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Subject Matter Patentability: To Treat or Not To Treat?

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To treat or not to treat? That was the question in the U.S. Court of Appeals for the Federal Circuit decision in *INO Therapeutics LLC v. Praxair Distribution Inc.*[1] *INO* provides an interesting development in the patent eligibility of method of treating patent claims, even though the decision was designated as non-precedential. A dissenter in the *Vanda*[2] method of treatment decision, Judge Prost wrote for the majority here.

INO Therapeutics LLC v. Praxair Distribution Inc.

In *INO*, the claims of U.S. Patent No. 8,795,741 (the '741 patent) at issue regarding the subject matter patentability analysis purported to claim a method of treatment. The main independent claim recites a method of treating neonatal patients with inhaled nitric oxide to increase pulmonary capillary wedge pressure comprising five steps:

1. Identifying patients in need of the treatment;
2. Determining that a first patient does not have left ventricular disorder (LVD);
3. Determining that a second patient has LVD;
4. Administering inhaled nitric oxide to the first patient; and
5. Not treating the second patient with inhaled nitric oxide to reduce the risk of pulmonary edema adverse event.[3]

It is this last clause—the non-treatment clause—that is at the center of the subject matter eligibility discussion. Judge Prost agreed with the district court holding that claim 1 of the '741 patent was invalid as directed to patent ineligible subject matter.[4]

Judge Prost reasoned that because it is undisputed that the treatment of neonatal patients with inhaled nitric oxide (iNO) has existed for decades, the patent claim is directed to the non-treatment of the excluded patients, and allowing their bodies' natural processes to take place. Judge Prost further opined that because the

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remaining steps of the claim were well-understood, routine, and conventional, the claim failed to recite patent eligible subject matter.

Taking it step-by-step, Judge Prost first examined whether the claim was "directed to" a natural phenomenon according to the *Mayo/Alice* [5] two-part test. Judge Prost viewed the claims as drafted as instructing "a physician to administer iNO gas to non-LVD patients as before, while now excluding the LVD patients."[6] INO (Mallinckrodt) in contrast characterized the claims as directed to a selective administration invention as no treatment protocol had previously screened for this adverse event. But Judge Prost found INO's argument to lead directly back to the problem of claiming a natural phenomenon—with the added step being nothing more than an instruction not to treat—not a new way of treating LVD patients. Judge Prost viewed the claimed step of not to treat—or not to disturb natural processes—as being at a risk of "monopolizing the natural processes themselves."[7]

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Judge Prost then distinguished the current claim from the claims at issue in the relatively recent *Vanda, Endo*, and *Natural Alternatives* cases because each of those cases involved claims to a new method of treating a disease. Judge Prost reasoned that the claims in *Vanda* were directed to a dose adjustment based on whether the patient was a good or poor metabolizer of the drug. Likewise, Judge Prost found that *Endo*[8] involved a dose adjustment based on the degree of renal impairment. And Judge Prost reasoned that the claims in *Natural Alternatives*[9] were directed to administering sufficient amounts of beta-alanine to alter the athlete's physiology.[10] In contrast, Judge Prost found that the '741 patent's claims do not recite administering dosage amounts to achieve a corresponding improvement in treating patients, but simply instruct physicians not to treat certain patients, and thus the claims are directed to a natural phenomenon under the first step of *Mayo/Alice*.[11]

Turning to step two of *Mayo/Alice*, Judge Prost examined whether the other claim elements contain an inventive concept sufficient to transform the claimed natural phenomenon into a patent eligible invention, or whether they were directed to nothing more than routine and conventional steps with a general instruction to apply the natural phenomenon.[12] Judge Prost found that each of the remaining steps—identifying patients for treatment with iNO, determining whether the patient has or does not have LVD, and treating patients without LVD with iNO—were routine and conventional. Judge Prost found that INO (Mallinckrodt) did not meaningfully dispute these findings.[13]

Again, Judge Prost did not find that the last step—the not to treat step—was sufficient to render the claims patent eligible, as that step was in essence a step to apply the natural law. Judge Prost did indicate, however, that this "would be quite a different case if the inventors had invented a new way of titrating the dose," but it was not.[14] Judge Prost then disposed of INO's argument regarding preemption finding that the claim was broadly preemptive, reiterating that the Federal Circuit has found that "[p]reemption is sufficient to render a claim ineligible under § 101, but is not necessary."[15]

Judge Prost, however, included a footnote to limit the holding stating "[t]o be certain, we do not hold that every treatment that contemplates adverse events—whether known or newly discovered—will lack claim elements that prove transformative. But, here, proceeding with the prior art treatment for hypoxic respiratory failure while offering no solution for neonatal patients with LVD does not transform these particular claims."[16] Thus, it was the failure to offer a solution, *i.e.*, the method not to treat, that Judge Prost found rendered the claim patent ineligible.

The Dissent

Judge Newman dissented.[17] Judge Newman disagreed with the finding that the claims were directed to a natural phenomenon (step one of the *Mayo/Alice* inquiry) because the claims as a whole recited a method of treatment.[18] Judge Newman believed it was improper to find that the claim was directed to screening instead of the method of treatment as a whole.[19]

Two Other Issues on Appeal

The remainder of the majority opinion discusses two other issues on appeal—the proper claim

construction of the term "verify" in U.S. Patent No. 8,776,794[20] and whether the district court erred in not limiting its final judgment order to the asserted claims.[21] Judge Prost affirmed the claim construction issue and reversed the final judgment issue finding that the judgment should have been limited to the asserted claims.[22]

Conclusion

While non-precedential, the Federal Circuit's *INO* decision opens the door to further subject matter eligibility challenges of method of treatment patent claims that contain routine and conventional steps along with a step that is nothing more than a statement of a natural law along with an instruction to apply the natural law. Practitioners challenging the validity of patents should carefully consider making arguments that the claims at issue recite methods "not to treat," while those defending patents should assert that the claims recite methods "to treat."

Notes

1. 2018-1019, Docket No. 2018-1019.
2. Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals, Inc., 887 F.3d 1117 (Fed. Cir. 2018).
3. *INO*, at 5-6.
4. *Id*. at 9.
5. Mayo v. Prometheus, 566 U.S. 66 (2012).
6. *INO*, at 10.
7. *Id*.
8. Endo Pharmaceuticals, Inc. v. Teva Pharmaceuticals, Inc., 919 F.3d 1347 (Fed. Cir. 2019).
9. Natural Alternatives Int'l v. Creative Compounds LLC, 918 F.3d 1338 (Fed. Cir. 2019).
10. *INO*, at 12-15.
11. *Id*. at 16.
12. *Id*. at 17.
13. *Id*. at 18-19.
14. *Id*. at 19.
15. Athena Diagnostics, Inc. v. Mayo Collaborative Services, 915 F.3d. 743, 752 (Fed. Cir. 2019).
16. *INO*, at 22.
17. *Id*. at 26.
18. *Id*. at 27.
19. *Id*. at 30.
20. *Id*. at 22-24.
21. *Id*. at 24-25.
22. *Id*. at 25.