IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PLC, MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED, MALLINCKRODT HOSPITAL PRODUCTS IP UNLIMITED COMPANY, and INO THERAPEUTICS LLC, Plaintiffs, v. AIRGAS THERAPEUTICS LLC and AIRGAS USA LLC, Defendants.	Civil Action No. 22-1648-RGA-LDH

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Before me are Defendants' renewed motion for judgment as a matter of law, for a new trial, or to alter or amend the judgment (D.I. 570); and Plaintiffs' motion for an order to the FDA to redate Airgas's ANDA's approval date, for enhanced damages, and for pre- and post-judgment interest (D.I. 567). I have reviewed the parties' briefing. (D.I. 571, 575, 585 for Defendants' motion; D.I. 568, 577, 583 for Plaintiffs' motion). I heard oral argument on the motions on September 24, 2026. (Min. Entry Sept. 24, 2026). For the reasons set forth below, Defendants' motions are all DENIED, Plaintiffs' motion for redating is GRANTED, Plaintiffs' damages award is VACATED, and Plaintiffs' motion for enhanced damages and pre- and post-judgment interest is DISMISSED as moot.

I. BACKGROUND

Plaintiffs Mallinckrodt plc, Mallinckrodt Pharmaceuticals Ireland Limited, Mallinckrodt Hospital Products IP Unlimited Company, and INO Therapeutics LLC (together, "Mallinckrodt") own three patents relevant here: U.S. Patent No. 8,776,794 (the "'6794 patent"); U.S. Patent No. 9,279,794 (the "'9794 patent")[1]; and U.S. Patent No. 9,919,118 (the "'118 patent") (together, the "asserted patents"). The asserted patents describe and claim systems and devices for the administration of nitric oxide for treatment purposes. (D.I. 455-1 Ex. 1 ¶¶ 7, 17, 26). The '6794 patent is titled "Nitric oxide delivery device" (*id.* ¶ 7) and the '9794 and '118 patent are both titled "Systems and methods for compensating long term sensitivity drift of electrochemical gas sensors exposed to nitric oxide" (*id.* ¶¶ 17, 26). The '6794 and '9794 patents are listed in the FDA's

[1] Patents are normally referred to by their last three digits. I use the last four digits for the two patents that have the same last three digits.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). (*Id.* ¶ 11, 21). The '118 patent is not listed in the Orange Book. (*See id.* ¶¶ 26–29).

Defendants Airgas USA LLC and Airgas Therapeutics LLC (together, "Airgas") submitted Abbreviated New Drug Application ("ANDA") No. 203144 to the FDA seeking approval of a generic version of Mallinckrodt's nitric oxide inhalation product. (*Id.* ¶ 33). Airgas represented that its generic product would practice the '6974 and '9794 patents, among others. (*Id.* ¶¶ 34–36). Airgas's product is comprised of the ULSPIRA nitric oxide drug product and the ULSPIRA TS nitric oxide delivery system. (*Id.* ¶¶ 38–40).

Mallinckrodt sued Airgas for infringement of six patents: infringement under § 271(a) of all six patents for Airgas's commercialization of its generic product; and infringement under § 271(e) of a subset of four Orange Book patents, including the '6974 and '9794 patents, for Airgas's ANDA submission. (*See* D.I. 173 ¶ 1). At trial, the case was narrowed to claims 7 and 13 of the'6794 patent; claim 6 of the '9794 patent; and claims 2, 5, 6, and 9 of the '118 patent (together, the "asserted claims"). (*See* D.I. 518).

A jury trial was held from September 8 to 12, 2025.[2] The jury found that Airgas infringed all the asserted claims and that Airgas's infringement was willful. (D.I. 519). The jury awarded a total reasonable royalty amount of about $3.3 million for Airgas's infringement of the '6794 patent, the "Pre-Use Gas Verification Patent" (*id.* at 2), and a total reasonable royalty amount of about $6.1 million for Airgas's infringement of the '9794 and '118 patents, the "Sensor Drift Correction Patents" (*id.* at 4). The jury did not award separate damages for the '9794 and '118 patents.

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[2] The transcript of the trial is docketed at D.I. 602, 603, 604, 605, and 606. It is consecutively numbered and I cite it as "Tr. _____".

Airgas now renews its motion for judgment as a matter of law that it does not infringe the '6794 patent, it does not infringe the '9794 patent, and it does not willfully infringe any of the asserted patents.[3] (D.I. 570). Airgas also moves to alter or amend the judgment of infringement under 35 U.S.C. § 271(e) and for a new trial on infringement. (*Id.*). Mallinckrodt moves for an order to the FDA to redate the approval date of Airgas's ANDA to a date not earlier than the latest expiration dates of the infringed Orange Book patents as well as enhanced damages and pre- and post-judgment interest. (D.I. 567)

II. LEGAL STANDARDS

A. Judgment as a Matter of Law

Judgment as a matter of law is appropriate if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1). "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, 'granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.'" *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted).

"A post-trial Rule 50 motion can only be made on grounds specifically advanced in a motion for a directed verdict at the end of plaintiff's case." *Kars 4 Kids Inc. v. Am. Can!*, 8 F.4th 209, 220 (3d Cir. 2021) (cleaned up). "To prevail on a renewed motion for JMOL following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed.

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[3] Airgas first moved for judgment as a matter of law during trial. (*See* Tr. 820:20–828:11).

Cir. 1998). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984).

In assessing the sufficiency of the evidence, the Court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor and, in general, view the record in the light most favorable to him." *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991). The Court "must not weigh evidence, engage in credibility determinations, or substitute its version of the facts for the jury's." *Pitts v. State*, 4 F.3d 151, 155 (3d Cir. 2011); *Perkin-Elmer*, 732 F.2d at 893. Rather, the Court must determine whether the evidence supports the jury's verdict. *See Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998); 9B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury might reasonably find a verdict for that party.").

B. Motion for New Trial

Federal Rule of Civil Procedure 59(a)(1)(A) provides:

> The court may, on motion, grant a new trial on all or some of the issues—and to any party—as follows: (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . . .

Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's

verdict was facially inconsistent. *Zarow-Smith v. N.J. Transit Rail Operations, Inc.*, 953 F. Supp. 581, 584–85 (D.N.J. 1997) (citations omitted).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem. Corp.*, 9 F.3d 282, 289 (3d Cir. 1993) (reviewing district court's grant or denial of new trial motion under the "abuse of discretion" standard). Although the standard for granting a new trial is less rigorous than the standard for granting judgment as a matter of law—in that the Court need not view the evidence in the light most favorable to the verdict winner—a new trial should only be granted where "a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or where the verdict "shocks [the] conscience." *Williamson*, 926 F.2d at 1352–53.

III. DISCUSSION

I first address Airgas's motions, which focus on the verdict of infringement. I then turn to Mallinckrodt's motions, which center on the appropriate remedies.

A. Airgas's Motions

Airgas presents three motions to challenge the verdict of liability: a renewed motion for judgment as a matter of law, a motion for a new trial, and a motion to alter or amend the judgment. (D.I. 570).

1. Airgas's renewed motion for judgment as a matter of law is denied.

Airgas argues for judgment as a matter of law on three issues: whether Airgas infringes the '6794 patent, whether it infringes the '9794 patent, and whether it willfully infringes the three asserted patents.

a. Infringement of the '6794 patent

According to Airgas, the jury's finding of infringement of claim 7 and claim 13 (which depends on claim 7) of the '6794 patent is not supported by substantial evidence. (D.I. 571 at 2, 15–16). Claim 7 is below:

> A therapy gas delivery system comprising:
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> > a gas delivery device comprising:
> >
> > a ***gas source*** to provide therapy gas comprising nitric oxide;
> >
> > a valve attached to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve; and
> >
> > a circuit comprising:
> >
> > > a first memory to store ***gas data*** comprising one or more of gas identification, gas expiration date and gas concentration of the gas source; and
> > >
> > > a first processor and a first transceiver in communication with the first memory; and
> >
> > a control module that delivers the therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure, the control module comprising a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory,
> >
> > ***wherein the first transceiver and the second transceiver send and receive signals to communicate the gas data to the control module and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.***

'6794 patent, claim 7 (emphases added). I construed the term "[g]as data" as "[d]ata of the actual gas inside the gas source" and the term "[g]as source" as "[a]ny gas source, including a gas cylinder, gas tank, or other pressurized vessel used to store gas at above atmospheric pressure." (D.I. 287 at 1; D.I. 509 at 1).

Airgas contends that Mallinckrodt did not provide sufficient evidence that the accused device communicates and verifies gas data. (D.I. 571 at 15–16). Airgas states that Mallinckrodt offered evidence only of verifying the gas concentration inside the accused device (Airgas's ULSPIRA TS nitric oxide delivery device), not inside the gas source (*e.g.*, a gas tank of nitric oxide). (*Id.* at 15; D.I. 585 at 2–4). Airgas focuses heavily on evidence showing that the gas source's concentration was 800 parts per million ("PPM"), but the accused device's gas concentration was only 15 PPM. (D.I. 571 at 15 (citing Tr. 467:3–20; 517:14–18; 521:8–11; 857:11–23)). Airgas's complaint is that the gas concentration of the source is not measured. Instead, what is measured is the concentration of the gas in the accused device. Mallinckrodt's response is that the measurement of the gas in the device is indirectly measuring the gas inside the source.

I am not persuaded that the jury's infringement verdict is insufficiently supported by the evidence. At trial, Mallinckrodt's expert Mr. Goodin testified that the accused ULSPIRA TS device communicates and verifies the gas concentration inside the gas source by measuring the concentration of the gas when it reaches the head unit, sending that information to the control module, and determining whether the concentration falls within a particular tolerance. (Tr. 448:2–271:10, 489:16–491:20, 495:8–498:1 (Goodin)). Mr. Goodin stated that the gas concentration at the head unit was "reflective of the gas concentration that's in the bottles" (*id.* at 460:22–24) and explained how measuring the gas concentration at the head unit is used to verify the gas concentration of the gas source (*id.* at 461:22–471:10). Mallinckrodt presented a document that Airgas submitted to the FDA, describing the accused device as "[v]erif[ying] . . . connected gas bottles." (D.I. 575 at 7 (citing PTX-228.63); *id.* at 1 (same)). Based on this evidence, there is substantial evidence for a reasonable jury to find that the accused device practiced this limitation.

b. Infringement of the '9794 patent

Airgas argues that Mallinckrodt did not establish infringement of claim 6 of the '9794 patent. (D.I. 571 at 16–19). The relevant language of claim 1, on which claim 6 depends, is below:

> A method for compensating for output drift of an electrochemical gas sensor exposed to nitric oxide in a controlled environment comprising:
>
> . . .
>
> detecting, via the system controller, if an alarm is active or has been active within a predetermined timeframe at the time the calibration is to be executed, ***wherein the calibration is postponed if the active alarm is detected or has been detected within the predetermined timeframe***, and the calibration is executed if the active alarm is not detected or has not been detected within the predetermined timeframe . . . .

'9794 patent, claim 1 (emphasis added).

Airgas argues that Mallinckrodt only showed that the accused device's calibration event—a daily check reminder—was canceled, not postponed as required by the claim language. (D.I. 571 at 16–19 (citing Tr. 392:25–393:5, 405:10–22, 416:16–417:12; 879:2–880:2, 880:23–881:8, 885:18–22)). Airgas's view of the accused device is that if a specific day's calibration event is interrupted, the only option is to cancel the event. (*Id.* at 17 (citing Tr. 392:25–393:5, 405:10–22)). That day's event cannot recur, and any subsequent calibration event is a different event. (*Id.* at 17–18). Mallinckrodt's position, Airgas contends, depends on improperly conflating postponement and cancellation. (*Id.* at 20 (citing cases)).

I think Mallinckrodt provided evidence that the daily check reminder is postponed, not canceled. Mr. Goodin testified and demonstrated that if the calibration is interrupted, then it is postponed for 24 hours. (Tr. 421:2–22). Relevant here, Mr. Goodin reviewed the accused device's source code and found that the device brings up a daily check reminder 24 hours after the last calibration event. (Tr. 479:7–481:4). Specifically, the device checks whether it is in dosing mode before displaying a daily check reminder and brings up a reminder if it has been 24 hours since

dosing. (*Id.*). This seems to me sufficient evidence for a reasonable jury to find that a calibration is postponed rather than canceled outright. I thus reject Airgas's motion for judgment as a matter of law on infringement of the '9794 patent.

c. Willful infringement

"[T]he concept of 'willfulness' requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1330 (Fed. Cir. 2021) (quoting *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1378 (Fed. Cir. 2020)). Copying requires "evidence of efforts to replicate a specific product, which may be demonstrated through internal company documents, direct evidence such as disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a replica, or access to the patented product combined with substantial similarity to the patented product." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Airgas argues that no reasonable jury could conclude that Airgas willfully infringed the asserted patents. (D.I. 571 at 20–23). It is undisputed that Airgas knew of the asserted patents. (D.I. 455-1 Ex. 1 ¶ 35; Tr. 698:22–701:20). The main point of contention is whether Mallinckrodt presented sufficient evidence that Airgas sought to copy Mallinckrodt's product, which embodied the asserted patents. Airgas mounts three attacks on Mallinckrodt's copying theory: Airgas provided testimony of no copying contrary to Mallinckrodt's theory (D.I. 571 at 21–22), Airgas had no knowledge of its own device's source code functionality (*id.* at 22), and Airgas subjectively believed it was not infringing (*id.* at 22–23).

These arguments are unpersuasive. Hearing differing testimony does not render a jury verdict invalid. If anything, it is expected that the opposing parties would present conflicting accounts. It is the jury's role to consider "conflicting elements in the evidence." *Shopify Inc. v.*

Express Mobile, Inc., 2024 WL 2260900, at *1 (D. Del. May 17, 2024), *aff'd in part, appeal dismissed in part*, 2025 WL 3511442 (Fed. Cir. Dec. 8, 2025) (citing *Perkin-Elmer*, 732 F.2d at 893). Airgas's reliance on *Shopify* is misplaced. In that case, one party's expert gave internally inconsistent testimony that made it "impossible to have any confidence in the verdict." *Id.* at *5–7. This case is different. Mallinckrodt presented a consistent set of evidence that Airgas copied Mallinckrodt's device. (*See, e.g.*, *id.* at 770:17–771:5, 772:14–16, 779:12–785:7). That Airgas presented evidence to the contrary does not warrant judgment as a matter of law.

Airgas's lack of knowledge of the source code in its own product is no defense against willfulness here. Airgas does not understand its own device's source code because it hired a third party to develop the device. (*See* Tr. 771:12–772:4). There is nevertheless evidence that Airgas directed its third-party device developer to follow a requirements list based on Airgas's analysis of Mallinckrodt's device. (*Id.*). Moreover, the jury heard testimony that Airgas did not make changes to its own device to avoid infringement. (*Id.* at 703:11–19). Even though Airgas does not know how the accused device's source code works, there is substantial evidence for a reasonable jury to find that Airgas deliberately copied Mallinckrodt's product.

Airgas's assertion that it had reasonable non-infringement defenses does not help here. "Proof of an objectively reasonable litigation-inspired defense to infringement is no longer a defense to willful infringement." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016). The relevant question is what Airgas knew or thought "at the time of the challenged conduct." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 105 (2016). Airgas does not provide evidence of its purported subjective belief that its conduct was non-infringing at the time it developed the accused device (*see* D.I. 571 at 23; *see generally* D.I. 585), so this argument is baseless.

Airgas briefly argues that "willfulness is not an available remedy" for infringement under 35 U.S.C § 271(e)(2). (D.I. 571 at 23). This argument is unavailing for at least two reasons. First, as Mallinckrodt points out (D.I. 575 at 17–18), Airgas forfeited this argument by not raising it in a Rule 50(a) motion (*see* Tr. 824:5–21). Second, the jury found infringement under § 271(a), which allows for a finding of willfulness.

I thus deny judgment as a matter of law on all of Airgas's proposed grounds.

2. Airgas's motion for a new trial is denied.

Airgas moves for a new trial on willfulness based on "improper leverage of a series of evidentiary rulings" and "violation of a Court instruction . . . relating to Plaintiffs' characterization of Patricia-Ann Therriault," a former Airgas employee who previously worked at Mallinckrodt. (D.I. 571 at 23). As an initial matter, I see no instance where Airgas lodged objections at trial, so these arguments are forfeited. (*See* D.I. 575 at 21 (Mallinckrodt asserting Airgas forfeited its new trial arguments); D.I. 585 at 13–15 (Airgas not contesting forfeiture)).

Even on the merits, I reject these arguments. Airgas asserts that my rulings precluding certain evidence "substantially constrained" its willfulness defense.[4] (*Id.* at 23–25). Nowhere does Airgas argue that any rulings were incorrect, only that because of the rulings, there were certain pieces of evidence it did not get to show the jury. (*See id.*). This assertion is not a good reason for a new trial. Airgas criticizes Mallinckrodt's description of Ms. Therriault in its closing argument as "insinuating improper conduct" (D.I. 571 at 25; *see id.* at 26) and contrary to my instructions (Tr. 815:23–25 ("[Y]ou're not going to, in closing argument, suggest or in any other

[4] One example Airgas provides of a substantial restriction is when Mallinckrodt objected to an Airgas employee's testimony on Airgas's state of mind. (D.I. 571 at 24 (citing Tr. 687:19–25, 688:6–9)). I overruled Mallinckrodt's objections and allowed in this testimony (Tr. 688:1, 688:10), a fact Airgas glosses over in its brief (D.I. 571 at 24).

way infer that there was something bad going on here, other than routine acquisition of knowledge.")). The specific closing argument section Airgas challenges is below:

> Ms. Hagin testified she worked closely with Patricia Therriault to come up with this list of requirements for the ULSPIRA TS, for Airgas's device. Who is Patricia Therriault? She's the former Mallinckrodt employee. She worked at Mallinckrodt for seven years before joining Airgas. She has extensive knowledge about Mallinckrodt's DSir Plus machine. Ms. Hagin and Patricia Therriault worked together. They used all of this information to come up with a list of requirements they want for their ULSPIRA TS device.

(Tr. 1047:14–24; *see* D.I. 571 at 25–26 (providing block quote)). This quote explains that Ms. Therriault had knowledge of Mallinckrodt's products through the ordinary course of her employment. There is nothing untoward or improper here that calls for a new trial.

3. Airgas's motion to alter or amend the judgment is denied.

Airgas provides several bases to alter or amend the judgment of infringement under 35 U.S.C. § 271(e).[5] (D.I. 570). As I explain below, none are persuasive.

a. No evidence of infringement under § 271(e)(2)

Airgas says Mallinckrodt did not prove that Airgas, in submitting its ANDA, infringed Mallinckrodt's Orange Book patents, *i.e.*, the '6794 and '9794 patents. (D.I. 571 at 27–30). Airgas maintains that Mallinckrodt's trial presentation focused only on the accused ULSPIRA TS device, not on the drug for which Airgas sought approval in its ANDA. (*Id.* at 27–28; *see also* D.I. 577 at 2; D.I. 585 at 10). Airgas's reasoning is that Mallinckrodt's evidence of § 271(a) infringement "cannot support a verdict of infringement by Airgas's ANDA drug product under § 271(e)"

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[5] Airgas mentions in passing that it is moving for a new trial on the issue of infringement under § 271(e). (*See* D.I. 571 at 27–28, 30). Without "any arguments in favor of its new trial motion," Airgas "has forfeited its new trial arguments." *MHL Custom, Inc. v. Waydoo USA, Inc.*, 2023 WL 5748755, at *1 n.1 (D. Del. Sept. 6, 2023); *see also Higgins v. Bayada Home Health Care Inc.*, 62 F.4th 755, 763 (3d Cir. 2023) (quoting *John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997)) ("[T]he District Court was not required to consider [an argument] because 'arguments raised in passing . . . but not squarely argued, are considered forfeited.'" (cleaned up in relevant part)).

because "infringement under § 271(e)(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product." (D.I. 571 at 27–28 (quoting *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1350 (Fed. Cir. 2002))).

Airgas waived this argument when it made certain stipulations. In the pretrial conference, the parties agreed there is "no difference from an evidentiary perspective" between a § 271(a) or (b) trial and a § 271(e) trial, and based on that, further agreed that the verdict on the § 271(e) issues would follow the jury's verdict on the § 271(a) or (b) issues. (D.I. 466 at 37:24–38:22, 39:5–11 (pretrial conference transcript); D.I. 465 (adopting proposed pretrial order, "as modified by any discussion at the pretrial conference"); *see also* D.I. 560 at 1 ("I think the record is clear, based on the jury verdict and Defendants' on-the-record agreement with the procedure we followed at trial, that Plaintiffs have won the ANDA case.")). Airgas now seeks release from its agreement.

The Third Circuit makes clear that stipulations are generally binding on the parties:

> [The] decision to bind a party to its stipulation [involves the exercise of discretion]. In general, courts encourage parties to enter into stipulations to promote judicial economy by narrowing the issues in dispute during litigation. Allowing parties easily to set aside or modify stipulations would defeat this purpose, wasting judicial resources and undermining future confidence in such agreements. Thus, it is a well-recognized rule of law that valid stipulations entered into freely and fairly, and approved by the court, should not be lightly set aside. However, in spite of the severe limitations placed on withdrawing stipulations, they are not absolute, and courts can grant parties relief from them.

Waldorf v. Shuta, 142 F.3d 601, 616 (3d Cir. 1998) (citations omitted and cleaned up). A stipulation "carries the risks of any agreement, one of which is that a party will commit itself to something that it will later wish it had not." *Jackson v. NuVasive, Inc.*, 2025 WL 580306, at *2 (D. Del. Feb. 21, 2025), *reconsideration denied*, 2025 WL 1042556 (D. Del. Apr. 8, 2025). Regret is generally not a good enough reason to release a party from a stipulation. *See, e.g., id.*

The circumstances here do not merit withdrawal of the stipulation. Airgas's overarching argument here is that Mallinckrodt did not present a § 271(e) infringement case at trial (*see* D.I.

571 at 27–28; D.I. 585 at 9–11), but Mallinckrodt relied on the stipulation to decide what to present at trial (*see* D.I. 575 at 24–25, 27). Airgas says it objected to the pretrial stipulation and only agreed to it under "the assumption that there would be no evidentiary difference between Plaintiffs' § 271(e) infringement claim and its §§ 271(a) and (b) claims." (D.I. 585 at 11). Airgas now suggests that Mallinckrodt's decision to drop the '741 patent (which covers nitric oxide use) before trial undermines the stipulation's validity. (*Id.* (citing (D.I. 466 at 20:9–15)). This makes no sense, considering the timing of the stipulation. Airgas knew Mallinckrodt was not asserting the '741 patent at trial *before* agreeing to the stipulation. (*Compare* D.I. 446 at 20:9–15 (pretrial conference transcript discussion of dropping '741 patent), *with id.* at 37:24–38:22 (later agreeing to stipulation); *see also* D.I. 455 ¶ 3(A) (Joint Proposed Pretrial Order listing patents to be asserted at trial, notably omitting '741 patent)). I reject Airgas's attempts to shirk the consequences of its stipulation.

Moreover, the circumstances here do not call for a distinct evidentiary showing of infringement under § 271(e)(2). Airgas characterizes *Bayer* as holding that § 271(a) and § 271(e) infringement cases require different evidentiary showings. (D.I. 571 at 27–28 (quoting *Bayer*, 279 F.3d at 1350)). This difference arises because in a § 271(e) case, "the allegedly infringing product has not yet been marketed." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). Before a product is commercialized, proving infringement under § 271(e)(2)(A) does not necessarily prove infringement under § 271(a) because "[e]vidence of actual infringement (contrasted with evidence of a 'hypothetical' infringement) may differ in substance and may become available only after manufacture of the composition." *Bayer*, 279 F.3d at 1350. Once a product in an ANDA is commercialized, proving infringement under § 271(a) is sufficient to prove infringement under § 271(e) as well.

Here, Airgas's commercialized device is the product described in its ANDA. Airgas, in its opposition brief to Mallinckrodt's motion for redating, argues that the commercialized product is not the ANDA product because the ANDA does not cover use of the accused ULSPIRA TS device. (*See* D.I. 577 at 9–10 (citing *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380–81 (Fed. Cir. 2012); and *Warner-Lambert*, 316 F.3d at 1360–61)). In Airgas's words, "[l]ooking solely at the ANDA, as required by § 271(e)(2), there is merely a speculative possibility that the ANDA drug product could be used with delivery devices that in operation, may infringe these claims." (*Id.* at 10). I think Airgas has made it clear that such usage is not merely speculative. The parties' undisputed facts from the Pretrial Order state, "Airgas's nitric oxide product is comprised of two parts: (1) the Ulspira drug product described in Airgas's ANDA; and (2) the Ulspira TS nitric oxide delivery system described in Airgas's 510(k)." (D.I. 455-1 Ex. 1 ¶ 40; *see id.* at ¶¶ 39, 41–42, 48; *see also* D.I. 576-1 Ex. 4 at 1 (Airgas's representations to the FDA that the Ulspira product is comprised of "Ulspira (nitric oxide) gas, for inhalation, and the Ulspira TS Nitric Oxide Therapy System")). Because the commercial product and the ANDA product are the same product, showing that Airgas's commercial activities infringed on the patents suffices to show that Airgas's ANDA submission is infringing.

b. § 271(e) infringement by devices

In its reply brief, Airgas argues that, as a matter of law, "§ 271(e) infringement is inapplicable to infringement by a medical device in the first place." (D.I. 585 at 11; *see also id.* at 1). Airgas contends that the § 271(e) statutory schema applies only to drugs, not medical devices. *Id.* at 10 n.2. Airgas relies on *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 678 (1990), for the proposition that § 271(e)(4) applies only to certain drug applications. (*Id.*).

This argument was not made in Airgas's Opening Brief.[6] (*See generally* D.I. 571). It is therefore waived. *See Laborers' Int'l Union of N. Am., AFL-CIO v. Foster Wheeler Energy Corp.*, 26 F.3d 375, 398 (3d Cir. 1994) ("An issue is waived unless a party raises it in its opening brief."); *see also* D. Del. LR 7.1.3(c)(2) ("The party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief.").

Even on the merits, though, I am not persuaded. Section § 271(e)(2) provides that it is infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." A drug is claimed in a patent if the patent claims "an invention containing the active ingredient." *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898, 919 (Fed. Cir. 2024). This case is unlike the patents in *Eli Lilly* and *Teva v. Amneal*, which claimed medical devices without claiming a drug or use of a drug. *See Eli Lilly*, 496 U.S. at 664 (claiming medical devices used to treat certain heart conditions); *Teva v. Amneal*, 124 F.4th at 903 (claiming "components of a metered inhaler device" but not claiming any active ingredient). The '6794 and '9794 patents both claim inventions that use the active ingredient nitric oxide. '6794 patent, claim 7 ("A therapy gas delivery system comprising: a gas delivery device comprising: a gas source to provide therapy gas comprising *nitric oxide*"); '9794 patent, claim 1 ("A method for compensating for output drift of an electrochemical gas sensor exposed to *nitric oxide* in a controlled environment comprising") (emphases added). Because Mallinckrodt's Orange Book patents claim a drug or the use of a drug, the § 271(e) statutory scheme applies to them. Therefore, upon finding infringement of these patents under § 271(e)(2), Mallinckrodt is entitled to relief under § 271(e)(4).

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[6] Airgas makes a similar argument in its brief opposing Mallinckrodt's motion for redating. (*See* D.I. 577 at 8, 10–13). Because the opposition brief is the first opportunity Airgas has to respond to Mallinckrodt's arguments, the argument there is not waived.

c. Section viii carveout of '9794 patent

The ANDA statutory scheme provides applicants with a way to streamline the regulatory process by disclaiming certain uses of a drug covered by patents:

> An abbreviated application for a new drug shall contain . . . if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(j)(2)(A)(viii). What this dense language means is, "Where the Orange Book lists a method of use patent that 'does not claim a use for which the applicant is seeking approval,' an applicant may instead submit a [section viii statement] averring that the ANDA excludes all uses claimed in the patent." *AstraZeneca*, 669 F.3d at 1374 (quoting *Warner-Lambert*, 316 F.3d at 1360–61).

While section viii statements may allow generic manufacturers to "limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a § 271(e)(2) infringement suit," *id.* at 1379, making a section viii statement does not necessarily avoid infringement. "It is not a simple matter to determine whether an ANDA applicant has successfully carved out language from a label to turn infringement into non-infringement." *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2023 WL 3496373, at *2 (D. Del. May 17, 2023), *aff'd*, 98 F.4th 1056 (Fed. Cir. 2024); *see id.* at *2 n.3 (providing an example where the parties "hotly disputed" at trial whether a carveout was successful). Indeed, submitting a section viii statement, including "carv[ing] out" patented methods from the brand's approved label, "do[es] not foreclose the possibility that an approved ANDA may still interfere with a patented method of use." *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, 608 U.S. 580, 585–86 (2026). "[A]n unfounded Section viii statement" would not "necessarily immunize an ANDA that actually seeks approval for a patented treatment or necessarily leave the patentee without recourse under § 271(e)(2)."

AstraZeneca, 669 F.3d at 1380. To determine whether a carveout avoids infringement requires an analysis of the facts.

Airgas argues it carved the '9794 patent out of its ANDA with a section viii submission, which "precludes liability" for this patent under § 271(e)(2). (D.I. 571 at 28–30 (citing D.I. 571-7 Ex. 7 at 2–3 (Patent and Exclusivity Certification))). Mallinckrodt argues that Airgas failed to timely raise its section viii argument. (D.I. 575 at 27). Airgas responds that it preserved this argument. (D.I. 585 at 12–13 (citing D.I. 182 at 26; D.I. 455 § II(C) ¶ 5)). At oral argument regarding post-trial motions, I asked Airgas to identify where it preserved its section viii noninfringement defense as to the '9794 patent. (D.I. 601 at 1 (citing D.I. 601-1 Ex. A, Tr. 52:23–53:5; 92:25–93:4)). Airgas points to its eighth affirmative defense and counterclaims in its operative answer (*id.* (citing D.I. 182 at 26, Counterclaims ¶¶ 62, 113)), the Pretrial Order (*id.* (citing D.I. 455 §§ I ¶¶ 4.H, 4.O; II(C) ¶ 5)), and two joint trial exhibits (*id.* at 2 (citing JTX-0037, JTX-0039)).

I think that Airgas waived this argument.[7] In the Pretrial Order, Airgas states, "Airgas's Answer set forth the following defenses: (1) failure by Mallinckrodt to state a claim, (2) non-infringement of the Asserted Patents, (3) invalidity of the Asserted Patents, (4) Mallinckrodt's claims were barred by equitable doctrines such as estoppel or unclean hands, and (5) unenforceability of the Asserted Patents." (*See* D.I. 455 § II(C) ¶ 5). Airgas's Pretrial Order statements make no mention of its section viii carveout at all. (*See* D.I. 455 §§ I ¶¶ 4.H, 4.O; II(C)

[7] "The Court of Appeals for the Third Circuit has in recent years clarified its preferred terminology in connection with waiver and forfeiture. A party waives an argument when the party knows that it has the argument and chooses not to make it. A party forfeits an argument when it fails to assert it at an appropriate time." *Acceleration Bay LLC v. Amazon Web Servs., Inc.*, 2026 WL 837160, at *7 n.10 (D. Del. Mar. 26, 2026) (citations omitted). I consider this an instance of waiver for the reasons stated in the text.

¶ 5). Moreover, the Pretrial Order does not incorporate Airgas's answer in full.[8] (*See generally id.*). The Joint Pretrial Order "shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice." (*Id.* ¶ 129; D.I. 465 (adopting proposed pretrial order "as modified by any discussion at the pretrial conference"); *see* D. Del. LR 16.3(d)(4)). Based on the Pretrial Order, Airgas failed to preserve this argument.

Airgas concedes, "The Section viii defense did not appear during trial" but insists that this argument is timely in response to Mallinckrodt's post-trial motion for an injunction under § 271(e). (D.I. 601 at 2; *see also* D.I. 585 at 13). Airgas appears to argue that because "the legal effect of the carve-out is an issue of law for adjudication by the Court, not one of fact for the jury to decide," it is appropriate to bring up this issue during post-trial proceedings. (D.I. 585 at 13).

That is not quite right. As explained above, to determine the legal effect of a carveout, I need to consider the facts about the carveout. The parties did not present such facts to me. They agreed these facts were not necessary for the purposes of trial. My view is Airgas waived its arguments specific to § 271(e), including the carveout, when it agreed to use the § 271(a) and (b) issues as proxies for the § 271(e) issues (D.I. 466 at 37:24–38:22, 39:5–11). It is too late, at the post-trial motions stage, to hash out disputes on the carveout.[9]

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[8] Airgas's section viii defense in its answer is brief. Its Eighth Affirmative Defense states, "Furthermore, Airgas has amended its ANDA to include a Section viii Statement with regard to the '9,794 patent and will not infringe the '9,794 patent for this additional reason." (D.I. 182 at 26; *see also id.* at Counterclaims ¶ 113). Airgas does not identify any point in the record before post-trial motions where it develops this argument in any way. Airgas did nothing to preserve this argument. And, as noted in the text, it was not preserved by the pretrial order.

[9] For instance, the briefing shows that the parties, at some point, disagreed on whether the section viii carveout was in effect. (*See, e.g.*, D.I. 571 at 28 (Airgas asserting it submitted a section viii statement in December 2022); D.I. 575 at 27 (Mallinckrodt asserting that Airgas withdrew the carveout on July 11, 2023); D.I. 585 at 12 (Airgas asserting that it confirmed the carveout was still in effect on July 19, 2023)).

B. Mallinckrodt's Motions

Mallinckrodt moves for an injunction to redate Airgas's ANDA approval and for increased damages via enhanced damages and pre- and post-judgment interest.

1. Mallinckrodt's motion to redate Airgas's ANDA approval is granted.

Mallinckrodt moves for an injunction redating approval of Airgas's ANDA to a date "not earlier than the latest expiration of the infringed Orange-Book patents (January 6, 2031 for the '6,794 patent and February 19, 2035 for the '9,794 patent), or later due to any extensions and/or additional periods of exclusivity to that date" under 35 U.S.C. § 271(e). (D.I. 567 at 1; D.I. 568 at 1–2, 5). I postponed entering an injunction with the jury verdict to the post-trial motions stage, in part because awarding both injunctive relief and lump sum damages for the life of the patents "seem[ed] like double-counting." (D.I. 560 at 1–2).

For an act of infringement under § 271(e)(2), "the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). "[U]pon a finding of patent infringement under § 271(e)(2), the district court must order remedies in accordance with § 271(e)(4)." *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1138 (Fed. Cir. 2018). This is a statutory mandate.

Airgas makes four arguments against redating: (1) Airgas's delivery device is not covered by the ANDA; (2) § 271(e)(4)(A) applies only to drugs, not devices; (3) Airgas carved the '9794 patent out of the ANDA; and (4) awarding both injunctive relief and the jury's damages award would constitute double recovery. (D.I. 577 at 8–9). These arguments are unavailing. As discussed above, I reject the first three arguments. As for the fourth, Airgas asserts that Mallinckrodt forfeited its right to injunctive relief "by proceeding at trial with [its] request for

damages in the form of a fully paid-up license." (*Id.* at 2–3; *see id.* at 9, 14–16). I am concerned by the double recovery issue, but I cannot disregard my statutory directive. And, in any event, Mallinckrodt says that, if "forced to choose between the injunction and future damages, it wants the injunction." (D.I. 583 at 8).

Thus, in the final judgment, I will order the FDA to redate Airgas's ANDA approval as specified in Mallinckrodt's motion. I discuss the damages award below.

2. Mallinckrodt's damages award is vacated, and its motion for enhanced damages and pre- and post-judgment interest is dismissed as moot.

Mallinckrodt maintains that it is entitled to an injunction as well as the jury's damages award, enhanced damages, and pre- and post-judgment interest. (*See* D.I. 567; D.I. 568 at 1; D.I. 583 at 1, 7–8). Mallinckrodt says § 271(e)(4)(A)–(C) "provide[s] for a redating remedy and monetary damages where, as here, 'there has been commercial manufacture, use, offer to sell, or sale.'" (D.I. 583 at 7 (citing H.R. Rep. No. 98-857, pt. 1, at 46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679 (("If the infringing party has begun commercial marketing of the drug, damages, and other monetary relief and injunctive may be awarded for the infringement and to prevent further infringement. In addition, the FDA would be mandated to change the effective date of the approved ANDA to the expiration of the infringed patent.")))). Airgas disagrees, arguing that because "Plaintiffs' damages award amounts to a fully paid-up license to all of the Asserted Patents," an injunction would result in double recovery. (D.I. 577 at 2; *see id.* at 14–15).

I agree with Mallinckrodt's general statement that both damages and a redating remedy may be appropriate to compensate it fully. (*See* D.I. 583 at 7). Nevertheless, the award must not be overcompensatory. "[D]ouble recovery for the same injury is inappropriate." *Texas Advanced Optoelectronic Sols., Inc. v. Renesas Elecs. Am., Inc.*, 895 F.3d 1304, 1328 (Fed. Cir. 2018) (quoting *Aero Prods. Int'l, Inc. v. Intex Recreation Corp.*, 466 F.3d 1000, 1017 (Fed. Cir. 2006)).

The court may make "appropriate adjustments to avoid double recovery." *Aero Prods.*, 466 F.3d at 1017 (quoting *Bowers v. Baystate Techs., Inc.*, 320 F.3d 1317, 1327–28 (Fed. Cir. 2003)). Courts have long contemplated both granting an injunction and awarding damages in patent infringement cases. When both forms of relief are granted, "[o]rdinarily an injunction is designed to prevent future infringement, and damages are awarded as compensation for past infringement. Where the damage award is based upon an assumed license for the life of the patent, there is no need to enjoin use, since the license fee authorizes use." *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1565 (Fed. Cir. 1984). Stated differently, an injunction and a damages award that covers the lifetime of the patent would constitute double recovery, specifically for the patent's remaining lifetime.

I will grant the injunction. What remains is to determine what the jury's damages award covers. I think the award covers the asserted patents' lifetimes. The record shows that at trial, Mallinckrodt presented damages theories based on a one-time lump sum reasonable royalty payment. (*See, e.g.*, Tr. 20:4–6 ("This relates directly to the parties' expectations of future sales, which is the fundamental basis of the damages theory."), 598:10–20 (summary of Mallinckrodt's damages expert Ms. Trexler's opinions), 623:1–625:16 (Ms. Trexler explaining why she formulated damages as a one-time lump sum); 632:1–633:17 (considering Airgas's forecasted profits through an asserted patent's expiration date in 2031)). The jury did not hear a damages theory based solely on compensation for past infringement, and the jury was not presented with information necessary for computing past damages. (D.I. 482 (excluding Airgas's actual sales data at Mallinckrodt's request, *see* D.I. 473); *see also* Tr. 176:22–25 (indicating that Airgas was not permitted to present actual sales data), 20:22–21:14 (Mallinckrodt's opposition to showing Airgas's "disappointing" actual sales to the jury)); D.I. 449 (Mallinckrodt's motion in limine to

exclude evidence of actual sales). This is a problem for damages awards for the '6794 and '9794 patents, the Orange Book patents. There is no reasoned principle for me to convert the damages awards, as currently conceptualized, into awards compensating only past infringement.

Mallinckrodt makes no argument that the damages award for the '6794 patent is anything other than a "fully-paid up lump sum royalty." (D.I. 583 at 8). As for the '9794 and '118 patents, Mallinckrodt contends that the damages award was calculated by assessing the development costs Airgas avoided by licensing the patents. (*Id.* at 7–8 (citing Tr. 614:21–616:4, 623:1–17)). I do not find this argument persuasive, as the damages are presented as a lump sum royalty arising from a hypothetical negotiation (Tr. 623:1–17), rather than an accounting of damages for past infringement. More importantly, Mallinckrodt does not address a fundamental problem: The jury's damages award does not allocate damages between the '9794 and '118 patents. (D.I. 518 at 4). The '118 patent is not covered by the injunction. In the abstract, I am not opposed to awarding damages for the '118 patent, even a lump sum royalty, but there is no methodical way for me to separate out the damages for the '118 patent from those for the '9794 patent.

Overall, the damages award does not make clear what damages are necessary to compensate Mallinckrodt once the injunction is granted. I therefore vacate the entire damages award. Nevertheless, Mallinckrodt is entitled to past damages for infringement of the '6794 and '9794 patents that occurred before redating and for infringement of the '118 patent. As there is no longer a damages award in place, Mallinckrodt's motion for enhanced damages and pre- and post-judgment interest is dismissed as moot.

IV. CONCLUSION

An appropriate order will issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT PLC, MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED, MALLINCKRODT HOSPITAL PRODUCTS IP UNLIMITED COMPANY, and INO THERAPEUTICS LLC, Plaintiffs, v. AIRGAS THERAPEUTICS LLC and AIRGAS USA LLC, Defendants.	Civil Action No. 22-1648-RGA-LDH

ORDER

For the reasons stated in the accompanying Memorandum Opinion, Defendants' motions (D.I. 570) are all DENIED, Plaintiffs' motion (D.I. 567) for redating is GRANTED, Plaintiffs' damages award is VACATED, and Plaintiffs' motions for enhanced damages and pre- and post-judgment interest (*id.*) are DISMISSED as moot.

IT IS SO ORDERED.

Entered this 3rd day of November, 2026

Richard G. Andrews
United States District Judge