NOW + NEXT

INTELLECTUAL PROPERTY ALERT | NIXON PEABODY LLP

December 16, 2019

# Personalized therapy and subject matter eligibility

**By Ravinderjit Braich**

Does excluding a group of patients from treatment when a second group receives the treatment based on a selection make a method of treatment claim patent-ineligible?

Yes, according to a divided Federal Circuit in *iNO Therapeutics LLC v. Praxair Distribution Inc.* (Fed. Circ. August 27, 2019). The majority in *iNO*, comprising Judges Dyk and Prost, with Judge Newman dissenting, affirmed a district court determination that claims directed at reducing the risk that inhalation of nitrous oxide by neonatal patients identified as having hypoxic respiratory failure, who are also identified as having left ventricular dysfunction (LVD), were patent-ineligible. Because the claims in *iNO* encompassed withholding nitrous oxide administration to patients identified as having LVD, the majority reasoned that a "method of treatment" that simply tells a doctor to hold back treatment is "not focused on changing the physiological state of the patient to treat the disease," and such claims "remain 'directed to' the natural phenomen[on] itself."

Does the *iNO* decision means all personalized therapy claims are patent-ineligible? Maybe not. The underlying rationale for the *iNO* decision appears to be the majority's attempt to define a method-of-treatment claim as requiring a doctor to affirmatively administer a drug to alter a patient's condition from their "natural" state. The *iNO* decision provides some insight into what types of personalized therapy claims can be patent-eligible.

Before the *iNO* decision, the Federal Circuit held up patent-eligible "method of treatment" claims in a number cases. In distinguishing the claims in *iNO* from those held eligible in the earlier cases, the majority stated that the claims in the earlier cases used the natural law to produce a change in the natural state of the patient to treat a condition. In *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018), the Federal Circuit explained that method-of-treatment claims that are directed to particular methods of treatment are patent-eligible even if they rely on an underlying natural law. In *Vanda*, the Federal Circuit reasoned that the claims did not instruct doctors to stop treating patients based on the information gathered from the natural relationship between drug metabolism and a patient's relative risk due to a difference in the drug metabolism. Instead, the Federal Circuit in *Vanda* noted that the claims provided specific dosing protocol that treated all patients while still lowering the risk associated with the natural phenomenon.

This newsletter is intended as an information source for the clients and friends of Nixon Peabody LLP. The content should not be construed as legal advice, and readers should not act upon information in the publication without professional counsel. This material may be considered advertising under certain rules of professional conduct. Copyright © 2019 Nixon Peabody LLP. All rights reserved.

In *Natural Alternatives International, Inc. v. Creative Compounds*, 918 F.3d 1338 (Fed. Cir. 2019), the Federal Circuit reversed a district court determination that claims directed to using dietary supplements to increase an athlete's anaerobic working capacity were patent-ineligible. According to the Federal Circuit, the claims were not "directed to" the natural law itself and, instead, the invention used information from the natural law to produce a change in the natural state of the patient to treat a condition. In reversing the district court's decision, the Federal Circuit opined that the claims used a particular dose of a substance to obtain a specific "benefit" by "altering the subject's natural state."

Similarly, the Federal Circuit in *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.,* 919 F.3d 1347 (Fed. Cir. 2019), reversed a district court determination that claims directed to a method of using oxymorphone to treat pain in patients with impaired kidney function were patent-ineligible. The Federal Circuit noted that the claims were not directed to the relationship between oxymorphone and patients with renal impairment; instead, the claims were directed to an application of the information from the relationship: "a method of treatment including specific steps to adjust or lower oxymorphone dose for patients with renal impairment."

The majority panel distinguished the claims from these earlier cases from those in *iNO* by reasoning that *iNO* "does not delve into the complexities of dosing to more effectively 'treat' different classes of patients as in *Vanda*, *Natural Alternatives[,]* and *Endo Pharmaceuticals* — by *leveraging* knowledge about a natural correlation to understand what amounts of a particular drug [proving] therapeutic for each patient." Thus, while the *iNO* decision is non-precedential and appears to be a setback for personalized therapy claims, the decision does provide some guidance by highlighting the importance of method-of-treatment claims that practically apply a natural relationship to those that merely recite the natural phenomena.

Recently, the United States Patent and Trademark Office (USPTO) issued new patent-eligibility guidance. The new guidance discussed a number of factors relevant to determining whether a method-of-treatment claim applies or uses a recited judicial exception, i.e., natural phenomena or law, to choose a particular treatment for a disease or medical condition. The guidance notes the following:

- The treatment limitation must be particular. A method that includes a step of administering a lower dosage than the normal dosage is particular, but a step of "administering a suitable medication" is not particular.
- The treatment limitation must have more than an insignificant relationship to the exception. A method that includes a step of administering a drug known to treat the disease is particular. However, a step of administering a drug that is not known in the art to treat the disease or medical condition is not particular, since it only has a nominal relationship to the exception.
- The treatment limitation cannot simply be an extra-solution activity or field-of-use. A method that includes a step of administering a drug to obtain information but taking no concrete steps based on that information is not particular, since the administering step is performed only for gathering the information and therefore is an extra-solution activity.

It remains vitally important to consider particular nuances of personalized therapy claims on a case-by-case basis against the evolving law when formulating and revisiting a strategy for

personalized therapy treatment patent protection. However, successful prosecution of patent applications directed to personalized therapy treatments can still be achieved by following a few guidelines. Applicants can increase their chances by drafting their claims so that a treatment is not withheld from a selected patient, a particular dosage is administered, and the administered drug will treat the disease or medical condition.

For more information about the content of this alert, contact your Nixon Peabody attorney or:


— Ravinderjit Braich at **rbraich@nixonpeabody.com** or 617-345-1089