Intellectual Property Protection of Medical Devices

Intellectual Property rights (“IP rights”) are in the essence of the medical device industry where there are new inventions and products manufactured every day. This is why companies in this sector should be aware of the need to protect one of their most valuable assets of the products – their intellectual property. Innovations are crucial for this highly competitive sector. However, innovations need legal protection in order to actually generate profits for the company.


Steps towards protection

Every company must consider the possible IP rights related to their new products and their protection during each step of the product’s creation before the initiation of the product’s launch.

1. Before starting the creation process of a new device, an IP analysis is suggested because IP protection is available only for objects which are new. Otherwise, IP protection will be rejected when applying to register it with the respective authority. This analysis should be conducted not only in Bulgaria, but in all countries considered as prospective markets as well. It is estimated that around 25
% of development and research is wasted on products which already exist. The latter clearly indicates that the IP analysis is vital in order to minimize or erase entirely the risk of resources waste.

2. The next step towards IP protection should start from the agreement drafting. In cases where the product is going to be created by an employee, or a team of employees, special non disclosure clauses should be added to the labour agreements or separate non disclosure agreements should be concluded. This will mitigate the risk of information leaks to competitors and any other type of non-permitted disclosure which may jeopardize the IP rights of the product.

3. Finally, before launching the product on the market the most important thing is registering the product in order to ensure its IP protection. At this stage it is important to decide whether to patent the product, to register it as a trade mark, or as an industrial design, depending on its characteristics and the company’s goals.

BWSP Ilieva, Voutcheva & Co. Law Firm’s IP and Medical Law teams provide research and analyses of the opportunities regarding the establishment and protection of IP rights on national and international level. Furthermore we consult and draft employment agreements and non disclosure agreements regarding creation and development of medical device. The Law Firm’s IP representatives are eligible before Bulgarian Patent Office (“BPO”), the Office for Harmonization in the Internal Market (“OHIM”) and World Intellectual Property Organization (“WIPO”). Our advice is orientated to establish the best method of IP rights protection, considering the specific medical device and the company’s goals.

Further below we will examine the different regimes which should be considered when registering a medicinal product or medical device.
Different IP protection

There are 3 initial types of IP protection and 1 subsequent method of IP protection. In the following paragraphs we shall elaborate on different types and method of IP protection.

The first type of IP protection is registration of a patent. Patents protect technical inventions which are novel, involve an inventive step and are industrially applicable. The patent’s protection over the invention consists of the opportunity for its holder to take legal action against individuals or legal entities using the invention without permission. Patent protection lasts 20 years as of the filing date of the application with BPO. However, an application can be filed for a single patent issued by the European Patent Office choosing for which member states it will be valid. The EU patent lasts for 20 years as of the filing date of the application. Patents are suitable for medical devices, for example therapeutic or surgical apparatus and ensure stable protection.

The second type of IP protection is registration of an industrial design. If an industrial design is new and has individual character, it can be registered in order to establish protection over the respective medical device. Registered designs are used in order to stop counterfeit products which use the design’s popularity which is a common bad practice in highly competitive sectors like the medical device industry. Industrial designs registered with BPO are valid only in Bulgaria for an initial period of 10 years. A registered industrial design can be renewed for periods of 5 years up to the maximum of 25 years. An industrial design can also be registered with OHIM and thus obtaining a registered community design protection valid for all Member States\(^1\). The registered community designs initially last for 5 years and can be renewed for periods of 5 more years up to the maximum of 25 years.

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\(^1\) European Union
Trademark protection is another type of protecting IP rights over medical devices. When registering a trademark you should choose as much relevant classes for your product as possible in order to obtain the best protection possible. Our IP specialists provide practical advice on the specific classes under the Nice and Vienna classifications. The trademark’s registration can be done on a national, community² or international level. The different levels of registration are done before the different respective authorities – the national registration is done before the BPO, the community registration is before OHIM and the international one is before the WIPO. The different registrations have different territorial action – the national registration is valid for Bulgaria, the community registration is valid for all the Member States and the international one is valid for all the states members of the Madrid System. All of the registrations last for 10 years and can be renewed infinitive times.

After the creator of the medical device has obtained one or several of the types of IP protection above, the latter can be implemented and strengthen on practical level by a customs protection.

Customs protection can be established by recording trademarks, patents and industrial designs with the Bulgarian customs authority or any other Member State customs authority. Due to the obligation of customs authorities to check goods which enter the EU they will also be entitled to seize them and to destroy them in case they infringe IP rights. In case the customs authority finds any goods which are suspected in infringing IP rights they are authorized to detain them and obliged to inform the holder of IP rights. The latter has to submit an application for action. If the customs authority finds that the goods detained infringe IP rights, they can take certain measures, e.g. deny the goods to enter in the Community customs territory, deny release for free circulation, etc. This is an effective method in

² European Union
preventing counterfeit products from entering the EU from non-EU states, thus limiting the products on the market which try to copy the company’s medical device.

BWSP Ilieva, Voutcheva & Co. Law Firm consults and provides registration of patents, industrial designs and trademarks on national and international level. We consider the initial research regarding the type of protection, geographical location and specific classes as one of the most important steps in the establishment of IP protection. The initial research will provide important information on the future structure of IP protection and the related cost for its establishment. A well thought IP protection structure shall allow the creator of the medical device to strengthen its business and market position thus leading to a sustainable business model.

*The article above is intended for information purposes only by drawing your attention to the applicable IP rights protection. It should not be construed as binding legal advice. For a thorough understanding of the subjects covered and prior acting on any issue discussed we kindly recommend Readers consult BWSP Ilieva, Voutcheva & Co. Law Firm attorneys at law.*