UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ENDO PAR INNOVATION COMPANY, LLC *et al*,

Plaintiffs,

v.

XAVIER BECERRA *et al*,

Defendants,

and

BPI LABS, LLC,

Intervenor-Defendant.

Civil Action No. 24-999 (TJK)

UNDER SEAL

MEMORANDUM OPINION

Plaintiffs (collectively "Par") manufacture and sell Adrenalin®, an epinephrine injection drug product manufactured in both 1 mg/mL and 30 mg/30 mL vials. In April 2023, Intervenor-Defendant BPI Labs, LLC ("BPI") submitted Supplement 13—a new drug product—to the FDA for approval. Like Adrenalin®, Supplement 13 is also a 30 mg/30 mL vial of injectable epinephrine. In Par's view, it was entitled to a statutorily mandated 30-month stay of Food and Drug Administration (FDA) approval for Supplement 13 so that it could pursue patent infringement claims against BPI. And at first, the FDA agreed. But before the expiration of that 30-month stay, the FDA changed its mind and granted final approval to Supplement 13. In response, Par brought this suit against the FDA and related federal officials, alleging that they violated the Administrative Procedure Act (APA) in approving Supplement 13. BPI intervened shortly afterward. Par also moved for preliminary injunctive relief, seeking to stay the FDA's final approval. For the reasons explained below, the Court finds that Par has shown that preliminary injunctive relief is warranted

and so it will grant Par's motion to temporarily stay the FDA's final approval of Supplement 13 for six weeks, while the FDA conducts an administrative review of its decision.

I. Background

A. Legal Background

Under the Food, Drug, and Cosmetic Act, as amended in 1984 through the Hatch-Waxman Amendments, there are three methods of obtaining drug approval from the FDA: (1) a full New Drug Application (NDA); (2) an Abbreviated New Drug Application (ANDA); and (3) an intermediate process known as a 505(b)(2) application.[1] *See Veloxis Pharms., Inc. v. FDA*, 109 F. Supp. 3d 104, 108 (D.D.C. 2015). While the full NDA requires a sponsor to submit detailed safety and efficacy data for the drug, both an ANDA and a 505(b)(2) application allow a sponsor to rely on clinical trials performed in connection with previously approved drugs. The drug for which the borrowed studies were conducted is called the "Reference Listed Drug" (RLD). *Id.* at 109 (citation omitted). The 505(b)(2) application pathway is often used "when the new drug differs only slightly from the [RLD]." *Id.* (citation omitted).

As a protection for RLD drug makers, when a 505(b)(2) applicant relies on studies conducted in connection with an RLD, they must certify in one of four ways that their drug will not infringe on any patent related to that RLD. *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000); 21 U.S.C. § 355(b)(2)(A). The certification relevant here is known as a "Paragraph IV certification," in which the applicant attests that any relevant patent held by the RLD drug maker is "invalid or will not be infringed" by the new drug. *Mylan Pharms., Inc.*, 81 F. Supp. 2d at 32; 21 U.S.C. § 355(b)(2)(A)(iv).

The filing of a Paragraph IV certification "has important legal ramifications." *Mylan*

[1] Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355).

Pharms., Inc., 81 F. Supp. 2d at 32. Once filed, the 505(b)(2) applicant must provide notice to the patent holder and the holder of the originally approved NDA. 21 U.S.C. § 355(b)(3)(C). Upon receiving such notice, those parties have 45 days within which to sue the 505(b)(2) applicant for patent infringement. *Id.* § 355(c)(3)(C). If none of them sue within that time, the FDA can approve the 505(b)(2) application immediately. *Id.* But if a suit is brought, then the approval of the application can only be made effective after 30 months from the date the notice was received or such time as the court may order. *Id.* Thus, the suit effectively stays FDA approval for 30 months.

B. Factual Background

Par manufactures Adrenalin®, the first FDA-approved epinephrine injection product. ECF No. 1 ¶ 4. It is used for the emergency treatment of allergic reactions and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock. *Id.* ¶ 5. Par manufactures this drug in both a 1 mg/mL single dose vial and a 30 mg/30 mL multiple dose vial. The 1 mg/mL vial received FDA approval on December 7, 2012, and the 30 mg/mL vial received the same on December 18, 2013. *Id.* ¶¶ 2, 3. Par also obtained several patents in connection with these drugs. Two of those patents, Nos. 9,119,876 and 9,295,657, were listed for both the 1 mg/mL and the 30 mg/mL vials. *Id.* ¶ 7. The third patent, No. 10,130,592, was listed for the 30 mg/mL only.[2] *Id.* ¶ 8. Currently, Par's 30 mg/mL Adrenalin® vial has only one direct competitor, a generic epinephrine owned by International Medication Systems, Ltd. (IMS). ECF No. 7-1 at 34.

BPI is Par's competitor that also manufactures a 1 mg/1 mL epinephrine injection. That drug was submitted to the FDA for approval via a 505(b)(2) application and was approved on July

[2] The patents were listed on the following dates: The 9,119,876 patent was listed for the 1 mg/mL vial on January 14, 2016, and for the 30 mg/mL on September 1, 2015. The 9,295,657 patent was listed for the 1 mg/mL vial on April 12, 2016, and for the 30 mg/mL on April 12, 2016. The 10,130,592 patent was listed for the 30 mg/mL on November 26, 2018. ECF No. 1 ¶¶ 9, 11, 13.

29, 2014.[3] ECF No. 7-1 at 13. Because BPI sought approval through a 505(b)(2) application, it relied on the previous findings of safety and efficacy from Impax Laboratories' Twinject Auto-Injector epinephrine injection product. *Id.* at 14. Since then, BPI has submitted several supplements to that original 505(b)(2) application—including, most recently, Supplement 13, which was submitted on April 21, 2023. *Id.* Through Supplement 13, BPI sought approval for a new 30 mg/30 mL multi-dose vial version of injectable epinephrine. *Id.*

To support the safety and efficacy of Supplement 13, BPI again relied on Impax's Twinject Auto-Injector, but it *also* relied on Par's 1 mg/mL Adrenalin® product. ECF No. 7-1 at 14. Because BPI relied on safety and efficacy findings from Par's 1 mg/mL Adrenalin®, it certified as to Par's relevant patents with respect to that drug, and, on July 18, 2023, it provided notice to Par of its Paragraph IV certification.[4] *Id.* Within forty-five days of that notice—on August 29, 2023—Par sued BPI for patent infringement. *Id.* at 14–15.

Four months after Par sued for patent infringement, on December 28, 2023, the FDA issued to BPI tentative approval for Supplement 13. ECF No. 7-1 at 15. It explained that "final approval of your application may not be granted at this time" because "[f]inal approval of your application is subject to expiration of the 30-month period provided for in [the statute]." ECF No. 23-1 at 2. From Par's perspective, at least, the process was proceeding as expected. Then, on February 14, 2024, the FDA reversed course and granted final approval to Supplement 13. ECF No. 23-5 at 4. BPI began shipping its new product on March 21, 2024. ECF No. 23 at 5. But its efforts to enter the market were interrupted just a week later when the FDA administratively stayed its February

[3] That original 505(b)(2) application was submitted by Belcher Pharmaceuticals, LLC, which is BPI's predecessor in interest. ECF No. 7-1 at 13.

[4] Although the original notice was sent on July 18, 2023, BPI sent a second notice on August 9, 2023, after Par informed it of deficiencies in the initial notice.

14 final approval because "[q]uestions have been raised regarding FDA's conclusion that there was no 30-month stay blocking approval of Supplement 13." ECF No. 23-3 at 2. That stay lasted only a week. On April 5, the FDA released a Memorandum explaining that Par was not entitled to a 30-month stay, that the original tentative approval was issued in error, and that the February 14 final approval "accurately reflects the status of [Supplement 13] as approved." ECF No. 23-5 at 5.

C. Procedural History

Three days after the FDA released its April 5 Memorandum, Par filed this case, in which it alleges that the FDA's final approval of Supplement 13 was unlawful under the APA. Par also filed an emergency motion for a temporary restraining order (TRO) to stay the FDA's final approval under Section 705 of the Administrative Procedure Act and Federal Rule of Civil Procedure 65. ECF No. 7 at 1. The Court held a status conference with the parties on April 10. During that conference, the FDA represented that to consider certain issues raised in Par's TRO, it planned to re-impose its administrative stay of Supplement 13's final approval. But after BPI Labs intervened and brought a separate suit to challenge that anticipated action, the FDA, once again, changed its tune.[5]

On April 12, rather than enter an administrative stay, at an emergency status conference the FDA and Par effectively jointly proposed that the Court enter a preliminary injunction ordering the FDA to stay Supplement 13's approval for about two months, while the FDA conducted an administrative process to review the issues raised by Par. *See* ECF No. 19 at 2 ("Plaintiffs' motion raises unique issues that FDA believes warrant a brief stay of approval.") BPI opposed that request.

[5] *See BPI Labs, LLC v. FDA et al.*, No. 24-cv-966, ECF No. 9 (April 11, 2024).

Over the following weekend, the parties proposed—and then the Court ordered—a highly expedited briefing schedule related to the request for a preliminary injunction. And as part of that scheduling order, BPI agreed not to solicit, fulfill, or ship Supplement 13 until after April 19, and it consented to the Court ordering it not to do so. *See* ECF No. 26. After reviewing the parties' submissions on April 19, to maintain the status quo for several more days for the parties to complete their briefing, and in particular, to give BPI an opportunity to respond to the merits of Par's original request for a TRO, the Court entered a brief administrative stay temporarily enjoining BPI from soliciting, fulfilling, or shipping Supplement 13 until after April 25. *See* ECF No. 26. The Court also scheduled a hearing for that same day. *Id.*

Meanwhile, the FDA started the administrative process discussed at the April 12 status conference. ECF No. 24-1 at 12. It solicited additional input from both Par and BPI on April 17 and planned to receive their responses by May 9. *Id.* ECF No. 19 at 2. The FDA expects to issue a new decision on the final approval of Supplement 13 within 30 days of receiving those responses, or by June 10. ECF No. 19 at 2.

II. Legal Standard

Parties seeking preliminary relief, whether through a temporary restraining order, preliminary injunction, or preliminary relief under the APA, are governed by the same standard. *See Gomez v. Trump*, 485 F. Supp. 3d 145, 168 (D.D.C. 2020). A movant must show (1) likely success on the merits; (2) likely irreparable harm in the absence of preliminary relief; (3) that the balance of the equities tips in its favor; and that (4) the injunction is in the public interest. *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016). This Circuit's precedent suggests that these factors may be evaluated on a "sliding scale," and that "an unusually strong showing on one of the factors" may compensate for a subpar showing on another. *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291–92 (D.C. Cir. 2009) (citation omitted). But after *Winter v.*

NRDC, 555 U.S. 7 (2008), the Circuit has suggested that a plaintiff must independently establish both likelihood of success on the merits and irreparable harm. *See, e.g.*, *Sherley v. Sebelius*, 644 F.3d 388, 392–93 (D.C. Cir. 2011). At this preliminary stage, a plaintiff may rely on "evidence that is less complete than in a trial" but "bears the responsibility of producing credible evidence sufficient to demonstrate entitlement to injunctive relief." *CAPPS v. DeVos*, 344 F. Supp. 3d 158, 166–67 (D.D.C. 2018) (cleaned up).

III. Analysis

Although Par originally moved for a TRO, it and the FDA have since requested that the Court consider its request as a motion for a limited preliminary injunction staying the approval of Supplement 13 until the FDA's administrative review of the issues surrounding its approval is complete. *See* ECF Nos. 19, 20. The FDA estimates that to be 30 days after May 9, or about June 10. *Id*. The Court will do so. *Cf. Nat'l Mediation Bd. v. Air Line Pilots Ass'n, Int'l*, 323 F.2d 305, 306 (D.C. Cir. 1963) ("An order extending a temporary restraining order beyond the . . . days allowed by Civil Rule 65(b) is tantamount to the grant of a preliminary injunction."). Thus, BPI is the only party that opposes that request. As explained in more detail below, the Court finds that (1) Par is likely to succeed on the merits, at least as to its claim that the FDA's final approval of Supplement 13 was arbitrary and capricious; (2) Par is likely to suffer irreparable harm because of the permanent price erosion of its Adrenalin® product and the potential loss of customer goodwill; (3) the public interest favors preliminary relief, especially because the FDA requests such relief; and (4) the balance of the equities favors Par, rather than BPI. For these reasons, the Court will grant the request for a limited preliminary injunction and stay the FDA's final approval of

Supplement 13 until June 10.[6]

A. Likelihood of Success on the Merits

Par argues that the FDA's final approval of Supplement 13 was unlawful under the APA for three reasons: (1) it was arbitrary and capricious; (2) it impermissibly permitted BPI to treat its new drug product as a "supplement" rather than a completely different drug; and (3) it failed to require BPI to certify to the correct patents. Because the Court finds that Par is likely to succeed on the merits of its first argument, it need not reach the remaining ones.[7]

According to Par, the FDA's final approval of Supplement 13 was arbitrary and capricious for two reasons. First, it provided no explanation when it changed its position and gave final approval to Supplement 13 on February 14. Second, the explanation it eventually did provide in its April 5 Memorandum inadequately justified the agency's change of position. As explained below, the Court agrees with Par on both counts.

The FDA takes no position on whether it provided an explanation when it changed its

[6] Both Par and the FDA suggest that under these circumstances, when the plaintiff and the government agency-defendant consent to preliminary injunctive relief, the Court may grant that relief without considering the traditional four factors outlined above. But they identify no case that stands for that proposition when an interested party like BPI has intervened and objected. That they have come up empty makes sense. "Intervenors under Rule 24(a)(2) assume the status of full participants in a lawsuit and are normally treated as if they were original parties once intervention is granted." *District of Columbia v. Merit Sys. Prot. Bd.*, 762 F.2d 129, 132 (D.C. Cir. 1985). Thus, despite the FDA's effective request for preliminary injunctive relief along with Par, the Court must consider the four factors, and the arguments advanced by BPI, in evaluating whether such relief is appropriate.

[7] BPI suggests that because the FDA has started an administrative review process of its decision to give final approval to Supplement 13, Par's claims are not prudentially ripe, and the Court should deny its motion on that basis. But under the APA, a party who is "adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702. BPI does not contest that the FDA's final approval of Supplement 13 was final agency action. And Par alleges that it is likely to suffer irreparable harm from that action without preliminary relief. Under these circumstances, the Court sees no basis to deny the motion on ripeness grounds.

position and gave final approval to Supplement 13. And BPI offers no response at all to Par's argument that the FDA's decision lacked an explanation. That lack of opposition alone permits the Court to treat this argument as conceded. *See Campaign Legal Ctr. v. FEC*, 520 F. Supp. 3d 38, 50 (D.D.C. 2021) ("It is well-settled that where a party fails to respond to arguments in opposition papers, the Court may treat those specific arguments as conceded." (internal quotations omitted)). That is especially so here, where Par need only "demonstrate a likelihood of success on the merits . . . not establish 'an absolute certainty of success.'" *Pan Am Flight 73 Liaison Grp. v. Dave*, 711 F. Supp. 2d 13, 37 (D.D.C. 2010) (quoting *Population Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986)). But even putting aside whether the argument is conceded, it is obvious that the FDA offered no such explanation. While arbitrary and capricious review is "narrow," at the very minimum it requires agencies to engage in "reasoned decisionmaking." *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (citation omitted); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must "articulate a satisfactory explanation for its action."). Here, when the FDA changed its position and approved Supplement 13, not only did it fail to provide a satisfactory explanation, it provided no explanation at all. *See* ECF No. 23-2 at 2.

Of course, the FDA eventually tried to justify its change in position through the April 5 Memorandum. But "[i]t is a foundational principle of administrative law that judicial review of agency action is limited to the grounds that the agency invoked when it took the action." *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (cleaned up). A post-hoc justification in a memorandum issued six weeks later does not suffice. And while there are some circumstances under which an agency's later explanation may be considered, none of them obtain here. First, this is not any situation in which the later explanation is merely an "elaboration" of an "initial explanation." *End Citizens United Pac v. FEC*, 69 F.4th 916, 922 (D.C. Cir. 2023) (quoting

Regents, 140 S. Ct. at 1908). In this case, the FDA offered no initial explanation at all, and an agency "may not . . . offer post-hoc rationalizations where no rationalization exists." *Id.* (quoting *AT&T Info. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233, 1236 (D.C. Cir. 1987)). Nor did the April 5 Memorandum represent new agency action through which the agency chose to "deal with the problem afresh." *Regents*, 140 S. Ct. at 1908 (citation omitted). The Memorandum makes clear that it was intended to explain the February 14 approval. *See* ECF No. 23-5 at 4. Indeed, the FDA concluded by explaining that "[t]he letters issued on February 14, 2024, and February 16, 2024, accurately reflect the status of [Supplement 13] as approved." *Id.* at 5. Thus, the Memorandum was not new agency action but a post-hoc explanation for a previously made decision. But as explained above, an "agency must defend its actions based on the reasons it gave when it acted." *Regents*, 140 S. Ct. at 1909. Here, the FDA gave *no* reasons for its action when it changed its position and approved Supplement 13 on February 14. For that reason alone, Par has shown a likelihood of success on its claim that the FDA's final approval of Supplement 13 was arbitrary and capricious.[8]

Finally, even if the Court considered the belated explanation that the FDA ultimately offered for its changed policy in the April 5 Memorandum, Par would have still shown a likelihood of success on this claim. That is so because in the Memorandum, the FDA did not consider alternatives under its old policy or address any reliance interests on that policy.

Some background: under the statute, a party can only obtain a 30-month stay if its relevant

[8] The Court recognizes that requiring an agency to go through the motions of issuing a new decision may seem pointless. But the Supreme Court has been clear that "[p]rocedural requirements can often seem such." *Regents*, 140 S. Ct. at 1909. Nevertheless, "the rule serves important values of administrative law." *Id.* This case highlights why that is so. Given the FDA's shifting positions, it is entirely uncertain to the Court how it will come down as its administrative process unfolds over the next six weeks.

patent was filed "before the date on which the application (excluding an amendment or supplement to the application) was submitted." 21 U.S.C. § 355(c)(3)(C). In other words, a party cannot seek to stay approval of a drug on this basis if the application for that drug was submitted to the FDA *before* the relevant patent was filed. And with a supplement, the relevant "application date" is the date the original application (not the supplement) was submitted. Despite that statutory text, before the April 5 Memorandum, the FDA had interpreted the statute—at least for certain strength supplements that reference a new listed drug not referenced in the original application—to allow for 30-month stays measured from the time the supplement, not the original application, was submitted. ECF No. 23-5 at 5 n.5. Such was the case here. Supplement 13 was a new strength supplement that referenced a new listed drug (Par's 1 mg/mL Adrenalin®) not referenced in the original 505(b)(2) application. And although the original 505(b)(2) application associated with Supplement 13 was submitted before Par listed its relevant patents, Supplement 13 itself was submitted after those listings. Thus, under the FDA policy that had been in place, Par was entitled to a 30-month stay of Supplement 13's approval because it was submitted after Par had listed the relevant patents.

But as the FDA explained in the April 5 Memorandum, the FDA decided to change that policy because it had "reevaluated" the relevant statutory text. ECF No. 23-5 at 5 n.5. Under the new policy, all supplements, including strength supplements that reference a new listed drug—like Supplement 13—related back to the date the original application was filed. Under this policy, because the original 505(b)(2) application associated with Supplement 13 was submitted before Par's patents, Par would not be entitled to a 30-month stay of Supplement 13's approval.

To be sure, an agency may change or rescind its policy so long as it shows "that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc*. 556 U.S. 502, 515 (2009). And here, the FDA did explain that this new policy would "bring it into conformity with the

statutory text." ECF No. 23-5 at 5 n.5. But a change of policy must also "consider the alternatives that are within the ambit of the existing policy" and must "address whether there was legitimate reliance on the" old policy. *Regents*, 140 S. Ct. at 1913 (cleaned up). "It would be arbitrary and capricious to ignore such matters." *Id.* (citation omitted) While the April 5 Memorandum provides a reason for the change, it does not discuss any reliance interests or consider any regulatory alternatives that would conform to the statutory text while also protecting the interests of drug patent holders.

Once again, the FDA takes no position on whether the reasoning in its April 5 Memorandum survives arbitrary and capricious review, even putting aside that it was issued weeks after the FDA changed its policy without explanation. And again, its silence is deafening. Nor does BPI directly contest that the FDA failed to provide an adequate analysis for its change of policy; instead, BPI argues only that there was no change in policy in the first place. But BPI's position makes little sense. According to BPI, while the FDA did have a policy of recognizing 30-month stays for certain strength supplements, that policy only applied to supplements for ANDAs, not 505(b)(2) applications. And because Supplement 13 was supplementing a 505(b)(2) application, the April 5 Memorandum did not represent a change of policy. But it strains credulity to suggest that the FDA's previous policy of recognizing 30-month stays for certain strength supplements did not apply to 505(b)(2) applications when the very reason it issued the April 5 Memorandum at all was to explain why the FDA had reversed its previous decision to recognize a 30-month stay with respect to Supplement 13 by granting it only tentative approval.

At the hearing on the motion, BPI's counsel suggested that the original grant of tentative approval to Supplement 13 did not reflect a previous policy but was due to a factual error on the FDA's part. But nothing in the April 5 Memorandum refers to a factual error. To the contrary, the Memorandum makes clear why the FDA believed the tentative approval was issued in error—

because "the statute explicitly excludes the date of submission of an amendment or supplement." ECF No. 23-5 at 5. In other words, the FDA acknowledged that it was changing its interpretation of the statute for supplements like Supplement 13. Moreover, while it is true that the FDA referred to its prior policy in terms of ANDAs, rather than 505(b)(2) applications, it also made clear that it treats these two types of applications the same because the language in both "largely mirrors" each other. *Id.* at 5 n.5.

In summary, the belated explanation offered by the FDA for granting final approval to Supplement 13 relied on a change of FDA policy related to strength supplements. And because no party disputes that the FDA failed to adequately consider alternatives or reliance interests impacted by this change of position, that too is a reason to find the final approval arbitrary and capricious.

For all these reasons, the Court finds that Par has shown a likelihood of success on the merits of its claim that the FDA's final approval of Supplement 13 was arbitrary and capricious.

B. Irreparable Harm

Next, Par must show that it is likely to suffer irreparable harm in the absence of preliminary relief. The injury "must be both certain and great, actual and not theoretical, beyond remediation, and of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 555 (D.C. Cir. 2015) (cleaned up). The Court agrees that Par has shown that it will likely suffer irreparable harm because the loss of its statutory right to the 30-month stay, and Supplement 13's presence in the market for even this six-week period, will lead to permanent price erosion for Par's Adrenalin® product and the potential loss of customer goodwill if Par attempts to maintain or restore its current pricing.

The first hurdle is that the harm at issue must be not reparable—in other words, that it must be beyond remediation. Par clears that hurdle. "'[T]he general rule' in this Circuit is 'that

economic harm does not constitute irreparable injury.'" *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 211 (D.D.C. 2012) (quoting *Davis*, 571 F.3d at 1295). That is so because typically, economic harm can be remediated in the form of damages. But this Court has also recognized "that a clear statutory entitlement is not 'merely economic' harm, and its loss may be sufficiently irreparable to justify emergency injunctive relief because '[o]nce the statutory entitlement has been lost, it cannot be recaptured.'" *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) (quoting *Apotex, Inc. v. FDA*, 2006 WL 1030151, at *17 (D.D.C. Apr.19, 2006), *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006)). That is the case here. Par argues that the harm it will suffer without preliminary relief flows from the loss of its statutory entitlement to the 30-month stay that it asserts should be in place now, and at least—for purposes of this motion—for the next six weeks. And of course, that stay would still be in place, but for a decision the Court has found is likely to have been arbitrary and capricious. Such harm is unrecoverable because it cannot be recaptured later.

Par also argues that it faces irreparable injury from the downstream effects of the loss of this statutory entitlement in the form of lost market share, goodwill, and price erosion—all of which are "typically considered to be economic harms." *Air Transp. Ass'n of Am., Inc. v. Exp.-Imp. Bank of the U.S.*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012). As noted above, economic harm is typically not irreparable injury. But such harm can be irreparable if it is unrecoverable from any other party.[9] Although the "fact that economic losses may be unrecoverable does not, in and of itself, compel a finding of irreparable harm," it can constitute irreparable injury if the "harm [is]

[9] Economic loss can also be irreparable if it "threatens the very existence of the movant's business." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (citation omitted). But Par does not claim that to be the case here. Par alleges that as a result of Supplement 13's entry into the market, it may have to cease marketing less profitable drugs, close some research and development activities, and will be slower to bring new drugs to market, *see* ECF 8-1 ¶¶ 30–32, but none of those harms rise to level of threatening the existence of Par's business.

also . . . great, certain and imminent." *Cardinal Health*, 846 F. Supp. 2d at 211 (quoting *Nat'l Mining Ass'n v. Jackson* 768 F. Supp. 2d 34, 53 (D.D.C. 2011)); *see also Air Transp. Ass'n*, 840 F. Supp. 2d at 335 ("The wiser formula requires that the economic harm be significant, even where it is irretrievable . . . ."). Putting the other requirements aside for the moment, Par's economic harm is unrecoverable. It cannot recover damages against the FDA for its claims in this suit on account of the FDA's sovereign immunity. *See Figg Bridge Eng'rs, Inc. v. Fed. Highway Admin.*, No. 20-cv-2188 (CKK), 2020 WL 4784722, at *8 (D.D.C. Aug. 17, 2020). And it is not clear to the Court how Par could recover from BPI, whether through the pending patent infringement suit (as BPI claims) or otherwise. Par's entitlement to a 30-month stay is independent of whether its patent claims against BPI turn out to succeed. Indeed, the point of the 30-month stay is to "allow[] the patent holder to assert its patent rights before the generic competitor is permitted to enter the market." *Mylan Pharms., Inc.*, 856 F. Supp. 2d at 201 (citation omitted).

Par meets the other requirements for showing that its economic harm is irreparable harm as well, because—at least with respect to its claim of price erosion and related potential loss of goodwill—it has shown that the harm it will suffer is "great, certain, and imminent."[10]

[10] Par also claims that its loss of market share constitutes irreparable harm. On the record here, the Court is doubtful. Par's product has [redacted] of the relevant market while IMS has [redacted]. ECF No. 8-1 ¶ 21. Par estimates that if BPI enters the market, it will take [redacted] of market share from Par. *Id*. ¶ 23. But Par provides no concrete support for this assertion. *See Benoit v. District of Columbia*, No. 18-cv-1104 (RC), 2018 WL 5281908, *6 (D.D.C. Oct. 24, 2018) ("In all circumstances, the irreparable harm alleged must be 'concrete and corroborated, not merely speculative.'" (citation omitted)). In fact, the example Par provides suggests the opposite. When IMS introduced the first generic competition to Par, it took [redacted] of market share in the first month and [redacted] in two months. ECF No. 21-1 ¶ 5. Even by six months, it had [redacted] market share. ECF No. 24-4 ¶ 7. And here, there is reason to believe BPI's market penetration will be even slower given that (1) it is not the first competing drug on the market and (2) it is not considered a "generic drug" of Par's Adrenalin® but only "pharmaceutically equivalent." ECF No. 24-4 ¶ 9. It is therefore far from "certain" that in just six weeks, Par will lose a "great" amount of its market share to BPI, as it alleges. Nor is there any reason why any market share Par does lose would not be recoverable if the FDA withdraws its approval of Supplement 13 at the end of its administrative process in six

The harm Par will likely suffer is great. As a general matter, courts have recognized that irreversible price erosion can constitute irreparable harm. *See Bayer HealthCare, LLC v. FDA*, 942 F. Supp. 2d 17, 26 (D.D.C. 2013) (collecting cases). Par contends that it will have to reduce its prices [redacted] to retain its business because of Supplement 13's entry into the market. ECF No. 8-1 ¶ 24. Par's calculation appears to be mostly based on a comparison between the Wholesale Acquisition Cost (WAC) of Par's drug [redacted] compared to BPI's [redacted]. ECF No. 21-1 ¶ 10. BPI does not dispute these figures but argues that WAC is an inadequate measure of price, and that Net Sale Price (NSP) is more accurate.[11] But even using that measure, BPI's prices are still [redacted]. ECF No. 24-1 at 19. Par's expected gross margins for its 30 mL vial over the next four years are [redacted]. ECF No. 8-1 ¶ 19. Thus, even using BPI's more conservative estimate, Par could lose up to [redacted] due to price erosion over the next several years. And using Par's favored measure, WAC, it could lose up to [redacted].[12] And that is only over the next several years. Those sums would continue to rise afterward because—as explained below—price erosion is typically irreversible.

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weeks. Thus, the Court does not find that Par's loss of market share is sufficiently "great, certain and imminent" as to be irreparable.

[11] BPI's argument is persuasive on this point, given that when IMS entered the market, Adrenalin's® [redacted]. *See* ECF No. 24-5.

[12] The Court has no reason to believe this substantial sum is not "great" when viewed in the context of Par's business. Adrenalin® is the highest grossing product for the corporate component that manages it, Par Sterile, and it is the third highest grossing product for Endo International plc, Par Sterile's ultimate parent. ECF No. 8-1 ¶ 15. *Cf. Mylan Pharms., Inc.*, 81 F. Supp. 2d at 43 (holding that a loss of only $3 million was "[s]uch a minor loss [that it] does not constitute irreparable harm" because the plaintiff was the nation's largest generic drug manufacturer). Indeed, as noted above, Par alleges that as a result of Supplement 13's entry into the market, it may have to [redacted]. *See* ECF 8-1 ¶¶ 30–32.

The harm suffered by Par is also great because, even if Supplement 13 is removed from the market after the six-week period, the harm caused by the price erosion will likely remain. This is because "[o]nce a less expensive version of a drug enters the market, the original drug manufacturer cannot maintain its initial price and stands to lose good will among its customers when a less expensive drug with the same efficacy becomes available." *Bayer HealthCare, LLC*, 942 F. Supp. 2d at 26. That is precisely what Par alleges here. As it explains, its customers [redacted]. ECF No. 21-1 ¶ 11; *see also Fox Television Stations, Inc. v. FilmOn X LLC*, 966 F. Supp. 2d 30, 50 (D.D.C. 2013) (explaining that "damage to [a plaintiff's] contractual relationships and ability to negotiate" constitutes irreparable harm). BPI does not offer any persuasive argument countering Par's sworn assertions that the effects of even just six-weeks of price erosion will be permanent.

In addition, the harm Par will suffer is both certain and imminent. As noted, BPI does not contest that its NSP price is lower than Par's, which would drive down prices on its own. Moreover, as Par explains, [redacted]. ECF No. 8-1 ¶ 16. That means that Supplement 13's entry into the market will inevitably cause Par to lower its prices. And even if Par tried to maintain or restore its price if the FDA withdrew Supplement 13's approval, Par explains, consistent with common sense, that this would risk goodwill with their customers. ECF Nos. 8-1 ¶ 27, 21-1 ¶ 11. The data surrounding IMS's entry into the market further confirms the notion that price erosion under these circumstances is certain—and strongly supports that it is imminent as well. As shown by BPI's own data, in the first month after IMS entered the market, Adrenalin's® NSP

dropped [redacted], and by the second month, it had dropped [redacted]. ECF No. 24-5 at 2–4. Thus, the record reflects that price erosion occurs within the first few weeks of a similar competing product's entry into the market.

In response, BPI suggests that a significant price decline happens only when the first generic drug hits the market. But the case BPI cites for that proposition then states that "[t]he branded drug's sales volume and price usually continue to decline as additional generic products enter the market. The full decline in the price of the drug usually occurs after three or four generic drugs have entered the market." *FTC v. Shkreli*, 581 F. Supp. 3d 579, 596–97 (S.D.N.Y. 2022). BPI also suggests that Supplement 13 has already entered the market and yet there has been no price erosion. [redacted]

For all these reasons, the Court finds that Par has shown that within six weeks, Supplement 13's entry into the market will likely cause permanent price erosion for Adrenalin® and the potential loss of goodwill that establishes irreparable harm.

C. The Public Interest and the Balance of the Equities

As far as the public interest goes, the FDA, which "is charged with the primary responsibility of safeguarding the lives and health of consumers of food and drugs," *Glass Packaging Inst. v. Regan*, 737 F.2d 1083, 1084 (D.C. Cir. 1984), effectively requests the injunctive relief here. *See* ECF No. 19 at 2 (The FDA's position is that "a brief stay of approval" is appropriate). And as the Circuit has explained, when considering the public interest in the context of preliminary injunctive relief, "the government's interest *is* the public interest." *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016). That all but resolves any question about where the public interest lies. In addition, that the Court has found Par likely to succeed on the merits also suggests that a

stay is in the public interest because "[t]he public interest is served when administrative agencies comply with their obligations under the APA." *Damus v. Nielsen*, 313 F. Supp. 3d 317 (D.D.C. 2018) (citation omitted); *see also Bayer HealthCare, LLC*, 942 F. Supp. 2d at 27 ("The public has an interest in federal agency compliance with its governing statute.").

BPI argues that the requested relief would not be in the public interest because the FDA has already approved Supplement 13, it would disrupt the FDA's approval process, and would harm prospective patients. ECF No. 23 at 21–22; ECF No. 28 at 28. But given the above, its arguments get it nowhere fast on this front.

The balance of the equities also favors the requested preliminary injunctive relief. Without such relief, as explained above, Par is facing a permanent erosion to its product's price—and related effects on goodwill with its customers if it tries to maintain or restore that price—and therefore its profits. For its part, BPI argues that the effect of a stay would be "dramatically greater" to it than to Par. ECF No. 28 at 4. It explains that it has already manufactured significant quantities of its product and contacted the industry to promote its sales, and a stay would risk its own goodwill and reputation in the industry. ECF No. 24-1 at 24. But most of its argument is contradicted by its representations elsewhere that its sales [redacted] *Id.* at 20 (emphasis added). In terms of sales, BPI stands to lose six weeks at most. And while Par has provided actual estimates on the damages it expects to suffer if no relief is granted, BPI has provided no similar estimate with which the Court might compare its expected losses.

More broadly, the purpose of a preliminary injunction is to "preserve the object of the controversy in its then existing condition—to preserve the status quo." *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) (citation omitted). And while BPI suggests that the status quo favors its position because Supplement 13 is currently approved, the status quo is defined as "the last

uncontested status which preceded the pending controversy." *Beacon Assocs., Inc. v. Apprio, Inc.*, 308 F. Supp. 3d 277, 291 (D.D.C. 2018) (quoting *Dist. 50, United Mine Workers of Am. v. Int'l Union, United Mine Workers of Am.*, 412 F.2d 165, 168 (D.C. Cir. 1969)). The pending controversy here began with the FDA's February 14 final approval. As a result, the status quo for the purposes of a preliminary injunction is the status that preceded that—*i.e.*, before the final approval of Supplement 13.

* * *

Because the Court finds that Par has shown that it is likely to succeed on the merits, is likely to suffer irreparable harm, and that both the public interest and balance of the equities tilt in its favor, the Court finds that Par has shown that it is entitled to preliminary injunctive relief.

IV. Conclusion

For all these reasons, the Court will grant Par's request for a preliminary injunction staying the FDA's approval of Supplement 13 until June 10, 2024. Because this Memorandum Opinion cites portions of the record filed under seal, the Court will file the Memorandum Opinion provisionally under seal and allow the parties to propose redactions to it. A separate order will issue.

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: May 1, 2024