“Providing . . . Information” to Medical Providers Is Not Given Patentable Weight

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Addressing the application of the “printed matter” doctrine, the Patent Trial and Appeal Board (PTAB) determined that claim elements directed to “providing [certain] information” fell within the doctrine and therefore were not entitled to patentable weight. *Praxair Distribution Inc. v. Mallinckrodt Hospital Products IP Ltd.*, Case No. IPR2015-00529 (PTAB, July 7, 2016) (Pollock, APJ).

Mallinckrodt produces INOmax®, a US Food and Drug Administration (FDA) approved inhaled nitric oxide therapy for hypoxic respiratory failure in infants—a potentially deadly condition also referred to as “blue baby” syndrome. A decade after the drug was approved, a clinical study found that patients with pre-existing left ventricular dysfunction experienced an increased risk of serious adverse events when treated with the product. Based on these findings, the FDA approved a supplemental label for INOmax®, which included new warnings and precautions related to patients with left ventricular dysfunction. Mallinckrodt also filed for and obtained a patent directed to methods of “providing pharmaceutically acceptable nitric oxide gas” aimed at reducing the risk or preventing the occurrence of adverse events associated with inhaled nitric oxide therapy. The claims of the patent included steps related to “providing [certain] information” to a medical provider.

*Praxair* filed for *inter partes* review of Mallinckrodt’s patent. At issue was whether the claimed step of “providing [certain] information” to a medical provider should be given patentable weight. Reading the claims as a whole and applying US Court of Appeals for the Federal Circuit precedent, the PTAB determined that the “providing . . . information” step qualifies as printed matter, which is not entitled to patentable weight. According to the PTAB, “because printed matter itself is non-statutory subject matter, it must have a functional relationship to other claim elements to be accorded patentable weight.” Otherwise, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product.

Mallinckrodt argued that the claims require more than simply providing information; they transform the ordinary methods by providing the information “sufficient to cause a medical provider . . . to elect to avoid” treating patients at risk. The PTAB disagreed because the “method of providing pharmaceutically acceptable nitric oxide gas” can be performed irrespective of whether the “information” required by the claim is “provided.” In addition, the “sufficient to cause” claim language does not specify any particular outcome and therefore does not “transform” the claimed method in a way that requires giving the step any patentable weight.

In light of the PTAB’s determination that the informational and deliberative steps of the challenged claims carry no patentable weight, Mallinckrodt’s arguments regarding non-obviousness were deemed immaterial, and all but one claim of Mallinckrodt’s patent were held unpatentable under 35 USC §§ 102(a) and 103(a).

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