IP Alert | Federal Circuit Gets Tied up in the Metaphysics of Not-Doing

Federal Circuit Gets Tied up in the Metaphysics of Not-Doing: INO v. Praxair

By Sarah A. Kagan, Ph.D.

In late August, Mallinckrodt[1] lost its bid at the U.S. Court of Appeals for the Federal Circuit to maintain its five patents directed to methods of treating only patients for whom a particular treatment is determined to be appropriate. The Federal Circuit affirmed the holding of the district court that the subject matter of the patents was not patent eligible because it fell under the judicial exception to patent eligibility for natural phenomena. INO Therapeutics LLC v. Praxair Distribution Inc. (2018-2019) (August 27, 2019).

Chief Judge Sharon Prost filed the opinion of the court, while Judge Pauline Newman filed a dissent in part. The court designated its opinion as non-precedential, and the majority emphasized that its holding is narrow, limited to the particular claims at issue and the particular involved circumstances. The claims at issue indeed are particular, in a certain aspect. That aspect is the step of not treating a certain class of patients. Nevertheless, the claims may be representative of a host of present and future inventions in the field of personalized medicine.

Claim 1 of U.S. Patent 8,795,741 was discussed as representative of the involved method claims. It is directed to processing a group of patients with a first condition, hypoxic respiratory failure, for possible treatment with a standard dose of inhaled nitric oxide (iNO). The method tests the patients for a second condition, left ventricular dysfunction (LVD). Those patients without LVD are treated with nitric oxide and those with LVD are excluded from treatment.[2] Withholding nitric oxide treatment from patients with LVD avoids a serious side effect in the patients, pulmonary edema.

The representative claim of the Mallinckrodt patents recites:

1. A method of treating patients who are candidates for inhaled nitric oxide treatment,

which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:

(a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;

(b) determining that a first patient of the plurality does not have left ventricular dysfunction;

(c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide;

(d) administering 20 ppm inhaled nitric oxide treatment to the first patient; and

(e) excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.

U.S. Patent 8,795,741 ,col. 14 ll. 28–49.[3] All of the court's analysis focused on steps (d) and (e).

Majority Opinion

Rather than viewing step (e) as positively excluding patients from treatment, the court construed step (e) as doing nothing but letting the underlying hypoxic respiratory failure run its natural course, emphasizing the negativity of step (e): "Properly understood, this added step is simply an instruction not to act."[4] "The claim is directed to…doing nothing…."[5] "[T]he patented method does not propose a new way of treating LVD patients…by titrating the iNO dose…."[6] The majority concluded that by not treating, the claim "risks monopolizing the natural processes themselves."[7] Step (e) could not provide an inventive concept to the claim, the court reasoned, because it involved leaving nature to run its course.

The court reasoned that step (d) could not provide an inventive concept because step (d) recited administering a standard dose of nitric oxide to a patient with hypoxic respiratory failure. The majority opinion dismissed Mallinckrodt's contention that the presence of step (d), a treatment step, was sufficient to render the claim patent eligible. Mallinckrodt's contention is based on an oversimplification of the Mayo/Alice test, the court responded, in which the claim as a whole must be analyzed, not just a single step. Yet the court did not consider step (d) and step (e) together, nor did it consider that step (d) might be inventive in the context of the entire method because the method achieved a 90 % reduction in severe adverse events. Because this reduction was the result of the natural phenomenon itself, the court would not consider it as contributing to an inventive concept in the Mayo/Alice test.

The majority opinion distinguished Mallinckrodt's claims from those in prior cases that the Federal Circuit has found patent eligible, such as in Vanda Pharm. v. West-Ward Pharm.,[8] Natural Alternatives Int'l. v. Creative Compounds,[9] and Endo Pharm. v. Teva Pharm.[10] In those cases, the court reasoned, the claims provided some level of treatment to the

affected patients (based on the natural law), such as a modified dose. In contrast, the court stated that step (e) of Mallinckrodt's claim "collapses into a claim focused on the natural phenomenon." Slip opinion at page13, paragraph 1.

Amazingly, the majority seemed to be affronted that the at-risk patients were withdrawn from exposure to a drug that risked causing pulmonary edema without offering them an alternative treatment. "In short, after observing an adverse reaction, the inventors could have developed a way to treat the diseases in question here based on their knowledge about the body's ability to undergo the phenomenon."[11] "Nor does it recite a way of reducing the risk of pulmonary edema while providing some level of treatment to those patients."[12] "[P]roceeding with the prior art treatment for hypoxic respiratory failure while offering no solution for neonatal patients with LVD does not transform these particular claims."[13] Saving the patients from one risk was not enough for the panel; the inventors should also have treated the remaining, underlying disease with a yet-to-be-discovered treatment. Perhaps this concern is more than humanitarian caring; perhaps it is patent pertinent. The court may be signaling that a way to save this claim would have been to recite treatment of the LVD patients with any alternative. That would have potentially turned step (e) into a non-disappearing claim element. It would have flipped the negative step into a positive action.

Dissenting opinion

Judge Newman's dissent rests on two pillars: first, that a claim must be considered as a whole and not dissected into individual steps considered in isolation; and second, that the claimed multistep method of treatment does not occur in nature. Although Judge Newman's position may be gaining traction with the patent bar, the majority of the Federal Circuit finds itself constrained by Supreme Court holdings in the last decade that are inconsistent with these fundamentals. (See a description of the judges' positions in our July 11, 2019 IP Alert here.) Finally, Judge Newman reminded her colleagues of the basis of the patent system, to incentivize disclosure to the public which itself promotes progress in the useful arts. This precept is ignored, she stated, when the court bases its decisions on the premise that patents will impede scientific and technological advances.

Implications

The majority was unpersuaded by Mallinckrodt's policy arguments regarding the negative effect of an ineligibility decision on the burgeoning field of personalized medicine.[14] Indeed, a major goal for personalized medicine is determining which patients will respond well to certain treatments to maximize efficacy in the treated population and to minimize ineffective treatments and adverse side effects. Achieving this goal serves the interests of individual patients as well as of the society that pays for these treatments. It is easy to see how genetic personalized medicine inventions could be expressed in claims similar to Mallinckrodt's. Absent a legislative fix to roll back the Supreme Court's Section 101 jurisprudence, only the skill of a claim drafter might be able to protect such inventions.

To view the court's opinion in INO v. Praxair click here.

To read our report of the oral hearings in this appeal click here.

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[1] Mallinckrodt merged with Ikaria, the parent of INO Therapeutics. Mallinckrodt is the patent owner.

[2] Note that the method requires processing of both a patient with and a patient without LVD. Thus, practicing the method would never result in merely assessing but not treating anyone.

[3] The majority's opinion did not discuss whether any of steps (a) – (c) required performance of diagnostic steps, rather than reviewing or collating results from third parties. Under current tests involving assessing what the claim is directed to, different constructions of steps (a) – (c) would not change the outcome.

[4] Slip opinion at page 10, paragraph 3.

[5] Slip opinion at page 10, paragraph 3.

[6] Slip opinion at page 10, paragraph 4.

[7] Slip opinion at page 10, paragraph 4.

[8] 887 F.3d 1117 (Fed. Cir. 2018)

[9] 918 F.3d 1388 (Fed. Cir. 2019)

[10] 919 F.3d 1347 (Fed. Cir. 2019)

[11] Slip opinion at page 16, first full paragraph.

[12] Slip opinion at page 11, second full paragraph.

[13] Slip opinion at page 22, footnote 6.

[14] Slip opinion at paragraph spanning pages 21 and 22.

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