.53 does not broaden the term "method" such that reciting a condition of use turns a system patent into a listable method-of-use patent. Rather, [Section 314.53] narrows that category of listable patents to those that (1) claim methods of use, wherein (2) those methods of use are directly relevant to the NDA in question."). The Court is not convinced that Jazz's incorrect interpretation of Section 314.53 was "objectively reasonable." *Id.*; *see also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 10 (1st Cir. 2020) (holding that further proceedings beyond a Rule 12 motion were necessary to determine whether a defendant should be held liable under the Sherman Act for an alleged antitrust injury when the plaintiff adequately plead that the defendant's patent was not eligible for listing in the Orange Book).

B. There Is A Genuine Dispute Of Material Fact Regarding Whether Jazz's Filing Of This Action Was Protected Conduct.

Jazz argues that Avadel has not stated a claim under Section 2 of the Sherman Act because Jazz's filing of this action is *Noerr-Pennington*-protected litigation. D.I. 22 at 19. Accordingly, Jazz argues that the Court should dismiss any damages claims by Avadel arising from the filing of Jazz's infringement action.[5] *Id.* Avadel disagrees, and argues that *Noerr-Pennington* does not apply because (1) the FDA's decision to list the '963 patent was a "ministerial" decision, (2) Jazz engaged in *Walker Process* fraud by fraudulently listing the '963 patent, and (3) Jazz's instant suit is "sham litigation." D.I. 25 at 16.

[5] Jazz does not argue that its listing of the '963 patent in the Orange Book was protected conduct under *Noerr-Pennington*.

The Court agrees with Jazz that its filing of the instant action is protected under *Noerr-Pennington*. A party's decision to list a patent in the Orange Book is distinct from its decision to file a patent infringement suit. *Organon*, 293 F. Supp. 2d at 459. Thus, while listing a patent in the Orange Book is not petitioning activity entitled to immunity under *Noerr-Pennington* because the FDA acts ministerially when it lists a patent, a party's patent litigation suit is protected under *Noerr-Pennington* unless an exception applies. *Id.*

One such exception is the "sham litigation" exception. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993). To overcome *Noerr-Pennington* immunity with that exception, Avadel must show that Jazz's claims in the instant action are "objectively baseless" and subjectively "in bad faith." *Id.* Stated another way, Avadel must show that (1) no reasonable litigant could realistically expect success on the merits in its suit against Avadel, and (2) the instant litigation conceals "an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id.* (cleaned up).

The Court is not convinced that Avadel has adequately alleged that no reasonable litigant could realistically expect success on the merits in the instant action. Avadel argues that Jazz's suit is objectively baseless because (1) the Court construed the claims of the '963 patent as system claims, and (2) the Court construed a single (or "central") computer database in the claims of the '963 patent as "one and only one computer database," while Avadel's REMS has multiple computer databases. D.I. 25 at 18. However, as the Third Circuit explained in *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), the Court considers whether the litigation was a sham "at the time it was filed," *id.* at 148, and "[w]hile it is no doubt important to think about possible constructions for patent claims before filing a case, it

would be unfair to require parties to divine the outcome of claim construction before filing."[6] *Id.* at 151-152 n.22. The Court, under the circumstances of this case, is not convinced that Avadel has plead facts sufficient to show that Jazz knew, or should have known, that the Court's constructions would render its decision to file the instant action objectively basis. *See Upper Gwynedd Equities, LLC v. Provco Pinegood Sumnytown, LLC*, 2022 WL 16927795, at *5 (E.D. Pa. Nov. 14, 2022) (losing a lawsuit "does not by itself render that litigation 'objectively baseless'"); *cf. In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002) (finding objective baselessness when a party "repeatedly argued for a position that requires establishing a number of claims, each one of which has no basis, and each one of which depends upon reframing or mischaracterizing some critical issue or legal standard for its apparent cogency").

Another exception to *Noerr-Pennington* immunity is *Walker Process* fraud. That doctrine allows for a plaintiff to bring an antitrust suit against a defendant when that defendant fraudulently obtains its patent and seeks to maintain a monopoly over a product by bringing patent infringement suits against competitors based on that fraudulently-obtained patent. *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 176–77 (1965). To date, the Supreme Court and the Federal Circuit have not determined whether the *Walker Process* fraud exception applies to a fraudulent listing of a patent in the Orange Book followed by lawsuits seeking to exploit that listing for anticompetitive advantage. At least one district court to consider the issue, however, has applied the *Walker Process* fraud exception when an antitrust claimant plead that a patentee had made "knowingly false statements about [the] scope"

[6] The Court issued its Markman Order construing the claims of the '963 patent after the instant action was filed. *Compare* D.I. 151 in C.A. No. 1:21-cv-01138-GBW (entered November 11, 2022), *with* D.I. 1 (filed July 15, 2022).

of its patent to the FDA when those statements could have "palpable anticompetitive effects." *In re Buspirone*, 185 F. Supp. 2d at 374.

The court in *In re Buspirone* explained that the *Walker Process* fraud exception extends to false statements made before the FDA to obtain a listing in the Orange Book because the Supreme Court, in *Walker Process*, explained that a claim under Section 2 of the Sherman Act that alleges that the defendant asserted a fraudulently-obtained patent for anticompetitive advantage avoids *Noerr–Pennington* immunity because a patent is "an exception to the general rule against monopolies," and the public has a "paramount interest" in seeing that "such monopolies are kept within their legitimate scope." *Id.* at 373 (citing *Walker Process*, 382 U.S. at 177). The *In re Buspirone* court also explained that a patent owner exceeds the legitimate scope of its monopoly when it (1) commits fraud on the FDA—a governmental agency that is required to rely on a new drug applicant's representations in making publication decisions without further analysis—by listing a patent in the Orange Book that the patent owner knows is not eligible for listing, and (2) uses that listing to extend its monopoly by filing a patent infringement lawsuit to obtain a delay in the FDA's approval of a competitor's drug. *Id*; *see* 21 U.S.C. § 355(j)(5)(B)(iii).

The Court finds the rationale of the court in *In re Buspirone Patent Litig.* persuasive concerning whether the *Walker Process* fraud exception applies to alleged fraud before the FDA. The Court finds that Avadel has plead facts sufficient to show that the *Walker Process* fraud exception applies in this case. Specifically, Avadel plead that Jazz committed fraud on the FDA by listing the '963 patent (a patent that it knew did not qualify for listing) in the Orange Book for the purpose of delaying competition by obtaining a stay of up to thirty (30) months of the FDA's approval of LUMRYZ. D.I. 14. Finding that the *Walker Process* fraud exception applies under

the circumstances of this case, the Court declines to consider whether it should adopt the "causal connection" test laid out in *Hynix Semiconductor Inc. v. Rambus, Inc.*, 527 F. Supp. 2d 1084 (N.D. Cal. 2007), in the pharmaceutical context. *See Staley v. Gilead Scis., Inc.*, 2020 WL 5507555, at *19 (N.D. Cal. July 29, 2020) (noting that *Hynix* dealt with an alleged anticompetitive use of market power through litigation instead of an alleged anticompetitive use of the governmental process to obtain market power).

For the reasons stated above, the Court finds that Avadel has adequately alleged an antitrust injury and that Jazz is not entitled to *Noerr-Pennington* immunity because the *Walker Process* fraud exception applies. Thus, the Court denies Jazz's motion to dismiss.

C. There is A Genuine Dispute of Material Fact Regarding Whether XYREM's ODE Would Have Prevented LUMRYZ From Entering The Marketplace.

Avadel alleges that Jazz violated Section 2 of the Sherman Act by listing the '963 patent in the Orange Book because that listing delayed the entry of LUMRYZ into the marketplace. *See* D.I. 14. Specifically, Avadel avers that the FDA would have approved LUMRYZ in October 2021—and Avadel would have begun selling LUMRYZ by April 2022 (the "Alleged Launch Date")—but for Jazz's improper listing of the '963 patent. *Id.* As a result of Jazz's listing of the '963 patent, however, LUMRYZ's launch was delayed until June 2023 because Avadel was unable to obtain regulatory approval from the FDA until May 1, 2023. *Id.*

In response, Jazz argues that Avadel has failed to state a claim for violation of Section 2 of the Sherman Act because Avadel lacks antitrust standing. D.I. 50 at 6. Specifically, Jazz contends that Avadel has not suffered an antitrust harm (a pre-requisite of antitrust standing) because Jazz's product, XYREM, was under a period of orphan drug exclusivity (ODE), *id.* at 1,

and a consult letter that the FDA recently made publicly available shows that LUMRYZ would not have overcome that ODE until May 2023. Jazz had delisted the '963 patent by that date. *Id.*

The FDA granted XYREM ODE for the treatment of cataplexy or excessive daytime sleepiness prior to Avadel's NDA for LUMRYZ. D.I. 48 at 2. Thus, pursuant to the Orphan Drug Act, Jazz argues that the FDA could not approve another application for a different drug that contains the same active ingredient as XYREM and is intended for the same use as XYREM until XYREM's ODE expired. D.I. 49 at 3. However, according to the FDA, two drugs are not the "same drug" if one of those drugs is clinically superior. D.I. 48 at 4. As a result, the FDA will "break" an earlier-developed drug's ODE and approve another applicant's NDA if that applicant can demonstrate that its new drug is clinically superior to the drug that was previously granted ODE. *Id.*

The FDA determined that LUMRYZ was clinically superior to XYREM on May 1, 2023. *Id.* at 2. Avadel contends that, but for Jazz's listing of the '963 patent, the FDA would have determined LUMRYZ's clinical superiority by October 15, 2021. That date was the initial target date that the FDA set to resolve Avadel's NDA (the "Target Date"). D.I. 53 at 3. Avadel argues that the FDA did not meet the Target Date because the FDA would not grant final approval while the '963 patent remained listed. *Id.*

In response, Jazz argues that the FDA would not have granted LUMRYZ final approval by the Target Date—even if the '963 patent had not been listed—because, at that time, the FDA had taken the position that LUMRYZ was not clinically superior to XYREM. In support, Jazz cites a letter issued by the FDA's Review Division (the "Consult Letter") which was issued on August 30, 2021. D.I. 48 at 2. The Consult Letter states that "no evidence has been provided by [Avadel] that Lumryz™ is clinically superior to Xyrem® or Xywav™ as defined in the orphan

drug regulations." *Id.*, Ex. A at 12. Moreover, Jazz argues that the FDA relied on evidence submitted after the Target Date to conclude that LUMRYZ was clinically superior to XYREM because, after the Consult Letter issued, Avadel continued to submit evidence in support of its position that LUMRYZ was clinically superior. D.I. 48 at 4. On May 1, 2023, the FDA ultimately agreed with Avadel's position, broke XYREM's ODE, and granted Avadel's NDA for LUMRYZ. *Id.*

In response, among other arguments, Avadel argues that the hypothetical date by which the FDA would have granted LUMRYZ final approval, and the evidence the FDA would have relied upon in doing so, is a question of fact not suited for resolution at this stage of the proceedings. D.I. 53 at 11. The Court agrees. The Consult Letter merely raises a genuine issue of material fact regarding whether the FDA would have found that LUMRYZ was clinically superior to XYREM prior to Jazz's delisting of the '963 patent in February 2023. Viewing the facts in the light most favorable to Avadel, Avadel has plead facts sufficient to show that the FDA would have granted Avadel's NDA for LUMRYZ prior to Jazz's delisting of the '963 patent. For example, Avadel avers that (1) the FDA concluded that LUMRYZ was clinically superior to XYREM only eight weeks after Jazz delisted the '963 patent, *id.* at 16; (2) the relevant FDA authorities responsible for assessing the clinical superiority of LUMRYZ had no reason to determine whether LUMRYZ was clinically superior to XYREM while the '963 patent remained listed in the Orange Book because the "FDA's general practice is not to make a determination regarding the impact of ODE on the approvability of an application until [the] FDA is otherwise ready to take an approval action on such [a] application," *id.*; and (3) Jazz has previously taken the position that the FDA did not rely on evidence submitted after the Target Date. *See* D.I. 48-2, Ex. I ¶ 201.

The Court finds that those disputed issues are sufficient to establish that there is a genuine dispute of material fact regarding when the FDA would have approved Avadel's NDA for LUMRYZ but for Jazz's listing of the '963 patent. Accordingly, the Court denies Jazz's motion to file a supplemental brief in support of its motion to dismiss because that brief would be futile.[7]

D. The Court Will Defer Ruling On Jazz's Supplemental Motion For A Stay Until After The Hearing In The Related Case On Jazz's Motion For A Permanent Injunction.

For the reasons stated below, the Court will defer ruling on Jazz's supplemental motion for a stay until after the hearing in the Related Case about whether Jazz is entitled to a permanent injunction against Avadel's future infringement of the '782 patent.

In its supplemental motion to stay, Jazz argues that Avadel lacks antitrust standing because Avadel's launch of LUMRYZ was blocked by the '782 patent. D.I. 80. In the Related Case, Avadel stipulated that LUMRYZ infringes the '782 patent, and the jury in that case found the '782 patent was not invalid. Related Case, D.I. 579. Accordingly, Jazz contends that its alleged anticompetitive conduct (delaying Avadel's entry into the market) did not harm Avadel because Avadel's entry into that market "would have been illegal" due to the '782 patent. D.I. 80 at 2. Thus, Jazz contends that Avadel cannot state a claim under Section 2 of the Sherman Act unless it can show that the '782 patent is invalid because, otherwise, that patent breaks the causal chain between Jazz's purported anticompetitive conduct and Avadel's alleged antitrust injury. *Id.*; *see In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017) ("[i]t [was] not enough for the Appellants to show that [the generic manufacturer]

[7] Jazz's motion to stay sought a stay pending resolution of Jazz's motion to dismiss. Accordingly, having denied Jazz's motion to dismiss, the Court denies Jazz's motion to stay as moot.

wanted to launch its drug; they must also show that the launch would have been legal" because "if the launch were stopped because it was illegal, then the Appellants' injury … would be caused not by the settlement but by the patent laws prohibiting the launch"); *Fresenius Kabi USA, LLC v. Par Sterile Products, LLC*, 841 Fed. Appx. 399, 403 (3d Cir. 2021).

Avadel disagrees, and argues that *In re Wellbutrin* and *Fresenius* are distinguishable. In support of that position, Avadel avers that LUMRYZ would have entered the market as of the Alleged Launch Date *regardless* of whether LUMRYZ infringes the '782 patent because (1) the jury in the Related Case found that Jazz was entitled to only $233,562.83, *see* Related Case, D.I. 579, for Avadel's infringement of that patent—a damages award that Avadel characterizes as "de minimis," and (2) Jazz has not obtained an injunction in that case which prevents Avadel from selling LUMRYZ. D.I. 82 at 1.

In response, Jazz contends that *In re Wellbutrin* and *Fresenius* do not contain a "no injunction" or "de minimis damages" exception. Instead, Jazz argues, the Third Circuit's holdings in those cases set forth a bright-line rule: If a party's entry into a market would have been illegal because of a blocking patent, that party cannot state a claim under Section 2 of the Sherman Act based on the theory that another party anticompetitively delayed its entry into that market unless it can show that (1) it does not infringe that patent, or (2) the alleged blocking patent is invalid or unenforceable. D.I. 84 at 2.

The Third Circuit's decision in *Fresenius* provides some support for Jazz's position. In that case, the Third Circuit explained that "[w]e [the Third Circuit] recognized [in *In re Wellbutrin*] that when a product infringes a valid patent, that patent blocks the plaintiff's entry into the market and precludes a claim that the defendant's allegedly anticompetitive conduct caused the plaintiff's injury." 841 Fed. Appx. at 403. Courts in other districts, applying *In re*

Wellbutrin, have explained that "the law will not allow [plaintiffs that infringe a valid patent] to use illegal behavior as a link in their chain of causation"—bolstering Jazz's argument that the Third Circuit's holding in *In re Wellbutrin* should not be limited to only those cases where the blocking patent's owner would likely be entitled to an injunction. *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *13 (N.D. Ga. June 14, 2018); *see also Eagle Pharm., Inc. v. Eli Lilly & Co.*, 2018 WL 6201704, at *2 (D. Del. Nov. 27, 2018) ("[I]f [plaintiff's] product infringes a valid claim of [defendant's] patent, then [plaintiff] may not have an antitrust claim, because [plaintiff's] product was lawfully prohibited from going on the market before [defendant's] patent expires, regardless of the propriety of [defendant's] use code.").

However, the plaintiff's only argument in *In re Wellbutrin* for why it would have been able to enter the market in spite of the alleged blocking patent at-issue in that case was that the patent at-issue in that case was invalid or not infringed. *See In re Wellbutrin*, 868 F.3d at 136. As such, the Third Circuit did not have the opportunity to address whether a plaintiff could show that a valid and infringed patent does not break the causal chain between the plaintiff's delayed market-entry and defendant's allegedly anticompetitive conduct by pleading that (1) no injunction would have issued for plaintiff's infringement of defendant's patent, and (2) the hypothetical damages award would not have prevented plaintiff's entry into the relevant market. *See id.*

The Court finds that a plaintiff advancing a delayed market-entry theory under Section 2 of the Sherman Act may be able to show that a valid and infringed blocking patent does not break the causal chain between the plaintiff's injury and the defendant's allegedly anticompetitive conduct by adequately alleging that its infringement of that patent would not

have been enjoined, and that the hypothetical damages award for its infringement of that patent would not have prevented its entry into the relevant market.

The Court is not convinced that *In re Wellbutrin* sets forth the only means by which a plaintiff advancing a delayed market-entry theory antitrust claim under Section 2 of the Sherman Act can attempt to show that an allegedly blocking patent did not break the causal chain. Instead, in *Fresenius*, the Third Circuit explained that the *Wellbutrin* analysis is triggered when a plaintiff argues that an allegedly blocking patent is invalid, unenforceable, or not infringed. Accordingly, the Court is not convinced that the Third Circuit's holdings in *In re Wellbutrin* and *Fresenius* foreclose Avadel's argument that Jazz's purported blocking patent would not have blocked Avadel's hypothetical launch because (1) an injunction would not have issued had Jazz sought an injunction on or near the Alleged Launch Date, and (2) the hypothetical award for Avadel's infringement would not have excluded Avadel from the market as a practical matter. *Fresenius*, 841 Fed. Appx. 399, 404 (3d Cir. 2021).

Also, patent infringement that does not result in an injunction is different-in-kind from the illegal conduct that broke the causal chain in the cases that the Third Circuit relied upon in holding that the plaintiff in *In re Wellbutrin* suffered its alleged antitrust injury because of federal patent law, rather than the defendant in that case. *See In re Wellbutrin*, 868 F.3d at 165 (discussing *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785 (8th Cir. 2006), *RSA Media, Inc. v. AK Media Group., Inc.*, 260 F.3d 10 (1st Cir. 2001), and *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256 (3d Cir. 1998)). Those cases dealt with categorical restrictions—i.e., federal restrictions on the importation of foreign drugs in *In re Canadian*, a near-total state-law ban on new billboards in *RSA Media*, and a regulatory framework where utility companies were barred from providing retail electric services unless they first obtained permission from an independent

administrative agency in *City of Pittsburgh*—that precluded those plaintiffs' entry into those markets by virtue of the existence of those laws. *In re Canadian*, 470 F.3d at 791; *RSA Media,* 260 F.3d at 15; *City of Pittsburgh*, 147 F.3d at 259-260, 263-264. Similarly, when a court enjoins a party from infringing a valid and infringed patent, federal patent law, rather than the patent owner, blocks the infringer's entry into the relevant market. However, if a court awards damages, instead of an injunction, for a party's infringement of a valid and infringed patent, then it is legal for that party to participate in the relevant market subject to the ongoing royalty that the court awards. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) ("Both the terms of the Patent Act and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that right."). Thus, the Court finds that a plaintiff advancing a delayed market-entry theory under Section 2 of the Sherman Act may be able to show that a valid and infringed blocking patent does not break the causal chain between the plaintiff's injury and the defendant's allegedly anticompetitive conduct by showing that the plaintiff's infringing product would have entered the relevant market notwithstanding the defendant's patent. *Cf. City of Pittsburgh*, 147 F.3d at 266 ("Without demonstrating that there was competition, a plaintiff cannot show that the defendants' actions have had or will have anticompetitive effects."). Such a showing requires adequately alleging that (1) an injunction would not have issued against the plaintiff's infringement, and (2) the plaintiff would have entered the relevant market even if it had to pay a hypothetical damages award for its infringement. *See In re Wellbutrin*, 868 F.3d 132, 166-167 (3d Cir. 2017) (explaining that, at the summary judgment stage, a plaintiff arguing that its launch would have been legal because the defendant would have granted it a license must "produce evidence from

which a reasonable jury could conclude that it is more likely than not that [plaintiff] would have obtained a license").

The Court will defer ruling on Jazz's supplemental motion to stay at this time. The Court will issue a ruling on Jazz's supplemental motion to stay in a timely manner following the parties' hearing on Jazz's motion for a permanent injunction in the Related Case because resolution of that motion is likely to moot, or at least simplify, the issues presented in Jazz's supplemental motion to stay. Whether Jazz is entitled to a permanent injunction enjoining LUMRYZ from infringing the '782 patent involves many of the same issues of law and fact that are relevant to whether Jazz would have been entitled to such an injunction at or near the Alleged Launch Date. The Court is not convinced by Avadel's argument that Jazz conceded Avadel's ability to enter the market as of the Alleged Launch Date by seeking only a limited injunction. *See* D.I. 89. The blocking effect of a patent turns on what that patent would have blocked as of the date that the antitrust claimant contends that it would have entered the market. *See, e.g., In re Wellbutrin*, 868 F.3d at 136. Jazz's injunction is "limited" in that "Jazz does not seek to enjoin Avadel from continuing to make, use, or sell Lumryz for patients who, at the time of the injunction, have already been prescribed Lumryz." Related Case, D.I. 587 at 1. Avadel has not presented any evidence that patients were prescribed LUMRYZ prior to LUMRYZ's entry into the market. Accordingly, based on the record before the Court at this time, it appears that Jazz's limited injunction, if granted, would have blocked LUMRYZ's entry into the market had that injunction been issued on or near the Alleged Launch Date.[8]

[8] The Court notes, however, that even if it ultimately grants Jazz's Motion for a Permanent Injunction and for an Ongoing Royalty in the Related Case, additional briefing and/or oral argument may be necessary regarding whether an injunction would have issued had Jazz sought an injunction as of the Alleged Launch Date. Evidence that Jazz is entitled to an injunction now (if the Court finds that Jazz is so entitled) would be evidence that Jazz would have been entitled to an injunction at the Alleged Launch

IV. CONCLUSION

For the foregoing reasons, this 24th day of May, 2024, **IT IS HEREBY ORDERED** that:

1. Plaintiff's Motion to Dismiss is **DENIED**. D.I. 21.

2. Plaintiff's Motion to File A Supplemental Brief in Support of its Motion to Dismiss is **DENIED**. D.I. 48.

3. Plaintiff's Motion to Stay is **DENIED-AS-MOOT**. D.I. 49.

4. The Court will rule on Plaintiff's Supplemental Motion to Stay at a timely point in the future, following the hearing currently scheduled for June 4, 2024 on Jazz's Motion for a Permanent Injunction and for an Ongoing Royalty (D.I. 587) in C.A. No. 21-691.

Date. However, such evidence would not be dispositive, because the parties may have been situated in materially different positions as of the Alleged Launch Date.