

Patent Validity Challenges in the Medical Device and Diagnostic Industry

To protect their patents, inventors and companies in the medical industry must know how to win the obviousness argument.

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The medical device and diagnostic industry often relies on patents to protect its innovations. In 2007, the U.S. Supreme Court issued its decision in *KSR International Co. v. Teleflex Inc.*, which clarified certain standards for assessing whether an invention is obvious and, therefore, not patentable.¹ This decision influences every stage of the patent lifecycle, including recording evidence of invention conception, applying for a patent, asserting an issued patent against an accused infringer, and defending a patent lawsuit.

Inventors and companies in the medical industry need to understand the KSR decision's impact so they can better position themselves to win the obviousness argument—whether as patent applicant, patentee, or accused infringer. Inventors and companies should leverage their internal resources, including internal inventors, researchers, and company personnel, to assist in developing compelling arguments for or against the obviousness of an invention.

Is It Patentable? Is the Patent Valid?

A utility patent may be granted to anyone who invents a new and useful process, machine, article of manufacture, composition of matter, or

a new and useful improvement of any of these. However, inventors and companies face a number of hurdles in navigating the U.S. patent system.

The KSR case concerned the hurdle of obviousness, which requires patent applicants to demonstrate to the U.S. Patent and Trademark Office (USPTO) that one or more prior references, such as articles, white papers, patents, etc., alone or together would not have rendered the alleged invention obvious to a person of ordinary skill in the art.² If the USPTO concludes that an alleged invention would have been obvious, it will not issue a patent for the invention.

Even if the hurdles presented during the patent application process are successfully overcome and the USPTO awards a patent, additional challenges await inventors and companies when they attempt to enforce the patent against an infringer in court. Accused infringers, for example, will likely argue that the court should invali-



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date the patent because the patented invention would have been obvious, despite the fact that the USPTO found otherwise. Parties accused of infringing a patent sometimes even rely on the same references that were considered and overcome in the patent application process.

Evolving Standards for Determining Obviousness

The U.S. Patent Act states that “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter per-

tains,” a patent cannot be obtained.

Over time, this statutory provision has been interpreted and clarified by the courts. For many years, the U.S. Court of Appeals for the Federal Circuit (charged with hearing appeals of patent-related decisions by the federal trial

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courts) used the so-called teaching, suggestion, motivation (TSM) test to determine whether an invention was obvious. The TSM test required that some teaching, suggestion, or motivation to combine prior references to achieve the alleged invention be shown.

In the KSR decision, the Supreme Court rejected the Federal Circuit's rigid application of the TSM test, and it instead confirmed that four factors should be considered when assessing obviousness

- “[T]he scope and content of the prior art.”
- “[D]ifferences between the prior art and the [patent] claims at issue.”
- “[T]he level of ordinary skill in the pertinent art.”
- [A]nd secondary considerations such as “commercial success, long felt but unsolved needs, failure of others, etc., [which] might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”

The Supreme Court emphasized that an expansive and flexible analysis should be performed and provided a few key hints as to what is, or is not, obvious. In particular, the Supreme Court stated

- “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”
- “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”
- “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.”

Since the KSR decision, law practitioners have had the benefit of seeing how lower courts have interpreted and applied the decision in the industry. These decisions provide insight as to how inventors and companies can position

themselves to win an obviousness argument in the application stage, when asserting an issued patent against an accused infringer, and when defending technology against accusations of patent infringement.

Obviousness and the Patent Application or Issued Patent

One key consideration culled from these court decisions is the impact that inventors and other company personnel can have on arguments concerning obviousness. The following are practical suggestions for patent applicants and patentees derived from post-KSR court decisions concerning obviousness.

Maintain Detailed Records of the Invention Process. Medical device inventors should maintain engineering or laboratory notebooks detailing and recording the invention, including unexpected results achieved from it. To help establish the legal definitions of conception, reasonable diligence, and reduction to practice regarding the invention, these notebooks should include dates and details of key meetings, conversations, and activities; figures and enabling descriptions of the invention, including test results; and signatures of the inventor and a witness. This documentation can be important in supporting a patent application or an issued patent, or in invalidating another entity's issued patent by proving which party first invented the invention at issue.

Create a Compelling Story of Invention. When asserting an issued patent against an infringer, inventors and companies in the medical device and diagnostics industry need to tell a compelling story of invention. This story, for example, may spring from the detailed engineering or laboratory notebooks maintained by the inventors. Additionally, the story may be tied to a need in the industry. For example, did doctors approach the inventor with a problem, stating they could not perform a particular medical procedure because no medical devices had been created for this purpose and the inventor then conceived the solution? Did the inventor observe that patients were unable to adequately heal after a procedure and conceive a solution? Did the inventor develop a medical device that

is low-cost, machine-made, and disposable, thereby providing better performance, reliability, and access to care for low-income people? Is the patented device saving lives or providing benefits that would have been forgone without it? Answers to these types of questions can be woven into a captivating invention story that may go a long way toward showing the invention at issue was not obvious.

Anticipate Questions of Obviousness. Patent owners should also be prepared to address obviousness arguments made by accused infringers. Inventors and other company personnel can help their attorneys by suggesting medical experts who are respected, knowledgeable, and relied upon in their field. Ideally, these medical experts should be able to help persuade the judge or jury that a patented invention is not obvious, explaining why in layman's terms.

Identify Meaningful Differences Between Prior Art and Your Invention. When applying for a patent, medical device inventors should strategize with patent counsel to conduct a prior art search before a patent application is drafted. That way, their patent counsel will be better able to differentiate the invention from prior inventions and prove it was not obvious. In addition, inventors and other company personnel can help evaluate prior art references cited by accused infringers in support of their obviousness arguments and point out meaningful differences between such references and the invention.

For example, does the difference mean the prior procedure's outcome would be a failure, result in additional healing time, or put the patient at greater risk of injury or death? Are the device sizes different, and does that matter because a larger device cannot access small areas of the body necessary to perform the procedure the patented device addresses? Is the prior art solution for addressing an adult ailment irrelevant for treating an unborn infant because the latter's anatomy is sufficiently different from an adult's and significantly more difficult to access? These types of differences, when shown to be meaningful, help support an argument that the invention was not obvious.

Emphasize Unexpected Results. Inventors and other company personnel can help explain how a patented invention yielded unexpected results. For example, does a medical device configured for adding fluid to a certain part of the body actually cause that portion of the body to be less hydrated, thereby addressing a medical ailment? In general, the more un-

expected the outcome, the more likely it is that the invention was not obvious.

Establish Skepticism Regarding the Invention. Inventors and other company personnel can help articulate why others were, or would have been, skeptical, unwilling, or unable to do what is patented. For example, perhaps the patented invention is coated with a material that is typically toxic to the body, but, as the inventor discovered, it can be used in an unexpected, helpful, and successful manner for some other medical purpose. Maybe it was discovered that removing a portion of an organ using the patented medical device achieved some successful result despite the fact that others would have been unwilling to try to remove that portion of the organ. In general, a patent owner should collect and highlight all evidence available regarding skepticism, unwillingness, or lack of ability.

Show Other Secondary Considerations in Support of Nonobviousness. Such considerations include evidence of commercial success achieved by, for example, selling caseloads of the invention; public accolades and awards; and articles praising the invention in medical journals, trade journals, newspapers, and magazines. Others include consumer testimonials addressing how the invention improved their lives; evidence addressing how the invention is being used in other technologies, including those outside the medical arena; evidence that the patented technology has been licensed or that licenses are being sought; and that a lengthy period of time passed between recognizing the problem and conceiving a solution (i.e., if the solution was obvious, it would not have taken so long to conceive it).

Obviousness as a Defense Against Allegations of Infringement

In the event a competitor asserts a patent covering a medical device or diagnostic against your company, your counsel may try to prove the invention was obvious and, as a result, the asserted patent is invalid. Counsel may also enlist the help of researchers and other technical company personnel to develop, articulate, and support the obviousness argument, as follows.

Examine the Prior Art for Obviousness. Company personnel can explain their understanding of the prior art and provide arguments for why that the alleged invention is a predictable variation or improvement within the reach of a person of ordinary skill in the relevant field.

For example, combining functions in one device that were previously provided in two separate devices may very well have been obvious.

Consider Technologies Outside the Field. Company personnel can also help attorneys better understand how and why they consider technologies outside their field in developing medical devices and diagnostics. Doing so may help uncover relevant prior art references that can lead to a successful obviousness argument. For example, do cardiac medical device engineers consider plumbing technologies in developing devices to navigate a curved, narrow, and difficult pathway? Do suture engineers consider materials and methods used in the craft-sewing arts to create and develop innovative devices to better hold together human or veterinary tissue? If so, prior art references in these alternative fields should be reviewed to see if they disclose the alleged invention alone or together with a prior art reference from the medical field at issue.

Minimize Differences Between the Prior Art and the Alleged Invention. As noted earlier, in preparing a defensible patent application, the patentee should seek to maximize differences between the invention and the prior art. Conversely, in defending against claims of patent infringement, a company should seek to minimize the importance of any differences between the prior art and the alleged invention.

For example, if the prior art device can only be used under fluoroscopy but the invention can be used under fluoroscopy and ultrasound, is this difference inconsequential to the success of the medical procedure? Why is it unimportant that a prior art medical device was only usable for veterinary procedures but not for use on humans? Would it have been an obvious variant to take the veterinary solution and apply it to humans? Would it have been obvious to use concepts for addressing adult medical concerns with children? Alleged infringers should strive to minimize the differences between the prior art and the alleged invention, and to establish that any differences are insignificant or merely represent the application of common sense.

Look for Secondary Considerations that Can Indicate Obviousness. Secondary considerations, such as those regarding the assertion of a patent, may also help establish that a patent is invalid due to obviousness. For example, evidence that the commercial embodiments of the patented invention are unsuccessful, received negative press, or were never

licensed may help illustrate that the alleged invention is trivial and would have been obvious.

Respond to the Patentee's Obviousness Arguments. Company personnel—like the inventors named on the patent at issue—can help their attorneys respond to the patentee's obviousness arguments by suggesting respected medical experts. Such experts can provide key insight and testimony—in layman's terms—regarding how and why the alleged invention is obvious. Furthermore, they can assist the attorneys with respect to the issues already discussed and rebut any experts testifying on behalf of the patent owner.

Conclusion

Even more than before, inventors and other company personnel play an essential role throughout the patent lifecycle when the issue of obviousness is raised, as illustrated in numerous court decisions applying KSR's principles. From conceiving the invention and maintaining meticulous engineering or laboratory notebooks to helping provide an understanding of an invention for the litigation arguments that may ensue, inventors and other company personnel are often in the unique position of understanding the technology as well as its medical application and benefit to society. That understanding can help the patent applicant or patentee develop compelling arguments that the invention would not have been obvious or, conversely, help alleged infringers seeking to show that an invention would have been obvious.

References

1. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).
2. *Patent Laws*. U.S. Code 35, § 103.

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