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Does a Broad (Genus) Patent Invalidate a Narrow (Species) Patent?

No, according to the Federal Circuit in *UCB v. Accord Healthcare.*

UCB had a patent that covered its anti-epileptic drug Vimpat. Accord was a generic drug maker who stipulated to infringement but argued the patent was invalid.

The UCB patent covered "lacosamide" which belongs to a class of compounds called functionalized amino acids ("FAAs"). Before the filing date of the UCB patent application, FAAs had not been approved as an anti-epileptic drug, had not been the subject of clinical trials, and had not been disclosed for efficacy or safety.

The inventor of the UCB patent filed a prior patent application that disclosed FAAs "useful in the treatment of epilepsy." The lower court determined that the prior patent disclosure included "millions of possible compounds."

Lacosamide is a "species" of the "genus" disclosed in the earlier patent application.

The Federal Circuit explained that a person of ordinary skill in the art would not have selected a "lead compound" from one of several prior art disclosures, including the prior UCB patent. A "lead" compound" is one that would have been selected as a starting point for further development by one skilled in the art.

In fact, according to the Federal Circuit, one of the prior art references that disclosed an arguably relevant class of compounds "showed little potency."

The Federal Circuit concluded that the prior broader disclosures did not make obvious the narrower UCB patent.

COMMENTS:

The unstated emphasis for finding the narrow invention patentable seemed to be that it was just one of "millions" of combinations disclosed by the prior art.

Is Treating Schizophrenia With a Drug Patentable?

Yes, when based on patient genotype.

Vanda held patents to methods of treating schizophrenia with iloperidone. The dosage range was based on the patient's genotype.

West -Ward sought to make a generic drug of the Vanda drug. Vanda sued.

West-Ward argued that the patent claims were merely a "natural relationship"
among iloperidone, metabolism, and associated risks. Therefore, the patent claims were invalid, according to West-Ward.

The Federal Circuit disagreed. The patent claims were not directed to just the relationship among iloperidone, metabolism, and associated risks. The patent was for the "application of that relationship." The treatment dosage was based on a "genotyping assay." It was a "new way of using an existing drug."

The Federal Circuit concluded that the patent contained patent eligible subject matter.

COMMENTS:

The court seemed to emphasize the treatment nature of the patent claims, as opposed to unpatentable claims that just recite a recognition of a natural relationship.

Recent USPTO Guidance on What Treatment Methods Are Patentable

The USPTO recently updated its Manual of Patent Examining Procedures to include Section 2106.04. It provides guidance on what treatment methods can be patentable.

Section 2106.04 starts by explaining that "[l]aws of nature and natural phenomena . . . include naturally occurring principles/relations and nature-based products that are naturally occurring or that do not have markedly different characteristics compared to what occurs in nature."

Importantly, however, "not every claim describing a natural ability or quality of a product, or describing a natural process, is necessarily" patent ineligible.

Therefore, as an example, "a method of treating cancer with chemotherapy is not directed to the cancer cell's inability to survive chemotherapy." Thus, the patent claim may be patent eligible.

In another example, "a method of treating headaches with aspirin is not directed to the human body's natural response to aspirin." Thus, again, the patent claim may be patent eligible.

Section 2106.04 clarifies that "[f]or a process claim, the general rule is that the claim is not subject to the markedly different analysis for nature-based products used in the process. This is because the analysis of a process claim should focus on the active steps of the process rather than the products used in those steps."

COMMENTS:

The "focus" on "active steps" appears to be key. The patent claim cannot merely recite a naturally occurring relationship between two things. The patent claim must add "active steps" in using the relationship to achieve a result.

Is It Surprising That Electronic Medical Records Are Not Patentable?

Intelligent Medical Objects (IMO) appealed to the Patent Trial and Appeal Board a rejection of their patent application for "electronic record-keeping, organizing, and managing."

The patent examiner rejected the patent claims because they were directed to patent ineligible subject matter - "implementing a controlled vocabulary in a longitudinal electronic medical record by data objects pertaining to encounters, creating and storing a vocabulary with associated codes, [and] tagging a medical record with the vocabulary."

A longitudinal electronic medical record is a patient medical history since birth.

The Board reiterated that "collecting, storing, and organizing data" is patent ineligible. Classifying data, or remotely accessing the data, is likewise patent ineligible.

The Board pointed out that the patent specification described the inventive solution as "collecting, storing and managing electronic records over time.

Therefore, the Board affirmed the rejection.

COMMENTS:

The unstated hurdle for the applicant may have been that the invention was too broadly described in the patent specification.

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