IP Alert: Capturing Inventions from FDA Label Changes

Capturing Inventions from FDA Label Changes

By Sarah A. Kagan

The U.S. Court of Appeals for the Federal Circuit on January 9, 2018, heard oral arguments in Praxair Distribution, Inc. v. Mallinckrodt Hospital Products, Fed. Cir. No. 2016-2616, -2656, involving an appeal and cross-appeal of an inter partes review (IPR) from the U.S. Patent and Trademark Office. The Federal Circuit panel consisted of Chief Judge Prost, and Judges Newman and Lourie.

When the U.S. Food and Drug Administration (FDA) requires or approves a new label for an already approved drug, the drug proprietor typically asks itself if the new label describes a patentable invention. New labels may, for example, add new disease indications, safety warnings, dosage modifications, counter-indications, or a food effect. Conversion of the information in a new label into a commercially useful patent claim may run into obstacles, however. First, a new claim must be novel and non-obvious over the prior art, including the original drug label. Second, a new patent claim must present patent-eligible subject matter. Third, a new patent claim should be enforceable against a commercially significant infringer and preferably not only against an individual patient or doctor.

These considerations are common when drafting claims for an original therapeutic label, but the options may be more constrained for a revised label. First, the prior art is inherently closer in this situation. Second, the ability to attribute infringement to a competitor drug manufacturer may be more difficult due to the nature of the change in the new label. Third, new label information may be hard to convert into a physical act or step of a method claim or an element of a product claim. This task has become more difficult because U.S. courts have recently expanded the scope of “laws of nature” and “abstract ideas,” two categories of subject matter excluded from patent eligibility.

Additionally, claims based on a new label may be subject to bias against companies trying to "evergreen" their patent protection. Judges and juries may be suspicious that a company is trying to extend its patent franchise based on a slim advance in the art. Such bias may creep into, for example, an obviousness determination.

INO Therapeutics and its successor in interest, Mallinckrodt Hospital Products, faced these issues in obtaining and defending U.S. Patent 8,846,112 (the '112 patent). INO Therapeutics filed a patent application that matured into the '112 patent to protect its finding embodied in a new drug label, that inhaled nitric oxide (iNO) therapy may be detrimental to patients with preexisting left ventricular dysfunction (LVD). iNO therapy was previously approved by the FDA for treating neonates with persistent pulmonary hypertension; the initial label, however, contained no warning about patients with LVD.

Praxair Distribution challenged the '112 patent in an IPR at the USPTO. The USPTO Patent Trial and Appeal Board (PTAB) found all claims, except claim 9, unpatentable over prior art. All of the '112 patent's claims included a step of providing information to a medical provider. That information contained a warning about LVD patients. The PTAB construed the information as "printed matter" entitled to no patentable weight unless it were functionally related to other elements or steps of the claims. Only in the case of claim 9 did the PTAB find such a functional relationship, permitting the PTAB to give patentable weight to the content of the information. The PTAB found the functional relationship in claim 9's recitation: "in accordance with the recommendation of (iii)[1] discontinuing the treatment with inhaled nitric oxide due to the neonatal patient's pulmonary edema." This recitation functionally linked the information of (iii) to the recited step of discontinuing.

Praxair appealed the PTAB's failure to find claim 9 to be unpatentable, whereas Mallinckrodt appealed the PTAB's finding of all other claims as unpatentable. Praxair challenged the PTAB's reasoning for finding a lack of obviousness of claim 9. Mallinckrodt challenged the PTAB's claim construction procedure, particularly its application of the printed matter doctrine and its disregarding of mental steps with regard to the other claims.

On appeal, both sides ascribed procedural errors to the PTAB's consideration, including raising and deciding issues sua sponte without giving the adversely affected party a chance to respond. Both sides asserted that the PTAB's claim construction was erroneous, albeit in different ways. The appeal panel showed more interest in the substantive issues of claim construction and obviousness than any of the procedural errors alleged by either party. Indeed, Chief Judge Prost asked Praxair's counsel to skip over the procedural issues and get right to the obviousness issue, stating that it had more "heft."

Judge Lourie raised the issue of subject matter eligibility under 35 U.S.C. § 101 with both parties, despite the fact that Section 101 cannot be a ground of unpatentability in an IPR.[2] He asked whether "printed matter" is not just an abstract idea reduced to writing. He also asked whether the printed matter doctrine survived the U.S. Supreme Court's Alice decision.[3] Both Praxair and Mallinckrodt replied that the "printed matter" doctrine survives. Listening to a discussion of precedent on the printed matter doctrine, Judge Lourie commented that it sounded like Mayo, with minor physical steps and an abstract idea.[4]

We will have to wait to see how the appeal panel construes the claims. In a proceeding where 35 U.S.C. § 101 is not a ground for challenging patentability, a claim construction process employing the printed matter doctrine may act as its surrogate.

This case highlights the difficulty in finding a proper format to translate a drug label into a patentable and subject-matter-eligible patent claim. The '112 patent seems to have taken a variety of different approaches, with only one of the approaches passing muster at the PTAB. And, that approach was dependent on a claim construction that the PTAB found only after revising its initial claim construction.

Click here to hear the oral arguments in Praxair Distribution, Inc. v. Mallinckrodt Hospital Products.

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[1] "(iii)" refers to the information provided to the medical provider. The information of (iii) is "a recommendation that, if pulmonary edema occurs in a patient who has pre-existing left ventricular dysfunction and is treated with inhaled nitric oxide, the treatment with inhaled nitric oxide should be discontinued."

[2] "A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b).

[3] Alice Corp. PTY. Ltd. v. CLS Bank Int'l, 134 S. Ct. 734 (2013).

[4] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 130 S. Ct. 1289 (2012).

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