IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Before me is Plaintiff's Motion for Preliminary Injunction. (D.I. 75). I have considered the parties' briefing. (D.I. 76, 120, 123, 196, 197, 330, 342). For the reasons set forth below, the motion is DENIED.

I. BACKGROUND

Plaintiffs Mallinckrodt Pharmaceuticals Ireland Limited and Mallinckrodt Hospital Products IP Unlimited Company (together, "Mallinckrodt") sued Defendants Airgas USA LLC and Airgas Therapeutics LLC (together, "Airgas"), alleging patent infringement. (D.I. 173 at 1–2). At issue for this preliminary injunction are two of Mallinckrodt's asserted patents, U.S. Patent Nos. 8,795,741 (the "'741 patent") and 8,776,794 (the "'794 patent"). (*Id.*; D.I. 76 at 1).

Mallinckrodt's patents cover its "INOMax" and "DS_{IR} Plus" products, which operate in the inhaled nitric oxide gas ("iNO") market. (D.I. 76 at 1). iNO medication is typically administered bedside in a hospital, and most commonly to neonates and children suffering from hypoxic respiratory failure. (*Id.*; D.I. 173 at 7). Mallinckrodt's INOMax product is nitric oxide 800 ppm and its DS_{IR} Plus product is a delivery system. (D.I. 173 at 7–8). The asserted patents are generally directed to methods of treating patients using iNO while reducing the risk of adverse effects. (*Id.* at 8). One claimed treatment is for neonates who suffer from left ventricular dysfunction ("LVD"). (*Id.*). If these patients take iNO, they have a high risk of experiencing serious adverse effects, like pulmonary edema. (*Id.*). Mallinckrodt affixes labels to its INOmax products with instructions on how to safely administer INOmax to these high-risk patients. (*Id.* at 8–9). Its patents reflect those methods. (*Id.*).

Airgas submitted ANDA No. 203144 seeking FDA approval of generic INOmax and a delivery system, called "Ulspira" and "Ulspira TS," respectively. (*Id.* at 1–2). Airgas filed for

its ANDA "twelve years ago." (D.I. 76 at 5). Mallinckrodt received notice of the ANDA and Airgas' challenge to its patents on November 18, 2022.[1] (D.I. 173 at 4). Mallinckrodt filed its Complaint on December 30, 2022. (D.I. 76 at 5). Airgas received approval for its ANDA and delivery system on July 27, 2023 and June 30, 2023, respectively. (*Id.*). Mallinckrodt filed this Motion for Preliminary Injunction on September 13, 2023. (D.I. 75). Mallinckrodt filed a First Amended Complaint ("FAC"), pursuant to a stipulation between the parties, on February 12, 2024. (D.I. 172, 173).

Mallinckrodt accuses Airgas of infringing multiple claims of its patents. (D.I. 173 at 30–57). For purposes of this motion, Mallinckrodt alleges Airgas infringes at least three claims: claims 24 and 26 of the '741 patent and claim 1 of the '794 patent. (D.I. 76 at 1). Those claims recite:

> 24. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk of inducing an increase in PCWP [pulmonary capillary wedge pressure] leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:
> (a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;
> (b) determining that a first patient of the plurality does not have pre-existing left ventricular dysfunction;
> (c) administering a first treatment regimen to the first patient, wherein the first treatment regimen comprises administration of 20 ppm inhaled nitric oxide for 14 days or until the first patient's hypoxia has resolved;
> (d) determining that a second patient of the plurality has pre-existing left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide; and
> (e) administering a second treatment regimen to the second patient, wherein the second treatment regimen does not comprise either (i) administration of inhaled nitric oxide for 14 days or (ii) administration of inhaled nitric oxide until the second patient's hypoxia has resolved.

[1] Mallinckrodt's First Amended Complaint ("FAC") says Mallinckrodt received notice on November 18, 2022. (D.I. 173 at 4). Its Motion for Preliminary Injunction says November 17, 2022. (D.I. 76 at 5). Though this discrepancy seems inconsequential, I will assume the FAC is correct.

26. The method of claim 24, wherein the second treatment regimen comprises beginning administration of inhaled nitric oxide but discontinuing the administration upon determination that inhaling nitric oxide has increased the second patient's PCWP and/or induced pulmonary edema in the second patient.

('741 patent at 16:31–53, 16:57–62).

1. A gas delivery device comprising:
a gas source to provide therapy gas comprising nitric oxide;
a valve attachable 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 to allow the gas through the valve to a control module that delivers the therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure; and
a circuit including:
a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

('794 patent at 17:15–32).

Mallinckrodt filed its Motion for Preliminary Injunction, seeking to stop Airgas from launching its products. (D.I. 76 at 1). Airgas launched its Ulspira and Ulspira TS products while this motion was pending. (D.I. 330 at 2 of 4).

II. LEGAL STANDARD

"The decision whether to enter a preliminary injunction is committed to the sound discretion of the trial court." *Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1437 (3d Cir. 1994) (quoting *Merchant & Evans, Inc. v. Roosevelt Bldg. Prods. Co.*, 963 F.2d 628, 633 (3d Cir. 1992)). The Third Circuit has cautioned that a preliminary injunction is "an extraordinary remedy" to be granted "only in limited circumstances." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir.

2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)). When seeking a preliminary injunction, a movant "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The movant must establish the first two requirements before a court considers, to the extent relevant, the remaining two prongs of the standard. *K.A. v. Pocono Mountain Sch. Dist.*, 710 F.3d 99, 105 (3d Cir. 2013).

III. DISCUSSION

A. Injunction

1. Likelihood of Success on the Merits

To demonstrate a likelihood of success on the merits, "the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009).

"[V]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." *Abbott Lab'ys v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (citation omitted). "[T]he patent challenger retains the burden of establishing invalidity, and the applicant for preliminary injunctive relief retains the burden of showing a reasonable likelihood that the attack on the validity of the patent would fail." *Impax Lab'ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 392 (D. Del. 2002) (citation omitted).

If an alleged infringer raises a substantial question concerning validity or infringement, and the patentee is unable to prove that the question "lacks substantial merit," a preliminary injunction will not issue. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

a. Infringement of the '741 Patent

Mallinckrodt argues it is likely to succeed on its allegation that Airgas induces infringement of claims 24 and 26 of the '741 patent. (D.I. 76 at 6). Mallinckrodt argues the label on Airgas' Ulspira product encourages medical professionals to infringe the claims because it instructs them on how to perform the claimed method. (*Id.*). Airgas' label recites:

> [The ANDA Product is to be used in] neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension[.] . . . The recommended dose is 20 ppm, maintained for up to 14 days or until the underlying oxygen desaturation is resolved. . . . *Patients with left ventricular dysfunction treated with [the ANDA Product] may experience pulmonary edema, increased pulmonary capillary wedge pressure . . . . Discontinue [the ANDA Product] while providing symptomatic care.* . . . Avoid abrupt discontinuation of [the ANDA Product]. To wean [the ANDA Product], downtitrate in several steps.

(*Id.* at 7, citing D.I. 77-1, Ex. G at 1, 2–3) (omissions and alterations in original) (emphasis added to language in the "Warnings and Precautions" section of the label). Mallinckrodt argues all the steps in claims 24 and 26 appear in the label. (*Id.*).

Airgas offers two reasons why Mallinckrodt fails to show its label induces infringement. (D.I. 120 at 12–13). First, Airgas argues Mallinckrodt erroneously relies on the "Warnings and Precautions" section of its label to show induced infringement. (*Id.* at 12). Airgas argues the warnings state adverse effects may occur and that "warnings are not instructions." (*Id.*). Airgas further argues Mallinckrodt erroneously interprets the label to direct doctors "to administer iNO to a patient already determined to have pre-existing LVD," when the label is meant to direct

doctors to discontinue treatment of an LVD patient after administering iNO. (*Id.*). Airgas argues Mallinckrodt improperly relies on "a physician's professional judgment" to show infringement, which "is not a substitute for instructions to either directly infringe or induce infringement of [the] claim." (*Id.* at 13).

Second, Airgas argues Mallinckrodt's argument is contrary to a position it took in a previous case, *Praxair*. (*Id.*). Airgas argues Mallinckrodt alleged in *Praxair* that infringement of the '741 patent requires a doctor to identify a patient with LVD and exclude them from iNO treatment, but now argues that infringement requires a doctor to administer iNO to a patient known to have LVD. (*Id.*).

Airgas also argues Mallinckrodt failed to adequately address the intent requirement of induced infringement for both of the patents. (D.I. 120 at 13). Airgas again argues Mallinckrodt's reliance on its products' "Warnings and Precautions" portion of the label is insufficient because warnings are not instructions. (*Id.*).

Mallinckrodt argues Airgas admits the warnings are instructions when it argues the label tells doctors to discontinue treatment for patients with LVD. (D.I. 123 at 2). Mallinckrodt further argues the label instructs doctors to "downtitrate in several steps" if treatment must be discontinued, such as if the patient has LVD. (*Id.*). Mallinckrodt argues those steps will inevitably lead some doctors to practice the claimed method, which is sufficient for a finding of induced infringement. (*Id.* at 2–3). Mallinckrodt argues that, in light of the label, "some neonatologists would inevitably determine a neonate's LVD status before beginning iNO and then practice the remaining claimed steps as instructed." (*Id.* at 3).

Mallinckrodt argues its current position is not inconsistent with its position in *Praxair*. (*Id.*). Mallinckrodt argues the cases cited by Airgas about warnings are inapplicable here

because they stand for the proposition that warning labels by themselves cannot induce infringement. (*Id.*). Mallinckrodt argues Airgas' label includes steps and warnings which, taken together, can induce infringement. (*Id.* at 4).

I think Mallinckrodt has not shown it is likely to succeed in proving Airgas infringes claims 24 and 26 of the '741 patent. Claim 24 requires a treating doctor to identify a patient with LVD and treat that patient without "either (i) administration of inhaled nitric oxide for fourteen days or (ii) administration of inhaled nitric oxide until the . . . patient's hypoxia has resolved." ('741 patent at 16:31–53). Airgas' label advises that patients with LVD treated with Ulspira may experience adverse effects and, if so, Ulspira should be discontinued. (D.I. 77-1, Ex. G, at 250–51 of 395). I think there are sufficient differences and ambiguity in Airgas' label and the claims to prevent me from finding Mallinckrodt is likely to succeed on the merits. It is unclear to me whether Airgas' label falls within the scope of claim 24. I think one plausible interpretation of Airgas' label instructs doctors to discontinue Ulspira once the doctor learns the patient has LVD only after starting the treatment. I think it is quite possible that does not fall within claim 24, which requires identifying an LVD patient before treatment, then treating them without either iNO administration for fourteen days or iNO administration until their hypoxia is resolved. I do not think Mallinckrodt has met its burden to show it is likely to succeed on proving infringement of claims 24 and 26 of the '741 patent.

b. Validity of the '741 Patent

Mallinckrodt argues it is likely to succeed on validity challenges to claims 24 and 26 of the '741 patent. (D.I. 76 at 9). Mallinckrodt argues the '741 patent survived two IPR petitions where "the PTAB determined that there was no reasonable likelihood of unpatentability." (*Id.* at 10).

Airgas argues claims 24 and 26 are invalid under 35 U.S.C. § 101. (D.I. 120 at 7). Airgas points out that another district court invalidated claim 1 of the '741 patent, which the Federal Circuit affirmed.[2] (*Id.*). Airgas argues claims 24 and 26 are also unpatentable and any differences between invalidated claim 1 and the asserted claims do not make the claims patent eligible. (*Id.* at 8). Airgas argues Mallinckrodt is collaterally estopped from asserting infringement of claims 24 and 26 based on the previous judgment invalidating claim 1. (*Id.* at 11).

Mallinckrodt argues invalidated claim 1 is materially different from the claims asserted here. (D.I. 76 at 10). Mallinckrodt argues claim 1 was directed to a natural law itself and did not "recite affirmative treatment steps" like claims 24 and 26. (*Id.*).

I think Airgas has raised a substantial question of validity of claims 24 and 26 of the '741 patent.

In holding that claim 1 is directed to a natural phenomenon and adds no inventive concept, the Federal Circuit explained:

> The patent claim does no more than add an instruction to withhold iNO treatment from the identified patients; it does not recite giving any affirmative treatment for the iNO-excluded group, and so it covers a method in which, for the iNO-excluded patients, the body's natural processes are simply allowed to take place.

INO Therapeutics LLC v. Praxair Distrib. Inc., 782 F. App'x 1001, 1005 (Fed. Cir. 2019). I think the same line of reasoning applies here, even though the claim language is different.

[2] The district court also invalidated claims 4, 7, 9, and 18, which were the only other asserted claims of the '741 patent. *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distrib., Inc.*, 2017 WL 3867649, at *55 (D. Del. Sept. 5, 2017). Those claims were all direct or indirect dependent claims of claim 1. *Id.* at *18–22. The Federal Circuit affirmed those invalidations too. *INO Therapeutics LLC v. Praxair Distrib. Inc.*, 782 F. App'x 1001, 1012 (Fed. Cir. 2019).

Claim 24 is very similar to invalidated claim 1. The biggest difference seems to be that, instead of excluding a patient from iNO treatment as required by claim 1, claim 24 requires a doctor to "administer[] a second treatment regimen to [a] second patient, wherein the second treatment regimen does not comprise either (i) administration of inhaled nitric oxide for 14 days or (ii) administration of inhaled nitric oxide until the second patient's hypoxia has resolved." ('741 patent at 16:31–53). I do not think that the second treatment regimen meaningfully distinguishes claim 24 from claim 1. The Federal Circuit multiple times explained that claim 1 would be different it included some "specific new treatment to provide a therapeutic benefit" or the like. *INO*, 782 F. App'x at 1007. Claims 24 and 26 do not do that. They remain rooted to the discovery of the natural law that doomed claim 1. Claim 24 can be read as requiring the same thing as claim 1: excluding a patient with LVD from the recommended iNO treatment.

Mallinckrodt asserts that, unlike claim 1, claim 24 "recite[s] a way of reducing the risk of pulmonary edema while providing some level of treatment to . . . patients," which the Federal Circuit indicated may be patent eligible. (D.I. 76 at 10); *INO*, 782 F. App'x at 1006–07. But claim 24 recites treating a patient with LVD by withholding at least some version of iNO treatment, very similar to invalidated claim 1. I think Airgas has raised a substantial question as to claim 24's validity.

Claim 26 recites discontinuing iNO treatment in a patient after determining an adverse effect has worsened. ('741 patent at 16:57–62). Airgas points to testimony relied on by the district court in invalidating claim 1 about discontinuing treatment. (D.I. 120 at 8); *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distrib., Inc.*, 2017 WL 3867649, at *18 n.5 (D. Del. Sept. 5, 2017). The testimony was from an inventor of the patent who admitted that, prior to the priority date, "physicians would likely discontinue treatment with iNO in neonates that experienced

pulmonary edema." *Id.* It is unclear whether Airgas argues this renders claim 26 invalid under step one or step two of the 101 inquiry. Regardless, I think Airgas has raised a substantial question of validity as to claim 26. Airgas has pointed to testimony that any claimed improvements over the prior art recited in claims 24 and 26 are, in fact, not improvements, but conventional steps directed to the abstract idea of a natural phenomenon that add nothing more to render the claims patent eligible. (D.I. 120 at 8–11).

For these reasons, I think Airgas has raised a substantial question of validity as to claims 24 and 26 of the '741 patent.

c. Infringement of the '794 Patent

Mallinckrodt argues it is likely to succeed on its allegation that Airgas induces infringement of claim 1 of the '794 patent. (D.I. 76 at 8). Airgas' Ulspira TS product connects to Airgas' iNO gas cylinder by a valve and contains circuitry to store and to communicate data. (*Id.* at 9). Mallinckrodt argues these features infringe claim 1 of the '794 patent. (*Id.*).

Airgas offers two arguments for why its Ulspira TS product does not infringe claim 1 of the '794 patent. (D.I. 120 at 2). First, Airgas argues the claimed "gas data" relates to "the actual gas inside the cylinder," pointing to the previous *Praxair* district court decision and the '794 patent specification for support. (*Id.* at 2–3). Airgas argues that under this interpretation, it does not induce infringement because none of the "gas data" measured by Airgas' product as alleged by Mallinckrodt is "the actual gas inside the cylinder." (*Id.* at 3–4).

Mallinckrodt argues that there was no claim construction for "gas data" in *Praxair* and Airgas improperly relies on a statement from the court rejecting an infringement argument specific to defendant Praxair's product. (D.I. 123 at 4). Mallinckrodt argues that even if I accept Airgas' interpretation of "gas data," Airgas still infringes. (*Id.*).

Second, Airgas argues Mallinckrodt's interpretation of "gas data" is inconsistent with its previous argument in *Praxair* and the patent itself. (D.I. 120 at 2). Airgas argues Mallinckrodt previously alleged the '794 patent covers communicating gas data to a doctor before administration, while it now alleges claim 1 requires communicating gas data that is actively being administered. (*Id.* at 4–5).

After briefing for this motion was completed, Mallinckrodt accepted Airgas' proposition that "gas data" means "data of the actual gas inside the gas source." (D.I. 279 at 3 of 4; D.I. 287 at 1).

I do not think Mallinckrodt has shown it is likely to succeed on showing Airgas infringes claim 1 of the '794 patent. I think Airgas has pointed to sufficient evidence to question whether its products practice the "gas data" limitation of claim 1. Airgas points to language from the Federal Circuit and the '794 patent that suggests "gas data" means data related to "the actual gas inside the cylinder." (D.I. 120 at 2–3). Based on that interpretation, Airgas pointed to evidence that its products do not verify data of "the actual gas data inside the cylinder." (*Id.* at 3–4). Since the parties filed their briefs, Mallinckrodt accepted Airgas' "gas data" construction that is very similar. (D.I. 279 at 3 of 4). The only difference is "gas data" comes from a "gas source" in the agreed construction, as opposed to from "the cylinder" as argued by Airgas in its brief. I think this difference is inconsequential. "Gas source" is recited in claim 1 and Mallinckrodt's expert alleges Airgas' "cylinders" satisfy the "gas source" limitation. ('794 patent at 17:15–32; D.I. 78-1, Ex. Q, at 10 of 429). Airgas seems to think the two are interchangeable, too. (*See* D.I. 120 at 2–3). I think the evidence Airgas used to support its position when it filed its brief also supports its position under the agreed upon construction.

Before the parties agreed to the construction, Mallinckrodt argued that, even using Airgas' interpretation of "gas data," Airgas infringes claim 1, citing its expert's reply report. (D.I. 123 at 4). Airgas argued Mallinckrodt conceded that the gas concentration measured by Ulspira TS is not gas in the cylinder, citing Mallinckrodt's expert's earlier declaration. (D.I. 120 at 3–4; D.I. 78-1, Ex. Q). Both parties have pointed to contentions in Mallinckrodt's expert's reports that support their respective positions. I do not think Mallinckrodt has met its burden to show that it is likely to prove Airgas infringes claim 1 of the '794 patent.

d. Validity of the '794 Patent

Mallinckrodt argues it is likely to succeed on validity challenges to claim 1 of the '794 patent. (D.I. 76 at 9).

Airgas argues claim 1 of the '794 patent is invalid under Mallinckrodt's "new interpretation" of "gas data." (D.I. 120 at 6). Airgas argues claim 1 is invalid as anticipated over U.S. Patent No. 5,558,083 ("Bathe"), which issued in 1996 and shares the same lead inventor as the '794 patent. (*Id.*). Airgas argues all the limitations of claim 1 are disclosed in Bathe and, though it failed to invalidate the '794 patent in a prior IPR proceeding, it failed due to arguments made by Mallinckrodt about "gas data" that it now seeks to avoid. (*Id.*).

I do not think Airgas has raised a substantial question as to the validity of claim 1 of the '794 patent. The '794 patent withstood a validity challenge at the PTAB over the same prior art. (*Id.*). Airgas' argument hinges on its contention that Mallinckrodt attempts to allege a broad construction of "gas data" that encompasses the prior art. (D.I. 120 at 6–7). I think that argument is moot now that Mallinckrodt accepted Airgas' "gas data" construction. (D.I. 279 at 3 of 4; D.I. 287 at 1). Airgas does not argue the PTAB was wrong. (D.I. 120 at 6–7). I think

Airgas has not raised a substantial question of validity and Mallinckrodt has shown a reasonable likelihood that the attack on the validity of the '794 patent will fail.

For the reasons explained above with respect to both the '741 and '794 patents, I think Mallinckrodt has failed to show that it is likely to succeed on the merits.

2. Irreparable Harm

"A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). The moving party must show that immediate irreparable harm—rather than possible harm in the future—is likely in the absence of an injunction. *See Winter*, 555 U.S. at 22 ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy."). The moving party must make a "clear showing" regarding a likelihood of irreparable harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

Mallinckrodt offers four arguments to show it will be irreparably harmed by Airgas' supposed infringement. (D.I. 76 at 11–15). First, Mallinckrodt argues its customer contracts and market share will be harmed. (*Id.* at 11). Mallinckrodt points to the nature of iNO contracts, explaining they are finalized months in advance and can last for years. (*Id.* at 11–12). Mallinckrodt argues Airgas could bid on its expiring contracts, 91% of which were up for renewal within eighteen months of Mallinckrodt filing its motion. (*Id.*). Mallinckrodt also argues Airgas has a competitive advantage in the marketplace because of its size and will likely destabilize the iNO market by driving down prices and making it difficult for Mallinckrodt to retain customers. (*Id.* at 12–13). Second, Mallinckrodt argues it will be harmed by Airgas'

lower-priced generic, which will result in irreversible price erosion for Mallinckrodt's products. (*Id.* at 13). Third, Mallinckrodt argues its overall business will be harmed, pointing to its precarious financial situation which includes multiple bankruptcies. (*Id.* at 13). Fourth, Mallinckrodt argues its goodwill will be harmed because it will take the blame if Airgas must exit the market after entry and will need to scale back its support program, potentially harming healthcare providers. (*Id.* at 14–15).

Mallinckrodt argues there is a causal nexus between Airgas' supposed infringement and Mallinckrodt's irreparable harm. (*Id.* at 15). It argues the methods in its asserted claims are the key to providing safe and effective treatment, which drives its products' market success. (*Id.* at 15–16). Mallinckrodt argues its harm is directly tied to Airgas' infringement because Airgas "specifically utilized the patented features to obtain [a generic] approval." (*Id.* at 16).

Airgas argues Mallinckrodt has not met the high standard for irreparable harm. (D.I. 120 at 14). Airgas argues money can adequately compensate Mallinckrodt, rendering an injunction unnecessary. (*Id.* at 15). Airgas argues the harm alleged by Mallinckrodt is speculative. (*Id.*). Airgas argues the iNO market is already competitive, Mallinckrodt's precarious financial situation is not attributable to Airgas, and Mallinckrodt's bankruptcy proceedings have already tarnished its reputation. (*Id.* 15–17).

On December 6, 2024, I issued an oral order requesting an update from Mallinckrodt on its contract renewals. (D.I. 326). Mallinckrodt renewed about 90% of the contracts that were up for renewal in 2023, and about 90% of the contracts that were up for renewal in 2024. (D.I. 330 at 2 of 4). Mallinckrodt claims these renewals came with "significant price concessions." (*Id.*).

Mallinckrodt recently filed another letter, stating Airgas signed a contract in December 2024 with one of Mallinckrodt's (now previous) customers. (D.I. 342 at 2 of 3). The contract is for three years, renewable yearly. (*Id.*).

I do not think Mallinckrodt has shown it will suffer irreparable harm under any of its arguments.

First, Mallinckrodt's argument that it will be harmed because Airgas could bid on its expiring contracts is not convincing. Mallinckrodt renewed about 90% of its contracts, and, regardless, "lost sales standing alone are insufficient to prove irreparable harm." *Automated Merch. Sys. v. Crane Co.*, 357 F. App'x 297, 300 (Fed. Cir. 2009).

According to deposition testimony put into the record by Mallinckrodt, as of October 1, 2024, Airgas had sold zero units of, and obtained zero revenue from, Ulspira. (D.I. 330-1, Ex. F, at 95 of 98 (Hagin testimony)). Based on that testimony and Mallinckrodt's recent letter informing that Airgas had signed a service contract with a customer on December 11, 2024 (D.I. 342 at 1), that service contract appears to be the first time Airgas has taken a customer away from Mallinckrodt. The other non-renewals are likely because of a third competitor—Praxair—in the market. (*See* D.I. 76 at 3).

Mallinckrodt alleges it had to make price concessions to renew its contracts, citing deposition testimony of its Vice President of Sales. (D.I. 330 at 2 of 4). Even if Mallinckrodt had to lower its prices due to Airgas entering the market, it has not shown it will be irreparably harmed in a manner incurable by money should I not issue an injunction. Indeed, that Mallinckrodt continues to operate with many renewed contracts shows it is not being irreparably harmed by Airgas.

Mallinckrodt's argument about market share is also unavailing. Mallinckrodt points to its expert's reports to show it will lose its market share and be irreparably harmed. (D.I. 76 at 11; D.I. 78-3, Ex. R; D.I. 78-4, Ex. S). "[L]ost market share must be proven (or at least substantiated with some evidence) in order for it to support entry of a preliminary injunction." *Automated Merch.*, 357 F. App'x at 301. Mallinckrodt has offered insufficient analysis to allege how much of the market share it will lose should Airgas not be enjoined and why money could not compensate any lost contracts. Again, it is telling that Mallinckrodt renewed many of its contracts. (D.I. 330 at 2 of 4).

Second, as for price erosion, Mallinckrodt has not shown it will be irreparably harmed in a way that money cannot compensate. Mallinckrodt claims competition will erode prices and asserts its relationships with hospitals could deteriorate if it is forced to lower, then raise, its prices. (D.I. 76 at 13–14). Bare allegations of price erosion alone are insufficient to warrant an injunction. *Takeda Pharms. U.S.A. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1349 (Fed. Cir. 2020). Mallinckrodt offers declarations from two experts that say price erosion may occur. (D.I. 78-3, Ex. R ¶¶ 38–42; D.I. 78-4, Ex. S ¶¶ 126–38). I do not think these statements provide sufficient evidence to warrant an injunction. *See Automated Merch.*, 357 F. App'x at 301. Even if Mallinckrodt must lower its prices, I do not think Mallinckrodt has met the high burden to show money cannot compensate its loss if Airgas is found to infringe. Any erosion of Mallinckrodt's relationships with hospitals or hospitals' refusal to pay increased prices is speculative.

Third, Mallinckrodt's argument about harm to its overall business is unconvincing. (D.I. 76 at 14). Layoffs and reduced research and development may be irreparable injuries. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1063 (Fed. Cir. 2010). But Mallinckrodt's

having to do those things is speculative. INOmax accounted for 14.7% of Mallinckrodt's revenue in 2022; considering there is already competition in the market, it is speculative that Mallinckrodt would be forced to take such drastic business measures if Airgas launches a competitive product less than a year before trial. (D.I. 120 at 16–17; D.I. 175). Indeed, Mallinckrodt has not indicated it has taken such measures since Airgas' launch. Further, harm must be immediate, not in the future, to render an injunction proper. *See Winter*, 555 U.S. at 22. Speculation about what Mallinckrodt may or may not have to do in the future is not immediate harm. There is no indication Mallinckrodt has suffered these injuries since this motion has been pending and Airgas entered the market.

Fourth, Mallinckrodt's argument about harm to its goodwill and reputation is unavailing. (D.I. 76 at 14–15). I think it is highly speculative that hospitals would blame Mallinckrodt for any lag time or training mishaps that may occur as a result of a hospital's choice to contract with another iNO provider.

For these reasons, I do not think Mallinckrodt has shown a likelihood of irreparable harm. Since I think there is no irreparable harm, I will not address whether there is a causal nexus between the alleged infringement and harm.

3. Balance of Hardships and Public Interest

The balance of hardships and the public interest factors are considered, only to the extent relevant, after the plaintiff has made a showing on likelihood of success on the merits and irreparable harm. *K.A.*, 710 F.3d at 105. Since I think Mallinckrodt has not made a showing on likelihood of success on the merits or irreparable harm, I will not consider the balance of hardships and public interest factors.

B. Equitable Estoppel

Mallinckrodt argues the doctrine of equitable estoppel helps its case for injunctive relief. (D.I. 76 at 17). Mallinckrodt argues it was prejudiced because Airgas misled it to believe there was a typical FDA thirty-month stay in this case when there, in fact, was not. (*Id.* at 18). Mallinckrodt filed suit within forty-five days after receipt of Airgas' certification challenging validity and infringement of Mallinckrodt's patents, which would usually trigger an automatic thirty-month stay. (*Id.* at 5). Mallinckrodt's asserted patents issued in 2014, but that was after Airgas had filed its ANDA. (*Id.*; '741 patent; '794 patent). Thus, the FDA Orange Book listing of the patents occurred after the filing of the ANDA. (D.I. 76 at 5). There is no thirty-month stay in such a situation. (*Id.*). Mallinckrodt did not know Airgas' ANDA was filed before the asserted patents were listed in the Orange Book, and thus did not know the thirty-month stay would not be triggered. (*Id.* at 5–6, 18). According to Mallinckrodt, Airgas told the FDA there was no thirty-month stay on September 14, 2022, and Mallinckrodt was not informed until June 2023. (*Id.* at 18–19). Mallinckrodt alleges it relied on Airgas' silence and was misled and prejudiced by such silence. (*Id.*).

Airgas offers five reasons why Mallinckrodt's claim for an injunction under equitable estoppel fails: (1) Mallinckrodt misapplies equitable estoppel, which is an affirmative defense, (2) Airgas was not obligated to disclose its confidential FDA communications to Mallinckrodt, (3) Mallinckrodt should have known it was possible there would be no thirty-month stay, (4) Mallinckrodt alleges no facts to show it detrimentally relied on Argas' silence, and (5) Mallinckrodt fails to explain why it was prejudiced by not being able to seek an injunction prior to FDA approval of Airgas' ANDA. (D.I. 120 at 19–20).

Mallinckrodt argues courts have flexibility to apply equitable estoppel to "unique situations," including in an injunction scenario, citing a Federal Circuit case that said, "[E]quitable estoppel is not limited to a particular factual situation." (D.I. 123 at 10).

I do not think principles of equitable estoppel support issuing an injunction. Mallinckrodt cites no cases where equitable estoppel was used, or even considered as a basis, to issue an injunction. (D.I. 123 at 10). I strongly doubt that such a case exists. The case Mallinckrodt cites to support its argument discusses equitable estoppel as a defense and explains that district courts can act in their discretion to decide if the defense applies because "equitable estoppel is not limited to a particular factual situation." *A.C. Aukerman Co. v. R.L. Charles Const. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992).[3] This discussion seems to be exclusive to equitable estoppel as a defense, not as a principle more generally as alleged by Mallinckrodt.

Equitable estoppel is not a factor considered when deciding an injunction motion. *See Winter*, 555 U.S. at 20. Mallinckrodt does not offer it as a defense, which is how equitable estoppel is used in the cases it cites. *See A.C. Aukerman*, 960 F.2d at 1041. I do not think equitable estoppel principles support issuing an injunction in this case.

IV. CONCLUSION

An appropriate order will issue.

[3] The full quote is, "Like laches, equitable estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules." *Aukerman*, 960 F.2d at 1041. A few sentences earlier: "Equitable estoppel to assert a claim is another defense . . . ." *Id.* Nothing in the opinion suggests it has any applicability as a factor favoring the grant of a preliminary injunction.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ORDER

For the reasons stated in the accompanying Memorandum Opinion, Plaintiffs' Motion for Preliminary Injunction (D.I. 75) is DENIED.

IT IS SO ORDERED.

Entered this 12th day of February, 2025

Richard G. Andrews
United States District Judge