MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Best Practices: Designers and Patent Attorneys Unite

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Laying the groundwork for success means designers should involve a patent attorney early in the product design phase.
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Rampant litigation in the medical device industry not only costs companies millions of dollars each year, but it can also stifle innovation and put entire product lines in peril. It is a common misconception that patent clearance and filing for patent protection can only take place when a product is nearing completion or ready to go into the marketplace. Designers who evaluate the intellectual property (IP) implications of a new design in the early stages of development can avoid potential problems down the road.

It is important for the designer to work with a patent attorney during the process of designing a new device. The designer is responsible for developing the structure and functionality of the device. The patent attorney is responsible for determining whether aspects of the new design are covered by existing patents and whether aspects of the new device are patentable. The designer and patent attorney can work together throughout the design process to achieve these goals.

Involving a patent attorney in the design process lays the groundwork for a more successful and profitable device. Understanding the process can help designers get the most out of the interaction and ensure that they develop strategic designs from not only a functionality perspective, but also a legal one. This article focuses on the challenges that occur during the design process for products that are developed, made, used, or sold within the United States. Many of these concepts might also apply to foreign countries; however, it is necessary to consult a patent attorney in the specific foreign country to ensure compliance with the applicable patent laws.

Step 1: Determine Basic Design Features
The design process begins with the designer developing the basic structure and functionality for the new device. At the earliest design stages, the designer might only

know of basic conceptual ideas for the new design. For this article, an example of a new artificial heart design is used. Initially, the designer may have rudimentary ideas of main features related to the device's power source, valve layout, and pump configuration. Ideally, the designer should involve the patent attorney at this stage of development. The patent attorney helps the designer determine important criteria for the new design.

Step 2: Perform a Patent Search

The patent attorney evaluates design details to determine when there is sufficient information to perform a patent search that uncovers existing patents on this technology. There is a fine line between the time when the search is premature and the time when it is too late. If the criteria for the new design are too vague, the search may uncover too many patents or irrelevant patents. If the design is too far along in the development stage, the search may uncover patents that would be infringed by the new design and, therefore, a redesign of the original concept would be required.

Multiple searches are often performed during the design process. The specific details of the progressing design enable the search to be more specifically tailored and to uncover more relevant patent documents. The patent attorney and designer can work together on determining when to perform the searches.

By using a variety of available electronic databases, the patent attorney can perform the initial searching (see the sidebar, "How to Perform a Patent Search" [3]). Since the design is still in its infancy, vague criteria are used. The searches provide a general indication of the patent documents related to the design. The patent attorney may also have the patent search performed by a professional firm that can obtain more complete results. This type of searching requires the patent attorney to write a general description of the invention, along with an optional list of competitors or specific inventors for a more targeted approach. However, a professional firm often performs the final search, because it can be more thorough than a patent attorney at finding all the relevant documents. The electronic databases that are available to the patent attorney can be limited in their search capability, whereas professional firms specialize in performing searches.

The main focus of the patent search is usually to uncover documents that include technical aspects that are relevant to the present invention. It might also reveal other business-related information such as the number of patents owned by competitors, overall patents in the technical area, and how many patents fall within each of the product's main features. Using the artificial heart example, a given search could uncover a hundred or more patents relating to the technology, with perhaps dozens of them focused on the power source and relatively few focused on the valve layout. The dates of the discovered patents also reveal whether there is significant current interest in the technology.

Step 3: Clear the Patents

The next step is to ensure that the new design will not infringe on any of the patents uncovered in the search. The patent attorney compares the claims of each patent against the new design. During this stage, the designer and the attorney flesh out specific technical aspects of the new design and, when necessary, work on a redesign to avoid potential

infringement issues. Continuing the artificial heart example, a patent may be on point with the valve layout that was being considered by the designer. The patent attorney and designer can work together to further develop or change the valve layout to ensure it does not infringe on the patent.

Sometimes, a patent design cannot be worked around, or the designer does not want to change the new design to avoid potential infringement issues. The patent attorney can develop an invalidity opinion showing why the patent is invalid and therefore not a potential problem. The invalidation process may include the patent attorney searching for written documents that predate the patent and ideally were not considered by the U.S. Patent and Trademark Office (USPTO) during its examination of the patent. The basic concept of the invalidity opinion is to document that the patent would not have been issued if the USPTO had known about the one or more written documents. The invalidation process may also detail that the patent has a fundamental defect, such as not enabling someone of ordinary skill in the field to know how to make and use the invention of the patent. An issued U.S. patent has a presumption that it is valid. Therefore, the patent attorney may not be able to find prior art that overcomes this presumption and proves the patent is invalid.

Invalidation of a patent can only occur through a reexamination process at the USPTO or through the federal court system, which requires the submission of written documents. The USPTO performs an examination of the patent and determines that either the patent is valid as it was issued or that one or more of the claims are not patentable in view of the written documents. If the USPTO determines the claims are not patentable, the owner of the patent is given the opportunity to present arguments explaining why the patent is valid or amend the claims to differentiate them from the written documents. The reexamination process results in the patent either being reallowed with the same claims, being reallowed with one or more different claims, or being determined to be unpatentable and therefore invalid. The federal court system can officially invalidate a patent during a litigation process.

Deciding how to handle a potentially problematic patent is a business decision. Some businesses consider an invalidity opinion by the patent attorney adequate to overcome the patent and continue the design process. Others businesses require the patent to be officially invalidated through the reexamination process or the federal court system. The patent attorney can
provide guidance on making the determination, but ultimately the decision is based on the level of risk that a business is willing to take.

The patent search and clearance process usually concentrates on issued U.S. patents. The search may also be more thorough and include pending patent applications and non-U.S. patents. Pending U.S. patent applications have been filed but not yet determined to be patentable by the USPTO. Since the applications are still pending, the claims may change before issuance. This uncertainty about whether and in what form a pending application's claims will be issued complicates the infringement risk analysis. However, the patent attorney can review the disclosure of the pending application and determine whether the disclosed subject matter is novel and nonobvious, and whether any claims would be

infringed by the new design. Also, the patent attorney may watch the pending application by periodically reviewing its status at the USPTO. If the pending application eventually issues, the patent attorney can make a complete analysis of the patent and determine whether there are any infringement issues with the new design.

The patent search may also uncover foreign patent documents. These documents may be relevant for determining whether there are corresponding U.S. patents or pending applications. They could also be relevant as written documents for invalidity purposes.

Patentability Considerations

In addition to avoiding other patents, the design clearance process also helps to identify patenting opportunities for various aspects of the new design. The new design is patentable when it is novel and nonobvious over previously existing information. Unlike the clearance aspects that focus only on issued patent claims, patentability requires novelty and nonobviousness over all public information in existence before the conception of the design. It includes information from existing patent documents, including both what is claimed in the patents and what is disclosed but not necessarily claimed. It also encompasses nonpatent information, such as technical journals, product literature, textbooks, competitor products, and conference proceedings.

Both the designer and the patent attorney are aware of the differences between the new design and the uncovered patents, because each party has been involved during the clearance process. They may also search for any additional public information that could affect the patentability. In many cases, the designer is aware of other information such as technical manuals, competitor products, or research papers that may affect the patentability.

The patent attorney can review this information and determine whether there are one or more patentable aspects to the new design. From there, one or more patent applications can be crafted to specifically highlight and emphasize the differences between the new design and the previously obtained public information. Likewise, the information may reveal that patent protection isn't available for certain aspects of the new design. For the artificial heart example, the design process may lead to a valve layout that is fundamentally different than currently known layouts. These differences provide the patent attorney with the opportunity to craft one or more patent applications focusing on the key advances embodied in the new valve design. Conversely, the design of the pump may be different enough to avoid infringement issues but not different enough to be afforded patent protection.

Conclusion

The design process and related patent searching provides many benefits. The designer and the patent attorney collaborate to understand the technical aspects of the invention and work around existing related patents. Designers should avoid design elements that hold existing patent protection to help the company avoid costly, time-consuming legal battles.

A patent search may also uncover information about the competitors within the field of the invention. In an increasingly competitive marketplace, companies need to know as much

about industry peers as possible. A business's IP portfolio can expose weaknesses and provide advantages that shape strategy, budgets, and future design. This combined effort can lead to meaningful patent protection for new product design.

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