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# The Shape Of Things To Come: The Value Of Registered Designs In Protecting Medtech Products

by

As the digital revolution continues to sweep across health care, and the consumer/patient line becomes ever more blurred, healthtech manufacturers are increasingly aware of the need to protect the visual appearance of their products, says legal firm Allen & Overy.

The release of IT-assisted health technology products, such as wearable technology for health monitoring, diagnostics, automated robotics, clinical imaging, virtual reality tools and novel drug dispensing devices, is transforming health care delivery.

Given that many of these products are consumer-focused, their visual appearance plays an important role in influencing consumer choice and ultimate preference over competitor products. It follows that medtech companies who have invested in well-designed products must maximize their competitive advantage by obtaining IP rights that protect their technology's visual appearance.

Registered designs can help to protect the shape of any healthtech or medical device, the associated logos, packaging and trade dress, as well as the graphical user interface (GUI) and individual icons used in health care apps or portals. This article refers to the UK and the EU, which offer very design-friendly protection regimes.

## Medtech Needs A Broad Range Of IP Protection

A comprehensive patent portfolio plays a vital role in preventing third party theft of key innovations, and can also be useful for companies seeking to secure finance and provide leverage with joint venture, collaboration and licensing partners.

However, it can take years to obtain patent protection, and this may be problematic in the

medtech industry where smart-tech products reach the market far quicker than traditional medicines. In addition, there can be real difficulties in circumventing the exclusions to patentability for software and methods of treatment, therapy and diagnosis.

Trade secrets protection can help in some circumstances, but this requires continued diligence and is not appropriate when marketing strategies require the publication of product details.

A multipronged approach to IP protection is therefore recommended for digital health technology. Overall, the broader a company's IP protection, the more

weapons the company will have to prevent look-alike competitor products or counterfeits from entering the market. And in an increasingly consumer-focused industry, brands and designs can start to play a key role.

Good design not only makes health care products comfortable and effective for the user, but also helps to differentiate from competitors in a crowded market. A product that works well and looks good to consumers is generally worth the investment in obtaining protection for its visual appearance. That is the purpose of registered design protection.

## **Designs Are Quick And Relatively Inexpensive To Register**

On receipt of a design application, UK and EU registries only check filing formalities and whether the design is contrary to public order or morality. Their role is not to check whether earlier designs on the register might invalidate the application. This means that a design registration can be obtained very quickly—in the EUIPO's case, as early as the day of filing.

This can give the owner some immediate protection (lasting up to 25 years) whilst the patent application is processed. The owner can print the design number on the product and its packaging to discourage copying.

### **About The Author**

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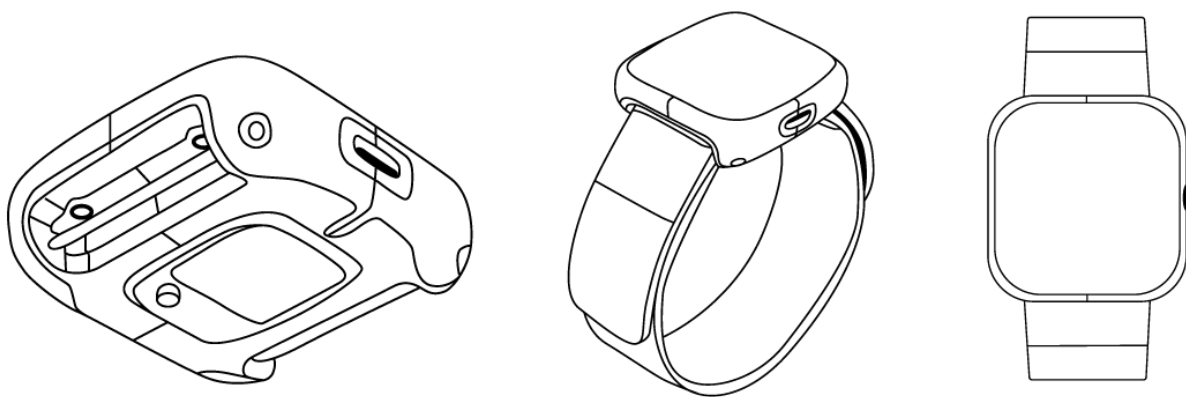
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***"It is not necessary to prove copying, so the right can be enforced against identical or similar designs, even if the third party has never seen the product before."***

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A registered design gives its owner the exclusive right to the design in the particular territory, and the owner can prevent others from exploiting the design on any product that creates the same overall impression. It is not necessary to prove copying, so the right can be enforced against identical or similar designs, even if the third party has never seen the product before.

Exhibit 1.



Registered designs are also a relatively inexpensive form of IP protection. In very general terms, the cost of design protection is nothing in comparison to the cost of researching, developing and bringing a medical device or health care app to market.

It is also worth considering that many digital health products are likely to have shorter product lives than pharmaceutical products, so immediate protection as a registered design might be more suitable and cost-effective than waiting a number of years for a patent monopoly.

Furthermore, registered designs might continue to protect a product and to provide licensing opportunities after a relevant patent has expired (after 20 years).

### **Design Registrations Can Protect Designs In Many Ways**

Registered designs are available in the UK and EU to protect the appearance of the whole or part of a product. This flexible and inclusive definition makes designs particularly attractive to owners, as it is broad enough to cover not only the contours, colors, shape, material or texture of

a product and its packaging, but also its ornamentation and 2D aspects, such as the relevant logos, icons and fonts.

### Helping To Protect The Shape Of Products Where Trademarks Fail

One benefit of registered designs is their ability to provide some protection for non-traditional signs that may be refused trademark registration for lack of distinctiveness. This can be particularly important for the shape of products (i.e. without an associated brand name or label), which are increasingly refused protection as trademark (*see Exhibit 1.*)

A registered design can provide quick and inexpensive interim protection while the product is used and evidence collected that consumers are starting to perceive the shape of the product as a distinctive sign of its origin.

In due course, for any product that proves to have real commercial value and longevity, the evidence of acquired distinctiveness might then be used to obtain trademark protection with unlimited duration. Practically, it is always best to file for the registered design at the same time or before the trademark to avoid disclosing the design too early.

In the UK and EU, an owner only has a maximum “grace period” of 12 months to file for a design registration after the design is first made available to the public anywhere in the world, and this includes any trade mark application. There is no grace period in many countries, so it is important to

### **Practical Tips When Filing Design Applications**

- **File early:** It is vitally important to file a design application as early as possible, and particularly before the product is marketed, to ensure that the design is still considered to be new. This also reduces the risk of competitors registering similar designs beforehand.
- **Seek broad protection:** To provide the best protection against infringement, it is preferable to consider several designs for key products, e.g. some claiming color, others claiming essential elements of the product (using dotted lines for those parts that are not protected). The scope of the protection is determined by the graphical representation, so it is important to supply good quality images. In practice, line drawings offer a broader scope of protection than photographs of the product. There may also be benefits in doubling up protection for key products and logos, i.e. filing for design and trademark protection, as described above.
- **Do multiple filings:** To help minimize the costs of filing designs in the EU, there is a “bulk discount” available for multiple filings in the same Locarno (product) class. This means, for example, that it is cost-effective to file for slight variations, e.g. in the shape of a product or different aspects of a GUI.

coordinate filing dates around the world to avoid destroying the possibility of validly registering a design in other territories.

Another advantage of design protection is that there is no use requirement. As such, numerous designs can be filed, even if there is no clear commercial intention to use them at the date of filing. This can be contrasted with trademarks, which can be revoked if they are not put to genuine use for a period of five years and invalidated if they are registered in “bad faith” by attempting to cover goods for which the mark will never be used.

### Protecting Graphical User Interfaces

GUIs play a vital role in allowing user interaction with health trackers on smartphones and other digital devices.

Product innovators should therefore reflect the importance and value of a well-designed GUI by protecting its visual appearance as a registered design. Many jurisdictions, including the EU, US and UK, allow design protection for GUIs, both in general and in relation to particular design elements, such as essential icons. The EU has reported a significant increase in design filings for screen displays and icons (from 456 in 2004 to 3,892 in 2019). This shows the growing importance of digital designs and this trend is expected to continue.

### Protecting Parts Of GUIs (Icons)

It is also possible in the UK/EU to obtain a

- **Link IP strategy with business plans:** Designs should be filed in key jurisdictions, which are likely to depend on commercial strategy such as the target market or the manufacturing territories of major competitors. It is then advisable to consider the most convenient and cost-effective filing route. Separate national registrations (e.g. in China or Australia) may suffice to obtain protection in one or two territories, but regional filings (e.g. the EU) or international filings through the Hague System can be a cost-effective way to target multiple jurisdictions through a single application. Care should be taken when using the Hague System to meet all the formality requirements in each designated country.
- **Fight look-alikes:** Successful consumer products such as wearable technology, monitoring devices and/or the related user interfaces may unfortunately face look-alike issues. To make life more difficult for potential look-alike producers, it is advisable to consider filing a range of registered designs for the product and packaging styles, possibly including those that are not fully developed and/or the expected design of copycat products. This should make it harder for competitors to come up with something that avoids creating the same overall impression.
- **Defer publication:** It is possible to defer publication of a design in the EU for 30 months (12 months in the UK). This

design registration for just one GUI element, most often an icon. The basic rule of representation must be complied with, i.e. the drawing or photograph needs to show clearly the claimed part and any disclaimed part must be outlined clearly in dotted lines or by coloring or blurring.

## Protecting Animated GUIs

It is also possible to protect animated GUIs through a design application. This is done by representing the design through a sequence of drawings or photographs that are visually linked and therefore reflect the animation (*see Exhibit 2*).

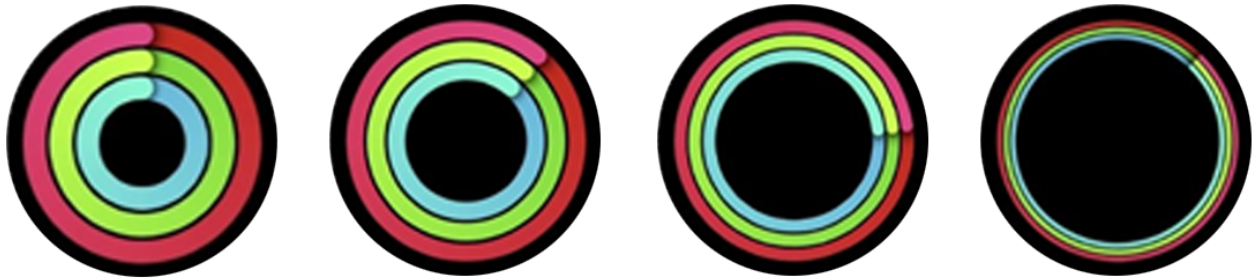
Currently, the EU and many national systems, are constrained to static views only. However, in its recent evaluation of EU legislation on design protection, the European Commission indicated that it would facilitate the filing of designs for GUIs and other animated designs if it were possible to file dynamic views of design through, for instance, 3D digital representations and video files.

provides backdated protection while allowing a product to be developed in confidence and without giving competitors access to the information from public records.

- File for a GUI: Filing a representation of a GUI itself without depicting a physical product can be advantageous (if allowed in the particular jurisdiction) as this extends the scope of protection to any physical product. Making separate applications, for e.g. the layout of the overall GUI, different screen displays and individual GUI elements, can help to ensure protection of the overall design and individual components. For animated GUIs, it is preferable to include as many representations as practically allowed (e.g. seven in the EU) to ensure they accurately reflect the animation.

Exhibit 2.





APPLE INC. (EU 003512383-0017)

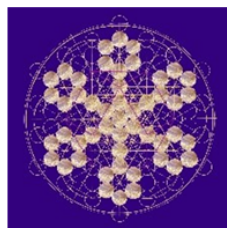
### Protecting Logos

Medtech companies should also consider registering any new logos as registered designs to complement the protection provided by trademarks. Logos (*see Exhibit 3*) have their own design product class under the WIPO Locarno classification (32—Logos), so the protection is not restricted to any particular type of goods. This means that these rights can be enforced against other designs creating the same overall impression on the informed user, regardless of the type of product. This may be more helpful than a trademark in circumstances, where a competitor uses a similar design in relation to dissimilar products (as mentioned above, trademarks are registered in respect of certain goods and services).

Exhibit 3.



Otsuka Pharmaceutical Co Ltd  
EU: 002275412



MEDI-KS Berlin GmbH  
EU: 6433496



Linkcare Health Services S.L.  
EU: 008043327

## Helping To Stop Infringing Products At The Border

The 25-year protection provided by a registered design in the UK/EU can be an important weapon in the fight against counterfeits. Registered designs can be notified to customs authorities so the rights can be enforced at the border. Stopping an infringing product entering the jurisdiction can be more cost-effective than having to track them down once they have been distributed.

### The Validity Test

To be valid, a design must meet a two-stage test. First, it must be new, i.e. no identical design has been made available to the public anywhere the world through publication (such as in a newspaper or magazine), exhibition (such as at a trade fair), or non-confidential use in trade. The requirement for global novelty stops parties from monopolizing old, known designs.

Second, to be valid, a design must have “individual character” – this is defined as meaning that the overall impression it produces on the “informed user” does not differ from the overall impression created on such a user by an earlier design.

This stops parties from monopolizing designs which are similar to old, known designs. It should also be noted that you cannot obtain a design for any features of the appearance of a product that are solely dictated by function. Component parts of complex products also need to be visible during normal use.

Because design applications are not examined for validity before registration, there are likely to be many designs on the register that are invalid. It is worth watching the register, and taking action against some likely invalid designs: it may be preferable to commence invalidity proceedings at the relevant registry rather than waiting to test the issue in court. Invalidating a registration can remove potential infringement concerns before launching a product. It also potentially avoids seizure of similar goods by customs authorities.



## **The Designer Is Generally The First Owner**

The designer is generally the first owner of any design protection, even if the work has been commissioned and paid for by another company.

It is therefore important to consider ownership of IP at the outset of any collaboration, e.g. between tech and health care companies and to obtain assignments of designs from any outside agency designers, engineers or researchers (such as contractors who create design prototypes, packaging or software). In the UK/EU, designs created by an employee are owned by the employer.

## **Unregistered Design Rights Are More Limited**

It is worth remembering that if a product or device is new and has individual character, it will automatically have unregistered design protection in the EU and UK (but, following Brexit, not in both), if it is launched in either territory.

This is more limited than a design registration because it lasts for three years, not 25, and only protects against unauthorized copying, as opposed to any independently created product with a similar appearance. It is also easier to enforce a registered design because it is much easier to prove ownership.

## **Registered Designs Should Be An Essential Part Of IP Portfolio**

Over the last few years, there has been a general increase in the number of registrations for digital designs and that trend is expected to continue. Product innovators in the medtech space also need to be shifting their focus towards registering design rights.

Registered designs can be an effective tool for protecting the shape of medical devices, as well as the branding and user interfaces associated with other health care technology. For all of these reasons, registered designs should start to become an essential part of the IP portfolio of any medtech or digital health company.