

# Inherent Anticipation: Federal Circuit Cases Over the Past Two Years

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In my practice I typically find it more challenging to determine whether there exists a colorable inherent anticipation defense as compared to other anticipation arguments and obviousness arguments. With inherent anticipation, I find myself contemplating at length whether or not the defense fits in a given instance. I, therefore, thought it would be helpful to take a look at recent Federal Circuit case law applying the inherent anticipation doctrine in an effort to continue to gain clarity as to the nature and contours of the defense and the circumstances under which it is most likely to be asserted successfully. First, however, I provide a brief refresher on the fundamental tenets of the inherent anticipation doctrine.

A prior art reference anticipates a patent claim if the reference discloses each element of the claim, either expressly or inherently. A finding of anticipation is appropriate when the claim element that is not expressly disclosed in the single, allegedly invalidating, prior art reference nonetheless necessarily and inevitably results from the disclosed steps. It is not enough that the element may result. The Federal Circuit has repeatedly noted that inherency is a “very tricky” patent law concept and has warned that overly broad application of the doctrine threatens to stymie innovation. The Federal Circuit has further counseled that one of ordinary skill in the art must have been able to reasonably understand or infer that the reference disclosed the relevant claim element.

The Federal Circuit has substantively analyzed an inherent anticipation defense on seven occasions over the past two years. These cases are identified and described below. On reviewing these cases, a few takeaways become apparent. These takeaways are set forth below. As an initial matter, however, it bears noting that the Federal Circuit has made clear that the doctrine of inherent anticipation is distinct from instances where anticipation is found despite a lack of disclosure of the precise combination/arrangement of elements as recited in the patent claim at issue on the basis that the skilled artisan would “at on envisage the claimed invention.”

- Of the seven instances over the past two years where the Federal Circuit substantively analyzed an inherent anticipation defense, on four occasions the Court affirmed a finding of inherent anticipation. While this might sound favorable for patent challengers, it should be kept in mind that inherent anticipation is a factual determination reviewed for substantial evidence/clear error.<sup>[1]</sup>

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- These recent Federal Circuit cases make clear the significance of adhering as strictly as possible to the prior art procedures when conducting a prior art reproduction in an effort to demonstrate inherent anticipation.

- The Federal Circuit has continued to emphasize that a mere suggestion of a claim element not expressly disclosed in the allegedly anticipatory reference is insufficient. Rather, the claim element not expressly disclosed in the reference must necessarily and inevitably result.

- The Federal Circuit has had occasion to re-affirm the vitality of the burden-shifting frameworks set forth in *In re Schreiber* and *In re Spada*. The Federal Circuit has characterized the *In re Schreiber* framework as follows: if the examiner establishes that there is reason to believe that a functional claim limitation was taught in the allegedly anticipatory reference, the burden shifts to the applicant to disprove that the reference teaches the limitation. The Federal Circuit has made clear, however, that the examiner must expressly provide the rationale supporting the belief that a functional claim limitation was taught in the allegedly anticipatory reference. The *In re Spada* framework applies once the PTO has established a sound basis for believing that the applicant's products and the prior art products are the same, at which point the burden shifts to the applicant to show that they are not.

Below are brief synopses of each of the Federal Circuit's (referred to below as the "CAFC") decisions over the past two years substantively analyzing a patent challenger's inherent anticipation defense.

- *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345 (Fed. Cir. 2016): The patent claims challenged based on inherent anticipation were directed, in relevant part, to a controlled release dosage form comprising one or more active pharmaceutical ingredients (APIs) with abuse potential selected from the group consisting of opiates and opioids, wherein said dosage form has a breaking strength of at least 500N. The breaking strength claim limitation was not expressly disclosed in the allegedly anticipating prior art reference. Defendant argued that the limitation was necessarily present and, therefore, inherently disclosed in the reference. In support of this argument, defendant relied upon testing purportedly demonstrating that dosage forms otherwise meeting the requirements of the patent claims at issue exhibited a breaking strength of at least 500N. Based on this testing, the district court held that the relevant patent claims were invalid for inherent anticipation and the CAFC affirmed. The district court's holding and the CAFC's affirmance were based on defendant's testing expert having thermoformed thousands of tablets according to the procedures disclosed in the anticipatory reference, using a variety of chemical compositions, extruder temperatures, screw speeds, and die diameters, and, upon testing the tablets so formed, having demonstrated that not a single tablet had broken, including when forces in the thousands of newtons were applied.

- *3Form, Inc. v. Lumicor, Inc.*, 2016-1535, 2017 WL 443652 (Fed. Cir. Feb. 2, 2017): The CAFC affirmed the district court's grant of summary judgment of invalidity based on inherent anticipation. The relevant patent claims were product-by-process

claims directed generally to a decorative architectural panel comprising one or more compressible objects, wherein the one or more compressible objects maintain a substantially natural appearing conformation. Defendant's testing expert reproduced test panels according to the procedures described in the anticipating reference and testified that the test panels so produced maintained substantially natural appearing conformation. Further, when plaintiff's expert was presented with the test panels, he could not testify to the contrary with respect to any of the test panels prepared by defendant's expert. Significantly, the district court held analogous testing conducted by plaintiff's testing expert inadmissible due to the expert's failure to monitor certain significant control factors (e.g., time and temperature) and plaintiff did not challenge this evidentiary ruling on appeal.

- *In re Chudik*, 2016-1487, 2017 WL 74769 (Fed. Cir. 2017): The CAFC reversed the PTAB's holding that the application claims under consideration were anticipated and the Court remanded the matter. The applicant argued that the relevant prior art reference did not teach the functional limitation recited in the claims, that the claimed device can be used to create a passageway to a target site on a bone. The CAFC noted that there was no dispute that the case should be analyzed under the standard set forth in *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997), which the CAFC articulated as follows: If the examiner establishes that there is reason to believe that a functional claim limitation was taught in the allegedly anticipatory reference, the burden shifts to the applicant to disprove that the reference teaches the limitation. The CAFC further commented, however, that an examiner's belief must be "tethered to or grounded in" some rationale. The CAFC noted that while the Examiner believed that the claimed device was capable of reaching subdermal anatomical structures thereby satisfying the functional limitation recited in the claims, the examiner did not provide any justification/rationale for this conclusion. Accordingly, the CAFC held that the PTAB's decision was not supported by substantial evidence and reversed and remanded.

- *Eli Lilly and Company v. Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center*, 849 F.3d 1073 (Fed. Cir. 2017): The PTAB held, in the context of an inter partes review, that the patent claims under consideration was not anticipated. The CAFC affirmed. The key claim limitation under consideration required daily administration of a PDE5 inhibitor at a dosage of up to 1.5 mg/kg/day for not less than 45 days. The allegedly anticipatory reference taught daily administration for at least 3 days and more if the erectile dysfunction persists. The reference also taught administration for 8 to 12 weeks but did not teach daily administration for such a dosing regimen. The CAFC held that these teachings did not provide the "clear disclosure" required to find anticipation. The CAFC further noted that a "suggestion" of a claim limitation in the prior art does not suffice for purposes of an anticipation analysis.

- *White v. H.J. Heinz Co.*, 640 F. App'x 930 (Fed. Cir. 2016): The patent owner, White, appealed the PTAB's holding entered in an inter partes reexamination that the patent claims at issue were inherently anticipated. The CAFC affirmed. The relevant patent claims were directed generally to a condiment container for carrying various condiments comprising a cover for covering the open end of the container, where the cover is completely removable from the deep end of the container and is

from the shallow end of the container. The CAFC's opinion adopts the reasoning provided by the PTAB that there was not any structure disclosed that prevents the cover from being peeled beyond the handle portion; but rather the anticipatory reference states that the user stops the cover at a desired location. As to the patentee's argument that the reference did not anticipate the patent claims at issue because the reference could have but did not expressly disclose total removability of the container cover, the CAFC found more significant the absence of structure that would prevent removal of the container cover and noted case law holding that the possibility of drawing two inconsistent conclusions from the evidence will not render the Board's conclusion unsupported by substantial evidence.

- *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951 (Fed. Cir. 2016): The patent claims at issue were directed generally to a method for providing a polymeric material such as ultra-high molecular weight polyethylene ("UHMWPE") with superior oxidative resistance upon irradiation thereby generating UHMWPE implants with improved material properties. The patent owner Howmedica appealed the PTAB's holding during inter partes reexamination that the claims were invalid for inherent anticipation. The CAFC affirmed. The CAFC's opinion sets forth the burden-shifting framework articulated by the CAFC in *In re Spada* governing a comparison of a claimed product with a prior art product. According to this burden-shifting framework, once the PTO has established a sound basis for believing that the applicant's products and the prior art products are the same, the burden shifts to the applicant to show that they are not. Such a burden-shifting framework is fair, according to the CAFC, given the PTO's inability to manufacture products as well as the PTO's inability to obtain and make comparisons to prior art products. The CAFC affirmed the PTAB's application of this burden-shifting. The CAFC held that the heat treating and irradiation procedures disclosed in the anticipatory reference were not similar enough to the claimed procedures so as to allow for an inference that they are the same. The CAFC then turned to the declaration of Zimmer's testing expert. The Court affirmed the PTAB's finding that the expert declaration demonstrated that heat treating by the procedures described in the reference and those of the patent claims at issue generated UHMWPE with the same properties. The Court's holding was based on how faithfully defendant's expert reproduced the prior art procedure. The Court further rejected the argument that the PTAB accepted too many deviations from the prior art procedure, stating that a "sound basis" for finding identity does not require absolute certainty but rather requires the Board to make sufficient factual findings, such that it can reasonably infer that the prior art product and that of the patent at issue are the same. Based on the foregoing, the CAFC held that the PTAB correctly applied the *In re Spada* burden-shifting framework and that substantial evidence supported the PTAB's finding that Howmedica failed to meet its burden.

- *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345 (Fed. Cir. 2016): The patent claims at issue were directed to methods for reducing fouling (i.e., creation of insoluble deposits on processing equipment) when making ethanol by adding phytase. The district court granted summary judgment of invalidity based on inherent anticipation. The CAFC reversed. The CAFC held that there existed genuine issues of material fact as to whether the addition of phytase will always result in reduction of

fouling. The court identified opinions expressed by plaintiff's experts to the effect that factors other than addition of phytase can contribute to a reduction in fouling.

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[1] When an inherent anticipation defense is decided on summary judgment, however, whether or not there existed a genuine issue of material fact is reviewed on appeal de novo.

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