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Federal Circuit Does NOT Have to Follow USPTO Patentability Guidelines

Earlier this year, the USPTO issued new Guidelines on what subject matter is patentable. The Guidelines state that they do NOT have the force of law.

The Federal Circuit seems to have now re-enforced that they are not bound by the Guidelines.

In *Cleveland Clinic v. True Health*, the patents related to diagnostic tests to determine whether a patient was at risk for developing cardiovascular disease (CVD). According to the patents, the tests were "based on the discovery that patients with coronary artery disease (CAD) have significantly greater levels of leukocyte and blood myeloperoxidase (MPO) levels."

Cleveland argued that the patents are not directed to unpatentable natural laws "but to the technique of using an immunoassay to measure the blood MPO levels."

They also argued that the district court "failed to give the appropriate deference to subject matter eligibility guidance published by the PTO."

The Federal Circuit disagreed, explaining the patents "only recite applying known methods to detect MPO levels in plasma, comparing them to standard MPO levels, and

Patent to Monitor Loss of Pressure in a Body Cavity - Obvious?

If you guessed "yes", you would be correct.

Hologic owned a patent for a "method for detecting the presence of perforations in body cavities" during ablation. It involves pressurizing the body cavity and "detecting whether the body cavity can maintain a pressurized condition."

Minerva sought to invalidate the patent.

The Patent Trial and Appeal Board (PTAB) found the patent obvious and invalid.

The Federal Circuit explained that "[a]blation is a medical procedure which involves distending or inflating a body cavity with fluid and heating that fluid to a sufficiently high temperature to destroy the cells lining the cavity. It is often used to treat abnormal bleeding within the endometrial layer of the uterus. . . . If the uterus is perforated, "steam or hot fluids generated during ablation . . . can escape the uterus and cause serious injury to nearby organs."

A prior art reference to Masterson described a method of thermally ablating the uterus, including using a pressure sensor to monitor intrauterine pressure and optionally using a

reaching a conclusion: that the patient's blood MPO levels are elevated."

Also, the Federal Circuit noted that "[w]hile we greatly respect the PTO's expertise on all matters relating to patentability . . . we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law."

COMMENT:

Patent applicants may find themselves in a catch-22. They may successfully use the Guidelines for patentability in the USPTO, but then have to take a different (or even conflicting) approach to argue patentability in the courts.

flow control sensor to alert a physician "to a possible leak somewhere within the system . . . or within the patient."

Hologic argued that "Masterson is directed to maintaining a stable pressue in the uterus rather than tracking changes in pressure."

The Federal Circuit countered that "Masterson can be configured to alert users about abnormal operating conditions 'such as . . . over and under pressure. . . . If Masterson can alert users to these conditions, then it must be able to monitor for changes in pressure.

Therefore, according to the Federal Circuit, Masterson disclosed Hologic's step of "monitoring for the presence of a perforation in the uterus using a pressure sensor."

COMMENT:

Hologic had a tough burden to overcome what seemed to be very close prior art, especially if the point of novelty was to merely monitor pressure.

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