Fed. Circ. In July: Instability In IPR Requirements

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

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This article is part of a monthly column that highlights an important intellectual property appeal from the previous month. In this installment, we examine the Federal Circuit's ruling in Shockwave Medical v. Cardiovascular Systems.

When an inter partes review challenges an issued patent before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, it must be based on prior art consisting of patents or printed publications.

Despite that seemingly straightforward statutory requirement, more than a decade after IPR challenges were created, the USPTO and the U.S. Court of Appeals for Federal Circuit are still debating what evidence may be used in an IPR challenge.

The Federal Circuit's July 14 decision in Shockwave Medical v. Cardiovascular Systems **provided** an important, albeit short-lived, clarification to the role played by admissions made in the challenged patent, itself, to support an IPR challenge.

In many instances, patents discuss what was already known in the field. Such a discussion is often referred to as "applicant admitted prior art," or AAPA. Because a challenged patent is not prior art against itself, there has been confusion as to whether, and how, AAPA may be used in an IPR challenge.

Shockwave owns U.S. Patent No. 8,956,371, which is generally directed to treating atherosclerosis using a process called intravascular lithotripsy. Known treatments for atherosclerosis included balloon angioplasty, which used a balloon catheter to widen a blood vessel thereby increasing blood flow.

One common type of balloon catheter was known as an over-the-wire balloon catheter. Lithotripsy is a technique used in the treatment of kidney stones and involves using sonic waves, produced by an electrical charge or a laser, to break up the stones. The claims of the '371 patent were directed to an angioplasty catheter comprising both a pulse generator and an over-the-wire angioplasty balloon carrier.

Cardiovascular petitioned for IPR of the '371 patent. Its primary prior art publication, Levy, described using laser generated pulses to disintegrate plaque in blood vessels.

The petition also cited the '371 patent's discussion of what was already known in the field, specifically its AAPA discussion of "typical prior art over-the-wire angioplasty balloon catheters." Cardiovascular argued the claims of the '371 patent would have been obvious based on Levy as modified by the AAPA.

In July 2020, the board held most of the challenged claims unpatentable as obvious. In its decision, the board applied the AAPA as prior art under the statute. Soon after the board's decision, however, the USPTO issued binding guidance indicating that AAPA cannot constitute prior art consisting of patents and printed publications, as required by the

statute.

The board instituted rehearing and, in 2023, published a new decision that relied on the AAPA only as evidence of the background knowledge that would have been known to a person of ordinary skill in the art. In the new decision, the board again held most of the claims unpatentable as obvious.

Shockwave appealed and argued that the board had improperly relied on the AAPA as a basis for its petition. A few months before the Shockwave decision, the Federal Circuit **issued** an opinion in Qualcomm v. Apple holding that AAPA cannot form the basis for a petition, so it might have seemed that Shockwave's appeal was on good footing.

The Federal Circuit, however, explained that the petition in Shockwave was quite different from the petition in Qualcomm. In Qualcomm, the petitioner "expressly labeled AAPA as the 'basis' for its challenge"; this was an impermissible use of AAPA because only a patent or printed publication — and not AAPA — may form the basis for an IPR challenge.

In contrast, the petition in Shockwave used AAPA merely to demonstrate that the over-the-wire balloon catheter was well known. The Federal Circuit explained that AAPA may be used to establish general background knowledge, and such general background knowledge can supply a missing claim limitation.

Thus, the court held that the general background knowledge, as demonstrated by the AAPA, was appropriately used to establish the claims' limitations related to over-the-wire configurations.

Shockwave also argued that the board, in its decision on patentability, characterized the use of AAPA as a basis for the challenge and that AAPA cannot form the basis for an IPR challenge.

The Federal Circuit rejected this argument because the board's characterization was not controlling. Instead, as the court explained, the IPR petition itself defines the scope of the challenge. And unlike the petition in Qualcomm, Cardiovascular's petition did not clearly indicate that the AAPA was a basis for the obviousness arguments.

The Shockwave case appeared to provide a simple rule for practitioners: Cite AAPA as background knowledge when using it to supply a missing claim limitation and do not identify AAPA as the basis for the petition.

But Shockwave is not the end of the story. On July 31, the USPTO issued a memorandum to the board; this memorandum, nominally based on Qualcomm, indicated that the board would no longer be permitted to use general knowledge to satisfy a missing claim limitation.

Such general knowledge includes AAPA, expert testimony, common sense and other evidence that is not prior art consisting of patents or printed publications. Notwithstanding the prohibition, the board could still use general knowledge to support a motivation to combine or to demonstrate the knowledge of a skilled artisan.

The patent office indicated that it would implement the change by strictly enforcing Title 37 of the Code of Federal Regulations, Section 4,104(b)(4), which requires a petitioner to identify in the petition where each claim element is found in prior patents or printed publications.

The patent office cited Shockwave in a footnote and acknowledged that the requirement to find every claim element in a prior art patent or printed publication "as applied in some cases, may be narrower" than the corresponding statutory requirement. Nonetheless, the office concluded that its revised approach was being adopted because it would "allow for the efficient administration of the Office."

Shockwave illustrates the ongoing interplay between the USPTO and the Federal Circuit as they define and redefine the appropriate bases for IPR proceedings.

The initial board decision in Shockwave was modified on rehearing in response to the USPTO's binding guidance on AAPA. Qualcomm had clarified one situation where AAPA might not be permissible.

Shockwave, in turn, limited Qualcomm's applicability and endorsed the use of background knowledge to supply missing claim limitations. Following Shockwave, the patent office almost immediately narrowed the use of AAPA by indicating its intent to strictly enforce its own rules.

The USPTO's memorandum may be challenged in future litigation. For now, practitioners must account for both Federal Circuit precedent and the USPTO's guidance when citing AAPA in an IPR petition.

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