Keywords: Patentable Subject Matter

General: Using the subject matter eligibility examples provided by the USPTO does not guarantee that the claims comply with 35 U.S.C. § 101—especially claim 1 of Example 29.

Cleveland Clinic Foundation v. True Health Diagnostics
2018-1218 Fed. Cir. 2019
Decided April 1, 2019

I. Facts and Procedural History

Cleveland Clinic Foundation (Cleveland Clinic) sued True Health Diagnostics for infringement of several patents. The district court found claims in these patents invalid under 35 U.S.C. § 101 for being directed to an ineligible natural law. Cleveland Clinic appealed the decision to the Federal Circuit.

Atherosclerotic lesions are plaque buildups on artery walls. The formation of these lesions in the heart leads to atherosclerotic cardiovascular disease (the narrowing of the heart's arteries). Blood myeloperoxidase (MPO) was previously discovered in elevated levels in these atherosclerotic lesions. However, it had not been shown that elevated levels of MPO are present in the blood of someone suffering from atherosclerotic cardiovascular disease. Cleveland Clinic's patents disclose the ability to perform diagnostic tests to determine an individual's risk of developing cardiovascular disease by detecting MPO in the blood. This technique enables detection of atherosclerotic cardiovascular disease in people with low or moderate risk profiles. MPO is an enzyme that can be detected using an enzyme-linked immunosorbent assay (ELISA). These assays are well known and are able to determine a level of a molecule (antigen) by detecting the binding of the molecule to another molecule (antibody).

II. Issues

Is the detection of a molecule with a known technique patentable subject matter under 35 U.S.C. § 101?

III. Discussion

In the appeal Cleveland Clinic made four arguments:

1.) A technique that uses an immunoassay to measure the blood MPO levels of a patient with atherosclerotic cardiovascular disease is not a natural law;

2.) Correlating blood MPO levels to atherosclerotic cardiovascular disease is not a natural law because blood MPO can only be detected using certain techniques;

3.) Using an immunoassay to detect the correlation between blood MPO levels and atherosclerotic cardiovascular disease is an inventive concept that transforms the claims into patent eligible subject matter; and

4.) The district court erred in finding the claims invalid because the claims are analogous to patentable subject matter seen in Example 29 of the USPTO's Subject Matter Eligibility Examples.

First Argument

The Federal Circuit disagreed with Cleveland Clinic's first argument and found that the correlation between atherosclerotic cardiovascular disease and blood MPO is a natural law that exists in nature regardless of the technique used to observe it. The Federal Circuit ignored the argument that the claims were covering a technique not a correlation.

Second Argument

The Federal Circuit disagreed with Cleveland Clinic's second argument. The Federal Circuit found that just because a correlation can only be observed by using certain techniques does not make the correlation patent eligible subject matter—it is still a natural law.

Third Argument

The Federal Circuit disagreed with Cleveland Clinic's third argument. The Federal Circuit found that previous cases rejected the idea that using a known technique in a standard way to observe a natural law can create an inventive concept that overcomes Section 101. Therefore, because Cleveland Clinic was using a known technique in a standard way Cleveland Clinic's claims were directed to ineligible subject matter under Section 101.

Fourth Argument

The Federal Circuit disagreed with Cleveland Clinic's fourth argument as well. The USPTO publishes examples of claims that the USPTO considers patent eligible subject matter. One of these examples, Example 29, relates to a hypothetical method for detecting a protein in the blood. Claim 1 of Example 29 states:

> 1. A method of detecting JUL-1 in a patient, said method comprising:
>   a. obtaining a plasma sample from a human patient; and
>   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

Cleveland Clinic argued that the USPTO is an agency with expert knowledge relating to patentability, and that the USPTO provided claim 1 of Example 29 as an example of patent eligible subject matter. The district court therefore erred in finding that Cleveland Clinic's claims were directed to ineligible subject matter when the claims at issue are analogous to claim 1 in Example 29. The Federal Circuit did agree that courts should give some deference to informal agency interpretations of law. However, the Federal Circuit explained that it is not bound by the USPTO's interpretation of patent laws. The Federal Circuit justified this difference in interpretation by highlighting the similarities of the claims to the claims in another case (Ariosa) where the claims were found ineligible. To maintain consistency in decisions on patent eligible subject matter (i.e., Ariosa), the Federal Court found that the claims at issue are directed to patent ineligible subject matter.

IV. Conclusion

The Federal Circuit found that the district court did not err in finding that the claims were directed to ineligible subject matter under Section 101.

There are two takeaways from this case worth considering:

1. The Federal Circuit did not explicitly state that claim 1 of Example 29 is directed to patent ineligible subject matter. However, relying on claim 1 of Example 29 as an example of patent eligible subject matter is in doubt—at least in the courts.
2. The Federal Circuit is using Section 101 to invalidate claims they believe are not novel *enough* when the USPTO and litigants are unable to find references that anticipate claims or make them obvious. While not explicitly stating this, the Federal Circuit placed emphasis on the fact that Cleveland Clinic's patents did not disclose a new technique for detecting MPO and used statements from the patents as evidence. The result in this case would have likely changed if the ELISA were substituted with a more novel way of detecting MPO.

V. Claims from Cleveland Clinic's Patents

1. A method for identifying an elevated myeloperoxidase (MPO) concentration in a plasma sample from a human subject with atherosclerotic cardiovascular disease comprising:

a) contacting a sample with an anti-MPO antibody, wherein said sample is a plasma sample from a human subject having atherosclerotic cardiovascular disease;

b) spectrophotometrically detecting MPO levels in said plasma sample;

c) comparing said MPO levels in said plasma sample to a standard curve generated with known amounts of MPO to determine the MPO concentration in said sample; and

d) comparing said MPO concentration in said plasma sample from said human subject to a control MPO concentration from apparently healthy human subjects, and identifying said MPO concentration in said plasma sample from said human subject as being elevated compared to said control MPO concentration.

1. A method of detecting elevated MPO mass in a patient sample comprising:

a) obtaining a plasma sample from a human patient having atherosclerotic cardiovascular disease (CVD); and

b) detecting elevated MPO mass in said plasma sample, as compared to a control MPO mass level from the general population or apparently healthy subjects, by contacting said plasma sample with anti-MPO antibodies and detecting binding between MPO in said plasma sample and said anti-MPO antibodies.