



THINK FORWARD

The Expanded Scope of the Printed Matter Doctrine and Effect on "Mental Steps"

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May 30, 2018

In *Praxair Distribution, Inc. v. Mallinckrodt Hospital Products IP LTD.* (Fed. Cir. 2018), the Federal Circuit agreed with the PTAB's application of the printed matter doctrine, which extended the doctrine to claim limitations involving mental steps.

The printed matter doctrine, which is the primary issue underlying this dispute, has historically stood for the principle that 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. See *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). Under recent case law, the scope of printed matter has been expanded to include claim limitations directed to "the content of information." See *In re DiStefano*, 808 F.3d 845 (Fed. Cir. 2015). Thus, the court in *Praxair* summarized the printed matter doctrine as:

[c]laim 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.

The court further expanded the scope of the printed matter doctrine to limitations involving mental steps. Specifically, the court reasoned 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 a obviousness analysis.

The patent-at-issue in *Praxair* is U.S. Patent 8,846,112. The '112 patent relates to providing nitric oxide gas as a treatment for dilating pulmonary blood vessels in neonates. Claim 1 includes a step that requires "**providing** to the medical provider ... information that a recommended dose of inhaled nitric oxide gas for treatment of neonates with hypoxic respiratory failure is 20 ppm nitric oxide ..." The Federal Circuit agreed with the PTAB's holding that the "providing information" step invokes the printed matter doctrine and, thus, is not afforded any patentable weight in an obviousness analysis under 35 U.S.C. § 103. The Federal Circuit further noted that claim 1 does not provide additional limitations that invoke the functional-relationship exception of the printed matter doctrine that would otherwise allow the claim limitation to be afforded patentable weight.

The Federal Circuit's analysis looked to dependent claims 3 and 9 of the '112 patent to provide examples of claim limitations that invoke (and do not invoke) the functional-relationship exception. The Federal Circuit found that claim 3, which included an additional step of "**evaluating** the potential benefit of treating the [neonatal patient] with 20 ppm inhaled nitric oxide ..." did not invoke the functional-relationship exception because the evaluating step of claim 3 is a mental process. The court reasoned that "adding an ineligible mental process to ineligible information still leaves the claim limitation directed

to printed matter." Thus, no patentable weight was given to the "evaluating information" step of claim 3.

Conversely, the Federal Circuit invoked the functional relationship exception of the printed matter doctrine for claim 9, which requires: "in accordance with the recommendation ..., discontinuing the treatment with inhaled nitric oxide due to the neonatal patient's pulmonary edema." Requiring a medical provider to take a specific action (discontinuing treatment) as a result of the recommendation limitation creates the necessary functional relationship to impart patentable weight to the "discontinuing treatment" and the "providing information" limitations. Ultimately, however, the court still found claim 9 obvious, despite the patentable weight given to the additional features.

The *Praxair* holding marks an increased overlap between §101 patent eligibility analysis and §102/§103 patentability analysis. This court's discussion of the printed matter doctrine suggests that mental steps that involve evaluating printed matter may qualify as patent ineligible subject matter under §101 and therefore, such claim limitations may not be afforded patentable weight in determining novelty under §102 or non-obviousness under §103. However, printed matter doctrine issues for information-based limitations may be addressed and possibly avoided as early as the claim drafting stage. For example, inclusion of an "action" limitation that is based on an information limitation and that is more than a mental step may provide a functional correlation sufficient to invoke the functional relationship exception and impart patentable weight to the information limitation.

Judge Newman's concurrence regarding the unpatentability of certain claims at issue in *Praxair* had sharp words for this holding as it pertained to the printed matter doctrine and its application to "information" and "mental steps:"

Mental steps are mental, not printed. The printed matter doctrine is directed to printed matter, not information and not mental steps. [...] 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 creation of a new printed matter doctrine in today's jurisprudence serves no purpose other than adding to the uncertainty of patent eligibility.