Keywords: **person of ordinary skill in the art, reasonable expectation of success, effective claim limitations**

General: **A POSITA would have no reasonable expectation of success in using a particular method where no evidence is shown in the prior art and, further, the particular method is said in the prior art to be unsuccessful.**

University of Strathclyde v. Clear-Vu Lighting LLC
United States Court of Appeals, Federal Circuit
No. 2020-2243
Decided November 4, 2021

I. Facts

University of Strathclyde ("Strathclyde") owns U.S. Patent No. 9,839,706 ("the '706 patent"), which is directed towards methods for controlling transmission of and sterilization of antibiotic-resistant bacteria. The '706 patent discloses that prior art methods involve treating infections by applying a photosensitizing agent and activating the photosensitizing agent using visible light. Scientists at Strathclyde ran a series of experiments and found that blue light was effective at inactivating *Staphylococcus* bacteria without applying the photosensitizing agent. Based on the experiments and findings, the scientists claimed a method in the '706 patent that inactivated bacteria by exposing it to blue light without applying a photosensitizer.

Clear-Vu filed a petition for *inter partes* review of claims 1-4 of the '706 patent and the Board instituted review. Clear-Vu argued that the claims of the '706 patent were anticipated by Nitzan or, in the alternative, were obvious over Ashkenazi in view of Nitzan.

Nitzan studied the difference between inactivation results for bacteria grown on a media supplemented with porphyrins and a control without supplemental porphyrins. Nitzan reported that there was no decrease in viability of the bacteria without supplemental porphyrins after applying blue light.

Ashkenazi discusses applying blue light to a Gram-positive bacteria[1] after applying a photosensitizer that produced porphyrins, a molecule that absorbs visible light. Ashkenazi concluded that greater amounts of porphyrin in the bacteria resulted in better inactivation results.

[1] Gram-positive refers to a "Gram" stain test which is used to determine what type of cell wall structure a bacterium has. Staphylococcus bacteria and the bacteria tested in Ashkenazi are both Gram-positive.

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The Board determined that Clear-Vu failed to prove Nitzan anticipates the claims because Nitzan did not demonstrate inactivation without a photosensitizer. However, the Board agreed with Clear-Vu that the claims would have been obvious over Ashkenazi and Nitzan. The Board found that Ashkenazi and Nitzan teach or suggest all the limitations and a person of ordinary skill in the art ("POSITA") would have been motivated to combine the references and would have had a reasonable expectation of success in doing so.

The Board concluded that the only dispute regarding the claim limitations was whether the prior art taught exposing bacteria to light without using a photosensitizer and determined the references teach this limitation. Both parties agreed that *Staphylococcus* bacteria naturally produces at least some porphyrins. The Board then found that a POSITA would have a reasonable expectation of inactivating bacteria using blue light without applying a photosensitizer due to naturally produced porphyrin in the bacteria. The Board determined that increased light doses taught by Ashkenazi would cause some amount of inactivation. The Board concluded that the claims do not require any specific amount of inactivation and a POSITA would have reasonably expected some amount of inactivation. Strathclyde appealed to the Federal Circuit.

II. Issue

Did the Board err in holding that claims 1-4 are unpatentable over Ashkenazi in view of Nitzan under 35 U.S.C. § 103 by finding (1) that Ashkenazi and Nitzan disclosed all the claim limitations and (2) that a POSITA would have a reasonable expectation of success in inactivating bacteria using blue light without a photosensitizer?

III. Discussion

Yes. The Federal Circuit first examined the Board's finding (1) that the prior art disclosed all the claim limitations, in particular inactivating bacteria using blue light without a photosensitizer. The Federal Circuit determined that the Board's finding is not supported by substantial evidence. The Federal Circuit stated that all of Ashkenazi's experiments involved use of a photosensitizer and there is no evidence Nitzan successfully achieved inactivation without use of a photosensitizer. The Federal Circuit pointed to the Board's finding that Nitzan failed to anticipate the '706 patent claims because of the lack of inactivation. The Federal Circuit found that the Board articulated no rational basis for combining the photosensitizer experiments of Ashkenazi with Nitzan's non-photosensitizer experiments which did not show inactivation. The Federal Circuit particularly pointed out that Nitzan disclosed non-photosensitizer experiments were wholly unsuccessful in achieving activation.

The Federal Circuit then turned to the Board's finding (2) that a POSITA would have a reasonable expectation of success in inactivating bacteria using blue light without a photosensitizer. The Federal Circuit determined that the Board's finding was based on pure conjecture and hindsight. Specifically, the Federal Circuit found that neither reference provides evidence or promising information for inactivation without using a photosensitizer. The Federal Circuit found that Nitzan's results are directly contrary to the Board's rationale because Nitzan's results indicated that natural levels of porphyrins would be insufficient for inactivation without the use of photosensitizers. The Federal Circuit stated there is a complete lack of evidence that

any bacteria were inactivated without use of a photosensitizer and, additionally, there is evidence that others failed previously to inactivate bacteria without use of a photosensitizer. The Federal Circuit cited a similar pharmaceutical case[2] where the Board's obviousness determination was reversed because the cited references contained no evidence or data regarding a drug's efficacy in treating lung cancer and there was a 99.5% failure rate for other lung cancer drugs in clinical trials. The Federal Circuit found in that case that "the only reasonable expectation at the time of the invention was failure, not success."[3] The Federal Circuit reaffirmed that absolute predictability or guaranteed success is not a requirement, only a reasonable expectation of success and that the prior art in this case evidences only failures such that no reasonable POSITA could find an expectation of success.

IV. Conclusion

The Federal Circuit reversed the Board's decision and reinstated the '706 patent. The Federal Circuit pointed to the complete lack of evidence of success in the prior art references in reversing the obviousness determination. Furthermore, there was evidence that applying blue light without a photosensitizer would fail in inactivating bacteria.

V. Representative Claim from '706 Patent

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, wherein the one or more pathogenic Gram-positive bacteria are selected from the group consisting of Methicillin-resistant *Staphylococcus aureus* (MRSA), Coagulase-Negative *Staphylococcus* (CONS), *Streptococcus*, *Enterococcus*, and *Clostridium* species, and wherein a portion of the visible light that inactivates the one or more pathogenic Gram-positive bacteria consists of wavelengths in the range 400-420 nm, and wherein the method is performed outside of the human body and the contact surfaces or the materials are non-living.

[2] *OSI Pharmaceuticals, LLC v. Apotex Inc.*, 939 F.3d 1375 (Fed. Cir. 2019)
[3] *OSI Pharmaceuticals* at 1385.

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