IP Alert: INO Therapeutics v. Praxair Distribution: Trying to make sense out of subject matter eligibility

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INO Therapeutics v. Praxair Distribution: Trying to make sense out of subject matter eligibility

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February 22, 2019 — Praxair Distribution Inc. challenged a set of patent claims for a similar infirmity under 35 U.S.C. § 101 in a district court and under 35 U.S.C. § 103 in an inter partes review (IPR) at the U.S. Patent Trial and Appeal Board (PTAB). In one venue, Praxair argued that the claims were invalid as directed to a law of nature and, in the other venue, Praxair argued that the claim relied on a mental step (printed matter). The juxtaposition of these two theories of invalidity for addressing a claim that contains a mental step or abstract idea invites us to ask how the theories are related and how they may clarify each other.

Praxair would like to market a generic version of INO Therapeutics' inhaled nitric oxide product to treat neonates with hypoxic respiratory failure. However, Praxair cannot get regulatory approval from U.S. Food and Drug Administration (FDA) until INO's patents expire or are invalidated. Praxair has taken its quest to the U.S. District Court of Delaware and to the PTAB. It has pursued an appeal of the PTAB decision at the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). Praxair and Mallinckrodt (the indirect owner of INO Therapeutics) reached another stage in their litigation early in February[1] when the Federal Circuit heard oral arguments in Mallinckrodt's appeal of the district court's decision holding Mallinckrodt's claims invalid for lack of patent eligible subject matter under 35 U.S.C. § 101. INO Therapeutics LLC v. Praxair Distribution Inc., (No. 2018-1019) (Fed. Cir.).

Mallinckrodt holds a U.S. Food and Drug Administration-approved New Drug Application for the inhaled nitric oxide product, first approved in 1999, listing its corresponding patents in the Orange Book. Praxair filed an Abbreviated New Drug Application (ANDA) for a similar product in 2014, certifying that Mallinckrodt's Orange Book-listed patents were invalid, unenforceable, and/or would not be infringed by its proposed commercial activities. Mallinckrodt then sued Praxair for infringement in district court of a first group of five patents related to methods of treatment and a second group of patents related to a device for delivering nitric oxide gas.[2] On September 5, 2017, the district court found the method claims invalid for subject-matter ineligibility under § 101 and the device claims not infringed.[3]

An agreed-upon representative claim, claim 1 of U.S. Patent No. 8,795,741 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:

(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.

While the district court litigation was percolating, Praxair petitioned the PTAB to institute an IPR of claims of one of the method patents, U.S. Patent No. 8,846,112, asserting they were obvious. The PTAB found all claims but one obvious. Praxair appealed the decision of the sole claim not proven obvious and Mallinckrodt cross-appealed the decision that the bulk of the claims were obvious. The Federal Circuit agreed with Praxair and held all claims of the '112 patent unpatentable as obvious on May 16, 2018. Much of the Federal Circuit's opinion relied on application of the printed matter doctrine, broadly applying it to steps or elements reciting the content of information as well as to mental steps.[4]

Meanwhile, in the infringement suit, Mallinckrodt appealed the district court's holding of its method patent claims as invalid under § 101 to the Federal Circuit. Although the IPR appeal related to just one of the five method patents and its invalidity as obvious under 35 U.S.C. § 103, similar issues undergird both the § 101 and § 103 statutory analyses. As Judge Lourie stated in the May 16, 2018 opinion of the appeal of the IPR, "[W]hile subject matter eligibility underlies the printed matter doctrine, many of our printed matter cases have arisen in the context of anticipation or obviousness. The printed matter doctrine thus raises an issue where the § 101 patent-eligibility inquiry and the § 102 and § 103 novelty and non-obviousness inquiries overlap." Praxair Distribution, Inc., v. Mallinckrodt Hospital Products IP LTD., 890 F.3d 1025, 1033 (2018) (citations omitted).

Under the printed matter doctrine, a limitation that merely recites information receives no patentable weight unless it is functionally related to the substrate on which it is printed or interrelated with the rest of the claim. This framework for determining "functionally related" may be directly analogous to the § 101 inquiry as to whether a law of nature is practically applied in a claim.[5] For example, Mallinckrodt argued at the oral hearing this month that the step of determination of left ventricular dysfunction in a patient (step c) is applied in step e when a patient is excluded from treatment based on the determination of left ventricular dysfunction. Mallinckrodt urged that in order for a claim to pass § 101 muster it must do more than merely recite a discovery; it must apply it. This may be equivalent to saying that the information must bear a functional relationship to the rest of the claim for a printed matter doctrine analysis.

At the oral argument, Judge Dyk pushed on the edges of Mallinckrodt's statement of the law, asking Mallinckrodt's counsel if it would be sufficient if the claim instructed a doctor to "consider" the law of nature (Mallinckrodt answer: no) or if the claim recited altering the treatment depending on the law of nature (Mallinckrodt answer: I think so). Judge Newman asked if the key to patent eligibility Mallinckrodt advanced was that the recitation of the application of the law of nature must be in the claim, rather than merely disclosing it in the specification (Mallinckrodt: yes). Judge Dyk seemed skeptical that a specific recitation of an application of a law of nature was sufficient to overcome the admonition in the Supreme Court's Mayo decision that a claim that states "apply it" is

not sufficient.[6] Mallinckrodt articulated a view of the case law that distinguishes between a claim that recites how a law of nature is applied (eligible) and a claim that does not specify and leaves it to the reader (not eligible).

Both Judges Dyk and Newman seemed dismayed that such a reading of the case law turned too heavily on the wordsmithing of the claim ("that would turn on the draftsman's art").[7] However, the notion that the validity of a claim considered under any criterion would not depend on the language of the claim seems untenable. How could the validity of a claim not rely on the claim language?

Perhaps the strongest attack that Mallinckrodt made on the district court's holding of invalidity was based on the April 24, 2018 Federal Circuit opinion in Vanda Pharm. Inc. v. West-Ward Pharm. Int'l LTD, 887 F.3d 1117 (Fed. Cir. 2018), in which hybrid diagnostic/therapeutic claims were found patent eligible. Mallinckrodt asserted that its claims were very similar to Vanda's claims. The only difference it noted was that, as a consequence of a diagnostic result, Vanda recited reducing a dosage whereas Mallinckrodt's claims recited excluding certain patients from treatment entirely. Mallinckrodt rhetorically asserted that the difference between patent eligibility and patent ineligibility could not be the difference between using a very low dose (as in Vanda) and a zero dose (as in Mallinckrodt's claims).

Praxair, in contrast, painted the claims at issue as very similar to the Mayo claims held unpatentable by the Supreme Court. It highlighted the negative action at the heart of the Mallinckrodt claims (excluding a patient from treatment), calling it "unusual." Praxair implied that a negative limitation has no weight and should be ignored. It reminded the panel that the district court equated the Mallinckrodt claim to a claim that recites a law of nature and instructs the reader to "apply it." Mallinckrodt countered that view by focusing on the combination of treating and excluding steps as together describing a selective treatment.

While recognizing that pre-emption is not the sole determinant of subject matter eligibility, each party argued that the consideration of pre-emption favored its case. Mallinckrodt argued that the claim did not prevent others from performing the diagnostic portion of the claims followed by treating appropriate patients with the regular dose of nitric oxide and treating inappropriate patients with a low dose or a combination of the normal dose plus a yet-to-be-discovered side-effect mitigating agent. It therefore did not have a large pre-emptive effect, Mallinckrodt concluded. Praxair urged that the claim would prevent others from performing the diagnostic portion followed by treatment of appropriate patients with the regular dose of nitric oxide and inappropriate patients with some yet-to-be-discovered alternative treatment. Praxair concluded that this was too pre-emptive.

This case exposed some of the difficulties present in the Supreme Court's § 101 jurisprudence. What does it take to transform a law of nature into a patentable invention? Is the discoverer of the

law of nature unable to obtain a patentable claim? Are only later users of the law of nature able to obtain claims to a non-obvious application of the law of nature? Are courts too easily and too frequently finding laws of nature in claims? Does the bar need to be raised so it is closer to catching only fundamental building blocks of science? An intriguing possibility arises when comparing the INO v. Praxair IPR to the infringement litigation: can the functional relationship required by the printed matter doctrine be borrowed to clarify the standard for § 101 patentability?

[1] February 6, 2019.

[2] The filing of the ANDA constitutes a form of infringement. See 35 U.S.C. § 271 (e) (2).

[3] This account discusses only the fate of the method claims.

[4] The claim recited discontinuing treatment based on adverse side effects, rather than based on the results of the diagnostic steps.

[5] See 2019 Revised Subject Matter Eligibility Guidance, 84 Fed. Reg. (January 7, 2019) (Prong 2 of revised Step 2A).

[6] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012) ("Still, as the Court has also made clear, 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.' See, e.g., Benson, supra, at 71–72, 93 S.Ct. 253. Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said 'apply the algorithm'"; "A patent, for example, could not simply recite a law of nature and then add the instruction 'apply the law;'" "And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients").

[7] See Parker v. Flook, 437 U.S. 584, 593 (1978) ("First, respondent incorrectly assumes that if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101 and the substantive patentability of the particular process can then be determined by the conditions of §§ 102 and 103. This assumption is based on respondent's narrow reading of Benson, and is as untenable in the context of § 101 as it is in the context of that case. It would make the determination of patentable subject matter depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for "ideas" or phenomena of nature").

Click here to listen to the oral argument.

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