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Prior Art Reporting Failure Does Not Provide Expectation of Success

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In *University of Strathclyde v. Clear-Vu Lighting LLC*, the Federal Circuit reversed the USPTO Patent Trial and Appeal Board (PTAB) decision finding certain method claims obvious, because the evidence did not support the PTAB's finding that a person of ordinary skill in the art would have had a reasonable expectation of success. Notably, the court instead found the prior art to report failure.

The Patent at Issue

The patent at issue was the University of Strathclyde's U.S. Patent No. 9,839,706, directed to methods for inactivating Gram-positive bacteria such as MRSA.

Claim 1 of the '706 patent recites, in relevant part:

1. A method for disinfecting air, contact surfaces or materials by inactivating one or more pathogenic Gram-positive bacteria in the air, on the contact surfaces or on the materials, said method comprising exposing the one or more pathogenic Gram-positive bacteria to visible light ***without using a photosensitizer*** …

The highlighted phrase was a feature at issue.

The IPR Decision

Clear-Vu challenged the patent in an Inter Partes Review (IPR) proceeding. The PTAB found claims 1-4 obvious over two prior art references: Ashkenazi, which reported an experiment to photoinactivate Gram-positive bacteria using photosensitizers, and Nitzan, which reported an experiment showing photoinactivation of MRSA only when photosensitizers were used. The PTAB nevertheless found that "Ashkenazi and Nitzan teach or suggest all the limitations of claims" 1-4 of the '706 patent (in part because Nitzan tested samples without photosensitizers), and also found "a reasonable expectation of successfully" combining the references to arrive at an effective method (in part because Ashkenazi stated that blue light "may" inactivate other bacterial cells that naturally produce photosensitizers).

The University of Strathclyde appealed.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Stoll and joined by Judges Clevenger and Reyna.

The Federal Circuit decision focused on the University of Strathclyde's arguments that the PTAB erred in finding that Ashkenazi and Nitzan together teach photoinactivation without the use of photosensitizers, and erred in finding a reasonable expectation of success.

With regard to the first argument, the court found that Ashkenazi only teaches photoinactivation ***with*** photosensitizers, and does not disclose or suggest photoinactivation without photosensitizers, and that Nitzan similarly showed successful photoinactivation only ***with*** photosensitizers and a failure to photoinactivate without photosensitizers. The court rejected Clear-Vu's argument that a skilled artisan would have combined Ashkenazi's teaching of increasing light dosage or frequency of illumination with Nitzan's test condition without photosensitizers, explaining (with emphasis added):

Given neither Ashkenazi nor Nitzan teaches or suggests inactivation of any bacteria without using a photosensitizer, we fail to see why a skilled artisan would opt to entirely omit a photosensitizer when combining these references. Indeed, the Board articulated no rational basis—and we discern none—for combining Ashkenazi's P. acnes experiments, which at all times used a photosensitizer, with Nitzan's non-ALA MRSA experiment, ***which did not achieve inactivation***, to arrive at an embodiment in which MRSA is inactivated by exposing it to 407–420 nm blue light without using a photosensitizer.

On the second argument, the court focused on the PTAB's finding that a skilled artisan would have reasonably expected to achieve photoinactivation of MRSA without photosensitizers because Gram-positive bacteria endogenously produce porphyrins (a type of photosensitizer). The court found:

The only support for such a finding is pure conjecture coupled with hindsight reliance on the teachings in the '706 patent.

The court rejected the PTAB's reliance on Ashkenazi's statement that blue light "may" inactivate "other bacterial cells that produce porphyrins," because there was "no evidence of record at the time of the '706 patent" that supported such an effect against MRSA. To the contrary, the court cited another publication by Nitzan indicating that natural porphyrin levels "are insufficient to inactivate MRSA using 407–420 nm blue light without also using a photosensitizer."

The court reasoned (with emphasis added):

Not only is there a complete lack of evidence in the record that any bacteria were inactivated after exposure to 407-420 nm blue light without using a photosensitizer, there is also evidence showing that ***others had failed*** to inactivate MRSA—one of the claimed Gram-positive bacteria—without using a photosensitizer, despite experimenting with different light doses and different wavelength ranges of blue light. We have found that such failures undermine a finding of a reasonable expectation of success.

Analogizing the facts at issue to *OSI Pharmaceuticals, LLC v. Apotex Inc.*, in which the court reversed a PTAB "obviousness determination because its finding of a reasonable expectation of success was not supported by substantial evidence," the court stated:

In view of Dr. Nitzan's reported failures for MRSA and lack of any "reliable indicator of success," we fail to see how Ashkenazi's prophetic statement about what "may" happen when "other bacterial cells" are exposed to blue light would lead a skilled artisan to reasonably expect that MRSA could be inactivated when exposed to 407–420 nm blue light without using a photosensitizer. The Board's finding that a skilled artisan would expect at least "some" inactivation for non-ALA MRSA—in view of Ashkenazi's teaching that increasing the light doses, the number of illuminations, and the length of time the bacteria are cultured can result in greater inactivation based on experiments that were conducted using a photosensitizer—is not supported by substantial evidence.

The court also soundly rejected Clear-Vu's argument that the success reported in the '706 patent itself supports the PTAB's finding. Noting such a theory rests on improper hindsight, the court explained (internal quotations omitted):

[T]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.

Thus, the court reversed the PTAB's obviousness determination.

Failed Prior Art Supports Non-Obviousness

The Federal Circuit decision concludes with this summary:

In this case, where the prior art evidences only failures to achieve that at which the inventors succeeded, no reasonable fact finder could find an expectation of success based on the teachings of that ***same*** prior art. The Board's finding is not supported by substantial evidence, and we therefore reverse its obviousness determination.

But it is the rare case where the prior art will evidence failure. If Dr. Nitzan hadn't published his "failed" experiments, would Ashkenazi's "prophetic" statement about what "may" happen have been sufficient to support a finding of reasonable expectation of success?

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