UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

and

MSN PHARMACEUTICALS INC., *et al.*,

Intervenor-Defendants.

No. 24-cv-02234 (DLF)

MEMORANDUM OPINION

Plaintiff Novartis Pharmaceuticals Corporation brings this action against the Secretary of Health and Human Services ("HHS") and the Commissioner of the Food and Drug Administration ("FDA") for injunctive relief. Novartis alleges that FDA unlawfully approved an application by MSN Pharmaceuticals Inc. and MSN Laboratories Private Ltd. ("MSN") to market a generic version of Novartis's heart failure medication ENTRESTO (generic combination sacubitril/valsartan). MSN intervened as defendant. Before the Court is the plaintiff's motion for a temporary restraining order and/or preliminary injunction to stay FDA's approval of MSN's drug application. Dkt. 3. For the reasons that follow, the Court will deny Novartis's motion for a preliminary injunction.

I. BACKGROUND

A. Statutory Background

To obtain FDA approval to market a new, brand-name drug, a manufacturer must submit a New Drug Application (NDA) containing clinical data from studies demonstrating that the drug is safe and effective. *See* 21 U.S.C. § 355(b)(1). The brand-name manufacturer often holds patents for the drug product, as well as patents for methods-of-use of the drug. FDA maintains a publication, colloquially referred to as the "Orange Book," which lists active pharmaceutical patents including method-of-use patents.

After the period of patent exclusivity expires for a drug product, other manufacturers may obtain FDA approval to market a generic version through an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. § 355(j). ANDAs need not include independent clinical data of safety or effectiveness; the applicant need only establish the generic drug is "the same as" a previously approved brand-name reference drug. *See id.* § 355(j)(2). To demonstrate "same"-ness, the applicant must prove the generic is (1) the pharmaceutical equivalent of, (2) labeled for the same conditions of use as, and (3) bioequivalent to the reference drug. *See id.* § 355(j)(2)(A). ANDA applicants that seek approval for generic drugs with use-cases listed in the Orange Book must file either a "paragraph IV certification" challenging the validity of listed patents, *id.* § 355(j)(2)(A)(vii)(IV), or a "section viii statement" certifying the applicant does not seek to market the drug for use-cases covered by patent, *id.* § 355(j)(2)(A)(viii). Section viii ANDA applicants may "carve out" patented use-cases from the generic's label, subject to statutory and regulatory constraints.

FDA regulations supplement the statutory scheme by, as relevant here, clarifying the "same labeling" requirement. *Id.* § 355(j)(2)(A). FDA regulations provide that a generic label may differ

from a reference label when a drug is produced by a "different manufacturer[]," in order to address differences in marketing exclusivity or patent rights:

> Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act.

21 C.F.R. § 314.94(a)(8)(iv). However, the labeling differences may "not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use." *Id.* § 314.127(a)(7).

B. Factual Background

In 2015, FDA approved the heart failure drug ENTRESTO. *See* Pl.'s Ex. A (ENTRESTO Labeling) § 1.1, Dkt. 1-1. Since that time, Novartis has marketed ENTRESTO without generic competition and has generated over $10.5 billion in revenue in the United States. Compl. ¶ 79, Dkt. 1. Novartis still owns several ENTRESTO-related method-of-use patents that hinder generic entry in two ways. First, Novartis patents No. 9,517,226; No. 9,937,143; and No. 11,135,192 purport to cover use of the drug to treat a certain population of chronic heart failure patients, classified as those with "preserved ejection fraction." *See id.* ¶ 40. Second, Novartis patent No. 11,058,667 purports to cover a specific dosing regimen of the drug. *See id.* ¶ 39.

In September 2022, Novartis submitted a citizen petition requesting that FDA refrain from approving any ENTRESTO-related ANDA that would carve out labeling language related to those patented methods. Pl.'s Mot. for TRO at 10–11. Novartis raised essentially the same arguments that it does in the instant motion, namely, that the two carve outs violate both the Federal Food Drug and Cosmetic Act and FDA's regulations and present safety and efficacy risks. On July 24, 2024, FDA denied Novartis's citizen petition in a 45-page letter detailing why the carveouts would

be proper under statute and regulation and would not risk the drug's safety or efficacy. Pl.'s Ex. H, Dkt. 1-8. That same day, FDA approved MSN's ANDA No. 213748 for generic sacubitril/valsartan, which contains the disputed carveouts. The carveouts are described below.

1. *Indication Carveout*

ENTRESTO's indication currently reflects that it is approved to treat all adult patients with chronic heart failure. Chronic heart failure patients are sometimes classified by a diagnostic criterion called left ventricular ejection fraction (LVEF)—that is, the ability of the left heart ventricle to pump out blood with each contraction. *See* Pl.'s Ex. I § 14, Dkt. 1-9. At the time of ENTRESTO's approval by FDA, reduced ejection fraction patients (HFrEF) were understood to suffer from a more severe form of the disease. Pl.'s Mot. for TRO at 6. ENTRESTO was initially approved based on the results of a clinical trial that enrolled only reduced ejection fraction patients. *Id*. After ENTRESTO's approval, Novartis completed another clinical trial evaluating the drug's effectiveness on patients with only mildly-reduced or normal LVEF—that is, *preserved* ejection fraction patients. Pl.'s Ex. F (Labeling Carve-Out Citizen Petition) at 7–8, Dkt. 1-6. That trial demonstrated that chronic heart failure patients with preserved ejection fraction (HFpEF) also benefitted from ENTRESTO, albeit less so than reduced ejection fraction patients. Accordingly, in 2021 FDA approved a supplement to ENTRESTO's indication reflecting the drug's broader application. *See* Pl.'s Ex. I § 1.1. ENTRESTO's indication currently reads:

> ENTRESTO is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in *adult patients with chronic heart failure.* Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.
>
> *LVEF* is a variable measure, so use clinical judgment in deciding whom to treat.

Pl.'s Ex. A § 1.1, Dkt. 1-1.

MSN's generic label modifies that indication, to carve out the subset of *preserved* ejection fraction patients covered by Novartis's patents. The modified label reads:

> Sacubitril and valsartan tablets are indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in *adult patients with chronic heart failure and reduced ejection fraction.*
>
> *Left ventricular ejection fraction (LVEF)* is a variable measure, so use clinical judgment in deciding whom to treat.

Def.'s Ex. A § 1.1, Dkt. 13-1.

2. *Dosing Regimen Carveout*

ENTRESTO's label also provides dosing instructions to manage the risks of side effects for patients new to medications with certain effects on the circulatory system. Section 2.6 of ENTRESTO's label describes a modified regimen for patients not taking—or taking only low doses of—angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB), which have similar effects on the circulatory system as ENTRESTO. Section 2.6 recommends a lower starting dose and longer titration period for new patients:

> **2.6 Dose Adjustment for Patients Not Taking an ACE inhibitor or ARB or Previously Taking Low Doses of These Agents**
>
> **In patients not currently taking an ACE inhibitor or an angiotensin II receptor blocker (ARB) and for patients previously taking low doses of these agents**, start ENTRESTO at half the usually recommended starting dose. After initiation, increase the dose every 2 to 4 weeks in adults and every 2 weeks in pediatric patients to follow the recommended dose escalation thereafter *[see Dosage and Administration (2.2, 2.3)]*.

Pl.'s Ex. A § 2.6. The dosing regimen described in Section 2.6 is covered by Novartis patent No. 11,058,667. *See* Miller Decl. ¶ 4, Dkt. 3-2. MSN's generic label omits section 2.6 altogether. *See* Def.'s Ex. A § 2.6.

C. Procedural History

On July 30, 2024, Novartis filed its motion for injunctive relief, requesting that the Court set aside FDA's (1) denial of Novartis's September 22 citizen petition and (2) approval of MSN's ANDA. Novartis argues that FDA's actions have violated the FDCA and FDA regulations 21 C.F.R. §§ 314.127(a)(7) and 314.94(a)(8)(iv), although Novartis does not challenge the regulations here. Novartis contends that FDA's illegal actions will cause Novartis substantial and imminent injury because MSN is poised to bring its generic product to market immediately. Pl.'s Mot. for TRO at 12; *see also* Int.-Def.'s *Ex Parte* Submission, Dkt. 15-1. On August 9, the Court held a hearing on the motion.

II. LEGAL STANDARDS

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). To prevail, a party seeking preliminary injunctive relief must make a "clear showing that four factors, taken together, warrant relief: likely success on the merits, likely irreparable harm in the absence of preliminary relief, a balance of the equities in its favor, and accord with the public interest." *League of Women Voters v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016) (citations and internal quotation marks omitted). Where a federal agency is the defendant, the last two factors merge. *See Am. Immigr. Council v. DHS*, 470 F. Supp. 3d 32, 36 (D.D.C. 2020). The plaintiff "bear[s] the burdens of production and persuasion." *Qualls v. Rumsfeld*, 357 F. Supp. 2d 274, 281 (D.D.C. 2005) (citing *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)).

Failure to show a likelihood of irreparable harm is sufficient to defeat a motion for a preliminary injunction "even if the other three factors entering the calculus merit such relief." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). The D.C.

Circuit "has set a high standard for irreparable injury." *Mdewakanton Sioux Indians of Minn. v. Zinke*, 255 F. Supp. 3d 48, 52 (D.D.C. 2017) (quoting *Chaplaincy*, 454 F.3d at 297). "First, the injury must be both certain and great; it must be actual and not theoretical. The moving party must show the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm. Second, the injury must be beyond remediation." *Chaplaincy*, 454 F.3d at 297 (cleaned up). On the first prong, to show that an injury is "of such imminence that equitable relief is urgently necessary," *id.* at 298, the injury must be "*likely* in the absence of an injunction . . . before a decision on the merits can be rendered," not "some remote future injury," *Winter*, 555 U.S. at 22. The mere "possibility of irreparable harm" at some unspecified point in the future does not justify awarding the "extraordinary remedy" of a preliminary injunction, *id.*, even if "the other . . . factors entering the calculus" weigh in favor of preliminary injunctive relief, *Chaplaincy*, 454 F.3d at 297. Finally, the appropriate measure for the anticipated injury is the time-period until the Court can address the full merits of the case. *See Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 221 (D.D.C. 1996) (evaluating effect on sales "over the duration of the litigation"); *Apotex, Inc. v. FDA*, No. 06-0627-JDB, 2006 WL 1030151, at *17 (D.D.C. April 19, 2006).

III. ANALYSIS

The Court's analysis will begin and end with irreparable harm. Novartis advances three theories of irreparable harm, but none of them rise to such imminence and severity as to meet this Circuit's "high bar" for the "extraordinary remedy" of preliminary injunctive relief. *Id.* The Court commits to resolving the merits of this action on an expedited basis—within the next 60 days or less—so any harm that Novartis purports to suffer will be short-lived. Because Novartis has not

shown that it is likely to suffer irreparable harm while this litigation is pending, it is not entitled to preliminary relief. *See Chaplaincy*, 454 F.3d at 297.

A. Economic Losses

Novartis asserts that it will suffer economic losses from a dramatic reduction in sales after MSN's generic entry. In the D.C. Circuit, however, it is "well settled that economic loss does not, in and of itself, constitute irreparable harm." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). "Monetary loss, even irretrievable monetary loss, may constitute irreparable harm only if it is so severe as to cause extreme hardship to the business or threaten its very existence." *Mylan Lab'ys Ltd. v. FDA*, 910 F. Supp. 2d 299, 313 (D.D.C. 2012). "[E]ven unrecoverable economic losses do not constitute irreparable harm . . . if they do not spell financial disaster for the moving party." *Watson Lab'ys, Inc. v. Sebelius*, No. 12-1344-ABJ, 2012 WL 13076147, at *3 (D.D.C. Oct. 23, 2012). "Monetary figures are relative, and depend for their ultimate quantum, on a comparison with the overall financial wherewithal of the corporation involved." *Mylan Lab'ys, Inc. v. Leavitt*, 484 F. Supp. 2d 109, 123 (D.D.C. 2007).

The present record does not establish that the introduction of MSN's generic will threaten the viability of Novartis's business or cause such "extreme" hardship as to justify injunctive relief. *Mylan Lab'ys Ltd.*, 910 F. Supp. 2d at 313. Novartis's public disclosures from 2023 reveal that ENTRESTO sales in the United States accounted for roughly $3 billion, as compared to Novartis's roughly $45 billion of total global sales revenue. *See* Novartis AG FY2023 Annual Report at 43, 46 (Jan. 31, 2024), https://perma.cc/G6RP-3LDY. Novartis projects that upon entry of a lower-priced generic, it will lose 85 to 90% of ENTRESTO's sales within three months. Pl.'s Mot. for TRO at 12. Those losses will purportedly result from automatic substitution laws—mandating that physicians prescribe a lower-priced generic drug once it becomes available—as well as natural market dynamics. Miller Decl. ¶ 9. Novartis further predicts that it will be unable to maintain its

current prices if MSN is permitted to enter the market, even if the generic is later removed as a result of a merits decision in favor of Novartis. *See* Pl.'s Mot at 25.

The Court is unpersuaded that Novartis's market share loss will be as high as it anticipates, particularly given the short time frame in which the Court will address the merits of this case. Past instances of generic entry into Novartis product markets suggest that generic penetration will be lower than 90%. As a specific example, the realized market share loss after generic entry for Novartis's drug Gilenya was only 47%, on a year-over-year basis. *See* Int.-Def.'s Opp'n at 18, Dkt. 14 (citing Novartis AG, Form 6-K, Exhibit 99.1, Financial Report Q4 2022 (Feb. 1, 2023)). Across *all* of its product lines, Novartis reported only a 4% decrease in sales due to generic entry over the first half of 2024. *See id.* (citing Novartis AG, Form 6-K, Exhibit 99.2 Interim Financial Report (July 18, 2024)). Likewise, industry authorities, including a longitudinal study cited by Novartis in its own briefs, report that generic market penetration is closer to 50% at the one-month mark. *See id.* (citing Grabowski et al., *Continuing Trends In U.S. Brand-Name And Generic Price Competition*, 24 J. OF MED. ECON., Fig. 5 (2021)). Furthermore, Novartis has not explained why it would not be able to recover some of its market share losses through competition, for example, by changing its marketing strategy or lowering the price of ENTRESTO to compete with MSN's generic. *See Cent. & S. Motor Freight Tariff Ass'n v. United States*, 757 F.2d 301, 308–09 (D.C. Cir. 1985) ("[R]evenues and customers lost to competition which can be regained through competition are not irreparable."). Taking into account the evidence in the record, including the statistics drawn from Novartis's public filings, the Court finds that Novartis has not met its burden of demonstrating that it is likely to experience sales losses at the magnitude that it predicts. *See Benoit v. District of Columbia*, No. 18-cv-1104-RC, 2018 WL 5281908, at *6 (D.D.C. Oct. 24,

2018) ("In all circumstances, the irreparable harm alleged must be concrete and corroborated, not merely speculative." (citations and internal quotation marks omitted)).

Even if the Court *were* to credit Novartis's worst-case-scenario, its projected loss of sales still would not constitute irreparable harm. The loss of 90% of ENTRESTO's sales revenue would amount to only a 5.7% loss in Novartis's total global revenue over a three-month period, based the numbers from Novartis's public filings. *See* Int.-Def's Opp'n at 16 (citing Novartis AG, Form 6-K, Exhibit 99.1 Financial Report Q2 2024 (July, 18 2024)) (making rough calculations that, over a 3-month period, a loss of $675 million of ENTRESTO sales out of $11.9 billion in global revenue constitutes a 5.7% reduction). That level of economic loss does not constitute irreparable harm, because Novartis "will undoubtably survive as a going business concern absent injunctive relief." *Bristol-Myers,* 923 F. Supp. at 220-21. In *Bristol-Myers*, the anticipated loss was less than 1% of revenue, *id.*, but courts in this district have determined that economic losses comprising of a much larger fraction of a movant's total sale revenue do not justify a preliminary injunction. *See, e.g.*, *Varicon Int'l v. Office of Personnel Mgmt.*, 934 F. Supp. 440, 447-48 (D.D.C. 1996) (loss of contract representing 10% of plaintiff's revenue); *TGS Tech., Inc. v. Dept. of Air Force*, 1992 WL 19058, at *3-4 (D.D.C. Jan. 14, 1992) (loss of contract constituting 20% of plaintiff's business); *Arrow Air, Inc. v. United States*, 649 F. Supp. 993, 995 (D.D.C. 1986) (loss of contract constituting 25% of plaintiff's revenue).

The Court concludes that Novartis's anticipated harms from longer term price erosion are speculative. Novartis argues that once MSN's generic is introduced, patients' exposure to the generic's lower price would permanently and irreparably affect the price patients are willing to pay for heart failure medication, regardless of whether MSN's generic is eventually removed from the market. Pl.'s Mot. for TRO at 25. But unlike comparator cases like *Endo Par*, where the

brand-name drug had only one direct competitor, *see* 2024 WL 2988904, at *2, MSN's drug is the *only* generic sacubitril/valsartan currently positioned to enter the market. *See* Int.-Def.'s Opp'n at 21. If MSN's generic were introduced and later removed, ENTRESTO would resume its dominant market position as the only medication of its kind available to chronic heart failure patients. The Court does not find it likely that patients experiencing heart failure would refuse to pay for a critical medication—at prices that they are currently paying—due to the effects of price anchoring. Novartis also offers no evidence or projections suggesting that it *actually* plans to lower ENTRESO prices, contrary to *Endo Par*, where the brand-name proffered that "it [would] have to reduce its prices [to a concrete figure]," calculated "based on a comparison between [its] Wholesale Acquisition Cost" and the generic's. 2024 WL 2988904, at *2. The Court thus rejects Novartis's price erosion contention as entirely speculative.

B. Reputational Harm and Loss of Goodwill

As its second theory of irreparable harm, Novartis contends that MSN's generic might cause irreparable reputational harm and loss of goodwill among patients, physicians, distributors, and the like. Novartis asserts that ENTRESTO's favored position on prescribers' lists of approved prescription drugs could disappear once a generic is introduced. Pl.'s Mot. for TRO at 28. Even if true, the Court is unpersuaded that Novartis's loss of reputational standing would be irreversible if MSN's generic were later removed from the market. *Id.* Given that MSN's generic would be the first and only ENTRESTO substitute on the market, *see* Int.-Def.'s Opp'n at 21, at least during the period relevant to this motion, patients and prescribers would necessarily revert back to ENTRESTO. *See Bristol-Myers*, 923 F. Supp. at 221 (addressing the time-period of relevance). Thus, there is little, if any, basis to conclude that any shifts in prescription or usage patterns would have enduring effects, should Novartis prevail on the merits of its claims.

Furthermore, courts regularly reject as unduly speculative the argument that a brand-name manufacturer will lose general customer goodwill due to the deficiencies of a generic competitor. *E.g.*, *Bristol-Myers*, 923 F. Supp. at 220-22; Prelim. Inj. Mot. Hr'g Tr., at 39:11-40:6, *Vanda Pharms., Inc. v. FDA*, No. 1:23-cv-280-TSC (D.D.C. Mar. 6, 2023), Dkt. 36 (finding reputational damage and loss of goodwill unduly speculative). Novartis challenges only the label alterations of MSN's generic and does not assert that MSN's drug product itself is unsafe or lacks pharmaceutical or bio-equivalence. *See* 21 U.S.C. § 355(j)(2)(A). As Judge Chutkan explained in *Vanda Pharmaceuticals*, any loss of goodwill or reputation would require a protracted chain of events. *See Vanda Pharms., Inc. v. FDA*, No. 1:23-cv-280-TSC, Dkt. 36, at 39:11-40:6. First, a prescriber would have to change their behavior or dosage recommendation due to the differences between MSN's generic label and the ENTRESTO label. Second, such changes would have to result in harm to a patient that would not have occurred under ENTRESTO's label. Finally, the harmed patient or the prescriber would have to "irrationally" blame any negative outcome on Novartis rather than on MSN, the manufacturer of the generic. *See id.*

That chain of events is speculative and unsupported by the record. As to the second link, Novartis contends that the dosage carveout—the elimination of section 2.6 of the ENTRESTO label—*might* pose safety risks to a certain category of vulnerable patients. But as the FDA unambiguously concluded when rejecting Novartis's citizen petition, the "omission of the subsection 2.6 modified dosing regimen from the labeling of generic sacubitril and valsartan tablets would *not* render these drugs less safe or effective." *See* Resp. to Citizen Pet. at 39, Dkt. 1-8 (emphasis added). Indeed, contrary to Novartis's out-of-context quotation, FDA explained that "[w]hether the [S]ection 2.6 dosing modification is the safest and best-tolerated option for [the relevant populated of] patients . . . is unknown." The Supreme Court has long recognized that

agency judgments on technical issues within their scope of expertise are to be given persuasive weight based on their thoroughness and the validity of the agency's reasoning. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). The Court finds the FDA's judgment on this point, which is set forth in 10-pages of highly technical analysis, thorough and well-reasoned. Its conclusion calls into serious question Novartis's assertion that the omission of section 2.6 of the ENTRESTO label from the MSN generic label would put patients at risk. As a caveat, the Court is not reaching a decision on the merits here; in other words, it is not deciding whether the dosage carveout makes MSN's generic any "less safe or effective" under 21 C.F.R. § 314.127(a)(7). Nonetheless, FDA's expert determination that the MSN dosage carveout does not pose safety risks is, in a more general way, relevant to Novartis's goodwill claims. The Court thus credits the agency's findings as evidence that Novartis's assertions of potential harms to patients are unconvincing.

Even setting aside the harms to patients, the Court is unpersuaded that patients and prescribers would attribute negative outcomes from MSN's label to Novartis. It seems far more likely that if patients experience problems resulting from MSN's drug, they would be more likely to *prefer*, rather than reject, Novartis's product. That patients may not realize when their medication is being automatically substituted is not credible because—as the parties explained in *Vanda Pharmaceuticals*—patient co-pays would presumably change upon prescriptions being swapped to a lower-priced generic." *See Vanda Pharms., Inc. v. FDA*, No. 1:23-cv-280-TSC, Dkt. 36, at 36:14–25. Aside from the conclusory assertions in the affidavit of Kristin Miller, Vice President and General Manager of Heart Failure and LP(a), *see* Miller Decl. ¶ 40, Novartis has produced no evidence to demonstrate how deficiencies in MSN's label would undermine Novartis's reputation or goodwill. Courts routinely reject such ungrounded speculation. *See Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 165 (D.D.C. 2006) (unduly speculative to assume that

generic drug's deficiencies "will inevitably reach" brand-name reputation); *Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10, 23 (D.D.C. 2009) (same).

C. Research & Development and Personnel Decisions

Third and finally, Novartis asserts that its investment in research and development and its personnel decisions will be irrevocably harmed if MSN's generic is permitted to enter the market. According to Novartis, the loss of revenues from ENTRESTO will force it to curtail spending on research and development and initiate significant restructuring, including firing "cardiovascular product-trained representatives." Pl.'s Mot. for TRO at 29. But these assertions are no more than a reframing of Novartis's arguments about economic loss—such business decisions simply reflect the downstream effects of decreased revenues from ENTRESTO. *See Mylan Lab'ys Ltd.*, 910 F. Supp. 2d at 313 (loss of "sale opportunities, long term contracts, and other market advantages" are merely a reframing of economic loss"). Indeed, Novartis does not concretely assert that projects would be put on hold were it to lose revenues from ENTRESTO—it only vaguely suggests that its plans might be "jeopardized." Pl.'s Mot. for TRO at 29. But Novartis's $8.5 billion in profits from the previous fiscal year suggest that the company has ample alternative revenue streams to fund its research and development. Def.'s Opp'n at 21.

The impending entry of generic competition should come as no surprise to Novartis, as the ENTRESTO patents have a known end date of mid-2025. *See* Novartis AG, *2024 Q1 Results Presentation and Transcript*, https://www.novartis.com/investors/financial-data/quarterly-results/2024-q1-transcript. It is not credible that Novartis has not taken steps to reposition itself, as a matter of business strategy, in anticipation of the incipient generic competition. *See Otsuka Pharm. Co. v. Burwell*, No. GJH-15-852, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) (finding no irreparable harm because Otsuka had been aware of and planned for generic

competition for Abilify). The Court thus rejects Novartis's business strategy arguments for the same reasons it rejected its economic loss argument: Novartis has not demonstrated that decreases in ENTRESTO's sales will be severe enough to "spell financial disaster" or endanger Novartis's viability as a business. *Watson Lab'ys*, 2012 WL 13076147, at *3.

CONCLUSION

For these reasons, Novartis has not established on the current record that it is likely to suffer irreparable harm if injunctive relief is not granted. The Court therefore denies the plaintiff's motion for a preliminary injunction without prejudice. A separate order consistent with this decision accompanies this memorandum opinion.

Dabney L. Friedrich
DABNEY L. FRIEDRICH
United States District Judge

August 13, 2024