United States Court of Appeals for the Federal Circuit

PRAXAIR DISTRIBUTION, INC.,
Appellant

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Cross-Appellant

2016-2616, 2016-2656

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-00529.

Decided: May 16, 2018

WILLIAM R. PETERSON, Morgan, Lewis & Bockius LLP, Houston, TX, argued for appellant. Also represented by SANJAY K. MURTHY, MICHAEL J. ABERNATHY, MARIA DOUKAS, Chicago, IL; JULIE S. GOLDEMBERG, Philadelphia, PA.

KENNETH G. SCHULER, Latham & Watkins LLP, Chicago, IL, argued for cross-appellant. Also represented by DAVID K. CALLAHAN, MARC NATHAN ZUBICK; GABRIEL BELL, INGE OSMAN, JONATHAN M. STRANG, Washington, DC; ROBERT STEINBERG, Los Angeles, CA.

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

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion filed by *Circuit Judge* NEWMAN, concurring in the judgment.

LOURIE, *Circuit Judge.*

Praxair Distribution, Inc. ("Praxair") appeals from the *inter partes* review decision of the United States Patent and Trademark Office Patent Trial and Appeal Board ("the Board") holding claim 9 of U.S. Patent 8,846,112 (the "'112 patent") not unpatentable as obvious under 35 U.S.C. § 103 (2006).[1] *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, No. IPR2015-00529, 2016 WL 3648375 (P.T.A.B. July 7, 2016) ("*Decision*"). Mallinckrodt Hospital Products IP Ltd. ("Mallinckrodt") cross-appeals from the same decision holding, *inter alia*, claims 1–8 and 10–11 unpatentable as obvious. Because we conclude that the Board did not err in its conclusions as to claims 1–8 and 10–11, but did err with respect to claim 9, we affirm the Board's decision in part and reverse it in part.

BACKGROUND

Mallinckrodt owns the '112 patent, which is directed to methods of distributing nitric oxide gas cylinders for pharmaceutical applications. Inhaled nitric oxide is approved by the U.S. Food and Drug Administration ("FDA") for treating neonates with hypoxic respiratory failure, '112 patent col. 1 ll. 21–25, a condition where oxygen levels in the blood are too low. Nitric oxide func-

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[1] Because the application of the '112 patent was filed before March 16, 2013, the pre-Leahy-Smith America Invents Act version of § 103 applies. *See* Pub L. No. 112-29, 125 Stat. 284 (2011); 35 U.S.C. § 103 (2006).

tions to dilate blood vessels in the lungs and can thereby improve blood oxygenation. *Id.* col. 3 ll. 34–56. Mallinckrodt exclusively supplies inhaled nitric oxide in the United States for pharmaceutical use under the brand name INOmax®.

Administering nitric oxide may cause harmful side effects. For example, the specification of the '112 patent describes a clinical study, INOT22, which identified patients with preexisting left ventricular dysfunction ("LVD") as having an increased risk of serious adverse events ("SAEs"), which include pulmonary edema ("PE"), when administered nitric oxide. *Id.* col. 14 ll. 17–25. Patients with preexisting LVD are characterized by having a pulmonary capillary wedge pressure ("PCWP") greater than 20 mm Hg. *Id.* col. 1 ll. 56–61. Accordingly, after identifying the relationship between preexisting LVD and SAEs in patients administered nitric oxide, the INOT22 protocol was updated to exclude from the study patients having PCWP greater than 20 mm Hg. *Id.* col. 14 ll. 19–21. The specification of the '112 patent, however, advises only that "[t]he benefit/risk of using [inhaled nitric oxide] in patients with clinically significant LVD should be evaluated on a case by case basis," *id.* col. 14 ll. 21–25, and further proposes amending the INOmax prescribing information to include "a precaution for patients with LVD," *id.* col. 9 ll. 51–53.

The claims of the '112 patent generally require supplying a medical provider with a cylinder of nitric oxide gas and providing the medical provider with certain prescribing information relating to the harmful side effects of nitric oxide for certain patients identified in the INOT22 study. Claim 1 is illustrative and reads as follows:

> 1. A method of providing pharmaceutically acceptable nitric oxide gas, the method comprising:

> obtaining a cylinder containing compressed nitric oxide gas in the form of a gaseous blend of nitric oxide and nitrogen;
>
> supplying the cylinder containing compressed nitric oxide gas to a medical provider responsible for treating neonates who have hypoxic respiratory failure, including some who do not have left ventricular dysfunction;
>
> providing to the medical provider (i) information that a recommended dose of inhaled nitric oxide gas for treatment of neonates with hypoxic respiratory failure is 20 ppm nitric oxide
>
> and (ii) information that, in patients with pre-existing left ventricular dysfunction, inhaled nitric oxide may increase pulmonary capillary wedge pressure (PCWP), leading to pulmonary edema, the information of (ii) being sufficient to cause a medical provider considering inhaled nitric oxide treatment for a plurality of neonatal patients who (a) are suffering from a condition for which inhaled nitric oxide is indicated, and (b) have pre-existing left ventricular dysfunction, to elect to avoid treating one or more of the plurality of patients with inhaled nitric oxide in order to avoid putting the one or more patients at risk of pulmonary edema.

Id. col. 14 ll. 28–52. We refer to the last two claim limitations of claim 1 collectively as the "providing information" limitation.

Certain dependent claims add additional steps directing what a recipient of the provided information should do with it. Claim 3 depends from claim 1 and requires determining that a neonatal patient has preexisting LVD and then "evaluating the potential benefit of treating the [neonatal patient] with 20 ppm inhaled nitric oxide vs. the

potential risk that inhaled nitric oxide could cause an increase in PCWP leading to pulmonary edema" (the "evaluating" limitation). *Id.* col. 14 ll. 57–66. Claim 9 depends from independent claim 7. Claim 7 concludes with a "recommendation that, if pulmonary edema occurs in a patient who has pre-existing [LVD] and is treated with inhaled nitric oxide, the treatment with inhaled nitric oxide should be discontinued" (the "recommendation" limitation). *Id.* col. 15 ll. 60–63. Claim 9 then reads:

> 9. The method of claim 7, further comprising:
>
> performing at least one diagnostic process to identify a neonatal patient who has hypoxic respiratory failure and is a candidate for inhaled nitric oxide treatment;
>
> determining prior to treatment with inhaled nitric oxide that the neonatal patient has pre-existing left ventricular dysfunction;
>
> treating the neonatal patient with 20 ppm inhaled nitric oxide, whereupon the neonatal patient experiences pulmonary edema; and
>
> *in accordance with* the recommendation of [claim 7], *discontinuing the treatment with inhaled nitric oxide due to the neonatal patient's pulmonary edema.*

Id. col. 16 ll. 2–13 (emphases added).

Praxair petitioned for *inter partes* review of claims 1–19 of the '112 patent, which the Board instituted. The Board held that claims 1–8 and 10–19 would have been obvious over the INOmax Label,[2] Bernasconi,[3] Loh,[4] and

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[2] INOmax Final Printed Labeling, NDA 20845, Center for Drug Evaluation and Research, http://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20

Goyal.[5] *Decision*, 2016 WL 3648375, at *22. But the Board concluded that claim 9 was not unpatentable as obvious over those same references. *Id.* at *19.

The present appeal involves several disputes over the Board's claim constructions and obviousness analysis. The Board found that a person of ordinary skill was at least a physician with experience treating pediatric heart and lung disease and administering vasodilators, and found "that the overall level of skill in the art is high." *Id.* at *4. In construing the claims, the Board applied the printed matter doctrine. The Board interpreted the providing information, evaluating, and recommendation claim limitations to be either printed matter or purely mental steps not entitled to patentable weight, as those limitations lacked a functional relationship to the other claim limitations except in claim 9. *Id.* at *9–10. For claim 9, however, the Board interpreted "in accordance with" to mean "based on, or as a result of" the recommendation to discontinue nitric oxide treatment from claim 7, thereby establishing a functional relationship to the recommendation limitation. *Id.* at *11.

The Board also construed "pharmaceutically acceptable nitric oxide gas" in the preambles of claims 1 and 7 as

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845_INOmax_prntlbl.pdf (Aug. 9, 2000) ("INOmax Label").

[3] A. Bernasconi & M. Beghetti, *Inhaled Nitric Oxide Applications in Paediatric Practice*, 4 Images in Paediatric Cardiology 4 (2002) ("Bernasconi").

[4] E. Loh et al., *Cardiovascular Effects of Inhaled Nitric Oxide in Patients with Left Ventricular Dysfunction*, 90 Circulation 2780 (1994) ("Loh").

[5] P. Goyal et al., *Efficacy of Nitroglycerin Inhalation in Reducing Pulmonary Arterial Hypertension in Children with Congenital Heart Disease*, 97 British J. Anaesthesia 208 (2006) ("Goyal").

"nitric oxide gas that is suitable for pharmaceutical use," and rejected Mallinckrodt's proposed construction of "pharmaceutically acceptable" that would require considering information provided in the label of the supplied product. *Id.* at *6–7.

Turning to patentability, the Board found that the cited prior art collectively taught each limitation of claims 1–8 and 10–19 that did have patentable weight, and that a person of ordinary skill in the art would have been motivated to combine the INOmax Label, Bernasconi, Loh, and Goyal references. *Id.* at *14–18. The Board therefore held claims 1–8 and 10–19 unpatentable for obviousness. *Id.* However, the Board did not so conclude with respect to claim 9. The only reference considered by the Board regarding claim 9 was Bernasconi. *Id.* at *19. Bernasconi disclosed administering nitric oxide to newborns with hypoxic respiratory failure at the FDA-recommended dose of 20 ppm. Bernasconi also discussed several reports of "negative effects of inhaled [nitric oxide] in patients with [LVD]," including "rapid left heart failure and pulmonary oedema." J.A. 249. Accordingly, Bernasconi emphasized "the need for careful observation and intensive monitoring during [nitric oxide] inhalation in patients with left ventricular failure." *Id.*

The Board found that Bernasconi did not teach or suggest discontinuing nitric oxide treatment when a patient with LVD experiences a pulmonary edema, but rather, "contrary to the claim language," contemplated administering nitric oxide to patients with LVD as long as they were carefully monitored. *Decision*, 2016 WL 3648375, at *19. Furthermore, the Board found "compelling" Mallinckrodt's argument based on secondary considerations, namely that "if it were obvious to a person of ordinary skill in the art to exclude children with LVD from treatment with [nitric oxide], the experts in the field who designed the [INOT22] study would have excluded those children from the original protocol." *Id.* As a result,

the Board held that Praxair did not prove by a preponderance of the evidence that claim 9 was unpatentable as obvious. *Id.*

Praxair timely appealed from the Board's decision as to claim 9, and Mallinckrodt cross-appealed from the same decision as to claims 1–8 and 10–11. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Our review of a Board decision is limited. *In re Baxter Int'l, Inc.* 678 F.3d 1357, 1361 (Fed. Cir. 2012). We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board's factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Obviousness is a question of law with underlying factual issues, including the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill, and relevant evidence of secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Claim construction is also a question of law that may involve underlying factual inquiries. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 841 (2015). We review the Board's claim construction based solely on intrinsic evidence *de novo*, while we review subsidiary factual findings regarding extrinsic evidence for substantial evidence. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017).

I. CLAIMS 1–8 AND 10

Because it underlies the ultimate obviousness issue, we first address Mallinckrodt's cross-appeal challenging

the Board's application of the printed matter doctrine to claims 1–8 and 10.[6] Mallinckrodt argues that the Board erred in applying the printed matter doctrine during claim construction rather than when it assessed patentability. Mallinckrodt also argues that the Board substantively misapplied the printed matter doctrine by extending it to encompass mental steps. Furthermore, Mallinckrodt contends that the Board erred in construing the term "pharmaceutically acceptable," and that the broadest reasonable interpretation of the term supplies a functional relationship between any claimed printed matter and the other limitations of the claims of the '112 patent. Finally, even assuming the Board properly applied the printed matter doctrine, Mallinckrodt argues that the Board improperly discounted its evidence of secondary considerations.

Praxair responds that, except for claim 9, the Board correctly applied the printed matter doctrine, including to mental steps claimed in the '112 patent. Praxair also argues that the Board correctly construed "pharmaceutically acceptable," and appropriately weighed the evidence of secondary considerations.

Claim limitations directed to printed matter are not entitled to patentable weight unless the printed matter is functionally related to the substrate on which the printed matter is applied. *E.g.*, *In re DiStefano*, 808 F.3d 845, 848 (Fed. Cir. 2015); *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). While early cases developing this doctrine applied it to claims literally encompassing "printed" materials, *e.g.*, *In re Russell*, 48 F.2d 668, 669 (CCPA

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[6] The Board addressed claim 11 together with claims 1–8 and 10 because it erroneously considered claim 11 as only dependent on claim 7, but claim 11 is also dependent on claim 9. Thus we address claim 11 together with claim 9 *infra*.

1931) (claim to phonetically-arranged directory was printed matter), our cases have not limited the doctrine to that particular factual context, *e.g.*, *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) (holding that a claimed step of informing someone about an inherent property of a method was printed matter). Rather, we have held that a claim limitation is directed to printed matter "if it claims the content of information." *DiStefano*, 808 F.3d at 848.

Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010) ("This court has generally found printed matter to fall outside the scope of § 101."); *In re Chatfield*, 545 F.2d 152, 157 (CCPA 1976) ("Some inventions, however meritorious, do not constitute patentable subject matter, e.g., printed matter . . . ."); *cf. Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1349–50 (Fed. Cir. 2014) ("Data in its ethereal, non-physical form is simply information that does not fall under any of the categories of eligible subject matter under section 101."); *Guthrie v. Curlett*, 10 F.2d 725, 726–27 (2d Cir. 1926) (stating that the plot of a printed work may be copyrighted but not patented). While the doctrine's underlying rationale is in subject matter eligibility, its application has been in analyzing other patentability requirements, including novelty under 35 U.S.C. § 102, *e.g.*, *King*, 616 F.3d at 1279, and nonobviousness under 35 U.S.C. § 103, *e.g.*, *In re Huai-Hung Kao*, 639 F.3d 1057, 1072–74 (Fed. Cir. 2011).

If a claim limitation is directed to printed matter, then the next step is to ascertain whether the printed matter is functionally related to its "substrate." Printed matter that is functionally related to its substrate is given patentable weight. *DiStefano*, 808 F.3d at 850. Likewise,

"[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (alteration in original) (internal quotation marks omitted). We have held that merely adding an instruction sheet or other informational content to a drug product is not sufficient to create a functional relationship, even if required by the FDA for approval. *AstraZeneca*, 633 F.3d at 1065 (holding that FDA-required instructions did not create functional relationship to drug); *King*, 616 F.3d at 1279 (same for step of "informing" patient about properties of drug). Rather, the printed matter must be interrelated with the rest of the claim. For example, in *Ngai*, 367 F.3d at 1339, there was no functional relationship between claimed instructions and a diagnostic kit, as the instructions "in no way depend[ed] on the kit, and the kit [did] not depend on the" instructions. *Ngai* distinguished *Gulack*, where there was a functional relationship between printed digits on a circular band because "the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for educational and recreational mathematical purposes." *Id.* (internal quotation marks omitted); *see also In re Miller*, 418 F.2d 1392, 1396 (CCPA 1969) (concluding that there was a functional relationship between a measuring receptacle and "volumetric indicia thereon indicating volume in a certain ratio").

Applying precedent to this case, we agree with Praxair that the Board properly addressed the printed matter doctrine during claim construction. The Board's printed matter analysis here only required analyzing and interpreting the meaning of the claim language. That is claim construction, which is ultimately a legal inquiry. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). And to the limited extent the Board considered extrinsic evidence in weighing competing expert testimo-

ny in arriving at its claim constructions, Mallinckrodt does not point us to any error by the Board in doing so.

Mallinckrodt also argues that the Board erred at the first step of the printed matter analysis by concluding that claim limitations reciting mental steps were not entitled to patentable weight. According to Mallinckrodt, whether claims are directed to mental steps may only be considered in determining patent eligibility, not obviousness, and thus the Board erred in not giving patentable weight to the evaluating limitation of claim 3. Cross-Appellant Br. 27.

We disagree. Like the information claimed by printed matter, mental steps or processes are not patent eligible subject matter. *See, e.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1378 (Fed. Cir. 2016); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011). And while subject matter eligibility underlies the printed matter doctrine, *see AstraZeneca*, 633 F.3d at 1064, many of our printed matter cases have arisen in the context of anticipation or obviousness, *see, e.g.*, *DiStefano*, 808 F.3d at 848 (anticipation); *Kao*, 639 F.3d at 1072 (obviousness); *King*, 616 F.3d at 1278 (anticipation); *Ngai*, 367 F.3d at 1338 (anticipation); *Gulack*, 703 F.3d at 1385 (obviousness). The printed matter doctrine thus raises an issue where the § 101 patent-eligibility inquiry and the § 102 and § 103 novelty and nonobviousness inquiries overlap. *Cf. Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012). Because claim limitations directed to mental steps may attempt to capture informational content, they may be considered printed matter lacking patentable weight in an obviousness analysis. Accordingly, a limitation that merely claims information by incorporating that information into a mental step will receive patentable weight only if the limitation is functionally related to the substrate.

The evaluating limitation in claim 3 is directed to a mental step that is also printed matter. It requires a medical provider to weigh:

> the potential benefit of treating the [neonatal patient] with 20 ppm inhaled nitric oxide vs. the potential risk that inhaled nitric oxide could cause an increase in PCWP leading to pulmonary edema in patients who have pre-existing [LVD], in order to arrive at a decision of whether or not to treat the [neonatal patient] with inhaled nitric oxide.

'112 patent col. 14 ll. 57–66. This limitation merely requires a medical provider to *think about* the information claimed in the providing information limitation of claim 1. But adding an ineligible mental process to ineligible information still leaves the claim limitation directed to printed matter. To hold otherwise would make the printed matter doctrine a dead letter, requiring no more than a "think about it" step to give patentable weight to a claim limitation directed to information content. There is no meaningful distinction between claim limitations directed to written information in *Kao*, *Ngai*, and *AstraZeneca*, verbal information in *King*, and mentally-processed information here. An applicant cannot "continue patenting a product indefinitely provided that they add a new instruction sheet," *Ngai*, 367 F.3d at 1339, or as we now hold, information together with a purely mental step.

Even if the providing information, evaluating, and recommendation limitations are directed to printed matter, Mallinckrodt argues that they are functionally related to the other claim limitations. According to Mallinckrodt, this is because the term "pharmaceutically acceptable" incorporates the claimed information into the concrete step of supplying nitric oxide gas. Cross-Appellant Br. 30–31.

The preambles of independent claims 1 and 7 both recite a "method of providing pharmaceutically acceptable nitric oxide gas." '112 patent col. 14 ll. 28–29, col. 15 ll. 43–44. Applying the broadest reasonable interpretation standard, the Board construed "pharmaceutically acceptable nitric oxide gas" as "nitric oxide gas that is suitable for pharmaceutical use." *Decision*, 2016 WL 3648375, at *4, *7. We agree with the Board that the ordinary meaning of "pharmaceutically acceptable" here only refers to the physical condition of the gas, not prescribing information that may accompany it. If the term "pharmaceutically acceptable" impliedly included the information regarding the relationship between inhaled nitric oxide, LVD, and side effects like pulmonary edema, there would have been no need to explicitly recite that information later in the claim. And even if "pharmaceutically acceptable" did include the informational content, it would only make the claim redundant, not supply a functional relationship, as "providing" a drug product together with FDA-required prescribing information does not suffice to create a functional relationship between the information and methods of providing and potentially administering the drug. *See AstraZeneca*, 633 F.3d at 1065; *King*, 616 F.3d at 1279. Thus the Board did not err either in construing "pharmaceutically acceptable" or in concluding that the term did not create a functional relationship. Mallinckrodt does not specifically point to any other source of a functional relationship. Accordingly, we hold that the printed matter in claims 1–8 and 10 lacks a functional relationship to its substrate.

Mallinckrodt also argues that in construing "pharmaceutically acceptable," the Board violated Mallinckrodt's procedural rights by adopting a claim construction that neither party proposed. *See SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341 (Fed. Cir. 2016), *rev'd on other grounds sub nom.*, *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

Mallinckrodt's argument is meritless. The Board did not "change theories in midstream." *Id.* at 1351. It reasonably declined to construe the generic term "pharmaceutically acceptable" at institution, then rejected Mallinckrodt's further arguments regarding this term in its final decision. Nor did Praxair, as Mallinckrodt alleges, ever agree that the plain and ordinary meaning of "pharmaceutically acceptable" included prescribing information about the product. Rather, the parties litigated the meaning and relevance of the term "pharmaceutically acceptable," and the Board resolved the issue in Praxair's favor. Nothing proffered by Mallinckrodt indicates that the Board violated its procedural rights.

Mallinckrodt's final argument regarding claims 1–8 and 10 is that the Board improperly discounted evidence of secondary considerations. Mallinckrodt contends that we must weigh secondary considerations of nonobviousness even if the secondary considerations only relate to printed matter lacking patentable weight. Specifically, Mallinckrodt argues that the INOT22 study unexpectedly uncovered the potentially harmful effect of inhaled nitric oxide on neonates with preexisting LVD.

While we agree with Mallinckrodt that relevant evidence of secondary considerations must be considered in an obviousness analysis, *see, e.g.*, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), the evidence submitted here was not relevant to claims 1–8 and 10. The only secondary consideration Mallinckrodt alleges is based on the information claimed in the providing information limitation, which we have held lacks any functional relationship to the non-printed matter limitations in claims 1–8 and 10. That claimed information has no patentable weight in an obviousness analysis because printed matter without a functional relationship to a substrate is not eligible subject matter, *see AstraZeneca*, 633 F.3d at 1064. Such printed matter cannot be brought within the ambit of patent eligibility by showing that it

was surprising. No patentable weight means no patentable weight.

Because we conclude that the Board did not err in applying the printed matter doctrine to claims 1–8 and 10, and Mallinckrodt does not on appeal challenge the Board's other findings regarding these claims, we affirm the Board's decision holding claims 1–8 and 10 unpatentable as obvious.

II. CLAIMS 9 AND 11

Praxair argues in its principal appeal that the Board erred in holding claim 9 not unpatentable as obvious. Praxair contends that the Board improperly construed "in accordance with" in claim 9. Properly construed, Praxair argues that there is no functional relationship between the discontinuing step of claim 9 and the recommendation limitation. And even accepting the Board's construction, Praxair argues that claim 9 would have been obvious.

Mallinckrodt responds that the Board correctly construed "in accordance with," and that substantial evidence supports the Board's findings regarding Bernasconi and Mallinckrodt's evidence of secondary considerations.

We assume that the Board properly construed the term "in accordance with" as meaning "based on, or as a result of." Under this construction, claim 9 requires: (1) determining that a neonatal patient has preexisting LVD; (2) treating that neonate with nitric oxide, whereupon the neonate experiences pulmonary edema; (3) providing information and a recommendation to the medical provider to discontinue nitric oxide treatment for a patient with preexisting LVD who experiences a pulmonary edema; and (4) "based on" the recommendation, discontinuing nitric oxide treatment due to the pulmonary edema. *See* '112 patent col. 16 ll. 5–13, col. 15 ll. 53–63. Thus, claim 9 requires a medical provider to take a specific action, discontinuing treatment, as a result of the

recommendation limitation. Both parties agree that this suffices to create a functional relationship, and so do we. By interrelating the claimed information regarding correlations between nitric oxide, LVD, and pulmonary edema with the concrete step of discontinuing treatment because of the information, we agree with Mallinckrodt that the Board did not err in concluding that the printed matter in claim 9 has a functional relationship to the rest of the claim and giving the printed matter patentable weight.

That does not end the inquiry, however, as we must still consider whether claim 9 as a whole would have been obvious to a person of ordinary skill at the time of the invention. In assessing obviousness, the Board found that Bernasconi taught that inhaled nitric oxide may lead to pulmonary edema in patients with LVD, and emphasized the "need for careful observation and intensive monitoring during [nitric oxide] inhalation" in patients with LVD. *Decision*, 2016 WL 3648375, at *13. Nonetheless, the Board held that Bernasconi did not render claim 9 obvious for two reasons, both of which we reject.

First, in addressing the differences between the prior art and claim 9, the Board found that Bernasconi did not "teach[] or suggest[] that treatment with [nitric oxide] should be discontinued in pediatric patients with LVD that experience pulmonary edema," as required by claim 9. *Id.* at *19. Rather, the Board found Bernasconi to be "*contrary to* [its] interpretation of the claim language" because Bernasconi taught "that [nitric oxide] may be given to patients with LVD, as long as those patients are monitored carefully during treatment." *Id.* (emphasis added). The Board's finding is premised on an incorrect reading of claim 9, and under the correct reading Bernasconi is not "contrary to" claim 9. The Board conflated excluding a patient with LVD from nitric oxide treatment and discontinuing nitric oxide treatment in a patient with LVD after that patient experiences a pulmonary edema. But claim 9 does not permit, let alone require, excluding

patients with LVD from nitric oxide treatment. Instead, claim 9 recites that nitric oxide be given to patients with LVD, and be discontinued *if* a pulmonary edema occurs. Thus Bernasconi's teaching that patients with LVD could be treated with nitric oxide if carefully monitored is not contrary to the claim language, and the Board erred by interpreting claim 9 otherwise.

Second, the Board found "compelling" Mallinckrodt's evidence of secondary considerations that "patients were not excluded" from the INOT22 study, despite the known relationship between nitric oxide treatment and pulmonary edema for patients with LVD. *Decision*, 2016 WL 3648375, at *19. The Board found persuasive the inference that "if it were obvious to a person of ordinary skill in the art to exclude" such patients from the study, the researchers conducting the INOT22 study would have done so. *Id.* The Board's secondary considerations analysis also rested on its "excluding" interpretation of claim 9. But, because we conclude that claim 9 requires administering nitric oxide to patients with LVD, Mallinckrodt's evidence of secondary considerations regarding the failure of researchers to exclude such patients from the INOT22 study lacks sufficient nexus to the claim. *See Classco, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016).

In sum, both the Board's findings regarding the differences between the prior art and claim 9 and its findings on secondary considerations depended on an incorrect interpretation of that claim, and we therefore hold that they are not supported by substantial evidence. *See In re Smith Int'l, Inc.*, 871 F.3d 1375, 1384 (Fed. Cir. 2017).

We also conclude that remand is unnecessary. The Board's uncontested findings regarding Bernasconi render claim 9 obvious under the proper reading of the claim. The Board found that Bernasconi taught that nitric oxide treatment may lead to pulmonary edema in patients with

LVD, and emphasized a "need for careful observation and intensive monitoring during [nitric oxide] inhalation" in patients with LVD. *Decision*, 2016 WL 3648375, at *13. Thus, the only remaining question relevant to this appeal is whether "careful observation and intensive monitoring" includes discontinuing nitric oxide treatment when a side effect that warranted such intensive monitoring actually occurs.

It is undisputed that discontinuing a treatment in response to a serious side effect was known in the prior art. *See* INOmax Label, J.A. 334–35. It is also undisputed that pulmonary edema is a potentially fatal condition. *See* '112 patent col. 4 ll. 47–57; *id.* col. 12 l. 62–col. 13 l. 36. And Bernasconi taught that administering "[nitric oxide] may lead to pulmonary edema in patients with LVD." *Decision*, 2016 WL 3648375, at *13. Based on these teachings, we conclude that "there is only one permissible factual finding," *Corning v. Fast Felt Corp.*, 873 F.3d 896, 903 (Fed. Cir. 2017), that "careful observation and intensive monitoring" of patients with LVD treated with nitric oxide, motivated by the dangerous possibility of a pulmonary edema known to result from that treatment, includes or at least suggests to a person of ordinary skill discontinuing nitric oxide treatment after a patient with LVD administered nitric oxide suffers a pulmonary edema. Where the level of ordinary skill in the art is high, *Decision*, 2016 WL 3648375, at *4, and the claim applies a known solution to a known problem, it is "likely the product not of innovation but of ordinary skill and common sense." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). That is the case here. Consequently, we reverse the Board's decision holding that claim 9 is not unpatentable as obvious.

Finally, claim 11 depends from claim 9. The Board erroneously indicated that claim 11 depends only from claim 7, and held claim 11 obvious on that basis. *Decision*, 2016 WL 3648375, at *16–17. Given our conclusion

that claim 9 would have been obvious at the time of the invention, and that Mallinckrodt has not presented any separate argument regarding claim 11, we conclude that the Board's error was harmless.

We have considered Mallinckrodt's remaining arguments, but find them unpersuasive.

The concurrence states that the printed matter doctrine is "not relevant to the claimed method of administering nitric oxide to infants with [LVD]." Concurring Op. at 2. We disagree with the concurrence's characterization of the claims. The claims at issue containing printed matter limitations that we have held lack patentable weight do not have any additional limitations which recite administering nitric oxide to infants and relate functionally to the printed matter limitations. They do not recite "adjusting the nitric oxide treatment according[]" to any claimed information. Concurring Op. at 4. They merely recite providing a canister of nitric oxide gas to a medical provider together with information or information coupled to a purely mental step, with no required adjustment in treatment. The printed matter doctrine is thus relevant to the obviousness of claims consisting of nothing but information or mental processes and functionally unrelated steps already known in the art.

Claim 9, on the other hand, does recite an adjustment in treatment as a result of the claimed information. And for that claim, we agree with the Board that even the claim limitation directed to information has patentable weight, because the claimed adjustment provides a functional relationship to a substrate. Thus, we do not hold that claim invalid because of the printed matter doctrine, but because it would have been obvious to a person of ordinary skill based on the teachings of the prior art.

Finally, it is our task to review decisions based on the grounds relied on by the tribunal being reviewed and on the arguments raised before us. The Board relied on the

printed matter doctrine in its analysis of obviousness, and Mallinckrodt, in its cross-appeal, spent virtually its entire brief on the printed matter doctrine. That is what the majority has reviewed.

CONCLUSION

For the foregoing reasons, we affirm the Board's decision with respect to claims 1–8 and 10–11, and reverse the Board's decision with respect to claim 9.

AFFIRMED IN PART AND REVERSED IN PART

COSTS

Costs to Praxair.

United States Court of Appeals for the Federal Circuit

PRAXAIR DISTRIBUTION, INC.,
Appellant

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Cross-Appellant

2016-2616, 2016-2656

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2015-00529.

NEWMAN, *Circuit Judge,* concurring in the judgment.

I concur in the judgment of unpatentability of claims 1–11. However, I respectfully disagree with the court's view of the "printed matter doctrine" and its application to "information" and "mental steps."

The "printed matter doctrine" does not apply to unprinted matter. My colleagues err in holding that "[b]ecause claim limitations directed to mental steps may attempt to capture informational content, they may be considered printed matter lacking patentable weight in an obviousness analysis." Maj. Op. at 12. Mental steps are mental, not printed. The printed matter doctrine is directed to printed matter, not information and not mental

steps. This "doctrine" is not relevant to the claimed method of administering nitric oxide to infants with left ventricular dysfunction.[1] The claimed method warrants analysis in accordance with the traditional grounds of sections 102, 103, and 112; not as a newly created category within section 101.

The "printed matter doctrine" arose in response to the patenting of business forms. *See* Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility*, 22 Berkeley Tech. L.J. 855 (2007):

> [B]eginning in the mid-nineteenth century, the USPTO and the courts began rejecting applications claiming purportedly novel types of business forms under the "printed matter" doctrine. By most accounts, the doctrine was intended to preserve the boundary between patent and copyright law.

Id. at 860 n.15. The principle was elaborated by Kevin Emerson Collins, *Patent Law's Authorship Screen*, 84 U. Chi. L. Rev. 1603 (2017):

> A book may be a "manufacture" under the plain meaning of the word, but it is not the type of manufacture that Congress meant to make patentable. Much of copyrightable subject matter involves the representation of information—including books, diagrams, and photographs—and it is the printed matter doctrine, operating as part of patent eligibility, that keeps innovation in these subject matters from infiltrating the patent re-

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[1] *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, IPR2015-00529, 2016 WL 3648375 (P.T.A.B. July 7, 2016) ("Board Op."); Paper No. 12 (P.T.A.B. July 29, 2015) ("Institution Dec.").

> gime and upsetting copyright's competition–protection balance.

Id. at 1640–41. Precedent relates to printed documents. *See, e.*g., *In re Russell*, 48 F.2d 668, 669 (CCPA 1931) ("The mere arrangement of printed matter on a sheet or sheets of paper, in book form or otherwise, does not constitute 'any new and useful art, machine, manufacture, or composition of matter,' or 'any new and useful improvements thereof,' as provided in section 4886 of the Revised Statutes, 35 USCA § 31."); *In re Reeves*, 62 F.2d 199, 200 (CCPA 1932) ("It seems to be settled patent law that invention cannot rest alone in novel printing arrangement, although it may reside in some physical structures of printed matter.").

The Federal Circuit summarized, in *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994):

> The printed matter cases "dealt with claims defining as the invention certain novel arrangements of printed lines or characters, useful and intelligible only to the human mind."

Id. at 1583 (quoting *In re Bernhart*, 417 F.2d 1395, 1399 (CCPA 1969)); *see generally* John F. MacNab, *Invention and Patentability Under the Patent Statutes as Applied to So-called Printed Matter and Methods or Systems of Doing Business* 4. J. Pat. Off. Soc. 480 (1921) (explaining that businesses began seeking patent protection after the Court in *Baker v. Seldon*, 101 U.S. 99 (1879) established that authors could no longer receive copyright protection for "printed matter subjects, such as blank books and leaves therefor, ruled in different ways forming rows and columns, headings therefor, spaces for totals, items of special kinds for bookkeeping adapted for different kinds of business or purposes of various natures"). None of these criteria is here present.

Unprinted matter does not become "printed" if it carries information, nor even if it requires thinking, as my colleagues hold. The panel majority holds that patent claims such as these for administering nitric oxide to neonates with cardiac problems are barred as "printed matter" because "adding an ineligible mental process to ineligible information still leaves the claim limitation directed to printed matter." Maj. Op. at 13. However, "printed matter" is not a "mental process," whatever its content.

The creation of a new printed matter doctrine in today's jurisprudence serves no purpose other than adding to the uncertainty of patent eligibility. An illustration is today's decision, where the majority holds that "information"—apparently the information that an infant with hypoxic respiratory failure who also has preexisting left ventricular dysfunction is at increased risk for pulmonary edema, and adjusting the nitric oxide treatment accordingly—violates the printed matter doctrine. This information is described in Bernasconi[2] and other cited references (INOmax Label,[3] Loh,[4] and Goyal[5]), and pa-

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[2] A. Bernasconi & M. Beghetti, *Inhaled Nitric Oxide Applications in Paediatric Practice*, 4 Images in Paediatric Cardiology 4 (2002) ("Bernasconi").

[3] INOmax Final Printed Labeling, NDA 20845, Center for Drug Evaluation and Research, http://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20845_INOmax_prntlbl.pdf (August 9, 2000) ("INOmax Label").

[4] E. Loh et al., *Cardiovascular Effects of Inhaled Nitric Oxide in Patients with Left Ventricular Dysfunction*, 90 Circulation 2780 (1994) ("Loh").

[5] P. Goyal et al., *Efficacy of Nitroglycerin Inhalation in Reducing Pulmonary Arterial Hypertension in*

tentability is readily analyzed under the straightforward procedures of section 103. Review of the cited references supports finding the challenged claims invalid based on an obviousness analysis in accord with the law of obviousness.

The panel majority converts the patentability analysis into eligibility under section 101, and states: "[l]ike the information claimed by printed matter, mental steps or processes are not patent eligible subject matter." Maj. Op. at 12. However, the role of information in patentability depends on the novelty and non-obviousness of the invention as a whole. Neither the inclusion of information in the patent claim, nor the mental component of the practice of process steps, negates eligibility under Section 101. The discovery of previously unknown information may well lead to new and useful technology; and mental steps often are needed to move through a sequential process. The conflation of "information" with "mental steps," whereby both are designated "printed matter," adds neither clarity nor precision to the law.

The majority admonishes that "mental steps may attempt to capture informational content," and deems such attempt inimical to patentability. However, if the "informational content" is novel and non-obvious, it may well constitute patentable subject matter. Analysis of all of the claims herein is readily based on the law of obviousness, for there is extensive precedent on this use of nitric oxide for neonates. It was known that patients with preexisting left ventricular dysfunction are at increased risk for adverse events from inhaled nitric oxide. It is noteworthy that Praxair's petition for inter partes review was on the ground of obviousness, not printed matter.

Children with Congenital Heart Disease, 97 British J. Anaesthesia 208 (2006) ("Goyal").

The INOmax Label contains information regarding iNO uses and contraindications, including a recommended dose of 20 ppm iNO for neonatal patients with hypoxic respiratory failure and a caution that it "should not be used in the treatment of neonates known to be dependent on right-to-left shunting of blood." *See generally* INOmax Label, J.A.331–38; J.A. 335.

Bernasconi reviews "delivery and monitoring aspects of inhaled nitric oxide, its potential toxic and side effects and its applications in several cardiopulmonary disorders in paediatrics," Bernasconi Abstract, and states that the recommended dose for treatment of neonatal hypoxic respiratory failure is 20 ppm. Bernasconi at 4. Bernasconi cautions that iNO may lead to pulmonary edema in neonatal patients with LVD, and emphasizes "careful observation and intensive monitoring during NO inhalation in patients with left ventricular failure." *Id*. at 3.

Loh describes the effects of inhalation of nitric oxide in patients with moderate to severe heart failure due to LVD. Goyal describes a study of the efficacy of inhaled nitroglycerin in reducing pulmonary arterial hypertension in children with congenital heart disease. The prescribing information and warnings combined with the Bernasconi teaching of increased risk for developing pulmonary edema in neonatal patients with LVD, and the need for physicians to monitor such patients, support an obviousness determination of all of the challenged claims.

The Board created this unsound new section 101 ground, stating at "institution" that "the information described in [claim clauses] (i) and (ii) as tantamount to printed matter." Institution Dec. at *8–9. The Board reasoned that although the asserted invention is not directed to printed matter, claim 5 "expressly provides that the information 'appear[s] in prescribing information supplied to the medical provider with the cylinder containing compressed nitric oxide gas.'" *Id*. at *9 (alteration

in original); *see also* Board Op. at *7. The Board then held that the "providing information" limitation is of "no patentable weight" because it "lacks a functional relationship to the remaining claim elements," Board Op. at *8, and that the "evaluating" limitation is of "no patentable weight" because it uses purely mental steps. *Id*. at *10. The Board then excised the "providing" and "evaluating" limitations from the claims, and analyzed patentability based on the remainder of the claims. My colleagues are in accord.

However, the form of analysis whereby limitations are removed from the claim before the claim is analyzed for patentability, is contrary to the patent statute, which requires determination of patentability of the claimed subject matter as a whole. It is improper to pluck limitations out of the claims, as of "no patentable weight," and then to review patentability of the remainder. *See In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) ("Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole."). The Board stated that it afforded no patentable weight to the "providing information" and "evaluating" limitations, but gave patentable weight to the "recommendation" limitation in claim 9. Such piecemeal analysis does not impart precision to patentability analysis.

My colleagues support the Board's analysis, and add that the "providing information" limitation is not of patentable weight because it is "printed matter." Unprinted information or mental steps are not "printed matter." As stated in *Flood v. Coe*, 31 F. Supp. 348, 349 (D.D.C. 1940): "The invention here is more than an arrangement of printed matter on a piece of paper." The Federal Circuit noted in *In re Gulack,* 703 F.2d at 1385 n.8 that:

> A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art.

The *Gulack* court, explaining this doctrine in the early days of the Federal Circuit, stressed the statutory

> requirement that the claim be viewed as a whole in determining obviousness. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The CCPA has considered *all* of the limitations of the claims, including the printed matter limitations, in determining whether the invention would have been obvious. *See In re Royka,* 490 F.2d 981 (CCPA 1974); *In re Cavrich,* 451 F.2d 1091 (CCPA 1971). In *Royka,* 490 F.2d at 985, the CCPA, notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated.

Id.

Some recent cases on "printed matter" have focused on the difference between "substrate" and "function," but the generalization that unprinted matter is printed matter if it is "information" or "mental" departs from the printed matter doctrine. The panel majority errs in endorsing that "a claim limitation is directed to printed matter 'if it claims the content of information,'" Maj. Op. at 10 (quoting *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015)), and that "claim limitations directed to mental steps may attempt to capture informational content, they may be considered printed matter lacking patentable weight in an obviousness analysis." Maj. Op. at 12. This

is not a sound application of either the printed matter doctrine or the law of obviousness.[6]

I conclude that the cited references render all of the claims unpatentable on the ground of obviousness. The error lies in the analysis in which the court, like the Board, first applies the "printed matter doctrine" to remove some limitations from the claim, and then reviews what is left of the claim. Thus I must, respectfully, dissent from the court's reasoning.

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[6] The panel majority states that our review is limited to "the arguments raised before us." Maj. Op. at 20. I suggest that the appellate role is to assure that the case is decided on correct law and fact.