

Fed. Circ. In April: Introducing New Evidence During IPR

By **Sean Murray and Jeremiah Helm** (May 28, 2025)

This article is part of a monthly column that highlights an important patent appeal from the previous month. In this installment, we examine the Federal Circuit's ruling in Sage Products LLC v. Stewart.

In its April 15 decision in Sage Products LLC v. Stewart, the U.S. Court of Appeals for the Federal Circuit **gave a boost** to patent challengers seeking to invalidate patents in inter partes review proceedings. The case is notable because the court upheld the decision of the Patent Trial and Appeal Board to allow a petitioner to rely on case-dispositive evidence beyond the prior art references raised in the petition.



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Inter Partes Review Background

Congress created the inter partes review process to provide a streamlined procedure for canceling invalid patents. Unlike in district court, where any ground for invalidity may be raised, an IPR petitioner may only assert theories of anticipation or obvious, and only based on paper prior art such as patents and publications.



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The rationale for the new IPR procedure was compelling: If the invalidity of a patent can be determined just by looking at a handful of documents, an accused infringer should not be required to spend a small fortune litigating in federal court until, years later, it finally gets the opportunity to present its invalidity case to a judge or jury.

The IPR process is streamlined because it generally does not attempt to resolve factual disputes about what occurred in the real world. District court litigation is more expensive and time-consuming because it addresses many such questions.

District court litigants conduct extensive discovery and adduce evidence to resolve real-world disputes such as whether the defendant induced others to infringe, whether the defendant's alleged infringement was willful, whether the named inventors derived their invention from a third party, whether the plaintiff obtained by the patent by perpetrating a fraud on the U.S. Patent and Trademark Office, and whether the alleged infringement caused harm to the plaintiff.

Certain validity theories also require proof about what happened in the real world. For example, a patent may be invalidated in district court by proving that the invention was publicly known or in public use before the plaintiff's invention date or patent application.

But such invalidity theories have never been permitted in IPR proceedings. An IPR petitioner can invalidate a patent only by showing (1) that the patent is anticipated because all the elements of a challenged patent claim are disclosed in a single prior art document; or (2) that the elements are disclosed in a handful of documents and combining them would have been obvious.

The Sage Products Dispute

The Sage Products decision is significant because the Federal Circuit approved the board's decision to rely on evidence beyond the prior art references themselves, including confidential corporate documents that were not published and therefore could not possibly qualify as prior art.

The dispute began when Becton Dickinson & Co. filed two petitions seeking inter partes review of two patents owned by Sage. Sage's patents related to sterilized chlorhexidine products, such as applicators filled with an antiseptic composition for disinfecting skin. The challenged patent claims all required that the claimed chlorhexidine products be sterilized.

BD's primary prior art reference was the Chloraprep public assessment report, a publication of the U.K. government approving the sale of Chloraprep, an antiseptic solution containing chlorhexidine. BD argued that the public assessment report anticipated the challenged patent claims because it disclosed each element of those claims.

In its patent owner response, Sage argued that the public assessment report did not disclose that Chloraprep was sterilized, only that it was sterile. Sage pointed out that nothing in the public assessment report stated that the Chloraprep product had been subjected to a sterilization process.

With its petitioner's reply, BD submitted documents and expert testimony to prove that a person of ordinary skill in the field would have understood that Chloraprep was sterilized.

One of these documents was the British standard for the sterilization of medical devices. BD also submitted a declaration by its expert in which the expert opined that a person of ordinary skill in the field would have understood that Chloraprep was subject to the British sterilization standard and therefore would have been sterilized.

The board accepted BD's argument. It found that a person of ordinary skill in the field would be familiar with the differing regulatory regimes in the U.S. and the U.K., and consequently would have interpreted the public assessment report in view of the British sterilization standard. The board therefore found that a person of ordinary skill would have understood the public assessment report to disclose a sterilized Chloraprep product.

The board's sterilization finding allowed it to conclude that Sage's patent claims were anticipated because all of the claim elements were disclosed in a single prior art reference.

This is significant because, to reach this conclusion, the board had to rely on another document: the British sterilization standard. Normally, when the elements of a patent claim are disclosed by a combination of prior art documents, the claim can only be invalidated under an obviousness theory.

The Federal Circuit Decision

On appeal, the Federal Circuit affirmed the board's final written decisions invalidating Sage's patents, including the board's finding that the public assessment report anticipated both patents. The court ruled that substantial evidence supported the board's findings about the background knowledge that a person of ordinary skill in the field would possess.

Interestingly, the Federal Circuit was not concerned that the board found anticipation — which requires that everything in the patent claim be disclosed in a single prior art reference — by looking to multiple documents. The court ruled that there was "nothing improper in

the Board relying on evidence outside of the PAR to make findings as to what the skilled artisan would understand the PAR to be disclosing."

This ruling was essential to BD's IPR challenge to Sage's patents. The board could not have found the patents obvious in view of the combination of the public assessment report and the British sterilization standard, because BD did not assert this obviousness theory in its IPR petitions. So instead, the board and the Federal Circuit treated the British standard not as a prior art reference, but as evidence of how the PAR would be understood.

In its opinion, the Federal Circuit downplayed the significance of the case. The court cited two cases to show it had previously approved the use of expert testimony to determine how an allegedly anticipating reference would be understood.

But those cases involved claims of inherent anticipation. When a patent challenger argues that a claim element not mentioned in a reference is inherently disclosed by the reference, expert testimony is necessary to prove that the element would necessarily be present. BD did not argue that ChloroPrep was necessarily sterilized or that the sterilized element was inherently disclosed by the public assessment report.

Conclusion

Despite the Federal Circuit's attempt to frame its Sage Products decision as a mere application of earlier precedent, the decision has real significance for intellectual property practitioners. The court's ruling affords petitioners in IPR proceedings greater latitude in the type of evidence they may present and when they may present it. Petitioners do not need to anticipate — at the time they file their petitions — all of the prior art documents they will need to prove invalidity.

If the patent owner responds to the petition by arguing that a claim element is not disclosed by the petitioner's prior art, the petitioner can introduce new evidence in its reply to show that one of its prior art references would be interpreted to disclose the missing element. The Sage Products decision is therefore a boon to those seeking to invalidate a patent in an IPR proceeding.

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