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Praxair And The Printed Matter Doctrine

By **Paul Zagar** (May 18, 2018, 3:20 PM EDT)


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On May 16, 2018, the Federal Circuit decided Praxair Distribution Inc. v. Mallinckrodt Hospital Products IP Ltd.[1] This case has implications for both litigators and prosecutors.

Praxair calls attention to the printed matter doctrine as an additional means for attacking diagnostic method and personalized medicine claims, already under siege from Section 101 subject matter eligibility challenges. To avoid a printed matter doctrine issue, claim drafters should include a specific action limitation, which creates a functional interrelation between information, evaluating, and/or recommendation limitations and the remainder of the claim. For those challenging diagnostic method and personalized medicine claims, the printed matter doctrine may provide an avenue for removing troublesome limitations not easily found in the prior art.

The Claims

At issue in this appeal from an inter partes review decision were claims directed to methods of providing pharmaceutically acceptable nitric oxide to certain neonatal patients. Claim 1 included the steps of supplying a cylinder of compressed nitric oxide gas to a medical provider responsible for treating neonates with hypoxic respiratory failure, and providing the medical provider with information that: (1) a recommended dose of inhaled nitric oxide for such patients is 20 ppm, and (2) in patients with pre-existing left ventricular dysfunction, inhaled nitric oxide may increase pulmonary capillary wedge pressure (PCWP), leading to pulmonary edema; the information being sufficient to cause a medical provider considering such treatment for neonatal patients who are suffering from a condition for which inhaled nitric oxide is indicated and have pre-existing left ventricular dysfunction, to elect to avoid treating the patient in order to avoid pulmonary edema.

Dependent claim 3 added an "evaluating" limitation, which required the medical provider to weigh the potential benefit of treating the patient with 20 ppm inhaled nitric oxide versus the potential risk of an increase in PCWP leading to pulmonary edema.

Dependent claim 9 added limitations of performing a diagnostic process to identify a neonatal patient who is a candidate for the treatment, determining if the patient has pre-existing left ventricular dysfunction, treating the patient with 20 ppm inhaled nitric oxide, whereupon the patient experiences pulmonary edema, and in accordance with the recommendation [of the independent claim] discontinuing the treatment with inhaled nitric oxide due to the neonatal patient's pulmonary edema.

The Board Decision

Applying the printed matter doctrine to claim construction, the Patent Trial and Appeal Board interpreted the providing information, evaluating, and recommendation limitations to be printed matter or purely mental steps that lacked a functional relationship to the other claim limitations, and gave them no patentable weight. The board interpreted "in accordance with" in claim 9 to mean "based on, or as a result of" the recommendation to discontinue treatment, thereby establishing a functional relationship between the printed matter and the other limitations.

The board found that claims 1-8 and 10-19 were obvious because the prior art taught each limitation

that had patentable weight. The prior art cited against claim 9 taught "the need for careful observation and intensive monitoring during [nitric oxide] inhalation in patients with left ventricular failure." According the board, this was not a teaching or suggestion to discontinue nitric oxide treatment. Thus, the board found claim 9 not to be obvious.

The Federal Circuit Appeal

The Federal Circuit considered whether the printed matter doctrine was properly applied to claims 1-8 and 10, whether it should have been applied during claim construction, and whether it extends to encompass mental steps.

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. For example, merely adding an instruction sheet to a drug product is not sufficient to create a functional relationship.[2] A functional relationship was found between a measuring receptacle and "volumetric indicia thereon indicating volume in a certain ratio."[3]

The Federal Circuit stated that, while early cases literally applied the doctrine to "printed" materials, a claim limitation is directed to printed matter "if it claims the content of information."[4] In the absence of a functional relationship, the content of information is not patent eligible subject matter. The doctrine may also be applied in analyzing novelty and non-obviousness.

The Federal Circuit held that the board properly addressed the printed matter doctrine during claim construction. Further, the court held that the printed matter doctrine raises an issue where patent eligibility, and novelty and nonobviousness inquiries overlap. "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."[5] The Federal Circuit held that the board did not err in applying the printed matter doctrine to claims 1-8 and 10, and affirmed the board's holding that these claims were unpatentable as obvious.

Claim 9 requires a medical provider to take an action, discontinuing treatment, in response to a recommendation limitation. The majority reasoned that "[b]y interrelating the claimed information regarding correlations between nitric oxide, LVD [left ventricular dysfunction], and pulmonary edema with the concrete step of discontinuing treatment because of the information, … 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."[6]

The board did err, however, in finding that the cited prior art did not render claim 9 obvious. The board interpreted the prior art as teaching that nitric oxide may be given to patients with LVD as long as they are carefully monitored. The board interpreted claim 9 to exclude patients with LVD from nitric oxide treatment. The correct interpretation of claim 9, according to the Federal Circuit, is that nitric oxide may be given to patients with LVD and discontinued if pulmonary edema occurs. Further, contrary to the board, the prior art's teaching of "careful observation and intensive monitoring" includes, or at least suggests, discontinuing nitric oxide treatment after a patient with LVD suffers pulmonary edema. The board's finding that secondary evidence was compelling also rested on its misinterpretation of claim 9. Accordingly, the board's holding that claim 9 was nonobvious was reversed.

Judge Newman's Concurrence

Judge Pauline Newman concurred in the judgment, but disagreed with the majority's view of the printed matter doctrine and its application. According to Judge Newman, the printed matter doctrine does not apply to unprinted matter, including mental steps, and is not relevant to the claimed method of administering nitric oxide. The doctrine arose to preserve the boundary between patent and copyright. For example, a book may fall within the plain meaning of a "manufacture," but it is not the type of manufacture that Congress meant to make patentable.

Further, Judge Newman stated that applying the printed matter doctrine to remove limitations from a claim before a patentability analysis is contrary to the patent statue, which requires an analysis of the claim as a whole.

Judge Newman concurred in the judgement, however, because all of the claims are unpatentable based upon a traditional obviousness analysis.

Takeaways for Prosecutors

In construing "providing … information," the board noted that claim 5, which depends from claim 1, "expressly provides" that the information "appear[s] in prescribing information supplied to the medical provider with the cylinder containing compressed nitric oxide gas." The board, "[r]eading the claims as a whole, [viewed] the information described … as printed matter, and, thus, not entitled to patentable weight." Claim limitations in Praxair encompassed both actual printed matter and mental steps. A future tribunal may opt to read Praxair narrowly if language avoiding an express or inferred reference to actual printed matter is avoided. For example, a limitation for "assessing" a patient for pre-existing LVD, rather than a limitation for "providing information" on the risk to patients with pre-existing LVD, is not likely to conjure up actual printed matter.

For added protection from the printed matter doctrine, a limitation requiring a specific action based on an information or mental step limitation should be included to create a functional relationship with the remainder of the claim.

Takeaways for Validity Challengers

Praxair provides parties challenging the validity of diagnostic or personalized medicine claims with a means for addressing a potentially troublesome limitation by removing the limitation in claim construction. This is what occurred in the Praxair IPR: "we [the Board] accord these informational and deliberative steps no patentable weight… we, therefore, find immaterial Patent Owner's arguments that leading experts … did not recognize that iNO therapy should be contraindicated in neonates with pre-existing LVD."[7] Removing a limitation in claim construction is an attractive option where, for example, the alternative is having to make a difficult inherency in obviousness argument where the limitation is not expressly taught in the prior art.

Claims with mental step or informational limitations are susceptible to subject matter eligibility challenges under 35 U.S.C. § 101 in district court. A question we are left with after Praxair is whether such claims are still subject to these challenges if the mental step or informational limitations are given no patentable weight during claim construction.

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The author thanks Leason Ellis partners Robert M. Isackson and Safet Metjahic for their assistance in reviewing this article.

[1] Praxair Distribution Inc. v. Mallinckrodt Hospital Products IP Ltd., Case No. 2016-2616, 2016-2656

[2] AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1065 (Fed. Cir. 2010).

[3] In re Miller, 418 F.2d 1392, 1396 (CCPA 1969).

[4] Quoting In re DiStefano, 808 F.3d 845,848 (Fed. Cir. 2015).

[5] Praxair at 12.

[6] Id. at 17.

[7] Id. at 29-30.