

Diversify Your Medical Device Patent Portfolio with Design Patents

by *Jason M. Honeyman and Shannon M. Vittengl*

As a business-savvy medical device executive, you likely are well versed on the value of utility patents. But are you aware that a design patent for your product can be an equally important component of your intellectual property portfolio? This article explains the differences between utility and design patents, and details why your company should consider diversifying its IP investment with design protection.

Design Patents Looking Good

A utility patent is the most popular type of patent. It protects the structural or functional aspects of a new, or improved, product or system. A design patent, on the other hand, covers the unique look or appearance of a device. It embraces elements such as a specific product shape or a particular surface ornamentation. If you purchased a home blood-pressure monitor recently, for example, you may have noticed that the cuff is housed in a sleek-looking container. The shape of this container may be protected with a design patent.

Or consider your most recent visit to the dentist. Perhaps you noticed a futuristic-looking tool with a unique surface texture. The surface ornamentation of this tool also may be protected with a design patent. Just as with a utility patent, a design patent may be directed at only a part or subassembly, rather than the device as a whole. (Quick tip: You can tell the type of patent from the patent number on the cover page. A design patent starts with a letter "D" and includes a number, as of June 2009, that is less than 600,000. In contrast, the numbering scheme for utility patents will surpass 7,500,000 by June 2009.)

The content of the two patents also differs. A design patent consists primarily of drawings and very little text other than a brief sentence that describes each drawing, e.g., "Figure 1 is a sectional view." A utility

patent, on the other hand, routinely includes many columns of text that describes the various embodiments of an invention and then ends with one or more claims that define the scope of the invention. A design patent has only one claim, a short characterization of the illustrated device, e.g., "The ornamental design for a medical device as shown in the drawings."

A design patent expires earlier than a utility patent. The term of a design patent is 14 years from the issue date, whereas the term of a utility patent (with some exceptions) is 20 years from filing date. The starting point for measuring the term, as well as the term length, are different for design patents and utility patents. Once a design patent is issued, or granted, no further action is required to keep the design patent in force. In contrast, maintenance fees must be paid on three separate occasions to the U.S. Patent Office to keep a utility patent in force. These fees are due 4 years, 8 years, and 12 years after the issue date. Failure to pay any of the maintenance fees will cause the utility patent to lapse.

Reasons to Consider Design Patents

Here are seven good reasons to consider a design patent:

1. **To protect your investment.** Product design can critically impact market acceptance and success. If your company has invested in the look and feel of a product, filing a design patent application enables you to protect this investment. A new product may include innovative technical features that may be covered by a utility patent and an eye-catching appearance that may warrant design patent protection. But in some cases, utility patent protection is not available because the technical features may be old. However, if you recast this old product in a new design, it could be the subject of a design patent. For example,

stethoscopes have been around for years, but if you redesign even just a portion of the stethoscope, you may be able to protect the new stethoscope with a design patent.



Jason Honeyman is a Shareholder at Wolf Greenfield and Chair of the Mechanical Technologies Group. He has practiced

exclusively in the IP space for almost 25 years, providing full service to clients ranging from start-ups to industry leading companies and top tier academic institutions.

Telephone: 617.646.8222

Email: jhoneyman@wolfgreenfield.com



Shannon Vittengl is an Associate at Wolf Greenfield and a member of the Mechanical Technologies Group. She focuses her practice

on patent prosecution in the areas of mechanical devices, medical products, and athletic equipment.

Telephone: 617.646.8297

Email: svittengl@wolfgreenfield.com

2. To prevent knockoffs. A competitor or knockoff artist may want to sell a device that looks like your company’s product, taking advantage of the technology, customer service, or branding that distinguishes your product from your competitors’ device. Particularly for over-the-counter goods, a customer may not take the time to discern the genuine product from an imitator and mistakenly purchase the wrong product, thinking it’s your company’s device. Although less common, the same mistake can be made even by hospital purchasing agents. If the confusingly similar product does not incorporate your company’s technical innovation, then there may be no utility patent infringement. There is, however, a design patent violation.

3. For faster patent protection. Design patents tend to be issued more quickly than utility patents. It’s common to wait several years before the U. S. Patent and Trademark Office (USPTO) reviews your utility application. Although backlogs also exist for the examination of design patents, the delays are typically much shorter. A review of recently issued medical device design patents reveals that some design patents are being issued in less than one year. If having a patented product out in the marketplace quickly provides you with a competitive advantage, filing a design patent application could be beneficial.

4. To save money. A design patent costs much less to prepare than a utility patent. An illustrator, known as a patent draftsman, creates the various drawings. An attorney’s time for reviewing the figures and completing the application is often minimal. In contrast, a utility application includes a long and detailed description of the invention and consequently requires more time and increased costs to prepare. Once a design application is filed at the USPTO, an examiner reviews it and frequently grants the patent in the first pass, unlike a utility application where the examination process can require several rounds before reaching a favorable outcome.

5. For special remedies. Remedies for design patent infringement are stronger than those offered for utility patent infringement.

For example, a prevailing design patent plaintiff can recover all of an infringer’s profits for selling the offending design. A utility patent owner, in contrast, typically recovers only a reasonable royalty for infringement or, in certain circumstances, its own lost profits but *never* the profits of the infringer. Thus, the threat of losing all profits is a *big stick* that tends to motivate a design patent infringer to seek a quick settlement.

6. For advantages over trade dress rights. Some may wonder whether design patent protection is overkill if the company intends to rely on trade dress rights, which also protect the look and feel of a product or its packaging. To recover for trade dress infringement, however, one must first establish that the trade dress has obtained “secondary meaning” or “acquired distinctiveness” in the marketplace. In other words, the public has come to associate the trade dress with a particular producer of the goods. Although trade dress protection is valuable, it typically takes at least several years and considerable advertising and marketing expenditures before the requisite secondary meaning or acquired distinctiveness can be established. Consequently, during at least the first few years after a product launch, if not longer, no trade dress rights are available to put an end to copycat products. On the other hand, a design patent usually will be granted long before this evidentiary hurdle can be met, enabling the design patent owner to deal immediately with infringers.

7. To match your competitors. Yet another reason to consider adding design patents to your patent portfolio is that your competitors may already be doing so. The chart below lists the number of U.S. design patent families for various leading companies in the medical device field.

Company	U.S. Design Patent Families
J&J/Ethicon	150
Baxter	123
Zimmer	116
3M	103
Tyco	98
Medtronic	59
Stryker	45

Table 1. Leading companies and number of design patent families.

Design Patents Now More Valuable?

A recent decision by the U.S. Court of Appeals for the Federal Circuit may make design patents even more valuable. In *Egyptian Goddess, Inc. v. Swisa, Inc.*, the Federal Circuit simplified the test for design patent infringement, reducing it from two prongs to one. Before *Egyptian Goddess*, the owner of a design patent had to establish, one, that the accused infringer’s device was substantially similar to the patented design and, two, the accused infringer’s device contained substantially the same “point of novelty” that distinguished the patented design from previous arrangements, called “prior art.” Before this ruling many cases had become mired in the “point of novelty” issue, leading to substantially increased litigation costs. And, paradoxically, it became harder to prove infringement of patents covering designs that markedly departed from the prior art or included several distinguishing features.

In *Egyptian Goddess*, the Federal Circuit eliminated the point-of-novelty test. Now, the sole test is whether the accused design is substantially similar to the patented design. Such overall similarity, however, is viewed in the context of the prior art, so that the point-of-novelty test may still influence the infringement determination in certain circumstances.

The simplified test should make it easier to prove design patent infringement and should give particular pause to companies that sell copycat designs. Obtaining a preliminary injunction to prevent the sale of offending designs during the pendency of a lawsuit also may be more readily granted. To illustrate with a working example, suppose your R&D director recently came to you with a new endoscope product, shown below in Figure 1.

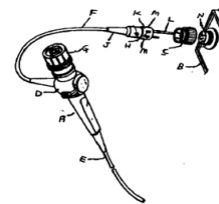


FIG. 1

The endoscope (A) includes many standard components: a light source (B), a connector assembly (K), a controller (D), an eyepiece (G), and a flexible guide cable (E). Your R&D team may have developed a new fiber optic visual assembly that makes it easier for a user to view through the eyepiece. In addition, the R&D team may also have developed a new disposable flexible guide cable. Both of these unique functional/structural elements of the endoscope may be the subjects of one or more utility patent applications.

At first glance, you may think that these two new technical features are the only aspects of the endoscope worthy of patent protection. But think again. The endoscope controller may rely on conventional technology, but the outer shape of the controller may be unique—the contribution, for example, of an outside industrial design firm. If so, the controller configuration may be protected with a design patent.

Figures 2–5 are from design patents that relate to endoscopes. In a design patent, the portion of the figure shown in solid lines represents what is being protected, whereas the portion of the figures shown in dashed lines represents environment or boundaries, or both, and is not part of what is being protected. Thus, the less that is shown in solid lines, the broader the scope of the U.S. design patent.

The design patents illustrated in Figures 2 and 3 both protect the unique shape of an endoscope controller. As shown, the non-controller portions of the endoscope, such as the eyepiece and guide cable, are shown in dashed lines.

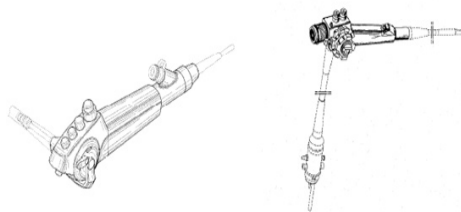


FIG. 2

FIG. 3

The design patent illustrated in Figure 4 protects the shape of the knob on the

endoscope, while the remaining portions of the endoscope are shown in dashed lines. The design patent illustrated in Figure 5 protects the endoscope handle shape.

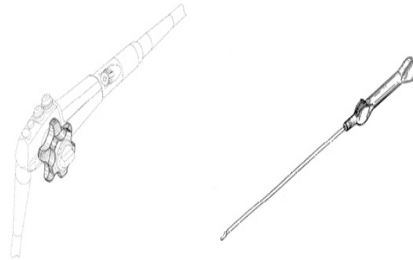


FIG. 4

FIG. 5

Foreign Patent Protection

A U.S. design or utility patent gives its owner the right to exclude others from commercializing the patented product *only* in the United States. As a result, foreign patents must be obtained to provide coverage in non-domestic markets. Foreign design patent protection can be effective at preventing foreign companies that manufacture your products from using your molds and tooling to replicate your product, particularly after the manufacturing relationship has ended. Additionally, the European Union and countries such as China and Japan have laws that allow customs officials to enforce certain design patent rights.

Foreign filing of design patents differs in certain key aspects from that of utility patents. After a U.S. utility patent application is filed, the owner has one year to file applications abroad and still claim the benefit of the earlier U.S. filing date in the counterpart foreign applications. A popular approach is to file a Patent Cooperation Treaty (PCT) application, which preserves the ability to file in almost 200 countries for a still further 18 to 19 months (or approximately 30 to 31 months from the earliest U.S. filing date). A PCT application allows the applicant to deal with issues pertaining to patentability up front, before the application branches out into each country of interest. By the end of the 30 to 31 months, the applicant should have a good idea whether the subject matter can be protected and how meaningful that protection should be.

On the other hand, the period for filing a

U.S. design patent overseas is much shorter. You have only six months from the earliest U.S. filing date to make your preferential priority foreign filings, and there is no equivalent PCT application. Therefore, a U.S. applicant must decide in what countries to pursue a design patent at an earlier date than it would for a utility patent. In addition, the owner doesn't have the benefit of an initial examination of design patentability that it receives with the PCT application for utility patents.

There is some good news concerning procuring foreign design patents, however, because the EU has significantly streamlined the process for obtaining design protection. In 2002, the European Union Office of Harmonization in the Internal Market (OHIM), which is the organization that registers European trademarks, was given the authority to issue community-wide design registrations. Such a design registration extends to each member country and automatically applies to new members of the European Union. These design registrations have a maximum term of up to 25 years (subject to renewal fees every five years) and cover a wide range of product designs. One of the most impressive aspects of the European design registration process is that applications will be processed within three months of the filing date.

Be aware that the rules and practice governing design applications may differ abroad. As mentioned above, solid lines in the figures of a U.S. patent illustrate the features that one is trying to protect, whereas dashed lines are used to indicate environment or boundaries, or both. Some countries, such as Canada and the countries of the European Union, also permit the use of dashed lines. However, other countries, including China, Japan, and Taiwan, do not allow dashed lines and thus require patent applicants to prepare a different version of the drawings.

Pursue A Combined Strategy

For a medical device company, utility patents will always be a valuable part of your patent strategy. For reasons detailed in this article, however, it is essential that

device firms also consider whether unique design elements are equally important to a product's identity and market-share. If this

is true for your firm, you may want to secure design patent protection. A combined strategy of filing for both utility and design

patent protection will serve the purpose of protecting not only the functional aspects of your products but their unique appearances as well.