

The Printed Matter Doctrine ? Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.

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PRACTICES Patent Office Trials, Patents, Intellectual Property

In *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 2016-2616, -2656 (Fed. Cir. May 16, 2018), in a decision authored by Judge Lourie, the Court of Appeals for the Federal Circuit held that the printed matter doctrine is properly applied during claim construction and can include not just printed matter, but also mental steps.

The printed matter doctrine dictates that “[c]laim 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.” Slip op. at 9. Determining if the printed matter doctrine applies is a two-step process. The first step involves determining whether a claim limitation is directed to printed matter. If the claim limitation is not directed to printed matter, the doctrine does not apply. If, however, the claim limitation is directed to printed matter, then the second step involves determining whether the printed matter has a functional or structural relation to the substrate on which it is printed. If the claim limitation has a functional or structural relation to the substrate on which it is printed, the doctrine does not apply and the limitation is given patentable weight.

In *Praxair Distrib.*, the panel upheld an *inter partes* review decision by the Patent Trials and Appeal Board (“PTAB”) of the United States Patent and Trademark Office finding that claims 1-8 and 10-11 of U.S. Patent No. 8,846,112 (“the ’112 patent”), owned by Mallinckrodt Hospital Products (“Mallinckrodt”) and directed to methods of supplying a cylinder of nitric oxide gas to medical professionals along with information regarding potential harmful side effects of nitric oxide when treating certain neonates for hypoxia (“the providing information limitation”), were unpatentable because they were obvious in view of the prior art.¹ *Id.* at 3-4. Various dependent claims of the ’112 patent added additional steps, directed to what a recipient of the provided information should do with that information. In particular, claim 3 recited “evaluating the potential benefit” of treatment (“the evaluating limitation”), claim 7 provided a recommendation that treatment should be discontinued in certain patients if certain events occur (“the recommendation limitation”), and claim 9 recited that treatment should be discontinued in accordance with the recommendation of claim 7. *Id.* at 4-5. The PTAB had found that claim 9 was patentable, and the panel reversed that finding based on obviousness in view of prior art.

In construing the claims, the PTAB applied the printed matter doctrine and “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 6. Mallinckrodt argued that the PTAB “erred in applying the printed matter doctrine during claim construction, rather than when assessing patentability, [and] substantively misapplied the printed matter doctrine by extending it to encompass mental steps.” *Id.* at 9. Mallinckrodt further argued that “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.” *Id.* at 12.

The panel held that the PTAB had properly applied the printed matter doctrine. First, the panel discussed how it was not improper to apply the printed matter doctrine to mental steps stating that, although early cases developing the printed matter doctrine applied it to claims literally encompassing “printed” materials, the doctrine is not so limited, and “a claim limitation is directed to printed matter ‘if it claims the content of information.’” *Id.* at 9-10 (citing *In re DiStefano*, 808 F.3d 845, 848 (Fed. Cir. 2015)).

The panel also held that it was not improper to apply the printed matter doctrine to claim construction, stating: “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.” *Id.* at 11.

The panel also disagreed with Mallinckrodt’s argument that the issue of whether claims are directed to mental steps, e.g., the evaluating limitation of claim 3, may only be considered in determining patent eligibility, not obviousness. *Id.* at 12. The panel reasoned that mental steps may attempt to capture informational content and, therefore, may be considered printed matter. *Id.* The panel stated that “while subject matter eligibility underlies the printed matter doctrine, many of our printed matter cases have arisen in the context of anticipation or obviousness” and “[t]he printed matter doctrine thus raises an issue where the § 101 patent-eligibility inquiry and the § 102 and § 103 novelty and nonobviousness inquiries overlap.” *Id.*, citations omitted. Thus, the panel held: “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.” *Id.*

With regard to claim 9, the panel found that the providing information limitation did have patentable weight because the claim “requires the medical provider to take a specific action, discontinue treatment, as a result of the recommendation limitation” and, therefore, was functionally related to the other limitations of the claim. *Id.* at 9-10. The panel, however, found that claim 9 was obvious in view of prior art.

Judge Newman, although concurring with the decision, argued that “the printed matter doctrine does not apply to unprinted matter.” Concurring op. at 1. According to Judge Newman “[m]ental steps are mental, not printed[, and t]he printed matter doctrine is directed to printed matter, not information and not mental steps.” *Id.* at 1-2. Judge Newman stated that she would have simply held the claims unpatentable based on obviousness in view of prior art.

Praxair Distrib. further expands the scope of the printed matter doctrine, beyond just printed matter, and beyond informing someone of information (as in *King Pharm. Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010)), to also include mental steps. This holding allows the printed matter doctrine to encompass thinking about information. The panel opinion cautioned that otherwise a claim limitation that simply adds printed matter and a “think about it” step would give patentable weight to information content. Slip op. at 13. Accordingly, when drafting a claim that includes an information provision, it may be worthwhile to recite a functional relationship, e.g., taking action based on the information, so as to avoid having the information discarded as “printed matter.”

¹ The providing information limitation of claim 1 recited “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 preexisting

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.” Slip op. at 4.