

FEDERAL CIRCUIT DISAGREES ON *ALICE/MAYO*
APPLICATION TO MEDICAL TREATMENT
PATENTS

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On August 27, 2019, a split panel of the Federal Circuit in *INO Therapeutics LLC v. Praxair Distribution Inc.*¹, invalidated Mallinckrodt's patent claims on using inhaled nitric oxide ("iNO") to treat newborns with low blood oxygen levels, reasoning that they were directed to a natural phenomenon with no inventive step.² The disagreement in the panel revolved around whether the patents were directed to a natural phenomenon under the first step of the *Mayo/Alice* test. Although non-precedential, the decision raises questions about the future of Section 101 eligibility jurisprudence with respect to medical treatment patents.

Mallinckrodt asserted two sets of patents against Praxair's iNO gas cylinders in an infringement suit in the District of Delaware.³ Five of the patents, sharing a common specification, related to methods of administering inhaled nitric oxide (the "heart failure" or "HF" patents).⁴ The remaining five patents related to devices and methods for administering gas (the "delivery system infrared" or "DSIR" patents).⁵ The district court ruled that claims of the HF patents were invalid as directed to unpatentable subject matter and that the claims of the DSIR patents were not infringed.⁶ The Federal Circuit affirmed both the invalidity and noninfringement findings but vacated and remanded to correct a clerical error.⁷ This case comment, as well as Judge Newman's partial dissent, focuses on the invalidation of the five HF patents.

At the time of the invention, treatment of hypoxic respiratory failure with iNO gas had been a common practice in medicine, as nitric oxide dilates blood vessels in the lungs to increase blood oxygenation.⁸ Scientists in a Mallinckrodt-sponsored clinical study

¹ *INO Therapeutics LLC v. Praxair Distribution Inc.*, No. 18-1019, 2019 WL 4023576 (Fed. Cir. Aug. 27, 2019).

² *Id.* at *4.

³ *Id.* at *3.

⁴ *Id.* at *1.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.* at *1. The clerical error was that the district court erroneously entered judgment on unasserted claims of the Mallinckrodt patents.

⁸ *Id.*

in 2004 discovered that newborns with a heart condition known as left ventricular dysfunction (“LVD”) had increased risk of adverse events such as pulmonary edema, or the collection of excess fluid in the lungs, when treated with iNO gas.⁹ Mallinckrodt then designed and eventually patented a protocol to reduce the risk of pulmonary edema in iNO treatment of newborns, of which claim 1 of U.S. Patent No. 8,795,741 (“the ’741 patent”) is representative.¹⁰ The method recited in claim 1 includes multiple steps: identifying candidates for 20 ppm iNO treatment, determining which patients have LVD, administering 20 ppm iNO treatment to patients without LVD, and excluding patients with LVD from iNO treatment.¹¹

Writing for the majority, Chief Judge Prost reasoned that because the “exclusion” step is an instruction not to act, the claim is directed to the natural phenomenon of the relationship between LVD and an adverse reaction to iNO.¹² She expressed that “a claim not to treat—i.e., not to disturb these naturally-occurring physiological processes within the LVD patient’s body—risks monopolizing the natural processes themselves.”¹³ The difference between administering no dosage versus a smaller, nonzero dosage to a subset of patients was, to the majority, what reconciled this holding with precedents such as *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*¹⁴ and *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*¹⁵ In *Vanda*, a split panel held that a patent for treatment of schizophrenia that required a lower dosage for patients with a poor metabolizer genotype was not directed to a natural phenomenon.¹⁶ Similarly, in *Endo Pharmaceuticals*, the Federal Circuit held that a method of treating pain with oxymorphone that required a smaller dosage for patients with renal impairment was

⁹ *Id.*

¹⁰ *Id.* at *2.

¹¹ ’741 patent, col. 14 ll. 28–49.

¹² *INO Therapeutics*, 2019 WL 4023576 at *4.

¹³ *Id.*

¹⁴ *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019).

¹⁵ *Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018).

¹⁶ *Id.* at 1134.

not directed to a natural law.¹⁷ In contrast to the claims at issue in those cases, the Mallinckrodt HF patent claims, the majority stated, were “not focused on changing the physiological state of the patient to treat the disease Once the information is detected, no iNO treatment is given. And as far as the claim specifies, the patient’s state may remain unchanged and natural bodily processes may proceed.”¹⁸ Thus, if the HF patent claims had directed doctors to administer a lower dosage of iNO to newborns with LVD instead of no dosage, they would have passed Section 101 muster.¹⁹

A similar reasoning is employed for the step two analysis, where the majority concluded that the patent claims lacked an inventive step in their application of the natural phenomenon.²⁰ Under *Mayo*, simply stating the law of nature while adding the words “apply it” is not enough to transform a law of nature into patent-eligible subject matter.²¹ The opinion examined the five steps of claim 1 of the ’741 patent individually to see if any step provides “something inventive, beyond mere well-understood, routine, conventional activity,” and concluded that none did.²² Additionally, the majority concluded, even viewed together, that the claim could be characterized as stating a law of nature and directing the doctors to apply the law when treating their patients, thus failing the inventive step test laid out in *Mayo*.²³

Judge Newman was not convinced by the majority’s distinction between treatment and no treatment. She pointed out

¹⁷ *Endo Pharm.*, 919 F.3d at 1353.

¹⁸ *INO Therapeutics*, 2019 WL 4023576 at *7.

¹⁹ *See id.* at *4 (“The patent claim does no more than add an instruction to withhold iNO treatment from the identified patients; it does not recite giving any affirmative treatment for the iNO-excluded group, and so it covers a method in which, for the iNO-excluded patients, the body’s natural processes are simply allowed to take place. Consequently, the claim here is directed to the natural phenomenon.”).

²⁰ *INO Therapeutics*, 2019 WL 4023576 at *9.

²¹ *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012)).

²² *Id.*

²³ *Id.* at *10 (citing *Mayo Collaborative Servs.*, 566 U.S. at 79).

that the ruling conflicts with the Federal Circuit's precedent establishing method of treatment inventions as patent-eligible subject matter.²⁴ Judge Newman, like Mallinckrodt, characterized the claim as a "multi-step method of administering inhaled nitric oxide."²⁵ Thus, as a "new way of using an existing drug," the '741 patent claims would be eligible subject matter per *Mayo*.²⁶ In response to the majority's finding that the claims are directed to a natural phenomenon, Judge Newman criticized that the majority "improperly separates the claims into old and new steps" and "avoids the requirement that a claimed invention is considered as a whole,"²⁷ laid out in the Supreme Court case *Diamond v. Diehr*.²⁸ In her view, the claim viewed as a whole is not a law of nature, but a method of treatment.²⁹

Interestingly, Chief Judge Prost had herself dissented in *Vanda*, asserting that the claims at dispute did not differ in a legally significant way from those invalidated in *Mayo*.³⁰ Whether her distinction of this case from *Vanda* was an attempt to shift the Section 101 jurisprudence more towards her view of harmony with *Mayo* or was legally significant on its own merits is up for debate. The majority's line-drawing between action and inaction in medical treatment methods has been received with some skepticism.³¹ Could

²⁴ *Id.* at *13 (Newman, J., dissenting).

²⁵ *Id.* at *14.

²⁶ *Id.* at *13. (citing *Mayo Collaborative Servs.*, 566 U.S. at 87).

²⁷ *Id.*

²⁸ *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

²⁹ *INO Therapeutics*, 2019 WL 4023576 at *14.

³⁰ *Vanda Pharm.*, 887 F.3d at 1140 (Prost, C.J., dissenting).

³¹ See Ryan Davis, *Fed. Circ. Clouds Landscape For Medical Treatment Patents*, Law360, (Sept. 6, 2019)

<https://www.law360.com/articles/1196283/fed-circ-clouds-landscape-for-medical-treatment-patents> ("The majority suggested that if the patents advised doing something for the at-risk patients, rather than nothing, the outcome could have been different. But it's not clear that admonition could be translated into viable patent claims . . ."); Kevin Noonan, *INO Therapeutics LLC v. Praxair Distribution Inc.* (*Fed. Cir.* 2019), Patent Docs, (Sept. 3, 2019) <https://www.patentdocs.org/2019/09/ino-therapeutics-llc-v-praxair-distribution-inc-fed-cir-2019.html> (criticizing

such a distinction be overcome by a direction, instead, to administer a different kind of drug, or a negligible but nonzero dosage of the drug used in the patent? The majority emphasized the narrowness of their eligibility holding,³² but its analysis seems like it would apply to any method of treatment claims that call for exclusion of treatment in response to potential side effects. Because this case is non-precedential, the law's apparent departure from *Vanda* leaves the viability of exclusionary treatment patents unclear for pharmaceutical patentees and innovators.

the majority's assertion that the claim is directed to a natural phenomenon because it implies that "nature it seems provid[es] a caregiver who can give the gas as well as knowing without benefit of the invention when to refrain from giving it").

³² *INO Therapeutics*, 2019 WL 4023576 at *11.