SHIMOKAJI IP
INTELLECTUAL PROPERTY

July 2017

Shimokaji IP specializes in the litigation and registration of patent and trademark matters. We serve start-ups, Fortune 100 companies, government entities, and universities. Our expertise and representation extends across the US and throughout Asia.

Keep in touch! Email us ClientServices@shimokaji.com and explore www.shimokaji.com

What is Required to Patent a Diagnostic?

The Cleveland Clinic accused True Health of infringing the former's patents for testing the presence of myeloperoxidase (MPO) that indicates risk of cardiovascular disease.

The correlation between MPO and risk was based on the inventors compiling MPO data from a population to create a "control" value. The inventors analyzed the data, using statistical methods, based on whether the person was healthy or had cardiovascular disease.

According to the patents, if a patient's MPO exceeded the "control" value, the patient had a risk of cardiovascular disease.

In the Federal Circuit's view, the patents were methods for "observing the law of nature that MPO correlates to cardiovascular disease." Further, the patented method "starts and ends with naturally occurring phenomena with no meaningful non-routine steps in between - the presence of MPO in a bodily sample is correlated to its relationship to cardiovascular disease."

Moreover, the Federal Circuit observed that the patents have "not created a new laboratory technique; rather, [they use] well-known techniques to execute the claimed method." Nor did the patents create "new statistical methods."

Therefore, the patents do not involve "an inventive concept that transforms the natural phenomena of MPO being associated with cardiovascular risk into a patentable invention."

COMMENT:

This decision re-emphasizes that diagnostic inventions continue to face a patent hurdle. They need to do something more than detect something that is naturally occurring when the patient has a particular disease.

Merck Ordered to Pay Gilead $14M in Attorney Fees For "Unconscionable Acts" in Patent Suit

Gilead conceded that it infringed Merck's drug patents for hepatitis, if the patents were valid. A jury found the patents valid and awarded Merck $200M for patent infringement by Gilead.

Before Merck obtained its patents, Merck entered into a confidentiality agreement with Pharmasset to discuss the later's research efforts and compounds to treat hepatitis. The parties also entered into a material transfer agreement that enabled Merck to evaluate Pharmasset's compound - PSI-6130. The structure of PSI-6130 was to remain confidential.

A Merck in-house patent attorney, Durette, was handling Merck's own patent applications for hepatitis, as well as hepatitis patent applications for a Merck-Isis collaboration. Durette participated in a Merck-Pharmasset due diligence phone call in which the PSI-6130 structure was disclosed.

Durette later added to Merck's own patent application claims that "targeted Pharmasset's work" based on information he learned in the due diligence call. He also amended Merck's patent claims, after the Pharmasset patent application for PSI-6130 published.

In deposition, Durette testified that he was not on the due diligence call. He also testified that he never learned of the PSI-6130 structure. At trial, Durette recanted his deposition testimony.

The district court concluded that Merck engaged in "numerous unconscionable acts", including "misusing Pharmasset's confidential information, breaching confidentiality . . . agreements, and lying under oath at deposition and trial. . . . These acts unmistakably constitute egregious misconduct that equals or exceeds the misconduct previously found by other courts to constitute unclean hands."

Notwithstanding the jury verdict, the court ruled that Merck's unclean hands barred it from recovery for Gilead's patent infringement. The court also awarded Gilead $14M in attorney's fees for the unconscionable acts.

COMMENTS:

This is an example of the severe consequence to a party whose witness is found to be lying - not only is the finding of infringement taken away, but the party ends up paying attorney fees.

Does Your Patent Sufficiently Describe Your Testing Methodology?

The patent laws require that a patent describe the invention in a manner that allows a person skilled in the art to recognize that the inventor invented what is claimed.

Stanford and the Chinese University of Hong Kong (CUHK) were involved in a patent office interference proceeding to determine who invented a method for diagnosing fetal chromosomal abnormalities ("aneuploidies"). Both parties used cell-free fetal DNA ("cff-DNA") from maternal blood.

Stanford used a "digital analysis" method to analyze a large number of samples to detect small changes in the quantity of an aneuploid chromosome relative to quantities of targeted normal chromosomes.

However, Stanford argued that its patent specification also disclosed "random sequencing."

CUHK's "random sequencing " method did not require the detection of specific target sequences. Instead, sequence fragments were aligned to a reference genome to determine a chromosomal origin.

CUHK argued that when Stanford became aware of CUHK's patent claims, Stanford amended its patent claims to cover "random sequencing".

The Federal Circuit explained that Stanford's patent specification "could disclose both random and targeted sequencing." However, the issue of adequate disclosure could not be based on whether the specification "does not preclude targeted . . . sequencing."

They further noted that the Stanford patent specification referenced the use of an Illumina product for carrying out the method, but there was no indication of whether the reference meant random sequencing.

COMMENT:

The Federal Circuit sent the case back to the Patent Board for additional factual findings. But its decision points out the need for explicit, rather than implied, patent description of your invention.

Millennium Regains its Velcade Cancer Patent

The patented compound included bortezomib which was previously known as being effective against cancer. However, bortezomib never obtained FDA approval because of its instability.

The invention used a process of freeze-drying ("lyophilization"), during which a new chemical compound was formed, to provide stability to bortezomib. The new drug, Velcade, received FDA approval.

Millennium sued several generic companies for patent infringement. The latter argued that lyophilization was known in formulating pharmaceuticals, bulking agents were known to be used in lyophilization, and mannitol is a bulking agent.

The Federal Circuit countered that the "prior art does not teach or suggest that lyophilization of bortezomib in the presence of mannitol would produce a chemical reaction and form a new chemical compound, or provide a reason to make this specific new chemical compound, or that this new chemical compound would solve the previously intractable problems of bortezomib formulation."

The court explained that a "result is obvious when it is 'the natural result flowing from the operation as taught,' or a 'property that is necessarily present' when applying a process disclosed in the prior art."

COMMENT;

The decision points out, though implicitly, that finding obviousness cannot be based on merely finding each process component in the prior art. Nevertheless, perhaps the tipping factor in favor of non-obviousness in this case was the presence of a "new chemical compound".

Contact Us

SHIMOKAJI IP
8911 Research Drive
Irvine California 92618 USA
www.shimokaji.com
info@shimokaji.com
949-788-9961