iNO Therapeutics LLC v. Praxair Distribution Inc.
(United States Court of Appeals for the Federal Circuit, 2019)

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Case Summary

In this decision, the Court of Appeals for the Federal Circuit (hereinafter "the Court") ruled on the patent eligibility of a claim concerning a natural phenomenon. To evaluate the patentability, the Court utilized the criteria developed in previous case law to determine a) whether the claim is directed to a natural process/phenomenon; b) if so, whether the claim contains an eligible subject matter that can transform the claim itself into a patent eligible one.

The Facts

Inhaled nitric oxide (iNO) gas as a medical treatment for hypoxic respiratory failure in infants is a well-known prior art. In 2004, scientists working for the claimant, Mallinckrodt, made an important observation that administering iNO gas to "neonates or children" who have a specific heart condition may cause adverse effect.[1] In 2009, the claimant obtained several patents, including the '741 patent' related to methods of administering iNO gas for treating infants with hypoxic respiratory failure. It also registered patents related to a delivery device. Claim 1 of the '741 patent' provides for a method that includes:

(a) identifying infants with hypoxic respiratory failure that are ready for iNO treatment;
(b) determining that a first patient of the identified patients does not have the specific heart condition;
(c) determining that a second patient of the identified patients has the specific heart condition;
(d) administering iNO to the first patient; and
(e) excluding the second patient from iNO treatment.

The respondent Praxair is a gas company seeking to sell generic iNO gas cylinders with a delivery device. It filed an application with the Food and Drug Administration to obtain approval and to engage in the commercial manufacture, use or sale of its product. Mallinckrodt sued Praxair in a district court in 2015 alleging that Praxair's proposed product would infringe its '741 patent' and when used with its delivery system, infringes its patents on the device. It also claimed that Praxair's delivery device infringed a method claim of the patents on its device. This summary focuses on the patent eligibility of the '741 patent' claim.

The Legal Issues

The legal issues in this case concern the patentability of the claimed invention as a new and useful process, machine, article of manufacture, or composition of matter in accordance with Section 101 of Title 35 of the United States Code (i.e. patentable subject matter). The United States Supreme Court has ruled that laws of nature, natural phenomena and abstract ideas are not patent eligible as they are basic tools of scientific and technological work (*Mayo*

[1] Administering iNO gas to children with a congenital heart condition—known as left ventricular dysfunction ("LVD")— increases the risk of pulmonary edema.

collaborative Services vs Prometheus Laboratories). The same court, however, emphasized that an invention is not considered to be ineligible for patenting simply because it involves an excluded matter. It adopted a two-step test (known as the *Alice/Mayo* test) to determine whether claims are patent eligible (*Alice Corp vs CLS Bank Int'l*). The first step is to determine whether the claims at issue are directed to one of those patent-ineligible concepts. If the first step is affirmed, then, the second step examines what other elements are recited in the claims that individually or collectively can transform the nature of the claim into a patent-eligible inventive concept. In the present case, the district court ruled that, though some of the claimed steps in the '741 patent' require human action, the core of the alleged invention of the '741 patent is the natural phenomenon of an increased risk that develops when administering iNO to patients with the specific heart conditions, and hence, is ineligible for patent protection. Applying the second test, the district court determined that some of the steps in the '741 patent' only repeat the prior art while the others do not transform the natural phenomenon to the level of a patent eligible inventive concept.

Before the Court of Appeals (the Court) the claimant argued that its claim is not directed to a natural phenomenon, because it is a "selective administration" to exclude the patients with the special condition from iNO treatment through screening steps that had not been instructed before. In Mallinckrodt's view, the "exclusion" step is the reason the claims are not directed to a natural phenomenon as no treatment protocol had screened for such an adverse event before. Hence, Mallinckrodt argues that its claims cover an eligible "method of treatment."

Applying the first step, the Court stated that the causation of adverse effects by iNO treatment for infants who have the specific condition is a credibly testified natural phenomenon that has been taught to first-year medical students.[2] The Court agreed with the district court that the '741 patent is ineligible because it is directed to a natural phenomenon. In the Court's view, a closer look at the claim language as a whole confirms that the focus of the invention is not on a new way of actually treating the underlying condition of hypoxic respiratory failure. Nor does it recite a way of reducing the risk for patients with the identified specific condition while providing them with some level of treatment. Rather, the focus of the invention is screening for a particular adverse condition that, once identified, requires iNO treatment to be withheld. Contrary to Mallinckrodt's view, the Court considered that it is the *not to treat instruction* in the '741 patent' that directs the claim to the natural phenomenon. The claimant failed to prove that the patented method provided *a new way* of treatment or reducing the adverse effect by providing at least *some level* of treatment, such as changing the dosage of iNO or providing any other affirmative treatments. Conducting the first step of the Mayo/Alice test, the Court stated that merely a treatment step - an "act" involved in its claim - is insufficient to meet the requirement of patent eligibility.[3]

At step two of the test, the Court examined the claim elements, individually and as an ordered combination, to determine whether they contain an "inventive concept" that can transform a natural phenomenon into a patent-eligible application.[4] First, the Court stated that a separate "inventive concept" is necessary and cannot be substituted by the novelty of the discovery itself. What constitutes an inventive concept in a claim could be some "additional features", in addition to the recitation of an [abstract idea, law of nature or natural phenomenon], that to ensure 'that the [claim]' is more than a drafting effort designed to monopolize the [abstract

[2] P9, para. 3 of the judgement
[3] P17, para.1 of the judgement
[4] P17, section B, para 2, citing *Cleveland Clinic Found. V. True health Diagnostics LLC*, 859 F.3d 1352, 13s61 (Fed. Cir. 2017) (citing *Mayo*, 566 U.S. at 71-72).

idea, law of nature, or natural phenomenon]'.[5] Second, the Court reiterated the reasoning in *Mayo* that the " application of the claim must provide something inventive, beyond mere well-understood, routine, conventional activity."[6] In this regard, the Court held that apart from the "natural law", the steps of identifying, determining and administering in the claims of the '741 patent' are routine and conventional in the prior art,[7] whereas the final step of instructing (i.e. *do not treat patients with the specific heart condition*) essentially embodies the natural phenomenon. Thirdly, the Court ruled that the steps in the '741 patent' as 'an ordered combination' do not transform the claims into a patent-eligible application. The combination of treating patients without the specific heart condition with an existing dosage while excluding patients with specific heart condition from iNO treatment amounts to little more than an instruction to doctors to "apply" the applicable natural law when treating their patients. The claimant argued that there are benefits out of withholding iNO treatment that has resulted in significant reduction of adverse side effects. However, the Court disagreed and held that these benefits result solely from the discovery of this "natural phenomenon".[8] In conclusion, the Court upheld the district court's decision that the '741 patent' is ineligible.

One judge of the Court dissented from the majority ruling and argued that it was the claimant who discovered the relationship between iNO treatment and the adverse effect and the reasons why the adverse effect occurs. Accordingly, the claim is a multi-step method and apparatus of treatment that is designed and developed by a human to avoid adverse effects; it does not exist in nature as a natural phenomenon.[9] Therefore, the method shall not be considered as a claim that directs to a natural phenomenon. The dissenting opinion affirmed that the claim is still patent eligible as a method of treatment regardless of the natural phenomenon in it. In addition, the judge held that examining a specific step of a claim contravened the rule that a claim should be considered as a whole in terms of patent eligibility.[10] Furthermore, in the dissenting view, the majority's broad pronunciation of ineligibility of medical treatments relating to human physiology contravenes precedents on the patentability of medical treatments and the national interest in promoting innovation in that area.[11]

Points of Significance

- In this case, the Court examined what constitutes patentable subject matter. Under Article 27.1 of the TRIPS Agreement, WTO Members are required to provide patent protection for 'any invention' that meets the patentability criteria. The term 'invention' is not defined under TRIPS. National laws may exclude naturally occurring substances, processes and abstract ideas as subjects not considered as 'invention', as they need to be widely available for use and follow-on research. In *Association for Molecular Pathology v. Myriad Genetics, Inc*., No. 12-398 (U.S. June 13, 2013), the United States Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. The US Supreme Court in its decisions in *Mayo* affirmed that laws of nature/natural phenomena or natural processes

[5] P18, para.1 of the judgement, citing *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fe. Cir. 2015), quoting Mayo, 566 U.S. at 77-78
[6] Ibid. (quoting *Mayo*, 566 U.S. at 73)
[7] P18, para.3, found by District Court and confirmed by the Appeal Court
[8] P18, para.1 of the judgement, citing *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fe. Cir. 2015), quoting Mayo, 566 U.S. at 77-78
[9] P2, para.3 of Dissenting Opinion
[10] P5, para.3 of Dissenting Opinion, quoting from *Diamond v. Diehr*, 450 U.S. 175 (1981) at 188; *see Parker v. Flook*, 437 U.S.584, 594 (1978); *Aro Mfg. Co. v. Convertible Top Replacement Co.*,365 U.S. 336, 344 (1961)
[11] P7, para.3 of Dissenting Opinion

are patent in-eligible. For both naturally occurring substances and natural phenomena or processes, there is a need for additional elements to transform the subject matter from a realm of nature to a realm of invention (also referred as an 'inventive concept').[12]

- According to *Mayo* and *Alice*, methods of medical treatment are patentable if despite their being directed at a natural phenomenon, they constitute a specific human application of this natural phenomenon. In the case at hand, the Court clarified that an instruction not to treat, but to let a natural phenomenon take effect, lacks the affirmative human intervention required under *Mayo/Alice*, i.e. to turn a mere law of nature into a patentable invention. In that sense, the claimed method could have been eligible if it had provided a new way of treatment or reducing the adverse effect by providing at least some level of treatment, such as changing the dosage of iNO or providing any other affirmative treatments. But a mere instruction not to treat in the view of the Court "risks monopolizing the natural processes themselves"[13] – which could in that case no longer be relied on by medical practitioners in their daily work.
- An invention should be examined based on the specific circumstances in order to transform the claim of a discovery of a natural phenomenon into an eligible patent. Steps, taken separately, that only state the routine and conventional wisdom in the prior art do not transfer the claim into a patent-eligible inventive concept. The novelty of the discovery of a natural phenomenon itself is not transformative for patentability. Nor should a claimed benefit of reducing adverse side effects solely result from the discovery of a natural phenomenon. An inventive concept is missing in this case, since the combination of the steps for treating patients amounts to little more than an instruction to doctors to "apply" the applicable laws of nature.
- Developing countries are not required to follow this approach. Under the TRIPS Agreement, they are free to exclude naturally occurring substances and processes from subject matter eligible for patent protection, even where a claimed invention constitutes a specific human application of this natural phenomenon.

Key words: patentable subject matter, law of nature, natural phenomenon, Mayo/Alice test.

Decision available at: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-1019.Opinion.8-27-2019.pdf

[12] See the summaries of the *Myriad* and *Mayo* decisions in this database.
[13] P.10, para 4 of the judgement.