

# Morgan Lewis

## LAWFLASH

# MEDICAL DEVICE COMPANIES: THREE WAYS TO STRENGTHEN YOUR DESIGN PATENT PORTFOLIO IN 2020

January 14, 2020

## AUTHORS AND CONTACTS

**John L. Hemmer, Scott D. Sherwin**

Rapid advancements in medical device technology have brought unprecedented changes to the industry. Increasingly, innovative medical devices also combine developments from other industries such as software, hardware, lighting, and 3D printing, resulting in a surge of new and improved medical equipment. To leverage these innovations, many medical device companies have focused on developing a traditional patent portfolio of utility patents. However, several recent legal and legislative developments suggest that it is time for medical device companies to reassess how they protect, license, and—if necessary—enforce their medical device intellectual property.

While utility patents protect the way an article is used and works,[1] design patents protect the appearance of the article.[2] Design protection is often overlooked in the medical industry, an industry that views itself as particularly utilitarian focused. However, medical device designs often have some degree of industrial and ornamental design that may be protected.

As a result, design patents may supplement a utility patent portfolio for a medical device and may provide protection for products that might not otherwise qualify for utility patent protection. Additionally, many medical devices include design features that garner consumer attention or loyalty, particularly if the doctor or patient is trained to use the device or otherwise spends a significant amount of time using the device. Medical devices may include replaceable, single-use components, which may also be protected by design patents. While the end product of a medical device design patent application—a few words and some drawings—is seemingly simple, care should be given to the filing and enforcement strategy to maximize protection.

Based on recent legal and legislative developments, the following three strategies should be considered by medical device companies to maximize the value of their innovations.

## **FIRST: PROPERLY ADDRESS FUNCTIONALITY IN DESIGN PATENTS**

The first design patent strategy that medical device companies should consider is claiming, or at least illustrating, functional aspects of the underlying useful article to maximize the value of their portfolio.

A design patent must claim an “ornamental” design, not one “dictated by function.”[3] Although a valid design patent may contain some functional elements, the design patent may not claim a “primarily functional” design.[4] However, in *Sport Dimension*, the US Court of Appeals for the Federal Circuit in 2016 found that the design at issue included functional elements, but held that a proper construction included at least some consideration of those elements that should not be completely ignored.[5]

More recently, ABPA sued Ford and sought declaratory judgment of invalidity regarding two of Ford’s design patents.[6] These design patents were directed to hood and headlamp designs for Ford’s F-150 truck. These components serve functional purposes, but ultimately, the Federal Circuit found Ford’s design patents valid because there were other hood and headlamp designs in the market that could serve the same function and fit on an F-150 truck, just as the patented designs do.[7] Particularly, the Federal Circuit found that the presence of a suitable alternative design “increase[s] the likelihood that a design serves a primary ornamental purpose.”[8]

The impact of *Sport Dimension* and *ABPA* for medical device companies is further confirmation that medical devices can be protectable by design patents. Although medical devices perform a function, this does not necessarily mean that the industrial design of the device is primarily functional. As such, medical device design applicants should take care in how the functional features are claimed to achieve the broadest protection for their design patents.

In fact, medical device applicants should even consider showing *unclaimed* functional features, particularly if a third party is likely to include such features, to further extend the scope of their design patents. The US District Court for the Northern District of California recently found that a screw distinguished an accused product from the patented design that omitted the sheer tube and screw shaft.[9] Side-by-side comparisons of the patented design (left) and the accused design (right) are shown below.[10]



The court found that no ordinary observer could fail to see that the shear tube protrudes from the bottom of the washer, and the shafts of the screws protrude several inches, even though both features were not claimed.[11] The court also stated that the accused products have a slightly softer curved look than the claimed design.[12]

The impact of *Simpson Strong-Tie* for medical device companies is that claiming more of the overall design of a medical device may, in some instances, have the counterintuitive effect of broadening the scope of protection. By claiming the entire medical device, or at least more of the device, minor differences, such as the slight beveled edge in the example above, are not as accentuated, and that may lead to a broader scope for the design patent.

In light of *Sport Dimension*, *ABPA*, and *Simpson Strong-Tie*, medical device companies should consider filing design patents on their medical devices and including the functional or environmental features in those design patent applications. By showing these optional features, an applicant can argue that the presence of such features is not distinguishing and can preserve the ability to claim such features later, both of which will help medical device companies secure comprehensive design patent protection for their medical devices.

## **SECOND: PROTECT REPLACEMENT COMPONENTS**

The second design patent strategy that medical device companies should consider is reassessing the litigation viability and strength of their design patent portfolios, particularly for replaceable components. This strategy is also based on lessons learned from *ABPA*.

In addition to the Federal Circuit's ruling on the validity and scope of a design patent in *ABPA*, the Federal

Circuit also ruled on ABPA's argument that the patents were unenforceable under the doctrine of exhaustion and the related repair doctrine. Patent exhaustion can occur when a patent owner sells a patented product. Such a sale can prevent the patent owner from asserting the patent against that same product in the future—in other words, the patent owner's rights are "exhausted." The repair doctrine generally allows the owner of a patented product to repair that same product without incurring any infringement liability. As applied to the design patents in the *ABPA* case, the Federal Circuit found that neither doctrine would allow ABPA to avoid infringement.

ABPA argued that when the F-150 truck is sold, the doctrine of exhaustion should totally exhaust the design patents covering the components in the truck.[13] The Federal Circuit, however, ruled that as applied to design patents, the doctrine of exhaustion permits "the purchaser [to] use or dispose of that product without incurring liability for infringement," but this doctrine does not prevent Ford from suing a manufacturer for making new replacement components.[14]

ABPA also argued that the repair doctrine gives owners of F-150 trucks the right to purchase replacement parts, even if those replacement parts are covered by design patents. The Federal Circuit again disagreed with ABPA, holding that "the right of repair does not, however, permit a complete reconstruction of a patented device or component. . . . [a]nd it does not permit a purchaser to infringe other patents by manufacturing separately patented components of the purchased article." [15]

These rulings are important to medical device companies because the Federal Circuit has now confirmed that an accused infringer cannot avoid design patent infringement liability under the exhaustion and repair doctrines simply because the design patent owner also sells a medical device component that embodies the patented design. The overall impact of *ABPA* is that it may now be easier for a medical device company to protect the replaceable components of their devices with design patents and protect their market share when third-party suppliers attempt to sell knockoff replacement components.

In short, although the value of design patents is often overlooked and underestimated by medical device companies in favor of utility patents when deciding to assert intellectual property against infringers, the new *ABPA* case suggests that this traditional perspective should be challenged and new intellectual property enforcement strategies should be considered to conform with and take advantage of the Federal Circuit's recent ruling.

### **THIRD: REASSESS YOUR MEDICAL DEVICE INTELLECTUAL PROPERTY ENFORCEMENT STRATEGY**

The third strategy that medical device companies should consider is reassessing how they assert their intellectual property against infringers. In general, the business goal is to stop infringers, maintain market share, and receive monetary compensation—all in a timely and financially efficient manner. To accomplish this goal, the typical legal strategy involves a utility patent lawsuit in district court and/or a utility patent infringement action before the International Trade Commission (ITC). However, the recent Federal Circuit rulings in *Swagway v. ITC* along with the proposed Counterfeit Goods Seizure Act of 2019 legislation may result in a new and complementary enforcement strategy.[16]

In *Swagway*, the Federal Circuit addressed whether a ruling from the ITC in a nonpatent matter (including trade dress, trademark, trade secret, and false advertising disputes) has preclusive effect in a subsequent district court case. The Federal Circuit initially held that, like patent disputes, there was no preclusive effect.

However, after granting a petition for rehearing, the Federal Circuit *removed* the portion of its opinion directed to the preclusivity of an ITC decision. While removal of its prior statements is not an explicit holding that ITC rulings *have* preclusive effect in a subsequent district court case, it does strengthen the argument that ITC rulings will be given significant weight—and possibly even a preclusive effect—by a district court.

Based on the *Swagway* cases, a medical device company could file an ITC action based on its nonpatent intellectual property rights, such as its trade dress rights on the entire medical device. This action would likely be less expensive than a traditional utility patent dispute at the ITC, while still proceeding to a final determination quickly. If successful at the ITC, the result would be an importation ban. The medical device company could then seek to convert that favorable decision into a monetary award and injunction in a district court. Based on the *Swagway* ruling, the district court could then quickly proceed to judgment because the prior ITC decision is likely to be given significant weight, if not complete preclusive effect, by the district court.

In an effort to expand the scope of protection against the infringer, the medical device company could then add its patent infringement allegations, particularly its design patent infringement allegations, to the same district court case. While a design patent dispute is a distinct legal theory from a trade dress dispute, a judge may be very sympathetic to the medical device company's argument that the infringer of its trade dress is also an infringer of its design patents. If successful in expanding the scope of the district court case, the medical device company could potentially add an injunction and monetary relief to its remedies against the infringer. Not only does this strategy optimize the plaintiff's unique advantages at the ITC and district court, it may also be implemented faster and more cheaply than a traditional multiprong utility patent enforcement strategy at the ITC and at a district court.

Furthermore, this strategy could be implemented in parallel with an enforcement action under the proposed Counterfeit Goods Seizure Act of 2019 legislation, which adds design patent infringement as justification for US Customs and Border Patrol to seize goods at the US border. If this bill becomes law, it may be possible to also obtain importation bans against infringers based on the medical device company's design patents.

The impact of *Swagway*, and the potential impact of the Counterfeit Goods Seizure Act of 2019, is that medical device companies may now have more efficient enforcement mechanisms available to help them enforce their intellectual property rights, and in particular, their design patent rights.

The medical device field is highly competitive and dynamic. With increasing prior art hurdles, utility patents may be narrowly tailored, take years to obtain, and in some instances, not be available at all. However, distinctive industrial designs may provide a competitive edge, especially against similar or knockoff competitor components. By strategically procuring and enforcing design patents for these designs, medical device companies can better protect their innovations against competitors and counterfeiters.

## **CONTACTS**

If you have any questions or would like more information on the issues discussed in this LawFlash, please contact the authors, John L. Hemmer (Philadelphia) and Scott D. Sherwin (Chicago), or any of the following lawyers from Morgan Lewis's IP medical device practice:

**Boston**

Steven J. Frank

**Century City**

Olga Berson, Ph.D.

**Chicago**

Michael J. Abernathy

Christopher J. Betti, Ph.D.

Hersh Mehta

Sanjay K. Murthy

Scott D. Sherwin

Kevin P. Shortsle

Jason C. White

**Orange County**

Christopher D. Bright

Kenneth Cheney

M. Todd Hales

Soyeon Pak "Karen" Laub

Nathan S. Smith

**Philadelphia**

Louis W. Beardell, Jr.

Kenneth J. Davis

Christopher I. Halliday

John L. Hemmer

Michael S. Ryan

**San Francisco**

Brent A. Hawkins

Brett A. Lovejoy, Ph.D.

Michael J. Lyons

**Shanghai**

Shaobin Zhu

**Silicon Valley**

Douglas J. Crisman

Dion M. Bregman

**Washington, DC**

J. Kevin Fee

Hosang Lee

Janice H. Logan, Ph.D.

---

[1] 35 U.S.C. § 101.

[2] 35 U.S.C. § 171.

[3] *High Point Design LLC v. Buyers Direct, Inc.*, 730 F.3d 1301, 1315 (Fed. Cir. 2013).

[4] *Sport Dimension, Inc. v. Coleman Co., Inc.*, 820 F.3d 1316 (Fed. Cir. 2016).

[5] *Id.*

[6] *Auto. Body Parts Ass'n v. Ford Global Techs. Inc.*, 930 F.3d 1314 (Fed. Cir. 2019).

[7] *Id.* at 1319.

[8] *Id.*

[9] *Simpson Strong-Tie Co. v. Oz-Post Int'l (dba OZCO Building Prods.)*, 2019 WL 6036705 (N.D. Cal. Nov. 14, 2019).

[10] *Id.* at 11.

[11] *Id.*

[12] *Id.*

[13] *ABPA*, 930 F.3d at 1322.

[14] *Id.*

[15] *Id.* at 1323.

[16] *Swagway, LLC v. ITC*, 934 F.3d 1332 (Fed. Cir. 2019).

Copyright © 2020 Morgan, Lewis & Bockius LLP. All rights reserved.