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INO v. Praxair – Time for the Supreme Court to Step Up to the Plate?

Article By:

Before you read this post, please back up and read my post of September 3, 2019 which discusses the Fed. Cir.'s ruling that the claims of U.S. Pat. No. 8,794,742 are patent-ineligible as attempts to claim a natural phenomenon. The claims are directed to reducing the risk that inhalation of nitrous oxide ("NO") by neonatal patients identified as having hypoxic respiratory failure, and who also have left ventricular dysfunction ("LVD") will lead to pulmonary edema. The claims essentially recite dividing a group of such patients into two groups. The patients who do not have LVD are administered the standard dose of NO, while the at-risk patients are not treated with NO.

The majority of the panel ignored the treatment step and reasoned that the added exclusion step "is simply an instruction not to act. In effect the claim is directed to detecting the presence of LVD in a patient and them doing nothing [to those patients] but leaving the natural processes taking place in the body alone for the group of LVD patients. Accordingly the claim is directed to the natural phenomenon."

I suggested that the underlying rationale for this decision may well be the majority's attempt to define a "method of medical treatment" as requiring an action step that alleviates the pathology. The panel wrote:

"Here by contrast [to Vanda], the invention is not focused [ed.'s note – this ambiguous term is used to justify ignoring the treatment step] on changing the physiological state of the patient to treat the disease. The claimed invention is focused on screening for a natural law…once information about the LVD is detected no NO treatment is given. And as far as the claim specifies, the patient's state may remain unchanged and natural bodily processes may proceed."

I didn't mean to spend so much time summarizing my earlier post, but this trip down precedent lane was prompted by the petition for cert. filed by INO a few days ago. The question posed is "[w]hether a method of treatment that requires doctors to selectively administer a drug to certain patients and not others to enhance patient outcomes is eligible for patent protection under s. 101."

INO's brief argues that the Mayo decision "carefully distinguished the claims before it from method of treatment claims, which it indicated should remain patent-eligible as specific applications of natural phenomena." The Mayo Court warned that the Mayo claims "threaten to inhibit the development of

more refined treatment recommendations" based on "later discovered features of …individual patient characteristics." The brief notes that the Fed. Cir. attempted to distinguish Vanda "which held that a method of selective treatment was patent eligible, on the ground that claims in Vanda 'did not simply instruct doctors to stop treating those patients' but 'required the doctor to treat a patient with a specific low dose range [if they were in the poor metabolizer pool of patients]. Such patients are to receive a dose of the drug of "12 mg/day or less." [ed. note: during prosecution, an alert Examiner will note that "or less" reads on zero – moving the Vanda claim even closer to INO's.]

The petition urges the Court to consider that "[t]he decision below breaches that firewall [protecting the patent-eligibility of methods of medical treatment], holding for the first time that a method of selective treatment is not patent-eligible….[INO's] claims are thus not directed to inaction, but to selective action: the selective administration of [NO] based on a diagnostic step….Selective treatment claims…are not simply diagnostic methods designed to generate information about a physiological condition. They apply that knowledge to achieve remarkable improvements in health through specific, real world action." [ed. note: note the difficulty in claiming a negative.]

The INO petition spends some space distinguishing Mayo, ending with "Critically, the [Mayo] claim did not require doctors to act on that information [derived from the metabolite concentrations], merely trusting them to use those laws appropriately where they are relevant to their decision making." The Brief argues that, unlike Mayo the "excluding" step does change the course of treatment by requiring selective administration of NO. The Brief goes on to argue that both Vanda and INO claim new ways of using an existing drug, quoting from Mayo. The Brief argues that the INO claims are narrower than the Vanda treatment claims, because Vanda's claims included a range of doses, while the INO claims "cover only a single specific course of action."

Reading the Brief, I noted that it referenced the United States amicus brief that was filed during consideration of Hikima v. Vanda's petition for cert. While it recommended against granting cert., on the basis that Vanda had been correctly decided, it performed a yeoman's (yeoperson's) job of deconstructing Mayo. That will be the subject of my next Post.

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