

INTELLECTUAL PROPERTY LITIGATION

Distinguishing Unexpected Results
In Evaluating Non-Obviousness

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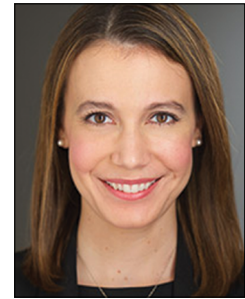
The Patent Act seeks to encourage innovation by protecting new and useful inventions. However, many inventions build on or combine previously known elements, requiring the Patent Office and courts to determine which combinations of, or improvement on, previously known elements are entitled to protection. In doing so, whether or not the claimed invention is patentable often involves asking whether the invention provides unexpected results. We report here on the Federal Circuit's recent decision in *In re Couvaras*, No. 2022-1489, 2023 WL 3984753 (Fed. Cir. June 14, 2023), which addresses whether finding a purportedly unknown mechanism of action constitutes unexpected results supporting patent protection.

**35 U.S.C. Section 103:
Non-Obviousness**

In order to be eligible for patent protection, the claimed invention as a whole cannot have been obvious to a person having ordinary skill



By
**Catherine
Nyarady**



And
**Crystal
Parker**

in the art at the time the patent was filed. 35 U.S.C. Section 103. The Supreme Court has explained that in determining if a claimed invention is obvious, one must consider: the scope and content of the prior art; the differences between the prior art and the claims at issue; the level of ordinary skill in the field of invention; and any objective indicia of non-obviousness. See *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966).

In evaluating obviousness, the Supreme Court further noted that "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See *KSR International v. Teleflex*, 550 U.S. 398, 416 (2007).

The court recognized that “the fact that [two known elements] worked together in an unexpected and fruitful manner” had been found to support “the conclusion that [the combination] was not obvious to those skilled in the art.” (discussing *United States v. Adams*, 383 U.S. 39 (1966)). As a result, patent applicants seeking to patent inventions that include known elements often argue that their combination is entitled to patent protection because it yields unexpected results.

Patent Background and Patent Trial Appeals Board Decision

In *Couvaras*, John L. Couvaras filed a patent application for a method of combatting hypertension, also known as high blood pressure. *In re Couvaras*, 2023 WL 3984753, at *1. In particular the filed claims were directed to a method of increasing the release of a particular compound (i.e., prostacyclin) in the body. The claimed method achieved this increase “by co-administering two well-known types of anti-hypertensive agents: a GABA-a agonist and an Angiotensin II Receptor Blocker (ARB).”

While prosecuting his patent application, Couvaras acknowledged that both GABA-a agonists and ARBs were known to treat hypertension independently. The patent examiner rejected Couvaras’s application finding that the claimed result (i.e., increased prostacyclin release) naturally flowed from the administration of the two known antihypertensive agents.

Couvaras appealed to the Patent Trial and Appeal Board (the board) arguing that the patentability of the combined administration of the two compounds was supported by a number of

objective indicia of non-obviousness including unexpected results. While Couvaras argued that his claimed drug combination resulted in unexpected prostacyclin release, the board concluded that there was no “showing of unexpected results here.” *Ex Parte John L. Couvaras*, Appeal 2022-001037, 2021 WL 6124743, at *7 (Patent Tr. & App. Bd. Dec. 1, 2021). In doing so, the board distinguished between discovering unknown drug properties and an invention that results in unexpected patient benefits. In particular, the board found that the purportedly unexpected increase in prostacyclin release was “simply a recitation of an inherent, but unknown, property of an otherwise obvious formulation” and that identifying an “inherent result” of com-

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binning two known compounds “does not constitute a patentable invention unless there is also a showing that the newly discovered inherent result also provides an unexpected benefit of some sort.” Contrasting unknown properties with unexpected benefits, the board found that the claimed combination did not “result in unexpectedly better control of hypertension, less toxicity to patients, the ability to use reduced dosages, or some other unexpected advantage.”

Federal Circuit Appeal

Couvaras appealed to the Federal Circuit, arguing that his invention was patentable

under *Honeywell International v. Mexichem Amanco Holdings*, which cautioned, in relying on inherency in the context of obviousness, that “that which may be inherent is not necessarily known and that which is unknown cannot be obvious.” 865 F.3d 1348, 1350 (Fed. Cir. 2017) (internal quotation marks omitted). In *Honeywell*, the Federal Circuit explained that “all properties of a composition are inherent in that composition, but unexpected properties may cause what may appear to be an obvious composition to be nonobvious.” As a result, the court found that the board had erred as a matter of law in assessing obviousness where it dismissed properties of the at-issue *Honeywell* claims as merely inherent without further consideration as to any potential unexpectedness or unpredictability of their results. The case was remanded to the Board to apply the correct law.

The Federal Circuit, however, rejected Couvaras’s argument and upheld the board’s finding of obviousness. The court explained that “reciting the mechanism for known compounds to yield a known result cannot overcome a prima facie case of obviousness, even if the nature of that mechanism is unexpected.” The court reasoned that because the two antihypertension agents resulted in a decrease in blood pressure separately, the combination of the two to treat high blood pressure was inherent. The court

explained that new results of known processes directed to the same purpose are inherent and therefore unpatentable.

In its decision, the Federal Circuit distinguished *Honeywell*, stating that *Honeywell* “held that ‘unexpected properties may cause what may appear to be an obvious composition to be nonobvious,’ not that unexpected mechanisms of action must be found to make the known use of known compounds nonobvious.”

The court also rejected Couvaras’s argument that the unexpected mechanism of action itself should have been given weight as an indicium of non-obviousness. Instead, the court found that to establish unexpected results, Couvaras needed to show that the combination provided an unexpected benefit (e.g., better control of hypertension, less toxicity to patients or the ability to use surprisingly low dosages). As Couvaras had demonstrated no such benefit, the unexpected mechanism was given no weight.

The Federal Circuit’s decision may provide some further guidance to patentees, in particular those in the pharmaceutical industry, in seeking to patent new combinations of known elements. In particular, the decision highlights the need of prospective patentees to tie any unexpected mechanism of action to a new, unexpected benefit.