NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

INO THERAPEUTICS LLC, MALLINCKRODT HOSPITAL PRODUCTS INC., MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Plaintiffs-Appellants

v.

PRAXAIR DISTRIBUTION INC., PRAXAIR INC.,
Defendants-Appellees

2018-1019

Appeal from the United States District Court for the District of Delaware in No. 1:15-cv-00170-GMS, Judge Gregory M. Sleet.

Decided: August 27, 2019

SETH P. WAXMAN, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by CLAIRE HYUNGYO CHUNG, THOMAS SAUNDERS, DAVID P. YIN.

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K. MURTHY, JASON C. WHITE, Chicago, IL; JULIE S. GOLDEMBERG, Philadelphia, PA.

Before PROST, *Chief Judge,* NEWMAN and DYK, *Circuit Judges.*

Opinion for the court filed by *Chief Judge* PROST.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* NEWMAN.

PROST, *Chief Judge*.

INO Therapeutics LLC, Mallinckrodt Hospital Products Inc., and Mallinckrodt Hospital Products IP Ltd. (collectively, "Mallinckrodt") sued Praxair Distribution Inc. and Praxair Inc. (collectively, "Praxair") for patent infringement. Mallinckrodt asserted five patents related to methods of administering inhaled nitric oxide, including U.S. Patent Nos. 8,282,966 ("the '966 patent"), 8,293,284 ("the '284 patent"), 8,795,741 ("the '741 patent"), 8,431,163 ("the '163 patent"), and 8,846,112 ("the '112 patent") (collectively, "heart failure patents" or "HF patents"). Mallinckrodt also asserted five patents related to devices and methods for administering gas, including U.S. Patent Nos. 8,573,209 ("the '209 patent"), 8,776,794 ("the '794 patent"), 8,776,795 ("the '795 patent"), 9,265,911 ("the '911 patent"), and 9,295,802 ("the '802 patent") (collectively, "delivery system infrared patents" or "DSIR patents"). After a bench trial, the United States District Court for the District of Delaware held all claims of the HF patents ineligible and all claims of the DSIR patents not infringed. For the reasons below, we affirm-in-part, vacate-in-part, and remand.

BACKGROUND

I

Inhaled nitric oxide ("iNO") is a gas that is well known in the prior art. The U.S. Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. N020845 for 100 and 800 ppm nitric oxide for inhalation on December 23, 1999.

Use of iNO gas as a treatment has been "studied and reported in the literature." '741 patent col. 1 ll. 25–26. In particular, since at least the early 1990s, iNO gas has been used to treat infants experiencing hypoxic respiratory failure. According to the Background of the Invention of the '741 patent, iNO "is an approved drug product for the treatment of term and near-term neonates . . . having hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension." *Id.* at col.1 ll. 20–24. Hypoxic respiratory failure is "a condition where oxygen levels in the blood are too low. Nitric oxide functions to dilate blood vessels in the lungs and can thereby improve blood oxygenation." *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1028 (Fed. Cir. 2018) (citing '112 patent col. 3 ll. 34–56).

A dose of 20 ppm iNO was also well known in the prior art for treatment of hypoxic respiratory failure in infants. J.A. 24–25. For example, one of the asserted patents cites as prior art U.S. Patent No. 5,485,827 ("Zapol"), which discloses administering 20 ppm iNO treatment. The Zapol patent issued in 1996.

In 2004, Ikaria Inc. ("Ikaria") commissioned a study involving iNO gas, referred to as the INOT22 study. The INOT22 study observed adverse events in certain patients. Specifically, the study concluded that neonates with a congenital heart condition—known as left ventricular dysfunction ("LVD")—were at an increased risk of pulmonary edema when treated with iNO gas. *See* J.A. 22; '741 patent

col. 9 ll. 48-52. According to the '741 patent specification, the observation of pulmonary edema among patients in the INOT22 study was "of interest because pulmonary edema [had] previously [been] reported with the use of iNO in patients with LVD, and may be related to . . . overfilling of the left atrium." '741 patent col. 13 ll. 26–29.

The effect of iNO gas on a newborn with LVD is a matter of human physiology. J.A. 22. For patients with LVD, the left ventricle cannot sufficiently pump blood out of the heart. LVD patients depend on the right ventricle to shunt blood out, a process that requires constriction of the blood vessels. Administering iNO gas to "neonates or children with LVD may cause pulmonary edema because iNO causes the pulmonary vessels to relax." J.A. 22 (citing Trial Tr. 1201:5–11). Relaxation of those vessels leads to increased pulmonary blood flow, which causes increased pulmonary capillary wedge pressure ("PCWP"), which in turn may lead to pulmonary edema.[1] *Id.* (citing Trial Tr. 1201:12–17, 1203:9–16).

Beginning in 2009, Ikaria's subsidiary, INO Therapeutics, began pursuing patents based on this observation. Eventually, it obtained the five HF patents, which share a common specification. Claim 1 of the '741 patent is representative. Claim 1 recites:

> 1. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:

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[1] Pulmonary capillary wedge pressure "provides an estimate of left atrial pressure." '741 patent col. 5 ll. 20–22.

> (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 left ventricular dysfunction;
>
> (c) *determining* that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide;
>
> (d) *administering 20 ppm inhaled nitric oxide* treatment to the first patient; and
>
> (e) *excluding the second patient* from treatment with inhaled nitric oxide, *based on the determination that the second patient has left ventricular dysfunction*, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.

'741 patent col. 14 ll. 28–49 (emphases added).

INO Therapeutics also obtained patents related to devices and methods for providing iNO gas to patients via gas cylinders. These patents, known as the DSIR patents, share a specification. Claim 1 of the '794 patent is representative of the device claims and reads:

> 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*.

Id. at col. 17 ll. 15–32 (emphases added).

II

Ikaria eventually merged with Mallinckrodt Hospital Products Inc. Mallinckrodt Hospital Products IP Ltd. now owns approved NDA No. N020845 for nitric oxide. Mallinckrodt is the exclusive supplier of iNO gas in the United States, which it sells under the brand name INOmax®.

Praxair is an industrial gas company seeking to sell generic iNO gas cylinders. Praxair filed an Abbreviated New Drug Application ("ANDA") seeking approval to market Noxivent, a generic form of 100 and 800 ppm nitric oxide gas for inhalation.[2] J.A. 8. In addition, Praxair acquired a company that developed a gas delivery system, called the NOxBOXi iNO system.

Mallinckrodt sued Praxair in the District of Delaware in 2015. Mallinckrodt alleged that Praxair's proposed

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[2] Praxair filed a letter advising that the FDA approved its ANDA for Noxivent on October 2, 2018.

ANDA product, Noxivent, infringed Mallinckrodt's HF patents and device claims of the DSIR patents when used with Mallinckrodt's DSIR system. Mallinckrodt also alleged that Praxair's proposed NOxBOXi device infringed a method claim of the DSIR patents.

The case proceeded to a seven-day bench trial. In September 2017, the district court issued a memorandum and order concluding that the HF patents were ineligible under § 101 and the DSIR patents were not infringed.[3] J.A. 1–45, 46. The district court entered judgment. J.A. 47–48.

Mallinckrodt now appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

For entry of judgment under Rule 52(c), we review the district court's factual findings for clear error and its legal conclusions de novo. *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1312 (Fed. Cir. 2016) (citing *EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 273 (3d Cir. 2010)). "Eligibility under 35 U.S.C. § 101 is a question of law, based on underlying facts." *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018).

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[3] In a related appeal, this court recently held that claims 1–11 of the '112 patent were obvious. *Praxair*, 890 F.3d 1024. We concluded that: "It is undisputed that discontinuing a treatment in response to a serious side effect was known in the prior art. It is also undisputed that pulmonary edema is a potentially fatal condition. And [the prior art] taught that administering '[nitric oxide] may lead to pulmonary edema in patients with LVD.'" *Id.* at 1037 (alteration in original) (citations omitted) (holding claim 9 was obvious).

Mallinckrodt's appeal proceeds in three parts. First, Mallinckrodt contends that the district court erred by concluding that the asserted claims of the HF patents are ineligible under § 101. Second, Mallinckrodt argues that the district court erroneously construed the term "verify" when analyzing whether Praxair's proposed gas cylinder infringes the DSIR patents. Third, Mallinckrodt avers that the district court improperly entered judgment on certain unasserted claims. We address each argument in turn.

II

Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, § 101 "contains an important implicit exception. '[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) (alteration in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

To analyze whether a claim involves eligible subject matter, we apply a two-step test. First, we evaluate whether the claims are "directed to" a patent-ineligible concept, such as a natural phenomenon. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 749 (Fed. Cir. 2019) (quoting *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014)). If so, we ask whether the limitations of the claim, considered individually and as an ordered combination, "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 78).

Applying this test, we agree with the district court that claim 1 of the '741 patent is ineligible. It is undisputed that treatment of infants experiencing hypoxic respiratory failure with iNO gas has existed for decades. The inventors observed an adverse event that iNO gas causes for certain

patients. 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. Consequently, the claim here is directed to the natural phenomenon. The claim, apart from the natural phenomenon itself, involves only well-understood, routine, and conventional steps. For the reasons below, claim 1 of the '741 patent fails to recite eligible subject matter.[4]

A

We begin with the first step of the *Mayo*/*Alice* test. A close review of representative claim 1 confirms that the claim is "directed to" a natural phenomenon.

The natural phenomenon here is undisputed. A neonate patient's body will react to iNO gas in a certain way depending on whether or not the patient has a congenital heart condition called LVD. Namely, if the patient has LVD, iNO gas can induce a life-threatening event known as pulmonary edema. As the district court found, Praxair's expert, Dr. Lawson, credibly testified that "the 'standard observation' that a dysfunctional ventricle, in combination with increased blood flow, could cause a backup of venous blood, and, in turn, edema," is a phenomenon "taught to first year medical students." J.A. 22 (quoting Trial Tr. 1203:17–24). In short, while nitric oxide lessens constriction, increases blood flow, and can help normal patients with hypoxic respiratory failure, it will harm a patient suffering from LVD and may even result in death.

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[4] The district court treated claim 1 of the '741 patent as representative of the HF patents. J.A. 21. The parties did not argue the eligibility of the claims separately on appeal.

Turning to the claim language, claim 1 is "directed to" that observation about the natural phenomenon. As drafted, the claim instructs a physician to administer iNO gas to non-LVD patients as before, while now excluding the LVD patients. The exclusion step merely restates the natural law. It expressly recites "excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide." '741 patent col. 14 ll. 45–49.

On appeal, Mallinckrodt characterizes this as "selective administration." Appellant's Br. 3. In Mallinckrodt's view, the "exclusion" step is the reason the claims are not directed to a natural phenomenon as no treatment protocol had screened for such an adverse event before. *Id.* at 27. Ironically, it is this "new" instruction that directs the claims to the particular natural phenomenon here.

Properly understood, this added step is simply an instruction *not* to act. In effect, the claim is directed to detecting the presence of LVD in a patient and then doing nothing but leaving the natural processes taking place in the body alone for the group of LVD patients. Accordingly, the claim is directed to the natural phenomenon.

Indeed, Mallinckrodt cannot dispute that the patented method does not propose a new way of *treating* LVD patients that leverages this discovery (e.g., by titrating the iNO dose). Instead, the claim simply requires that the patient *not* be treated with iNO. This is significant because a claim not to treat—i.e., not to disturb these naturally-occurring physiological processes within the LVD patient's body—risks monopolizing the natural processes themselves.

Resisting this conclusion, Mallinckrodt argues that its claims cover an eligible "method of treatment." Appellant's Br. 33. In Mallinckrodt's view, the HF patent claims

cannot be directed to a natural phenomenon because they recite a treatment step. Specifically, claim 1 requires the affirmative act of "administering 20 ppm inhaled nitric oxide treatment"—a well-known dosage—to a patient without LVD. '741 patent col. 14 ll. 43–44. According to Mallinckrodt, claims drafted to include treatment steps are automatically patent eligible because they involve an "act," and *Mayo* requires nothing more. We disagree.

Mallinckrodt oversimplifies the *Mayo*/*Alice* test and our subsequent case law. The first step of the Supreme Court's test requires us to evaluate whether the claim is "directed to" a natural phenomenon. This determination involves a probing inquiry, which demands a careful reading of the claim language in relation to the particular natural phenomenon in each case. Therefore, in "this first step, we consider the claims 'in their entirety to ascertain whether their character as a whole is directed to excluded subject matter.'" *ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 765 (Fed. Cir. 2019) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)); *see also Athena*, 915 F.3d at 750 ("The step one 'directed to' inquiry focuses on the claim as a whole.").

A closer look at the claim language as a whole confirms that the focus of the invention is not on a new way of actually treating the underlying condition of hypoxic respiratory failure. Nor does it recite a way of reducing the risk of pulmonary edema while providing *some* level of treatment to those patients. Rather, the focus of the invention is screening for a particular adverse condition that, once identified, requires iNO treatment be withheld. A treatment step of administering a prior art dosage is also present. But that step is plainly not the focus of the claimed invention. Mallinckrodt concedes this step is not innovative. Mallinckrodt does not point to "any innovation other than its [purported] discovery of the natural law." *Athena*, 915 F.3d at 752.

Mallinckrodt's reliance on *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), is therefore misplaced. In *Vanda*, the claims recited an actual improved treatment for schizophrenia. The inventors discovered a set of natural relationships between iloperidone, a patient's CYP2D6 metabolism, and the relative risk of "QTc prolongation." *Id.* at 1135. QT prolongation in patients can lead to "serious cardiac problems." *Id.* at 1121. After the risk of QT prolongation was identified for certain metabolizers, the claims did not simply instruct doctors to stop treating those patients with iloperidone based on that information. Instead, the claims leveraged the natural phenomenon to improve treatment for schizophrenia. The claims required the doctor to *treat* a patient with a specific low-dose range if she had a "poor metabolizer genotype" or a specific high-dose range if she did not have the genotype. *Id.* at 1135. By leveraging the natural phenomenon, the specific dosing protocol treated all such patients while still "lowering the risk of QTc prolongation." *Id.* at 1136.

As a result, the majority concluded that the claims in *Vanda* were not "directed to" a natural law under the first step of the analysis. As a whole, the invented treatment recited a specific new way to provide a therapeutic benefit to patients suffering from schizophrenia:

> The claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome. They recite *more than the natural relationship* between CYP2D6 metabolizer genotype and the risk of QTc prolongation. Instead, they recite a method of treating patients based on this relationship that makes iloperidone safer by *lowering the risk of QTc prolongation*.

Id. (emphases added).

Here, the invention does not improve treatment of the underlying conditions in question—pulmonary edema and hypoxic respiratory failure—by taking advantage of the body's natural processes. The inventors observed a natural phenomenon about how the body reacts to iNO gas that appears to be relevant to such diseases: patients with LVD can be harmed while other patients will not face such harm. But the claim language stops well short of an improved treatment method. Unlike *Vanda*, claim 1 does not recite a specific method of treating the disease using an improved set of specific doses in light of this discovery. Instead, the broad directive to exclude all neonatal patients with LVD from iNO treatment (while continuing to treat other patients according to the established dose), collapses into a claim focused on the natural phenomenon.

Our recent decisions following *Vanda* bolster our conclusion. *See Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019); *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019). In *Natural Alternatives* and *Endo Pharmaceuticals*, we explained why the specific method claims at issue recited treatments like those in *Vanda* that utilized the natural law in a patent-eligible manner. In particular, we reasoned that the claims were not "directed to" the natural law itself. Instead of focusing on the information about the natural law, the invention used the law to produce a change in the natural state of the patient to treat a condition.

In *Natural Alternatives*, the claims related to using dietary supplements to increase an athlete's anaerobic working capacity. 918 F.3d at 1341. If certain quantities of beta-alanine are given to a human, "homeostasis is overcome, and the subject's body will produce greater levels of creatine," which "in turn, results in specific physiological benefits for athletes engaged in certain intensive exercise." *Id.* at 1344. "The claims not only embody this discovery, they require . . . actually administer[ing] the dosage form

claimed in the manner claimed, *altering* the athlete's physiology *to provide the described benefits*." *Id.* (emphases added).

Thus, the focus of the invention in that case was a "treatment." The claim used a particular dose of a substance to obtain a specific "benefit" by "altering the subject's natural state." *Id.* at 1345.

Likewise, in *Endo Pharmaceuticals*, we concluded that the asserted claims were not "directed to" patent-ineligible subject matter but "a patent-eligible method of using oxymorphone or a pharmaceutically acceptable salt thereof *to treat pain* in a renally impaired patient." 919 F.3d at 1353 (emphasis added). That conclusion was supported by the specification. "The specification predominantly describes the invention as a method that treats renally impaired pain patients with less oxymorphone while still treating their pain. Indeed, the specification explains that the method 'avoid[s] possible issues in dosing' and allows for treatment with 'the lowest available dose' for patients with renal impairment." *Id.* We reasoned:

> In *Vanda*, the inventors recognized the relationship between iloperidone dosage and the patient's CYP2D6 poor metabolizer genotype, but that was not what they claimed. Similarly, the inventor here recognized the relationship between oxymorphone and patients with renal impairment, but that is not what he claimed. Rather, he claimed an application of that relationship—specifically, a method of treatment including specific steps to adjust or lower the oxymorphone dose for patients with renal impairment.

Id. at 1354 (discussing *Vanda*, 887 F.3d at 1135).

Here, by contrast, the invention is not focused on changing the physiological state of the patient to treat the disease. The claimed invention is focused on screening for

a natural law. Information about an adverse event was observed by the inventors. The patent instructs doctors to screen for that information. Once the information is detected, no iNO treatment is given. And as far as the claim specifies, the patient's state may remain unchanged and natural bodily processes may proceed.

Therefore, the claims here are readily distinguishable from other cases that actually integrate or leverage natural laws to an eligible method of treatment for a particular disease. The patent does not delve into the complexities of dosing to more effectively "treat" different classes of patients as in *Vanda*, *Natural Alternatives*, and *Endo Pharmaceuticals*—by *leveraging* knowledge about a natural correlation to understand what amounts of a particular drug prove therapeutic for each patient.

Mallinckrodt's attempt to liken this case to *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016), is also unsuccessful. The claims in *CellzDirect* are distinguishable for at least two reasons. First, unlike the claims in *CellzDirect*, the HF patents do not claim an improved laboratory method. *Id.* at 1048 ("Indeed, the claims recite a 'method of producing a desired preparation of multi-cryopreserved hepatocytes.'"). Second, the pitfall in the district court's reasoning in *CellzDirect* is not present here. There, the district court essentially stopped its analysis after identifying a "natural law"—the cells' "capability of surviving multiple freeze-thaw cycles." *Id.* We cautioned that the cells' ability to "undergo the process does not make the claim 'directed to' that natural ability." *Id.* Rather, we examined how the claims used that purported natural law and concluded the specific steps used the law to improve the process for actually "preserving" the "cells for later use." *Id.*

Here, a careful reading of the claim language confirms no such corresponding improvement in "treating" patients is achieved. Claim 1 does not recite a set of dosages that

offer some relief to LVD infants while minimizing the risk of an adverse event. It simply sets out an observation of the adverse event, and then instructs the physician to withhold iNO treatment.[5]

In short, after observing an adverse reaction, the inventors could have developed a way to treat the diseases in question here based on their knowledge about the body's ability to undergo the phenomenon. The claimed inventions in *Vanda*, *Natural Alternatives*, and *Endo Pharmaceuticals* all did so. But the HF patent claims do not. Instead, they remain "directed to" the natural phenomenon itself.

Mallinckrodt's remaining arguments carry little force. First, Mallinckrodt takes issue with the district court's phraseology. Specifically, it points to a single sentence in the decision that suggests the first step of *Mayo*/*Alice* is satisfied if the claims "touch upon" the natural law. J.A. 20. However, Mallinckrodt concedes that a few sentences later, the district court recites and applies the proper standard. J.A. 21 ("At step one of the *Alice* two-step framework, the court asks whether the claims are directed to patent ineligible subject matter . . . .").

Next, Mallinckrodt latches onto the Supreme Court's statement in *Mayo* that "a new way of using an existing

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[5] Mallinckrodt's reliance on *Prometheus Laboratories, Inc. v. Roxane Laboratories*, Inc., 805 F.3d 1092 (Fed. Cir. 2015), is unavailing. In *Prometheus*, we noted that "[s]ingling out a particular subset of patients for treatment . . . may reflect a new and useful invention that is patent eligible despite the existence of prior art or a prior art patent disclosing the treatment method to patients generally." *Id.* at 1098. But *Prometheus* did not concern § 101. In addition, Mallinckrodt's claims do not resemble the method of treatment postulated in *Prometheus*.

drug" remains patentable. Appellant's Br. 40 (quoting *Mayo*, 566 U.S. at 87). But Mallinckrodt did not develop a *new use* for an old drug that provides a therapeutic benefit. The claimed method here recites an old use of an old drug. Then it proposes no use. Per the exclusion step, the identified patient population is simply not treated with iNO at all. Mallinckrodt cites no authority for the proposition that such claims constitute an eligible new "use" as contemplated by *Mayo* and its progeny.

Finally, Mallinckrodt contends that neither the Supreme Court nor this court has held that a "new protocol" is ineligible subject matter. Appellant's Br. 35. But a patent draftsman's decision to pen a claim as a "protocol" does not exempt those claims from being scrutinized under the Supreme Court's controlling two-part test. As with all patent claims, we must first determine whether the claimed method is "directed to" a natural phenomenon. Having done so, we turn to the second step of the analysis.

B

Mallinckrodt contends that the district court erred at the second step of the *Mayo*/*Alice* test by concluding that the additional limitations do not recite an "inventive concept" that transforms the claims. In response, Praxair argues that the additional limitations amount to nothing more than routine and conventional steps and a general instruction to apply the natural phenomenon.

Under the second step, we examine the elements of the claims, individually and as an ordered combination, to determine whether they contain an "inventive concept" sufficient to "transform the claimed naturally occurring phenomena into a patent-eligible application." *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017) (citing *Mayo*, 566 U.S. at 71–72). "A claim that recites an abstract idea, law of nature, or natural phenomenon must include 'additional features' to ensure 'that the [claim] is more than a drafting effort

designed to monopolize the [abstract idea, law of nature, or natural phenomenon].'" *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015) (alterations in original) (quoting *Mayo*, 566 U.S. at 77–78). "[S]imply appending conventional steps, specified at a high level of generality" to the claimed law does not make it patentable. *Mayo*, 566 U.S. at 82.

Critically, the "inventive concept necessary at step two of the *Mayo*/*Alice* analysis cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016). "That is, under the *Mayo*/*Alice* framework, a claim directed to a newly discovered law of nature (or natural phenomenon or abstract idea) cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility; instead, the application must provide something inventive, beyond mere 'well-understood, routine, conventional activity.'" *Id.* (quoting *Mayo*, 566 U.S. at 73).

Mallinckrodt does not meaningfully dispute the district court's findings that the various steps of claim 1 of the '741 patent are routine and conventional. Here, "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Mayo*, 566 U.S. at 73.

First, the claim recites the step of "identifying" candidates for treatment with 20 ppm iNO. As the district court found, "[t]he specification . . . makes it clear that identifying patients who have hypoxic respiratory failure and are candidates for 20 ppm of iNO treatment is routine and conventional in the art." J.A. 24 (discussing '741 patent col. 1 ll. 20–24, 49–50).

We then turn to the two "determining" steps. The claim instructs a doctor to determine that a first patient "does not have left ventricular dysfunction" and determine

that a second patient "has left ventricular dysfunction, [putting that patient] at particular risk of . . . pulmonary edema upon treatment with inhaled nitric oxide." '741 patent col. 14 ll. 39–42. Mallinckrodt concedes it did not invent a new way of detecting LVD. Indeed, as the district court concluded, "the specification explicitly states that '[i]dentifying patients with pre-existing LVD is known to those skilled in the medicinal arts, and such techniques for example may include assessment of clinical signs and symptoms of heart failure, or echocardiography diagnostic screening.'" J.A. 24–25 (quoting '741 patent col. 5 ll. 15–19).

The next step—"administering" a dosage of 20 ppm of iNO gas—is well-known. *See* J.A. 25 (quoting '741 patent col. 14 ll. 43–44). Mallinckrodt does not challenge the district court's finding on this point.

Finally, the last step of claim 1 directs physicians to "exclud[e]" a patient with LVD from iNO treatment because of the determination that he is at an increased risk of pulmonary edema when treated with iNO. '741 patent col. 14 ll. 45–49. As discussed above at length, this "do not treat" step essentially embodies the natural phenomenon at issue in this case—the insight that nitric oxide will adversely affect a neonate with LVD. "To transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo*, 566 U.S. at 72. This would be quite a different case if the inventors had invented a new way of titrating the dose. But this claim, unaccompanied by a recitation of some affirmative treatment, is directed to the natural law.

In essence, claim 1 boils down to an instruction to doctors: when treating neonatal patients with iNO gas, take into account their natural reaction to iNO gas. Do not give iNO gas to patients with LVD; otherwise, proceed with treatment. Any other steps are either necessary to

manifest the natural law or are undisputedly routine and conventional.

As in *Mayo*, such an instruction, even when viewed as an ordered combination with other active steps, does not transform the claims. In *Mayo*, the Court reasoned that "[a]nyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Mayo*, 566 U.S. at 79.

The same is true with the natural phenomenon here that iNO gas causes an adverse reaction in LVD patients. Anyone who wants to use the natural phenomenon must first identify "candidates for inhaled nitric oxide gas treatment" and determine whether a given patient has the LVD heart condition. In turn, the claimed combination of treating patients without LVD with an existing dosage while excluding patients with LVD from iNO treatment amounts to little more than an instruction to doctors to "apply" the applicable law when treating their patients.

Therefore, whether viewed individually or as an ordered combination, the claims here do not recite a patent-eligible application under the second step of *Mayo*/*Alice*.

Even if a newly discovered natural law could somehow render the claims patent eligible at step two of *Mayo*/*Alice*, that is not the situation here. Although the inventors claimed to have discovered that administration of iNO to neonates with LVD "may be detrimental," the specification suggests otherwise. '741 patent col. 9 l. 51. The specification explicitly notes that the incidence of pulmonary edema among patients in the INOT22 study was "of interest because pulmonary edema [was] previously reported with the use of iNO in patients with LVD, and may be related to . . . overfilling of the left atrium." *Id.* at col. 13 ll. 26–29. The district court found the instruction to "exclude"

patients potentially experiencing an adverse event was conventional. The court's finding was based in part on admissions from one of the named inventors. J.A. 26 n.5 (citing Trial Tr. 641:25–642:4); *see also* J.A. 26 ("Plaintiffs cannot seriously contend that it is a new practice to exclude certain patients from treatment with a drug when those patients are at an increased risk of experiencing negative side effects from the drug.").

Mallinckrodt argues there were benefits to not treating LVD patients with iNO. According to Mallinckrodt, its amended protocol resulted in "a 90% reduction in severe adverse events." Appellant's Br. 9. Relatedly, Mallinckrodt argues its alleged discovery "upend[ed]" the prior standard of care as no FDA counterindication existed for patients with pre-existing LVD. Appellant's Reply Br. 20. But these arguments fail. These benefits result solely from the alleged discovery of the phenomenon itself—not an inventive application of it, and the patent applicant here did not in fact discover the natural phenomenon.

Mallinckrodt's argument that its claims do not broadly preempt treatment of neonates with LVD is a red herring. Appellant's Br. 48. As it stands, Mallinckrodt has observed that use of iNO gas with LVD patients suffering from hypoxic respiratory failure leads to adverse events. It has claimed not treating those patients with the gas. At least as a practical matter, as far as the record shows, this claim is broadly preemptive of uses of the natural phenomenon. Regardless, Mallinckrodt's attempt to argue that a lack of total preemption confers *eligibility* misses the mark. "Preemption is sufficient to render a claim *ineligible* under § 101, but it is not necessary." *Athena*, 915 F.3d at 752 (emphasis added).

Inviting us to ignore the governing inquiry under *Mayo*/*Alice*, Mallinckrodt makes several policy arguments. Principally, Mallinckrodt argues that the district court's decision hampers the emerging field of personalized

medicine. Appellant's Br. 50–51. Mallinckrodt's position is unpersuasive. While § 101 precludes bare monopolies on natural phenomena, new and inventive methods of treatment in personalized medicine remain patent eligible.[6] We conclude that the specific claims here are ineligible. But we emphasize the narrowness of our holding today, which is limited to the particular claims at issue and is driven by the particular circumstances here.

For the reasons above, we affirm the district court's decision that claim 1 of the '741 patent is ineligible under § 101, as are asserted claims 4, 7, 9, and 18 of the '741 patent, claim 20 of the '966 patent, claim 18 of the '284 patent, claims 9, 11, 13, and 15 of the '163 patent, and claims 1, 7, and 9 of the '112 patent.

III

Turning to the DSIR patents, Mallinckrodt takes issue with the district court's interpretation of the "verify" term. Claim 1 of the '794 patent requires the device "verify one or more of the gas identification, the gas concentration and that the gas is not expired." '794 patent col. 17 ll. 30–32.

The term "verify" was never formally construed by the district court. Thus, the district court applied the term's plain and ordinary meaning. It found that the system does not "verify" the gas data when one simply takes a meter from Mallinckrodt's gas cylinder (containing data about the gas from the manufacturer) and uses it with a Praxair gas

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[6] To be certain, we do not hold that every treatment that contemplates adverse events—whether known or newly discovered—will lack claim elements that prove transformative. But, here, proceeding with the prior art treatment for hypoxic respiratory failure while offering no solution for neonatal patients with LVD does not transform these particular claims.

cylinder (which does not contain a meter with gas data). *See* J.A. 36–39. The district court interpreted the claim term to require that the gas delivery system verify data about the actual gas in the "gas source" (i.e., the cylinder being used). J.A. 37–38. In Mallinckrodt's view, the DSIR patent claims are practiced when any iNO cylinder is combined with a circuit storing gas data—even if the data is unrelated to the particular gas in the cylinder. Mallinckrodt's attempt to undo its loss on infringement by redrawing the metes and bounds of the claim is unavailing.

The plain language of the representative claim confirms the district court's determination was correct. Claim 1 of the '794 patent recites a "gas delivery device" with "a gas source" to provide iNO "therapy gas." '794 patent col. 17 ll. 15–16. "A valve" is used to control the gas via a "control module." *Id.* at col. 17 ll. 17–20. Finally, there is a "circuit," which includes "a memory" to store "gas data" about "gas identification, gas expiration date and gas concentration." *Id.* at col. 17 ll. 23–26. A "processor and a transceiver" send gas data between the circuit's memory and the control module on the valve to "verify one or more of *the gas* identification, *the gas* concentration and that *the gas* is not expired." *Id.* at col. 17 ll. 27–32 (emphases added). The "gas" throughout the claim consistently refers to the specific contents of the "gas source" administered to the patient. Thus, "gas data" relates to the actual gas inside the cylinder.

This conclusion is further confirmed by the specification. The fundamental purpose of the invention is to improve patient safety by reducing error during the administration of iNO gas. As the specification states, "[t]here is a need for a gas delivery device that integrates a computerized system to ensure that patient information contained within the computerized system matches the gas that is delivered by the gas delivery device." *Id.* at col. 1 ll. 40–43.

Accordingly, the district court's interpretation of the plain language of the claims was correct. Mallinckrodt does not dispute that under the district court's interpretation of the plain meaning of the claims, Praxair's cylinder does not infringe.

Relatedly, the district court found that because Praxair's delivery system (NOxBOXi) does not "verify" the gas either, it does not infringe claim 15 of the '794 patent, which is representative of the DSIR patents' method claims. We agree. Mallinckrodt's expert, Dr. Schaafsma, testified that the NOxBOXi's gas data does not come from the gas source. J.A. 40–41 (discussing J.A. 1449, 1451). Instead, Dr. Schaafsma testified that "verification" could occur when certain data from one circuit board—the MediBoard—is compared to data on another circuit—the Single Board Computer ("SBC"). *Id.* But as the district court found, the MediBoard's data is populated with the value held by the SBC. *Id.* Therefore, under Mallinckrodt's reading, the data is "verified" by comparing the value to itself. The district court correctly found it difficult "to understand how comparing a value to itself could satisfy the claim phrase 'verify the gas data.'" *Id.* In light of the intrinsic evidence above, Mallinckrodt's position is unsupported. Therefore, we affirm the district court's determination of noninfringement for asserted claims 1 and 15 of the '794 patent, claim 6 of the '209 patent, claims 1 and 15 of the '795 patent, claims 1 and 10 of the '911 patent, and claims 1 and 10 of the '802 patent.

IV

Finally, Mallinckrodt challenges a technical error in the district court's final judgment order. Specifically, the district court did not limit its ruling to the asserted claims before it. Instead, the court erroneously made a blanket ruling that each Mallinckrodt patent in its entirety was invalid or not infringed. J.A. 47. In Praxair's view, the judgment was justified. But Praxair offers no authority for

expanding a judgment in this manner to unasserted claims under the present circumstances. Therefore, we remand to allow the district court to correct this clerical error.

CONCLUSION

For the reasons above, we affirm the district court's conclusion regarding § 101 and noninfringement as to the claims at issue, but vacate and remand for the limited purpose of correcting the judgment as to unasserted claims.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

The parties shall bear their own costs.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

INO THERAPEUTICS LLC, MALLINCKRODT HOSPITAL PRODUCTS INC., MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Plaintiffs-Appellants

v.

PRAXAIR DISTRIBUTION INC., PRAXAIR INC.,
Defendants-Appellees

2018-1019

Appeal from the United States District Court for the District of Delaware in No. 1:15-cv-00170-GMS, Judge Gregory M. Sleet.

NEWMAN, *Circuit Judge*, concurring-in-part, dissenting-in-part.

I concur in correction of the technical error, where the district court included in its decision some claims that were not there at issue. However, I respectfully dissent from the majority's rulings that the claims at issue are ineligible for patenting under Section 101. The claims are for a method of medical treatment—a class of subject matter whose eligibility under section 101 is established by precedent.

The claimed inventions are for a method of treatment of hypoxic respiratory failure in neonates, and an apparatus for administering dosages of gaseous nitric oxide for this purpose. INO and Mallinckrodt scientists discovered the relationship of inhaled nitric oxide to pulmonary edema in certain infants, and also discovered why certain infants experience adverse effects. These scientists then developed a method and apparatus of treatment, avoiding adverse events.

The method that is described and claimed does not exist in nature; it was designed by and is administered by humans. However, the majority holds that this method is ineligible for patenting because the claims are directed to a "natural phenomenon." Maj. Op. at 8–9 ("The inventors observed an adverse event that iNO gas causes for certain patients. The patent claim does no more than add an instruction to withhold iNO treatment from the identified patients . . . so it covers a method in which, for the iNO-excluded patients, the body's natural processes are simply allowed to take place."). The majority does not acknowledge that the claimed multi-step method of treatment of hypoxic respiratory failure does not occur in nature. The majority improperly separates the claims into old and new steps, describes some claim steps as a "natural phenomenon" and some steps as "well-understood, routine, and conventional steps," and avoids the requirement that a claimed invention is considered as a whole.

Mallinckrodt states that: "It would be remarkable and unprecedented to conclude that a new treatment protocol that is capable of reducing the incidence of severe adverse events by as much as 90% is not inventive." Appellants Br. 46. The majority's holding contravenes the section 101 guidance of the Supreme Court, and directly contradicts this court's precedent applying section 101 to methods of medical treatment. The Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), cautioned against misapplication of its holding,

reaffirming that a "new way of using an existing drug" is eligible for patenting under section 101. *Id.* at 87. My colleagues nonetheless hold that since the effect of nitric oxide is "human physiology," Maj. Op. at 4, and since physiologic response is a natural phenomenon, this method of treatment is ineligible for patenting. *Id.* at 8–9.

Heretofore, Federal Circuit precedent has been reasonably consistent in holding that methods of medical treatment are eligible for patenting. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1367–68 (Fed. Cir. 2019) (Newman, J., dissenting from denial of rehearing *en banc*) (collecting cases on eligible methods of treatment and ineligible methods of diagnosis). The subject matter herein routinely complies with section 101; the court mis-steps in holding that "[t]he natural phenomenon here is undisputed," whereby the method of treatment is also deemed to be a natural phenomenon. Maj. Op. at 9.

Mallinckrodt's method of treatment may or may not pass the tests of sections 102 or 103,[1] but this court's precedent and that of the Supreme Court do not exclude methods of treatment from access to the patent system under section 101. Today's change of law adds to the inconsistency and unpredictability of this area of patent-supported innovation.

The INOT22 Study led to the claimed method

Treatment of neonates with gaseous nitric oxide was approved by the FDA in 1999 for "the treatment of term

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[1] In a separate proceeding, the Patent Trial and Appeal Board in *Inter Partes Review* held invalid the claims of one of the patents here in suit, on the ground of obviousness in view of prior art, section 103. The Federal Circuit affirmed. *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024 (Fed. Cir. 2018).

and near-term . . . neonates having hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension." '741 patent, col. 1, ll. 20–24. The patent explains that the treatment was contraindicated for neonates who were known as dependent on right-to-left shunting of blood. *Id.*, col. 3, ll. 53–56.

In 2004 Mallinckrodt sponsored a clinical study known as INOT22, seeking to understand the occasional severe adverse effects of nitric oxide, including pulmonary edema and death. *Id.*, col. 12, ll. 49–58. The study led to understanding the relation among left ventricular dysfunction, pulmonary capillary wedge pressure, and the adverse events. *Id.*, col. 12, ll. 55–61. Mallinckrodt then designed a treatment protocol for neonates that reduced the adverse events. In 2009 the FDA approved this protocol, which is the basis of the patents in suit, and Praxair's ANDA and this Hatch-Waxman litigation.

Claim 1 of the '741 patent is deemed representative of the method-of-treatment claims.

> 1. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) 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 left ventricular dysfunction;
>
> (c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to

> pulmonary edema upon treatment with inhaled nitric oxide;
>
> (d) administering 20 ppm inhaled nitric oxide treatment to the first patient; and
>
> (e) excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.

The claims recite a multi-step method of administering inhaled nitric oxide so that patients with left ventricular dysfunction are at reduced risk of adverse events. This method is not a law of nature, it is not a natural phenomenon.

The majority's argument that a method of treatment of an affliction affecting human physiology is ineligible under section 101 contravenes precedent. *See, e.g.*, *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048–49 (Fed. Cir. 2016) (method of treating disease "to achieve 'a new and useful end,' is precisely the type of claim that is eligible for patenting" (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014))). My colleagues acknowledge that the claims include "[a] treatment step of administering," Maj. Op. at 11, but state that this step is "not the focus of the claimed invention," *id.*, and that "[t]he claimed invention is focused on screening for a natural law," *id.* at 14–15. However, patent eligibility is determined not for isolated steps, but for the claimed invention as a whole. Eligibility does not depend on whether some of the claim steps were known. The Court reiterated in *Diamond v. Diehr*, 450 U.S. 175 (1981):

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is

> inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.

Id. at 188; *see Parker v. Flook*, 437 U.S. 584, 594 (1978) ("[A] patent claim must be considered as a whole."); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961) ("[I]f anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant."). The majority's analysis is an explicit departure from this rule.

The majority's ruling conflicts with extensive precedent

Heretofore, this court has appropriately viewed section 101 eligibility for method-of-treatment inventions. *See, e.g.*, *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018) (method of treatment of schizophrenia with the drug iloperidone where the dose is adjusted based on whether the patient is a CYP2D6 poor metabolizer); *Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019) (method of increasing athletic performance by administering beta-alanine); *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019) (method of treating patients with oxymorphone based on the discovery that patients with impaired kidney function need less oxymorphone for pain relief). Despite precedent, the majority today holds that this method-of-treatment is not patent-eligible under section 101.

Section 101 states the eligibility for patenting of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," while "subject to the conditions and requirements of this title." The purpose of section 101 is to introduce the statute and define the scope of its subject matter, as distinguished from the subject matter of copyright, also

authorized in Article I, Section 8, Clause 8 of the Constitution. In turn, eligible subject matter is reviewed for compliance with the conditions of patentability in sections 102, 103, 112, and the rest of Title 35.

The majority attempts to meet these concerns by stating "we emphasize the narrowness of our holding today, which is limited to the particular claims at issue and is driven by the particular circumstances here." Maj. Op. at 22. This disclaimer appears at the end of a lengthy exposition, whose wide-ranging pronouncements of law and policy are not tied to narrow circumstances or claims. The persistent theme of the majority's analysis is that if a claim contains limitations that concern human physiology, ineligibility arises under section 101, whether or not the claimed method of medical treatment meets the requirement of patentability.

The majority's broad pronouncement of ineligibility of medical treatment that relates to human physiology not only contravenes precedent, but contravenes the national interest in achieving new methods of medical treatment with the assistance of the patent incentive.

The policy of patent-supported innovation

My colleagues state that the new method presented by INO and Mallinckrodt is ineligible under section 101 because it is "broadly preemptive of uses of the natural phenomenon," Maj. Op. at 21, and "risks monopolizing" information. *Id.* at 10. We are not told how this method preempts any known or unknown uses of this "natural phenomenon" or forecloses use of scientific information.

The patents at issue arose from discovery of the relation among left ventricular dysfunction, gaseous nitric oxide, and pulmonary edema—a discovery disclosed in the patent for all to understand and study and evaluate and test and improve upon. The Court has reiterated, "the federal patent system thus embodies a carefully crafted

bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). *See J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974))).

My colleagues' position that patents impede scientific and technologic advance ignores the principle, first stated in *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813), that: "It could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." This common-law research exemption was remarked in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., dissenting) ("Today's accelerated technological advance is based in large part on knowledge of the details of patented inventions and how they are made and used. Prohibition of research into such knowledge cannot be squared with the framework of the patent law."). *See also* Giles S. Rich, *Principles of Patentability*, 28 Geo. Wash. L. Rev. 393, 400 (1960) ("It should never be forgotten that *patented* inventions are published and become a part of the technical literature. This publication itself promotes progress in the useful arts and it is the prospect of patent rights which induces disclosure and the issuance of the patent which makes it available.") (emphasis original).

Patents provide the economic incentive for medical scientists and industries to devise new treatments to serve the afflicted public. My colleagues' holding that such inventions are broadly ineligible for patenting, will simply add disincentive to medical advance. From my colleagues' holding that this improved method of treatment of

neonates having left ventricular dysfunction is ineligible under section 101, I respectfully dissent.